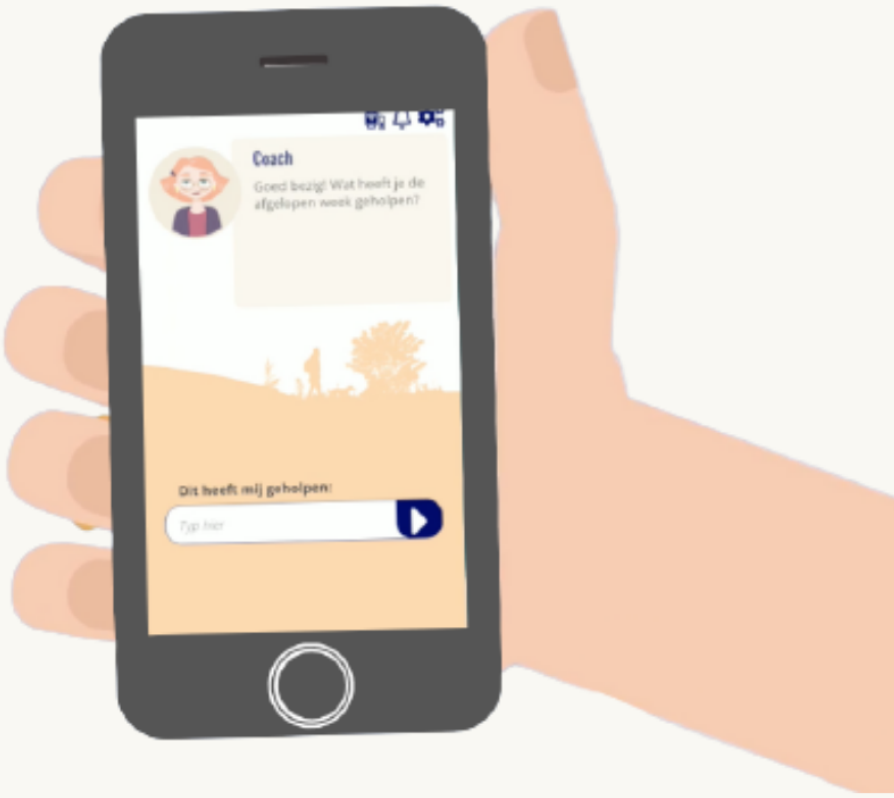
UNIVERSITY OF TWENTE.

Implementation of the Diameter within primary diabetes care

perspectives from patients and healthcare professionals in the pre-implementation phase



Student information

Name: Eva van ‘t Hul

Student number: S2358662

Email e.m.vanthul@student.utwente.nl

University of Twente

Faculty of Science and Technology

Master Health Sciences

Personalised Monitoring and Coaching

Supervisors

Dr. A. Middelweerd

Prof. Dr. G.D. Laverman

Prof. Dr. M.M.R. Vollenbroek-Hutten

July 15th 2021

Abstract

Background: In the Netherlands, over 1.1 million inhabitants are diagnosed with diabetes mellitus (2019), with over 50.000 new diagnoses every year. The burden of the disease is high, and the need for improved self-management is evident. eHealth technologies have proven to be effective in the self-management of T2DM. Therefore, it is assumed that a technology-supported lifestyle intervention can have a positive effect on the self-management of T2DM patients in primary care as well. The Diameter is a mobile application in which the patient can monitor blood glucose values, physical activity and nutrition. Presumably, the Diameter could be of added value in primary care. However, this has not been researched yet and the conditions of implementation are missing.

Aim: This study aimed to gain insights into perspectives of T2DM patients and healthcare professionals involved in primary diabetes care on implementation of the Diameter in the pre-implementation phase.

Methods: This study applied a mixed-method approach with triangulation design in which the results of three sub-studies were used to gain insights into the influencing factors of implementation of the Diameter within primary diabetes care. The first sub-study included a survey with patients, in which the Diameter was evaluated on various constructs such as performance and effort expectancy. The second and third sub-study were used to conduct semi-structured interviews with T2DM patients and healthcare professionals involved in T2DM care to gain a deeper understanding on the added value of the Diameter in primary diabetes care. Furthermore, during the interviews, the perceived barriers and facilitators on implementation were identified. In addition, an interview was conducted with health insurer Menzis to reveal necessary conditions for the Diameter to be funded by the healthcare insurer.

Results: The Diameter was positively evaluated on perceived usefulness, ease of use, the design and the perceived added value within primary diabetes care by patients and healthcare professionals. Furthermore, barriers (e.g., low levels of (health) literacy in the patient group and the cost and time of implementation) and facilitators (e.g., interoperability of the Diameter with existing information technology (IT) systems and the ease of use of the application) towards implementation of the Diameter were found, from which the recommendations to implementation were written.

Conclusion: The Diameter was perceived to be of added value in primary care by healthcare professionals and patients. However, the barriers and concerns towards implementation need to be addressed before the Diameter can be implemented in primary care. Furthermore, the effectiveness of the Diameter with the identified target groups of the Diameter needs to be further researched. Therefore, implementation of the Diameter should be further investigated by means of a pilot study with a representative sample size.

Table of contents

01

INTRODUCTION

01

1. Introduction

Type 2 Diabetes Mellitus

Due to a growing and an aging population, the number of people with a(n) (age-related) chronic disease such as Type 2 Diabetes Mellitus (T2DM) is increasing [1]. T2DM is one of the three main types of diabetes mellitus as diabetes mellitus can be divided into Type 1 Diabetes Mellitus (T1DM), T2DM and gestational diabetes. Most of the patients with diabetes mellitus are diagnosed with T2DM, as T2DM occurs in 90% [2] of all the diabetes mellitus patients. T2DM is a form of diabetes mellitus which usually develops at an older age [3]. This can be explained by an increased insulin resistance combined with age-related deterioration of the pancreatic islet function [1]. Patients with T2DM have become (partly) insulin resistant and can encompass a relative insulin shortage [4] leading to impaired glycemic control [5].

Globally, the incidence of T2DM is rising quickly; its prevalence has quadrupled the past decades and the estimation is that the number of T2DM patients will rise to over 510 million in 2030 [6]. These numbers explain that (global) prevention campaigns and management of T2DM is indispensable. In the Netherlands, over 1.1 million [3] inhabitants are diagnosed with diabetes mellitus (2019). Every year, there are more than 50.000 new diagnoses of diabetes mellitus throughout the country [3]. More males than females seem to be subject to T2DM as shown in Figure 1. The burden of disease for T2DM is high, as for both women (i.e., 7th place) and men (i.e., 3rd place) the disease is listed in the top ten of greatest burdens of disease [7].

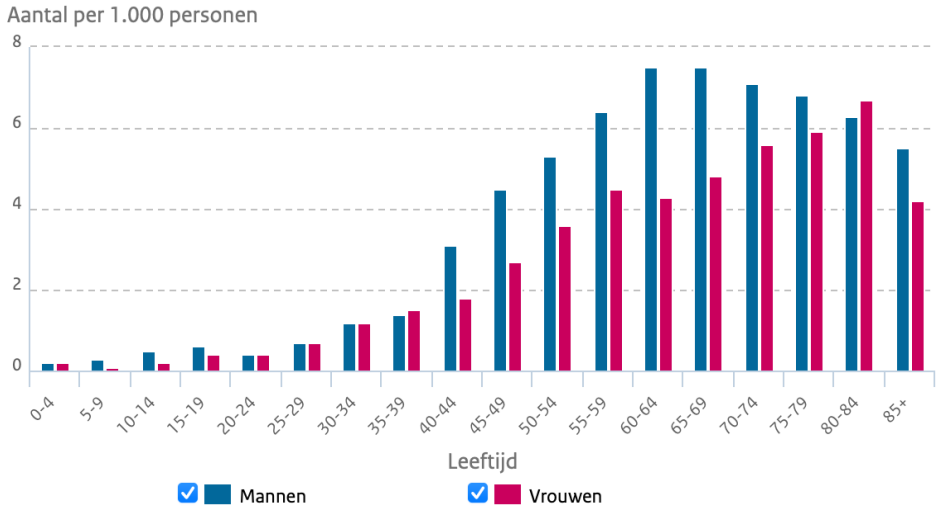


Figure 1. Prevalence diabetes mellitus (2019) by gender and age. [3]

Risk factors in development of T2DM

There are several genetic factors as well as lifestyle factors related to (the risk of) developing T2DM. Many T2DM patients possess (some of) these risk factors. The interaction [2] between these risk factors can lead to insulin resistance.

The genetic risk factors related to T2DM are specific genes that can contribute to the development of T2DM as they play a vast role in the functioning of β-cells in the pancreas. These genes also have an influence on (fasted) blood glucose values and the development of obesity [2]. However, these specific genes can at best explain 20% of the total genetic factors at risk to develop diabetes. Development of T2DM has been researched to be affiliated genetically; when both parents have T2DM there is a 70% chance that their children will develop T2DM as well [8].

Nevertheless, the most important risk factor related to T2DM is obesity [9] and the amount of fat in the abdomen [2]. This effect is partly explained by free fatty acids which can affect the β-cells [10].

Lifestyle components that are risk factors for developing T2DM are physical inactivity, unhealthy diet, smoking, processed food (meat) [2] and sleep, both too little and too much [11]. As the aforementioned factors are risk factors for developing obesity [12], development of T2DM is largely influenced by an unhealthy lifestyle. On the contrary, being more physically active and a healthier diet can benefit the management of T2DM [13].

Lifestyle and T2DM

As lifestyle plays a major role in the development and progression of T2DM, advice on physical activity and diet are part of the treatment of T2DM. The guidelines on physical activity for adults are prescribed by the Health Council of the Netherlands (2017) [14] and are as follows:

"Engage in physical activity of moderate intensity for at least 150 minutes every week, spread over multiple days (e.g., walking, cycling). Perform strengthening activities for your muscles and bones at least twice a week" [14]

Unfortunately, these guidelines on physical activity are often not met by patients with T2DM [13, 15, 16]. In addition, they are even less frequently met by patients with T2DM than people without T2DM [17]. For example, a recent study by the American Diabetes Association (ADA) presented that 69% of patients with T2DM performed less than recommended amount of physical activity [18]. In the Netherlands, only 52.9% of the Dutch people aged 18 years or older meet the guidelines on physical activity [19]. A recent study published by the Dutch Olympic Committee & Dutch Sport Federation (NOC*NSF) showed that the numbers of people practicing sport in 2020 have decreased to new record lows due to COVID-19 measures with half a million less people who practice a sport weekly [20].

In the Netherlands, nutrition guidelines are recommended as 'Richtlijnen Goede Voeding 2015' from the Health Council of the Netherlands. A few of these guidelines [21] are as follows:

- In general, eat a more plant-based diet
- Eat at least 200 grams of vegetables and at least 200 grams of fruit daily
- Eat at least 90 grams of brown bread, whole-grain bread or other whole-grain products daily
- Eat legumes every week
- Eat at least 15 grams of unsalted nuts a day
- Have several servings of dairy a day, including milk or yogurt
- Eat fish once a week, preferably fatty fish

The Wheel of Five [in Dutch: Schijf van Vijf] is used as a tool to provide guidance in following the 'Richtlijnen Goede Voeding 2015'. Providing tools for a healthy diet, which reduces the risk of diseases such as T2DM [22].

Figure 2. Wheel of Five: a visual presentation of the nutritional guidelines 'Richtlijnen Goede Voeding 2015' [22]

A study towards the food consumption of Dutch people in comparison with the 'Richtlijnen Goede Voeding 2015' [23] present that only 15% of the Dutch adults eat the recommended 200 grams of fruit and vegetables. Almost all adults consume sugary drinks twice a day, and only one in fifteen adults eat the recommended amount of nuts. Moreover, a recent study in 2017 by Gant presents that adherence to nutritional guidelines for T2DM patients was inadequate in 100% of the patient group [24].

Sustaining a healthy lifestyle with proper nutrition and physical activity plays a major role in the (potential) remission of T2DM [25]. Remission of T2DM can be defined as a state in which Hb1Ac levels are normalized and reduction or elimination of medication is achieved. Therefore, attention to lifestyle within diabetes care is crucial.

Treatment of T2DM in primary care in the Netherlands

Around 85% of patients with T2DM in the Netherlands receive treatment in primary care [26]. The care for T2DM in the Netherlands is researched to be of high quality [27]. Patients with T2DM receive treatment from a multidisciplinary team which follows several protocols such as the National Care Standard for T2DM [28] along with the specific guidelines of care for T2DM [29]. This multidisciplinary team consists of a cooperation between the general practitioner (GP), practice nurse [in Dutch*: praktijkondersteuner (POH*)], diabetes nurse and dietitian. Moreover, in specific cases, other specialists can also be involved in primary diabetes care, such as a physiotherapist, medical pedicure, podiatrist, and a pharmacist. Depending on complications and/or comorbidities of the patient, healthcare professionals in primary care cooperate with healthcare specialists in secondary care such as ophthalmologists, internists, nephrologists, cardiologists, neurologists, vascular surgeons, and clinical chemists [28]. The care process for T2DM patients focuses on treatment of complaints and prevention of complications of the disease, such as cardiovascular diseases, while preserving (and improving) quality of life [28].

There are three phases in the primary care process: the diagnostic phase, initial treatment phase and the chronic treatment phase [28]. Figure 3 presents the care process of T2DM in primary care. In the diagnostic phase, the patient's medical history, lifestyle and fitness will be mapped. Based on these characteristics the patient's risk profile will be examined and a personal care plan will be developed. The patients' needs and wishes are central in this care plan. To support the patient in their decision-making, the patient will go through an educational trajectory. In this trajectory, the patient will be educated on T2DM and self-management of this disease. After the diagnostic phase, the patient will continue to the initial treatment phase, which is roughly the first three months of care. The main goals in this phase are to stabilize blood glucose levels and control (present) risk factors. Within this phase, the focus of initial treatment is altering the lifestyle of the patient. Therefore, in this phase the patient will receive lifestyle advice on physical activity, nutrition, and if applicable, (quitting) smoking. The patient will receive target values and goals [28] for these lifestyle components. When altering a patients' lifestyle is not sufficient, the treatment of T2DM is supplemented with long-term therapy with blood glucose lowering drugs [30].

In the chronic treatment phase, patients will have check-ups with their POH every three months. If progression is going well, which means that risk factors are stabilized and the patient does not have any diabetes-related complaints, these check-ups can be brought back to once every six months. Patients will also receive a more extensive check-up once a year with their GP to exclude any complications related to T2DM. This extensive check-up includes measurements of weight, blood pressure and a check-up on the feet. Laboratory research is also included, such as fasting glucose levels, HbA1c, serum creatinine and albumin/creatinine ratio or albumin concentration in urine.

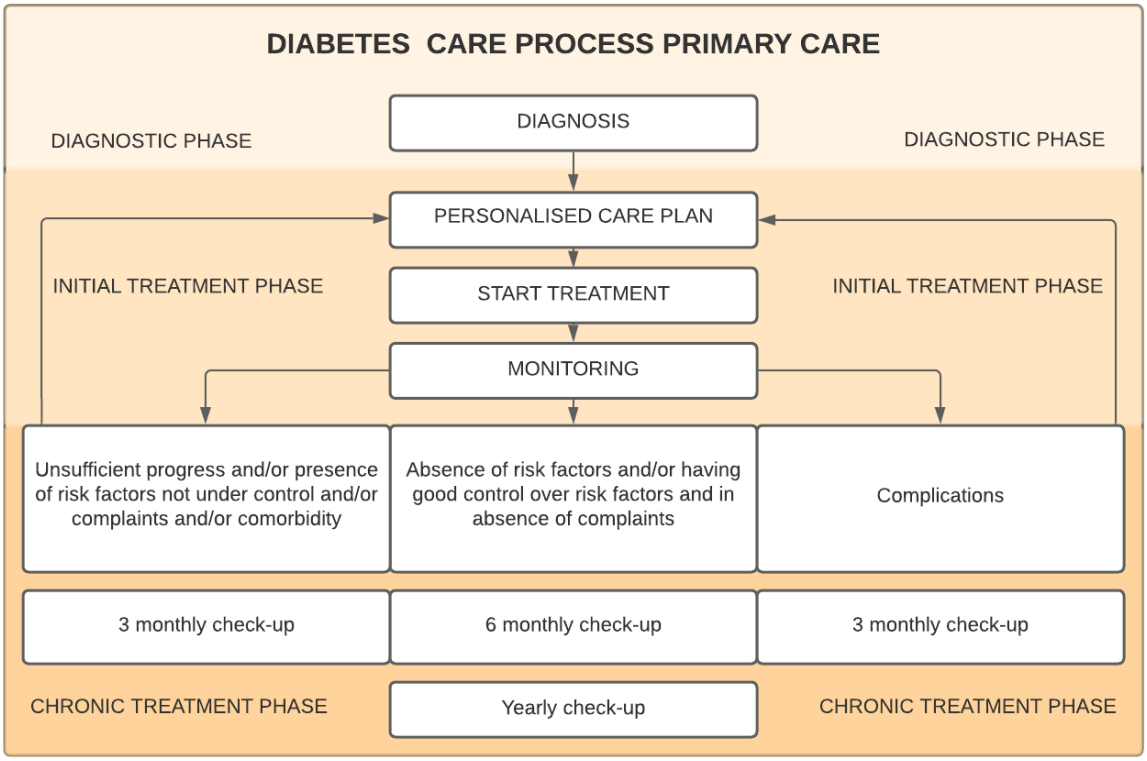


Figure 3. Care process of Type 2 Diabetes Mellitus (TDM) in primary care in the Netherlands. [29]

The guidelines National Care Standard for T2DM and specific guidelines of care for T2DM state that healthcare professionals should instruct, educate, advice and provide guidance for patients in their diabetes care process [28]. However, in practice it can be difficult for healthcare professionals to find adequate time [31] to discuss these topics. Healthcare professionals also find it difficult to give advice on lifestyle, such as physical activity [17]. Reasons for difficulties on giving lifestyle advice were mentioned, such as; sticking to protocol with a lack of time, understanding the behaviour of the patient, and the healthcare professionals' opinion on responsibility [17]. In addition, healthcare professionals have to motivate a patient group who generally isn't motivated in the first place to live a healthy lifestyle [17]. Therefore, there is a substantial group of patients in the Netherlands who do not receive advice and education on lifestyle from their healthcare professional up to the standards of national care. In a survey from Hesselink et al [32], 5.600 patients with T2DM in the Netherlands were questioned in 2012 about the advice on lifestyle they received from GP or POH. A little over 40% of respondents [32] reported that they hardly ever or never discussed their lifestyle, even though this patient group finds it important to get professional advice on their lifestyle and treatment of disease [17].

In summary, improvements in lifestyle are often required for better diabetes (self-) management, as patients with T2DM do not adhere to the guidelines of physical activity [18] and/or nutrition [24], but lifestyle is often insufficiently emphasized in current primary diabetes care [32].

Self-management

Self-management refers to the patients' ability to actively take care of their disease and health themselves [33]. It is a concept that has become more and more important in the treatment of T2DM and other chronic diseases, as the number of patients is growing rapidly along with the burden on the healthcare system [33]. It has been estimated that there will not enough GPs and POHs to treat the amount of T2DM patients in the -near- future with the current treatment standards. Improved self-management of the patient is necessary, to overcome the growing burden on healthcare professionals [34]. However, often patients find it difficult to adhere to self-management tasks given by their healthcare professional such as consuming a healthy diet [35]. Generally, lifestyle components such as diet and exercise have been proven to be challenging for T2DM patients [36].

There is much evidence for the use of eHealth technologies to support self-management in patients with T2DM [37-39]. However, eHealth technologies are not utilized yet in primary diabetes care in the Netherlands even though they can provide an opportunity to benefit the self-management and treatment of T2DM patients.

eHealth and T2DM care

eHealth [40] refers to the use of digital technology to benefit health, well-being and healthcare. As eHealth is independent of time and place [41] it has the potential to be used by many people and can be used as a tool in prevention, education, diagnostics and care. Furthermore, eHealth is not one type of technology but rather an overlapping term [40] used for many other digital technology concepts such as telemedicine, telemonitoring, mHealth or telehealth. eHealth can be used as a stand-alone concept, or as blended care where conventional healthcare through a healthcare professional is merged with digital technologies [40].

Literature provides extensive evidence in a number of eHealth technologies which can benefit self-management of T2DM [42] by monitoring diet, physical activity, blood glucose levels, insulin medication or a combination of these elements. For example, there are many stand-alone apps that can help patients take control of their lifestyle with apps on physical activity (e.g., SWEAT, Shreddy, VirtuaGym), nutrition (e.g., myFitnesspal, FatSecret, LifeSum) and the help of wearables (e.g., Fitbit). Moreover, patients with T2DM can utilize apps to track variations in blood glucose levels (e.g., mySugr, Health2Sync). In addition to these stand-alone apps that track several (lifestyle) components, there are also opportunities created with eHealth technologies in the treatment of T2DM in the clinical setting. Patient Health Records (PHR) and diabetes registries [43, 44] can be useful for both GPs as well as the patient to easily store and monitor values such as BMI, blood pressure, weight, blood glucose values etc. Furthermore, both web-based computer interventions and app-based interventions can have a positive effect on the control of blood glucose levels and HbA1c-levels [45, 46] [47] [48]. This is beneficial in decreasing the risk of complications related to T2DM such as hypertension, nephropathy and retinopathy [49].

Blended care combines traditional face-to-face care with online care, which has become possible through the internet since patients are now able to quickly have a chat or email communications with their GP or other healthcare professionals, allowing for real-time feedback [50-52].

The Diameter

As eHealth technologies have proven to be effective in the self-management of T2DM [42], it is assumed that a technology-supported lifestyle intervention can have a positive effect on the self-management of T2DM patients in primary care as well. The Diameter is a mobile application in which the user can monitor certain lifestyle components such as their blood glucose values, physical activity and nutrition. This application is the result of a project between Ziekenhuisgroep Twente (ZGT), the University of Twente, Roessingh Research and Development (RRD) and TNO with the aim to support self-management of T2DM as people with T2DM learn how to regulate their blood glucose values by making small adaptations in their lifestyle [53].

Other features of the Diameter include goal setting and coaching. Furthermore, the user can receive personalized and tailored messages and will be coached on certain lifestyle components (i.e., physical activity and/or nutrition). The development of the Diameter has been an iterative long-term project, as the first elements of the Diameter started developing in 2017. Since then, these elements have been further developed and validated in multiple studies [54-56]. The aim of this application is to be used in a blended care setting in which the healthcare professional can monitor the patient and provide better person-centered advice. Therefore, the check-ups with healthcare professionals will be more effective and efficient.

Implementation of the Diameter

As mentioned earlier, the use of eHealth is shown to be beneficial in the self-management of T2DM patients [42], as the use of such technologies in blended care setting has been proven beneficial to improve HbA1c levels, physical activity, weight and more [34]. As the Diameter has potential to be of added value in primary diabetes care, it is important to involve key stakeholders in the early stages of implementation. By doing so, the contextual framework in which the Diameter will be implemented will be mapped in which stakeholders, the technology, the (organizational) setting and their interdependency will be revealed [57].

Previous research has presented various barriers and facilitators towards implementation of eHealth technologies within the care process. For both healthcare professionals as patients, implementation of the technology is facilitated when the technology is easy to use and user friendly [58] [59, 60]. The technology also has to be secure, as patients often have concerns about their privacy [61]. Furthermore, personal attributes such as age [58], poor -digital health- literacy [58] [62] [63] can be barriers towards implementation for both patients as healthcare professionals. Patients must be empowered in the self-management of their disease [61] to facilitate implementation. Moreover, for healthcare professionals implementation is facilitated when management is involved and approves of the technology [64] and if the technology has been proven effective [62]. It is mentioned in literature that there is a need for standards and regulation to support eHealth technologies and to validate the effectiveness [59]. Furthermore, it is important to healthcare professionals that the eHealth technology is adaptable to the work environment and interoperable with current technologies that are used [64, 65].

Furthermore, issues arise in the post-implementation phase that are referred to as nonadherence [34]. To improve adherence of patients to an eHealth technology, studies present that it is important to implement the technology in a blended care setting, where the healthcare professional can monitor the patient and adjust the treatment according to the needs [33].

Currently, there is ongoing research in which the Diameter is tested in secondary care with T2DM patients. Presumably, the Diameter could also be of added value in primary care. However, the contribution of the Diameter in primary care is unknown and the conditions of implementation are missing. Therefore, the primary aim of this study was to include both the perspective of T2DM patients and healthcare professionals involved in treatment of T2DM on the implementation of the Diameter in primary diabetes care. The results of this study are written for recommendation on the conditions of implementation of the Diameter in primary care. The research question is as follows:

How can the Diameter be implemented in the primary care process of T2DM according to the perspectives of patients and healthcare professionals?

As this study covered two key stakeholders of the Diameter, the sub-questions are split into two categories: the end-users (T2DM patients) and healthcare professionals.

Patients

1. What are the experiences of T2DM patients in primary care and how do they view their care process?
2. What is the opinion of patients with T2DM on the Diameter?
3. How can the Diameter be of added value to patients with T2DM in primary care?
4. What are the barriers and facilitators that influence patients with T2DM on implementing the Diameter in everyday life?

Healthcare professionals

5. What are the experiences of healthcare professionals on T2DM care and how can this be improved?
6. How can de Diameter be of added value in primary diabetes care according to healthcare professionals?
7. What are influencing factors for healthcare professionals on implementation of the Diameter in primary care?

02

THEORETICAL FRAMEWORK

02

2. Theoretical Framework

In this chapter, different concepts related to implementation and frameworks on implementation are outlined. Implementation research seeks to understand how interventions are used in the real-world setting [66]. For a long time, implementation was viewed as the last step in the development process with the main goal to introduce a new technology in the real-world setting where acceptance and adoption of the new technology were seen as successful implementation. However, the use of implementation models should not be done post-development but rather as a continuous feedback system in which values from different stakeholders are taken into account [67]. Actively involving stakeholders in the development process can benefit smooth and effective implementation [57].

There are various frameworks within implementation science that have found predicting factors of successful implementation [67]. As previously mentioned, the earlier models focus on acceptance, such as the Technology Acceptance Model (TAM) and the Diffusion of Innovation Theory. Later, it was noted that implementation research shouldn't be black and white, focusing only on causal implications but rather provide a framework to guide implementation such as the Consolidated Framework of Implementation Research (CFIR). In this chapter the Diffusion of Innovation Theory and the CFIR will be discussed. First, the concepts related to implementation: acceptance, adoption and adherence will be explained.

Acceptance, adoption and adherence

Acceptance, adoption, and adherence are three concepts related to implementation of (eHealth) technology. Literature research provides many definitions for acceptance and adoption and sometimes these terms are used interchangeably. Table 1 gives an overview of these concepts with their definition. Acceptance and adoption are related to the (decision) of using technology. However, merely using the technology will often not be enough to benefit the user. Generally, people need to use eHealth technologies for a longer period of time in a specific way to grasp the benefits of it [30]. Therefore, adherence is an important concept that explains if the target group uses the intervention as it is intended by the developers (long-term) [68, 69]. Often, studies show that eHealth technologies are not effective due to the fact that end-users do not use the technology as intended or will not continue to use it long-term [70].

Table 1. Concepts within implementation theories

Concept	Explanation
Acceptance	*"Acceptance can be referred to as a person's willingness to use the system [59]"* It is required for a new technology to be accepted, otherwise the user will not use it or engage with it. Therefore, it is a requirement for implementation of a new technology [71].
Adoption	*"Adoption refers to the decision of the target group to actually starting using the new intervention or (eHealth) technology [72]"*
Adherence	*Adherence refers to the (long-term) use of the intervention as intended by the developers [68, 69]. "*

The above-mentioned concepts relate to the implementation process as successful implementation requires the user to accept, adopt and adhere to the technology, in which he/she eventually has implemented the technology in their life [71]. This study focuses on acceptance of the Diameter in the pre-implementation phase.

Diffusion of Innovations Theory

Innovation (i.e., a new technology) and diffusion (i.e., spread of technology) is broadly discussed in the Diffusion of Innovation Theory by Rogers [72]. According to this theory [73, 74], there are five components related to the technology that will facilitate -or hinder- successful implementation of that

technology. These five components are as follows [72]:

- Relative advantage:
  The new technology should be better than existing technology.
- Complexity:
  The complexity of the technology can benefit or harm the adoption as simple technologies tend to be adopted quicker than complicated technologies.
- Compatibility:
  The technology needs to be compatible with the target audience, context and/or organization. The technology needs to fulfil some want or need.
- Trialability:
  This component refers to the fact that people like to try out new things, without being attached to it. When people can try out the technology, this will benefit the adoption of the technology.
- Observability:
  End-users should be able to view how the technology works when someone else is using it.

The theory of Rogers also recognizes five categories of adopters. These groups of adopters are the innovators, early adopters, early majority, late majority, and laggards [72] as presented in table 2. Each group has its own characteristics and therefore its own tactics to be persuaded in adopting the technology.

Table 2. Type of adopters within the diffusion of innovations theory by Rogers [72]

Type of adopters	Explanation
Innovators	*The first few people to try and implement a new technology.*
Early adopters	*This group characterizes as comfortable with change and implementing new technologies.*
Early majority	*The first larger group of people who will adopt a new technology before others. However, they need to believe that the technology is of added value and will work before implementing it.*
Late majority	*This group is hesitant of change and will start implementing the new technology once most people have already implemented it.*
Laggards	*This group of people is resistant to change and the latest to implement a new technology.*

Figure 4 shows the implementation of a new technology per type of adopter. As presented in this figure, the first group to adopt a new technology is the innovator. This group is small (2.5% of the total population). Therefore, they only make up for a small share of the market. The early adopters implement new technology after the innovators, as they are the next group to accept the technology. When this group has implemented the new technology, the market share curve (yellow) increases more rapidly. This curve further increases when the early majority implements the new technology. Furthermore, when innovators, early adopters and early majority have adopted a new technology, 50% of the market share is covered. Consequently, as the late majority implements a new technology, the market share does not increase as quickly anymore. Almost everyone has implemented the new technology by now but the laggards (84% of the total population). Laggards are the final group of people to implement the technology (16% of the population). As they are a small group of people, the market share curve increases very minimally until market share has reached 100%.

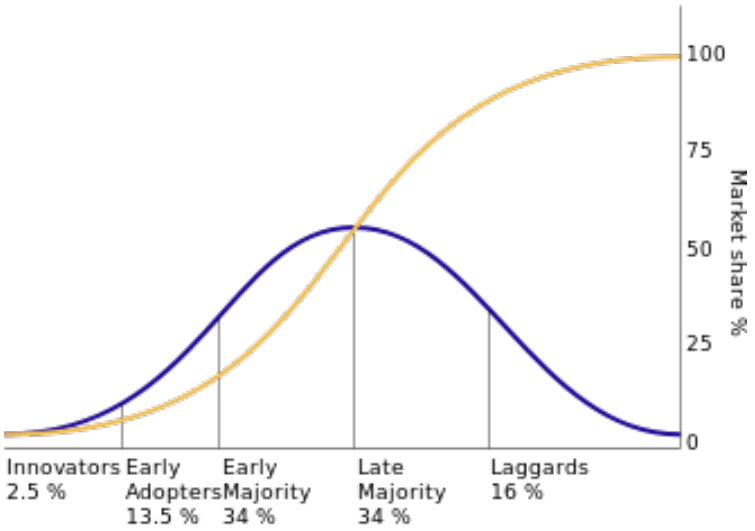


Figure 4: Implementation of a new technology by type of adopter [72]. The yellow curve is representative of the market share. The blue bell-shaped line presents the type of adopters in a market, where the early and late majority contribute to 68% of the total market. In this figure it is shown that when the early majority adopts a technology, the market share is 50% covered.

The diffusion of innovation theory is used in the development of the questionnaire for T2DM patients. As patients are the end-users of the app, it is beneficial for the implementation to determine in which category of adopters they can be categorized. Different type of adopters requires different strategies for them to adopt the new technology. Hence, knowing which type of adopter this patient group is could help understand the attitude they might have towards the Diameter and benefit the implementation with a fitting strategy to target them.

Unified Theory of Acceptance and Use of Theory (UTAUT)

The Unified Theory of Acceptance and Use of Technology (UTAUT) was formulated in 2003 by Venkatesh et al. in "User Acceptance of Information Technology: Toward a Unified View" [75]. The theory was created after empirical reviewing and researching eight other models, such as TAM. In the empirical comparison, four constructs were significant determinants of the acceptance and/or usage intention: performance expectancy, effort expectancy, social influence and facilitating conditions. These constructs are further explained in table 3.

Table 3. Constructs of the Unified Theory of Acceptance and Use of Theory (UTAUT) [76]

Construct	Explanation
Performance expectancy	*The level of intensity a person is convinced that the technology will help them perform well in their work setting.*
Effort expectancy	*The level of ease that the person associates to the use of the technology.*
Social influence	*The level in which a person believes that other (important) people view the new technology as valuable, and that they believe that this person should use this technology.*
Facilitating conditions	*The level in which a person believes that the new technology is supported by the current resources and technology used in a particular setting (such as their work).*

The UTAUT can provide guidance in predicting successful implementation (acceptance) of a new technology [75]. Furthermore, research showed that constructs of UTAUT account for 70% of the variance in accepting the new technology [77]. Therefore, this theory was used to develop the questionnaire for patients with T2DM, to gain more understanding on acceptance of the Diameter in the care process in the pre-implementation phase on the basis of the UTAUT constructs.

Consolidated Framework for Implementation Research

The consolidated framework for implementation research (CFIR) [78] is a framework developed after extensive research on models, frameworks and theories referring to implementation, mainly within the area of healthcare. The CFIR can be used as a guide to explore the factors that influence implementation [78].

There are five domains within the CFIR: intervention, inner and outer setting, individuals, and the implementation process. Each domain has specific characteristics, which can be relevant to the technology that needs to be implemented. In this study, the CFIR will be used as a guide to develop interviews to explore factors that influence acceptance of the Diameter in primary care by patients and healthcare professionals. The five domains of the CFIR are presented in figure 5 and further explained in figure 6.

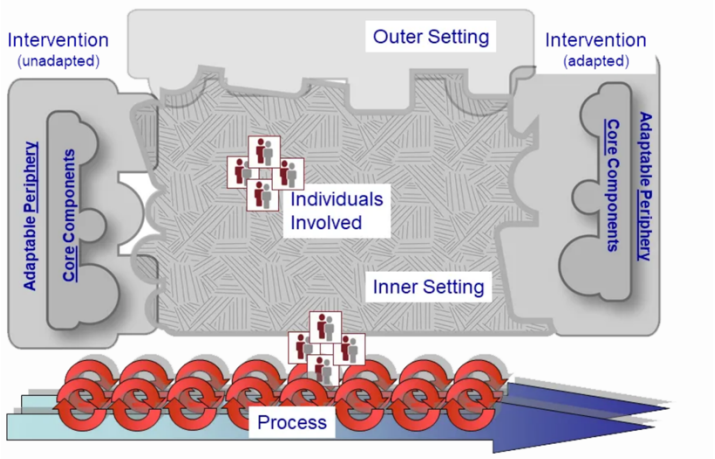


Figure 5. The Consolidated Framework of Implementation Research [78].

The domain intervention refers to the new technology that is aimed to be implemented; in this study this is the Diameter. The inner setting refers to the organization and setting in which the technology will be implemented in, which is primary care in this study. The outer setting is the context in which the inner setting is embedded such as external policies and incentives or the area where the implementing organization is connected to other organizations. Sometimes, the boundary between inner and outer setting is a grey area, in which it's not particularly clear to see where the inner and outer setting reside (i.e., they can be overlapping). For example, the Diameter will be implemented within primary care, so it needs to facilitate to the needs and resources of patients, but also has to commit to external policies such as 'zorgstandaarden' or policies with insurers. Furthermore, sometimes patients with T2DM receive care in primary as well as secondary care. Therefore, the inner and outer setting can have some overlap. The "individuals" in the CFIR refer to the people (e.g., stakeholders) involved in the implementation process. Although there are many stakeholders involved in the implementation process of the Diameter, this study is aimed at three stakeholders: patients with T2DM in primary care, the healthcare professionals involved in treatment of these patients within primary care and the healthcare insurer. Finally, the implementation process refers to the (sub-)processes related to effective implementation such as adequate training and sufficient marketing. As aforementioned, the five domains within the CFIR contain sub-categories, which characterizes each domain. The domains along with their sub-categories are presented in figure 6.

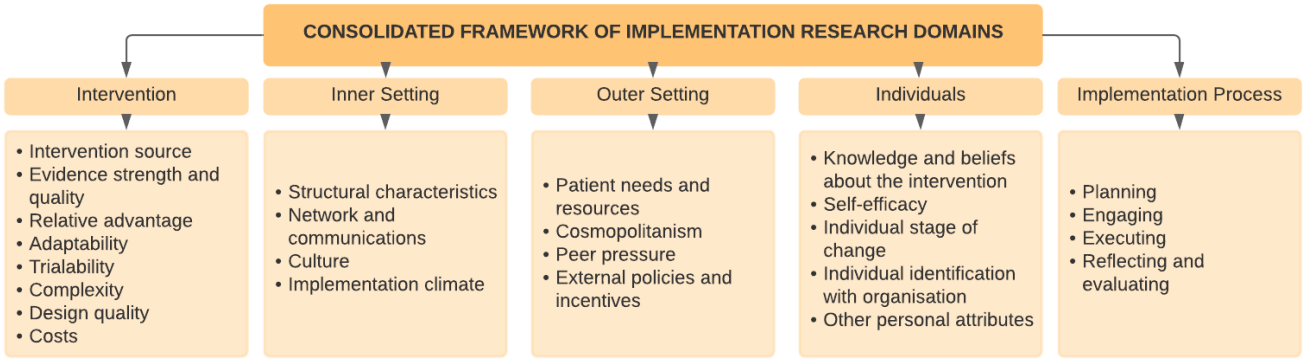


Figure 6. Domains and categories within the Consolidated Framework of Implementation Research (CFIR)

03

METHODOLOGY

03

3. Methodology

The design of this study consisted of a mixed-method approach with a triangulation design to gain insights into the influencing factors of implementing the Diameter within primary diabetes care. Triangulation design refers to the combination of both qualitative and quantitative research methods to obtain data and establish an interpretation on a certain topic [79], this is presented in figure 7. Furthermore, in triangulation design qualitative data and quantitative data are independently collected and the data is equivalent. In compliance with this definition, the goal of this research was to obtain data from different perspectives of stakeholders on acceptance of the Diameter and implementation within primary diabetes care.

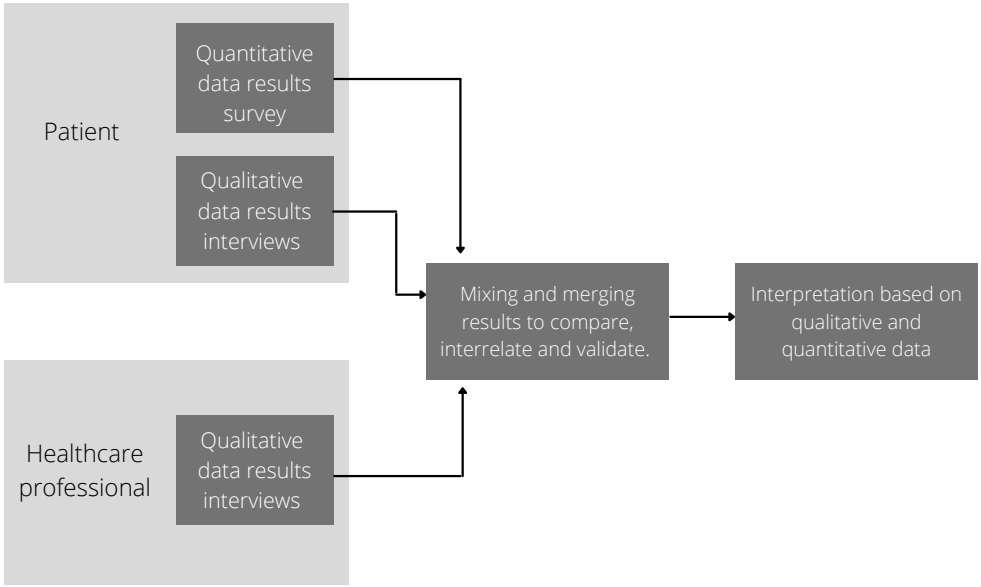


Figure 7. Triangulation design of the study

This study consists of three sub-studies:

- Sub-study 1: Survey Patients
- Sub-study 2: Interview Patients
- Sub-study 3: Interview Healthcare professionals and healthcare insurer

As both patients and healthcare professionals have similar research sub-questions, data from the studies was merged and compared where the topics overlapped (e.g., barriers and facilitators to implementation for both patients and healthcare professionals) to present in the results. Interpretation of these results were used in the discussion and recommendations of this study.

Sub-study 1: Survey patients

Objectives

The objective of the survey was to measure the acceptance of the Diameter according to the constructs of the UTAUT (e.g. performance expectancy, effort expectancy, social influence and facilitating conditions) and the perceived added value of the Diameter for patients with T2DM.

Design

The study design of this sub-study was a cross-sectional survey. Responses were recorded from April 21st until June 1st.

Participants and recruitment

Participants were included in the survey when:

- They gave informed consent to the terms and conditions of the study and data collection
- They were 18 years or older
- They were diagnosed with a form of diabetes, preferably T2DM (self-reported)

For the recruitment of survey respondents, the platforms "Diabetes Fonds" and "Diabetesvereniging Nederland" were contacted. "Diabetes Fonds" agreed to help in the recruitment of patients by providing a flyer (appendix 8.2), with a link to the survey and invitation for an interview on their website. Furthermore, the social media platform Facebook was used to recruit patients for the survey by posting an invitation to join the survey with a link and picture in several T2DM related groups. A group was requested to join, when the group specifically stated to be about T2DM for Dutch patients. The researcher requested a total of eight groups to join, from which four accepted this request. Three groups allowed distribution of the survey: "Diabetes En Zo", "Diabetes 2, we kunnen het allemaal omkeren!" and "De waarheid achter Diabetes". Table 4 provides an overview of the Facebook groups that were contacted and included in the distribution of the survey. In addition, on "Diabetes Trefpunt", the forum of "Diabetesvereniging Nederland", a post was created to invite patients to participate in the survey and interview.

Table 4. Facebook groups

Facebook Group	Members	Survey distributed?
Diabetes type 2 ?? … samen werken aan medicatie vrij !!	2.800	No
Diabetes en Zo	1.300	Yes
Diabetes 2 Doorbreken met je Leefstijl als Medicijn	1.700	No
Samen diabetes 2 omkeren TheNewFood	51	No
Diabetes 2, we kunnen het allemaal omkeren!	482	Yes
Diabetesproof	2.700	No
Diabetes Vrienden	3.700	No
De waarheid achter Diabetes	3.100	Yes

Sample size

In 2019, there were 1.030.00 patients with T2DM in the Netherlands [80]. A sufficient estimated survey sample size for this population with a 5% margin of error and 95% confidence level would be 384. However, the time for this study was restricted. Therefore, a confidence interval of 95% was chosen with a 10% margin of error. With these variables, 97 respondents would be needed [81].

Procedure

The survey was created using Qualtrics. The complete survey is presented in appendix 8.3. Before starting the survey, respondents were obligated to give consent and agree to the terms of the study. If they did not agree to the terms of the study, they were excluded and could not participate in the survey. The terms of the study included that the responses would be anonymously used for purposes of this study.

Respondents did not have to download or use the app themselves. By showing screenshots of the functions of the Diameter and an introduction video of the Diameter, in which the goal of the application was explained, respondents were able to answer the UTAUT questions.

Measurements

The survey was used to measure acceptance of the Diameter. The following constructs were measured; type of adopter, technology use, performance expectancy, effort expectancy, facilitating conditions, social influence, perceived added value of the Diameter within the care process, perceived usefulness and design.

Type of adopter

The type of adopter was based on the Diffusion of Innovation Theory by Rogers, in which five types of adopters were identified [72]. The question measuring the type of adopter was operationalized from this theory. Respondents chose a statement fitting their adoption of technology best. The statements ranged from 1, (innovator) "I am ahead of everyone when it comes to trying new technology, I'm the first to try out something new" to 5, (laggard) "I am usually behind everyone else. I only use new technology when this is necessary".

Technology use

In the survey, four items were related to the use of technology. This construct is not validated as the questions were created by the researcher to gather background information on the usage of technology by T2DM patients. The first question was multiple choice ('Do you use a health-related app?'), the follow-up questions were multiple choice with the option to motivate their response. As an example, if respondents did use health related apps, they were asked for which goals they used these apps.

UTAUT

As constructs of the UTAUT count for 70% of the variance in accepting new technology [77], these constructs were used in the survey. Items for performance expectancy (PE), effort expectancy (EE), facilitating conditions (FC) and social influence (SI) were used as designed by Venkatesh [75]. Questions from the constructs of the UTAUT were based on the UTAUT questions as used in the study of Fokkema [56]. It was not specified in this study whether the questions in Dutch were validated. The UTAUT questions were rephrased by the researcher as respondents did not use the Diameter yet. Furthermore, a 5-point Likert Scale was used ranging from 'strongly disagree' to 'strongly agree' for the constructs. Two yes/no questions were, in addition to the 5-point Likert Scale questions, used for the construct FC. Examples of 5-point Likert Scale questions per UTAUT construct are:

PE: "I think the Diameter can help me get control over my diabetes'
EE: "The Diameter looks easy to use"
FC: "I have sufficient knowledge on apps to use the Diameter"
SI: "It is important to me that my GP or specialist encourages use of the Diameter"

Value of the Diameter within care process

The added value of the Diameter within the care process of the respondents was measured through four items in which respondents had to answer on a 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree'. These questions were formulated, based the UTAUT construct of performance expectancy and originated from the pilot study of ZGT on the use of the Diameter in secondary care. The researcher rephrased these items to match the setting of primary care and the pre-implementation phase. The questions were not validated. An example of a 5-point Likert Scale question is: "I think the Diameter can make my treatment more personal". A 5-point Likert Scale was used ranging from 'strongly disagree' to 'strongly agree' to answer the questions.

In addition, the Diameter was rated by respondents to be of added value to their diabetes care on a scale from 1 through 10, in which 1 represented extremely poor and 10 represented excellent. This question was not validated but used by the researcher to receive an overall rating of the Diameter by respondents.

Design

Three 5-point Likert scale items were related to the design of the Diameter, ranging from 'strongly disagree' to 'strongly agree' These items were also based on the pilot study of the Diameter in secondary care (ZGT) and were not validated. Items which measured design contained statements about the appeal of the design, professionality and if the design was comprehensible.

Respondents were shown screenshots to answer these questions. An example of a 5-point Likert Scale item of the construct design was: “The Diameter looks appealing”.

Perceived usefulness

Perceived usefulness was measured through two multiple response questions in which respondents indicated which functions of the Diameter they perceived as useful and which as less useful. These questions were based on the pilot study of the Diameter in ZGT and were not validated. An example of a question is as follows: “Which function(s) of the Diameter do you perceive as useful to support you in monitoring your lifestyle and diabetes?”

Demographics

The first part of the survey consisted of multiple choice and multiple response questions about the demographics of the respondents. Age, gender, level of education, country of birth, type of diabetes, length of diagnose, place of treatment, and type of adopters were measured through multiple choice questions. Country of birth (parents), type of medication and presence of complications were asked through multiple response questions as multiple answers could be applicable.

Table 5 presents the type of question in the survey used for each measurement, starting with demographics. If respondents did not meet the inclusion criterium of having diabetes, they were taken to the end of the survey and could not complete the survey.

Table 5. Measurements of the Survey

Measurement	Type of question	Items
Demographics		
- Age	Multiple choice question	1
- Gender	Multiple choice question	1
- Level of education	Multiple choice question	1
- Country of birth	Multiple choice question	1
- Country of birth (parents)	Multiple response question	1
- Type of diabetes	Multiple choice question	1
- Length of diagnose	Multiple choice question	1
- Place of treatment	Multiple choice question	1
- Type of medication	Multiple response question	1
- Complications	Multiple response question	1
- Type of adopter	Multiple choice question	1
(Current) use of technology	Multiple choice question	4
UTAUT		
- Performance expectancy (PE)	5-point Likert scale	4
- Effort Expectancy (EE)	5-point Likert scale	4
- Facilitating conditions (FI)	5-point Likert scale	2
	Multiple choice question	2
- Social influences (SI)	5-point Likert scale	2
Added value of the Diameter within care process	5-point Likert scale	4
- Rating Diameter	Scale	1
Design of the Diameter	5-point Likert scale	3
Perceived usefulness	Multiple response question	1
- Useful functions	Multiple response question	1
- Less useful functions		

The survey consisted of four parts:

1. Introduction to the study
2. Background characteristics of the participants
3. Use (and adoption) of (new) technology by of the participants
4. Questions regarding the Diameter

All Likert-Scale questions were treated as ordinal data, as literature suggest that to treat data as a scale, the scale must consist of a minimum of eight items to measure construct [82]. The Likert-Scale used in this study contained five items: strongly disagree to strongly agree.

The 5-point Likert scale items from the measurements PE, EE, FC, SI, 'added value of the Diameter within care process' and design were tested on internal consistency and reliability with Cronbach's Alpha before merging the statements to single, independent 'measurement' variables. The general accepted rule is that an alpha >0.8 = very good, 0.6-0.7 = acceptable and <0.6 = poor [83]. As presented in table 6, the items of FC scored below 0.6. Therefore, the items of FC were not merged. PE, EE, SI, 'added value of the Diameter within care process' and design were all merged into a new variable.

Table 6. Cronbach's alpha for the variables in the survey

Variable	Likert Scale Items	**Cronbach's Alpha**
Performance Expectancy (PE)	The Diameter can make me aware of my lifestyle The Diameter can help me control my diabetes The Diameter can help me to reach lifestyle goals The Diameter has functions that I need to monitor lifestyle	.903
Effort Expectancy (EE)	The Diameter seems easy to use to me I think that I can learn to use the Diameter quickly The Diameter looks user friendly I think that it won't take much time for me to use the Diameter	.845
Social influence (SI)	It's important to me that other T2DM patients use the Diameter too It is important to me that my healthcare professional will encourage use of the Diameter	.792
Facilitating Conditions (FC)	I need help before I can use. The Diameter I have sufficient knowledge about apps to use the Diameter	.592
Added value Diameter within care process	The Diameter can make my care process more personal I don't have a problem that my data will be shared with healthcare professionals if this is of added value within my treatment. Healthcare professionals can have more insights in my lifestyle through the Diameter The Diameter seems to be of added value within my care process	.866
Design	The Diameter looks appealing The Diameter looks professional The Diameter looks comprehendible	.777

Data handling

For the distribution of the survey, an anonymous link was used. When using an anonymous link, no personal data of the respondents is recorded such as name or email address. The only personal data that was registered was the IP-address of the respondent as this was used to check for double responses. In the survey itself, no contact details were asked except for the email address of the respondent to be contacted for an interview. However, this was on a voluntary basis as the respondent was made aware that he/she could skip this question.

To prepare the data, the researcher rewrote the variable names and checked if the Likert Scale items were all positively phrased. Variable names were rewritten as this was easier for the researcher to interpret to which measurement they belonged. Question 12 implied the type of adopter from Rogers' Diffusion of Innovation theory, therefore the values 1 through 5 were recoded to the type of adopter the answer represented. Where 1 = innovator, 2 = early adopter, 3 = early majority, 4 = late majority and 5 = laggards. One 5-point Likert scale question about facilitating conditions had to be recoded as this item was negatively phrased. The question that was recoded was the statement: "I need help before I can use the Diameter".

Data analysis

The survey data was analysed with SPSS 26. Microsoft Excel was used to create an overview of the data per measurement. Only the complete responses were used for data analysis. Therefore, the dataset contained no missing values. Double recorded responses were checked for by IP address. If there were any double recorded responses, only the first response would be used for data analysis.

Descriptive statistics -measures of central tendency such as median-, with frequency analysis was used to explore differences in rating of the Diameter as this data was skewed. For the constructs PE, EE, SI, 'added value of the Diameter within care process' and design a central tendency of the median was used as these constructs were treated as ordinal data. Kruskal-Wallis H test was used, as the data of the dependent variable 'rating of the Diameter' was skewed, to determine significant differences between groups of respondents. Groups in age -used as a categorical variable in the survey-, education level, type of diabetes and type of adopter were used to find significant differences. Literature suggests that age, education [58] and type of adopter [72] can be influencing factors in implementation of technology, therefore these groups were used to determine significant differences. As the Diameter is intended for patients with T2DM, to measure whether other type of diabetes patients would view the Diameter as less useful, type of diabetes was used to measure significant differences between these groups. When the Kruskal-Wallis H test did not show any significant difference between groups, the categorical variables age and education were transformed into categorical variables with two levels. This was done to create groups that were more similar in size. For age, the levels were young (<55) and old (>56). The category education was split into lower (no education, lower and secondary vocational education) and higher education (general secondary and higher professional education, academic university). Although the groups were similar in size, the shape of the distribution between groups was different. Therefore, the Mann-Whitney U test [84] was used to determine significant differences in rating outcome between these groups.

Sub-study 2: Interview patients

Objectives

The objective of this second sub-study was to gain insight into the experiences of the care process, to gain a deeper understanding of the barriers and facilitators of using the Diameter and to understand if the Diameter could be of added value in primary care.

Design

Semi-structured interviews were conducted in this sub-study. These interviews were held from April 21st – May 20th.

Participants and recruitment

Participants were recruited for an interview if they met the following criteria:

- Must be at least 18 years of age
- Must have diabetes (preferably T2DM)
- Undergoes treatment within primary care

It was expected that five interviews would be sufficient to reach data saturation and would be manageable in the restricted time. Therefore, the aim was to include at least five patients for an interview.

Participants were selected for an interview through convenience sampling by contacting two in-law family members with T2DM and through respondents that left their email address in the survey. In total, thirteen survey participants were contacted for an interview. These people were emailed and asked if they would participate in an interview. Four of the thirteen replied and agreed to participate in the interview. After their consent through email, they would receive further instructions and information about the Diameter and the interview date and time was scheduled. A total of six patients were interviewed.

Procedure

Due to COVID-19 measures, the interviews were held by phone and lasted 30-45 minutes.

Measurements

First, literature research on factors influencing acceptance and implementation of eHealth technologies was conducted. Second, these factors were categorized by the CFIR as presented in appendix 8.1. Finally, these categorizations framed the interview questions. In total, six interviews were conducted with patients. During the interviews, patients were asked to elaborate on the following topics:

1. Care process of the patient and their view on diabetic care

- *Which type of diabetes does the patient have?*
- *What does living with diabetes mean to the patient?*
- *How long is the patient diagnosed?*
- *What does their current plan of treatment look like?*

2. The patients' current use of technology

- *Does the patient currently use apps or other technology related to health?*
- *What is their motivation to using these apps? Or why are they not using any apps?*

3. Added value of the Diameter by the patient

- *Does the patient believe that the Diameter could help them with monitoring their lifestyle or control their diabetes?*

4. Barriers/facilitators of using the Diameter by the patient

- *Does the patient see any barriers to using the Diameter?*
- *Does the patient see any facilitators in using the Diameter?*
- *Does the patient believe that the Diameter would be easy to use in everyday life?*

The interview scheme of patients can be found in appendix 8.4.1

Data handling
Interviews were recorded with an iPhone X. This iPhone was reset to factory settings and not linked to an apple ID or other account(s). After the interviews, recordings were directly transferred to the server of the University of Twente in which they were stored. Recordings were transcribed, but personal details such as names were left out of the transcription. These transcriptions were also uploaded to the server of the University of Twente. Transcriptions were saved under a number instead of a name to ensure anonymity. As most rough transcripts were created using Amber Script, the files were immediately deleted from this website after completion.

Data analysis
Interviews were recorded with permission of the interviewees and then transcribed verbatim by the researcher. A first rough transcript was created using Amber Script. One interview was transcribed non-verbatim, as it contained too much information not relevant to this study. A general inductive approach [85] was used to analyse and code the transcripts with Atlas.TI. The approach of inductive coding is used in many different works, such as Grounded Theory Research by Strauss & Corbin [86]. In short, inductive coding is used by the researcher to derive concepts and themes from data. In this study, inductive coding is used to analyse interview transcripts to derive concepts, facilitators and barriers related to acceptance of implementation of the Diameter. Therefore, three themes with sub-codes were created to answer the sub-questions of this study:

1. Experiences of patients with T2DM on their care process
2. Added value of the Diameter
3. Barriers & facilitators on the implementation process.

The researcher started with reading the transcripts. As questions of the semi-structured interviews were based on the sub-questions of this study, parts of the transcripts were given general themes according to the themes described above. From the data and these themes, the codes were developed. Codes that belonged to the same theme were grouped together to create code-groups with multiple codes. An alumnus (MSC) of Universiteit Twente selected one of the transcripts at random and coded these independently. If codes differed, the researchers discussed these until they reached consensus. In response to the altered codes, the codes from other transcripts were changed accordingly as well.

Sub-study 3: Interview healthcare professionals and healthcare insurer

Objectives
The objective of the interviews with the healthcare professionals was to answer the sub-questions and to gain understanding on the following topics:

- Their view on diabetes care
- Their opinion on the Diameter and if they view the Diameter as of added value
- If and how the Diameter could be implemented within primary diabetes care.

Design
Semi-structured interviews were used for this sub-study. Interviews with healthcare professionals were conducted from April 21st to June 8th.

Participants and recruitment
Healthcare professionals who are involved in the treatment of T2DM patients in primary care were eligible for an interview. These professionals ranged from general practitioners (GPs), diabetes nurses, practice nurses, practice-assisted GPs and dieticians. The inclusion criterium of healthcare professionals to be selected for an interview, was to be involved in the treatment of patients with T2DM within primary care.

This study aimed to include at least ten healthcare professionals (preferably from different general practices, with different job roles) to conduct the interviews with. This estimation was based on the amount being manageable in the restricted time and enough to reach saturation in their responses.

Healthcare professionals were contacted through Federatie Eerstelijnszorg Almelo (FEA) and Twentse Huisartsen Onderneming Oost Nederland (THOON). FEA and THOON first received information about the study from the researcher. Then, FEA and THOON distributed the information in their network of healthcare professionals actively involved in primary diabetes care. Healthcare professionals who were willing to conduct an interview, were contacted by the researcher by email. If the healthcare professional gave consent to participate in an interview, an interview appointment was scheduled. Two general practitioners were contacted through convenience sampling as they were family of the researcher.

During the interviews with healthcare professionals, it became apparent that the healthcare insurer would also play a role in the implementation of the Diameter. Therefore, healthcare insurer "Menzis" was contacted for an interview, and they agreed to conduct an interview with the project manager of digital care.

Procedure

Two interviews were held through Microsoft Teams, the other interviews were conducted by phone and lasted approximately 30-60 minutes.

Measurements

A semi-structured interview scheme was used to gather information on the following measurements:

1. Experiences and view on primary -type 2- diabetes care by healthcare professionals
- What does the care process for T2DM patients look like in practice?
- Are there currently eHealth technologies used within the care process?

2. Added value of the Diameter in perspective of the healthcare professional
- Is the Diameter of added value for T2DM patients?
- Can the Diameter contribute to the goals that healthcare professionals strive for with T2DM patients?

3. Barriers and facilitators to implementation of the Diameter
- Is it a necessity for implementation that the effectiveness of the Diameter must be proven?
- What is needed to facilitate implementation of the Diameter within the general practice?
- How would working with the Diameter be perceived by the healthcare professional?
- Which pros and cons does the healthcare professional perceive in using the Diameter?

The interview questions were formulated with the CFIR through literature research. First literature research was conducted on factors influencing healthcare professionals on implementation of eHealth technologies. This literature research was categorized by domains and sub-domains of the CFIR and from this scheme, the interview questions were framed. Categorization of the literature research by the CFIR is presented in appendix 8.1. In the interview scheme the domains of the CFIR along with the sub-themes are aligned with the interview questions. The interview scheme for healthcare professionals can be found in appendix 8.4.2. A modified, shortened interview scheme (appendix 8.4.3) was used to interview the dieticians and the lifestyle coach (appendix 8.4.3 and 8.4.4). The dieticians only had thirty minutes to conduct the interview or worked outside of the general practice, like the lifestyle coach. For these interviews, the questions regarding the inner setting were changed to the specific setting they were working in and/or with, such as regulations within their work environment. Questions regarding the specific setting of the general practice were left out as well as rules and regulations of the general practice.

Data handling

Interviews that were held over the phone were recorded with an iPhone X. This iPhone was reset to factory settings and not linked to an apple ID or other account(s). After the interviews, recordings were directly transferred to the server of the University of Twente in which they were stored. When the interview was held in Microsoft Teams, the recording was directly transferred to the same server as well and deleted from the computer. Recordings were transcribed, but personal details such as names were left out of the transcription. These transcriptions were also uploaded to the server of the University of Twente. Transcriptions were saved under a number instead of a name to ensure anonymity. As most first transcripts were created with Amber Scripts, the files were immediately deleted from this website after completion.

Data analysis

Interviews were transcribed verbatim first through Amber Script and then adjusted by the researcher. Atlas.TI was used to analyse the interviews. Furthermore, the interviews were analysed with a general inductive coding approach; the same method as used for interviews with patients. The codes were used to answer the three sub-questions for healthcare professionals in this study. Therefore, the following themes were established before coding to answer the sub-questions from this study:

1. Experiences and opinion on primary diabetes care
2. Added value of the Diameter
3. Barriers & facilitators on implementation of the Diameter

First, the researcher read the transcripts. The transcripts were broken down in smaller samples. From the data of these smaller samples, the codes were developed. The codes were later grouped to certain concepts. Some of these concepts were assigned to the themes above. An alumnus (MSC) of Universiteit Twente selected two transcripts of the interview -randomly- and coded these independently. If codes differed, the researchers discussed these until they reached consensus. In response to the altered codes, the codes from other transcripts were changed accordingly as well.

04

RESULTS

04

4. Results

This chapter provides the results from the first sub-study 'survey patients' and combined the results from the sub-studies 'interview patients' and 'interview healthcare professionals' as the interviews covered the same themes related to the sub-questions of this study.

Results sub-study 1: Survey patients

There were 102 responses to the survey, from which 57 were complete. Table 7 provides an overview of the characteristics of respondents who completed the survey. As presented from this table, most respondents (71.9%) were female, and more than half of the respondents were in the age category of 46 – 65 years old. Furthermore, it is presented that most respondents currently receive treatment in primary care. Diabetes medication is most used in the form of a tablet, although about one third of the respondents currently do not receive any medication, except possible alterations to lifestyle. Moreover, most respondents have type 2 diabetes. The largest group (77,2%) of the respondents are categorized as 'early adopter' or 'early majority'. The remaining respondents are categorized as 'laggards', 'late majority' and 'innovators'.

Table 7: Characteristics of survey respondents (N=57)

Respondent characteristics		n (%)
Age	18-35 years	4 (7,0)
	36-45 years	6 (10,5)
	46-55 years	16 (28,1)
	56-65 years	22 (38,6)
	66-75 years	7 (12,3)
	76 years or older	2 (3,5)
Gender	Male	16 (28,1)
	Female	41 (71,9)
Education	Lower vocational education (LBO, VBO, LTS, LHNO, VMBO (MAVO))	5 (8,8)
	Secondary vocational education (MBO, MTS, MEAO)	20 (35,1)
	General secondary education (high school – HAVO, VWO, Gymnasium)	4 (7,0)
	Higher professional education (HBO, HEAO, PABO, HTS)	23 (40,4)
	Academic University (WO)	4 (7,0)
	Other	1 (1,8)
Country of birth	Netherlands	54 (94,7)
	Belgium	1 (1,8)
	Germany	1 (1,8)
	Other	1 (1,8)
Type of diabetes	Pre-diabetes (glucose intolerant)	1 (1,8)
	Diabetes type 1	2 (3,5)
	Diabetes type 2	53 (93,0)
	Other	1 (1,8)
Length of diagnose	Less than one year	9 (15,8)
	1 – 5 years	20 (35,1)
	6 – 10 years	10 (17,5)
	Longer than 10 years	18 (31,6)
Treatment	Primary diabetes care	38 (66,7)
	Secondary diabetes care	12 (21,1)
	Both primary and secondary diabetes care	7 (12,3)

Diabetes medication*	None (possible alterations to lifestyle)	18 (31,6)
	Tablets	36 (63,2)
	Insulin	17 (29,8)
	Insulin pump	1 (1,8)
Complications*	None	46 (80,7)
	Retinopathy	5 (8,8)
	Neuropathy	8 (14,0)
	Nephropathy	0 (0,0)
Type of adopter		
	Innovator	2 (3.5)
	Early adopter	29 (50.9)
	Early majority	15 (26.3)
	Late majority	4 (7.0)
	Laggards	7 (12.3)

**Multiple response question, therefore, the total > 100%*

Perceived usefulness of functions of the Diameter

Figure 8 demonstrates the functions that were perceived as useful (in orange) and less useful (in grey). In general, most functions of the Diameter were perceived as useful and of added value in the diabetes care process. The functions that were counted as useful the most were keeping track of blood glucose levels, exercise and nutritional intake. Patients could motivate why they indicated certain functions as useful. The general response was that with these functions, patients have more insight on the influence of lifestyle (i.e., exercise, nutrition) on their blood glucose levels. With this information, they could get more control of their diabetes.

Functions that were perceived as less useful were setting goals (25.9%), the daily notifications (12.9%) and the digital coach (14.1%). Patients were able to motivate their response. Generally, the most frequent given explanation was that they know what to do and can do it themselves. Some respondents commented that it would give them stress and feel pressured to set goals and follow specific advice. In addition, respondents felt like they wouldn't keep track of the app or the advice and that is why it would not be useful to them. About one fourth of the respondents (27.1%) perceived all functions of the Diameter as useful. Furthermore, only 2 respondents (1.2%) indicated that none of the functions seem useful to them.

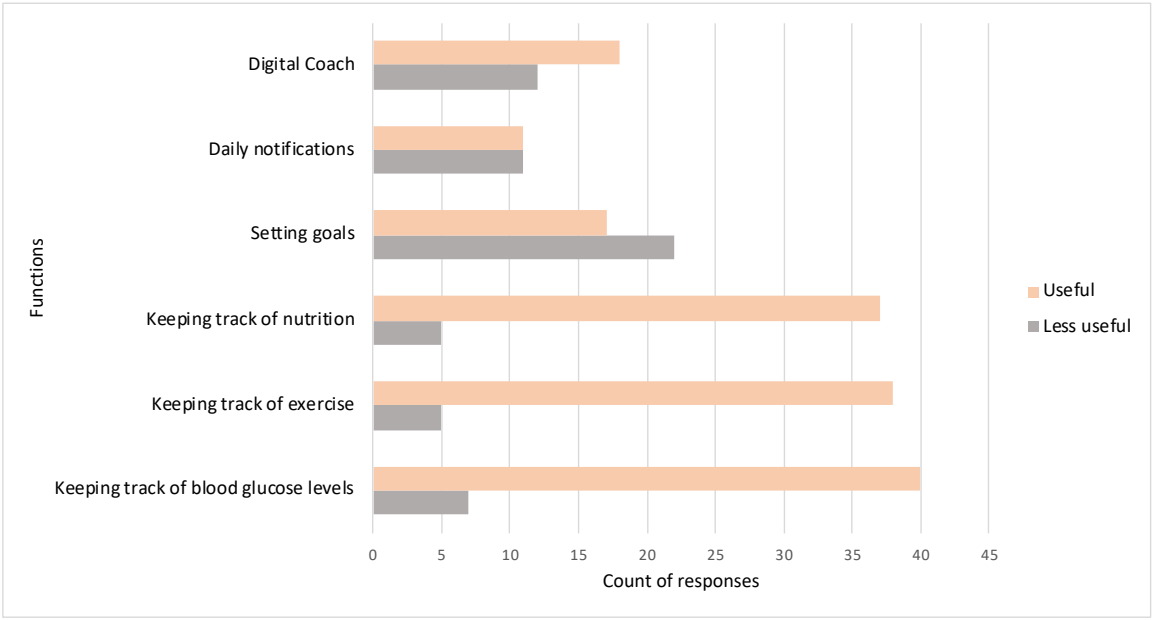


Figure 8. Perceived usefulness of functions of the Diameter by count.

Rating of the Diameter

Respondents were asked to rate the Diameter to be of added value within their care process on a scale of 1 (terrible) to 10 (excellent). The Diameter was rated with a median of 8.0 and the mean rating of all respondents was 7.3. As presented in figure 9, mean rating of the Diameter differed per level of education of respondents. The mean rating of respondents with lower and secondary vocational education was lower than respondents with general secondary education, higher professional education or academic university. However, Kruskal-Wallis H test did not show a statistically significant difference (*P*= .994) between these groups of educational level.

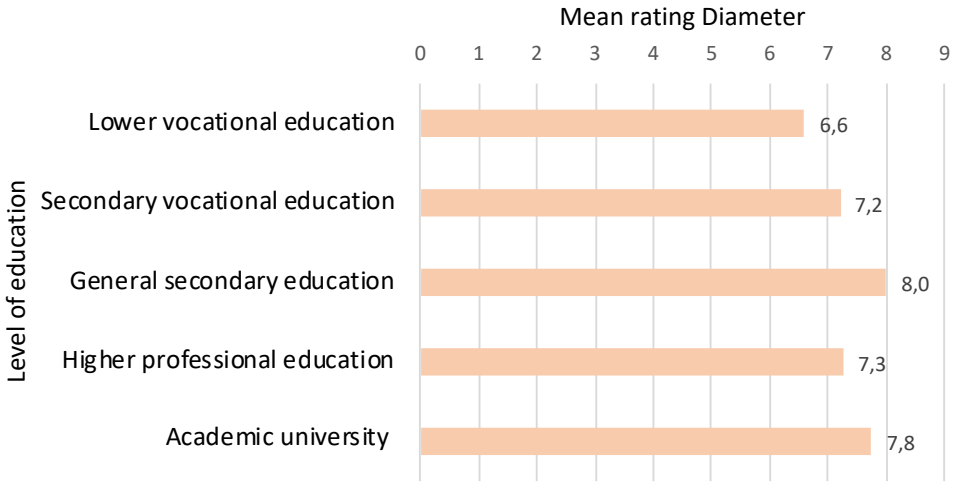


Figure 9. Rating (mean) of the perceived added value of the Diameter within the care process, presented by level of education.

Furthermore, Kurt Wallis H Test was also used to determine if there were statistically significant in rating of the Diameter between groups when respondents were divided into independent groups based on age, type of diabetes and type of adopter. However, no statistically different significance was found. Table 8 presents the overall mean rating of the Diameter per category group and the corresponding p value.

As Kurt Wallis H test did not conclude a significant difference, the Mann-Whitney U test was performed on the recoded variables age with two levels, “young” (<55 years) and “old” (>55 years) and education with two levels “lower” and “higher” education. Mann-Whitney U test concluded no significant difference in rating of the Diameter between these groups. Differences in groups were significant if *P* <.05. No significant differences (*P*<.05) in results were found for age (young/old, *P* = .674) as well as for education (lower/higher education, *P* = .265).

Table 8. Mean rating of the Diameter per group and significance of differences per group tested by Kruskal Wallis H Test.

Category	Group	Mean rating Diameter [range]	*P**
Age	18-35 years	7.0 [4.0 – 8.0]	.994
	36-45 years	7.2 [4.0 – 9.0]	
	46-55 years	7.4 [5.0 – 10.0]	
	56-65 years	7.3 [5.0 – 9.0]	
	66-75 years	7.1 [6.0 – 8.0]	
	76 years or older	7.5 [6.0 – 9.0]	
Education	Lower vocational education	6.6 [6.0 – 7.0]	.445
	Secondary vocational education	7.2 [4.0 – 9.0]	
	General secondary education	8.0 [7.0 – 10.0]	
	Higher professional education	7.3 [4.0 – 9.0]	
	Academic University	7.8 [7.0 – 9.0]	
Type of Diabetes	Pre-diabetes	8**	.664
	Diabetes type 1	6.0 [4.0 – 8.0]	
	Diabetes type 2	7.3 [4.0 – 10.0]	
	Other (MODY)	8**	
Type of Adopter	Innovator	7.0 [6.0 – 8.0]	.769
	Early adopter	7.4 [4.0 – 9.0]	
	Early majority	7.1 [4.0 – 10.0]	
	Late majority	7.0 [6.0 – 8.0]	
	Laggards	7.0 [6.0 – 8.0]	

*Results were significant when *P*<.05.
** Only one response recorded in this group, therefore the range is not presented

Constructs of the UTAUT, Design and Diameter within the care process

The median of the measurements PE, EE, SI, added value of the Diameter within the care process and design was 4.0 "agree" as presented in table 9. Therefore, respondents were positive about the performance expectancy (i.e., expected effectiveness of the Diameter) and effort expectancy (i.e., ease of use of the Diameter). In addition, the median score on the social influence statements showed it is important to patients that other people with T2DM would use the Diameter as well and that their healthcare professional would recommend using the Diameter. Furthermore, respondents agreed that they viewed the Diameter of added value within their healthcare process and were positive about the design of the Diameter, as the was 4 on both constructs.

Table 9. Frequency table with the median, range, minimum and maximum per construct

	Performance expectancy	Effort Expectancy	Social Influence	Added value of Diameter	Design
Responses	57	57	57	57	57
Median*	4.0	4.0	4.0	4.0	4.0
Minimum*	2.0	2.0	1.0	2.0	3.0
Maximum*	5.0	5.0	5.0	5.0	5.0

5-point Likert-Scale items were ranged as 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree and 5 = strongly agree.

Figure 10 presents the count of Likert-Scale Items per construct in the survey. As earlier mentioned, "agree" (4) was counted the most in all constructs. Furthermore, none of the respondents disagreed with any of the statements regarding the design of the Diameter. In the other constructs, disagreement with the statements was recorded in small numbers.

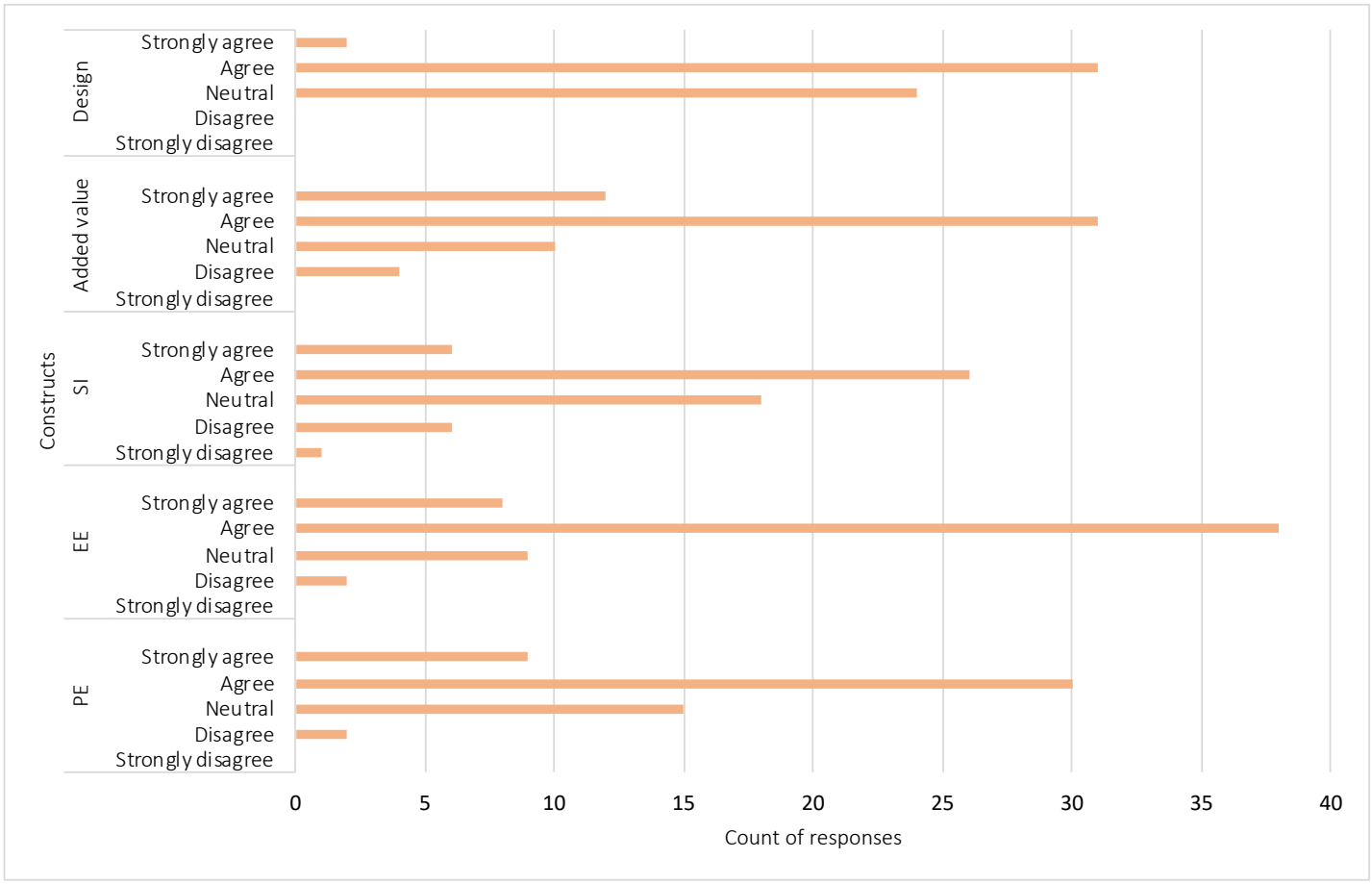


Figure 10. Count of Likert-Scale item responses of the constructs; performance expectancy (PE), effort expectancy (EE), social influence (SI), added value of the Diameter within care process (added value) and design.

The construct facilitating conditions contained two multiple response statements, in which respondents needed to indicate if they owned a Fitbit and Android phone. Figure 11 presents the number of respondents that own an Android phone. From the 57 respondents, 44 respondents (77.2%) did own an Android phone.

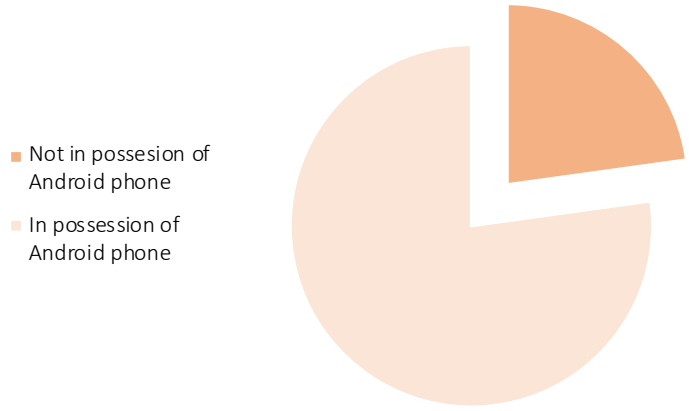


Figure 11. Number of respondents who are in possession of an Android phone.

Figure 12 presents the number of respondents who own a Fitbit. From the 57 responses, 37 respondents (64.9%) indicated that they did not own a Fitbit.

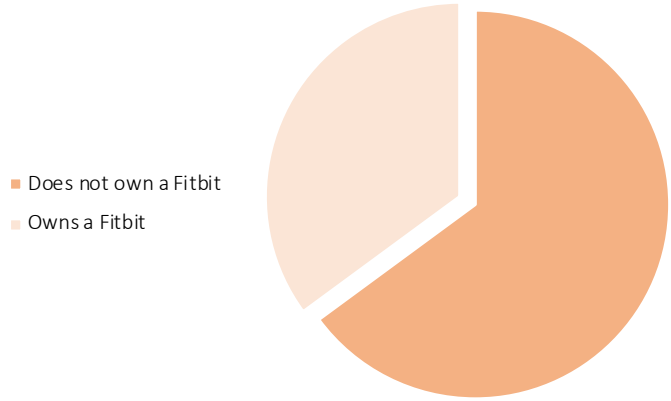


Figure 12. Number of respondents who own a Fitbit

Results sub-studies 2 & 3: Interviews patients and healthcare professionals

This section provides the results from semi-structured interviews with healthcare professionals, patients with diabetes and a project manager digital care of health insurer Menzis. The results of the following measurements are discussed:

- Diabetes care, perspectives from the patients and healthcare professionals
- Added value of the Diameter
- Barriers & Facilitators to implementation of the Diameter

Characteristics of respondents (interviews)

Table 10. Interviewee characteristics patients

Patient characteristics		Amount of people N= 6
Age	18-35 years	0
	36-45 years	1
	56-65 years	4
	66-75 years	1
	76 years or older	0
Gender	Male	4
	Female	2
Education	Higher professional education	6
Type of diabetes	Type 1 diabetes	0
	Type 2 diabetes	5
	MODY	1
Received diagnoses	3,5 years ago	1
	More than 10 years ago	5
Complications	None	3
	Neuropathy	3
Current treatment phase	Diagnostic phase	0
	Initial treatment phase	0
	Chronic treatment phase	6
Place of treatment	Primary care	6
	Secondary care	0
	Primary and secondary care	0

Table 10 presents the characteristics of the patients that were interviewed and table 11 presents the characteristics of the healthcare professionals that were interviewed. In total, eighteen people were interviewed, from which six patients who received treatment in primary care and twelve healthcare professionals who are involved in the treatment of T2DM patients. Ten of the healthcare professionals are working within standardized primary diabetes care, one lifestyle coach works in an independent practice providing combined lifestyle intervention, one dietician participated from an independent practice and one project manager from Menzis was interviewed.

Table 11. Interviewee characteristics healthcare professionals

Healthcare professional characteristics		Amount of people N=12
Primary care	General practitioner	3
	"Kaderarts"	1
	Dietician	3
	Practice nurse (POH)	2
Independent practice	Lifestyle coach	1
	Dietician	1
Insurance company (Menzis)	Project manager 'Digital Care'	1

Diabetes care: perspectives of patients and healthcare professionals

Positive remarks about diabetes care

In general, patients with T2DM expressed that they viewed their primary diabetes care as positive - although not all patients could mention a specific positive remark. As presented in table 12, half of the patients expressed that the positive remark in their care process is that they are in frequent contact with their GP or POH as they go for routine check-ups with them. One patient mentioned that the positive remark about his care process is having a FreeStyle Libre Sensor, which brought him much knowledge and insights on his blood glucose levels. Furthermore, all patients expressed lack of attention to lifestyle in their care process. In addition, all patients expressed that they did their own research on lifestyle in relation to diabetes. Most patients claimed they never received any information about exercise or diet beneficial to T2DM and a third of the patients expressed that they felt uneducated about their disease and the medication given to them. These patients would like to see improvements in educating patients in the care process. One patient (PT) commented the following:

"I hear all around me that a lot of people have no idea what a carbohydrate -a sugar- is, or how this works. For example, you see people who are newly diagnosed with diabetes eating a whole pizza in one sitting. Those kinds of things, there is a lot of ignorance in the area of nutrition" – PT (MODY, male)

Healthcare professionals were asked, just as patients, what the positive remarks and points of improvement were in primary diabetes care. The positive remark that was mentioned most frequently was providing person-centered care. As each patient' situation is different, they took pride in providing tailored care for each of their patients. Lifestyle was the second most mentioned positive remark about diabetes care. Most healthcare professionals were very enthusiastic about lifestyle and the positive effect this has on diabetes and one fourth of them mentioned this as a positive remark in the care process. This was in contradiction with the response from patients, as they viewed that they did not receive enough attention to lifestyle in the care process. Furthermore, healthcare professionals described that they truly know their patients outside of routine diabetes check-ups as well. For example, they know in what kind of family they live or if the patient has other (chronic) illnesses. They viewed knowing their patients as a positive remark of care.

Points of improvement in diabetes care

Points of improvements were also mentioned, self-management of patients was mentioned the most by healthcare professionals. GPs and POHs believed that patients can do more on their own in the management of their disease. They also see this as a necessity, as the number of patients with chronic illnesses like T2DM they see is growing. Therefore, having patients manage their own disease, where the healthcare professional can monitor them in the background was seen as a necessity in the future. One healthcare professional (HCP), a general practitioner explained this as:

"I think that these kinds of technologies could help with that [self-management], as we aim for more self-management in certain groups of patients. They can do it easily themselves." – HCP (GP, male)

One of the POHs explained that self-management is also a relevant subject for her, as she thinks that it is very important for patients to manage and monitor their own health. As her role is to guide the patients with T2DM and monitor and adjust their treatment, she feels that she doesn't want to become a 'policeman' [in Dutch: voor politieagent spelen], where she tells patients what to do and what not to do.

Table 12. Experiences in primary diabetes care by patients and healthcare professionals.

Main and sub codes	Definition of code	Codes[1]	HCP.[2]	PT.[3]
Experiences care process				
Positive:				
- Frequent check-ups	*Routine checks with each visit (3, 6 and 12 months)*	3		3 (3)
- Technology	*Use of technology (FreeStyle Libre Sensor)*	1		1 (1)
- Person-centered care	*Providing tailored care to each person*	11	11 (8)	
- Lifestyle	*Providing special attention to lifestyle*	5	5 (4)	
- Education	*Educating the patient on diabetes*	3	3 (2)	
- Knowing the patients	*Knowing the patient not only for their diabetes but other important life aspects as well.*	2	2 (2)	
Improvements				
- Lifestyle	*Attention to lifestyle within the care process*	18	1 (1)	17 (6)
- Education	*Educating the patient on diabetes*	9	4 (3)	5 (2)
- Self-management of patient	*Giving more power to the patient in terms of self-management; check-ups and results.*	9	9 (5)	
- Person-centered care	*Providing tailored care to each person*	4	4 (4)	
- Access to data	*Easy access to health-related data such as lab results*	3	3 (3)	
- Administrative paperwork	*Paperwork that needs to be filled in before/after patient visits*	1	1 (1)	

Total amount of times a code was found. [2]Total amount of times a code was mentioned by healthcare professionals (HCP) and (#) the number of different healthcare professionals that mentioned it. [3]Total amount of times a code was mentioned by patients (PT) and (#) the number of different patients that mentioned it.

Furthermore, education was mentioned by both patients and healthcare professionals as a point of improvement. Two GPs mentioned that often, T2DM patients don't have sufficient knowledge on a healthy lifestyle, and they had different examples of this. One of the examples was that often patients think that they are doing a good job – for example drinking a lot of orange juice as this is 'healthy' – but they fail to recognize that this 'healthy drink' contains a lot of (fruit)sugars as they lack knowledge on this topic. Another GP added to this that often, it is difficult for the patient to gain sufficient knowledge on a healthy lifestyle as this is a subject that is too difficult for them to understand. Furthermore, one POH also stated that education is a point of improvement within diabetes care, but from a different point of view. Her perspective on this topic was that there is a lot of information available to patients online, and this can be very overwhelming for them. Especially when the information is often contradicting. She commented this as:

"A point of improvement [in diabetes care] is the widely available information online. There is so much information available, that it can be overwhelming to understand what is true and helpful and what is not [in Dutch: door de bomen het bos niet meer zien]." – HCP (POH, female)

Furthermore, another point of improvement that was mentioned, is the amount of IT systems and portals currently used within primary diabetes care. Table 13 presents examples of the IT systems mentioned by healthcare professionals. One POH explained that leads to confusion, for the professionals as well as the patient, as there are different portals, webpages and logins for various purposes. She commented on this with an example of medicine for T2DM patients:

"T2DM medicine are not available in the regular pharmacy anymore, it has to be ordered from the digital pharmacy. It [the many systems] causes a lot of confusion, also for patients, but for us it is a lot of extra work" – HCP (POH, female)

GPs and POHs are required to fill in a lot of paperwork with every patient visit. This was also mentioned as a point of improvement; the load and/or burden of the administrative paperwork.

Use of information technology (IT) systems

The technologies that healthcare professionals use, are IT systems specialized for general practices (HIS) or chronic illnesses (KIS). One general practitioner mentioned that he sometimes uses video calls to check with his patients. A specific reason for this wasn't mentioned, other than that the practice was not that advanced yet in using technologies, and that it takes a lot of time to implement new technologies. Furthermore, it was mentioned that some practices have pilot tested portals in which patients could register health related measures, however this failed because patients did not adhere to it. A few practices explained that they were currently testing 'Engage', an online patient portal by Philips.

Table 13. Use of technology by patients and information technology (IT) systems by healthcare professionals (HCP).

Main and sub codes	Definition of code	Codes[1]	HCP. [2]	PT. [3]
Type of technology				
- Activity tracker	*Any activity tracker mentioned, such as Fitbit*	2		2 (2)
- Step counter app	*App on phone that counts steps*	4		4 (3)
- Samsung/Apple Health app	*Integrated health app on phone*	2		2 (2)
- "Ommetje" (app)	*App which tracks the minutes of walks*	1		1 (1)
- FreeStyle Libre Sensor	*Sensor to track blood glucose levels*	1		1 (1)
- Yazio	*App to track nutrition intake*	1		1 (1)
Motivation to use technology	*Keeping track of nutrition and/or exercise*	5		5 (2)
- Monitoring	*Insights into their exercise and/or nutrition*	4		4 (4)
- Insights	*Improving their fitness*	1		1 (1)
- Improvements				
IT system	*Patient portal by Philips*	2	2 (2)	
- Engage	*Patient portal*	2	2 (2)	
- Gezondheidnet	*'Huisarts/Ketenzorg informatie systeem'*	4	4 (4)	
- HIS/KIS	*'Keten en ondersteuning systeem'*	1	1 (1)	
- KOS	*Communication platform*	1	1 (1)	
- OZOverbindzorg	*Type of 'ketenzorg' information system*	1	1 (1)	
- Porta Vita				

Total amount of times a code was found. [2]Total amount of times a code was mentioned by healthcare professionals (HCP) and (#) the number of different healthcare professionals that mentioned it. [3]Total amount of times a code was mentioned by patients (PT) and (#) the number of different patients that mentioned it.

None of the patients used eHealth technology as part of their care process, but they did use stand-alone technologies and apps as presented in table 13. Patients use these eHealth technologies for the following purposes: to keep track of their activity and/or food, to gain insight into their activity and/or food, or to improve their exercise. The patient who used 'Yazio', an app to track food intake, explained she uses it to see how many calories she consumes daily. She also described that she synchronizes this app with her Fitbit, to see how many calories she burned. The downside of this app according to her, is that she does not see what the effect is of food on her blood glucose levels.

Added value of the Diameter

All patients perceived the Diameter as useful and of added value to primary diabetes care. However, as most patients received the diagnosis more than ten years ago, two patients expressed that at this moment the Diameter would not be that useful to them. These patients have figured out how exercise and nutrition affects them and their diabetes. In addition, they mentioned that the Diameter would have helped them tremendously in the early stages of diabetes care, when they received the diagnosis. In the beginning of their care process, they felt clueless on how to alter their lifestyle, or what would benefit them and needed more guidance. The motivations to use the Diameter are presented in table 14.

Table 14. Added value of the Diameter, conditions for implementation, concerns of using the Diameter and the target group of the Diameter according to healthcare professionals (HCP) and patients (PT).

Main and sub codes	Definition of codes	Codes[1]	HCP.[2]	PT.[3]
Added value of the Diameter				
Insights	*Effect of nutrition and exercise on blood glucose levels*	29	15 (6)	14 (6)
Control	*Improved control of diabetes and related complications*	6	4 (3)	2 (2)
Person-centered advice	*Improved person-centered advice*	8	8 (5)	
Awareness of habits	*Patients can become more aware of their habits*	9	9 (6)	
Education	*Becoming more knowledgably on diabetes*	2	2 (2)	
Setting goals	*Patients will be able to create small lifestyle related goals for themselves*	2	2 (2)	
Conditions for implementing the Diameter				
Blended care	*Combination of face-to-face and online treatment*	8	5 (4)	3 (3)
Time period	*The total period in which the Diameter should be used*	15	7 (4)	8 (3)
Group setting	*Implementation of the Diameter in a group*	6	5 (4)	1 (1)
Concerns of using the diameter				
Keeping track of nutrition	*Manually registering food intake*	14	4 (3)	10 (4)
Being continuously busy with diabetes	*Diabetes playing a more prominent than desired role in the life of the patient*	8	4 (2)	4 (3)
Target Group Diameter				
Motivated patients	*Patients who are motivated to use the Diameter*	8	8 (5)	
Patients who use insulin	*Patients who use insulin as part of their medication*	5	5 (4)	
Patients with fluctuating blood glucose levels	*Patients whose blood glucose levels vary greatly*	3	3 (2)	
Glucose-intolerant patients	*Patients with glucose-intolerance (pre-diabetes)*	2	2 (2)	
Newly diagnosed patients	*Patients in the diagnostic phase of treatment*	6	6 (4)	

[1]Total amount of times a code was found. [2]Total amount of times a code was mentioned by healthcare professionals (HCP) and (#) the number of different healthcare professionals that mentioned it. [3]Total amount of times a code was mentioned by patients (PT) and (#) the number of different patients that mentioned it.

The most mentioned added value of the Diameter by patients as well as healthcare professionals, was to gain more insight into the effect of exercise and nutrition on blood glucose levels. One patient with T2DM described this as:

"What I'm curious about is the relation between the things that you eat versus movement, exercise and versus your blood glucose levels, this could help me gain insights into the relation of my lifestyle and diabetes" – PT (T2DM, male)

As a result of more data and insight into the patients' lifestyle, healthcare professionals can provide better person-centred advice which makes this the second most mentioned motivator of using the Diameter by healthcare professionals. Furthermore, half of the healthcare professionals noted that through the Diameter, the patient would become more aware of his/her habits. For example, a patient might eat cereal for breakfast every day, but notices that with this habit he/she uses most of his/her carbohydrates for that day. Being more aware of the patients' habits, it would be easier for them to make smaller adjustable goals. Improved control of diabetes was mentioned by a third of the patients and a fourth of the healthcare professionals. This would be of added value, as with stabilized blood glucose levels, patients would have to see the GP or POH less often. One GP explained this as:

"*Hopefully, patients would have to come less to the practice [when using the Diameter]. We can monitor them from a distance, and when we see a change or difference in measurements, we can contact the patient or the patient can contact us" – HCP (GP, male)*

Education and setting goals were also mentioned as added value of the Diameter in the care process by healthcare professionals. Patients did not specifically mention to view the Diameter of added value for educational purposes. However, they did mention that they felt that this was missing in their care process as presented in table 12. Therefore, the Diameter could play a role in improving this part of the care process. Education and setting goals provide the patient with more knowledge on lifestyle and their disease, which could lead to improved self-management. This was specifically mentioned by the POH and lifestyle coach. The POH described this as:

"But if I look at the Diameter, patients can formulate goals for themselves and keep track of this. The goals can be as small as they want and that makes it very manageable [in Dutch: behapbaar]". – HCP (POH, female)

The lifestyle coach explained that it was good to help patients formulate their own goals to evaluate this with them. This could provide a domino effect, where small goals can have a big effect on people. To conclude, all the healthcare professionals perceived the Diameter as useful and to be of added value for T2DM patients. In addition, all healthcare professionals viewed the Diameter as fitting within the norms and values of the general practice and it would fit the protocols and guidelines that they follow.

Concerns of using the Diameter

As presented in table 14, more than half of the patients expressed concerns about keeping up with the Diameter for an extended period because of the information that is required to be registered manually, especially keeping up with a food diary. Healthcare professionals were concerned about this as well, as they commented that the patient would have to be extremely motivated to register their food intake and exercise manually. Keeping track of nutritional intake was mentioned specifically as a concern, where one dietician (female) commented:

"We notice that, in practice, when you ask people to keep track of a food diary, that nearly not everyone does this because it's a lot of work." – HCP (dietician, female)

Another concern that was raised by both patients as well as healthcare professionals, was that use of the Diameter can result in being continuously busy with diabetes. Constantly checking blood glucose levels can become addicting or give the patients' disease a prominent role in their life, which they do not want. A POH commented on this as follows:

"You thereby give the condition they have a significantly larger role in their lives than is actually desirable." – HCP (POH, female)

The other POH also confirmed this, as she explained that a pitfall of the Diameter could be that the patient will be too invested with their disease. The lifestyle coach commented on this that it could burden patients with extra stress and pressure, because instead of going for a check-up once every three months where they are measured, they can now see everything daily. One patient, who has been diagnosed with T2DM for over twenty years explained that it is not motivating for him when he focused on blood glucose levels the whole day. Another patient with type MODY confirmed this, as he explained that, as a patient, you do not want to be confronted with your disease all the time, especially not in the beginning where you might be in denial.

Target group the Diameter

The healthcare professionals expressed that they viewed the Diameter as fitting for the following target audience:

- Newly diagnosed patients with type 2 diabetes
- Patients with type 2 diabetes who use insulin or undergo changes in insulin dosage
- Patients with fluctuating blood glucose levels
- Patients with glucose intolerance (pre-diabetes)

The groups defined above are patients who are newly diagnosed or have unstable blood glucose levels. Newly diagnosed patients with T2DM are often unaware of their habits and don't really know what exactly a 'healthy lifestyle' means. The Diameter could provide insights into the effect of nutrition and exercise on their lifestyle for this patient group. Patients who use insulin or undergo changes in dosage must check their blood glucose levels multiple times a day and adjust the dosage accordingly. For this patient group to carefully monitor their blood glucose levels through an app, can benefit them as they become aware of the effects lifestyle has on their diabetes. Furthermore, patients with glucose intolerance were mentioned as a potential target group of the Diameter, as those people are recommended to make changes in lifestyle before their glucose intolerance progresses to T2DM. The Diameter could bring this patient group awareness into their habits and give them insights into their lifestyle. In general, healthcare professionals agreed that to use the Diameter, the patient must be motivated and must have some level of digital skills. In addition, for the older and complex-care patients with low digital skills the Diameter was viewed as not useful. It was also mentioned by three healthcare professionals that a large group of patients in diabetes care has low literacy and for this group the app might be too difficult to understand.

Conditions for implementing the Diameter

Most patients and healthcare professionals expressed that they would like to use the Diameter as blended care. Furthermore, a third of the healthcare professionals and one patient mentioned introducing the Diameter in a group setting, as making changes to lifestyle often includes other people such as their partner, family, or friends.

As mentioned in the interviews, generally patients need to be very motivated and disciplined to use the Diameter. Some patients expressed that they would not want to use the Diameter every day and certainly not for a long period of time. Therefore, patients and healthcare professionals noted that they would rather use the Diameter for a certain time, preferably at the beginning of their care process (i.e., within the diagnostic phase).

Perceived barriers & Facilitators for implementation of the Diameter

Table 15 provides an overview of the perceived barriers and facilitators to implementation of the Diameter in primary care by healthcare professionals and patients.

Barriers

As mentioned previously, most patients expressed that keeping track of nutritional intake was seen as a barrier of implementation. This barrier stems from experience of patients who have used apps in the past to keep track of their nutritional intake.

Privacy and security were also mentioned by half of the patients as they were concerned about who would view their data and what the consequences would be. One patient mentioned that he was scared that there would be consequences from his healthcare insurer if they would get access to his data. Another patient mentioned that he would be willing to share data with his GP, but not the dietician. Healthcare professionals expressed concerns about privacy and security as well, as the system needs to store personal data safely. In addition to this, concerns were raised about being overwhelmed with data. One general practitioner (male) explained the overload of data as:

".. So, there is a risk of getting a tsunami of data, if the patient is continuously measuring their blood glucose levels. You have to start carefully with patients and explain thoroughly so that they won't call the practice with every hypo or hyper they have." – HCP (GP, male)

Furthermore, lack of time was mentioned as a barrier for implementation by a POH, a GP and kaderarts, as they expressed that currently they already lack time in their work hours while performing their regular tasks. Implementing a new system will take time and therefore, they saw this as a barrier.

Lack of patients' motivation and discipline were used to express doubts about using the Diameter - for a longer period. The healthcare insurer also raised concerns about the usage of the Diameter long-term. They were specifically interested in using the Diameter as a motivation to change behaviour long-term but missed how the patient would be motivated in the process for that period and how the change in behaviour would be measured. In addition, the healthcare insurer raised a concern about usage of the Fitbit instead of a build-in phone activity tracker, which most phones have nowadays. Implying that the Fitbit would be an additional cost of funding, this would have to be justified.

Other barriers that were mentioned were not being digitally skilled, both for the patient group as well as healthcare professionals (GPs and POHs) in practice. Furthermore, it was mentioned that a large group of T2DM patients has low literacy and is older in age. Therefore, the Diameter might be too difficult for them to use. However, one practice nurse did mention that more and more patients are becoming more digitally skilled and use technology more often. Therefore, she expressed that in a few years to a decade, the Diameter might be easy to use for a larger patient group.

Furthermore, the kaderarts expressed that she could not see implementation of the Diameter happening, as there other currently other IT systems in use and there are many apps in the market that patients can download and use for free. She explained this as follows:

"The problem is that there are a lot of these kinds of apps and that you would have to choose together, for example with everyone in the region, that we [as healthcare professionals] are all going to use this app. So, it would help if more people would use the app, preferably in primary ánd secondary care. That would be very important to me. But I don't see that happening anytime soon to be honest, and that also has to do with how much there is indeed on the market at the moment." – HCP, kaderarts, female

To add to the comment of this kaderarts, the healthcare insurer also commented that it would be important for the Diameter -in case of funding- to have multiple practices and healthcare professionals who endorse the Diameter and are willing to use it in practice. This would improve chances of getting funded with the help of 'zorggroepen' (care groups) in the future.

Table 15. Perceived barriers and facilitators to implementation by healthcare professionals (HCP) and patients (PT).

Main and sub codes	Definition of codes	Codes	HCP[2]	PT[3]
Implementation barriers				
Digital skills	*Digital skills of HCP and patient*	7	7 (4)	
Low literacy	*Patient group often has low literacy*	5	5 (4)	
Time	*Lack of time*	4	4 (3)	
Saturated market	*Too many similar (stand-alone) apps*	4	4 (3)	
Finance	*Costs of implementing the Diameter*	4	4 (3)	
Age	*Age of the patient and HCP*	1	1 (1)	
IT Systems	*Currently there are other IT systems in use*	1	1 (1)	
Privacy & security	*Security of data and the system*	15	5 (3)	10 (4)
Motivation	*Motivation and discipline of patient to use the app*	13	4 (3)	9 (4)
Keeping track of nutrition	*Manually registering food intake*	14	4 (3)	10 (4)
Being continuously busy with diabetes	*Diabetes playing a more prominent than desired role in the life of the patient*	8	4 (2)	4 (3)
Implementation facilitators				
User friendliness	*Ease-of-use of the system*	4	2 (2)	2 (2)
Interoperability	*Interoperability of Diameter with other IT systems*	11	11 (5)	
Time	*Time savings*	7	7 (4)	
Agreement of use	*Use of the Diameter by all HCPs in primary care*	4	4 (4)	
Medical device	*Diameter should be recommended by Geneesmiddelen bulliten (Ge-Bu)*	2	2 (1)	

Total amount of times a code was found. [2]Total amount of times a code was mentioned by healthcare professionals (HCP) and (#) the number of different healthcare professionals that mentioned it. [3]Total amount of times a code was mentioned by patients (PT) and (#) the number of different patients that mentioned it.

Facilitators

The most mentioned argument by healthcare professionals that would facilitate implementation of the Diameter was interoperability of the Diameter with current IT systems such as the 'huisarts informatie systeem' (HIS) and 'ketenzorg informatie systeem' (KIS). As administrative paperwork is mentioned as a point of improvement in table 12, and time is mentioned as a barrier in table 15, interoperability of. The Diameter with other IT systems would save much time and paperwork.

In addition, time was mentioned as a facilitator because the Diameter could potentially be time saving. Having more data available to healthcare professionals would mean that it would be easier and faster to provide patient-centered care.

User friendliness of the system was mentioned by both healthcare professionals as patient as a facilitator of implementation. They further explained user friendliness as an app that is easy to use, with automatic synchronisation of exercise and blood glucose levels. One patient (T2DM) explained this, she mentioned that when everything is filled in automatically that using the app would be more appealing to her.

Furthermore, cooperation and use of the Diameter by all healthcare professionals of the multidisciplinary team in primary care was seen as a facilitator. When different healthcare professionals would all use the Diameter, this would facilitate implementation because it would be easier to exchange information and to have an overview of all the lifestyle components.

It was mentioned by the kaderarts that she would like the Diameter to be screened or recommended by 'Geneesmiddelen Bulliten' (Ge-Bu). As this would provide some sort of reliability of the effectiveness and security of the system. In addition to this, there was a division by healthcare professionals when the question was asked by the researcher if the Diameter needed to be proven to be effective before implementation. The consensus was that officially, general practitioners need to work with evidence-based medicine. Therefore, the Diameter should also be evidence-based and proven effective. However, all general practitioners agreed that they would be willing to pilot test the Diameter with selected patient groups when it has not yet been proven effective. The POHs added to this that for them, they were more reluctant to try the Diameter when the effectiveness was not proven, but argued that the GPs needed to work with evidence-based medicine.

It was mentioned by healthcare professionals that they believed that the Diameter would be easier to use and more effective for patients when they would make use of automatic synchronization of steps by a Fitbit and blood glucose levels with the FreeStyle Libre sensor. However, the big concern with these devices was the cost. It was mentioned by one healthcare professional that the healthcare insurer should be involved in the implementation process to think about the costs of the FreeStyle Libre Sensor and Fitbit in order to facilitate implementation.

All healthcare professionals that were interviewed were willing to implement the Diameter in their practice for pilot-testing. However, it was mentioned that there were some colleagues who could be resistant to change due to their age, digital skills or because they do not feel the need to use eHealth in their day-to-day work practice. Furthermore, the healthcare professionals expressed that they would like explanation and training in person of the Diameter in their practice before implementing the technology.

To facilitate funding of the Diameter by the healthcare insurer, it was explained that efficiency, affordability, effectiveness, privacy and ease of use were topics that were used to screen the technology. If the Diameter was proven efficient, affordable in care, effective and easy to use for the target group with a secure system that this would facilitate funding. The healthcare insurer further explained that funding of the Diameter would be facilitated if the Diameter was proven effective to relieve the burden of chronic illnesses in healthcare. For example, if using the Diameter would result in less complications and improved self-management of the patient, fewer patient visits would be needed in primary and secondary care. This would relieve the burden of work in primary and secondary care. As Menzis' vision is focused on lifestyle and prevention of -chronic- illnesses through behavioural change, funding of the Diameter could be facilitated by contributing to fulfil this vision.

05

DISCUSSION

05

5. Discussion

This study aimed to answer the research question: "*How can the Diameter be implemented in the primary care process of T2DM according to the needs of patients and healthcare professionals?"* through three sub-studies with T2DM patients and healthcare professionals involved in the treatment of T2DM in primary care.

This study provides a first exploration on implementation of the Diameter within primary diabetes care, where the overall added value of the Diameter is evaluated by patients with diabetes (in which the majority had T2DM), healthcare professionals involved in the treatment of T2DM and the healthcare insurer Menzis. All of these key stakeholders perceived that the Diameter was of added value as a contribution to primary diabetes care. Providing both patients as well as healthcare professionals with more insights into lifestyle components nutrition and exercise, and the effect this has on blood glucose levels of T2DM patients was the most mentioned added value of the Diameter. The Diameter was also evaluated by patients on several constructs such as performance expectancy (perceived usefulness), effort expectancy (perceived ease of use), social influence, design and the added value of the Diameter within the care process. All of these constructs were evaluated positively. Furthermore, conditions for implementation were established, such as implementation of the Diameter as blended care, for a restricted time period and in a group setting. In addition, healthcare professionals perceived the Diameter as useful for the following target groups: newly diagnosed T2DM patients, T2DM patients with fluctuating blood glucose levels, T2DM patients with insulin medication. In addition, patients who are glucose-intolerant were also included in the target groups as mentioned by healthcare professionals. These patient groups all receive a new treatment plan or undergo changes in their current treatment. The Diameter could provide them with the necessary tools to improve self-management for these patients.

Principal results and discussion

In the first sub-study 'survey patients' the Diameter was overall rated to be of added value in the diabetes care process with a mean rating of 7.3. In addition to the overall rating, patients were also positive about the perceived usefulness, perceived ease of use, the design of the Diameter and the value within their care process.

In the second and third sub-study, interviews with patients and healthcare professionals revealed the added value of the Diameter in the care process. The most frequent mentioned added value of the Diameter by healthcare professionals and patients was to gain more insights into the effect of exercise and nutrition on blood glucose levels. With these insights, T2DM patients could get more control over their disease and become aware of (un)healthy habits they might have. Previous research supports this, as various studies have promising results in which eHealth technologies are effective in stabilizing blood glucose levels [87]. Furthermore, having more control of diabetes matches the results of a study by Öberg, to the perceptions of patients on the implementation of eHealth technologies in treatment of T2DM. In this study [88], T2DM patients viewed eHealth technologies to be of added value in becoming more knowledgeable on their disease. Therefore, the perspective of participants was to be in better control of their diabetes through the support of eHealth. Supporting the result of awareness, in previous research, T2DM patients expressed that through a web-based eHealth technology, they became more aware of certain habits they created over the years. These habits revolved around their sedentary behaviour and exercise. eHealth helped participants with T2DM become aware of their habits and made them realize they need to change in this study [89].

Functions of the Diameter that were perceived as most useful were keeping track of blood glucose levels, exercise, and nutritional intake. This corresponds with what was mentioned in the interviews, that patients would use the Diameter because of the information it gives them about the inputs exercise and nutrition in relation to blood glucose levels.

This matches previous research *[38]* on the effectiveness of eHealth technologies in altering patients' lifestyle through tracking nutrition, exercise, and blood glucose levels. However, no further studies were found by the researcher on the perceived usefulness of certain functions in eHealth technologies by T2DM patients. Moreover, the functions perceived as less useful were setting goals, daily notifications, and the digital coach. However, these functions, such as setting goals, are effective techniques used to change behaviour [90]. Therefore, it is important to keep these functionalities. The motivation of patients why these functions were perceived as less useful were that patients would feel pressured and/or stressed to follow a certain advice. This finding matches concerns of using eHealth technology in a previous study by Budrionis [91] in 2020, where one fourth of the respondents indicated that they feel anxious or confused when using eHealth technologies. Although the significant demographic predictors were found in this study which explained feeling anxious, it was not further explained what exactly causes the anxiety as it was a quantitative survey study.

One of the conditions for implementation that was defined in this study, was implementation of the Diameter as blended care, rather than a stand-alone app. Both patients and healthcare professionals defined this condition. This result matches the results of other studies, where eHealth technologies are preferred as blended care because it is more effective in this setting than as a stand-alone technology [33] [92]. The improved effectiveness in blended care is explained by adherence of patients. Patients adhered to the eHealth technology longer and more frequently when it was used as blended care [33]. In the long-term, blended care is also promising in decreasing primary care check-ups [92] which could reduce the burden on primary healthcare.

Another condition that was defined in this study by healthcare professionals and one patient, was the implementation of the Diameter in a group setting. The patient expressed that he/she would feel more motivated to use the Diameter if he could speak with others about this. From the perspective of the healthcare professional, it was mentioned that often, treatment of T2DM needs to happen with the family, spouse or friends of the patient. Literature suggests promising results for group therapy compared to therapy for individuals in obese adults. In this study, weight loss of participants in the group setting was significantly more than of participants of individual therapy [93]. Moreover, the 2017 study of Singer [94] concluded that diabetes treatment in a group setting was as feasible and as efficient as in the individual setting.

Furthermore, from the interviews it became apparent that the Diameter was best used within a defined period, as patient and healthcare professionals had concerns regarding the motivation of patients to use the Diameter long-term. The problem of nonadherence to eHealth technologies is also noted in other studies, such as a study by Nijland [95], in which adherence to a web-based application for T2DM patients 'DiabetesCoach' was measured. In this study, a third of participants did not use the application for the complete research time (2 years). A systematic review researching eHealth technologies to alter lifestyle in T2DM patients also noted that in all the reviewed studies, adherence to the web-based technologies shrunk over time [38]. Cotter defined that further research was necessary to reveal patterns of adherence according to the specified target audience.

Results of this study included several perceived barriers and facilitators for implementing the Diameter both by healthcare professionals and patients. Barriers that were identified that matched with previous research were lack of digital skills [58] [62] [63], low levels of literacy [96], lack of time [64], cost of implementation [59] [60] [97], privacy and security reasons [61] [64], and lack of motivation by the end-user [58]. Keeping track of nutrition and being continuously busy with diabetes were newly identified barriers that did not match previous research.

Although age was found to be a perceived barrier to implementation, literature suggest personal characteristics such as age might influence the attitude of someone, but no significant relation was found between personal characteristics and implementation [64]. Furthermore, the use of other IT systems was mentioned as a barrier to implementing the Diameter, as well as the saturated market for certain apps. However, no previous research matched these barriers.

Facilitators for implementation that were identified and matched with results from previous research were user friendliness of the system [58] [58] [95], interoperability of the technology with existing (IT) systems [64, 65], time savings [98], and proven effectiveness of the technology [62]. The facilitator of having the Diameter screened and endorsed as a medical device matches literature where the need for standards and regulations of eHealth technologies is outlined [59]. As an example, a study to the quality of exercise apps concluded that one third of these apps in the market do not have a privacy policy and almost all apps were affiliated commercially in which the effectiveness was not proven [99]. This emphasizes the need for eHealth technologies to be screened as medical devices, where the effectiveness is proven.

Although previous research did not match the facilitator found in this study; agreement of use by all healthcare professionals, this facilitator could match previous research, where it was noted that eHealth technology needs to be fitting in the work practice [98]. As primary diabetes care consists of a multidisciplinary team, it will become easier for the patient as well as the healthcare professionals who are involved, to use the same eHealth technology.

A remarkable result of the interviews with patients was that none of them received -enough- attention to lifestyle in their care process. Possibly, patients expressed that they did not receive enough attention to lifestyle in their care process as most patients were diagnosed over ten years ago. According to the patients and healthcare professionals from this study, a decade ago, there was less attention to lifestyle in the care process of diabetes. In addition, literature suggests that T2DM patients often have low levels of (health) literacy. Depending on the study and sample size, low levels of (health) literacy ranged from 15 – 40% [100]. A study by van der Heide [101] concluded that in the Netherlands, low levels of health literacy in T2DM patients was associated with less knowledge and ability of self-management of diabetes, increased HbA1c levels and less physical activity. Therefore, lifestyle could have been discussed but patients were not able to comprehend this information.

During the interviews, healthcare professionals expressed concerns about patients using the Diameter long-term, as they felt that patients might lack motivation to fill everything in. This is in alignment with concerns on using the Diameter by patients. However, it takes a significant time to change behaviour, as a study by Lally [102] concluded that the average time to form a new habit takes 66 days. However, results vary greatly per individual as the range of habit formation was 18 – 254 days. In addition, to ease the burden of using the Diameter long-term, healthcare professionals were advocates of the Diameter in combination with the FreeStyle Libre Sensor and a Fitbit. However, using the Diameter with the FreeStyle Libre Sensor and Fitbit raised concerns about finances. Who would pay for these technologies?

This study matches perspectives on implementation of eHealth technologies from patients and healthcare professionals from previous studies. In a study by Öberg, primary healthcare professionals (nurses) express similar concerns towards the implementation of eHealth technology as in this study. Nurses expressed different views towards digitalization, some more enthusiastic than others and they were concerned about implementation of the technology in their work process [103]. A study by van der Kleij presents that development and implementation of eHealth technologies should be a participatory process, in which characteristics of patients and eHealth literacy should be taken into account [92]. This matches the concerns of the healthcare professionals, who expressed that the Diameter might be too difficult to understand for older, complex-care patients or patients with low levels of (eHealth) literacy.

Although all of the healthcare professionals were satisfied with the Diameter and willing to potentially implement it in their practice, several barriers towards implementation were mentioned during the interviews. This result could explain the numbers of a study by NIVEL [104] towards implementation of eHealth in primary care (2017). This study presented that most practices in primary care are willing to make use of eHealth technologies but are not making use of it yet. In addition, the use of eHealth technology is not increasing in primary care. This implies that concerns and barriers towards implementation need to be addressed before implementation is possible.

Strengths & Limitations

Strengths

One of the strengths of this study is that it applied a holistic approach to implementation, where various key stakeholders of the Diameter were involved. Participatory development and implementation involving various (key) stakeholders can increase the chances of effective implementation [57]. Involving perspectives from different stakeholders also provides more detailed information about the wants and needs of these stakeholders and provides a blueprint for future research [57].

The inclusion of at least five patients and ten healthcare professionals for the interviews was met and data saturation was reached. Therefore, results of the qualitative part of this study are representable.

This study was theory based. For the sub-studies where interviews were held, the interview questions were based on literature study and the CFIR. The CFIR provided a scientific framework for effective implementation. By framing the questions this way, potential influencing factors to implementation were systematically tackled. Furthermore, the first sub-study related to the survey of patients was based on constructs of the UTAUT (PE, EE, SI, FC) [75] and used the Diffusion of Innovations Theory by Rogers [72].

This study is of added value to existing literature about barriers and facilitators of implementing eHealth technologies within diabetes care. Perceived barriers specifically found in this study are keeping track of nutrition, the patient being continuously busy with their disease, the use of other IT systems by healthcare professionals and a saturated market of similar applications. Newly found facilitators include the Diameter to be endorsed as a medical device and agreement of all healthcare professionals to use the technology.

Limitations

A limitation of this study is the cognitive burden of the survey. Although the survey was tested by the researcher and friends and family of the researcher to ensure the questionnaire would be easy to understand and that it would work on all devices, the burden of the survey was too high for the respondents. From the 102 responses only 57 responses were complete. Therefore, the needed sample size of 97 respondents was not met and thus the results are not representable.

Distribution of the survey was biased, as it was distributed among Facebook groups, which suggests that the population is actively using technology. In addition, a large group of the respondents is interested in using technology, as more than 60% of respondents stated to use health related apps or indicated to have used them in the past. Therefore, effort expectancy (perceived ease-of-use) may be rated too positively for the general population as the less digitally skilled people were not reached.

Survey respondents were predominantly female (71.9%) and almost half of the respondents received their diagnosis over six years ago. Literature suggests that females use eHealth. Technology more often than males [88]. Therefore, results of the study might vary with more male respondents. About two thirds of respondents were in the age category of 46 – 65 years old and either completed secondary vocational education (35.1%) or higher professional education (40,4%). Therefore, results may differ when the survey is registered again among patients in different age groups or with other levels of education, as literature suggests that age and level of education are influencing factors in implementing eHealth technologies [105]. However, other studies contradict this as they could not find a significant relation between personal characteristics such as age and implementation [106] [107].

Furthermore, most of the respondents were categorized as early adopter or early majority. However, this could be explained as laggards would not be on Facebook or websites where the questionnaire was distributed, nor would they be motivated to fill in a technology related questionnaire. Therefore, the results might not be representative for the general population group as the different type of adopters react different to implementation.

Although extensive research has been conducted to explore personality traits in relation with adoption, empirical evidence for significant personality traits is lacking [108]. The type of adopters by Rogers have therefore also been criticised, as they should not be used as a factor to explain implementation according to a study by Greenhalgh [108].

During the interviews with patients, it became apparent that most patients were highly motivated to change their lifestyle, as they had done their own research on this topic. Therefore, it is plausible that the interviewed patient group is biased as literature [17] [109] suggests that T2DM are generally not motivated to change their lifestyle.

Another limitation of the interviews with patients is that no interviews with recently diagnosed T2DM patient were conducted. Therefore, the perspective of this group is missing. This is a limitation to the study as newly diagnosed T2DM patients is one of the identified target groups of the Diameter.

During the interviews, all healthcare mentioned to perceive the Diameter as useful and that it would fit within the norms and values of their practice but noticed that there could be some resistance from (older, less digitally skilled) colleagues. Presumably, healthcare professionals not interested in the use of eHealth technologies in their practice would not participate in this study. Therefore, it reflects that only motivated, enthusiast healthcare professionals were interviewed, and the results may be biased.

Furthermore, during the interview with the lifestyle coach it became apparent that she works at ZGT as a diabetes nurse and wanted to participate in a pilot study using the Diameter. Therefore, her response may be biased as during the interview, it became apparent that she was already involved with the T2DM patients of the pilot study in ZGT and was connected to the first researcher of this pilot study.

Finally, a limitation to this study is that the survey is not validated. The survey is theory-based (i.e., UTAUT, diffusion of innovations theory by Rogers) but the researcher adjusted and added questions based on the research-question and specific setting of this study.

Future research

This study provides a holistic approach to the acceptance of implementation of the Diameter in the primary care process. As the sample size of the survey was not sufficient, future research should include a bigger sample size, representative for the T2DM patient group to validate the results.

Furthermore, although the results of this study are generally positive about implementing the Diameter within primary care, acceptance has only been researched in the pre-implementation phase. Studies demonstrate that relevant factors to acceptance and implementation might differ when the technology has been implemented (post-implementation phase) [110]. Therefore, the Diameter needs to be tested in a pilot usability study to further research acceptance of implementing the Diameter in the post-implementation phase.

As newly diagnosed T2DM patients, patients with glucose intolerance and patients with insulin medication and/or fluctuating blood glucose levels were identified in this study as the target groups of the Diameter, future research should specifically be focused on these groups in primary care.

To facilitate the process of having the Diameter funded by healthcare insurers, future research should also focus on the effectiveness of the application, the ease of use of the application by the target group and the affordability of the application within healthcare.

Conclusion

In this study, a first exploration of implementation of the Diameter within primary care is evaluated among healthcare professionals, patients, and the healthcare insurer Menzis. Both healthcare professionals and patients agreed that the Diameter was perceived as useful and of added value in the care process to gain more insights into the effect of lifestyle components such as nutrition and exercise on blood glucose levels. Furthermore, the Diameter was positively evaluated on performance expectancy (i.e., the perceived usefulness), effort expectancy (i.e., perceived ease of use), social influence, design and added value within the care process by patients. In addition, healthcare professionals perceived the Diameter as useful for newly diagnosed T2DM, patients who use insulin, patients with fluctuating blood glucose levels and glucose intolerant patients because these patient groups undergo changes in their treatment in which the Diameter could be a helpful tool.

Perceived barriers that were identified for implementing the Diameter were (lack of) digital skills for both the healthcare professional as well as the patients, low levels of (health) literacy in the patient group and the time to implement the Diameter within current work process. Furthermore, healthcare professionals explained concerns about the saturated market of eHealth technology, in which many other apps are available with similar functionalities. Costs of implementing the Diameter was another barrier towards implementation, as the FreeStyle Libre sensor can become quite expensive for patients as well as the purchase of a Fitbit. As the T2DM patient group is relatively old, age was mentioned as a barrier to implementation as it is presumed that older patients and healthcare professionals are less capable of implementing the app. Use of other IT systems in practice such as patient portals was also mentioned as a barrier towards implementation. Furthermore, the security and privacy of the application as well as (lack of) motivation of the patient group are other barriers to implementation. Moreover, patients and healthcare professionals were concerned about tracking nutrition manually and the patient being continuously busy with diabetes. This could give the disease a prominent role in the patients' life, possibly more than the patient desires. The identified perceived facilitators were the user friendliness of the Diameter, as the perceived ease-of-use was rated positively. Interoperability of the Diameter with other IT systems in practice would facilitate implementation immensely. Furthermore, the potential time-saving capacity of the Diameter within the work process was mentioned as a facilitator, as well as use of the Diameter by all healthcare professionals in the multidisciplinary team. To conclude, rules and regulations are needed for eHealth technologies to be used in primary care. Therefore, a facilitator that was discovered was the Diameter to be endorsed as a medical device.

The next step for future research is a pilot usability test, in which acceptance can be evaluated in the post-implementation phase with the identified target groups. This pilot study can further outline the conditions necessary for implementation of the Diameter within primary care as well as contribute to research in which the effectiveness, privacy and security of the system and the ease of use can be further researched.

06

RECOMMENDATIONS

06

6. Recommendations

Based on the results of this study, this chapter provides recommendations for the implementation of the Diameter in primary care.

Target audience and treatment phase

Healthcare professionals formulated possible target groups, most suitable for using the Diameter:

- Newly diagnosed patients with T2DM
- Patients with T2DM who currently use insulin or undergo changes in insulin dosage
- Patients with fluctuating blood glucose levels
- Patients with glucose intolerance (pre-diabetes).

Figure 13 provides an overview of the identified target groups and in which phase of treatment they belong. Officially, patients with glucose intolerance do not fit in the care process of T2DM yet, as they have not fully developed the disease. However, when patients are diagnosed as being glucose-intolerant (pre-diabetes) they will receive similar treatment as T2DM patients, in which maintaining a healthy weight, nutritious diet and sufficient physical exercise play a major role. In figure 13, glucose-intolerant patients are therefore visualized in the diagnostic phase. Newly diagnosed T2DM patients will receive a personalized care plan in which lifestyle components are monitored to stabilize blood glucose levels. Therefore, the Diameter is of added value in the diagnostic phase for patients with glucose intolerance and in the initial treatment phase for newly diagnosed patients with T2DM, where the focus is on establishing a stability of blood glucose levels by controlling risk factors and adjusting lifestyle. As the initial treatment phase lasts approximately three months, the ten-week use of the Diameter fits perfectly within this time. Furthermore, patients with insulin (alterations) or fluctuating blood glucose levels can benefit from using the Diameter as a tool to improve self-management of their disease. They will become aware of their habits and will better understand the effect that lifestyle has on their disease. Table 16 provides an overview of the identified target groups, in which phase of treatment they belong, and what the added value of the Diameter is to them.

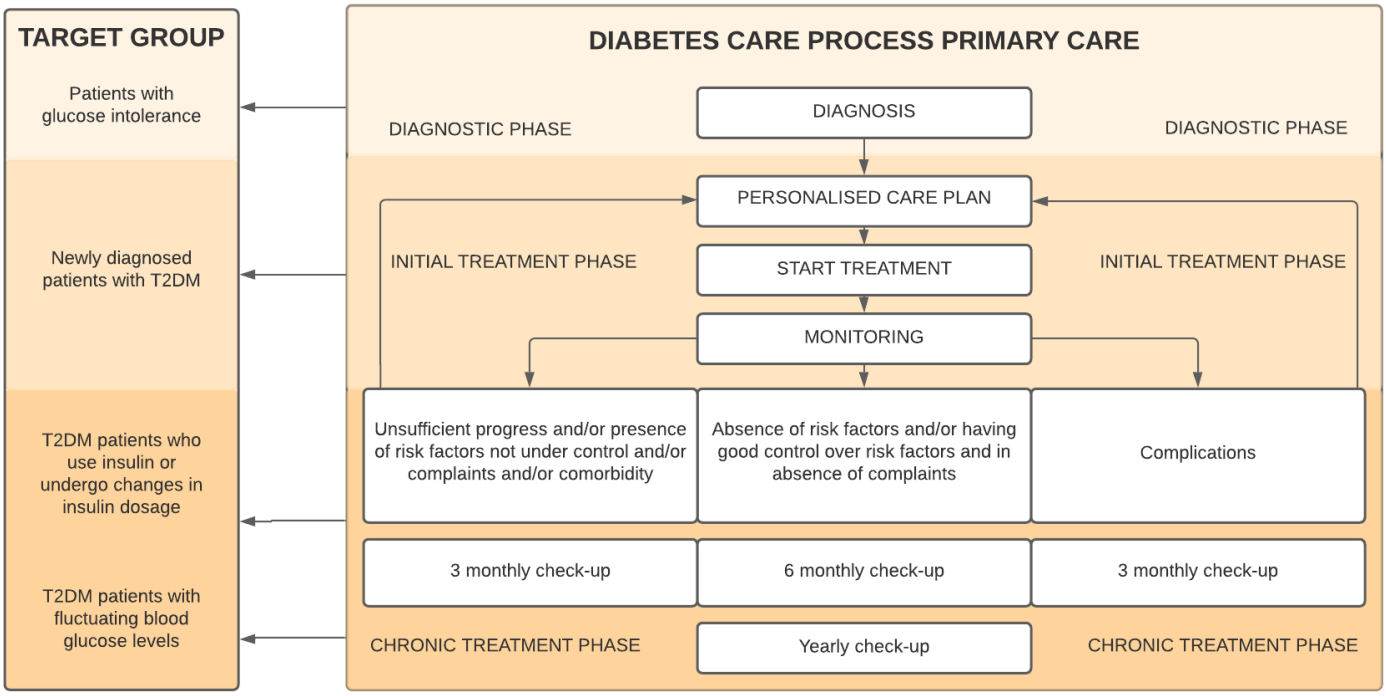


Figure 13. Implementation of the Diameter within primary care

Table 16. Identified target groups of the Diameter, corresponding treatment phase and added value of the Diameter to these target groups

Target group	Treatment phase	Added value
Patients with glucose intolerance (pre-diabetes)	Diagnostic	- Educating patients on the effects of lifestyle on their health, as glucose-intolerance can be reversed through changes in lifestyle. - Teaching patient principles of self-management by monitoring nutrition, exercise and blood glucose levels
Newly diagnosed patients with T2DM	Initial	- Educating patients on the importance of a (healthy) lifestyle - Setting small adjustable lifestyle goals for patients - Self-management of patient is encouraged
Patients with insulin medication and/or undergo changes in insulin dosage	Chronic	- Patient will gain insights on the effect of lifestyle and insulin on blood glucose levels - Providing the GP and POH with more data to improve patient-centred advice - Self-management of patient could be improved
T2DM patients with fluctuating blood glucose levels	Chronic	- Educating patients on the effects of nutrition and exercise on blood glucose levels - Patients can track blood glucose levels digitally (opposed to manually in a book that is often misplaced) - Creating awareness on habits that influence their blood glucose levels - Provides tools for improved self-management

In this study it was revealed through the semi-structured interviews that the POH will make use of the Diameter most often. Patient check-ups are done with the POH every three months and once a year with the GP. Therefore, it is important that implementation of the Diameter is focused on the role and tasks of the POH in the care process. The GP will also make use of the Diameter, but this will be more in a 'monitoring' role, in which the data on lifestyle can help the GP monitor the patient from a distance, in cooperation with the POH.

Use of patient advocates

The largest group of patient respondents was identified as early adopters. Early adopters are open to change and do not need convincing, they'll be motivated to use the Diameter when this is recommended by their GP or POH. Flyers and information sheets can help this category of adopter to implement the Diameter.

The second largest group of patient respondents was identified as early majority. As the early majority needs a bit more convincing to use the Diameter, early adopters can be used to share their 'success' stories with this adopter group (e.g., in a Facebook group or website). Evidence of the innovations' effectiveness can be used in an appeal for them to implement the Diameter. Furthermore, adding this type of adopter to a group with early adopters, the opinion leaders, they will be more eager to implement the Diameter and try the new technology themselves [72].

Using opinion leaders like the early adopters as advocates for the Diameter can help encourage patients who are less open to trying new technologies to try the Diameter and can help to give the Diameter more awareness.

Blended care is a must

The Diameter should be implemented as blended care in which the POH monitors the patients' glucose regulation and lifestyle on the basis of which a healthcare professional can give person-centered advice and make adjustments to treatment. As primary diabetes care consists of a multidisciplinary team, each individual healthcare professional should make use of the specific functions of the Diameter that are applicable to them, to personalize patient care. Furthermore, from the results of this study, it became apparent that the Diameter would be useful to be implemented in a group-setting within primary care, under supervision of healthcare professionals such as a POH, GP and dietician.

Privacy, security, and confidentiality
Patient and healthcare professionals should be assured of the privacy and security of the system, and that confidentiality is guaranteed. The patient should be informed on the data that is collected and why it is collected, and they should provide informed consent on who they want to share their data with.

Interoperability
As most general practices already use patient portals and IT systems, implementation of the Diameter would be facilitated when it is interoperable with IT systems already in use. The IT systems that are used were the 'ketenzorg informatie systeem' (KIS), such as 'Porta Vita' & 'Vital Health' (Philips) and 'huisarts informatie systeem' (HIS). In addition, the Diameter should be interoperable with patient portals such as 'MijnGezondheid' and 'Engage'.

Involvement of the healthcare insurer
In this study, healthcare professionals were largely concerned about the cost of implementing the Diameter as a whole, where the FreeStyle Libre Sensor and Fitbit are included to relieve the burden of manually registering blood glucose levels and exercise. Therefore, possible options for funding the Diameter by healthcare insurers were explored in which two options came to light, where it is recommended to pursue the second option:

The Diameter -as a supplier- can have the Diameter be evaluated by healthcare insurers
eHealth technologies are evaluated through the healthcare insurer in cooperation with "Zorgverzekeraars Nederland" (ZN), which is the trade association of health insurers in the Netherlands. The aim of ZN is to support healthcare insurers to realize good, affordable, and accessible care for all insured parties [111]. The supplier of the eHealth technology -the Diameter- will be held accountable for the following topics, which are evaluated in the process of funding:

- Efficiency
- Affordability
- Effectiveness
- Privacy
- Ease of use

The full list of topics which are evaluated when submitting an eHealth evaluation for funding can be found in appendix 8.5. If the eHealth technology is evaluated and "passed", then insurers can make individual financial agreements with the supplier. This is not the same for all healthcare insurers, as they are competitors from one another. Noted from the topics on this list and from the aspects that were mentioned in the interview, it is important to for eHealth technologies that they provide and can contribute to the quality of healthcare, that the technology is safe and secure to use, and the data is confidential. Furthermore, the effectiveness of the technology and validation for the certain target group is important. Therefore, before application for funding as a supplier, the Diameter needs to have conducted several studies to prove the effectiveness of the Diameter for T2DM patients in primary care. Furthermore, the contribution of the Diameter to the quality of care needs to be justified. These aspects can be researched in future research, with pilot studies in primary care.

The Diameter in cooperation with "zorggroepen" (care groups) in the Netherlands

Within primary care in the Netherlands, there are more than hundred "zorggroepen" (care groups). These care groups consist of healthcare professionals working in primary care who are in contract with healthcare insurers to coordinate chronic care in a selected region. Their objective is to improve the quality of delivered care [112]. There is a funding budget available nationwide, designated for digital care. Care groups in the Netherlands can apply a grant of this budget, to fund a certain part of primary diabetes care, for example, the Diameter. A specific business case with a plan of financial funding. Menzis is particularly keen on this strategy, as the past years this budget has been used too little because not enough plans were submitted or approved.

Therefore, as future research is recommended on the effectiveness of the Diameter and the contribution of this technology to primary diabetes care, the pilot study can be conducted in several practices in a region with the same preferred healthcare insurer (e.g., the region of 'Twente' in the Netherlands). If the pilot studies go well, the GP's who are affiliated with certain care groups can be used as advocates for endorsement of the Diameter and apply for funding with the healthcare insurer. Having several GPs from care groups endorse the Diameter can facilitate funding with the healthcare insurer.

Healthcare insurer 'Menzis' is focused on prevention, lifestyle and digital care. They also have an interest in relieving secondary care by having certain tasks or procedures done in primary care, or if possible, by the patient themselves at home. Menzis did not see the Diameter fit within "inkoopbeleid gecombineerde leefstijlinterventie" because diabetes care in the Netherlands is funded as "ketenzorg". This type of care comes from primary diabetes care in combination with the care groups, in which general practitioners play a central role. Therefore, funding for the Diameter needs to come either as a cooperation with these care groups, or as an individual supplier in contract with healthcare insurers.

07

REFERENCES

07

7. References

1. Yakaryılmaz FD, Öztürk ZA. Treatment of type 2 diabetes mellitus in the elderly. World J Diabetes. 2017;8(6):278-85.
2. Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. Nature Reviews Endocrinology. 2018;14(2):88-98.
3. Volksgezondheidenzorg.info. Prevalentie diabetes in huisartsenparktijk naar leeftijd en geslacht. 2021.
4. Diagnosis and Classification of Diabetes Mellitus. Diabetes Care. 2013;36(Supplement 1):S67-S74.
5. Maedler K, Donath MY. Beta-cells in type 2 diabetes: a loss of function and mass. Horm Res. 2004;62 Suppl 3:67-73.
6. Basu S, Yudkin JS, Kehlenbrink S, Davies JI, Wild SH, Lipska KJ, et al. Estimation of global insulin use for type 2 diabetes, 2018–30: a microsimulation analysis. The Lancet Diabetes & Endocrinology. 2019;7(1):25-33.
7. Volksgezondheidenzorg.info. Bijdrage diabetes mellitus aan ziektelast. 2021.
8. Ali O. Genetics of type 2 diabetes. World J Diabetes. 2013;4(4):114-23.
9. Hu Y, Bhupathiraju SN, de Koning L, Hu FB. Duration of obesity and overweight and risk of type 2 diabetes among US women. Obesity. 2014;22(10):2267-73.
10. Murea M, Ma L, Freedman BI. Genetic and environmental factors associated with type 2 diabetes and diabetic vascular complications. Rev Diabet Stud. 2012;9(1):6-22.
11. Shan Z, Ma H, Xie M, Yan P, Guo Y, Bao W, et al. Sleep duration and risk of type 2 diabetes: a meta-analysis of prospective studies. Diabetes Care. 2015;38(3):529-37.
12. Gray CL, Messer LC, Rappazzo KM, Jagai JS, Grabich SC, Lobdell DT. The association between physical inactivity and obesity is modified by five domains of environmental quality in U.S. adults: A cross-sectional study. PLoS One. 2018;13(8):e0203301.
13. Hagedoorn IJM, den Braber N, Oosterwijk MM, Gant CM, Navis G, Vollenbroek-Hutten MMR, et al. Low Physical Activity in Patients with Complicated Type 2 Diabetes Mellitus Is Associated with Low Muscle Mass and Low Protein Intake. Journal of Clinical Medicine. 2020;9(10):3104.
14. Netherlands HCoT. Physical Activity Guidelines 2017. The Hague2017. p. 45.
15. Tudor-Locke C, Craig CL, Aoyagi Y, Bell RC, Croteau KA, De Bourdeaudhuij I, et al. How many steps/day are enough? For older adults and special populations. Int J Behav Nutr Phys Act. 2011;8:80.
16. Jakicic JM, Gregg E, Knowler W, Kelley DE, Lang W, Miller GD, et al. Activity patterns of obese adults with type 2 diabetes in the look AHEAD study. Med Sci Sports Exerc. 2010;42(11):1995-2005.
17. Stuij MS. Physical activity in type 2 diabetes care: a critical narrative study: Vrije Universiteit Amsteradam; 2021.
18. Nelson KM, Reiber G, Boyko EJ. Diet and Exercise Among Adults With Type 2 Diabetes. Diabetes Care. 2002;25(10):1722.
19. Volksgezondheidenzorg.info. Huidige situatie: beweegrichtlijnen volwassenen. 2021.
20. NOC*NSF. Zo sport Nederland - Trends en ontwikkelingen in sportdeelname 2020. Arnhem, Sportparticipatie A; 2021.
21. Netherlands) GHCot. Richtlijnen Goede Voeding 2015. 2015.
22. Brink E, van Rossum C, Postma-Smeets A, Stafleu A, Wolvers D, van Dooren C, et al. Development of healthy and sustainable food-based dietary guidelines for the Netherlands. Public Health Nutrition. 2019;22(13):2419-35.
23. CTM vR, EJM B, FBC V, MH B, JJMM D, MC O. Voedselconsumptie in 2012-2014 vergeleken met de Richtlijnen goede voeding 2015. Food consumption in 2012-2014 compared to Guidelines for healthy food 2015: Rijksinstituut voor Volksgezondheid en Milieu RIVM; 2017.

24. Gant CM, Binnenmars SH, Berg EVd, Bakker SJL, Navis G, Laverman GD. Integrated Assessment of Pharmacological and Nutritional Cardiovascular Risk Management: Blood Pressure Control in the DIAbetes and LifEstyle Cohort Twente (DIALECT). Nutrients. 2017;9(7):709.
25. Pot GK, Battjes-Fries MC, Patijn ON, Pijl H, Witkamp RF, de Visser M, et al. Nutrition and lifestyle intervention in type 2 diabetes: pilot study in the Netherlands showing improved glucose control and reduction in glucose lowering medication. BMJ Nutrition, Prevention & Health. 2019:bmjnph-2018-000012.
26. Vektis. Diabetes 2015 [updated July 21st, 2015; cited 2021 March 10th]. Available from: https://www.zorgprismapubliek.nl/producten/patientgroepen/diabetes/.
27. Garrofé B.C. BrA, Phang, A.Y. . Euro Diabetes Index. Health Consumer Powerhouse; 2014.
28. NDF. NDF Zorgstandaard Diabetes, type 2. 2015.
29. NHG. NHG-Standaard Diabetes Mellitus Type 2. 2018.
30. Alja Sluiter HvW, Alexander Arntzenius, Alexander Bots, Lioe-Ting Dijkhorst-Oei, Ferdinand van der Does, Jan Palmen,, Bert-Jan Potter van Loon NS, Jacintha van Balen. Landelijke Transmurale Afspraak Diabetes Mellitus type 2. Huisarts & Wetenschap. 2012(55):1-12.
31. Poskiparta M, Kasila K, Kiuru P. Dietary and physical activity counselling on Type 2 diabetes and impaired glucose tolerance by physicians and nurses in primary healthcare in Finland. Scandinavian Journal of Primary Health Care. 2006;24(4):206-10.
32. Hesselink AF, P. Martens, M. . Onderzoek naar de kwaliteit van zorg voor mensen met diabetes. Diabetes Zorgmonitor. 2012.
33. Talboom-Kamp EPWA, Verdijk NA, Kasteleyn MJ, Numans ME, Chavannes NH. From chronic disease management to person-centered eHealth; a review on the necessity for blended care. Clinical eHealth. 2018;1(1):3-7.
34. Pon Ed. Improving self-management in type 2 diabetes: Radboud University Nijmegen; 2020.
35. Gorter KJ, Tuytel GH, de Leeuw JR, van der Bijl JJ, Bensing JM, Rutten GE. Preferences and opinions of patients with Type 2 diabetes on education and self-care: a cross-sectional survey. Diabet Med. 2010;27(1):85-91.
36. Funnell MM, Bootle S, Stuckey HL. The diabetes attitudes, wishes and needs second study. Clin Diabetes. 2015;33(1):32-6.
37. Rollo ME, Aguiar EJ, Williams RL, Wynne K, Kriss M, Callister R, et al. eHealth technologies to support nutrition and physical activity behaviors in diabetes self-management. Diabetes Metab Syndr Obes. 2016;9:381-90.
38. Cotter AP, Durant N, Agne AA, Cherrington AL. Internet interventions to support lifestyle modification for diabetes management: a systematic review of the evidence. J Diabetes Complications. 2014;28(2):243-51.
39. Duncan I, Ahmed T, Li QE, Stetson B, Ruggiero L, Burton K, et al. Assessing the value of the diabetes educator. Diabetes Educ. 2011;37(5):638-57.
40. Ossebaard HC, Van Gemert-Pijnen L. eHealth and quality in health care: implementation time. International Journal for Quality in Health Care. 2016;28(3):415-9.
41. Lisette van Gemert-Pijnen SMK, Hanneke Kip, Robbert Sanderman. eHealth Research, Theory and Development - a Multidisciplinary Approach. New York: Routledge; 2018. p. 3-25.
42. El-Gayar O, Timsina P, Nawar N, Eid W. Mobile Applications for Diabetes Self-Management: Status and Potential. Journal of Diabetes Science and Technology. 2013;7(1):247-62.
43. Pagliari C, Clark D, Hunter K, Boyle D, Cunningham S, Morris A, et al. DARTS 2000 online diabetes management system: formative evaluation in clinical practice. Journal of Evaluation in Clinical Practice. 2003;9(4):391-400.
44. Smith SA, Murphy ME, Huschka TR, Dinneen SF, Gorman CA, Zimmerman BR, et al. Impact of a diabetes electronic management system on the care of patients seen in a subspecialty diabetes clinic. Diabetes Care. 1998;21(6):972-6.
45. Pal K, Eastwood SV, Michie S, Farmer A, Barnard ML, Peacock R, et al. Computer-based interventions to improve self-management in adults with type 2 diabetes: a systematic review and meta-analysis. Diabetes Care. 2014;37(6):1759-66.

46. Pal K, Eastwood SV, Michie S, Farmer AJ, Barnard ML, Peacock R, et al. Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus. Cochrane Database Syst Rev. 2013(3):CD008776.
47. Wu Y, Yao X, Vespasiani G, Nicolucci A, Dong Y, Kwong J, et al. Mobile App-Based Interventions to Support Diabetes Self-Management: A Systematic Review of Randomized Controlled Trials to Identify Functions Associated with Glycemic Efficacy. JMIR Mhealth Uhealth. 2017;5(3):e35.
48. Hu FB, Manson JE, Stampfer MJ, Colditz G, Liu S, Solomon CG, et al. Diet, Lifestyle, and the Risk of Type 2 Diabetes Mellitus in Women. New England Journal of Medicine. 2001;345(11):790-7.
49. Tryggestad JB, Willi SM. Complications and comorbidities of T2DM in adolescents: findings from the TODAY clinical trial. Journal of Diabetes and its Complications. 2015;29(2):307-12.
50. Smith KE, Levine B, Clement S, Hu M-J, Alaoui A, Mun S. Impact of MyCareTeam for poorly controlled diabetes mellitus. Diabetes technology & therapeutics. 2004;6 6:828-35.
51. McMahon GT, Gomes HE, Hickson Hohne S, Hu TM, Levine BA, Conlin PR. Web-based care management in patients with poorly controlled diabetes. Diabetes Care. 2005;28(7):1624-9.
52. Hess R, Bryce CL, Paone S, Fischer G, McTigue KM, Olshansky E, et al. Exploring challenges and potentials of personal health records in diabetes self-management: implementation and initial assessment. Telemed J E Health. 2007;13(5):509-17.
53. den Braber N, Vollenbroek-Hutten MMR, Oosterwijk MM, Gant CM, Hagedoorn IJM, van Beijnum BF, et al. Requirements of an Application to Monitor Diet, Physical Activity and Glucose Values in Patients with Type 2 Diabetes: The Diameter. Nutrients. 2019;11(2).
54. Voorde ASt. Development of an eCoaching module for type 2 diabetes patients to increase their physical activity : integrating theory, healthcare professionals? and patients? perspectives. 2018.
55. Hietbrink EAG. Development and Evaluation of a Just-in-Time Adaptive eCoach to Encourage Physical Activity and Healthy Nutrition in People with Type 2 Diabetes Mellitus. 2020.
56. Fokkema EMS. The development and evaluation of an eCoaching module to improve healthy nutrition in type 2 diabetes patients. 2019.
57. van Gemert-Pijnen JEWC, Nijland N, van Limburg M, Ossebaard HC, Kelders SM, Eysenbach G, et al. A Holistic Framework to Improve the Uptake and Impact of eHealth Technologies. J Med Internet Res. 2011;13(4):e111.
58. Schreiweis B, Pobiruchin M, Strotbaum V, Suleder J, Wiesner M, Bergh B. Barriers and Facilitators to the Implementation of eHealth Services: Systematic Literature Analysis. J Med Internet Res. 2019;21(11):e14197.
59. Peek ST, Wouters EJ, van Hoof J, Luijkx KG, Boeije HR, Vrijhoef HJ. Factors influencing acceptance of technology for aging in place: a systematic review. Int J Med Inform. 2014;83(4):235-48.
60. de Grood C, Raissi A, Kwon Y, Santana MJ. Adoption of e-health technology by physicians: a scoping review. J Multidiscip Healthc. 2016;9:335-44.
61. Granja C, Janssen W, Johansen MA. Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature. J Med Internet Res. 2018;20(5):e10235.
62. Bally ELS, Cesuroglu T. Toward Integration of mHealth in Primary Care in the Netherlands: A Qualitative Analysis of Stakeholder Perspectives. Front Public Health. 2020;7:407-.
63. Scott Kruse C, Karem P, Shifflett K, Vegi L, Ravi K, Brooks M. Evaluating barriers to adopting telemedicine worldwide: A systematic review. J Telemed Telecare. 2018;24(1):4-12.
64. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implementation Science. 2016;11(1):146.
65. Adaji A, Schattner P, Jones K. The use of information technology to enhance diabetes management in primary care: a literature review. Inform Prim Care. 2008;16(3):229-37.
66. Peters DH, Adam T, Alonge O, Agyepong IA, Tran N. Implementation research: what it is and how to do it. BMJ : British Medical Journal. 2013;347:f6753.

67. Lisette van Gemert-Pijnen SMK, Hanneke Kip, Robbert Sanderman. The complexity of eHealth implementation: a theoretical and practical perspective. eHealth Research, Theory and Development. New York: Routledge; 2018.
68. Christensen H, Griffiths KM, Farrer L. Adherence in internet interventions for anxiety and depression. J Med Internet Res. 2009;11(2):e13.
69. Kelders SM, Kok RN, Ossebaard HC, Van Gemert-Pijnen JE. Persuasive system design does matter: a systematic review of adherence to web-based interventions. J Med Internet Res. 2012;14(6):e152.
70. Sieverink F, Kelders SM, van Gemert-Pijnen JEWC. Clarifying the Concept of Adherence to eHealth Technology: Systematic Review on When Usage Becomes Adherence. J Med Internet Res. 2017;19(12):e402.
71. Powell BJ, McMillen JC, Proctor EK, Carpenter CR, Griffey RT, Bunger AC, et al. A compilation of strategies for implementing clinical innovations in health and mental health. Med Care Res Rev. 2012;69(2):123-57.
72. Rogers EM. Diffusion of Innovations. New York: The Free Press; 1983.
73. Berwick DM. Disseminating innovations in health care. JAMA. 2003;289(15):1969-75.
74. Reinhardt R, Hietschold N, Spyridonidis D. Adoption and Diffusion of Innovations in Health Care. 2014.
75. Venkatesh V, Davis F. A Theoretical Extension of the Technology Acceptance Model: Four Longitudinal Field Studies. Management Science. 2000;46:186-204.
76. Venkatesh V, Morris M, Davis G, Davis F. User Acceptance of Information Technology: Toward a Unified View. MIS Quarterly. 2003;27:425-78.
77. Zuiderwijk A, Janssen M, Dwivedi YK. Acceptance and use predictors of open data technologies: Drawing upon the unified theory of acceptance and use of technology. Government Information Quarterly. 2015;32(4):429-40.
78. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
79. The SAGE Encyclopedia of Qualitative Research Methods. 2008.
80. NIVEL. Aantal mensen met diabetes stijgt naar ruim 1.4 miljoen in 2040 2020 [Available from: https://www.nivel.nl/nl/nieuws/aantal-mensen-met-diabetes-stijgt-naar-ruim-14-miljoen-2040#:~:text=In%202019%20waren%20er%20in,000%20met%20type%202%20diabetes.
81. Taherdoost H. Determining Sample Size; How to Calculate Survey Sample Size. International Journal of Economics and Management System. 2017.
82. Carifio J, Perla R. Resolving the 50-year debate around using and misusing Likert scales. Med Educ. 2008;42(12):1150-2.
83. Ursachi G, Horodnic IA, Zait A. How Reliable are Measurement Scales? External Factors with Indirect Influence on Reliability Estimators. Procedia Economics and Finance. 2015;20:679-86.
84. Statistics L. Assumptions of the Mann-Whitney U test 2021 [Available from: https://statistics.laerd.com/statistical-guides/mann-whitney-u-test-assumptions.php.
85. Thomas DR. A general inductive approach for analyzing qualitative evaluation data. Am J Eval. 2006;27(2):237-46.
86. Corbin J, Strauss A. Grounded Theory Research - Procedures, Canons and Evaluative Criteria. Z Soziol. 1990;19(6):418-27.
87. Seo HJ, Kim SY, Sheen SS, Cha Y. e-Health Interventions for Community-Dwelling Type 2 Diabetes: A Scoping Review. Telemed J E Health. 2021;27(3):276-85.
88. Öberg U, Isaksson U, Jutterström L, Orre CJ, Hörnsten Å. Perceptions of Persons With Type 2 Diabetes Treated in Swedish Primary Health Care: Qualitative Study on Using eHealth Services for Self-Management Support. JMIR Diabetes. 2018;3(1):e7-e.
89. Poppe L, Crombez G, De Bourdeaudhuij I, Van der Mispel C, Shadid S, Verloigne M. Experiences and Opinions of Adults with Type 2 Diabetes Regarding a Self-Regulation-Based eHealth

Intervention Targeting Physical Activity and Sedentary Behaviour. International Journal of Environmental Research and Public Health. 2018;15(5).
90. Virtanen L, Kaihlanen A-M, Laukka E, Gluschkoff K, Heponiemi T. Behavior change techniques to promote healthcare professionals' eHealth competency: A systematic review of interventions. International Journal of Medical Informatics. 2021;149:104432.
91. Budrionis A, Wynn R, Marco-Ruiz L, Yigzaw KY, Bergvik S, Oyeyemi SO, et al. Impact of the Use of Electronic Health Tools on the Psychological and Emotional Well-Being of Electronic Health Service Users (The Seventh Tromsø Study - Part 3): Population-Based Questionnaire Study. Journal of medical Internet research. 2020;22(3):e13118-e.
92. van der Kleij RMJJ, Kasteleyn MJ, Meijer E, Bonten TN, Houwink EJF, Teichert M, et al. SERIES: eHealth in primary care. Part 1: Concepts, conditions and challenges. European Journal of General Practice. 2019;25(4):179-89.
93. Paul-Ebhohimhen V, Avenell A. A systematic review of the effectiveness of group versus individual treatments for adult obesity. Obes Facts. 2009;2(1):17-24.
94. Singer J, Levy S, Shimon I. Group versus Individual Care in Patients with Long-Standing Type 1 and Type 2 Diabetes: A One-Year Prospective Noninferiority Study in a Tertiary Diabetes Clinic. Journal of Diabetes Research. 2018;2018:1807246.
95. Nijland N, van Gemert-Pijnen JEWC, Kelders SM, Brandenburg BJ, Seydel ER. Factors Influencing the Use of a Web-Based Application for Supporting the Self-Care of Patients with Type 2 Diabetes: A Longitudinal Study. J Med Internet Res. 2011;13(3):e71.
96. Werts N, Hutton-Rogers L. Barriers To Achieving E-Health Literacy. American Journal of Health Sciences. 2013;4:115-20.
97. Ainsworth BE, Haskell WL, Herrmann SD, Meckes N, Bassett DR, Jr., Tudor-Locke C, et al. 2011 Compendium of Physical Activities: a second update of codes and MET values. Med Sci Sports Exerc. 2011;43(8):1575-81.
98. Gagnon MP, Desmartis M, Labrecque M, Car J, Pagliari C, Pluye P, et al. Systematic review of factors influencing the adoption of information and communication technologies by healthcare professionals. J Med Syst. 2012;36(1):241-77.
99. Bondaronek P, Alkhaldi G, Slee A, Hamilton FL, Murray E. Quality of Publicly Available Physical Activity Apps: Review and Content Analysis. JMIR mHealth and uHealth. 2018;6(3):e53-e.
100. Cavanaugh KL. Health literacy in diabetes care: explanation, evidence and equipment. Diabetes Manag (Lond). 2011;1(2):191-9.
101. van der Heide I, Rademakers J, Schipper M, Droomers M, Sørensen K, Uiters E. Health literacy of Dutch adults: a cross sectional survey. BMC Public Health. 2013;13:179.
102. Lally P, Jaarsveld C, Potts H, Wardle J. How are habits formed: Modeling habit formation in the real world. European Journal of Social Psychology. 2010;40.
103. Öberg U, Orre CJ, Isaksson U, Schimmer R, Larsson H, Hörnsten Å. Swedish primary healthcare nurses' perceptions of using digital eHealth services in support of patient self-management. Scand J Caring Sci. 2018;32(2):961-70.
104. Wouters M, Swinkels, I., Sinnige, J., Jong, J. de, Brabers, A., Lettow, B. van, Friele, R., Gennip, L. van. Kies bewust voor eHealth: eHealth-monitor 2017. Den Haag; 2017.
105. Reiners F, Sturm J, Bouw LJW, Wouters EJM. Sociodemographic Factors Influencing the Use of eHealth in People with Chronic Diseases. International journal of environmental research and public health. 2019;16(4):645.
106. Oroviogoicoechea C, Elliott B, Watson R. Review: evaluating information systems in nursing. J Clin Nurs. 2008;17(5):567-75.
107. Waneka R, Spetz J. Hospital information technology systems' impact on nurses and nursing care. J Nurs Adm. 2010;40(12):509-14.
108. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629.

109. Linmans JJ, Knottnerus JA, Spigt M. How motivated are patients with type 2 diabetes to change their lifestyle? A survey among patients and healthcare professionals. Primary Care Diabetes. 2015;9(6):439-45.
110. Zheng K, Padman R, Johnson M, Diamond H. Evaluation of Healthcare IT Applications: The User Acceptance Perspective. Studies in Computational Intelligence. 2007;65.
111. (ZN) ZN. Organisatie 2020 [Available from: https://www.zn.nl/over-zn/organisatie.
112. (CFN) CFN. Wat is een zorggroep? 2021 [Available from: https://www.cfnijmegen.nl/wat-is-een-zorggroep/.

08

APPENDICES

08

8. Appendices

Appendix 1 Literature Research

8.1.1 **Literature research** factors influencing users (patients) eHealth implementation

Database	**Search term(s)**	**Hits**	**Article**	**Factors**
Pubmed	Barriers AND eHealth AND implementation	856	Barriers and Facilitators to the Implementation of eHealth Services: Systematic Literature Analysis [58]	<u>Barriers</u> • Poor digital health literacy • Lack of necessary devices • Financing • Cognition • Security • Motivation • Accessibility • Doesn't fit users needs • Confidentiality • Does not fit organization structure • Extra work(load) <u>Facilitators</u> • Ease of use • Improved communication • Motivation • Integrated into care • Involvement of relevant stakeholders • Availability • User-friendliness
Pubmed	Factors AND implementation AND eHealth AND patients	633	Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature [61]	<u>Barrier</u> • Privacy and Security <u>Facilitator</u>

				• Patient empowerment and self-management
Pubmed	Factors AND implementation AND eHealth AND patients	633	Evaluating barriers to adopting telemedicine worldwide: a systematic review [63]	<u>Barriers</u> • Age • Level of education • Poor eHealth literacy • Bandwidth • Unawareness • High expectations of users
Google	technology implementation primary care Netherlands	94.500.000	Toward Integration of mHealth in Primary Care in. the Netherlands: A Qualitative Analysis of Stakeholder Perspectives [62]	<u>Barriers</u> • Unawareness of technology • Poor digital health literacy

Table 17. Literature research on implementation barriers & facilitators categorized by the CFIR and summarized (patients)

Summary	Sub-categories	CFIR domain
• Literature suggests that to facilitate the implementation of eHealth technology, the technology must be easy to use, user friendly [58] and motivating [58]. • A barrier might be that the technology creates too much of a burden on the patient and this will hinder the patient from using it [58]. • The technology must also be secure. Often, patients don't have the necessary devices for the technology. The patient might have concerns for his/her security and privacy [61], this needs to be addressed.	• Adaptability • Complexity • Cost	Intervention
Literature suggests that barriers to implementation of eHealth technology for patients are related to the characteristics of the patient. For example: • the patient group is too old [58], • has poor digital health literacy [58] [62] [63] • or is unaware [62] of the technology.	• Knowledge and beliefs about the intervention • Self-efficacy • (other) personal attributes	Individuals
• Patient must be empowered in the self-management [61] of their disease.	• Structural characteristics • Networks & Communications	Inner setting
• To benefit implementation, the burden of using technology must be low and the technology needs to be easy-to-use [58].	• Patient needs and resources • External policy / incentives	Outer setting
• As patients are often unaware [62] of the technology, during the implementation process,	• Engaging	Implementation process

8.1.2 **Literature research** factors influencing healthcare professionals in eHealth implementation

Database	Search term(s)	Hits	Article	Factors
Pubmed	Factors AND implementation AND eHealth AND patients	633	Factors Determining the Success and Failure of eHealth Interventions: Systematic Review of the Literature [61]	Barriers • Workflow - increased amount of work/tasks - disrupted workflow - (non)alignment with clinical processes Facilitator • Quality of healthcare - improved diagnosis - better communication - supported patient-centred care
Pubmed	Factors AND implementation AND eHealth AND patients	633	Evaluating barriers to adopting telemedicine worldwide: a systematic review [63]	Barriers • Technically-challenged staff • Resistance to change • Licensing • Interoperability • Poor design • Perception of impersonal care
Google	adoption ehealth technology physicians	3.450.000	Adoption of e-Health technology by physicians: a scoping review [60]	Barriers • Design/Technical concerns - does not fit current systems used in workplace - Usability • Privacy and security concerns • Cost and liability concerns • Productivity loss • Patient-physician interaction • Workload

				• Clinical autonomy threatened Facilitators • Pre-analysis of data • Proof of utility • Training and support
Scopus	Technology AND primary AND care AND diabetes	1.064	The use of information technology to enhance diabetes management in primary care: a literature review [65]	Barriers • Lack of time • Poor access. To equipment and t raining • Fear of computers • Anxiety/resistant towards change Facilitators • Adequate training • Integration of the system into usual work process • Involvement of other colleagues with experience in using IT
Google	technology implementation primary care Netherlands	94.500.000	Toward Integration of mHealth in Primary Care in. the Netherlands: A Qualitative Analysis of Stakeholder Perspectives [62]	Barriers • Interoperability: information cannot be transferred quick and easy between healthcare professional and patients [• Not enough scientific evidence for a lot of mHealth technologies, professionals are hesitant to adopt without the scientific research proving the validity and effectiveness of the technology • Lack of time to learn and implement technology Facilitators • Reduced workload • Time-saving • Education: proper training and information to use and implement the new technology
Google Scholar	Factors + determining + implementation + ehealth	24.600	Factors that influence the implementation of e-health: a	Barriers • Costs (too high) • Technology does not fit in work practice and/or work routine • Lack of involvement from management

			systematic review of systematic reviews (an update) [64]	• Accessibility to knowledge and information (steady work environment, electricity, internet, necessary technology etc.) • Negative attitude of healthcare professionals • Fear of loss of autonomy • Concerns about liability • Privacy and security concerns • Distorted healthcare professional – patient relationship • Lack of strategic plan Facilitators • Adaptability to fit current workflow • Interoperability (system must work with current IT systems) • Complexity (system must be easy-to-use and useful) • Need for standards and regulations of eHealth technology may benefit implementation • Support from management • Positive attitude of healthcare professionals

Table 18. Literature research on implementation barriers & facilitators categorized by the CFIR and summarized (healthcare professionals)

Summary	Sub-categories	CFIR domain
• Literature suggests that implementation of eHealth technology by healthcare professionals has a better chance of success when the effectiveness of the eHealth technology has been proven [62]. • Furthermore, the eHealth technology must be adaptable to the current work environment and must be interoperable with current technologies used [64, 65]. • The technology must be easy to use and useful, and not cost too much to facilitate the acceptance and adoption of the technology [59, 60].	• Evidence strength • Relative advantage • Adaptability • Complexity • Cost	Intervention
• Literature suggest that implementation of a certain eHealth technology is facilitated when the technology has been researched and proven effective [62]. • A positive attitude towards the technology also facilitates implementation, whereas a negative attitude or believe that the technology is not effective may hinder implementation [62].	• Knowledge and beliefs about the intervention • (other) personal attributes	Individuals
• There are some concerns about the relationship between the professional and patient through an eHealth technology, worried that the clinical authority might be damaged [60]. • Implementation would be facilitated when management is involved and approves of the eHealth technology [64].	• Structural characteristics • Networks & Communications	Inner setting
• There is a need for standards and regulation to support eHealth technologies and validate its effectiveness [59].	• Patient needs and resources • External policy / incentives	Outer setting
• Lack of a strategic implementation plan might hinder the acceptance of the eHealth technology. Adequate training on the technology supports the implementation process and is encouraged [60, 62].	• Planning	Implementation process

8.2 Appendix 2 **Flyer Diabetes Fonds**

UNIVERSITY OF TWENTE. zgt

Gezocht!

Heeft u **Diabetes** Mellitus **Type 2?**

Wij zoeken geïnteresseerden die voor onderzoek een vragenlijst willen invullen en/of mee willen werken aan een (telefonisch) interview over een nieuwe app voor diabetespatiënten: De Diameter.

VRAGENLLIJST

De Diameter is een mobiele app waar u de mogelijkheid heeft om glucosewaarden, beweging en voeding te registreren om zo inzicht te krijgen in uw levensstijl. Hiernaast kunt u doelen stellen en ontvangt u coaching via een digitale coach in de app. Tijdens het invullen van de vragenlijst krijgt u te zien hoe de app eruitziet en hoe de app werkt. We zijn benieuwd naar uw mening als diabetespatiënt; wat vindt u van deze app? Zou de app van toegevoegde waarde zijn binnen uw behandeling?

Het invullen van de vragenlijst kost niet meer dan tien minuten en helpt de Universiteit Twente en Ziekenhuisgroep Twente (ZGT) om de app verder te ontwikkelen. U kunt deelnemen aan de vragenlijst via deze link: https://utwentebs.eu.qualtrics.com/jfe/form/SV_5z60dItX33KfTka

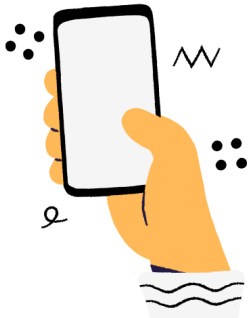
---

INTERVIEW

Ook zouden wij graag een interview willen houden met diabetespatiënten over het behandelingstraject en of de Diameter hierin van toegevoegde waarde kan zijn. Dit interview zal telefonisch plaatsvinden en ongeveer een half uur duren. Hiervoor zijn wij op zoek naar mensen die aan de volgende voorwaarden voldoen:

- U bent 18 jaar of ouder
- U heeft diabetes type 2
- U staat onder behandeling van een huisarts (eerstelijnszorg).

Voldoet u aan deze voorwaarden en heeft u interesse om mee te werken aan een interview? Neem dan contact op met Eva van ’t Hul (e.m.vanthul@student.utwente.nl)



De Diameter

Start van blok: Introductie Survey

Q1 Beste meneer, mevrouw,

Deze vragenlijst is onderdeel van het onderzoek naar het uitzetten van de app "de Diameter" binnen de diabeteszorg, een samenwerking tussen Ziekenhuis groep Twente (ZGT) en Universiteit Twente.

De Diameter is een gratis smartphone app voor patiënten met diabetes type 2. Met deze app kun je voeding, beweging en glucosewaarden bijhouden in één omgeving. Daarnaast kun je een persoonlijk doel stellen op het gebied van voeding en/of beweging. Iedere week bespreekt een digitale coach deze doelen en probeert zij te helpen met het behalen van deze doelen. Naast de wekelijkse coach-berichten kunnen patiënten gedurende tien weken informerende en motiverende berichten ontvangen op het gebied van voeding en beweging. Om deze vragenlijst in te vullen is het niet nodig de app zelf te downloaden of te gebruiken. Tijdens het invullen van de vragenlijst krijgt u te zien hoe de app werkt door middel van screenshots.

Ter afronding van mijn Master Health Sciences (Universiteit Twente) ben ik verantwoordelijk voor dit onderzoek. Door uw mening te delen over de Diameter, kan de app verder ontwikkeld en verbeterd worden. Het invullen van deze vragenlijst duurt ongeveer 10 minuten.

Uw deelname aan deze vragenlijst is vrijwillig en u kunt op elk gewenst moment stoppen. De antwoorden op de vragen zullen altijd anoniem blijven en uw gegevens worden niet gedeeld. Uw antwoorden worden enkel gebruikt voor de doeleinden van dit onderzoek.

Indien u vragen heeft over deze vragenlijst, kunt u deze mailen naar e.m.vanthul@student.utwente.nl.

Uw deelname aan deze vragenlijst wordt enorm gewaardeerd. Hartelijk bedankt voor uw tijd.

Met vriendelijke groet,

E.M van 't Hul
Master student Health Sciences
Universiteit Twente
e.m.vanthul@student.utwente.nl

Q2 **Bevestiging van uw deelname aan deze vragenlijst en daarmee dit onderzoek:**

- ○ Hierbij bevestig ik bovenstaande gelezen te hebben en akkoord te gaan met deelname aan dit onderzoek (1)
- ○ Hierbij bevestig ik bovenstaande gelezen te hebben en ik wens niet deel te nemen aan dit onderzoek. (2)

Ga naar: Einde enquête Als Bevestiging van uw deelname aan deze vragenlijst en daarmee dit onderzoek: = Hierbij bevestig ik bovenstaande gelezen te hebben en ik wens niet deel te nemen aan dit onderzoek.

Einde blok: Introductie Survey

Start van blok: Achtergrondkenmerken

Q3 **Wat is uw leeftijd?**

- ○ 18-35 jaar (1)
- ○ 36-45 jaar (2)
- ○ 46-55 jaar (3)
- ○ 56-65 jaar (4)
- ○ 66-75 jaar (5)
- ○ 76 jaar of ouder (6)

X→

Q4 **Wat is uw geslacht?**

- ○ Man (0)
- ○ Vrouw (1)
- ○ Anders (2)
- ○ Wil ik niet zeggen (3)

Q5 **Wat is uw hoogst afgeronde opleiding?**

- ○ Geen opleiding (1)
- ○ Lagere school/ basisonderwijs (2)
- ○ LBO, VBO, LTS, LHNO, VMBO (MAVO) (3)
- ○ MBO, MTS, MEAO (4)
- ○ HAVO, VWO, gymnasium (5)
- ○ HBO, HEAO, PABO, HTS (6)
- ○ WO (universiteit) (7)
- ○ Weet ik niet / wil ik niet zeggen (8)
- ○ Anders, namelijk... (9) _____

Q6 *Erfelijke en culturele factoren kunnen een rol spelen in de ontwikkeling van diabetes. Daarom zijn wij benieuwd naar uw achtergrond (en die van uw ouders). U bent niet verplicht deze vraag in te vullen. Indien u dit niet wilt, kunt u deze vraag overslaan.*

In welk land bent u geboren?

- ○ Nederland (1)
- ○ België (2)
- ○ Duitsland (3)
- ○ Polen (4)
- ○ Syrië (5)
- ○ Turkije (6)
- ○ Engeland (7)
- ○ Italië (8)
- ○ China (9)
- ○ India (10)
- ○ Bulgarije (11)
- ○ Marokko (12)
- ○ Spanje (13)
- ○ Roemenië (14)
- ○ Eritrea (15)
- ○ Frankrijk (16)
- ○ Anders, namelijk... (17) _____

Q7 *Erfelijke en culturele factoren kunnen een rol spelen in de ontwikkeling van diabetes. Daarom zijn wij benieuwd naar uw achtergrond (en die van uw ouders). U bent niet verplicht deze vraag in te vullen. Indien u dit niet wilt, kunt u deze vraag overslaan.*

In welk(e) land(en) is/zijn uw biologische ouder(s) geboren?

- [ ] Nederland (1)
- [ ] België (2)
- [ ] Duitsland (3)
- [ ] Polen (4)
- [ ] Syrië (5)
- [ ] Turkije (6)
- [ ] Engeland (7)
- [ ] Italië (8)
- [ ] China (9)
- [ ] India (10)
- [ ] Bulgarije (11)
- [ ] Marokko (12)
- [ ] Spanje (13)
- [ ] Roemenië (14)
- [ ] Eritrea (15)
- [ ] Frankrijk (16)
- [ ] Anders, namelijk... (17) _____

X→

Q8 **Welke type diabetes heeft u?**

- ○ Prediabetes (0)
- ○ Diabetes type 1 (1)
- ○ Diabetes type 2 (2)
- ○ Ik heb geen diabetes (4)
- ○ Anders, namelijk... (3) _____

Ga naar: Einde enquête Als Welke type diabetes heeft u? = Ik heb geen diabetes

Q9 **Hoe lang heeft u al diabetes?**

- ○ Minder dan 1 jaar (1)
- ○ 1 - 5 jaar (2)
- ○ 6 - 10 jaar (3)
- ○ Langer dan 10 jaar (4)

Q34 **Gaat u op dit moment voor uw diabetes controles naar het ziekenhuis of de huisartsenpraktijk?**

- ○ Huisartsenpraktijk (1)
- ○ Ziekenhuis (specialist) (2)
- ○ Huisartsenpraktijk en ziekenhuis (3)

Q10 **Welke medicatie gebruikt u voor uw diabetes?**

- [ ] Geen medicatie (eventueel wel leefstijl aanpassingen) (1)
- [ ] Tabletten (2)
- [ ] Insuline (3)
- [ ] Insulinepomp (4)

Q11 **Zijn er complicaties aanwezig als gevolg van uw diabetes?**

- [ ] Geen complicaties (1)
- [ ] Retinopathie (netvlies/ogen) (2)
- [ ] Neuropathie (zenuwen/doof/tintel) (3)
- [ ] Nefropathie (verminderde nierfunctie) (4)

Einde blok: Achtergrondkenmerken

Start van blok: Technische kenmerken

Q12 *In deze vraag komt de term 'technologie' voor. Technologie is een breed begrip. Zo kunt u denken aan glucosemeters, gezondheidsapps, stappentellers of hulp op afstand via de computer (bijvoorbeeld beeldbellen).*

Kies de uitspraak die het beste bij u past.

- ○ Ik loop meestal voor op de rest. Ik ben altijd de eerste die nieuwe technologie gebruikt. (1)
- ○ Ik houd ervan om nieuwe dingen uit te proberen. Ik probeer graag nieuwe technologie uit. (2)
- ○ Ik gebruik nieuwe technologie pas als ik weet dat dit handig en nuttig is. (3)
- ○ Ik gebruik nieuwe technologie niet snel. Ik blijf graag gebruiken wat ik al ken. (4)
- ○ Ik loop meestal achter op de rest. Ik gebruik nieuwe technologie pas als dit noodzakelijk is. (5)

Q13 *Een gezondheidsapp is een applicatie op de mobiele telefoon en kan informatie verzamelen over iemands leefstijl of gezondheid. Sommige apps geven ook adviezen om iemands leefstijl of gezondheid te verbeteren.*

Maakt u momenteel gebruik van (een) gezondheidsapp(s) naast de Diameter, of heeft u in het verleden gebruik gemaakt van een gezondheidsapp?

- ○ Ja, ik gebruik één of meerdere gezondheidsapps. (1)
- ○ Ja, ik heb in het verleden één of meerdere gezondheidsapps gebruikt. (2)
- ○ Nee, ik heb nog nooit een gezondheidsapp gebruikt. (0)

Deze vraag weergeven:

If Een gezondheidsapp is een applicatie op de mobiele telefoon en kan informatie verzamelen over iem... = Ja, ik gebruik één of meerdere gezondheidsapps.

Q14 **U geeft aan dat u op dit moment andere gezondheidsapps gebruikt. Is het voor u belangrijk dat de Diameter aansluit op deze app?** *Bijvoorbeeld door middel van een koppeling of het automatisch invullen van bepaalde waarden.*

- ○ Ja, ik wil dat de Diameter aansluit bij mijn andere gezondheidsapp(s) omdat... (1)
  _____
- ○ Nee, dit hoeft niet. (0)

Deze vraag weergeven:

If Een gezondheidsapp is een applicatie op de mobiele telefoon en kan informatie verzamelen over iem... = Nee, ik heb nog nooit een gezondheidsapp gebruikt.

Q15 **Waarom gebruikt u op dit moment geen gezondheidsapps?**

- Geen interesse in gezondheidsapps (1)
- Ik weet niet welke gezondheidsapps goed voor mij zijn (2)
- Door de vele gezondheidsapps vind ik het lastig om hierin een keuze te maken (3)
- Anders, namelijk... (4) _____

Deze vraag weergeven:

If Een gezondheidsapp is een applicatie op de mobiele telefoon en kan informatie verzamelen over iem... = Ja, ik gebruik één of meerdere gezondheidsapps.

Q16 **Met welk doel gebruikt u deze gezondheidsapps?**

- Ik vind het interessant deze informatie in te zien. (1)
- Ik vind het leuk om hiermee doelen te stellen. (2)
- Ik gebruik gezondheidsapps als hulpmiddel om mijn diabetes te controleren. (3)
- Ik gebruik het om mijn algemene gezondheid op peil te houden of te verbeteren. (4)
- Ik gebruik het om mijn eigen vooruitgang te monitoren. (5)
- Anders, namelijk... (6) _____

Einde blok: Technische kenmerken

Start van blok: De Diameter

Q17 **Hieronder volgt een korte introductievideo over de Diameter. Bekijk de video voordat u naar de volgende vragen gaat.**

Q18 **Geef aan in hoeverre u het eens bent met de volgende stellingen:**

*Een leefstijl doel is een doel dat u dagelijks probeert te halen op het gebied van beweging of voeding. Denk hierbij aan het lopen van een aantal stappen of het eten van twee stuks fruit.

	Sterk mee oneens (1)	Oneens (2)	Neutraal (3)	Eens (4)	Sterk mee eens (5)
De Diameter kan mij meer bewust maken van mijn leefstijl. (1)	○	○	○	○	○
De Diameter kan mij helpen controle te krijgen over mijn diabetes. (2)	○	○	○	○	○
De Diameter kan mij helpen om mijn leefstijldoelen* te bereiken. (3)	○	○	○	○	○
De Diameter bevat de functies die ik nodig heb om mijn leefstijl bij te houden. (4)	○	○	○	○	○

Q19 **Bekijk de volgende screenshots van de Diameter en geef in de stellingen hierna aan in hoeverre u het eens bent met de stellingen:**

	Sterk mee oneens (1)	Oneens (2)	Neutraal (3)	Eens (4)	Sterk mee eens (5)
De Diameter lijkt mij gemakkelijk te gebruiken. (1)	○	○	○	○	○
Ik denk dat ik snel met de Diameter om kan gaan. (2)	○	○	○	○	○
De Diameter ziet er gebruiksvriendelijk uit. (3)	○	○	○	○	○
Ik denk dat het weinig tijd kost om de Diameter te gebruiken. (4)	○	○	○	○	○

Q20 **Geef aan in hoeverre u het eens bent met de volgende stellingen:**

	Sterk mee oneens (1)	Oneens (2)	Neutraal (3)	Eens (4)	Sterk mee eens (5)
Het is voor mij belangrijk dat andere mensen met type 2 diabetes ook de Diameter zullen gebruiken. (1)	○	○	○	○	○
Het is belangrijk voor mij dat mijn huisarts en/of specialist het gebruik van de Diameter aanmoedigen. (2)	○	○	○	○	○

Q21 **Geef aan in hoeverre u het eens bent met de volgende stellingen:**

	Sterk mee oneens (1)	Oneens (2)	Neutraal (3)	Eens (4)	Sterk mee eens (5)
Ik heb uitleg nodig voordat ik de Diameter kan gebruiken. (1)	○	○	○	○	○
Ik heb genoeg kennis over apps om de Diameter te gebruiken. (2)	○	○	○	○	○

X→

Q22 **Op dit moment is de Diameter alleen beschikbaar in de Google Play Store (voor Android telefoons). Bent u in het bezit van een Android telefoon?**

○ Ja (1)

○ Nee (0)

X→

Q23 **Een Fitbit is een horloge dat activiteit (beweging) meet. Bent u in het bezit van een Fitbit?**

○ Ja (1)

○ Nee (0)

Q24 **Geef aan in hoeverre u het eens bent met de volgende stellingen:**

	Sterk mee oneens (1)	Oneens (2)	Neutraal (3)	Eens (4)	Sterk mee eens (5)
De Diameter kan mijn behandeling persoonlijker maken. (1)	○	○	○	○	○
Ik vind het geen probleem dat mijn gegevens met zorgverleners worden gedeeld als dit van toegevoegde waarde is binnen mijn behandeling. (2)	○	○	○	○	○
Zorgverleners kunnen door de Diameter meer inzicht krijgen in mijn leefstijl. (3)	○	○	○	○	○
De Diameter lijkt mij een goede toevoeging aan mijn behandeling binnen de huisartsenpraktijk. (4)	○	○	○	○	○

Q25 **Waarom vindt u de Diameter wel of geen goede toevoeging binnen uw zorgtraject?**

_____

Q26 **Bekijk de afbeelding met screenshots van de Diameter en geef aan in hoeverre u het eens bent met de volgende stellingen:**

	Sterk mee oneens (1)	Oneens (2)	Neutraal (3)	Eens (4)	Sterk mee eens (5)
De Diameter ziet er aantrekkelijk uit. (1)	○	○	○	○	○
De Diameter ziet er professioneel uit. (2)	○	○	○	○	○
De Diameter ziet er overzichtelijk uit. (3)	○	○	○	○	○

Q27 **Wat vindt u van de Diameter? Indien u opmerkingen, suggesties of verbeterpunten heeft welke u kwijt wilt kunt u deze hier achterlaten.**

_____

Q28 **Welke functie(s) binnen de Diameter lijkt/lijken u het meest nuttig om u te ondersteunen bij het controleren van uw leefstijl en diabetes?**

- [ ] Het bijhouden van glucosewaarden. (1)
- [ ] Het bijhouden van beweging. (2)
- [ ] Het bijhouden van voeding. (3)
- [ ] Het stellen van doelen. (4)
- [ ] De dagelijkse berichten met leefstijladviezen. (5)
- [ ] De persoonlijke coach (welke wekelijks feedback geeft op de gekozen doelen). (6)
- [ ] Geen enkele functie lijkt mij nuttig. (7)

Q29 **Waarom lijken deze functies u het meest nuttig?**

_____

Q30 **Welke functie(s) ziet u als minder nuttig?**

- ☐ Het bijhouden van glucosewaarden. (1)
- ☐ Het bijhouden van beweging. (2)
- ☐ Het bijhouden van voeding. (3)
- ☐ Het stellen van doelen. (4)
- ☐ De dagelijkse berichten met leefstijladviezen. (5)
- ☐ De persoonlijke coach (wekelijks gesprek in de Diameter). (6)
- ☐ Alle functies lijken mij nuttig (7)

Q31 **Waarom lijken deze functies u minder nuttig?**

_____

Q32 **Met welk cijfer zou u de Diameter beoordelen als toevoeging binnen uw zorgtraject?**

Een indeling van de getallen is als volgt:
10 = extreem goed
8 = zeer goed
6 = goed
5 = niet slecht
3 = slecht
1= verschrikkelijk

	1 2 3 4 5 6 6 7 8 9 10
Ik geef de Diameter het volgende cijfer: ()	

Q33 **Indien u open staat om mee te werken aan een interview met betrekking tot diabetes zorg en de Diameter, kunt u hier uw mailadres achterlaten. U bent niet verplicht om dit te doen en kunt deze vraag overslaan indien u hier niet aan mee wilt werken.**

_____

Einde blok: De Diameter

Appendix 4 Interview Schemes
8.4.1 Interview Scheme Patient

Goedendag,

Uw spreekt met Eva van ’t Hul. Ik zou u bellen met betrekking tot een interview over diabetes en de Diameter. Allereerst, hartelijk bedankt voor uw deelname aan dit interview. Ik studeer gezondheidswetenschappen aan de universiteit Twente en voor mijn afstudeeropdracht ben ik bezig om te kijken of er mogelijkheid en belang is om de Diameter in de zorg te implementeren. Vandaag zullen wij uw zorgtraject binnen type twee diabetes en uw mening over de Diameter bespreken. Met deze informatie kunnen wij de app verder verbeteren, uw feedback hierover waarderen wij dan ook enorm.

Met uw goedkeuring zou ik graag dit interview willen opnemen. Door middel van een opname kan ik op een later moment uw feedback nogmaals doornemen. Uw feedback zal altijd anoniem blijven en zal alleen gebruikt worden voor de doeleinden van dit onderzoek. Ik hoor graag of u hiermee akkoord gaat.

Heeft u nog vragen welke u aan mij wilt stellen voor het interview? Zo niet, dan zal ik de opname starten en beginnen wij aan het interview.

START AUDIO OPNAME

Het doel van dit interview is om uw mening over uw zorgtraject te bespreken en hoe hier mogelijk de Diameter aan kan worden toegevoegd. Wij zijn hierbij geïnteresseerd in een aantal onderwerpen gerelateerd aan uw zorg en de Diameter, bijvoorbeeld hoe u de app zou kunnen en willen gebruiken in uw dagelijks leven.

Ik zal mijzelf eerst even kort voorstellen.
KORTE INTRODUCTIE

Ik ben ook zeer benieuwd naar wie u bent, zou u uzelf kort willen voorstellen?
(naam, leeftijd, werk, hobby’s etc.)

Bedankt! Leuk om u wat beter te leren kennen. Dan zullen wij nu beginnen aan de vragen en het interview.

<< U heeft als het goed is de Diameter geïnstalleerd, *zo niet dan zal ik kort hier screenshots/ scherm opnames laten zien van de Diameter en de applicatie introduceren*. >>

0. **Welk type diabetes heeft u?**

Allereerst zou ik graag wat meer over uw leven met Type 2 Diabetes willen weten..

1. Zou u in uw eigen woorden kunnen uitleggen wat leven met Diabetes Type 2 voor u betekent?

a. Loopt u tegen bepaalde dingen aan in uw dagelijkse leven omtrent uw ziekte? *Bijvoorbeeld het rekening houden met voeding/bewegen, insuline spuiten etc.*

2. **Hoe lang heeft u al de diagnose diabetes type 2?**

a. Wat vindt u een belemmering aan het leven met diabetes?

3. Hoe ziet uw behandeling er op dit moment uit? *Denk hierbij aan het bezoeken van uw huisarts, controles, metingen, medicijnen etc.*

a. Bij welke arts en/of specialist staat u momenteel onder toezicht?
b. Hoe ziet uw behandeling er op dit moment uit? (medicijnen, adviezen, bezoeken aan zorgverleners)
c. Is er voldoende aandacht voor leefstijl binnen uw behandeling? Heeft u voldoende informatie over diabetes gekregen en bent u hier tevreden over?
d. Wat vindt u een sterk, positief punt binnen uw behandeling
e. Wat ziet u als een punt ter verbetering?
f. Wat denkt u dat u nodig heeft om uw behandeling tot een succes te brengen?

Graag zou ik het nu met u willen hebben over uw gebruik van mobiele applicaties (apps) en uw ervaring hiermee.

4. Gebruikt u op dit moment apps die iets met gezondheid te maken hebben? *Denk hierbij aan een stappenteller, glucosewaarden meter, hartslagfrequentie etc.*

a. Zo ja, welke apps gebruikt u en met welk doel?
b. Indien nee, waarom gebruikt u geen verdere apps? *Bijvoorbeeld geen interesse, u weet niet welke apps er zijn, door de vele apps is het moeilijk de juiste te kiezen etc.*
c. Staat u open voor het gebruik van een (extra) app zoals de Diameter ter ondersteuning van uw levensstijl en behandeling?

5. Denkt u dat de Diameter u zou kunnen helpen met bijvoorbeeld uw leefstijl en/of controle van uw diabetes? *Waarom wel of niet?*

a. *Welke functies ziet u bijvoorbeeld als nuttig?*
b. *Welke functies denkt u minder nodig te hebben?*
c. *Zijn er functies welke u nu mist in de Diameter, is er iets wat u graag toegevoegd zou willen hebben? Waarom zou u deze functies graag toegevoegd zien hebben?*

6. Ziet u redenen waarom u de Diameter niet zou kunnen gebruiken? Of zijn er bepaalde redenen die het lastiger maken om de Diameter te gebruiken? *Welke struikelpunten ziet u bijvoorbeeld in het gebruik van de Diameter.*

7. Zijn er redenen waardoor u de Diameter juist zou willen gebruiken? *Denk hierbij aan de mening van familie of vrienden, expertise van uw huisarts maar ook factoren als technische kennis, bewezen effectiviteit, kosten etc.*

a. Wat voor ondersteuning zou u nodig hebben om de Diameter te gebruiken?

8. Denkt u dat u de Diameter gemakkelijk in uw dagelijks leven zou kunnen gebruiken om uw leefstijl en diabetes te monitoren? Waarom wel of niet? *Indien ja, waarom denkt u dat u de Diameter gemakkelijk zou kunnen gebruiken. Indien nee, waarom niet en wat zou u nodig hebben om dit wel te kunnen?*

a. In hoeverre heeft u vertrouwen in uzelf om de Diameter dagelijks te gaan gebruiken?
b. Denkt u dat u het gebruik van de Diameter snel en gemakkelijk kan toepassen in uw dagelijks leven? *Waarom wel of niet?*

Dit was het einde van het interview. Ik wil u hartelijk bedanken voor uw deelname aan dit interview. Met uw antwoorden gaan wij de acceptatie van de Diameter onder mensen zoals u verder onderzoeken en zullen wij de applicatie verbeteren. Mocht u nog vragen hebben, hoor ik dit graag van u.

CFIR Interview Code Scheme

Question	CFIR Domain	Sub-category
1	*Introduction*	*Introduction*
2.	*Introduction*	*Introduction*
3		
3a.	*Introduction*	*Introduction*
3b.	Inner setting	Structural characteristics
3c.	Outer setting	Patient needs & resources
3d.	Inner setting	Structural characteristics
3e.	Inner setting	Tension for change
3f.	Outer setting	Patient needs & resources
4	Individuals	(other) personal attributes
4a.	Individuals	(other) personal attributes
4b.	Individuals	(other) personal attributes
4c.	Individuals	Individual stage of change
5	Outer setting	Patients needs and resources
5a.	Innovation	Relative advantage
5b.	Innovation	Relative advantage
5c.	Innovation	Design quality & packaging
6	Individuals/	Other personal attributes
	Innovation	Adaptability
7	Individuals	Knowledge & beliefs about the innovation
7a.	Outer setting	Patient needs and resources
8	Innovation	Adaptability
8a.	Individuals	Self-efficacy
8b.	Innovation	Adaptability

8.4.2 **Interview scheme** healthcare professional

Goedendag,

U spreekt met Eva van ’t Hul. Ik bel u vandaag voor een interview voor mijn afstudeeronderzoek rondonm de Diameter. Allereerst hartelijk dank voor uw deelname aan dit interview. Vandaag wil ik graag de Diameter met u bespreken. Hierbij hoor ik graag wat u verwacht van de Diameter, hoe en of u deze in de praktijk kunt toepassen en wat uw mening en ervaring is met dergelijke eHealth technologieën. Met deze informatie kunnen wij de app verder verbeteren, uw feedback waarderen wij dan ook enorm.

Met uw goedkeuring zou ik graag dit interview willen opnemen. Door middel van een opname kan ik op een later moment uw feedback nogmaals doornemen. Uw feedback zal altijd anoniem blijven en zal alleen gebruikt worden voor doeleinden van dit onderzoek. Ik hoor graag of u hiermee akkoord gaat.

Voordat wij beginnen aan het interview, heeft u nog vragen welke u aan mij wilt stellen? Zo niet, dan zal ik de opname starten en beginnen wij aan het interview.

START AUDIOOPNAME

Het doel van dit interview is om de Diameter te bespreken en om uw mening te horen rondom de implementatie van deze app in de praktijk. Wij horen graag uw ervaring en feedback zodat we dit kunnen meenemen in komend onderzoek.

U heeft alle ruimte om uw eigen mening te delen, er is geen goed of slecht antwoord. Indien u het antwoord niet weet op een bepaalde vraag, of u voelt zich niet gemakkelijk bij het geven van een antwoord kunt u dit aangeven.

Uiteraard zal ik mijzelf nog even kort voorstellen. **KORTE INTRODUCTIE**

1. **Zou u kort wat over uzelf kunnen vertellen? Wie u bent en wat voor werk u doet?**

Bedankt voor uw antwoord en fijn om u wat beter te leren kennen. Als het goed is heeft u de Diameter gedownload om te proberen of heeft u van mij de schermopname en informatiebrief gekregen om een beter beeld van de Diameter te krijgen. Tijdens dit interview zullen wij de Diameter, implementatie hiervan in de praktijk bespreken. Het interview bestaat uit 17 vragen.

Laten we beginnen met de vraag over hoe op dit moment de zorg voor T2DM patiënten binnen uw praktijk in zijn werk gaat.

2. Ik zou graag willen weten hoe op dit moment de zorg voor T2DM patiënten in zijn werk gaat binnen uw praktijk. Zou u hier kort uitleg over willen geven, wat is het zorgtraject voor deze patiënten?

a. Hoe vaak ziet u de patiënten?
b. Welke begeleiding is er voor deze patiënten? *Denk hierbij aan leefstijl, medicatie, routine checks, telemonitoring etc.*
c. In uw ervaring, wat zijn de sterke punten binnen dit zorgtraject?
d. Welke verbeterpunten zijn er binnen dit zorgtraject?

3. Zijn er momenteel eHealth technologieën waarmee u binnen de praktijk werkt binnen de zorg van T2DM patiënten?

a. In hoeverre is het belangrijk voor u dat de Diameter hierop aansluit?
b. Wat vindt u pluspunten in het gebruik van deze technologieën?
c. Wat mist u op dit moment in deze technologieën? Wat heeft u nodig in de ondersteuning in de zorg van deze patiënten?
d. Is er in de praktijk in het verleden geprobeerd om een soortgelijke technologie toe te passen bij een bepaalde patiëntengroep? *Indien ja, zou u hier wat meer over kunnen vertellen. Wat zijn de ervaringen hiermee, is dit doorgezet etc.*

4. De bewezen effectiviteit van eHealth is lastig te onderzoeken (maar niet onmogelijk). Is het voor u een vereiste dat de effectiviteit bewezen moet worden voordat een technologie geïmplementeerd wordt binnen de huisartsenpraktijk?

5. Heeft u vaker meegedaan met een dergelijk onderzoek naar de hulp van eHealth technologie en T2DM patiënten?
Indien ja, wat is hier de uitkomst van geweest? Is dit geïmplementeerd, wat is uw ervaring hiermee?

Ik ga nu beginnen met de vragen rondom uw mening over de Diameter en het (mogelijk) gebruik van deze applicatie binnen de praktijk.

6. U heeft de Diameter in kunnen zien of zelfs al even kunnen gebruiken. Denkt u dat de Diameter nuttig is voor patiënten met diabetes type 2? *Indien de Diameter niet als nuttig wordt gezien, wat zou de Diameter moeten kunnen om wel van toegevoegde waarde te zijn?*

a. Welke doelen streeft u na met de T2DM patiëntengroep?
b. Denkt u dat de Diameter kan bijdragen aan deze doelen?
c. Hoe denkt u dat de Diameter het beste kan worden ingezet binnen hun zorgtraject?

7. Wat zou u *als (huisarts, POHer, assistente)* graag willen en moeten kunnen met de Diameter om bij te dragen aan diabeteszorg?

De patiënt is natuurlijk uiteindelijk degene die de Diameter dagelijks zal gebruiken

8. Hoe denkt u dat patiënten zullen reageren op de Diameter?

a. Welke wensen en behoeften hebben deze patiënten en zijn bij u bekend als zorgverlener?
b. Hoe past de Diameter binnen deze behoeften?

9. In welke mate verwacht u dat uw patiënten de Diameter zullen gaan gebruiken?

a. Welke mogelijke redenen kunt u bedenken voor het gebruik of niet gebruik van de Diameter binnen deze patiëntengroep?
b. Op welke manier kunt u patiënten motiveren in het gebruik van de Diameter?

De volgende vragen gaan over eventuele implementatie van de Diameter binnen de praktijk.

10. Zou de Diameter binnen de normen, waarde en visie van de praktijk en uw collega's passen?

11. **Is er ruimte en/of mogelijkheid om de Diameter binnen uw praktijk te implementeren?**
Indien ja, hoe ziet u dit voor zich? Indien nee, waarom niet?

a. Hoeveel vertrouwen heeft u in het werken met de Diameter in de dagelijkse praktijk?
b. Welke voor- en nadelen ziet u in het gebruik van de Diameter?
c. Denkt u dat het introduceren en werken met de Diameter gemakkelijk zal gaan? Waarom wel of niet?

12. **Wat heeft u nodig in de praktijk om implementatie van de Diameter te ondersteunen?**
Denk hierbij aan training, uitleg, een test-fase, hulp door middel van chat o.i.d.

a. Wat zou mogelijk een belemmering kunnen zijn voor de implementatie van de Diameter?

13. Hoe denkt u dat het werken met de Diameter past in uw huisartsenpraktijk? Denkt u bijvoorbeeld dat de huisarts, POH of assistent hier het meest mee zal werken?

a. Hoe past het werken met de Diameter bij het behandelbeleid en protocollen waaraan u zich houdt? *Denk hierbij aan NHG-standaard, zorgstandaarden en protocollen rondom zorg en multidisciplinaire richtlijnen*
b. Welke rol zou de Diameter kunnen spelen binnen deze protocollen?
c. Zouden de richtlijnen en protocollen het gebruik van de Diameter kunnen faciliteren of juist verhinderen? Op welke manier? *Zijn er bijvoorbeeld protocollen of richtlijnen die het gebruik van de Diameter zouden kunnen beïnvloeden.*

14. *[Huisarts]* **Zijn er beleidsvormen binnen de zorgverzekeraar waarmee u samenwerkt welke het gebruik van de Diameter zouden kunnen beïnvloeden?**

Als zorgverlener werkt u natuurlijk nooit alleen, maar samen met uw collega's in de praktijk.

15. Hoe denkt u dat de Diameter onder uw collega's zal worden ontvangen?

a. Waarom denkt u dat de Diameter op deze manier ontvangen wordt?
b. Wat is de visie op dergelijke eHealth technologieën binnen de praktijk?
c. Is er behoefte aan een dergelijke eHealth technologie zoals de Diameter?
d. Is er ook ruimte binnen de praktijk om nieuwe technologieën zoals de Diameter uit te proberen en te implementeren?

16. Zou de Diameter een rol kunnen spelen in de werkrelatie en samenwerking binnen de praktijk met uw collega's? *Zou de Diameter bijvoorbeeld kunnen helpen binnen de communicatie tussen u en uw collega's door middel van een portaal.*

17. Heeft u het gevoel dat uw collega's en leidinggevenden u en uw collega's ondersteunen als het gaat om implementatie van nieuwe technologieën?

Dit was het einde van het interview. Ik wil u hartelijk bedanken voor deelname aan dit interview. Heeft u nog vragen voor mij op dit moment?

AFSCHEID

CFIR interview code scheme

Question	CFIR Domain	Sub-category
1	Introduction	
2	Introduction	
3 3a. 3b. 3c. 3d.	Inner setting / outer setting Inner setting Outer setting Inner setting	Needs, implementation & Compatibility Compatibility Needs & Resources Implementation Climate
4.	Innovation	Evidence strength
5.	Innovation	Relative advantage
6 6a. 6b. 6c.	Outer setting Outer setting Innovation Innovation	Patient needs and resources Patient needs and resources Compatibility Compatibility
7	Inner setting / Innovation	Needs & resources / adaptability
8 8a. 8b.	Outer setting Outer setting Innovation	Patient needs and resources Patient needs and resources Relative advantage
9 9a. 9b.	Outer setting Outer setting Individuals	Patient needs and resources Implementation climate (other) personal attributes
10	Inner setting	Culture / Compatibility
11 11a. 11b. 11c.	Characteristics of individuals / Characteristics of individuals Innovation Characteristics of individuals	Knowledge & beliefs Self-efficacy Relative advantage Self-efficacy
12 12a	Inner setting Inner setting	Access to knowledge & information Structural characteristics
13 13a. 13b. 13c.	Outer setting Inner setting Inner setting Inner setting	External policy Structural characteristics Compatibility Compatibility / internal policies
14	Outer setting	External policies and incentives
15 15a. 15b. 15c.	Inner setting Inner setting Inner setting Inner setting	Implementation climate Readiness for implementation Implementation climate Readiness for implementation
16	Inner setting	Networks and communications
17	Inner setting	Leadership engagement

8.4.3 **Interview scheme** dietician

Goedemorgen,

Welkom en hartelijk dank voor uw deelnamen aan dit interview.

Mijn naam is Eva van 't Hul en ik studeer aan de Universiteit Twente – Gezondheidswetenschappen of Health Sciences. Binnen deze opleiding heb ik gekozen voor de track 'personalized monitoring en coaching' waarbij gekeken wordt hoe technologie een rol kan spelen voor patiënten. Bijvoorbeeld op het gebied van zelfmanagement. Momenteel doe ik mijn afstudeeropdracht in samenwerking met Ziekenhuisgroep Twente om te kijken of de Diameter mogelijk een rol kan spelen in de zorg voor patiënten met type 2 diabetes in de eerstelijnszorg.

Zoals over de mail ook besproken wil ik jullie vandaag vragen naar jullie rol en taken binnen de diabeteszorg, ook ben ik benieuwd naar jullie mening over de Diameter en of dit van toegevoegde waarde kan zijn binnen de zorg die jullie leveren aan diabetes patiënten. U mag alles zeggen in dit interview, uw feedback blijft anoniem en zal alleen gebruikt worden voor doeleinden van dit onderzoek.

Voor dat wij beginnen, heeft u nog vragen?

Zo niet, wil ik jullie vragen of ik dit interview mag opnemen zodat ik het op een later moment nogmaals kan beluisteren.

Laten wij beginnen met het interview. Allereerst ben ik benieuwd naar wie jullie zijn.

1. **Wat voor rol spelen jullie binnen de diabeteszorg en wat zijn jullie taken?**

2. **Hoe ziet de zorg voor T2DM patiënten er op dit moment uit?**
   a. Hoe vaak ziet ut de patiënten?
   b. Welke begeleiding geeft u de patiënten? Adviezen, dieet, richtlijnen, educatie.
   c. Wat vindt u sterke punten in dit begeleidingstraject?
   d. Welke verbeterpunten ziet u?

3. **Zijn er momenteel eHealth technologieën waarmee u werkt binnen de zorg van T2DM patiënten? Of via Carintreggeland?**
   a. In hoeverre is het belangrijk voor u dat de Diameter hierop aansluit?
   b. Wat vindt u pluspunten in het gebruik van deze technologieën?
   c. Wat mist u op dit moment in deze technologieën? Wat heeft u nodig in de ondersteuning in de zorg van deze patiënten?

4. **U heeft de Diameter in kunnen zien of zelfs al even kunnen gebruiken. Denkt u dat de Diameter nuttig is voor patiënten met diabetes type 2?** *Indien de Diameter niet als nuttig wordt gezien, wat zou de Diameter moeten kunnen om wel van toegevoegde waarde te zijn?*
   a. Welke doelen streeft u na met de T2DM patiëntengroep?
   b. Denkt u dat de Diameter kan bijdragen aan deze doelen?
   c. Hoe denkt u dat de Diameter het beste kan worden ingezet binnen hun zorgtraject?

5. **Wat zou u als diëtist graag willen en moeten kunnen met de Diameter om bij te dragen aan diabeteszorg?**

De patiënt is natuurlijk diegene die de Diameter dagelijks zal gebruiken.

8. Hoe denkt u dat patiënten zullen reageren op de Diameter?

a. Past de Diameter bij hun behoeften?

De volgende vragen gaan over eventuele implementatie van de Diameter binnen de praktijk.

9. **Zou de Diameter binnen de normen, waarde en visie van Carintreggeland en uw collega's passen?**

10. **Is er ruimte en/of mogelijkheid om de Diameter binnen uw praktijk te implementeren?** *Indien ja, hoe ziet u dit voor zich? Indien nee, waarom niet?*

d. Hoeveel vertrouwen heeft u in het werken met de Diameter in de dagelijkse praktijk?

e. Welke voor- en nadelen ziet u in het gebruik van de Diameter?

f. Denkt u dat het introduceren en werken met de Diameter gemakkelijk zal gaan? Waarom wel of niet?

8.4.4 **Interview scheme** lifestyle coach

Goedendag,

U spreekt met Eva van ’t Hul. Ik bel u vandaag voor een interview voor mijn afstudeeronderzoek rondom de Diameter. Allereerst hartelijk dank voor uw deelname aan dit interview. Vandaag wil ik graag de Diameter met u bespreken. Hierbij hoor ik graag wat u verwacht van de Diameter, hoe en of u deze in de praktijk kunt toepassen en wat uw mening en ervaring is met dergelijke eHealth technologieën. Met deze informatie kunnen wij de app verder verbeteren, uw feedback waarderen wij dan ook enorm.

Met uw goedkeuring zou ik graag dit interview willen opnemen. Door middel van een opname kan ik op een later moment uw feedback nogmaals doornemen. Uw feedback zal altijd anoniem blijven en zal alleen gebruikt worden voor doeleinden van dit onderzoek. Ik hoor graag of u hiermee akkoord gaat.

Voordat wij beginnen aan het interview, heeft u nog vragen welke u aan mij wilt stellen? Zo niet, dan zal ik de opname starten en beginnen wij aan het interview.

START AUDIOOPNAME

Het doel van dit interview is om de Diameter te bespreken en om uw mening te horen rondom de implementatie van deze app in de praktijk. Wij horen graag uw ervaring en feedback zodat we dit kunnen meenemen in komend onderzoek.

U heeft alle ruimte om uw eigen mening te delen, er is geen goed of slecht antwoord. Indien u het antwoord niet weet op een bepaalde vraag, of u voelt zich niet gemakkelijk bij het geven van een antwoord kunt u dit aangeven.

Uiteraard zal ik mijzelf nog even kort voorstellen. **KORTE INTRODUCTIE**

1. **Zou u kort wat over uzelf kunnen vertellen? Wie u bent en wat voor werk u doet?**

Bedankt voor uw antwoord en fijn om u wat beter te leren kennen. Als het goed is heeft u de Diameter gedownload om te proberen of heeft u van mij de schermopname en informatiebrief gekregen om een beter beeld van de Diameter te krijgen. Tijdens dit interview zullen wij de Diameter, implementatie hiervan in de praktijk bespreken. Het interview bestaat uit 17 vragen.

Laten we beginnen met de vraag over hoe op dit moment de zorg voor T2DM patiënten binnen uw praktijk in zijn werk gaat.

2. Ik zou graag willen weten hoe op dit moment de zorg voor T2DM patiënten in zijn werk gaat binnen uw praktijk. Zou u hier kort uitleg over willen geven, wat is het zorgtraject voor deze patiënten?

e. Hoe vaak ziet u de patiënten?
f. Welke begeleiding is er voor deze patiënten? *Denk hierbij aan leefstijl, medicatie, routine checks, telemonitoring etc.*
g. In uw ervaring, wat zijn de sterke punten binnen dit zorgtraject?
h. Welke verbeterpunten zijn er binnen dit zorgtraject?

3. Zijn er momenteel eHealth technologieën waarmee u binnen het COOL-programma voor de zorg van T2DM patiënten?

e. In hoeverre is het belangrijk voor u dat de Diameter hierop aansluit?
f. Wat vindt u pluspunten in het gebruik van deze technologieën?
g. Wat mist u op dit moment in deze technologieën? Wat heeft u nodig in de ondersteuning in de zorg van deze patiënten?
h. Is er in de praktijk in het verleden geprobeerd om een soortgelijke technologie toe te passen bij een bepaalde patiëntengroep? *Indien ja, zou u hier wat meer over kunnen vertellen. Wat zijn de ervaringen hiermee, is dit doorgezet etc.*

4. De bewezen effectiviteit van eHealth is lastig te onderzoeken (maar niet onmogelijk). Is het voor u een vereiste dat de effectiviteit bewezen moet worden voordat een technologie geïmplementeerd wordt?

Ik ga nu beginnen met de vragen rondom uw mening over de Diameter en het (mogelijk) gebruik van deze applicatie binnen de praktijk.

5. U heeft de Diameter in kunnen zien of zelfs al even kunnen gebruiken. Denkt u dat de Diameter nuttig is voor patiënten met diabetes type 2? *Indien de Diameter niet als nuttig wordt gezien, wat zou de Diameter moeten kunnen om wel van toegevoegde waarde te zijn?*

a. Welke doelen streeft u na met de T2DM patiëntengroep?
b. Denkt u dat de Diameter kan bijdragen aan deze doelen binnen GLI/COOL-programma?
c. Hoe denkt u dat de Diameter het beste kan worden ingezet binnen hun zorgtraject?

6. Wat zou u als leefstijlcoach graag willen en moeten kunnen met de Diameter om bij te dragen aan diabeteszorg?

De patiënt is natuurlijk uiteindelijk degene die de Diameter dagelijks zal gebruiken

7. Hoe denkt u dat patiënten zullen reageren op de Diameter?

c. Welke wensen en behoeften hebben deze patiënten en zijn bij u bekend als zorgverlener?
d. Hoe past de Diameter binnen deze behoeften?

8. In welke mate verwacht u dat uw patiënten de Diameter zullen gaan gebruiken?

c. Welke mogelijke redenen kunt u bedenken voor het gebruik of niet gebruik van de Diameter binnen deze patiëntengroep?
d. Op welke manier kunt u patiënten motiveren in het gebruik van de Diameter?

De volgende vragen gaan over eventuele implementatie van de Diameter binnen de praktijk.

9. Zou de Diameter binnen de normen, waarde en visie van de GLI of het COOL-programma passen?

10. **Ziet u mogelijkheden om de Diameter binnen de GLI/COOL-programma te implementeren?** *Indien ja, hoe ziet u dit voor zich? Indien nee, waarom niet?*

g. Zou het passen binnen de richtlijnen van het COOL-programma?
h. Hoeveel vertrouwen heeft u in het werken met de Diameter in de dagelijkse praktijk?
i. Welke voor- en nadelen ziet u in het gebruik van de Diameter?
j. Denkt u dat het introduceren en werken met de Diameter gemakkelijk zal gaan? Waarom wel of niet?

11. **Wat heeft u nodig in de praktijk om implementatie van de Diameter te ondersteunen?**
Denk hierbij aan training, uitleg, een test-fase, hulp door middel van chat o.i.d.

a. Wat zou mogelijk een belemmering kunnen zijn voor de implementatie van de Diameter?

Als zorgverlener werkt u natuurlijk nooit alleen, maar samen met uw collega's in de praktijk.

12. Werkt u op dit moment samen met andere zorgverleners (huisarts/dietist)? Denkt u dat het nodig is dat zij de Diameter ook zullen gebruiken?

e. Hoe denkt u dat de Diameter door henontvangen wordt?
f. Zou het uw werk kunnen bevorderen en de samenwerking tussen andere zorgverleners?

Dit was het einde van het interview. Ik wil u hartelijk bedanken voor deelname aan dit interview. Heeft u nog vragen voor mij op dit moment?

AFSCHEID

8.4.5 **Interview scheme** healthcare insurer

Goedemorgen,

Welkom en hartelijk dank voor uw deelnamen aan dit interview.

Mijn naam is Eva van 't Hul en ik studeer aan de Universiteit Twente – Gezondheidswetenschappen of Health Sciences. Binnen deze opleiding heb ik gekozen voor de track 'personalized monitoring en coaching' waarbij gekeken wordt hoe technologie een rol kan spelen voor patiënten. Bijvoorbeeld op het gebied van zelfmanagement. Momenteel doe ik mijn afstudeeropdracht in samenwerking met Ziekenhuisgroep Twente om te kijken of de Diameter mogelijk een rol kan spelen in de zorg voor patiënten met type 2 diabetes in de eerstelijnszorg. Tijdens het interview met zorgverleners is de zorgverzekeraar een aantal keer ter sprake gekomen. Omdat de Diameter namelijk geautomatiseerd kan worden door middel van een Fitbit en in de toekomst waarschijnlijk de FreeStyle Libre sensore zodat zij continu monitoring hebben van bloedglucosewaarden maar ook de stappen (beweging). Dat dan echt het totaal plaatje compleet is en de inzichten qua leefstijl echt duidelijk worden.

Zoals over de mail ook besproken wil ik vandaag bespreken aan welke eisen een nieuwe technologie zoals de Diameter moet voldoen om vergoed te worden. Ook wil ik graag bespreken of er mogelijkheden zijn om de Diameter samen met de FreeStyle Libre Sensor en Fitbit te vergoeden voor deze patiëntengroep (in de toekomst). Ten slotte ben ik benieuwd hoe Menzis tegenover een dergelijke technologie staat, en wat jullie visie hierop is.

Voor dat wij beginnen, heeft u nog vragen?

Zo niet, wil ik jullie vragen of ik dit interview mag opnemen zodat ik het op een later moment nogmaals kan beluisteren.

1. Wat is er nodig van de zorgaanbieder, om in contract te gaan met de zorgverzekeraar, Menzis?

2. Wat is belangrijk wanneer er wordt gekeken naar de vergoeding van een nieuw product en/of service? *Denk hierbij aan kosten, effectiviteit, patiëntengroep, (S)ROI etc.*

3. Vanuit de basisverzekering wordt deelname aan 'Keer Diabetes2 Om' vergoed (naast eigen bijdrage van de patiënt). Wat is de redenatie dat deze cursus wordt vergoed?

4. Wat is de visie van Menzis op de vergoeding van dergelijke eHealth technologieën zoals de Diameter?

5. De Diameter is vooralsnog een gratis app, patiënten kunnen dit zonder enige hulpmiddelen gebruiken door zelf hun glucosewaarden of beweging in te voeren. Echter staan zorgverleners achter dit product wanneer er veel wordt geautomatiseerd voor de patiënt door middel van een FreeStyle Libre Sensor voor het continu meten van de glucosewaarden en een Fitbit voor het invoeren van stappen. Zowel de FreeStyle Libre sensor als de Fitbit worden op dit moment niet vergoed door de (aanvullende) verzekering, wat is hiervoor nodig om het wel vergoed te krijgen?

a. *Waarom wordt op dit moment de FreeStyle Libre Sensor niet vergoed voor de meeste patienten met type 2 diabetes?*
b. *Ziet u mogelijkheden voor de Diameter om vergoed te worden in de toekomst samen met de FreeStyle Libre Sensor en Fitbit? – Waarom wel of niet?*

6. Denkt u dat de Diameter past binnen het inkoopbeleid Gecombineerde Leefstijlinterventie (GLI) 2022 – 2023?

a. Indien ja: waarom past de Diameter binnen het inkoopbeleid?
Indien antwoord nee: wat is er voor nodig om de Diameter aan te laten sluiten bij dit inkoopbeleid? Of bij welk inkoopbeleid zou de Diameter wel aansluiten?

7. Wat is een vereiste om de Diameter vergoed te krijgen binnen de zorgverzekering?
a. Is er verschil in vereisten tussen de basis en aanvullende verzekering?

Appendix 5 Guidelines application and algorithms within care

8.5 **Guidelines application and algorithms within care**

0. Algemene informatie over de applicatie en de getoetsde	**Bron**
0.1 Applicatie (handelsnaam)	CE Declaration of Conformity
0.2 Leverancier	CE Declaration of Conformity
0.3 Ontwikkelaar	CE Declaration of Conformity
0.4 Type applicatie / algoritme (robotica, beeld, spraak, tekst, voorspelling, chatbot)	CE Technical File
0.5 Zorggebied (preventie, triage, diagnostiek, behandeling, anders)	CE Clinical Evaluation Report
0.6 Korte beschrijving van de applicatie (wat doet het? aan welke zorgsoort draagt het bij? Wat is de health claim?)	CE Clinical Evaluation Report
0.7 Fase van productontwikkeling (ontwikkeling, validatie, implementatie, gebruik)	Leverancier
0.8 Aantal huidige gebruikers per type (bijvoorbeeld zorgverleners, patienten)	Leverancier
0.9 welke stukken/documenten zijn aangeleverd voor de beoordeling	Leverancier

1. Inschatten risico	**Bron**
1.1 Behoren de gebruikers of doelgroep tot één van de volgende groepen: kinderen, ouderen, laaggeletterden?	Leverancier
1.2 Indien de applicatie of het algoritme niet werkt zoals beschreven, kan het gevolg voor de gebruiker zijn: mortaliteit of ernstige morbiditeit?	CE Clinical Evaluation Report
1.3 Is er sprake van een applicatie of het algoritme die zelfstandig een diagnose stelt of een medisch advies aan de patient geeft?	CE Technical File
1.4 Wordt er gebruik gemaakt van een data toepassing met een mate van onzekerheid ?	CE Clinical Evaluation Report
1.5 Heeft in de ontwikkeling van de applicatie ook expliciet het ethisch perspectief een rol gehad?	Leverancier

2. Eindgebruiker	**Bron**
2.1 Biedt de applicatie aantoonbaar de functionaliteit die de eindgebruiker verwacht?	Leverancier
2.2 Integratie mogelijkheden: Is de applicatie interoperabel?	Leverancier
2.3 Gebruikerservaringen: Is de functionaliteit van de applicatie negatief gereviewed?	Leverancier
2.4 Is er een website met instructie voor het gebruik van de applicatie?	Leverancier
2.5 Is de applicatie eenvoudig in gebruik voor: ouderen, laaggeletterden, (kinderen), chronisch zieken?	Leverancier
2.6 Is de applicatie of de data toepassing offline te gebruiken?	Leverancier
2.7 Is er mogelijkheid direct in contact te treden met de aanbieder en hoe is dat ingericht en/of wordt er een klachtenafhandelingsprocedure aangeboden?	Leverancier
2.8 Is de applicatie of output via elk device toegankelijk?	Leverancier
2.9 Is er een standaard procedure voor het onderhouden van de software?	Leverancier

3. Algoritmes en kunstmatige intelligentie	Bron
3.1 Zijn de testresultaten reproduceerbaar voor alle doelgroepen en eindgebruikers?	CE Clinical Evaluation Report
3.2 Is de kwaliteit van de gebruikte gegevens optimaal	CE Clinical Evaluation Report
3.3 Hoe betrouwbaar is het algoritme	CE Clinical Evaluation Report
3.4 Is er een risico analyse uitgevoerd om een potentiële negatieve uitwerking in kaart te brengen?	CE Clinical Evaluation Report
3.5 Wat is intended use van de applicatie of het algoritme en is het risico acceptabel in het licht van de intended use?	CE Clinical Evaluation Report
3.6 Is er een proces ingesteld om foutieve adviezen en besluiten te detecteren, te analyseren en te verbeteren?	Leverancier
3.7 Is er medisch inhoudelijke kennis gebruikt bij het ontwerpen van het algoritme?	Leverancier
3.8 Is de uitkomst gerelateerd aan internationale standaarden?	Leverancier
3.9 Kunnen de gemaakte adviezen of beslissingen door zorgprofessionals worden getraceerd en begrepen?	Leverancier
3.10 Wordt het gegenereerde advies of besluit geaccordeerd door een zorgprofessional? En kun je toelichten hoe dat zich vertaalt naar de praktijk?	Leverancier
3.11 Is vastgesteld of het algoritme een ongewenste toename of afname van zorggebruik zou kunnen genereren?	Leverancier
3.12 Is de controlelijst voor betrouwbare kunstmatige intelligentie van de Europese Commissie gebruikt?	Leverancier

4. Validatie	Bron
4.1a Is het algoritme of de applicatie wetenschappelijk gevalideerd? Zijn er publicaties in gerenomeerde tijdschriften?	Leverancier
4.1b Indien van toepassing, hoe is de split gemaakt tussen train, test en validatie? data?	
4.2 welke level of evidence is er in de gevalideerde doelgroep(en) als uitkomst verkregen	CE Clinical Evaluation Report
4.3 Wat is de PROBAST (Prediction model Risk Of Bias ASsessment Tool) appreciatie?	Leverancier
4.4 Zijn de testresultaten gevalideerd voor de doelgroep?	Leverancier
4.5 Wordt de applicatie of het algoritme onderschreven door een wetenschappelijke beroepsvereniging?	Leverancier

5. Kwaliteit & betaalbaarheid van zorg	Bron
5.1 Hoe draagt de toepassing bij aan de kwaliteit van de zorg?	Leverancier
5.2 Hoe draagt de toepassing bij aan doelmatige en duurzame vervanging van zorg? Hoe tonen jullie dat aan?	Leverancier
5.3 Zijn er duidelijke start en stop criteria vd zorg vastgesteld en worden ze ook controleerbaar gehanteerd door de zorgaanbieder?	Leverancier

5.4 Op welke manier voldoet de zorg (via de app/algoritme) aan de stand van wetenschap en praktijk.	Leverancier
5.5 Hoe draagt de toepassing bij aan gezondheidswinst	Leverancier

6. Data- en beveiligingsaspecten	**Bron**
6.1 Is de data encrypt opgeslagen (zo ja op welk niveau schijf/database/applicatie)?	Leverancier
6.2 Is het transport van data encrypt?	Leverancier
6.3 Is de toepassing enkel te benaderen met een multi factor authenticatie? Zo ja welke factoren? Zo nee, wat is de reden dat hier niet voor gekozen is?	Leverancier
6.4 In welk land staat de server waar de data opgeslagen wordt	Leverancier
6.5 Is er sprake van doorgifte in de zin van de AVG van data naar derde landen (waarbij onder doorgifte ook toegang verstrekken tot wordt verstaan)?	Leverancier
6.6 is de data op het device en/of in de database gescheiden van andere applicaties / klanten?	Leverancier
6.7 Wordt er aan de patient toegang gevraagd tot gegevens op het device?	Leverancier
6.8 Is de data alleen toegankelijk voor de gebruiker en/of na toestemming ook voor de zorgverlener?	Leverancier
6.9 wordt getest met anonieme data?	Leverancier
6.10 Is de toegang door beheerders afgeschermd met aanvullende maatregelen? (zo ja welke)	Leverancier
6.11 Is het beveiligingsbeleid van de leverancier gebaseerd op een algemeen aanvaarde standaard (b.v. ISO 2700x)	Leverancier
6.12 Is er een penetratietest uitgevoerd op de applicatie?	Leverancier
6.13 Is langdurige data opslag gegarandeerd indien de aanbieder verdwijnt?	Leverancier
6.14 Verstrekt de leverancier een TPM (b.v. ISO, ISEA, SOC2)	Leverancier
6.15 Is er een privacy impact assesment gemaakt? (kan die ter inzage worden overlegd)	Leverancier
6.16 Welke persoonsgegevens worden verwerkt?	Leverancier
6.17 Wie is controller, wie is processor?	Leverancier
6.18 maakt de processor gebruik van subprocessors?	Leverancier
6.19 Is er een duidelijk leesbare privacymededeling?	Leverancier
6.20 Op welk moment wordt de betrokkene op bovenstaande mededeling gewezen?	Leverancier
6.21 Wordt toestemming gevraagd voor het verzamelen van gegevens? En zo ja, op welke wijze kan deze toestemming worden ingetrokken?	Leverancier
6.22 Wordt er toestemming gevraagd voor het gebruik van gegevens door derden?	Leverancier
6.23 Wordt er toestemming gevraagd voor gebruik, aanpassen, verwijderen van ingevoerde of afgegeven gegevens?	Leverancier
6.24 als er geen toestemming wordt gevraagd voor bovengenoemde doelen, wat is dan de grondslag van de verwerking?	Leverancier
6.25 is er aantoonbaar goede consentmanagement?	Leverancier
6.26 is er sprake van geheel geautomatiseerde besluitvorming?	Leverancier

6.27 hoe lang worden de persoonsgegevens bewaard?	Leverancier
6.28 Wordt deze data voor verdere productontwikkeling (analyse doeleinden?) gebruikt?	Leverancier

7. Algemene voorwaarden en overige wet en regelgeving	**Bron**
7.1 Kunnen jullie de algemene voorwaarden overleggen?	Algemene voorwaarden

8. Certificering	**Bron**
8.1 Is het device CE gecertificeerd en onder welke MDR klasse?	CE Declaration of Conformity
8.2 Is het device ook buiten Europa gecertificeerd?	Leverancier
8.3 Is er een kwaliteitswaarborg system op bedrijfsniveau ?	Leverancier

9. Financiering	**Bron**
9.1 Wat is het verdienmodel achter de applicatie?	Leverancier
9.2 Is er een declaratietitel?	
9.3 Is een alternatieve vorm van financiering mogelijk?	

10. Organisatie impact	**Bron**
10.1 Wat moet de zorgaanbieder die de toepassing gaat gebruiken aanpassen in zijn processen, cultuur, opleidingen en organisatie van het werk?	Leverancier
10.2 Welk aspecten spelen een rol bij de beoordeling of de zorgaanbieder de onder 10.1 genoemde veranderingen succesvol kan doorvoeren?	Leverancier