EVALUATING AN EDUCATIONAL CARE PATHWAY SUPPORTED BY THE DIABETES BOX FOR PATIENTS WITH TYPE 2 DIABETES:

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A PILOT AND FEASIBILITY STUDY

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Master's Thesis

Evaluating an Educational Care Pathway supported by the Diabetes Box for patients with type 2 diabetes: A pilot and feasibility study

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"Before you heal someone, ask him if he's willing to give up the things that make him sick"

Hippocrates (460 BC - 377 BC)

Merel van der Maarel

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SUMMARY

This report represents the master's thesis for the graduation project of the Technical Medicine master (track Sensing and Stimulation). The project has been carried out at the department of internal medicine of the Leiden University Medical Center (LUMC). The aim of this project is to determine the feasibility of a new educational care pathway and additional Diabetes Box, based on acceptability, usability and adherence.

Chapter 1 provides a general introduction into the medical context of diabetes as well as an overview of e-health interventions. This chapter also contains a thesis overview with the thesis motivation, goals and objectives.

A literature review was conducted about the current state of e-health interventions in type 2 diabetes which is portrayed in **Chapter 2**. The literature review delves into the (long-term) effects of e-health interventions and the necessary improvements. Topics as cost-effectiveness and the need for additional long-term research with a large sample size are also discussed.

In **Chapter 3** an elaborate explanation of the study design is described. This chapter includes the complete concept of the new educational care pathway which is studied in this pilot study. The study population, details of the intervention, types of education and wearables used in the pathway are described. In addition, the questionnaires used in this research are described, as well as the interviews used to gather additional data. Data analysis of the questionnaire data and quantitative data extracted from the wearables is also described.

Chapter 4 discusses the results of the research. Including a qualitative study on the feasibility based on acceptability, usability & user-friendliness, use & adherence and the secondary outcomes. These results are based on three questionnaires and a final evaluation consult with six patients. Patients mainly wanted improvement in the ability to personalize the pathway to better fit individual needs. Patients shared their concern about the LUMC Care App which is not working properly. In depth interviews with five healthcare professionals were used to gain additional information. The in depth interviews are used to determine barriers and facilitators for the implementation of the educational care pathway. Factors such as the lack of simplicity in the pathway and the absence of a glucose monitoring sensor in the box serve as barriers. The gain of knowledge in patients, and the coverage of important topics in the content of the pathway serve as facilitators. To describe the perceived learning and patient activation, questionnaires at the baseline and the end of the pilot a were used in addition to the data extracted from the wearables and the blood glucose sensor. Qualitative research reveals that the pathway has an overall positive impact on patients. Patient activation has improved although not significantly (p=0.137). In addition, the time patients had a very high blood sugar did also decrease, but again not significantly (p=0.07). The at home monitoring measurements were more difficult to analyze as blood pressure measurements were not performed often enough. The amount of steps did increase during the pilot, but once again not significantly (p=0.65). The results seem promising, but future research is necessary to create more reliable results.

Chapter 5 Contains the discussion in which the results are interpreted. This chapter also contains the limitations of this study in which the different types of bias are discussed as well as the sample size and the lack of long term results. This chapter also includes the conclusion of the research. Based on the current state of the educational care pathway, future large scale research or implementation would not be recommended yet.

Chapter 6 includes improvements and future directions for the diabetes box and pathway divided into two components of the pathway: organization & logistics and the content of the pathway.

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LIST OF ABBREVIATIONS

Арр	Application
ΑΡΙ	Application Programming Interface
CGM CSQ CVD	Continuous Glucose Monitoring Client Satisfaction Questionnaire Cardiovascular Disease
DALY DiaBox	Disability Adjusted Life Year Diabetes Box
FAQ FGM	Frequently Asked Questions Flash Glucose Monitoring
HR	Heartrate
ΙοΤ	Internet of Things
LUMC LUMC App	Leiden University Medical Center LUMC Care Application
MDD	Medical Device Directive
PAM	Patient Activation Measure
SUS	System Usability Scale
T0 T1 T2DM TIR	Baseline The end of the eight-week educational care pathway Type two diabetes mellitus Time in Range

1 GENERAL INTRODUCTION

1.1 Medical Context

1.1.1 Diabetes Mellitus

Diabetes Mellitus is a chronic, metabolic disease which is characterized by the inability to regulate blood glucose levels, resulting in chronic hyperglycaemia. Diabetes occurs in different types. The most common types are type 1, type 2 and gestational diabetes.[1] Type 1 diabetes is an autoimmune disease. The body's immune system attacks the pancreatic islets that produce insulin. As a result the pancreas does not produce insulin.[2] In type 2 diabetes mellitus (T2DM), insulin resistance is the basis of the classic form of T2DM. In the course of time, the pancreas fails to produce enough insulin. It is possible that as a response the pancreas will produce more insulin causing hyperinsulinemia, but due to insulin resistance (IR) this will not be enough to prevent hyperglycemia.[3] Over time, diabetes can lead to micro- and macrovascular damage.[4, 5] Individuals diagnosed with diabetes face an elevated risk of developing hypertension, dyslipidemia, blindness, cardiovascular complications and kidney failure. [5, 6] Mentally, these individuals are twice as likely to experience depression and have a 20% higher likelihood of experiencing anxiety compared to the general population. Overall, there is an increased risk of worsening mental health and a decline in quality of life of patients and their family.[5-7] Longterm treatment causes a disease burden of psychosocial problems such as depression and anxiety, it also raises economic concerns such as being unemployed, having to make changes in lifestyle, losing one's self-care abilities and experiencing fewer social interactions.[8] Diabetes has significant health and economic consequences.[7] Complications of T2DM are very common, with half of the patients presenting with microvascular complications (e.g. retinopathy and neuropathy) and 27% with macrovascular complications (e.g. coronary heart disease).[9] Figure 1 shows the factors associated with the risk of developing a cardiovascular disease (CVD) and the interactions between them.[10] Developed complications as a result of T2DM can further contribute to rising healthcare expenses and putting additional pressure on healthcare systems.[11, 12] The global cost of diabetes has been estimated at 1.3 trillion US dollars, causing a great burden on healthcare systems around the world.[13]

1.1.2 T2DM

T2DM is widely acknowledged as the most common type of diabetes. Varying among different countries, T2DM accounts for 90-98% of diabetes mellitus cases. [5, 10, 14 -17] This condition is characterized by insufficient insulin secretion from pancreatic islet beta-cells, tissue IR, and an inadequate compensatory insulin secretory response.[10] T2DM tends to manifest gradually and is largely influenced by one's lifestyle choices. Nonetheless, there are additional risk factors associated with the development of T2DM, such as ethnicity, family history, and specific genetic mutations.[14]

T2DM is caused by the interplay of two main factors: impaired insulin secretion by pancreatic betacells and the reduced ability of insulin-sensitive tissues to respond to the effects of insulin. Maintaining



Figure 1: Figure adapted from 'Pathophysiology of Type 2 Diabetes Mellitus, Galicia-Garcia, U. et al'[10] showing the factors implicated in the risk to develop a cardiovascular disease

T2DM: Type 2 Diabetes Mellitus **CVD:** Cardiovascular disease

glucose homeostasis relies on the critical roles of insulin secretion and activity. Consequently, the molecular mechanisms responsible for insulin synthesis, release and detection are tightly regulated. Any disruptions of the mechanisms involved in these processes can result in a metabolic imbalance, which plays an important role in the development of the disease.[10] Malfunctioning of the feedback loops between insulin action and insulin secretion leads to abnormally elevated glucose levels in the blood, resulting in hyperglycemia. When beta-cell dysfunction occurs, there is a decrease in insulin secretion, which hinders the body's ability to maintain normal physiological glucose levels effectively. On the other hand, IR plays a role in increasing glucose production in the liver while reducing glucose uptake in muscle, liver, and adipose tissue.[10] Both processes can occur in the pathogenesis and play a role in the disease's development. However, beta-cell dysfunction typically

exhibits greater severity compared to IR. When both beta-cell dysfunction and IR coexist, hyperglycemia is exacerbated, accelerating the progression of T2DM.[10] In addition, individuals suffering from T2DM typically exhibit characteristics such as obesity or a higher body fat percentage, primarily concentrated in the abdominal area. Adipose tissue contributes to IR through a range of inflammatory mechanisms.[10] Figure 2 shows a schematic representation of the modifiable and non-modifiable risk factors leading to the perpetuation of insulin dysfunction.[10]



Figure 2: Figure adapted from 'Pathophysiology of Type 2 Diabetes Mellitus, Galicia-Garcia, U. et al'[10] showing the risk factor and pathological changes leading to the perpetuation of insulin dysfunction **ROS:** reactive oxygen species **ER:** endoplasmatic reticulum **AGEs:** advanced glycation end products **PKC** protein kinase C LPS: lipopolysaccharide miRNA: microRNA

1.1.3 Epidemiology of T2DM

Diabetes is a serious global health issue. It is one of the leading causes of morbidity and mortality with a continuous rise of prevalence worldwide.[4] In 2014 the amount of patients living with T2D was estimated to be 422 million. In 2021 this estimation increased to 510 million. This number is expected to rise to 743 million in 2045.[5, 16, 18] In 2017, T2DM was responsible for over 1 million deaths, making it the ninth leading cause of mortality. This increase is worrisome when comparing to 1990 when T2DM was ranked as the eighteenth leading cause of death. T2DM ranks as the seventh leading cause of disability and years of life lost, also described as Disability Adjusted Life Years (DALY). It has jumped in rank from the nineteenth position in 1990, to the seventh, highlighting a worldwide shift in disease patterns.[19] In the last two decades, the prevalence of T2DM in children and adolescents has increased dramatically and shows no sign of stabilization.[19, 20] The global surge of T2DM cases can be linked to several key factors: the increasing prevalence of obesity, sedentary lifestyles, high-caloric diets, and an aging population. These factors have collectively quadrupled the incidence and prevalence of T2DM.[10] These findings have implications for healthcare professionals, physicians, health

policy planners and society. Despite the significant investments in clinical and pharmaceutical research, the burden of suffering caused by diabetes, measured in DALY's, continues to rise. The increase of this burden surpasses the growth of the population and effects of aging. Remarkably, Western Europe exhibits a rate of increase in T2DM prevalence, higher than the global and Asian averages. Despite the high levels of clinical and public health expenditure in Western Europe, they are losing the battle against diabetes.[19]

1.1.4 Self-Management in T2DM

In order to halt the increase diabetes complications and to improve the quality of life of patients, lifestyle modification have to take a more prominent place in treatment of diabetes. [21–23] Physical inactivity, unhealthy eating habits, obesity and smoking are the key contributing factors associated with disease development of T2DM. The strong correlations between health behavior and disease outcomes indicate the importance of adopting a patient-centered, proactive and evidence-based approach to prioritize and implement healthy lifestyle choices. [5, 16] Previous results indicate that well-established diabetes programs, including prevention and health promotion measures, enhance patients' treatment adherence, self-care abilities and quality of life. [8, 16] Self-management entails an individual's proactive effort to effectively handle the management of their disease, including symptom control, treatment adherence and necessary lifestyle changes. [24] Lifestyle modifications such as a healthier diet, increased physical activity and blood glucose monitoring have proven effective in delay or prevention of T2DM complications, or even complete remission of T2DM.[25-27] Physical therapy and a healthy diet contribute to the treatment of T2DM. In addition, lifestyle therapy delays T2DM and improves cardio-metabolic markers. [28, 29] Furthermore, consistent adherence to self-care behaviors such as medication adherence, regular physical activity, healthy diet and blood glucose monitoring is linked to improved glycaemic control and decreased risk of complications.[30-32] Since T2DM is a chronic disease, patients have to maintain a lifelong commitment to a healthy lifestyle, in order to prevent or delay complications. In addition, the costs of diabetes, along with its negative impact on the labor market, have escalated over time and with disease severity. This underscores the importance of early investment in prevention and disease management, as they may yield particularly worthwhile outcomes.[33] But even though lifestyle interventions have proven effective on glycaemic control, long-term maintenance of lifestyle change remains difficult.[29, 34]

1.1.5 Challenges of self-management in T2DM

Even though there is evidence that living a healthy lifestyle is beneficial in managing chronic conditions like diabetes, patients with T2DM often struggle with the right methods to manage their condition. It is extremely challenging to make and sustain effective long-term lifestyle changes in our daily lives.[35] This results in a majority of patients struggling to adhere to one or more lifestyle changes, with diet and exercise being the most commonly neglected aspects.[30] In addition to problems with long-term adherence, low participation rates and drop-outs during studies is also common. These problems are frequently encountered when issues concerning accessibility and acceptance are encountered. These challenges can be particularly pronounced among patients with a lower socioeconomic status as they might have additional social problems to deal with that require more attention. T2DM is hard to manage effectively, but as a result of neglect, patients will experience more complications and put an extra (financial) burden on themselves and society.[7, 31, 36, 37]

1.2 E-Health

1.2.1 What is e-health

The definition of e-health changes through time, partly due to the rapidly evolving field of the internet and electronics. A definition of e-health as stated by Eysenbach is as follows: '*E-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies.*'.[38] Da Fonseca et al. defines e-health as a range of internet-based technologies aimed at enhancing the quality of life and streamlining healthcare delivery by providing healthcare services efficiently.[39] The World Health Organization (WHO) characterizes e-health as an efficient and secure utilization of information and communication technology to support health and health related domains. This encompasses health surveillance, health care services, health literature and health education, knowledge and research in a cost-effective manner.[40] Even though there is no consensus on a definition that paints a concise picture of e-health, it can be agreed upon that at least a part of e-health involves utilizing digital tools and exchanging information electronically to attain and exchange information electronically to attain and exchange information electronically to attain and sustain a high level of health.[4] Therefore, e-health has the potential to serve as a valuable resource within the healthcare system by assisting in self-management support. This includes

features like ongoing tracking of a patients' health status, enabling self-monitoring capabilities and providing information that empowers patients to make informed decisions regarding their chronic conditions. [29] E-health includes practices like mobile health (m-health) and telehealth, which utilizes electronic technologies to deliver healthcare resources, services and information effectively. [39] M-health involves medical and public health practice supported by mobile devices. [41] It consists of the use of mobile devices to enable patients to access healthcare services electronically, utilize apps to verify information and effectively manage or monitor their treatments and health problems. [39] As smartphone and internet access continues to expand globally, m-health provides a personalized, convenient and cost-effective approach for delivering healthcare services. [41] Telehealth can be defined as the utilization of telecommunication technologies (e.g. video- or phone consults) to enhance the care and education provided to both patients and professionals working in the healthcare field. [39] The most used technologies in e-health are displayed in Figure 3. The top three most used technologies based on the article by Da Fonseca et al. are security, Internet of Things (IoT) and cloud computing. [39] IoT generally refers to situations in which network connectivity and computing capability are extended to objects, sensors and ordinary objects not traditionally seen as computers, such as smart watches, cars and refrigerators. [42]



Figure 3: Types of e-health, adapted from da Fonseca et al. (2021) showing an overview of the most used types of e-health

IoT: Internet of Things

1.2.2 E-health interventions in T2DM patients

As mobile technology has become widely used around the world, the integration of technology in diabetes self-management, education and support have grown significantly. These technological advancements provide a flexible platform for creating personalized interventions that go beyond traditional computer and web-based programs, as well as underutilized educational programs.[43] While not widely adopted, the use of e-health tools has the potential to improve the management and prevention of diabetes. As more and more people own smartphones, e-health is expected to play an increasing role in the near future.[11] To enhance the quality of life of patients with T2DM and reduce the (financial) burden on healthcare systems, using suitable home health technologies can be beneficial. These technologies can help patients to learn how to take care of themselves and manage their condition effectively. This can potentially result in a delay or prevention of complications. Therefore, digital health interventions present a practical and effective way for patients with T2DM to manage their condition individually.[24, 44] To address the need for long-term self-care of diabetes treatment, e-health has been found to be very helpful and supportive. As a result, several applications (apps) have been developed with a focus on educating, treating, and assisting individuals with diabetes and related health conditions in managing their health. These apps enable users to monitor and track their physical activity, nutrition, blood glucose levels and medication or insulin dosage. In addition, these apps offer health feedback and educational resources.[24, 43, 44]

1.3 Thesis Overview

1.3.1 Thesis Motivation

Accurate treatment of T2DM requires that patients have a good understanding of health information and regular communication with healthcare providers. In order to prevent the neglect of healthcare changes, it is recommended that patients receive education and support from healthcare professionals. As a result, patients' knowledge, skills and tools necessary for sustainable control of T2DM, should improve. Therefore, education is considered crucial in achieving sustainable changes in the health behavior of patients with T2DM.[45] Having knowledge about the disease mechanism and the impact of lifestyle factors is believed to be essential for achieving metabolic control.[46–48] In order to reach and maintain lifestyle changes, education, practical training tools and techniques for self-management are deemed important.[44] To promote a healthy lifestyle and improve glucose regulation, a hospital-based, patient-centered care pathway for diabetes was developed as an addition to standard care. In order to test the feasibility of the pathway a pilot study was initiated.

1.3.2 Goals and Objectives

The aim of this pilot study was to determine the feasibility based on acceptability, usability and adherence of educational care pathway and additional Diabetes Box (DiaBox).

1. Acceptability

- (a) How satisfied are patients with the constituents of the educational care pathway (i.e., consultations, videos, apps and self-monitoring)?
- (b) What are the experiences of healthcare professionals with the DiaBox in terms of barriers and facilitators as well as positive and negative experiences?
- 2. Usability & User friendliness
 - (a) To what extent do the patients perceive the different constituents of the educational care pathway (i.e., consultations, videos, apps and self-monitoring) easy to use?
 - (b) How valuable do patients think the educational pathway and its constituents (i.e., consultations, videos, apps and self-monitoring) are?
 - (c) To what extent do healthcare professionals think the education care pathway is usable in daily practice?
 - (d) What can be improved about the educational care pathway according to patients and healthcare professionals?
 - (e) To what extent is the help desk used and what are the most frequent reasons for contacting?

3. Use & Adherence

- (a) What is the patients average attendance at individual and group consultations?
- (b) To what extent are the different aspects of the app used by patients?
- (c) To what extent do patients adhere to the measurement schedule of the self-monitoring?

4. Secondary outcomes

- (a) To examine whether the intervention leads to perceived learning of diabetes and its related lifestyle factors.
- (b) To examine whether the intervention improves patients' activation in terms of diabetes selfmanagement and optimized glucose regulation, from baseline to post-intervention. Glucose regulation is measured as percentage time in range (TIR, glucose between 3.9-10 mmol/L) as defined in the International Consensus on Time in Range.[26]
- (c) To determine necessary adaptions and improvements for the diabetes box and pathway.

1.3.3 Thesis Outline

The thesis consists of six chapters, including the introduction (Chapter 1), a literature study about the current state of e-health interventions in T2DM care (Chapter 2), the study design of the pilot study (Chapter 3) and the results of the pilot study about the educational care pathway (Chapters 4, 5 and 6). The pathway consists of three aspects: education, self-monitoring and a smartphone application. Education consists of group consultations organized by healthcare providers and individual consultations with a dietitian. In addition, online education videos are added. The pathway is supported with self-monitoring devices: a blood pressure monitor and an activity tracker. Included patients were already in possession of a flash glucose monitor. Furthermore, the pathway is supported by a smartphone app to bring it all together. The pathway is presented to patients in form of the DiaBox, which includes the devices and additional information to take home. Acceptability, usability and feasibility of the care pathway for both patients and healthcare professionals will be studied in this pilot study. These results will be displayed in Chapter 4. Secondary aims are to assess preliminary effects on perceived learning about diabetes and lifestyle factors related to T2DM, patient activation towards diabetes self-management and glucose regulation. These results will be displayed in Chapter 5. In addition, these results will be used to determine if the pathway and DiaBox are suitable for further large scale research. Necessary adaptations and improvements of the pathway and box will also be described, which will be further elaborated on in Chapter 6.

2 THE CURRENT STATE OF E-HEALTH INTERVENTIONS AS A TOOL FOR SELF-MANAGEMENT IN PATIENTS WITH TYPE 2 DIABETES: A LITERATURE REVIEW

2.1 Abstract

Introduction: By reducing blood glucose levels and addressing unhealthy lifestyles, the risk of adverse outcomes and the financial burden associated with managing type 2 diabetes can be decreased. While not widely adopted, the use of e-health tools has improved the management and prevention of diabetes. In order to improve quality of life of patients with T2D and to decrease the (financial) burden on healthcare systems, appropriate home health technologies can be helpful for patients to learn how to take care of themselves and manage their condition effectively, potentially resulting in a delay or prevention of complications. Due to the great heterogeneity of methods in studies it is hard to determine the actual effects of e-health interventions. This narrative review addresses the current state of e-Health interventions as tool for self-management in patients with type 2 diabetes.

Methods: A literature search was performed in the MEDLINE- database. After using the initial search strategy, snowballing was used in order to acquire additional articles.

Results: Overall, there are positive health effects, however, the majority was not significant. Some significant results were found in improvement of HbA1c. Results for long term effects were scarce, however, when short term results showed a significant improvement, this trend could not be maintained when patients were tracked for a longer amount of time. The lack of long-term effects makes it hard to determine cost-effectiveness of e-health interventions. Improvements based on research varied strongly per study.

Discussion: It is important to personalize the intervention in order to match to every patients wishes and demands. It should be kept in mind that patients who are willing to participate in research concerning e-health interventions might portray more optimistic outcomes for e-health interventions compared to the average type 2 diabetes patients. In addition, it might matter how long a patient has been diagnosed with diabetes and how old the patient is when they participate in a study. Long-term research with a large sample size is necessary to determine the efficacy and cost-effectiveness of e-health interventions.

Conclusion: There is a lack of well-designed and thoroughly conducted published interventions focusing on the use of e-Health apps to meet the specific needs of patients. However, it is also possible that the lack of significant results is not caused by a lack of well-designed studies. It might be possible that e-health interventions are not as beneficial as previously thought. Therefore, the effect of e-health interventions remains inconclusive.

2.2 Introduction

2.2.1 What is Diabetes?

Diabetes Mellitus is a chronic, metabolic disease which is characterized by the inability to regulate blood glucose levels, resulting in chronic hyperglycaemia. Over time, this could lead to micro- and macrovascular damage.[4, 5] Diabetes can take form in multiple different types. The most common types are type 1, type 2 and gestational diabetes. [1] Type 1 diabetes is an autoimmune disease. The body's immune system attacks the pancreatic islets that make insulin. As a result the pancreas does not make insulin.^[2] In type 2 diabetes mellitus(T2DM), the pancreas makes less insulin, additionally the body becomes resistant to insulin. This means the body has less insulin, and/or is not able to use the insulin available.[3] T2DM tends to manifest gradually and is largely influenced by one's lifestyle choices. Nonetheless, there are additional risk factors associated with the development of type 2 diabetes, such as ethnicity, family history, and specific genetic mutations.[14] T2DM is widely acknowledged as the most common type of diabetes. Varying among different countries, T2DM accounts for 90-98% of all diabetes cases. [5, 14-17] Physically, individuals diagnosed with diabetes face an elevated risk of developing hypertension, dyslipidemia, blindness, cardiovascular complications and kidney failure. Mentally, these individuals are twice as likely to experience depression and have a 20% higher likelihood of experiencing anxiety compared to the general population. Overall, there is an increased risk of worsening mental health and a decline in quality of life. [5, 6] These conditions can further contribute to rising healthcare expenses and putting additional pressure on healthcare systems.[11, 12]

2.2.2 Prevalence of type 2 diabetes

The prevalence of T2DM is escalating worldwide, posing significant economic challenges in numerous countries.[28] This global trend is contributing to rising rates of morbidity and mortality and health care resource

utilization.[7] As of 2021, the estimated global population affected by a form of diabetes was around 536.6 million, and this figure is expected to increase to 783.2 million by 2045. [5, 49, 50] With the notable rise in childhood obesity, there is a growing concern that the prevalence of diabetes type 2 will continue to rise for the foreseeable future. Global data provides evidence to support this concern, revealing that the incidence rate of type 2 diabetes among adolescents and young adults (aged 15 to 39 years) has risen from 117 to 183 per 100,000 population worldwide between 1990 and 2019.[51] Type 2 diabetes has become a global epidemic and is a worldwide public health crisis with an annual cost exceeding US \$1.2 trillion.[7, 44] By reducing blood glucose levels and addressing hypertension and dyslipidemia, the risk of adverse outcomes and the financial burden associated with managing this condition can be decreased.[18, 44] As a significant contributor to the growing burden of chronic illness, long-term treatments not only impose physical pain and psychosocial challenges (such as depression and anxiety) on individuals but also give rise to considerable economic worries for both individuals and their families. These concerns include unemployment, loss of self-care capabilities, reduced social and family interactions, and the need to adapt to lifestyle changes.[8] Since T2DM is associated with a low socioeconomic status it is crucial to focus on the development of interventions that are effective, comprehensive and easily accessible. [41, 52]

2.2.3 The role of self-management in the treatment of type 2 diabetes

Physical inactivity, unhealthy eating habits, obesity and smoking are the key contributing factors associated with disease development of T2DM. The strong correlations between health behavior and disease outcomes indicate the importance of adopting a patient-centred, proactive and evidence-based approach to prioritize and implement healthy lifestyle choices. [5, 16] Previous results indicates that well-established diabetes programs, including prevention and health promotion measures, enhance patients' treatment adherence, self-care abilities and quality of life. [8, 16] To reduce or even prevent complications as a result of T2DM, good self-management is necessary. Self-management entails an individual's proactive effort to effectively handle the management of their disease, including symptom control, treatment adherence and necessary lifestyle changes. [24] Research has shown that physical therapy and a healthy diet contribute to the treatment of T2DM. In addition, lifestyle therapy delays T2DM and improves cardiometabolic markers. [28, 29] Furthermore, consistent adherence to self-care behaviors such as medication adherence, regular physical activity, healthy diet and blood glucose monitoring is linked to improved glycaemic control and decreased risk of complications. [30–32] Since T2DM is a chronic disease, patients have to maintain a lifelong commitment to a healthy lifestyle, in order to prevent or delay complications. Therefore, evidence based sustainable lifestyle programs are crucial for patients as well as health care systems. [29]

2.2.4 The challenges of self-management in the treatment of type 2 diabetes

Even though there is evidence that living a healthy lifestyle is beneficial in managing chronic conditions like diabetes, patients with diabetes often struggle with the right methods to manage their condition. It is extremely challenging to make and sustain effective long-term lifestyle changes in our daily lives.[35] This results in a majority of patients struggling to adhere to one or more lifestyle changes, with diet and exercise being the most commonly neglected aspects.[30] In addition to problems with long-term adherence, low participation rates and drop-outs during studies is also common. These problems are frequently encountered when issues surrounding accessibility and acceptance are encountered. These challenges can be particularly pronounced among patients with a lower socioeconomic status as they might have additional social problems to deal with that require more attention. As a result of neglect patients will experience more complications and put an extra (financial) burden on themselves and society.[7, 31, 36, 37] Therefore, T2DM requires good understanding of health information and regular communication with healthcare providers. To prevent the neglect of healthcare changes, education and support from healthcare professionals have been recommended in order to improve patients' knowledge, skills and tools necessary for sustainable control of T2D. [44]

2.2.5 E-health

With the widespread adoption of mobile technology across the world, the integration of technology in diabetes self-management, education and support has experienced significant growth. These technological advancements offer a versatile platform for the development of personalized interventions that go beyond traditional computer, web-based programs and underutilized educational programs. [43] While not widely adopted, the use of e-health tools has improved the management and prevention of diabetes. With the growth of smartphone ownership and medical device innovations, e-health is likely to play an increasing role in the near future. [11] The definition of e-health changes through time, partly due to the rapidly evolving field of the internet and electronics. As stated in an article by Eysenbach, the definition of e-health is as follows: '*E-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies*.'.[38] E-health as stated in this article involves utilizing digital tools and exchanging information electronically to attain and exchange information electronically to attain and sustain a high level of health.[4] E-health has the potential to serve as a valuable resource within the healthcare system by assisting in self-management support. This includes features like ongoing tracking of a patient's health status, enabling self-monitoring capabilities and providing information that empowers patients to make informed decisions regarding their chronic conditions.[29] A subcategory of e-health, m-health, involves medical and public health practice supported by mobile devices. This includes mobiles phones, patient monitoring devices and other wireless devices. As smartphone and internet access continues to expand globally, m-health provides a personalized, convenient and cost-effective approach to delivering healthcare services.[41] As m-health is a form of e-health, the term m-health will not be used in this review, instead the term e-health will be used.

2.2.6 E-health as a tool to improve the treatment of diabetes

In order to improve quality of life of patients with T2DM and to decrease the (financial) burden on healthcare systems, appropriate home health technologies can be helpful for patients to learn how to take care of themselves and manage their condition effectively. This can potentially result in a delay or prevention of complications. Therefore, digital health interventions, present a practical and effective way for patients with T2DM to manage their condition individually.[24, 44] To address the need for long-term self-care needs of diabetes treatment, e-health has been found to be very helpful and supportive. As a result, various applications (apps) that focus on educating, treating and helping individuals with diabetes and related health conditions to manage their health have been created. These apps enable users to monitor and track their physical activity, nutrition, blood glucose levels and medication or insulin dosage. In addition, these apps offer health feedback and educational resources. Although several of these apps have shown clinical effectiveness, not all e-health interventions for managing diabetes and related health conditions are equally efficient.

2.2.7 Aim of the review

Still a lot is unknown about the effects of e-health interventions for patients with T2DM. Therefore, this review will attempt to answer the following questions regarding the treatment of T2Dm:

- 1. What are the effects of e-health?
 - (a) What are the long-term effects of e-health interventions?
 - (b) Does the usage of e-health reduce complications?
 - (c) Does the usage of e-health improve HbA1c?
 - (d) Does the usage of e-health improve the quality of life?
- 2. What needs to be improved to create a better efficacy?
 - (a) What types of e-health are used and what is the most effective type?
 - (b) Is the usage of e-health cost effective?
 - (c) What do patients like to see changed or improved while using e-health?

2.3 Methods

A literature search was performed in the MEDLINE-database. The search terms are further specified in Appendix A. Study protocols and letters to the editor were excluded. Due to the rapidly changing field of e-health articles written before 2010 were excluded. Articles concerning patients with gestational diabetes or exclusively type 1 diabetes, were excluded. To be included, the article had to be written in English or Dutch, in addition, full article availability was necessary. After using the initial search strategy, snowballing was used in order to acquire additional articles.

2.4 Results

1. What are the effects of e-health interventions in T2DM patients?

Access to hospitals can be problematic for patients with chronic diseases as not every patient lives near a hospital. e-health and telephone coaching to support self-management is a possible solution to overcome problems related to access.[31] Research often shows an improvement in various aspects, such as step counts, blood glucose levels, blood pressure and weight. However, depending on the research the results are often not significant.[53–58] Nonetheless, Chen et al.. shows a significant difference in activity, healthy eating, medication adherence and problem solving skills between an e-health and control group.[59] In addition, a significant decrease in blood pressure was found after intervention compared to standard care by Wu et al. and Toma et al. [60, 61] Interestingly, if patients with very poorly controlled blood glucose levels were removed from the analysis, the remainder of patients showed a significant improvement in time in rage (TIR).[56] Bretschneider et al.. did find a significant increase in the quality of life, ability to choose the right foods and physical activity.[55] Possibly, the results will improve if patients are included that are not insulin dependent yet or have had the diagnoses of diabetes for less than a year. Lastly, patient satisfaction and accessibility are very important for improving self-management efficiency. It is possible that the amount of pilot studies, in which app and wearables were not optimized yet, greatly influences the efficacy of the treatment. [53, 62] Even though not all results are significant, research shows improvement on various aspects such as activity, blood glucose levels, blood pressure and weight.

(a) What are the long-term effects of e-health interventions?

Additional studies with larger cohorts and a longer duration are necessary to analyze long-term effects. Current studies show promising results for usage of e-health in diabetes therapy, however they are inconclusive for long-term results. It is possible that positive effects will wear down over time. Adaptations to the interventions might be necessary over time. [54, 63] Research by Chen et al. confirms this as the mean value of HbA1c improves significantly in the first 6 to 12 months of the research. However, in the last period of the research the values slightly declined. At the beginning of the research patients were more self-conscious as they knew health care professionals were watching them, resulting in significant improvements. After a while patients were getting used to the program and a slight decline in HbA1c was observed. [59] Research by Lee et al. found comparable results as HbAc1 improved significantly in the first 12 weeks of the research but patients failed to further improve their HbA1c values in the following 14 weeks, the values even increased a bit. [53] Studies are mainly focused on short term effects. The long-term effects remain inconclusive

(b) Does the usage of e-health reduce complications?

Current literature does include information about the positive effects e-health interventions can have. Research has shown that health coaching aimed to improve the management of diabetes has positive effects on psychological and behavioral condition.[18] Even though e-health interventions have shown impact on physical activity and healthy eating, a long-term effect has not been shown. In addition, there are no results for largescale implementations. It is likely that the success rate of e-health depends on consumers' satisfaction with the communications platforms with their health care providers used in the e-health intervention.[29] Due to the lack of long term research, not much is known about the development of complications with and without e-health interventions.

(c) Does the usage of e-health improve HbA1c?

Based on the review written by Emonena et al. multiple studies have shown that HbA1c improved as a result of lifestyle interventions. However, these effects were not statistically significant. In addition, included articles in this review found no benefit of telemonitoring in order to improve HbA1c. Also, HbA1c remained unaffected by education aimed at self-management.[14] In addition to Emonena et al. there are articles that show that HbA1c was not significantly improved after an e-health intervention.[11, 59] On the other hand, additional research showed a significant improvement in HbA1c after e-health intervention, however the control group also improved significantly.[53] On the contrary, a review written by Greenwood et al. showed that 18 of the 25 included articles showed a significant reduction of HbA1c as an outcome measure.[43] Additional to the review of Greenwood et al., a meta-analysis by Bonoto et al. showed that a meta-analysis of 13 studies on mobile apps for diabetes suggested a significant improvement in HbA1c.[64] Emonena et al. stated that 78% of included patients had poor knowledge and understanding of HbA1c, which might explain why there

is a lot of improvement possible.[14] In addition to these reviews, multiples studies found a significant improvement of HbA1c after an e-Health intervention.[18, 55, 57, 58, 60, 61, 65–76] The differences in results could be explained by the extreme heterogeneity of methodologies used in lifestyle interventions. This is due to the rapidly evolving field concerning e-Health. There is, however, clear evidence that technology-enabled diabetes self-management and education is effective in reducing HbA1c.[43] Interestingly, research by Lee et al. showed a significant difference in HbA1c based on their first RCT with a smaller sample size (n=30). When the same app was tested in a real-world setting with more than a hundred patients, no intervention effects were found.[53] Lee et al. tried to explain the differences in outcomes and provided additional information to explain disappointing results in HbA1c values. First of all, age can be a barrier to the usage of digital health care, the mean age in all the different studies varies. A study with a higher mean age might show less improvement in HbA1c due to less digital literacy. In addition, a lot of included patients had a long duration of diabetes and were insulin users.[77] It is known that the effects of education and lifestyle changes decrease with the duration of diabetes. [78] To summarize, HbA1c values improved in some studies, however, these results were not always significant. The long-term effects on HbA1c values remain inconclusive.

(d) Does the usage of e-health improve the quality of life?

Previous research has shown that e-Health interventions consisting of real-time audio and video intervention has significantly improved physical and mental health in type 1 and 2 diabetes patients. Overall the interventions have a beneficial effect on the quality of life.[63] Even though lifestyle interventions are designed to assist patients to self-manage their chronic disease, the interventions can have the opposite effect. Some interventions increase the burden of living with and managing a chronic condition.[18] It must therefore be stated, that due to the lack of long-term results, the effects on quality of life, remain inconclusive.

2. What needs to be improved to create a better efficacy?

In order to be sure of adherence to interventions, usability and reliability of apps need to be excellent. Potter et al. has stated that patients wanted to continue using apps and devices even after the intervention had ended. However, they only wanted to do so if the reliability and usability of the app was improved. [56] Improvements for better usability as stated by patients can be one of the following: faster uploads, visible icon indicating the app is processing data, ability to zoom in on data displays, comparative visuals (blood glucose curves of people without T2DM), weekly summaries, ability to reach next steps to increase motivation. [56] Technological difficulties and poorly designed interfaces are one of the main reasons for a decline in the usage of e-health, especially in older adults. Chronic disease are more common among older adults, but it is also known that older individuals are less developed in digital literacy compared to younger individuals. [54, 59] Older patients have more difficulty in adopting new technologies and apps. Apps and wearables designed for self-monitoring should therefore be better accessible for older patients. Voice-based m-health could be a solution for older patients with limited digital literacy. This could also be beneficial for patients with poor vision.[54, 63] In addition, connecting patient information with mobile health apps (e.g. medication usage or comorbidities) could provide better insight into diabetes management.[53] To sum up previous findings, better reliability and usability of apps as well as better accessibility for patients with low digital literacy needs to be realized to improve efficacy.

(a) What types of e-health are used and what is the most effective type?

E-health interventions can consist of multiple modalities, such as, usage of apps, text messaging, educational videos, web-based tools, at home monitoring, etc. It is more effective to use multiple modalities at the same time, compared to a singular intervention. [43, 62, 79] Moreover, multiple studies have shown that mobile communication contributed in greater improvement of HbA1c compared to web-based interventions. [43] One-way communication had no impact on participant outcomes. One-way communication consists of communication from sender to receiver and serves to inform, persuade or command. Direct communication between health care providers and patients does improve outcomes. [43] In addition, the possibility to communicate with a healthcare professional or knowing that they were reviewing their messages facilitated engagement. [80] Also, one-way text messaging, is likely to be less effective, as it may appear irrelevant to patients. As a result the self-management goals might not be optimally adhered to. [43] Chen et al. stated that more patients used phone call services than messaging services in their intervention. Younger patients did use text messages more of than older patients. [59] When text messages are a part of the intervention, the optimum frequency is still unknown, however, multiple studies suggest that patient motivation can be increased by regular text-based feedback. [81–83] In addition, these text messages increase understanding of how nutrition and physical activity

can affect T2DM.[81–85] The perfect timing for receiving messages varies per patient, optimization of timing can therefore influence the acceptance and adherence to intervention programs. If a patient has a choice over what time of the day they want to receive a message, the feeling of being nagged is reduced. This may result in more reflection and interpretation of the messages.[56] Potter et al. states that in order to facilitate behavioral change, the visibility of real-time blood glucose profiles in combination with nudging messages for positive feedback are crucial. The idea is that frequent, positive and suggestive feedback, over time, will significantly modify behavior. As a results the development of diabetes and cardiovascular risks will be reduced.[56] In addition, patients really liked the feature of physicians assessing their individual data and sending feedback through SMS texts. It was stated as a key driver of motivation and emotional support. It should be kept in mind that patients could become addicted to this type of feedback. A solution for this could be a protocol to scale back feedback as a patient develops self-efficacy.[56] To summarize, Interventions are more effective when multiple modalities are used. When one modality is used, mobile communication worked best. Two-way communication worked better than one-way communication.

(b) Is the usage of e-health cost-effective?

A review by Emonena et al. showed different results in cost effectiveness of e-health as tool for glycaemic control.[14] Multiple studies showed that e-health interventions are expensive to initiate and install. Several studies showed that the usage of telemonitoring in T2DM patients is not cost-effective. However, there are studies that proclaim that e-health interventions have the potential to be cost-effective.[14] When it comes to e-health interventions it is not possible to completely isolate the issue of cost. The consensus based on this review shows that there is no unanimity of the cost-effectiveness of e-health interventions.[14] An other article stated that e-health interventions are a cost-effective approach in the short term. Important to state is that this concerns patients with a high level of engagement.[29] There are articles confirming the cost-effectiveness.[63] Four articles concluded that e-health interventions can be cost effective.[65, 86–88] On the other hand, Teljeur et al. reported that e-health interventions were not cost-effective at all.[89] Due to the lack of long-term results, cost-effectiveness of e-health interventions in T2DM patients remains unclear.

(c) What do patients like to see changed or improved while using e-health?

Based on results from several studies, input from patients was collected based on focus groups and in-depth interviews as well as questionnaires. [31, 54, 56, 59, 90]

Features

The most desired features for long time tracking for patients, is the ability to monitor information about sugar levels, medication adherence and activity.[56, 90, 91] Patients believed that tracking their data would help them track their progress and enhance self-awareness and motivation.[90] Even though patients agreed on the benefits of tracking, there were patients who found that consistent logging could be burdensome and did not ease the burden of living with a chronic disease.[90] If a function for food tracking is included in the app it should be easy to use, previous research showed that patients asked for easier functions to record food intake, and a more complete 'provided list'. When the food tracking function is not user-friendly patients are more often prone to stop with this part of the intervention compared to the tracking of medication use. [54] In addition, photographing food in public made patients self-conscious. Keeping track of food was stated as the biggest burden of the study. At the same time patients stated that keeping track of their food made them feel more accountable and aware of what they were consuming.[56]

Communication

The opportunity to discuss treatment options with health care professionals is found important by patients.[31] In addition, patients pointed out that recommendations based on lifestyle interventions were often unaware of the circumstances of patients' lives, such as financial or relational problems.[90] Patients found the personalized guidance based on their input of added value. Especially patients who were engaged in following healthy activities, but who were not reaching their goals liked to receive additional personalized coaching, real-time feedback and individualized plans based on their specific input.[90]Since some patients are reluctant to let people around them know about their disease it would be beneficial if there is flexibility in the timing and amount of messages in the intervention. Patients are able to turn messages of during for example working hours. Patients like the option of asynchronous messages, where they had the option to respond to a message at another time than when they received the message. This allowed them to communicate with health care professionals outside of working hours.[59] Patients prefer two-way communication in comparison with one-way

communication. It is important for them to have the possibility to for example clarify aspects of the meal they had photographed or ask a question about the text message they received.[56]

Responsibilities

Patients concluded that it was hard to maintain physical activities as prescribed in the lifestyle interventions due to existing (additional) illness or injuries. Also, work responsibilities or family commitments were found to be more important than physical activity.[90]

Notifications

The majority of patients as described in the article of Yoon et al. liked getting notifications to remember daily tasks such as, taking medication, going for a walk, doing exercises. It would be even better if notifications could be personalized to individual patients, so adherence to the complete package of self-management could be improved and healthy habits could be established. Nonetheless, too many notifications were found annoying. Notifications for food intake, medication and exercises should be personalized and there should be a possibility to turn the notifications off, otherwise the notifications would only be bothersome.[90]

Education & Information

Patients stated that even though there is a lot of information online, it is hard to be sure of the reliability of this information. Therefore, they would appreciate in-app resources to improve their knowledge about diabetes related topics and a healthy lifestyle. It would be even better if this resource could be customized to portray a source of information about a healthy lifestyle based on personalized profiles (e.g. age, diet, amount or type of exercise).[90] Patients also stated that personalized feedback based on their food journal was pleasant, as a patient stated 'it is nice having someone in your corner'. Some patients even looked forward to receiving feedback and especially appreciated the personalized aspects. [56]

Support group

A minority of patients was interested in an app-based support group as a possibility to chat with other patients to share experiences with like-minded people. A built-in chat function to chat with health professionals was also stated as a potential improvement.[90]

Goal setting

Patients stated that personalized goal setting and monitoring of progress on goal attainment is underexposed in routine care. This is worrisome as literature suggests that setting personal goals and keeping track of the accompanied behavioral changes are critical to enhance a patients' commitment to diabetes self-care. Patients stated time pressure in consultations as a major challenge to include goal-setting and monitoring in consultations.[90]

Privacy

Patients care about their privacy, Potter et al.. stated that some patients would not continue using the app used in their intervention, because they felt the wearables were too invasive. [56]

To resume, Patients would like to see more individualization in lifestyle interventions. In addition, educational tools and ways to monitor blood sugars levels were a must. Patients also prefer an ability to communicate with a healthcare professional about the intervention.

Table 1: Summary of Results

Question	Conclusion		References
What are the effects of e-health interventions in T2DM patients	Research shows improvement even though it is not always significant	+	Potter[56], Timm[31], Lee[53], Oh[54], Bretschneider[55], Marcolino[57], De Jong[58], Chen[59], Wu[60], Toma[61], Draznin[62]
What are the long-term effects of e-health interven- tions?	Due to the lack of long-term result, this re- mains inconclusive	-	Oh[54], Eberle[63], Chen[59], Lee[53]
Does the usage of e-health reduce complications?	Due to the lack of long-term result, this re- mains inconclusive	-	Hanlon[18], Woldamanuel[29]
Does the usage of e-health improve HbA1c?	HbA1c values improved during studies, but were not always significant. The long-term effects on HbA1c values remain inconclusive	+-	Emonena[14], Hanlon[18], Shan[11], Bretschnei- der[55], Marcolino[57], de Jong[58], Chen[59], Wu[60], Greenwood[43], Lee[53], Toma[61], Bonoto[64], Tchero[65], Tao[66], Baron[67], Kitsiou[68], Suksomboon[69], Hyun[70], Faruque[71], Polisena[73], So[74], Su[75], Su and McBride[76], Chow[77], Ko[78]
Does the usage of e-health improve the quality of life?	Due to the lack of long-term result, this re- mains inconclusive	-	Hanlon[18], Eberle [63]
What needs to be improved to create a better efficacy?	Better reliability and usability of apps as well as better accessibility for patients with low digital literacy	+	Oh[54], Potter[56], Chen[59], Yoon[90]
What types of e-health are used and what is the most effective type?	Usage of multiple modalities was more effec- tive. Mobile communication worked best for single modality use. Two-way communica- tion worked better than one-way communi- cation.	+	Greenwood[43], Lee[79], Draznin[62], Chen[59], Agboola[81], Capozza[84], Park[82], Nepper[83], Dobson[85], Potter[56], Eberle[63], Lee[5]
Is the usage of e-health cost- effective?	Due to the lack of long-term result, this re- mains inconclusive	-	Emonena[14],Woldamanuel[29],Eberle[63],Tchero[65],Siriwardena[86],Lee[87],Walker[88],Teljeur[89],Nelson[80]
What do patients like to see changed or improved while using e-health?	Patients want more individualization. Ed- ucational tools and ways to monitor blood glucose levels were a must. Patients prefer he ability to communicate with a healthcare professional.	+	Oh[54], Timm[31], Potter[56], Chen[59], Lee[53], Eberle[63], Yoon[90], Baptistac[91]

++= strong evidence, += evidence, +-= unclear evidence, -= no evidence

2.5 Discussion

With this narrative review, we attempted to gain insights in the effects of e-health interventions for patients with T2DM. Even though the effects of e-health are not always significant, research shows improvement in various aspects. Especially the effect on HbA1c is often studied. These results are comparable with other aspects previously mentioned in this review. The results show improvement, but were not always significant. Since most research is mainly focused on short term effects, the long-term effects remain inconclusive. The additional focus of this review is to find out what needs to be improved to create a better efficacy. Overall, a better reliability and usability of apps as well as a better accessibility for patients with low digital literacy was stated by patients as well as healthcare professionals. Due to the lack of long-term effects the cost-effectiveness of e-health interventions remains unclear. The main findings of this study are summarized in Table 1 Additional limitations, which might have an effect on the gained insights of this review are stated below.

Heterogeneity

Due to the heterogeneity and variety in methods and types of research on e-health interventions it is difficult to compare results. Also, the standard care with which the new interventions are often compared, might have differences per country. Even though this was not stated in studies included in this review. It is possible that a significant difference between a new intervention and standard care in for example India, could be

not significant if compared to standard care in Canada. Additionally, it is possible that efficacy of e-health interventions differs between age groups. The biggest factor of influence will probably be lower digital literacy in older patients. Additional research with younger patients could be valuable to see if this improves the efficacy.

Long term effects

Long term effects of e-health interventions are severely under researched. Most of the studies are following patients for a matter of weeks including a lot of face-to-face consults, which is not feasible on the long term. It would be more interesting to see how patients are doing in the course of years with the normal amount of appointments compared to standard care. Due to the lack of evidence on the long term it is very hard to determine the cost-effectiveness of these treatments.

Personalized medicine

Every patient is different, interfering in their lifestyle will therefore have a different impact on every individual. e-health interventions based on lifestyle adaptations and self-management should therefore be personalized. Current studies are often based on one type of intervention and tested on a group of patients. It is possible that the efficacy of this method is low in a certain group and high in a different group, especially when the amount of patients included is low. If a patient does not like a specific app or lifestyle intervention, it does not mean that e-health interventions all together will never work for this patient, but it does require more customization to optimize the treatment for this individual. This concept makes large scale usage of e-health interventions even more complicated as the heterogeneity in methods will expand even more. On the other hand, it would be naive to think that there will ever be one method that would meet all the different wishes and demands of different patients. However, if you want patients to use apps or wearables structurally, the usability and accessibility must be suitable for every one of them. Even when e-health interventions are individualized, it is possible that some patients might still do better on the current regular treatment.

Time since diagnosis

Multiple articles included patients that have been coping with diabetes for years. It is possible that the educative tools in the interventions are not informative anymore because they have already learned this information in the previous years. It might not be worth the investments if patients already come to learn this information along the way in current treatment. However, it might be possible that by providing all the relevant information in an early stage this might prevent or delay the beginning of complication. Due to the fact that a lot of participating patients have had diabetes for years, it is possible that they are less motivated because they have managed their disease in a certain way for years. Or maybe the patients are not necessarily less motivated, but it is just harder to make adaptions in a routine that has existed for years. Patients that are at the beginning of their diabetes journey may be more flexible in adapting to the e-health and self-management lifestyle.

Bias

It is hard to prevent bias in these types of research. Motivated patients who are interested in e-health and lifestyle interventions are more likely to participate in a study investigating these subjects. Introducing selection bias, more specifically volunteering bias. Therefore, it is possible that the results are too optimistic. If apps and lifestyle interventions would be included in standard care, it could be possible that there are patients that would not use them at all, possibly due to low digital literacy or lack of motivation. For this group of patients, it might only result in a decline of their health but these results will not be represented in studies as most of them include patients on a voluntary basis. Since a part of the included articles used interviews with patients, it is import to keep the interviewer bias in mind. It is possibly that interviewers (unintentionally) influence patients into giving different answers and thereby influencing the results. The concept of e-health as treatment for chronic diseases seems very promising. Therefore, it is important to be mindful about confirmation bias. Researchers start a research with the expectation to find positive results, however, the concept of e-health might be too good to be true. It is important that researchers remain objective and do not neglect the possible negative results. In addition, negative results in studies are often linked to external factors. However, it should be kept in mind that there is also the possibility that e-health just does not work as well as was previously expected.

Sample size

Most of the studies included in this paper were done with a small sample size, which causes a smaller power and less reliable results. More large-scale studies are necessary.

Long- or short-term motivation

It is interesting to see if the improvements in HbA1c are due to the type of intervention (e-health) or due to the fact that patients know that for a specific amount of time, healthcare professionals are watching them more closely. As is stated in the results there are studies that state that HbA1c also improved significantly in the control group. This could be explained by the fact that patients are trying harder, not for themselves, but for healthcare professionals when they are watched more closely for a specific amount of time. They might think that they need to do better for the sake of the research. Additional research is necessary to check this hypothesis.

Cost-effectiveness

It is hard to determine the cost-effectiveness of e-health interventions, especially in the short term. In the beginning a lot of time and money needs to be invested to optimize apps and wearables, but also education programs and logistic matters. When looking at a short term it is possible that the cost outweighs the costs of the standard care. However, if e-health interventions are effective in improving lifestyle and improving the time blood sugar are in range, it is also possible that this greatly affects the amount of complications later on. If for example, less patients need an amputation or treatment for their eyes, it is quite possible that in the long run, these e-health intervention will cost less money. The problem is that large scale, long-term research needs the be performed in order to test this hypothesis. It is difficult to perform such a complicated long-term study, which will cost a lot of money, if the cost effectiveness cannot be predicted forehand. However, a proper cost-effectiveness study can only be performed with more long-term data, which is currently not available. Nevertheless, previous cost-effectiveness studies concerning e-health interventions, show promising results. Elbert et al. stated that e-health interventions for somatic diseases were cost-effective.[92] In addition, Gentili et al. performed a cost-effective analysis on e-health intervention in general, in which cost-effectiveness was stated.[93] Both studies did state that heterogeneity between studies remains problematic and further research based on a standardized approach is necessary.[92, 93]

Conclusion

Published research suffers from limitations such as small sample sizes, under powered pilot studies, heterogeneity in used apps and program of the intervention, duration and measured outcomes. Furthermore, there is a lack of well-designed and thoroughly conducted published interventions focusing on the use of e-health apps to meet the specific needs per patients. Therefore, the effect of e-health interventions as treatment for T2DM patients remains inconclusive.

3 EVALUATING THE EDUCATIONAL CARE PATHWAY SUPPORTED BY THE DIABETES BOX: PROTOCOL OF A PILOT STUDY

3.1 Concept

The concept of this intervention is an educational care pathway that combines education, self-monitoring and a smartphone application. The pathway has a duration of eight weeks and is designed for patients with T2DM. The educational part will be delivered through five consultations: three individual and two group consultations. Additionally, there will be educational videos to watch. These videos explain the pathogenesis of diabetes, as well as detailing the impact of nutrition, physical activity, sleep and stress on glucose regulation. To support this pathway, the DiaBox was developed. This box contains two self-monitoring devices, a smart watch and a blood pressure monitor, which can be synced to a smartphone application. In combination with the blood glucose sensor the patient already posses, patients are able to monitor their blood glucose levels combined with: physical activity, sleep, stress and their diet. The smartphone application provides a platform where the measurements of the smartwatch and blood pressure monitor as well as dietary information are combined. The pathway will be used as an addition to the regular care pathway used in the LUMC. The regular care pathway consists of an appointment with a doctor and specialized nurse every six months. Appointments with a dietitian or psychologist are not included in standard care, but can be scheduled when the patient and their healthcare professionals think it is necessary and useful. 'The Box' is already a familiar concept in the LUMC. Multiple departments are cooperating with the box office. The box office is responsible for the distribution of boxes and can be contacted when patients or staff have questions or need help. Due to the rapidly growing field of 'health boxes', the box office has reached maximum capacity and was not available to assist with the DiaBox. The tasks which are normally performed by the box office were taken on by the researchers. The primary endpoint for this study is feasibility. To determine the feasibility, usability and acceptability of the educational pathway will be studied using questionnaires and interviews at baseline (T0) and at the end of the eight-week educational care pathway (T1). Secondary endpoints include: patient activation, perceived learning and glucose regulation. This pilot study will be performed to determine if future large-scale research is realistic and feasible. Figure 4 shows an overview of the study design of the eight-week educational care pathway.





Figure adapted from the protocol: 'Evaluating an educational care pathway supported by smart technology and selfmonitoring for patients with type 2 diabetes in a tertiary endocrinology setting' Showing the overview of the study design of the eight-week educational care pathway.

3.2 Study Population

In this study, seven T2DM patients following the educational care pathway and five healthcare professionals were included. All healthcare professionals involved in the eight-week pathway are asked to join the study and will be interviewed at T1, there are no further in- or exclusion criteria for healthcare professionals. These healthcare professionals include two specialized nurses, a dietitian, a psychologist and an endocrinologist. The in- and exclusion criteria for patients are stated below.

1. Inclusion criteria for patients

- (a) Have T2DM or post-transplantation diabetes, as diagnosed by a medical specialist or general practitioner
- (b) Understand, read and speak the Dutch language (i.e., based on self-report)
- (c) Is in possession of a flash glucose monitoring sensor (e.g., FreeStyle Libre)
- (d) Aged 18 or older
- (e) Own a smartphone
- (f) Have wireless internet access at home
- 2. Exclusion criteria for patients
 - (a) Disabling (near) deafness and/or blindness without means to compensate
 - (b) When patients are deemed to be unfit to participate in group consultations (this decision is left to the discretion of the responsible healthcare professional)
 - (c) Total pancreatectomy in medical history or during the study
 - (d) Received solid organ transplant less than one year ago
 - (e) Pregnancy

3.2.1 Withdrawal

If a patient wants to leave the study, they can do so at any time for any reason, without any consequences. Study data collected until the moment of withdrawal will still be used for this research. Patients can communicate their withdrawal verbally or by email to any of the healthcare professionals involved in the study. The researchers can also withdraw a patient from the study for urgent medical reasons.

3.3 Intervention

The intervention is a new care pathway with the main focus on education. The educational care pathway is an addition to regular care. Currently, T2DM patients visit their healthcare professional every three to six months, alternating between a specialist and a specialized nurse. It is possible to plan additional consults with a dietitian or psychologist about, for example, diet and/or stress. However, this is not included in standard care. These additional consults are planned as a shared decision between physician and patient. The new educational pathway aims to enhance patients' comprehension of diabetes and its associated lifestyle factors, with the goal of encouraging patients to adopt beneficial lifestyle habits. In this pilot study, all patients receive information about diabetes, diet, exercise, sleep, stress, (personalized) goal setting and how to handle barriers in disease management. The goal is to empower patients to increase their physical activities and improve their overall lifestyle. The pathway consists of three main aspects, education, self-monitoring, and the LUMC care application (LUMC App). Table 2 summarizes the most important differences between regular care and the educational care pathway.

Table 2: Comparison between regular care and the educational care pathway

Regular Care	New educational care pathway
Individual consultation with healthcare professional every three months	Two group consultations and three individual consultations with healthcare professionals in two months
Lifestyle is given attention	Lifestyle is the cornerstone
Diet, exercise and stress consultations only when decided to by physician and patient	All participants receive education regarding diet, exercise, sleep, stress, self-management and goal setting.
Patients with 4/day insulin injections get flash glucose mon- itoring reimbursed	All participants get continuous glucose monitoring
	Continuous self-monitoring of steps, sleep, diet and stress and the relationship of these parameters and glucose regu- lation
	Smart-phone app to combine all results from self-monitoring devices

Table extracted from the protocol: 'Evaluating an educational care pathway supported by smart technology and selfmonitoring for patients with type 2 diabetes in a tertiary endocrinology setting' Showing the most important differences between regular care and the educational care pathway

3.3.1 Education

The educational part of the pathway consists of five consultations and eight video's. There are three individual consultations and two group consultations over the course of two months as can be seen in Figure 4. Attendance to the consultations is registered. The aim of the group consultations is to create a combination of 'patient teaches patient' and 'expert teaches patient'. The first consultation is individual and includes the DiaBox pick combined with explanation about the box and the further course of the pilot study. The second (individual) consultation is with the dietitian. Dietary habits are discussed and personalized advice can be given. Thereafter the group consultations follow with the subject of 'Diet and exercise' and 'Stress and sleep'. The final consultation, with the dietitian, is used to evaluate progress of personal goals. The consultations can be prepared or continued at home with eight educational videos. The subjects of these videos and QR'codes to the video's can be found in Appendix B.1

3.3.2 Self-monitoring

Patients receive a smart watch (Withings Move) and a blood pressure monitor (BPM connect) from the brand Withings to measure physical activity, sleep and blood pressure. In addition, patients will measure their blood glucose values with their flash glucose monitoring sensor. The data generated by these devices is mainly used to provide insight to the patient. In this pilot study the data will also be used to gain insights in usage of the devices. Therefore, for each device, the number of measurements is registered.

Blood glucose monitoring

The pilot study does not offer a glucose monitoring sensor, therefore only patients that already possess one are included. The data generated with this sensor will be used to determine if the pilot study has an impact on average blood glucose values and the time in range (TIR). The blood glucose values measured by the patients are not visible in the LUMC App. Patient need to use the LibreView app to view their values.

Blood pressure monitoring

The Withings Blood Pressure Monitor is a CE-marked, Bluetooth-enabled blood pressure cuff. It can be used to measure systolic blood pressure, diastolic blood pressure and heart rate at a specific point in time. The results are shown on the cuff itself, Withings app and in the LUMC app. Measurements need be taken two to three times a week. Participants will receive instructions on when and how to use the blood pressure monitor. Reminders will be sent in the app. A measurement takes approximately 20 seconds.

Step counting and sleep monitoring

The Withings Steel HR (heartrate) is a wristwatch and a CE-marked, Bluetooth-enabled continuous HR monitor. In this study, it is used to count steps, as a measure of physical activity, and to register sleep duration. Results of the measurements are displayed on the watch itself, in the Withings app and in the LUMC app.

Food monitoring

Since filling out a food diary is an intensive task, patient can track their food intake by using the food-photo diary. For a period of five days before the consultations with the dietitian, patients are asked to take a photo of every consumption with the LUMC App. Food photos are not sent to the data platform, but saved in the app. Patients are able to show an overview of photo's displayed in the app when they visit the dietitian. The concept is that patient will be able to see peaks or lows in their blood glucose and can relate this to their consumption. The data generated with this feature is for personal insights of the patient and will not be used during the data analysis of this research.

Stress monitoring

The LUMC app has a feature in which subjective stress scores can be given. Through a pop-up, patients will be asked: "How do you feel at this moment?". The answer is given on a 5-point Likert scale ranging from "Not stressed" to "Very stressed" accompanied by color coding ranging from green to red. Results will be displayed in an overview of stress measurements in the LUMC app. The frequency with which the stress question pops up can be set by the participant within predetermined limits. The pop-up is set to daily during the week before the stress and sleep consultation. During the rest of the study the limits are adjustable from "never" to "twice a day". The data generated with this feature is for personal insights of the patient and will not be used during the data analysis of this research.

3.3.3 App

LUMC App

During the study, participants will use the LUMC App. An overview of the app and different diaries is shown in Figure 5. This app will visualize the data from participants' self-monitoring devices (i.e. blood glucose, activity, sleep), allows patients to enter data on diet and stress (i.e. food-photo diary and subjective stress) and sends reminders for measurements. The different types of measurements are visible in Figure 6. Patients will receive oral and written instructions by healthcare professionals when receiving the DiaBox. These instructions are added in Appendix B.1 and B.2. When patients run into technical problems, support is available. Patients are explicitly instructed to contact the hospital directly or call the national emergency helpline in case of any medical emergencies. The LUMC app is used and certified as a Class I (Medical device directive (MDD)) medical device. It is an application that can be used for multiple health conditions. However, in this study it will be used solely for diabetes. The app is co-created with Pharos, the advocate group for people with low literacy, to ensure that the measurements are understandable for a large group of patients. Data from the activity tracker and sleep registration are automatically collected and presented in the LUMC App. Elements that can be recorded in the app are the food-photo diary and the subjective stress score. All self-monitoring functionalities have their own tile on the home screen of the LUMC App. To ensure engagement and adherence to the measurements, reminders are sent via the app. At the end of the study participants can choose to keep or delete the app. In both cases data will no longer be sent to the data platform. Data on the app will be deleted when the app is deleted. Data already sent to the data platform will be stored for 15 years before deletion.

Withings App

The devices used in this pilot are from the brand 'Withings'. To use these devices the Withings Health Mate app needs to be installed on the patients' smartphone. The Withings Health Mate app initial logon requires privacy sensitive patient data: full name and date of birth. This procedure complies with the LUMC requirements and has been approved by the LUMC security officer. Only the minimum amount of data from measurements is registered. The data is stored within the Withings Health Mate app in encrypted form. For collecting the measurement data from the Withings Health Mate app, the LUMC uses an application programming interface (API) connection, which unlocks the patient measurement data. Physicians and specialized nurses can thus evaluate the e-Health measurements of the patients in the electronic medical records of 'EPD-vision'.

3.4 Questionnaires & Interviews

To test the feasibility of the educational care pathway three questionnaires are used, the Client Satisfaction Questionnaire 8 (CSQ 8), a general evaluation questionnaire and the System Usability Scale (SUS). The questionnaires can respectively be found in Appendix C.1, C.2 and C.3. In addition, in-depth interviews will be performed with healthcare professionals. The basis for these in-depth interviews can be found in C.1

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	LUMC Academy	Inname registreren	Activiteit toevoegen	Nieuwe meting
(a) Ap	op homepage	(b) Food diary	(c) Step count	(d) Stress diary

Figure 5: Overview of the LUMC App



Figure 6: Overview of different types of measurements in the LUMC App

Furthermore, patients will be asked additional questions in the evaluation consultations based on the questions as stated in Appendix C.2 to gain more insights in patient opinions and experiences. A perceived learning questionnaire combined with the patient activation measurement (PAM) will be used to answer secondary objectives.

3.4.1 Questionnaires

CSQ-8

The CSQ 8 (Appendix C.1) is a brief global measure of patient satisfaction. It is a short 8-item standardized global satisfaction measure. In the CSQ-8 there are four response choices based on the Likert scale, where "1" indicates the lowest degree of satisfaction and "4" the highest degree.[94] The total score is calculated by adding up the respondents scores (item ratings) for each scale item. In the CSQ-8 version, the individual scores range from 8 to 32, with higher values corresponding to higher satisfaction.[95] The CSQ-8 is often used across healthcare studies, because of its great reliability and validity. [94, 96]

General Evaluation

The general evaluation questionnaire (Appendix 7 is a 5-item questionnaire to determine the overall satisfaction of four constituents and an overall grade for the pathway. The overall grade is an open question and can be rated from zero to ten. The four questions about the constituents (Videos, LUMC App, consultations and at home measurements) are rated from 1 to 5. The scores are added and divided by the amount of respondents. The score is multiplied by two to gain the same range in score as the overall grade.

SUS

The SUS (Appendix C.3) allows for a quick and easy, but reliable and valuable evaluation tool for measuring the usability of various different products and services. [97, 98] The SUS is a 10-item questionnaire which is scored on a 5-point Likert scale, ranging from 'strongly disagree' to 'strongly agree'. Final SUS scores can range from 0 to 100, where a higher score indicates a better usability. [99] To calculate the SUS score, the score contribution from each item is calculated. The score contribution from each item ranges from 0 to 4. Items 1,3,5,7 and 9 have a scale contribution of the scale position minus one. For items 2,4,6,8 and 10 the contribution is five minus the scale position. The sum of the scores will then be multiplied by 2.5 to obtain the overall score of the system usability.[100]

The SUS will be used to determine the usability of four components of the educational care pathway: the LUMC Care App, smartwatch, blood pressure monitor and the video's.

PAM-13

At T0 as well as T1 the patient activation measurement (PAM) questionnaire will be filled in by patients. The PAM-13 consists of thirteen elements designed to assess one's knowledge, abilities and confidence in health and disease management. The PAM-13 serves as a reliable tool to measure patient activation.[101] Moreover, the PAM-13 demonstrated its predictive value for clinical parameters, such as cholesterol levels, blood pressure, and triglyceride levels, among individuals with diabetes.[102] The items in the PAM questionnaire are scored on a 4-point Likert scale. The scores range from "totally disagree" to "totally agree". "not applicable" Is also an option. The total score ranges from 1-100. With this score, patients can be divided into four levels of activation. PAM 1 defines more passive patients who take almost no initiative, whereas PAM 4 are active patients who are able to manage their diabetes and the additional involved care. A higher PAM score correlates with a better capability of self-management. The complete PAM questionnaire is added in Appendix C.4

Perceived learning

In order to assess patients' knowledge about diabetes in combination with lifestyle, patients had to fill in a perceived learning questionnaire at T1. Previous studies have utilized a Likert scale, ranging from "1" (totally disagree) to "5" (totally agree), to evaluate perceived learning as an indirect way to assess or estimate patients knowledge.[103, 104] A five-item questionnaire was constructed based on these studies, to measure patients' perceived learning in five domains: pathogenesis of T2DM and diet, physical activity, stress and sleep in relation to their diabetes. The complete perceived learning questionnaire is visible in Appendix C.5

3.4.2 Interviews

After the pilot study has finished, the five healthcare professionals involved (two specialized nurses, one dietitian, one psychologist and one specialist) will be interviewed. The questions of this in-depth interview can be found in Appendix D.1. Healthcare professionals will be interviewed to assess barriers and facilitators and

potential improvements for the educational care pathway. The interviews will be recorded for subsequent qualitative analysis. The audio records will be transcribed verbatim. In addition, patients have a final evaluation consultation at T1 in which question about the educational care pathway and the DiaBox will be asked. The aim of this consult is to gain a deeper understanding about the usability and acceptability of the pathway. In addition, suggestions for improvements are discussed and the perceived effect of the educational care pathway on lifestyle habits and glucose regulation will be examined.[105] Thematic analysis will be used to process the data generated by the interviews and evaluation consultations. With thematic analysis pattern of themes are identified within qualitative data. The purpose is to identify patterns in the data that are important or interesting and to cluster them into themes. The themes can be used to make statements about the research topic (e.g., necessary improvements, strengths and weaknesses of the DiaBox). The 6-step framework of Braun and Clarke is used for thematic analysis. This framework consists of the following steps: Step 1: Become familiar with the data, Step 2: Generate initial coded, Step 3: Search for themes, Step 4: Review themes, Step 5: Define themes, Step 6: Write-up.[106] As structural coding takes an excessive amount of time whilst not generating more reliable results step 2 and 3 are combined in this research. [107] The most discussed themes will also be displayed in word clouds. The Barriers and facilitators for implementing the educational care pathway will be identified. Based on previous research concerning the barriers and facilitators of implementing new e-health services, the barriers and facilitators were divided into three categories: individual factors, environmental and organizational factors and technical factors.[108] Individual factors concern cognitive, motivational, accessibility and trust-related factor of patients or healthcare professionals. Environmental and organizational factors concern financial issues, political factors and organizational structures. Technical factors include everything concerning the functioning of the apps and wearables.

3.5 Attendance and Use

During the intervention period, attendance to the consultations is registered by the healthcare professionals. In addition, the amount of measurements with the blood pressure monitor and the amount of days the smart watch is used are recorded. The usage of the smart watch will only count if the amount of steps surpasses the 500 step mark for a day. In addition, the use of technical support is registered by the researchers. The total number of calls, the reason for contacting, and the number of unique participants that require assistance is recorded by the technical support.

3.6 Glucose Monitoring

Flash Glucose monitoring (FGM) data will be gathered using the FreeStyle Libre. Patients will be able to see a complete graph of their blood glucose levels over time if they scan their sensor at least one time every eight hours. The FGM data will be gathered during the intervention period. Using the FGM data, time in range (TIR), time above range (very high and high), time below range (low and very low), average glucose values and time sensor active are calculated at T0 and at T1. This data will be used to assess the glucose regulation of patients. Glucose regulation is measured as percentage of TIR, this means the amount of time the glucose values are between 3.9-10 mmol/L as defined in the international Consensus of Time in Range. Very high values are values above 13.9 mmol/L, high is between 10.1-13.9, low is defined as 3.0-3.8 and a glucose measurement is very low under 3.0 mmol/L.

3.7 Data analysis

Descriptive analyses (mean \pm SD, N, percentages) will be used to evaluate the data. The data will be analyzed using SPSS. Descriptive analysis will be used for perceived learning, activation and glucose regulation. To examine whether the educational pathway improves glucose regulation from baseline to post-intervention, average time in range will be calculated using the self-monitoring data of the FGM. Average time in range will be compared at baseline and at post-intervention using paired t-tests. To examine whether the educational pathway increases activation, results from baseline and post-intervention will be compared using paired t-tests. Since activation and TIR could also decline, two-tailed significance will be used.

4 EVALUATING THE EDUCATIONAL CARE PATHWAY SUPPORTED BY THE DIABETES BOX: QUALITATIVE AND QUANTITA-TIVE RESULTS

4.1 Research Population

A total of seven patients was included in this pilot study, including five males and two females with an average time since diagnosis of $15.6(\pm 8.0)$ years and an average age of $55.4(\pm 10.5)$ years. The patient characteristics are displayed in Table 3

Table 3:	Patient	Characteristics
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		Total
Number of patients	Ν	7
Sex	male, N(%)	5 (71,4%)
	female, N(%)	2 (28,6%)
Age (years)	mean $(\pm SD)$	55.4 (±10.5)
Years since diagnosis	mean $(\pm SD)$	$15.6(\pm 8.0)$

Patient characteristics of the patients included in the pilot study

4.2 Use & Adherence

4.2.1 Average attendance

The attendance in the individual consultations was 100%. The group consultations scored a bit lower as is shown in Figure 7. In the first group consultation two patients were absent. One patient had canceled due to personal circumstances. The second patient canceled this group consultation because he did not like the concept of a group consultation and stated that he was already up to date on the topic of the first group consultation (Nutrition & Movement). In the second group consultation one patient was absent without notifying the healthcare professionals.



Figure 7: Attendance *The attendance per consultation*

4.2.2 Use of different aspects

In general, all aspects of the pathway are used. However, especially the nutritional photos and the videos were barely used. Whereas the smartwatch and blood pressure monitor were used by every patient. There were some patients who did not watch the videos or did not watch them at the right moments. In addition, there were also patients who did not make any photos of the nutrition. It did not seem useful to patients to make pictures of their food, or they found it too burdensome to make pictures of everything they consumed for a few days. Patients stated that the importance of watching certain videos on a certain moment was unclear until the end of the pilot.

4.2.3 Adherence to measurement schedule

Patients were asked to try to measure their blood pressure three times a week and to wear the smartwatch as much as possible. The stress- and sleep scores patients were able to track in the LUMC app was for individual use and will therefore not be discussed in the results. More than half of the patients did not comply with the request of three measurements per week, as is visible in Figure 8. Interestingly, not a single patient stated that they found this amount of measurements too much during this pilot. One patient did state the following:

"At a certain point, when you are further along in the process of the pathway, I would lower the amount of measurements. You should never let patients make too many actions concerning their disease, it will most certainly go wrong" - Patient 6

Only one patient performed the recommended three blood pressure measurements per week. Out of all patients, two patients used the blood pressure monitor more often, but four patients did not perform enough measurements. Most of the patients wore the smartwatch the majority of the time. Based on all the patients, the smartwatch was worn on 64% of the days of the pilot. One patient did not wear the smartwatch at all. In addition, some patients complained that wearing the watch every day resulted in irritation on the skin, which made them leave the watch off for a couple of days before they could wear it again. The results are also displayed in Figure 8.



Figure 8: Measurements

The amount of measurements performed per week with the blood pressure monitor and the percentage of days the patients wore the smartwatch

4.3 Acceptability

4.3.1 Satisfaction of different constituents

LUMC App

Overall, patients are not satisfied with the LUMC App. Figure 9 shows the opinions and findings about the LUMC App as found in thematic analysis. All the statements from patients and healthcare professionals are clustered per theme and used to create the word clouds. All the statements are visible (in Dutch) in Appendix H. Since one patient did not show up at the evaluation consultation, the total amount of patients who filled in the questionnaires was six. Based on the SUS and general evaluation, the lowest scoring constituent is the LUMC App, with a score of respectively 55.83/100 and 6.0/10 as can be seen in Table 4. The complete results per patient of these questionnaires is visible in Appendix E.1, E.2 and E.3. The biggest problem with the app can be found in data transmission between the Withings app and the LUMC app. Successful measurements were displayed in the Withings App but seemed to be missing in the LUMC App. The error cannot be found in the transmission from the Withings App as all the measurements are visible in EPD-vision and thus showing a successful transmission between these two platforms. Patients did express that they liked the concept of the app.



Figure 9: LUMC App

Opinions and findings about the LUMC App in which the size of the fond represents how many times that opinion has been shared

"If the LUMC App would work properly, it would make the whole care pathway so much better" - Patient 3

Apart from some technical difficulties at the beginning of the pilot study with the usage of the app, there were also patients who were predominantly positive about the app.

"The login is easy, and if you read everything well it works just fine" - Patient 2

Due to the technical difficulties in the beginning of the pilot study, it was not possible to use the LUMC App. Patients were advised to continue their measurements, if they wanted, they could check their data of the first few days in the Withings app. After a few days patients had the possibility to start using the LUMC App again as was advised. However, due to the fact that measurements continued to be absent in the LUMC App for some patients, they started neglecting the LUMC App for the remainder of the pilot and started focusing more on the Withings App. Patients also had some recommendations for the LUMC App.

"It would be nice if everything was combined in one app, in that way I would have been able to see what the effects of my sleep and movement habits are on my blood sugars. In addition, I would have liked the possibility to link my nutritional pictures to my blood sugar curves" - Patient 3

Even though patients are fond of the idea of the LUMC App they are not satisfied yet. The app shows room for improvement especially in data transmission and the absence of a blood sugar curve.

Table 4: Questionnaires

Constituent	SUS (N=6)	General Evaluation (N=6)
Blood pressure monitor	82.50/100	-
Smartwatch	76.67/100	-
LUMC Care App	55.83/100	6.0/10
Videos	72.92/100	6.6/10
At home monitoring	-	7.6/10
Consultations	-	8.0 /10
Grade	-	7.5/10

Results from the SUS and general evaluation questionnaire

Wearables

Patients were very satisfied with the wearables. The experience with the measurements were that it was quick and easy to do. Especially the ability to measure your blood pressure at home was highlighted. Patients stated that having the option to measure your blood pressure at home gave them a feeling of independence, due to the fact they did not have to depend on the hospital or health care professional to gain insights in their health.

"It is especially nice to be able to measure your blood pressure at home" - Patient 1

All patients were familiar with the concept of a smartwatch to count steps. However, the ability to track sleep was new for most patients. The only disadvantage of the watch was that it caused some irritation to the skin for two patients, resulting in not being able to wear the watch for a few days.

"The interesting part of the sleep tracker, is that I am able to see how many times I woke up during the night, without actually realizing this, this has helped me to understand why I am so tired all the time" - Patient 3

Videos

The amount of satisfaction patient gained from the videos differed between them. Some patients took no effort to watch the videos, others were not able to find them. The patients who did watch the videos were optimistic about the content of the videos but did also point out that it might have had more value for patients who had just gotten the diagnosis of T2DM. The content of the videos was found to be understandable for everyone and easy to follow. Even though some patients said that they were already familiar with the information shared in the videos there were also patients who found them very useful and learned from them. Since the majority of the patients included has had T2DM for years, some information has gotten lost along the way, the videos were stated as form of refresher course.

"I already know the information displayed in the videos, therefore it was not that interesting for me, however, for the 'starting' T2DM patient it is valuable. They get introduced to different topics you can take into account." - Patient 2

Patients did point out that it would have been nice if the app would have given notifications to watch the videos at the right moment, as the videos were meant as preparation and additional education to the consultations. Due to the lack of reminders, some patients watch all the videos at the start of the pilot and forgot about them.

"I did not watch every video before the accessory consultations, I noticed that I missed things because of that. If I had watched the right video before the right consultation, it would have been more clarifying" - Patient 4

Consultations

As the individual consultations with the dietitian did not differ much from individual consultations in regular care, patients did not have a lot of comments about them. The group consultations were new for most patients. At the start some patients had doubts about the group consultations as they did not feel the need to share their troubles with others. Figure 10 shows a collection of statements about the group consultations in which the size of the fond shows how many times this statement has been made by different patients. One patient had already experienced group consultations elsewhere and was hesitant at first, however, in the evaluation consultation they admitted that the consultations, as it helped them to put their problems in perspective, it gave them new insights and they learned new things. The (group)consultations scored high in the general evaluation questionnaire as is visible in Table 4.

"The biggest plus was being in contact with other people, learning how they handle the problems that come with T2DM, exchanging experiences, just the fact that you're not alone and you are in this together" - Patient 4

4.3.2 Experiences of healthcare professionals

Multiple health care professionals state that the pathway is not reaching its full potential yet. The most common remark is the mismatch between the content of this pathway with the average population found in the LUMC. A collection of the most commented topics is displayed in Figure 11. The statement 'it's not paying off' is mostly related to the fact that the health care professionals involved, are feeling like this concept would work much better in a primary health care setting, which would make it less feasible in an academic hospital. The healthcare professionals are worried that they will not be able to use this concept while they have put a lot of time and effort into it. All respondents graded the pathway, this resulted in an average grade of 5.5/10.

> "It's too bad that we have put so much time and energy into this, but that it will not work here" - Respondent 2

Not all respondents are equally pessimistic about the possibility to implement the pathway in the LUMC, although even the most optimistic ones address the need for improvements.

4.3.3 Barriers and Facilitators

In total, 20 barriers and 14 facilitators for the implementation of the new educational care pathway were described. A complete list of all barriers and facilitators can be found in Appendix F. The barriers and facilitators are summarized below.

Individual barriers and facilitators

When asked about the individual factors, the healthcare professionals answered about themselves but also individual factors for patients were discussed. All respondents agreed that the current pathway and especially the usage of apps and wearables is too complicated for patients.

"There are too many intermediate steps for patients, making it way too complex, the result is that the goals of the box are not achievable" - Respondent 3

Reducing the complexity is not necessarily the solution, since respondents stated that the problem might also be caused by the low digital literacy in this patient group. An additional remark is that with the current pathway it is not possible to make adaptations to fit the individual wishes and demands of patients. An example is that the content from the videos and consultations was too low leveled for some patients because they already have so much experience with diabetes since they have had the diagnosis for years. Respondents vouched for a more personalized approach in which the level of education can be adapted to the level of the individual patients.

"Maybe we should start looking at whether we can better tailor the content to an individual's needs" - Respondent 2

As facilitators, respondents described the effect the pathway had on patients as positive. It seemed like patients gained insights and knowledge. In addition, respondents pointed out that being occupied with improving healthcare and guiding patients into a healthier lifestyle brought them joy and increased their job satisfaction.

"It is nice to be engaged in the transformation of care like this, what can we do differently, how can we improve our traditional way of providing care" - Respondent 4

Environmental & organizational barriers and facilitators

Respondents agreed that the absence of a blood glucose sensor in the DiaBox influences the pathway negatively. Only patients who are already in possession of a sensor could be included in this pilot. As a result, the patients

Figure 10: Impression of the group consultations *Opinions and findings about the group consultations in which the size of the fond represents how many times that opinion has been shared*



who were suitable for this research could not be included. Instead, less suitable patients were included. The absence of the right target audience in the LUMC was also stated as a barrier. It takes a toll on the motivation of the staff involved in this study. They state that it was frustrating to have put much time and work into the development of this pathway only to discover that in their opinion, it is not suitable for their department.

"The box will only be sufficient if everything is included and with everything, I mean the blood glucose sensor" - Respondent 1

"I think the box is perfect for patients who have just gotten the diagnosis. It should be the base for every 'new' patient, I am convinced!" - respondent 5

In addition, the technical difficulties, and especially the time it takes to solve these technical issues for patients was mentioned as a barrier at this point. Due to technical difficulties with the LUMC App at the beginning of the pilot we were off to a false start, but this also resulted in additional problems later on, as patients were already frustrated with the app and lost confidence in the app. Respondents stated that these difficulties will have to be solved quicker for the pathway to have a chance of succeeding.

"These kind of problems take too much time and are frustrating, the technique needs to be improved to be able to deploy this concept any further" - respondent 4

One of the facilitators all respondents agreed on is the concept and content of the pathway and box. The content is complete and covers all the important topics for the average diabetic. In addition, respondents stated that the presence of an extra (non-medical) staff member who organizes the study but is also present for practicalities, is necessary to make the pathway a success. This needs to be someone who has the time to assists patients as well as the medical staff and makes sure everything is going well and everybody is up to date on their tasks and obligations. Group consultations, successful teamwork and guidance of the dietitian towards patients were also discussed as facilitators for the pathway.

"An advantage of this pathway is the diversity in subjects which are covered, since some of these subjects are often forgotten in the regular consultations" - respondent 3

"Support for patients is very important, the possibility to reach someone when they have questions is required. It's a prerequisite for being able to continue with this concept" - respondent 4

Technical barriers and facilitators

There was one barrier all respondents agreed on, the absence of a blood glucose curve in the app undermines the whole concept of this pathway. It was stated that the whole concept is that patients are able to see what the effects of their behavior is in relation to their blood sugar levels. Since the behavioral actions (e.g., food intake, stress, sleep, amount of exercise) are not displayed in the same app as the blood sugar curve, it is hard for patients to make connections. In addition, the lack of data transmission between the withings app and the LUMC App was stated as a barrier. Patients are getting demotivated and frustrated due to the lack of data transmission. However, the simplicity of the apps, when they were working, was stated as a facilitator. The apps are user friendly and easy to use after successful installation and access.

"The chance of success of this pathway depends on the ability to visualize the blood sugar curve in combination with the effects of all the lifestyle factors" - respondent 5

"Because of the difficulties in linking the apps and in data transmission, patients get demotivated" - respondent 4
4.4 Usability & User friendliness

4.4.1 Patient perception

Overall, the patients experience the pathway as something they do for healthcare professionals, not to gain insights for themselves. In addition, they experience frustration when wearables or apps are not working the way they are supposed to work. Furthermore, they stated that experiencing the technical errors is very demotivating. Table 4 shows the result from the SUS concerning the blood pressure monitor, smartwatch, LUMC App and the videos. A summary of patients findings based on the evaluation consultations is stated below.

Different constituents

Patients agreed that the smartwatch is a fun tool to use. The possibility to see how many steps you have walked on a day motivates to try and increase the amount the next day. As most patients were not familiar with the sleep tracking tool, they stated that it was nice to be able to visualize their sleep and gain insights. Patients experienced the possibility to monitor their blood pressure at home as the biggest win as they previously had to go see a healthcare professional. In addition, the blood pressure monitor was found easy to use, had a nice design and was lightweight and therefore easy to bring along when necessary. Table 4 shows that the blood pressure monitor also scored highest in terms of usability.



Figure 11: Impression of the job satisfaction while working with the pathway *Opinions and findings about the job satisfaction in*

which the size of the fond represents how many times that opinion has been shared

"The devices are very easy to use, no fuss, just simplicity" - Patient 3

The way patients perceived the videos differed between them. Not all patients have watched the videos. The patients who did, stated that the content of the videos was complete and informative, but might be more useful for patients who are just diagnosed with diabetes. Some patient stated that they learned nothing from the videos since they had gotten this information in an earlier stage of their disease during consults. However, other patients claimed that the videos were great as a refresher because after several years of having diabetes some information had slipped away.

"I could not find the videos at all, the idea of educative videos is very convenient, especially if you just found out you have diabetes though" - Patient 3

Patients were not very opinionated about the individual consultations as they have a lot of resemblances with regular care consultations. The group consultations were new for most patients and well received. The consultations were informative and at the right level, however, some patients mentioned that they did not learn new things and suggested that these consultations would have fit better with patients who had just gotten the diagnosis. The LUMC App caused a lot of frustration with patients. Patients did state that the app has potential and that it is easy to use when it is working. However, in the current state it contributed nothing to the pathway but frustration and demotivation. Table 4 shows that the LUMC app scored way below the other constituents questioned in this questionnaire.

"For every 10 times a measurement appears in the Withings app, only 2 measurements appear in the LUMC app, I am missing so much data and it is completely unclear why some measurements are transmitted successfully and some are not" - Patient 2

"I could describe the LUMC App is one word: worthless. Occasionally it worked, but most of the time it was very frustrating" - Patient 6

4.4.2 Added value for patients

Patients stated that even though they learned something from this pilot and gained some insight, there is a lot more to get out of this pathway. In addition, they had the impression that the pathway with its content is

more valuable for patients who are just diagnosed with diabetes. This is also visible in Table 5, where 'fulfilled my wishes' was the lowest scoring question. However, when patients were asked if they would recommend the pathway to other patients, potentially patients who are just diagnosed with diabetes, the score went up, as is also visible in Table 5. The complete results of the CSQ are visible in Appendix G.1. It is not said that this pathway was not suitable at all for these patients, but some adjustments to the content should be made to tailor it better to the more advanced patients. Patients were very enthusiastic about the concept of the pathway, one patient stated that when the pathway has improved he would like to participate again.

Table 5: CSQ-8

Components of the pathway	Score (N=6)	Grade
Concept	19/24	7.9
Received the help I hoped for	18/24	7.5
Fulfilled my wishes	17/24	7.1
Would recommend	22/24	9.2
Satisfied with the amount of help	21/24	8.8
Can handle my complications better	19/24	7.9
Satisfied overall	18/24	7.5
Would use again	18/24	7.5
Average total score	25.5/32	8.0

Results from the CSQ-8, with converted corresponding grades

4.4.3 Help desk usage

During this pilot study the box support office could not be used. Therefore, the patients had to seek help via e-mail with the researchers. The CSQ-8 covered the topic of satisfaction with the amount of help patients received during the pilot study. The patients scored this topic with a 7.5/10, as can be seen in Table 5.

"It was really nice that there was a possibility to ask questions" - Patient 1

If patients ran into problems, they had to send an e-mail which was answered as quick as possible. If a problem could not be solved via e-mail or a phone call the patient was invited to the hospital. If this was not possible, the solution was postponed until the first follow-up consultation. During the pilot 13 questions were asked via e-mail. Only one patient had to come to the hospital in order to get the problem solved since their smartwatch had to be swapped as it would not connect anymore. Figure 12 shows the ratio between patients who contacted the help desk and the patients who did not. In addition, the figure shows the amount of questions asked per week of the pathway. The most frequent reason for contacting were problems with the LUMC Care App as is also displayed in Figure 12.





4.4.4 Improvements

All patients and healthcare professionals agreed that the concept and corresponding content of this pathway, would match better with patients who have just gotten the diagnosis of diabetes.

"I think that it is an excellent invention for people with diabetes, it will work for patients who have had diabetes for years, but mainly for patients who have just gotten the diagnosis" - Patient 5

To improve the pathway, it should be transferred to a primary care setting, or the content should be adapted to the level of patients. A point of improvement that was often mentioned is the data transmission between the Withings app and the LUMC app as well as the presence of a blood glucose curve in the LUMC app.

4.4.5 Usability in daily practice

Since the collective of healthcare professionals is not convinced that the current pathway is valuable in their own setting, it is not ought to be usable in daily practice right now. Some healthcare professionals address that after changing some content and improve the individual tailoring of the pathway it would be suitable in the LUMC. The respondents differ about their opinions whether it is feasible in terms of time spent on this pathway. At this point, the new pathway is an addition to the standard care and not all healthcare professionals think they will be able to combine this workload with their already existing amount of work. Some respondents state that their motivation is decreasing because of more political oriented problems, such as the absence of the blood glucose sensor, and the mismatch in content and target audience. This makes it harder to give an objective opinion about the usability in daily practice.

I am a bit pessimistic about the future because it will be very hard to add a sensor to the box since we have to work with external parties on which we do not have any influence - Patient 4

4.5 Perceived learning

Table 6 shows that at T0 patients already scored very high on the PAM questionnaires. At T1 there is a slight improvement from a grade score of 8.2 to 8.4, which is not significant (p=0.137). With a grade score of 8.3 patients learned the most about nutrition and exercise during the pilot study. With a grade score of 7.1 the least about diabetes in general as is also visible in Table 7.

Table 6: PAM

PAM (N=6)	Score T0	Grade	Score T1	Grade	Significance (p)
Overall score	3.28(±0.55)	8.2	3.35(±0.52)	8.4	0.137

Results from the PAM, with converted corresponding grades at T0 and T1

Table 7: Perceived learning

Perceived learning (N=6)	Average score	Grade
Learned about diabetes	2.83(±0.75)	7.1
Learned about nutrition	3.33(±0.52)	8.3
Learned about exercise	3.33(±0.52)	8.3
Learned about sleep	$3.17(\pm 0.75)$	7.9
Learned about stress	$3.17(\pm 0.75)$	7.9

Results from the perceived learning questionnaire, with converted corresponding grades

Due to the lack of measurements the activity and health measurements displayed in Table 8 are not complete. The smartwatch has been used enough and shows that the average amount of steps per day has increased from an average step count of 3777 at T0 to 4053 at T1. The difference, however, is not significant. The results of patient activity and health measurements of all individual patients is visible in Appendix H

Table 8: Activity and	Health	measurements
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Measurement (N=6)	Average	то	T1	Significance
Step count	4017	3777 (±1936)	4053 (±2205)	0.65
Blood pressure	72/123	-	-	-
Heart Rate	76	-	-	-

Activity measurements at T1 and T0 in which the blood pressure and heart rate data are missing because four patients did not perform enough measurements per week

4.6 Glucose regulation

Even though there is no significant difference between the results at T0 and T1, there have been some improvements. The time the sensor was active increased from 84.5% to 92.0%. In addition, the time patients have spent in 'very high' glucose levels decreased from 15.14% to 9.71%. The average blood glucose levels have also improved from 9.71 mmol/L to 9.36 mmol/L. The TIR has remained the same during this pilot. More details about the TIR and average blood glucose levels are depicted in Tables 9 and 10.

Table 9: Time in Range

Glucose measurements (N=7)	Average Values T0 (%)	Average T1 (%)	Significance
Time sensor active (\pm SD)	84.50 (±9.65)	92.00 (±6.00)	0.07
Very high 13.9 $(\pm SD)$	15.14 (±17.41)	9.71 (±12.04)	0.06
High 10.1-13.9 (±SD)	24.00 (±15.20)	29.29 (±19.52)	0.24
Target 3.9-10 $(\pm SD)$	60.14 (±30.61)	60.14 (±20.28)	-
Low 3.0-3.8 (±SD)	0.14(±0.38)	0.43 (±0.79)	0.17
Very low 3.0 (\pm SD)	0 (0)	0.14 (±0.38)	0.36

Overview of the average percentages of time patients remain in a certain range of blood sugar levels at T0 and T1

Table 10: Blood Glucose levels

Glucose measurement (N=7)	Average values T0 (mmol/L)	Average Values T1 (mmol/L)	Significance
Blood glucose level (\pm SD)	9.71 (±2.80)	9.36 (±2.32)	0.48

The average values of blood sugar values from all included patients at T0 and T1

4.7 Important findings

Use & Adherence

Adherence to group consultations was a bit lower than for individual consultations. Some patients were skeptical about the group consultations but were positively surprised afterwards. The food diary of the app as well as the videos were not used properly due to lack of information and/or technical difficulties. The adherence to the measurement schedule differed greatly among patients. Even though not a single patients admitted that they found the amount of measurements too much, more than half of the patients did not perform enough blood pressure measurements and on one third of the days of the pilot study the smartwatch was not worn.

Acceptability

Patients were not satisfied with the LUMC App, but were satisfied with the wearables and consultations. The videos need more attention during the pilot as they were not watched by every patient. Healthcare professionals are fond of the concept of the pathway, but express their concerns about complexity of the pathway for patients and the mismatch between the content and the average population. In addition, a blood glucose sensor needs to be included in the DiaBox as well as the integration of a blood glucose curve in the LUMC App to reach the full potential of the pathway.

Usability & User friendliness

Patients experience the pathway as something they do for their healthcare professionals and not for themselves. In addition, technical difficulties with apps cause a lot of frustration. The wearables were described as fun an easy to use. Even though patients indicate that they have learned from the pathway, they did state that it might be more valuable for patients who have just gotten the diagnosis. Patients said that they would recommend the pathway to other patients. To improve the pathway, patients and healthcare professionals opted for better data transmission between the different apps and more options to adapt the pathway to individual needs. Healthcare professionals also stated that the pathway suitable for use in daily practice. They do address that after changing some content and improving the individual tailoring of the pathway it would be suitable in the LUMC.

Secondary outcomes

The educational care pathway caused a non-significant increase in the PAM-score. Patients learned the most about nutrition and exercise and the least about diabetes in general. The average amount of steps per day increased, but not significantly. The effects on blood pressure and heart rate could not be determined since not enough measurements were performed. The changes in glucose values and TIR were also not significant, but overall they did improve.

5 EVALUATING THE EDUCATIONAL CARE PATHWAY SUPPORTED BY THE DIABETES BOX: DISCUSSION AND CONCLUSION

5.1 Interpretation of results

The purpose of this research was to determine the feasibility of the educational care pathway and DiaBox based on acceptability, usability & user friendliness and use & adherence for both patients and healthcare professionals. Secondary outcomes were to determine if the pathway has contributed to perceived learning of diabetes and its related lifestyle factors as well as to check the improvement in patient activation from T0 to T1. The quantitative results show improvements, but were not significant. Overall, patients learned the most about nutrition and exercise and the least about diabetes in general. Blood glucose values have improved (not significant) and step count improved between T1 and T0 (not significant). These findings are visible in Tables 6, 7, 10 and 8.

5.1.1 Use & Adherence

Overall adherence to the consultation was good, with a lower adherence for group consultations as some patients were skeptical about these consultations at first. Patients were asked to measure their blood pressure three times a week, and wear the smartwatch every day. Even though patients claimed that they did not feel burdened by these tasks, more than half of the patients failed to perform enough blood pressure measurements and 36% of the total amount of days in this pilot the smartwatch was not worn. It is possible that patients did not dare to say they felt to burdened during the interviews, but it is also possible they forgot about the measurements from time to time due to the fact they were not making the measurements for themselves, but for the healthcare professionals. Patients did state that they did not think the pictures of their food were useful or they found it too burdensome. As a results, this feature was barely used as is in line with current literature. [54] If a function for food tracking is included in the app it should be easy to use. When the food tracking function is not user friendly patients are more often prone to stop with this part of the intervention compared to the tracking of medication use. [54] It does not help that the dietitian is not able to see the pictures in the electronic patients files before the consultations. During the consultation it is not possible for a dietitian to check all the pictures a patient has made over the course of multiple days, which strengthens the patients feeling that they have tracked their food and made the pictures for nothing.

Step count

In order to determine the amount of days patients had worn the smartwatch, the non-worn days had to be excluded. Usually, a minimum amount of hours the watch has been worn per day is used to determine if a day is counted as worn or not worn. The amount of time patients had worn the smartwatch was not available for researchers in this study. Therefore, a minimum amount of steps was used as cut-off. If a patient had walked 500 steps or less per day, that day was counted as 'not worn'. This amount of steps is an arbitrary cut-off point. We tried to find a cut-off value in literature, however, the studies that did provide information about a cut-off value were always based on the amount of time the patients had worn the watch. Since this data is lacking, it is impossible to guarantee that some excluded days were in fact days on which the watch was not worn long enough. On the other hand, it is also possible that some days have not been excluded due to a step count higher than 500, even though the watch had only been worn a small part of the day. This may result in a distorted image of smartwatch use and step count patterns. In future research the amount of time a patient is wearing the watch should be included in order to gain more reliable results.

5.1.2 Acceptability

Overall, patients were satisfied with the pathway, especially the (group)consultations, the wearables and athome monitoring. Patients were not satisfied with the LUMC App. Healthcare professionals are fond of the concept of the pathway, but express their concerns about complexity of the pathway for patients and the mismatch between the content and the average population. In addition, a blood glucose sensor needs to be included in the DiaBox as well as the integration of a blood glucose curve in the LUMC App to reach the full potential of the pathway.

LUMC App

At the start of the pilot, a malfunctioning of the LUMC App occurred. This resulted in a lot of frustration for patients as well as healthcare professionals. This resulted in the LUMC App being used less. This was expected as technical difficulties are one of the main reasons for a decline in usage of e-health.[59] In order to

create a high adherence of e-health applications, the usability and reliability of an app should be excellent.[56] Which was most definitely not the case during this pilot. However, this kind of malfunctioning can happen at any moment, but does not happen regularly. It probably has affected the results of this research since patients gave up the app before they were able to use it. In addition, it is not known if the malfunctioning of the app in week one affected the data transmission later on in the pilot study. Possibly it was bad luck to have planned the pilot study in the same period as a technical malfunctioning of the app, even though the app normally works faultlessly. Furthermore, not every constituent of the app has been used properly during this pilot study. The ability to make pictures of your nutrition was barely used, because the malfunctioning of the app was not fixed before the first consultation with the dietitian took place. Therefore, the statements made about the app in this research might not be reliable since the functioning of the app during the pilot might not have been representative of its usual functioning. In addition, it is hard to determine how simple constituents have to be to fit every patient's digital literacy. This does not mean that the patients with the lowest digital literacy should not be included in similar studies, but this means that some patient will always remain negative about the user friendliness or that some patients will not be able to use all the constituents of the pathway. However, they also deserve the chance to try out the pathway and use the constituents which do fit their abilities.

Critical healthcare professionals

When comparing the averages grades between patients and healthcare professionals, it is interesting to see that patients grade the pathway with a 7.5/10 whereas healthcare professionals gave an average grade of 5.5/10. In addition, there are healthcare professionals who think that the pathway needs major adjustments before it will have any added value for patients. Meanwhile patients are more positive and even though they also describe the need for adjustments they stated that they have learned from this pathway and would recommend it to others. It is possible that healthcare professionals are too negative or perfectionists, because even though the pathway is far from perfect the concept, content and some constituents were received with open arms by patients. It is true that the overall tendency about the pathway is that it would work better for patients who have just gotten the diagnosis, but this does not mean that it will do nothing for the more experienced patients. In addition, it seems like healthcare professionals are zoomed in too much into the absence of the blood glucose sensor and the 'problem' of the target audience. It is almost like they do not experience the part of the pathway which is going well. This might have had an influence on the results as they might have underestimated the feasibility of the pathway. Though it remains important that the involved healthcare professionals remain motivated and enthusiastic about this project. When they are not convinced of the feasibility of this pathway in the LUMC, it will most likely have no chance of succession.

5.1.3 Usability & User friendliness

Patients experience the pathway as something they do for their healthcare professionals and not for themselves. This is exactly the opposite of what the purpose of the pathway is. The goals is to improve the self-management of T2DM patients by educating them and improving their lifestyle. This might have affected the results, as patients might have been more critical if they had needed the apps and wearables to work properly for themselves instead of 'checking them for healthcare professionals'. Still, the technical difficulties caused a lot of frustration and demotivation in patients. Patients described the wearables as fun and easy to use, patients were familiar with the step count but gained insights from the sleep tracker. Even though patients indicate that they have learned and gained insights from the pathway, they did state that it might be more valuable for patients who have just gotten the diagnosis. This might be due to the content of the videos and (group)consultations which are more or less focused on the basics of T2DM. Because the patients did like the content as a refresher (after all these years with diabetes), patients did state that they would recommend the pathway to other patients, new to diabetes or not. Healthcare professionals also stated that the pathway would be better suitable for a primary care setting. Healthcare professionals do not deem the current pathway suitable for use in daily practice. They do address that after changing some content and improving the individual tailoring of the pathway it would be suitable in the LUMC. To improve the pathway, patients and healthcare professionals opted for better data transmission between the different apps and more options to adapt the pathway to individual needs. This would make a big difference in the amount of frustration patients encounter during the pilot.

5.1.4 Secondary outcomes

The educational care pathway caused a non-significant increase in the PAM-score, from 8.2 to 8.4 on a scale of 10. Based on the perceived learning questionnaire, patients learned the most about nutrition and exercise

(8.3/10) and the least about diabetes in general (7.1/10). The changes in glucose values and TIR were also not significant, but overall they did improve. The results indicate that patients were more actively busy with their blood sugar levels. In addition, the blood sugar values have also improved. Furthermore, there were multiple factors which might have influenced the results negatively. One included patient had a time in range of 100% at T0 which made it impossible for them to improve. Secondly, there was a patient who had to make adaptions in their medication during the pilot study, this resulted in a temporary disruption of their blood sugar values and TIR enormously. The fact that only seven patients were included, results in a bigger impact per individual patient. The adaptations in medication of one patient have therefore had a major impact on the overall results. Thirdly, one patient missed two of the five consultations and did not show at the evaluation consultation. Their results have been included in the research, but they have not followed the pathway as intended. It is possible that their absence in a substantial part of the pathway have influenced their results, the average blood sugar values have improved. The results were not significant, but concerning the factors stated above, these results seem very promising.

5.2 Limitations

5.2.1 Sample Size

Due to the absence of a blood glucose sensor in the DiaBox, only a small group of patients was suitable for this study. In addition, since this was a pilot study a smaller sample size was also preferred as multiple hiccups were expected to happen during the pilot. Due to the small sample size the effect of one patient is a lot bigger than with a larger sample size. A change in a singular highly motivated or demotivated patient can have an enormous effect on the results. Therefore, the results of this study should be interpreted carefully.

5.2.2 Bias

Participant bias

Since qualitative analysis is used in this study, there is always an increased risk of bias. which can be divided between participant and researcher bias. Participant bias is based on social desirability in which participants respond with the answer they think their interviewer would like to hear even though this answer is inaccurate. A possible example is that every patient stated that the amount of measurements they had to perform was 'just about right' or 'not too much at all' but more than half of the patients did not perform enough blood pressure measurements. This could have been caused by numerous things, but it is likely that they did not have the time for the measurements or they thought they had to do too much of them, which is contradictory to their response in the evaluation consultations.

Researcher bias

Researcher bias can be divided in three factors, confirmation bias, question-order bias and leading questions & wording bias. As multiple interviews, evaluation consultations and questionnaires are used in this research, there is a lot of qualitative data. In order to describe this collection of data in a clear and concise chapter a lot of data needs to be shortened and summarized. This introduces the risk of confirmation bias as it is easy to only interpret the data to support a preferable outcome, while non favorable data is omitted. We tried to make an accurate representation of the results, however, the risk of confirmation bias will still exist. In addition, there is the possibility of question-order bias due to the usage of interviews and questionnaires. In question-order bias the order of questions in an interview or questionnaire may influence the answer respondents will give. Participants may compare and judge subsequent questions based on their response to the first question resulting in a biased and inaccurate answer. As an example, patients were not satisfied with the LUMC App, in surveys patients had to answer questions about multiple constituents. When you have to answer a question about a smartwatch directly after a question about the app, it is possible that the smartwatch is scored higher because 'it was not as bad as the app' even though the smartwatch might not have been functioning perfectly as well. The last researcher bias is about leading questions and wording. For example, 'How wonderful did you think the educational pathway was'. This question is constructed so that there is no option for a different response because you have already made the assumption that you believed the pathway was wonderful. Respondents will only get the chance to rate the pathway from good to outstanding. The interviews and questionnaires were made with the intention to create questions which do not create the idea that there is only one correct answer. However, especially during interviews it is possible that the interviewer accidentally led the respondents to a certain answer.

Selection bias

In this research specialized nurses reached out to patients which they thought were suitable for this research. This caused a double risk for selection bias. Selection bias refers to a bias introduced when the selection of individuals was done without proper randomization. Firstly, patients who were not deemed suitable by the nurses, even though they fit the in- and exclusion criteria were not contacted. This concerns patients who for example were expected to drop out, had shown lack of perseverance in previous consultations or where just deemed unfit based on the nurses' opinions. This form of bias could have been prevented when a complete list was made in which all patients who fit the in- and exclusion criteria were collected. These patients should then be contacted by a researcher who does not know these patient and therefore is not able to exclude a patient based on their own opinion. Secondly, patients who agree to take part in the research are probably more motivated to change and improve their lifestyle in comparison to patients who did not want to participate. This influences the results and might create a too optimistic view of the pathway. Unfortunately, this type of bias is much harder to prevent as it is impossible to force the less motivated patients to participate in such a study.

5.2.3 Perceived learning

Even though chapter 3 states that most patients have not learned much during the pilot study, especially not concerning diabetes in general, a score of 7.1 came out of the questionnaire about perceived learning. This is the lowest score given for a constituent in the perceived learning questionnaire, but it is still a more than sufficient score, which is not in line with the findings of chapter 3. It is possible that the questionnaire, or the presence of the researcher in the evaluation consultation has contributed to some sort of participant bias based on social desirability. In future research it should be pointed out to patients that the research has more value if patients answer with honesty instead of what they think the researchers want to hear. However, this component remains an issue when questionnaires are used and is very hard to solve completely.

5.2.4 Patient population

The population included in this research has had diabetes for an average of 15.6 years. Because of this, they have already learned to cope with diabetes. In addition, they have already developed their own habits and in their minds they have less to lose since they are already insulin dependent and/or have multiple complications. To change your lifestyle, you will need a lot of perseverance and motivation, but also a goal to work towards. It is possible that patients who have just gotten the diagnosis can change their lifestyle easier because diabetes is new for them and they do not have ingrained habits yet. In addition, the possibility to delay the dependence on insulin can function as a very strong motivator. These factors might affect the results as six out of seven patients included in this pilot have had diabetes for years. It is possible that a group of 'new' diabetes patients might have had better results due to the pathway. In future research patient who have just gotten the diagnosis should be represented better in order to test this hypothesis.

5.2.5 Long-term results

Since this pilot had the duration of eight weeks, there are no long-term results. Even though the results seem promising, it is possible that the improvements made in these eight weeks will slowly fade after the pilot has ended. This could be linked to two factors. Firstly, patient who were doing their best for healthcare professionals or for the study in general will lose their external motivator and are likely to relapse to old habits. Secondly, during the pilot study, patients will receive help and will be constantly reminded of their lifestyle choices due to the pathway. When these impulses are gone, patients will only have their own motivation and perseverance to keep up the good work. Future research needs to include the long-term effect of this intervention in order to gain more insights on its efficacy.

5.2.6 Motivation

To interpret the results, it is important to know what currently motivates the patients. Based on the questionnaires and interviews it seems like patients are not intrinsically motivated. Patients are doing it for the healthcare professional. Patients are testing the constituents of the pathway and informing the researchers about it, or they perform measurements and show them to the healthcare professional with the intention to hear from them what they should improve. The whole concept of the pathway is that patients do it for themselves, gain insights and change their lifestyle based on their own acquired knowledge. Obviously, healthcare professional need to guide them in this process, but it should not be the other way around. It is possible that patients would have judged the pathway more negatively if they would have experienced the pathway as something they were doing for themselves. When something malfunctioned patients simply stopped using that component and excused themselves in the next consultations for the lack of data. If patients were intrinsically motivated and wanted the results for themselves, the impact of lacking data or malfunctioning components possibly would have been a lot bigger. To solve this in future research, the concept of the pathway needs to be explained better. However, as long as the pathway is not a part of regular care, patients will know they are participating in research which automatically has impact on the results as some patients are more easily motivated if they know they are doing it for somebody else, like their healthcare professionals.

5.3 Conclusion

The concept of the educational care pathway is good, but as long as no improvements or adaptations are made, it is not suitable for an additional large-scale study. The most important topics for improvement are the motivation of involved healthcare professionals, the ability to personalize the pathway to individual needs, data transmission to the LUMC App and the absence of a blood glucose sensor and the blood glucose curve in the LUMC App. Moreover, it is important to acknowledge the fact that the current content of the pathway does not necessarily matches optimally with the majority of the patients in the LUMC. In addition, perceived learning and patient activation improved during this pilot study, but the results were not significant. Based on the recommendations from this study, the pathway should be improved. Followed by additional research with a larger sample size and long-term results to prove efficacy and feasibility. When the efficacy and feasibility is proven, the pathway can be implemented.

6 ADAPTATIONS, IMPROVEMENTS AND FUTURE DIRECTIONS FOR THE DIABETES BOX AND EDUCATIONAL CARE PATH-WAY

6.1 Organization & Logistics

6.1.1 Box office

The collaboration between the diabetic department and the box office was not functioning properly during this pilot study, since the box office was undermanned during this period. Some patients experienced technical difficulties and needed support. Due to the small sample size of this pilot study it was possible for the researchers to solve these problems together with the patients. Nevertheless, future research with a bigger sample size will not be possible unless this collaboration has been improved. Ideally, patients can email or call (for urgent matters) the box office when problems occur or when they need support. If necessary, they could make an appointment at the box office to solve the problems. Researchers and healthcare professionals involved in the research would therefore be less taxed by this research.

6.1.2 Information provision

Patients need more additional information. Even though nurses and researchers tried their best to inform patients about the pilot study before it had started, some patients were not completely informed. At T0 patients received additional information in flyers which were also sent to them by e-mail. These flyers contained information about all consultations and QR-codes and links to the videos. However, patients lost the flyers and/or were not able to retrieve the e-mail which were sent in the beginning. A website needs to be created on which patients can find all the information about the intervention located in one place. The website could contain information about the pathway, as well as frequently asked questions (FAQs) and the educational videos.

Additional reminders

Since patients stated that they missed information or reminders about the videos and when and where to watch them, additional notifications should be implemented. It would be optimal if the videos are incorporated into the LUMC App, this would improve the accessibility of the videos. In addition, the app could 'hide' the videos until the right moment has arrived to watch the videos. The article of Yoon et al. described that the majority of patients liked getting notifications to remember daily tasks such as, taking medication, going for a walk, doing exercises.[90] Adding notifications could help patients to remind them when to watch the videos. It could also help to create a higher adherence in blood pressure measurements and activity tracking. Multiple studies suggest that patient motivation can be increased by regular text-based feedback and notifications.[81–83] Patients should not be flooded with notifications as this could cause frustration, but if a patient has a choice over what time of the day they want to receive a message, the feeling of being nagged is reduced. This may result in more reflection and interpretation of the message.[56]

6.1.3 Walk-in hours

After patients have received the DiaBox and everything is installed and connected correctly, there is always a chance that technical problems occur before the pilot study actually has started. During this pilot study patients were helped via e-mail, but if this did not solve the issue an additional appointment had to be made. Since the sample size was small, this was manageable, but with a larger sample size it is not possible to create enough time for additional appointments. It would be wise to create walk-in hours, possible in partnership with the box office. If problems occur after the hand-out of the box or even during the hand-out of the box, patients will have a back-up to go to, to get everything fixed before the first consultations. Even when problems occur later on, they have a place to go to, for additional help and the possibility to ask questions.

6.1.4 Healthcare professionals

In order to make the pathway a success, healthcare professionals are very important. Due to some factors as the target audience and blood glucose sensors not every staff member is very motivated to continue with this pathway. Before additional research is on the table, the complete team of healthcare professionals included in this pathway should be motivated and should acknowledge the importance of the project. If a new study is started without including every one's opinion this might reflect negatively on the results later on.

6.2 Concept

6.2.1 Study population

The population and target audience for the pathway was a trending topic during this pilot study. Mostly this was focused on the need to change the target group to a primary healthcare setting, or to change the content of the box. Even though these are both legitimate options, there is also a third partial solution. When a blood glucose sensor is part of the box, there are more eligible patients in the LUMC to take part in this pathway. This increases the possibility to perform additional large-scale research in the LUMC.

6.2.2 Apps

In order to let the concept of the pathway reach its full potential, the LUMC App needs to be improved. The malfunctioning of the app is something that can happen at any time, but because this happened at the beginning of the pilot study, patients were already frustrated with the app from day one. This tremendously affected the pilot study since patients might not have given the app a fair chance. Besides the app, there need to be made some improvements in the communication between the Wihtings app and the LUMC App since multiple measurements were not synced with the LUMC App, even though they were visible in the Withings app. If the LUMC App remains status quo, a large-scale research for this pathway is not achievable.

User friendliness

The Withings App is working well and the transmission between Wihting and EPD-vision are functioning. This makes the pathway easier for healthcare professionals. However, for patients it remains complicated because they have to work with three different apps (Withings, LUMC App and LibreView). This is due to the fact that not all measurements appear in the LUMC App resulting in the usage of the Wihtings app as a backup. In addition, the LibreView app has to be used because the blood sugar curve is not visible in the Withings and LUMC App. The LUMC app is supposed to function as an overarching app in which all measurements are visible, which would result in one clear overview of data for patients. Since the LUMC App is not functioning properly it is actually more complicating for patients than if they would not use this app at all. As long as the complexity for patients is not solved, additional research is not recommended.

LUMC App

Currently the photos made by patients from their food and drinks is not linked with EPD vision. The dietitian is therefore not able to see the pictures before a consultation, as a result they have less information to prepare for the consultation. Patients stated that making these pictures of every meal is quit time consuming and burdensome, when they found out the dietitian was not even able to view these photos it caused some frustration. This component of the app needs to be improved or skipped as it currently has no added value. In addition, the data transmission between the Withings App and the LUMC Care App needs to be improved as this is the biggest frustration of patients during the pilot.

6.2.3 Videos

Some patients asked for an additional educative video about insulin injections, medication in general and therapy compliance. These subjects are also discussed in regular care consultation, but patients stated that they would appreciate it if they had the possibility to re-watch these videos later on. In addition, a video for family members and friends was requested in which the pathway is explained, but also some information about the importance of a healthy lifestyle is given and in which way family members and friends can help and/or support.

6.2.4 Glucose monitoring

Since the DiaBox contains no glucose monitoring sensor at all right now, it might be beneficial to use a continuous glucose monitoring (CGM) sensor instead of an FGM sensor. This might lower the burden for patients slightly as they do not have to think about scanning the sensor since it is automatically transmitted.

6.3 To conclude

Even though the new educational care pathway is not yet ready for future (large-scale) research or implementation. The concept does offer a lot of potential. The non-significant improvements in patient activation and blood glucose levels, as well as the enthusiasm about the concept of the pathway in patients as well as healthcare professionals encourage the decision to continue with the improvement of this pathway. When (a part of) the adaptations as stated above are incorporated in the new pathway additional research will be necessary to determine the efficacy and feasibility of the pathway, preferably based on long term results.

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7 APPENDIX

A Search terms

- "Diabetes Mellitus, Type 2"[Mesh] OR "Ketosis-Resistant Diabetes Mellitus"[tw] OR "Non-Insulin-Dependent Diabetes Mellitus"[tw] OR "Diabetes Mellitus Type II"[tw] OR "NIDDM"[tw] OR "Maturity-Onset Diabetes Mellitus"[tw] OR "Maturity Onset Diabetes Mellitus"[tw] OR "MODY"[tw] OR "Type 2 Diabetes Mellitus"[tw] OR "Noninsulin-Dependent Diabetes Mellitus"[tw] OR "Noninsulin Dependent Diabetes Mellitus"[tw] OR "Maturity-Onset Diabetes"[tw] OR "Maturity Onset Diabetes"[tw] OR "Type 2 Diabetes Mellitus"[tw] OR "Maturity-Onset Diabetes"[tw] OR "Maturity Onset Diabetes"[tw] OR "Type 2 Diabetes Mellitus"[tw] OR "Maturity-Onset Diabetes"[tw] OR "Maturity Onset Diabetes"[tw] OR "Type 2 Diabetes"[tw] OR "Diabetes Type 2"[tw] OR "Adult-Onset Diabetes Mellitus"[tw]
- "Blood Glucose Self-Monitoring" [Mesh] OR "Self Care" [Mesh] OR "Self-Testing" [Mesh] OR "Self Medication" [Mesh] OR "Self-Management" [Mesh] OR "Blood Glucose Self Monitoring" [tw] OR "Blood Sugar Self-Monitoring" [tw] OR "Blood Sugar Self Monitoring" [tw] OR "Blood Glucose Monitoring" [tw] OR "Self Testing" [tw] OR "Self care" [tw] OR "Self -testing" [tw] OR "Self medication" [tw] OR "self treatment " [tw] OR "self management" [tw] OR "self care" [tw] OR "self medication" [tw] OR "self treatment" [tw] OR "self help" [tw]
- 3. "Telemedicine"[Mesh] OR "Telecommunications"[Mesh] OR "Remote Consultation"[Mesh] OR "Telecommunication*"[tw] OR "Telemedicine"[tw] OR "Remote Consultation*"[tw] OR "Tele-Referral"[tw] OR "Tele Referral"[tw] OR "Tele-Referrals"[tw] OR "Virtual Medicine"[tw] OR "Mobile Health"[tw] OR "Melalth"[tw] OR "Teleconferences"[tw] OR "Mobile Health"[tw] OR "Teleconferences"[tw] OR "Mobile Health"[tw] OR "Teleconferences"[tw] OR "Mobile Health"[tw] OR "Mobile Health"[tw] OR "Teleconferences"[tw] OR "Mobile Health"[tw] OR "Mobile Application*"[tw] OR "Mobile Application*"[tw] OR "Mobile App*"[tw] OR "Mobile Application*"[tw] OR "Portable Electronic Application"[tw] OR "Mobile Application*"[Mesh]
- 4. "Health Behavior" [Mesh] OR "Life Style" [Mesh] OR "Healthy Lifestyle" [Mesh] OR "Lifestyle Medicine" [tw] OR "healthy diet" [tw] OR "lifestyle" [tw] OR "daily lifestyle" [tw]

B Documents for patients

B.1 QR codes for educational videos

Introductie

De Diabetes Box is een zorgtraject ontwikkeld voor mensen met type 2 diabetes. In dit traject krijgen mensen apparatuur om thuis dingen als bloeddruk, slaap en stappen te meten. Daarnaast kunnen ze bloedsuikers bijhouden. Door deze combinatie krijgen mensen inzicht in de relatie tussen leefstijl en bloedsuikers. Om dit verband verder toe te lichten krijgen deelnemers ook informatie over type 2 diabetes, voeding beweging, slaap stress, doelen stellen en zelfmanagement. Hieronder vind je een overzicht van de verschillende momenten en de links naar de video's.

DiaBox - Wat is diabetes mellitus type 2?





Box Pick-up

Tijdens dit consult zal de Box worden uitgereikt door onze diabetes verpleegkundigen. Zij zullen instructies geven over de App, het horloge (activity tracker) en de bloeddrukmeter. Gezamenlijk worden alle apparaten aangesloten aan uw telefoon en zult u een vragenlijst invullen. Daarnaast zullen de Diabetes Box en de bijbehorende afspraken worden doorgenomen. ook zal het overkoepelende doel van de Diabetes Box worden uitgelegd. Hieronder vindt u een video over het aanbrengen van de glucosemonitor en over zelf management.

DiaBox - Zelfmanagement



Intake Diëtist

Tijdens deze individuele afspraak zal er goed worden gekeken naar uw persoonlijke voeding. Omdat iedereen anders reageert op verschillende voedingsmiddelen is het goed om hier per persoon naar te kijken. Belangrijk voor u is om te leren welke voedinsgmiddelen uw bloedsuiker doen verhogen en welke voedingsmiddelen dat minder doen. Een van onze diëtisten helpt u hierbij. hij zal uitleg geven over het gebruik van de App voor voeding en bruikbare tips geven voor uw situatie. Hieronder vindt u twee video's, één over voeding en diabetes en één over doelen stellen. kijk beide video's een week voor de afspraak met de diëtist. Maak in de periode voorafgaand aan de afspraak (5 dagen) gebruik van de voedingsfoto's in de App en houdt daarbij uw bloedglucose in de gaten.

DiaBox - Voeding en Diabetes & Doelen stellen



Dieet & Beweging

Deze afspraak is een groepsbijeenkomst met diëtist. Er wordt ingegaan op de invloed van voeding op de bloedsuikers en van beweging op de bloeduikers. Hierbij wordt gekeken naar de resultaten in de App van de deelnemers. Daar is namelijk te zien wat de relatie is tussen dieet, beweging en bloedsuikers. Er wordt gevragd hoe de deelnemers het ervaren hebben en waar e tegenaan lopen. Er kan uitleg gegeven worden over de invloed van voeding en beweging op bloedsuikers en er kan advies worden gegeven over het inpassen van gezonde voeding en beweging in het dagelijks leven. Onderstaande filmpjes geven informatie en voorbereiding aan voor dit consult. Het filmpje over voeding heeft u al bekeken maar dat kan gerust nog een keer. Maak in de periode voorafgaand aan deze afspraak gebruik van uw stappentellen en activiteitenregistratie. Houdt daarbij ook uw bloedglucose in de gaten.

DiaBox - Beweging en Diabetes & Herhaling: Voeding & Diabetes



Stress & Slaap

In deze groepsbijeenkomst gaan de psycholoog en de medisch specialist samen met u kijken naar de verbanden tussen stress, slaap en de glucoseregulatie. Aan de hand van praktijkervaringen van de deelnemers zal er uitleg worden gegeven. Daarnaast zullen ook tips en adviezen mee worden gegeven om beter te slapen en makkelijker te ontspannen. Probeer onderstaande filmpjes te kijken vóór het consult. Let in de periode voorafgaand aan deze bijeenkomst op de relatie tussen slaap en stress en u bloedglucose. Focus één week op slaap en één week op stress.

DiaBox - Slaap en Diabetes 1 & Slaap en Diabetes 2 & Stress en Diabetes



Conclusie Diëtist

Dit is het afrondende gesprek samen met de diëtist. Er zal worden geëvalueerd hoe u de zorg met de Diabetes Box heeft gevonden. Ook wordt er gekeken naar welke stappen u heeft gezet met de Diabetes Box. Als laatste zal nog gekeken worden hoe u deze veranderingen vast kunt houden en welke andere stappen er voor u nog zijn. Voor het stellen van doelen kunt u eventueel nog onderstaande video bekijken.

DiaBox - Doelen stellen



B.2 Manual for patients



We willen in Nederland de beste behandeling aanbieden. Daarvoor hebben wij een nieuw zorgtraject ontwikkeld om de patiënt in staat te stellen diabetes type 2 te beheersen: de Diabetes Box. Deze "box" omvat thuismeetapparatuur, onderwijs en het gebruik van een overzichtelijke app. De apparatuur wordt zonder kosten aangeboden en bestaat uit een bloeddrukmeter, een glucosemeter en een smartwatch. Met behulp van deze "gereedschappen" hopen wij patiënten te motiveren, activeren en meer kennis te geven over diabetes en onderliggende leefstijlfactoren.

Hoe ziet het traject eruit?

In totaal duurt het traject 8 weken en bestaat uit vijf onderwijsmomenten:

- 1. Individueel consult over zorgtraject en box pick-up
- 2. Individueel consult over voeding met diëtist
- 3. Groepsles over dieet & beweging
- 4. Groepsles over stress & slaap
- 5. Evaluatie en eindgesprek over doelen en voortgang met diëtist

Tijdens het traject zult u thuismetingen doen van bloeddruk, stappen en slaap. De gegevens hiervan zijn allemaal terug te vinden in de LUMCCare App. In deze App kunt u ook uw voeding en stress bijhouden. De zorgverleners zullen u vertellen wanneer welke metingen gedaan moeten worden. U kunt natuurlijk altijd zelf aan de slag met metingen. Tijdens het traject worden ook video's aangeboden over diabetes, voeding, beweging, slaap, stress, doelen stellen en zelfmanagement.

Wat gebeurt er na afloop?

Na afloop horen we graag wat u van het traject heeft gevonden. Ook tussendoor is uw feedback van harte welkom. We streven ernaar dit traject standaard te maken voor alle mensen met diabetes mellitus type 2.

De metingen

Bloeddruk meter

De bloeddruk zal gedurende dit onderzoek drie keer per week gemeten moeten worden. De bloeddruk dient gemeten te worden na een moment van rust. Dit kan bijvoorbeeld in de ochtend zijn direct na het wakker worden. Meet de bloeddruk niet direct nadat u actief bent geweest.

Stappenteller en slaapmeter

De stappen en kwaliteit van slaap zal bijgehouden en gemeten worden door het horloge. Het is de bedoeling dat dit horloge gedurende de 8 weken zo veel mogelijk gedragen wordt.

Voedingsdagboek

In de app kunnen foto's worden geplaatst van het eten en drinken dat u nuttigt. U wordt verzocht om de 5 dagen voor de het consult bij de diëtist al het eten en drinken wat u binnenkrijgt, vast te leggen in de app met foto's. Per foto kunt u een tijdstip toevoegen zodat het voor de diëtist duidelijk is wanneer op de dag u dit gegeten of gedronken heeft. De overige weken van de bent u vrij om foto's te plaatsen van uw eten en drinken. Hier zal door de diëtist echter niet naar gekeken worden. Let er op dat u geen privacy gevoelige informatie op de foto's hebt staan die u in de app plaatst.

Stress score

In de week voor de groepsles over stress en slaap wordt u verzocht om dagelijks een stress score in te vullen. U zult hier ook een melding over krijgen vanuit de app met de vraag of u deze score in wilt vullen. Gedurende de overige weken van het traject kunt u zelf instellen hoe vaak u deze stress score in wilt vullen.

FreeStyle Libre

Tijdens dit traject wordt u verzocht om uw glucosewaarde op dezelfde wijze in de gaten te houden ten opzichte van hoe u dit normaal gesproken ook zou doen. Zorg ervoor dat u minimaal één per 8 uur (vier keer per dag) meet, zodat er geen data verloren gaat.

Algemeen

Naast de hier boven genoemde momenten waarop we van u vragen om metingen te doen, staat het u vrij om extra metingen te doen. Tot slot is het belangrijk om te benoemen dat de waardes die in de app zichtbaar worden, niet constant gevolgd worden door diabetesverpleegkundigen, diëtisten of artsen. Mocht u onverklaarbare alarmerende waardes hebben, zich niet goed voelen, of is er sprake van een medisch noodgeval, neem dan altijd contact op met het ziekenhuis of het nationale alarmnummer (112). Bij vragen over de box kunt u contact opnemen met diabetes@lumc.nl t.a.v. Merel van der Maarel (BOX), met uw naam, geboortedatum en patiëntnummer.



C Questionnaires

C.1 Client Satisfaction Questionnaire 8 (CSQ 8)

De volgende vragenlijst vraagt naar uw tevredenheid over de **zorg met de Diabetes Box**. We bedoelen hiermee het complete plaatje: De onderwijsmomenten, de video's, de App en de thuismetingen. Uw antwoorden helpen ons om deze manier van zorg te evalueren en te verbeteren. Wij zijn geïnteresseerd in uw eerlijke mening over de hulp die u hebt ontvangen, of die positief of negatief is.

- 1. Wat vindt u van de kwaliteit van het algehele concept van de **zorg met de Diabetes Box** (inclusief onderwijs, App, video's en thuismetingen)
 - □ Uitstekend
 - \Box Goed
 - Redelijk
 - \Box Slecht
- 2. Heeft u het soort hulp ontvangen dat u hoopte te krijgen?
 - $\hfill\square$ Nee, beslist niet
 - □ Nee, nauwelijks
 - $\hfill\square$ Ja, in het algemeen wel
 - 🗆 Ja, zeker
- 3. In hoeverre heeft de zorg met de Diabetes Box aan uw wensen voldaan?
 - \Box Aan al mijn wensen is voldaan
 - $\hfill\square$ Aan de meeste van mijn wensen is voldaan
 - $\hfill\square$ Aan slechts enkele van mijn wensen is voldaan
 - $\hfill\square$ Aan geen van mijn wensen is voldaan
- 4. Stel dat een van uw vrienden of kennissen dezelfde hulp nodig heeft, zou u dan de **zorg met de Diabetes Box** aanbevelen?
 - \Box Nee, beslist niet
 - \Box Nee, nauwelijks
 - $\hfill\square$ Ja, in het algemeen wel
 - 🗆 Ja, zeker
- 5. Hoe tevreden bent u over de hoeveelheid hulp die u heeft ontvangen?
 - \Box Zeer tevreden
 - $\hfill\square$ Tamelijk tevreden
 - □ Tamelijk ontevreden
 - \Box Zeer ontevreden
- 6. Heeft de zorg met de Diabetes Box u geholpen om beter om te gaan met uw klachten?
 - \Box Ja, het heeft aanzienlijk geholpen
 - $\hfill\square$ Ja, het heeft wel wat geholpen
 - $\hfill\square$ Nee, het heeft eigenlijk niet geholpen
 - $\hfill\square$ Nee, het heeft de zaak alleen maar verergerd
- 7. Hoe tevreden bent u over het geheel genomen met de zorg met de Diabetes Box?
 - \Box Zeer tevreden
 - 🗆 Tamelijk tevreden
 - $\hfill\square$ Tamelijk ontevreden

- $\hfill\square$ Zeer ontevreden
- 8. Zou u de Zorg met de Diabetes Box nog een keer gebruiken, als dat nodig zou zijn?
 - $\hfill\square$ Nee, beslist niet
 - $\hfill\square$ Nee, nauwelijks
 - $\hfill\square$ Ja, in het algemeen wel
 - \Box Ja, zeker
- 9. Over welk onderdeel van de zorg met de Diabetes Box was u het meest tevreden?

10. Over welk onderdeel van de zorg met de Diabetes Box was u het minst tevreden?

C.2 General Evaluation

De volgende vragen gaan over de verschillende onderdelen van de onderwijsmodule over diabetes die u gevolgd heeft. Er wordt ingegaan op het nut van deze onderdelen. Er wordt steeds gevraag naar de onderdelen van de module, de video's, de app, de contactmoment en de thuismetingen.

1. Kunt u een rapportcijfer geven voor de zorg met de Diabetes Box? Een 1 is het allerlaagst, een 10 het allerhoogst haalbare

.....

- 2. Hoe nuttig vond u de video's?
 - \Box Erg nutteloos
 - \Box Nutteloos
 - \Box Neutraal
 - Nuttig
 - \Box Erg nuttig
- 3. Hoe nuttig vond u de app?
 - \Box Erg nutteloos
 - \Box Nutteloos
 - \Box Neutraal
 - □ Nuttig
 - □ Erg nuttig
- 4. Hoe nuttig vond u de contact momenten?
 - \Box Erg nutteloos
 - \Box Nutteloos
 - \Box Neutraal
 - Nuttig
 - \Box Erg nuttig
- 5. Hoe nuttig vond u de thuismetingen?
 - □ Erg nutteloos
 - \Box Nutteloos
 - \Box Neutraal
 - \Box Nuttig
 - □ Erg nuttig

C.3 System Usability Scale

Er volgen nu een aantal uitspraken om uw mening over de zorg met de Diabetes Box in kaart te brengen. Denk hierbij aan het gehele zorgpad met alle onderdelen: de onderwijsmomenten, de video's, de thuismetingen en de app. Hierbij is 1: helemaal oneens en 5: helemaal eens.

							_
1. Ik denk dat ik het frequent zou willen gebruiken		1	2	3	4	5	_
When Bebruiken	LUMC Care app						
	Horloge						
	Bloeddrukmeter						
2. IK vond het onnodig in- gewikkeld							
	LUMC Care app						
	Horloge						
	Video's						
3. Ik vond het makkelijk te ge- bruiken							
	LUMC Care app						
	Horloge						
	Bloeddrukmeter						
	VIDEO S						
4. Ik had technische support nodig om het te gebruiken							
	LUMC Care app						
	Horloge						
	Video's						
5. Ik vond het een goed samen- hangend geheeld							
	LUMC Care app						
	Horloge						
	Bloeddrukmeter						
	Video's						
 6. Ik vond dat er te veel tegenstri- jdigheden in zaten 							
	LUMC Care app						
	Horloge						
	Dioeaarukmeter Video's						
7 lk denk dat de meeste mensen							
het snel leren gebruiken		_	_	_	_	_	
	LUMC Care app						
	norioge Bloeddrukmeter						
	Video's						

8. Ik vond het lastig te gebruiken				
	LUMC Care app			
	Horloge			
	Bloeddrukmeter			
	Video's			
9. Ik voelde me zelfverzekerd tij- dens het gebruik van het product				
	LUMC Care app			
	Horloge			
	Bloeddrukmeter			
	Video's			
10. Ik moest veel over het prod- uct leren voordat ik het goed kon gebruiken				
	LUMC Care app			
	Horloge			
	Bloeddrukmeter			
	Video's			

C.4 Patient Activation Measurement (PAM-13)

Hieronder staan enkele uitspraken die mensen soms doen over hun gezondheid in relatie tot hun diabetes. Geef voor elke uitspraak aan, in hoeverre u het ermee eens of oneens bent. **Het gaat hier om uw diabetes-gerelateerde gezondheid**. Doe dit door het antwoord te kiezen dat het meest op uw persoonlijke situatie van toepassing is. *We willen dus weten wat u zélf vindt en niet wat u denkt dat de dokter of onderzoeker wil horen.*

Als de uitspraak niet op u van toepassing is, kies dan 'n.v.t.'

	Helemaal niet mee eens	Niet mee eens	Mee eens	Helemaal mee eens	n.v.t.
1. Uiteindelijk ben ik zelf verantwoordelijk voor mijn diabetes-gerelateerde gezondheid					
 2. Een actieve rol op me nemen in de zorg voor mijn diabetes-gerelateerde gezondheid, heeft de meeste in- vloed op mijn diabetes-gerelateerde gezondheid 					
 3. Ik heb er vertrouwen in dat ik kan bijdragen aan het voorkomen of verminderen van problemen met mijn diabetes-gerelateerde gezondheid 					
 4. Ik weet wat elk van mijn voorgeschreven diabetes- medicijnen doet. 					
5. Ik heb er vertrouwen in dat ik kan beoordelen of ik naar de dokter moet gaan of dat ik een diabetes- gerelateerd gezondheidsprobleem zelf kan aannakken					
 6. Ik heb er vertrouwen in dat ik een dokter mijn zorgen over diabetes durf te vertellen, zelfs als hij of zij daar niet naar vraagt 					
7. Ik heb er vertrouwen in dat het mij lukt om medis- che behandelingen die ik voor mijn diabetes thuis moet					
 8. Ik begrijp mijn diabetes-gerelateerde gezondheid- sproblemen en wat de oorzaken ervan zijn 					
 9. Ik weet welke behandelingen er zijn voor mijn diabetes-gerelateerde gezondheidsproblemen. 					
10. Ik heb veranderingen in mijn leefstijl (zoals gezond eten of bewegen) kunnen volhouden					
11. Ik weet hoe ik gezondheidsproblemen vanwege di- abetes kan voorkomen.					
12. Ik heb er vertrouwen in dat ik zelf oplossingen kan bedenken voor nieuwe problemen met mijn gezondheid als het gaat om diabetes.					
13. Ik heb er vertrouwen in dat ik veranderingen in mijn leefstijl (zoals gezond eten en bewegen) kan volhouden, zelfs in tijden van stress.					

C.5 Perceived learning questionnaire

U heeft de afgelopen 8 weken zorg ontvangen met een Diabetes Box. De volgende stellingen gaan over wat u geleerd heeft. Geef steeds aan in hoeverre u het eens bent met de stelling. Je kunt dit aangeven op een schaal van 'helemaal mee oneens' tot 'helemaal mee eens'

Als de uitspraak niet op u van toepassing is, kies dan 'n.v.t.'

	Helemaal niet mee eens	Niet mee eens	Mee eens	Helemaal mee eens	n.v.t.
Ik heb veel geleerd over diabetes					
Ik heb veel geleerd over de rol van voeding bij diabetes					
Ik heb veel geleerd over de rol van beweging bij diabetes					
Ik heb veel geleerd over de rol van slaap bij diabetes					
Ik heb veel geleerd over de rol van stress bij diabetes					

D Interviews

D.1 Healthcare professionals

Tijdens dit interview hebben we het over de zorg met de Diabetes Box waar u aan meegewerkt heeft. Het doel is om uw mening over haalbaarheid, bruikbaarheid en acceptatie van het onderwijsgerichte zorgpad te bespreken. Ook hebben we het over de representativiteit van de deelnemers en mogelijk barrières en succesfactoren.

- 1. Algemeen
 - (a) Hou oud bent u?
 - (b) Wat is uw beroep? Hoe lang doet u dat al? Wat is uw rol in de diabetes zorg?
 - (c) Wat was uw rol in de zorg met de Diabetes Box?
- 2. Wat is uw ervaring met de Diabetes Box?
- 3. Hoe uitvoerbaar vindt u het om op deze manier zorg te bieden?
 - (a) Tijd
 - (b) Energie
 - (c) Integratie
 - i. Waar had dat mee te maken?
 - ii. Zorgpad of bepaalde elementen?
 - iii. Vergelijking met reguliere zorg?
 - iv. Verbeterpunten?
- 4. Hoe gebruiksvriendelijk vindt u deze manier van zorg?
 - (a) Snel te bedienen/begrijpen
 - i. Waar had dat mee te maken?
 - ii. Zorgpad of bepaalde elementen?A. Grafiek glucose/leefstlijlparameters
 - iii. Vergelijking met reguliere zorg?
 - iv. Verbeterpunten?
- 5. Hoe prettig was deze manier van werken?
 - (a) Werkplezier
 - (b) Energie er van krijgen
 - i. Waar had dat mee te maken?
 - A. Enthousiasme patiënt
 - B. Soepelheid werken met de Diabetes Box
 - ii. Zorg pad of bepaalde elementen?
 - iii. Vergelijking met reguliere zorg?
 - A. Rapportcijfer voor Diabetes Box
 - iv. Verbeterpunten?
- 6. Wat vindt u heel goed aan de zorg met de Diabetes Box?
 - (a) Algemeen of een bepaald element?
- 7. Wat zou nog verbeterd kunnen worden aan de zorg met de Diabetes Box?
 - (a) Algemeen of een bepaald element?

D.2 Patients

Onderstaande vragen waren oorspronkelijk bedoeld als interview tijdens een focusgroep. Door de belasting van de studie en de kleine sample size is er voor gekozen om de focusgroep te laten vervallen en deze vragen als leidraad te gebruiken tijdens het individuele eind/evaluatie gesprek met patiënten.

- 1. Wat vond u van de onderwijsmomenten in het zorgpad?
 - (a) Hoe haalbaar vond u de onderwijsmomenten?
 - (b) Hoe prettig of aangenaam vond u de onderwijsmomenten?
 - (c) Hoe gebruiksvriendelijk vond u de onderwijsmomenten?
 - i. Wat vond u van de duur van de bijeenkomsten?
 - ii. Wat vond u van de frequentie van de bijeenkomsten?
 - iii. Hoe vond u de begeleiding tijdens de bijeenkomsten?
 - iv. Hoe nuttig vond u de bijeenkomsten?
 - (d) Wat zijn verbeterpunten?
- 2. Wat vond u van de video's?
 - (a) Hoe haalbaar was het om de video's te kijken?
 - (b) Hoe makkelijk vond u het vinden en afspelen van de video's?
 - (c) Hoe prettig vond u de video's?
 - i. Wat vond u van de hoeveelheid video's?
 - ii. Wat vond u van de duur van de video's?
 - iii. Wat vond u van de inhoud van de video's?
 - iv. Welke video's vond u heel goed en welke vond u minder goed?
 - v. Hadden sommige video's weggelaten kunnen worden?
 - vi. Miste u nog bepaalde onderwerpen in de video's?
 - vii. Heeft u ideeën om de video's te verbeteren? Zo ja welke?
- 3. Wat vond u van de LUMC Care App die u gebruikte tijdens het zorgpad?
 - (a) Hoe haalbaar was het om de LUMC Care App te gebruiken?
 - i. Hoeveel tijd besteedde u aan de app?
 - ii. Hoe vaak gebruikte u de app?
 - iii. Op welke momenten gebruikte u de app?
 - (b) Hoe gebruiksvriendelijk vond un de LUMC Care App?
 - i. Wat was er makkelijk in het gebruik van de app?
 - ii. Makkelijk te vinden?
 - iii. Grafieken leesbaar?
 - iv. Gegevens invoeren?
 - v. Hoe makkelijk was het automatisch sturen van thuismetingen naar de app?
 - (c) Hoe prettig vond u de LUMC Care App?
 - i. Wat was er prettig? Wat minder prettig?
 - ii. Welke onderdelen heeft u veel/minder gebruikt?
 - iii. Wat vond u van de hoeveelheid tijd die aan de app besteedde?
 - (d) Heeft u verbeterpunten?
- 4. Wat vond u van de thuismetingen?
 - (a) Hoe haalbaar waren de thuismetingen?
 - i. Hoe vaak?
 - ii. Welke momenten
 - iii. Hoeveel tijd kostte het per dag?

- (b) Hoe gebruiksvriendelijk ware de devices/apparaten?
 - i. Wat was er moeilijk of makkelijk aan het gebruik?
- (c) Hoe prettig was het thuis meten?
 - i. Wat was er prettig en wat minder prettig?
- (d) Wat vond u van de freestyle libre?
 - i. En van het plaatsen van de sensor?
- (e) Wat vond u van het horloge als stappenteller?
- (f) Wat vond u van het horloge als slaapmeter?
- (g) Wat vond u van de bloeddrukmeter?
- (h) Heeft u verbeterpunten voor de thuismetingen?
- 5. Zorg met de Diabetes Box
 - (a) Zijn er nog dingen niet aan bod gekomen die u kwijt wilt?
 - (b) Wat is de grootste top van de zorg met de DiaBox?
 - (c) Verbeterpunten van de zorg met de DiaBox?
 - (d) Wat heeft u geleerd?

E Questionnaires T1

E.1 System Usability Scale

Table	11:	Individual	results	SUS

Results	Pt. 1	Pt. 2	Pt. 3	Pt. 4	Pt. 5	Pt. 6	Average
Арр	7.5	97.5	30.0	12.5	92.5	95.0	55.8
Smartwatch	67.5	97.5	37.5	60.0	100	97.5	82.5
Blood pressure	85.0	97.5	50.0	67.5	100	95.0	82.5
Video's	60.0	97.5	-	82.5	100	97.5	72.9

E.2 General Evaluation

 Table 12: Individual results general evaluation

General Evaluation	Pt. 1	Pt. 2	Pt. 3	Pt. 4	Pt. 5	Pt. 6	Score
Grade	7	8	7	6	8	9	7.5
Video's	3	4	3	4	4	5	3.3
Арр	1	2	4	4	4	4	3.0
Consultations	5	4	5	5	5	5	4.0
Measurements	2	4	5	4	5	5	3.8

E.3 CSQ-8

 Table 13:
 Individual results
 CSQ-8

CSQ-8	Pt. 1	Pt. 2	Pt. 3	Pt. 4	Pt. 5	Pt. 6	Score
Concept	7	8	7	6	8	9	7.5
Received the help I hoped for	3	3	3	3	3	4	2.7
Fulfilled my wishes	2	3	3	3	3	4	2.7
Would recommend	1	3	3	3	3	4	2.7
Satisfied with the amount of help	3	4	4	4	3	4	3.2
Can handle my complications better	3	3	3	4	4	4	3.0
Satisfied overall	2	3	3	3	4	4	2.8
Would use again	2	3	4	2	3	4	2.8

F Barriers & Facilitators

Barriers	Ν	Facilitators	ſ
Individual			
Too complicated for patients which causes frustration and results in demotivated patients	5	Patients have gained knowledge during the pilot	3
Patients are not doing it for the staff not themselves, which is exactly the opposite of what the goal is	4	Guiding the (group)consultations gave the staff energy	2
There is no clear overview of the data collected which makes it hard for patients to gain insights	2	Improving healthcare brings joy to the staff	2
Low digital literacy in some patients causes them to not be able to use the app and wearables correctly	2	Patients have gained insights in health parameters	1
Patients are already familiar with content, the content should be more advanced for this target audience	1		
Pathway is not personalized per patient	1		
Environmental & organizational			
The absence of the flash glucose monitoring sensor in the box results in exclusion of perfectly suitable patients	5	The content of the educational care pathway is complete and covers the important topics for the average diabetic	Ę
The absence of the right target audience in the LUMC takes a toll on the motivation of the staff, since they have the	5	It is necessary to have someone who takes care of the prac- tical matters and the organization, someone who is on top	
feeling that the current pathway is not feasible in the LUMC because of this		of it. Preferable this is someone who does not belong to the medical staff	
When a technical difficulty occurs, it takes to long and causes too much frustration for patients and staff before everything	4	The consultations and guiding from a dietitian during this pathway is essential and helps with the improvement of edu-	2
is back on track There is a lack of help for patients to know how to interpret	2	cating patients The teamwork between the staff was great	2
the data they have created with the wearables from the box The adherence for patients to watch the educational to watch	2	An individual starting consult in which there is a possibility	2
the video s is low. Because of this, the consultations can not be optimally used		to explain everything to patients and where patients have the time to ask questions works really well	
If this pathway will be implemented in addition to regular care it might not be feasible for the staff to combine everything	2	Additional help from the box office would help to take some work of the plates of the current healthcare professionals in- volved	2
Dependence of external parties for the blood glucose sensors which is a source of frustration for the staff as they have identified a problem, but can do nothing to solve it	1	It is very efficient to work less with one-on-one consultations and more with group consultations	2
Lack of interaction during the group consultations	1	The diversity of topics along the road of the pathway works	1
Information provision needs to be improved, patients were	1	The group consultations are a perfect moment for patients	1
not complete aware of what kind of project they were starting with		to ask some additional questions and get help with technical difficulties from each other or the staff. In addition it is nice to have everyone together and make sure they are all on track	
Technical			
Due to the he absence of a blood glucose curve in the app the whole pathway is less useful because patients are not able to see what the effects of their behaviour is in relation to their blood glucose levels	5	Usage of the apps is really simple	1
The lack of datatransmission between the Withings and	4		
Patients complained about difficulties while logging into the	2		
There is barrier for the staff to use EPD vision to look into the data of the patients	1		
The data of the nutrition diary, stress scores and sleep scores	1		

Collection of all the barriers and facilitator extracted from the interviews with health care professionals
G Additional questionnaire results

G.1 PAM-13

 Table 15: Individual results PAM-13

	Pt.1 T0	Pt.1 T1	Pt.2 T0	Pt.2 T1	Pt.3 T0	Pt.3 T1	Pt.4 T0	Pt.4 T1	Pt.5 T0	Pt.5 T1	Pt.6 T0	Pt.6 T1
Responsible for own health	3	3	4	4	3	3	4	4	3	4	4	4
Participate actively	3	3	4	4	3	3	4	4	3	3	4	4
Able to prevent problems	4	3	4	4	2	2	2	2	3	3	4	4
Knowledge of medicine	3	3	4	4	3	2	3	4	3	4	4	4
When to go to a doctor	4	4	3	4	2	3	3	4	4	3	4	4
Share my worries with doctor	4	4	4	4	3	3	4	4	3	3	4	4
Execute medical procedures	4	4	4	4	3	3	4	4	3	4	4	4
Knowledge of complications	4	4	4	4	2	2	3	3	3	4	4	4
Treatment for complications	4	4	4	4	1	3	3	3	3	3	3	4
Perseverance in lifestyle change	3	3	3	3	3	3	1	1	3	3	4	4
Prevent health problems	4	4	4	4	3	2	3	3	3	3	4	4
Solve new problems	3	4	4	4	2	2	2	3	3	2	4	3
Maintain lifestyle changes under stress	3	3	3	3	3	2	1	1	3	2	4	4

G.2 Perceived learning

 Table 16: Individual results Perceived learning

Perceived learning	Pt. 1	Pt. 2	Pt. 3	Pt. 4	Pt. 5	Pt. 6	Score
Learned about diabetes	2	3	3	2	3	4	2.8
Learned about nutrition	3	3	3	3	4	4	3.3
Learned about exercise	3	3	3	3	4	4	3.3
Learned about sleep	2	3	4	4	3	3	3.2
Learned about stress	2	3	4	3	4	3	3.2

H Individual measurements

Table 17: Complete Diabox Measurements

	A	то	T1
	Average	10	11
Stepcount			
Patient 1	2129	3474	4759
Patient 2	-	-	-
Patient 3	3513	3956	4431
Patient 4	2167	2272	2499
Patient 5	2859	5410	2991
Patient 6	6480	6386	7897
Blood pressure			
Patient 1	77/128	75/127	76/127
Patient 2	61/101	67/108	-
Patient 3	70/123	-	-
Patient 4	95/153	96/157	-
Patient 5	76/119	78/124	-
Patient 6	63/114	64/120	62/106
Heartrate			
Patient 1	67	66	65
Patient 2	61	62	-
Patient 3	79	-	-
Patient 4	90	87	-
Patient 5	81	82	-
Patient 6	79	80	81

Results of patient activity and health measurements of all individual patients

I Thematic analysis

I.1 Patients

Apps

- De LUMC Care app werkt niet
- LUMC Care app werkt slecht, het idee is wel goed als het zou werken
- Als ie (LUMC care app) het had gedaan, was het een leuk systeem geweest
- Van de 10x dat er data in de withings app komt, komt het maar 2x in de LUMC Care app, je mist veel data en is geen pijl op te trekken waar het aan lag
- Uit withings en libre view kan je veel halen
- Als je alleen withing app en de losse libre view app gebruikt kom je ook al een heel eind, voor sommige mensen wel makkelijker als het in 1 app kan
- Aanmelden in de app gaat allemaal makkelijk, als je goed leest werkt het allemaal prima
- Je kon weinig met de LUMC Care app. Het idee is goed, als het zouwerken is het fijn
- Het zou fijn zijn als alles gerelateerd is aan elkaar. Dat je kan zien wat slaap en beweging doet op je bloedsuiker
- Was leuk geweest als je foto's van je eten kon koppelen aan je bloedsuiker
- Er werden metingen gevraagd door de LUMC Care app en dan kon ik die metingen niet meer terugvinden in de app
- Als de LUMC Care app zou werken zou dat het echt heel veel beter maken
- Duurde een tijdje voordat deze (LUMC App) uberhaupt ging werken, toen het werkte kwamen niet alle metingen door
- Stappen worden soms wel van withings naar lumc app doorgegeven, soms niet
- Ik kreeg om 12 uur snachts meldingen dat ik dingen moest meten, dat vond ik vervelend dus heb de meldingen uitgezet en ben vergeten deze weer aan te zetten
- Ik heb de withings app meer gebruikt dat de lumc app
- De LUMC care app mag wel verbeterd worden, vooral het doorgeven van het slaapritme. Mag wel goed aangepakt worden
- De app zelf was wel gebruiksvriendelijk, gaf seintjes van wat wanneer moest
- Ik heb de LUMC care app iedere dag wel gebruikt, vooral om te kijken of de stappen waren doorgekomen
- De app gaf ook goed aan wanneer de metingen gedaan moesten worden
- Koppeling tussen de apps werkt niet, daar was ik teleurgesteld over
- De metingen komen wel in withings app, maar niet in LUMC Care app
- LUMC Care app was in 1 woord waardeloos, heel af en toe deed ie het, maar meestal was het waardeloos en ergernis wekkend. Vooral het niet doorsturen van de data

Verkregen inzicht

- Dat sommige dingen toch een beetje zijn weggezakt, daar kom je dan met name in de groepsconsulten achter
- Ook al heb je al lang diabetes, zijn er toch nog dingen te leren, vooral omdat ze zijn weggezakt
- Voor mijn doen heb ik niet geleerd, maar ik heb al 30 jaar diabetes, het is allemaal niet nieuw
- Je krijgt makkelijk inzicht in je suikers en je ziet hoe erg je genaaid wordt met eten (bij ongezonde dingen waarvan je dacht dat ze gezond waren)
- je kan met alle inzichten makkelijker anticiperen
- Ik had dit zelf graag gehad toen ik net diabetes had, om bijvoorbeeld de injectie in mijn oog te kunnen voorkomen
- Dat stress en slaap effect heeft op diabetes wist ik wel een beetje, maar ik heb toch nieuwe dingen geleerd
- Het stimuleert wel om meer te gaan bewegen, dus dat is fijn
- Ik heb regelmatig naar de slaappatronen gekeken, daar heb ik inzichten in gekregen
- Hoe je beter om kan gaan met je diabetes, wat je het beste kan doen qua eten en drinken
- Ik had al veel informatie doordat mijn vader diabetes heeft, maar ik heb wel ook nog veel geleerd van jullie tijdens de dagen die bij de pilot hoorde
- Grootste top van de box is dat je goede inzichten krijgt in wat er allemaal gebeurt en wat de effecten ijn van voeding en beweging

• het maakt je bewuster, omdat je er meer mee bezig bent. Je doe toch je best voor jezelf en je wilt mooie uitslagen zien.

Video's

- De materie was voor mij bekend en niet interessant, voor beginnend suiker patient wel raakvlakken, waar moet je rekening mee houden
- Ik heb de video's helemaal niet gevonden
- Idee van educatieve filmpjes is erg handig, zeker als je net diabetes hebt
- ik heb de video's 1 of 2 keer niet gekeken voor de consulten, dan merk je dat je dingen mist. Als je de video's had gekeken was het verhelderend geweest
- Ik heb het belang van de video's onderschat
- Leuk om te zien hoe iedere professional op zijn eigen manier dingen uitlegde
- Ik heb ze bekeken, waren erg nuttig om meer inzichten te krijgen in diabetes
- Ik heb alle video's in 1 keer bekeken. Reminders van deze video hoort bij dit consult was fijn geweest
- De ene was informatiever dan de ander. Maar het was duidelijk genoeg
- Video over medicatie en hoe je moet spuiten zou een toegevoegde waarde kunnen hebben voor beginnend diabeten

Belasting

- De hoeveelheid consulten was prima
- De hoeveelheid metingen was prima
- Hoeveelheid afspraken is goed, het is niet te veel, was prima te doen
- De hoeveelheid metingen die werden gevraagd waren goed te doen, daarmee hou je het goed in de gaten
- Op een gegeven moment als je het wat langer hebt, kan het allemaal wel wat minder
- Je moet patienten nooit te veel handelingen laten doen met hun ziekte, dat gaat geheid fout

Concept

- Bij onbekende diabeet kan het zeker de moeite waard zijn, maar voor mij lost het niets op
- het kan voor veel inzichten zorgen als je nog niet veel kennis hebt
- Als je nog niets weet over diabetes en je krijgt de diagnose dan is het allemaal heel veel wat er over je heen komt, dan kan de box heel waardevol zijn
- Zeker als de koppeling tussen apps en databases straks goed gaat en je je bloedsuiker kan zien, is de box heel waardevol
- Als alles werkt zoals het zou moeten is het heel handig, maar op het moment nog niet zo. Het idee is fantastisch
- Ik denk dat het een hele goede uitvinding is voor de mensen met diabetes, het is goed voor de mensen die al langer diabetes hebben, maar voornamelijk voor de mensen die net de diagnose hebben
- het prinicpe van de box is fantastisch, daar kan je zo enorm veel mee doen. Zeker aan het begin om je eigen diabetes te leren kennen is het fantastisch
- Ik geloof er wel in, het prinicpe is denk ik heel goed, maar er moet een hoop aan verbeterd worden
- Het idee is niet gek, om mensen zichzelf te laten controleren en te zien wat de consequentie van hun daden is
- Het concept is goed, maar het komt er nog niet uit. Ik ben er van overtuigd dat het kan werken. Als het sterk verbeterd is dan wil graag weer meewerken.

Ondersteuning

- Fijn dat er de gelegenheid was om vragen te stellen
- iets meer technische ondersteuning zou fijn zijn, bij jongeren spreekt dat allemaal voor zich, maar ik ben daar niet mee opgegroeid dus dat zou fijn zijn
- Technische ondersteuning zou het beter maken
- Reminder voor de video's had geholpen, dat was voor het laaatste consult wel gedaan en dat was heel fijn

Devices

- Fijn dat je je eigen bloeddruk in de gaten kunt houden
- Met name de bloedsuikersensor blijft fantastisch
- Fijn dat de withings app goed werkt en dat je daar alles in kunt zien
- Vooral de freestyle libre is heel prettig

- Grappig aan slaap tracker dat je kan zien hoe vaak je wakker bent geweest zonder dat je het door had en dat je dan beter begrijpt waarom je zo moe bent
- Bloeddrukmeter is een fijn makkelijk ding, het horloge ook wel, maar ik ben niet zo'n horloge drager
- Bloeddrukmeter is eenbloeddruk meter, doet het wel, maar niet beter dan wat ik had, het was oke.
- Horloge om slaap te meten was oke, niet spectaculair

Thuismetingen

- Leuk om alle waardes in de app van withings te kunnen zien
- Vooral fijn dat je thuis je bloeddruk kunt meten
- Het meten ging wel, de waardes kwamen alleen niet door
- de apparaten zelf zijn heel handig, niet te veel poepsas, juist heel simpel
- Metingen zelf gaan goed, ik vind het leuk dat het dan na een minuut al in de withings app staat
- Je hoeft niet naar een ziekenhuis of dokter om dingen in te zien. Het is ideaal dat je zelf metingen kunt doen en daar inzicht in hebt
- De thuismetingen gingen goed, geen enkele keer problemen mee gehad.

Niveauverschil

- Mensen lezen niet goed, ik zit in de ICT voor mij is dit een eitje, maar zo makkelijk gaat het misschien bij andere mensen niet
- Geleerd dat ik compleet atechnisch ben
- Het basisprincipe ben ik het heel erg mee eens, maar het hangt er ook van af wat je allemaal al weet

I.2 Healthcare professionals

Inhoud Box

- Individueel start consult is een pre
- Alle onderwerpen die er in zitten zijn goed, daar krijgen patienten allemaal mee te maken
- Het is heel essentieel dat er uitleg van een diëtist bij zit
- Sensor kan inzicht geven in wat je doet en niet doet
- Eventueel kijken naar meer in groepsverband
- Het niet in kunnen zien van glucoses in je app is echt een manko
- Ze krijgen informatie die ze in andere consulten eigenlijk al 10x gehoord hebben
- Grootste pluspunt zijn de extra gegevens die patienten verkrijgen over zichzelf
- Met name de winst in inzicht is een pre, maar alleen als het goed zou werken, en het is nu nog niet echt top
- Misschien kijken of we beter kunnen aansluiten op de behoefte van individu
- Patienten krijgen basisvaardigheden waarmee ze verder kunnen, op lange termijn zou dat veel op kunnen leveren
- Goed dat er diverse onderwerpen worden meegenomen, sommigen worden in de spreekkamer nog wel eens vergeten (slaap)
- Patiënten moeten misschien meer geholpen worden bij interpretatie van data en stellen van doelen
- De inhoud die we hebben staan is goed
- Doordat we kijken naar verschillene aspecten (voeding, beweging, stress, slaap) is het een goed geïntegreerde aanpak
- Goed dat we heel erg na hebbend gedacht over wat wat de inhoud van de box moest worden en wat van toepassing is voor een nieuww type 2er
- Voor het doel wat we nu hebben is de box compleet qua inhoud
- Ik denk dat de Box valt of staat bij het inzichtelijk maken van bloedsuiker in combinatie met de effecten van alle factoren
- Je kan je afvragen of alleen het geven van de sensor al voldoende is, maar ik denk dat de box wel een meer compleet traject is
- Ik denk dat de Box veel effectiever zou kunnen zijn om mensen in beweging te krijgen en zelf hun diabetes regulatie te managen, daar zelf verantwoordelijkheid voor te voelen en te pakken dan de standaard zorg
- Educatie videao zijn goed, de materialen zijn er wel. Zou een voordeel zijn als patienten een freestyle libre krijgen om inzicht te krijgen

- De inhoud is in grote lijnen goed, met name voeding en beweging. Er zou nog iets meer aandacht mogen zijn voor het bewegen. Wat is het effect van type beweging op op bloedsuikers
- lets om patienten meer te laten bewegen zou mooi zijn, veel mensen dachter er door de box over na, maar ht zette nog niet aan tot bewegen.Misschien iets van motivatie/opdrachten in de app

Gebruiksvriendelijkheid voor patiënten

- Voor patiënten is het best ingewikkeld met die apps enzo.
- Het is allemaal niet vanzelfsprekend om alles te installeren
- · Het gebruik van de app is heel simpel als het eenmaal werkt
- · Wanneer er iets fout gaat kost het veel tijd, en merk je dat het veel vragen oproept
- Het is lastig voor patiënten om er 1 geheel van te maken en data van slaap, voeding, glucose etc overzichtelijk te tonen
- Tegenvallend, inloggen in diverse systemen, niet allles wordt verbonden, app werkt niet goed.
- Doordat koppelingen lastig zijn, raken patiënten gedemotiveerd
- Te veel tussenstappen voor de patiënt, het is daarmee te complex qua techniek waardoor het doel van de box niet wordt behaald
- Het is helemaal niet gebruiksvriendelijk vanwege de app die het niet doet

Belasting voor patiënten

- Patiënten deden het vooral voor ons, niet voor zichzelf
- Er wordt best veel in een korte periode van 8 weken gestopt
- Patienten geven aan dat het intensief is, dat kunnen we misschien nog verbeteren
- Ben benieuwd wat patiënten vinden van de hoeveelheid consulten, hoeveel het ze kost en wat het ze brengt

Integratie van de box in de dagelijkse zorg

- Deze box valt bij ons lastig te integreren omdat we de doelgroep niet hebben
- Qua zorg, hoe wij hier als team werken, welke onderwerpen wij belangrijk vinden, zou met devices heel mooi ondersteund kunnen worden
- · Het was nu extra voor patienten en is dus nog niet geïntegreerd

Verkregen inzicht patiënten

- Het doel is inzicht krijgen, dat mis je als je geen sensor hebt
- Het doel van bewustwording van effecten van handelingen en de reactie op bloedsuiker zijn nu 2 losse dingen
- Het is op dit moment nog lastig voor patiënten om er iets uit te halen
- Patiënten zijn aan het eind beter geïnformeerd, daar kunnen ze eventueel mee verder
- Het werkt nog niet zoals we willen, de kern van het kunnen leggen van de link tussen bloedsuikers en gedrag, daar schort veel aan
- Ik miste de connectie tussen bloedsuikers en dat direct in de app te zien was voor patiënten
- Je moet veel meer trekken aan patienten om ze het inzicht te geven wat ze zelf zouden verkrijgen als ze het zelf zouden zien en ervaren in de app
- Ik vind het zelf echt cruciaal dat de app voalt als iets om inzicht te krijgen, voor patiënten voelde het nu als, ik moet iets bijhouden voor jullie. Dat is totaal tegenstrijdig met wat we willen bereiken

Verkregen inzicht patiënten

- Het is heel goed als er iemand zoals jij is, die er bovenop zit ook naar patiënten toe
- Er moet iemand opzitten die de praktische zaken zoals een kapot horloge kan regelen
- Praktische/logistieke begeleiding zou ook vanuit box office kunnen zijn
- Fijn dat je alleen je eigen stukje hoefde te doen, en het ook duidelijk was wat die inhield
- We wisten goed wat er van ons verwacht werd, de organisatie etc. ging heel goed
- Fijn dat jij heel betrokken was en we samen de instructie deden
- Vereiste dat er iemand is waar je terecht kan met vragen, kan ook iemand van box support zijn
- Fijne toegevoegde waarde als iemand de regie houdt in praktische/logistieke zaken
- Het wordt nu allemaal in de spreekuren gepropt, dat moet opgelost, het moet buiten het standaard werk komen
- Extra ondersteuning van boxsupport zou fijn zijn, niet het gevoel dat we daar nu onderdeel van zijn

- Ondersteuning voor patienten is belangrijk, dat ze terecht kunnen met vragen. Is een voorwaarde om verder te kunnen
- Lastig om bijv een sensor te krijgen omdat je met externe partijen moet werken waar je geen invloed op hebt

Devices

- De box is alleen goed als alles er in zit, en met alles bedoel ik met name de sensor
- Die app moet gewoon werken, anders kan je er (Dia Box) niets mee
- De sensor moet er in, dat is echt essentieel
- De sensor geeft de meerwaarde
- Door die app (LUM Care) heb je er nu niks aan, je doet het dan maar half
- De app moet verbeterd en gekoppeld aan sensorgegevens
- Devices gaan in toenemende mate in ed zorg belangrijk zijn , denk dat wij ook in toenemende mate gebruik gaan maken van e-health

Visie & Doelstelling

- Ik denk dat het een prachtig project is, als je deze box bij mensen met DMT2 zet die net beginnen
- Je gaat bij de doelgroep van beginnend T2DM heel veel winst halen
- Het zou echt iets voor de eerste lijn zijn, daar zou het perfect geintegreerd kunnen worden
- Uiteindelijk meot je he tdoen met minder personeel, als de box goed wordt uitgevoerd kan je hierdoor met minder personeel toe
- Het kunnen zien van glucoses en dit kunnen koppelen aan andere factoren in een voorwaarde voor verbetering
- Om het bruikbaar te maken zijn er vervolgstappen nodig
- Ons aller doel is om te kijken of mensen een link kunnen leggen tussen allerlei factore en hun bloedsuikers
- We zouden het liefst een sceherm of dashboard hebben waar mensen alles tegelijk kunnen zien
- Qua type informatie en voorlichting zou het ontzettend goed passen in de eerste lijn, of perifere ziekenhuizen met nieuwe patienten
- mensen kennis te laten maken met alle factoren die van invloed zuijn op je bloedsuikers
- Als je de eerste bewustwording hebt gerealiseerd, wat doe je dan daarna, je bent dan nog niet klaar
- Doel van de box was dat patiënten meer inzicht krijgen. De relatie tussen voeding, beweging, slaap, stress en de bloedsuikers
- Ik denk dat de box ideaal is voor patienten die net gediagnosticeerd zijn. Dat zou de basis moeten zijn, daar ben ik van overtuigd
- Het is ook goed voor patienten die al langer diabetes hebben, maar nog nooit inzicht hebben gehad in hun bloedsuikers
- Wat we willen bereiken is dat ze zelf inzicht krijgen en dat wij uiteindelijk helemaal niks hoeven te doen. Mijn consulten (dietist) zouden eigenlijk bijna overbodig moeten voelen
- Patiënten moeten meteen bloedsuikers en daaronder voeding of beweging kunnen zien, doat ze direct het effect zien.
- De app heeft op dit moment veel potentie, maar functioneert nog niet zoals het zou moeten Vooral de app moet heel goed functioneren en voor de patiënt makkelijk zijn
- Het moet voor de patient niet meer voelen als, ik moet het voor jullie bijhouden, maar als ik krijg nu zoveel inzicht omdat ik alle informatie op 1 plek bij elkaar heb wat makkelijke te gebruiken is.

(Groeps)consulten

- Het is een hele diverse groep, ik kreeg niet zo veel terug tijdens het groepsconsult, al heb ik dit wel echt geprobeerd
- Groepsconsult was niet vervelend, het was niet een super energieke bijeenkomst, maar ik krijg er wel energie van
- De consulten zouden anders verlopen als je mensen hebt die nog niet zo veel weten, dus een ander edoelgroep
- Goed dat we kijken naar de mogelijkheden die groepsconsulten kunnen bieden
- De consulten hielpen om het allemaal enigzins goed te sturen en extra informatie te geven
- De consulten zelf vond ik een prettige manier van werken, eerst wat meer ondersteunend, minder 1 op 1, want 1 op 1 is inefficient proces, iedere patient los vanaf 0 educatie geven is inefficient.

Werkplezier

• We hebben geen duidelijk resultaat behaald

- We wisten voor de pilot al hoe het zou aflopen
- Uitleg geven aan patiënten over de box is leuk
- Het voelt als een verplicht iets omdat er geld was
- Uitkomst is niet wat we gewild hadden
- We dachten dat het een box voor bij ons zou zijn
- Heel leuk om deel te nemen aan opzet box, krijg daar energie van
- Je krijgt er meer energie van als je de juiste doelgroep hebt en resultaten gaat zien
- Zoals het op dit moment is, kost het alleen maar energie
- De juiste doelgroep zou mijn werkplezier vergroten, je ziet dan waar je het voor hebt gemaakt
- Wanneer patienten het echt voor zichzelf zouden doen en niet voor ons zou dat mijn werkplezier vergroten
- Ik word heel blij van het concept
- Het kost nu veel energie, maar dat komt meer door de technische problemen.
- Leuk om op deze manier met zorg bezig te zijn, kan het anders, efficienter, hoe kunnen we meer uit de zorg halen
- In de basis is het iets waar ik energie van ozu kunnen krijgen
- Het kost energie omdat je het extra doet en nieuw is, er gaat meer tijd inzitten en dus energie, maar het levert ook energie op omdat het een leuk project is met uitdagingen
- Het was voor mijn nu gebruiksvriendelijk, het was nog een beetje zoeken omdat niet alles soepel liep, maar als de box er is zoals het zou moeten zijn, denk ik dat het efficient is

Werkplezier

- Communicatie onderling ging goed, we waren een team
- De sanenwerking verliep goed
- Leuk om met het team aan een nieuw project te werken
- Ik vind dat we een heel fijn team hebben, prettig samenwerken in dit soort projecten

Digitale vaardigheden patiënten

- Deze doelgroep is dit soort metingen minder gewend en blijkt digitaal ook minder vaardig
- Patiënten hebben voor digitale zaken veel hulp nodig, en die hebben ze nu ook gekregen
- Hoe gebruiksvriendelijk moet het zijn om het foutloos te kunnen instrueren, in de basis is het best gebruiksvriendelijk
- In de praktijk is het lastig om er voor te zorgen dat iedereen het draaiende heeft (verschil in niveaus)

Haalbaarheid

- Bang dat er te veel op het bordje van diabetes vpk terechtkomt, wat niet haalbaar is
- Pessimistisch over de haalbaarheid van inzichtelijkheid van bloedsuikers in combi met alle factoren in 1 app