IMPROVING SELF-MANAGEMENT IN TYPE 2 DIABETES

THE ROLE OF GROUP EDUCATION AND PATIENT PARTICIPATION

ESTHER DU PON

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Every mountain top is within reach if you just keep climbing.

Barry Finlay

Voor Josien

Contents

Chapter I

General introduction

Background on type 2 diabetes

Type 2 diabetes mellitus (T2DM) is a chronic, progressive disease characterized by elevated levels of blood glucose and often hypertension and dyslipidemia [1]. This disease is caused by a combination of insulin deficiency and insulin resistance. T2DM can lead to microvascular and macrovascular complications, resulting in disability and premature death [1]. Symptoms of hyperglycemia are often less marked or absent entirely. As a result, the disease may go undiagnosed for several years, until complications have already arisen [1]. Important risk factors for developing T2DM are overweight or obesity, physical inactivity, and poor dietary habits, with genetic predisposition also playing a role. The control of hemoglobin A1C (HbA1c) levels is crucial to the successful treatment of patients with T2DM. HbA1c is the benchmark for defining glucose control over the previous eight to twelve weeks [2], and glycemic control has been shown to strongly predict complications of diabetes [3].

Since the second half of the 1990s, the number of patients with T2DM has been increasing [4]. This increase is due to population growth, higher life expectancy, and the increasing obesity epidemic [1]. In the Netherlands, 66 per 1,000 persons currently have T2DM [4,5] and the prevalence is expected to rise with 34% in the period 2015-2040 [4]. In 2018, the prevalence of T2DM per age group was as follows: 0–24 years, 3.8 (per 1,000 people); 25–44 years, 15.1; 45–64 years, 83.6; 65–84 years, 222.1; and 85+ years, 130.1 [4].

Diabetes care in the Netherlands

Patients with T2DM primarily receive treatment in primary care, most of which rely on a general practitioner (GP) as their main health care provider (HCP) who takes primary responsibility for their care [2]. In addition to annual GP visits, a practice nurse (PN) checks the patient's body weight, blood pressure, and (fasting) blood glucose levels every three to six months. PNs also inquire about their patients' well-being, hypoglycemia or hyperglycemia, nutrition, and physical activity [2,6]. In addition to a healthy lifestyle, T2DM treatment will often be complemented by long-term therapy with glucose-lowering medication, such as metformin, gliclazide, and insulin.

In the near future, the number of GPs and PNs will not be able to meet the projected growth of patients with T2DM [1]. To compensate, the workload per patient for HCPs must decrease, eventually resulting in less face-to-face time per patient [1]. In addition, the general growth in health care costs will further restrict the possibilities to spend adequate time with each patient [7]. Consequently, alternative forms of support, treatment, and patient self-management are needed [8].

Self-management behavior in T2DM

Nowadays, patients with chronic conditions, particularly T2DM, are encouraged to be active participants in their own health care. In contrast with many other chronic conditions, T2DM requires relatively demanding self-management activities to control the condition on a daily basis. Self-management can be defined as the active participation of patients in their treatment [9] that aims to minimize the effect of the chronic disease on physical health and daily activities and enable patients to cope with the psychological effects of the illness [10]. Thus, people with T2DM must make day-to-day decisions in response to their disease condition. As Funnell and Anderson noted, "more than 95% of diabetes care is done by the patient" [11]. As a result, today's care concepts focus on self-management. Influential self-management behaviors involve blood glucose monitoring at home (for insulin users), diet, daily physical activity, foot care, and medication use [12]. These factors have all been shown to markedly reduce the incidence and progression of complications associated with T2DM [1].

In the Netherlands, care for people with a chronic disease is often organized in multidisciplinary "chains". The content and organization of care in such chains are based on underlying care standards (in Dutch: Zorgstandaarden). These standards describe care by disease (e.g., care standards for diabetes) and are based on the chronic care model (CCM) (Fig. 1) [13]. The CCM comprises six interdependent elements that are key to high-quality chronic disease care: (1) community resources, (2) health system support, (3) self-management support, (4) delivery system design, (5) decision support, and (6) clinical information systems [13]. This model assumes that behavioral change will not succeed without the patient taking a leading role. Thus, patients with T2DM must take on the responsibility of self-management, while care providers primarily act to support patients in this process. According to the CCM, "self-management support" is defined as giving patients the knowledge, confidence, and skills to self-manage the disease.

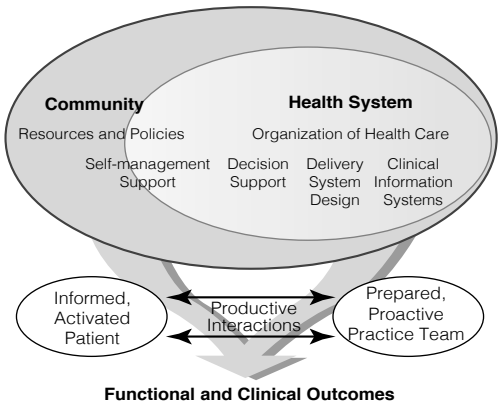

Figure 1. Schematic diagram of the Chronic Care Model [13].

In the Netherlands, protocol-based diabetes care is well-organized [14]. In recent decades, the quality of clinical care for patients with T2DM has improved considerably [3]. Although it depends on the age, treatment, and disease duration, the target value for HbA1c is typically <53 mmol/mol. In 1998, 45% of Dutch patients with T2DM younger than 75 years achieved this target level. This percentage increased to 71% by 2013 [3]. For patients aged 75 years and older, similar trends for HbA1c were found.

Self-management focuses on the act of fitting the disease into daily living. In short, this includes the following activities [15]: (1) adopting a healthy lifestyle, such as eating healthy food, monitoring blood glucose levels, and being physically active; (2) performing medical management such as self-monitoring, self-treatment, and taking medication; (3) dealing with the consequences of T2DM including psychosocial, emotional management; and (4) communicating and dealing with health care professionals, including shared decision-making. These self-management activities are necessary to ensure optimal glycemic control.

In addition, patients with T2DM must develop skills to self-manage the disease. Lorig & Holman (2003) described five core self-management skills, which could be applicable to T2DM[16]: (1) problem solving, (2) decision-making, (3) resource utilization, (4) forming of a patient/HCP partnership, and (5) taking action. Nevertheless, adherence to a diabetes treatment regimen is difficult for many patients. They often report that the most difficult parts of managing diabetes are changing their diet and taking the medication as prescribed [17].

Booth et al (2013) explored the views of people recently diagnosed with T2DM in relation to self-management. Patients were encouraged to continue when they feel healthier in response to the changes they have made. In addition, they were motivated by the desire to avoid long-term health consequences or to remain well. Thus, setting targets, self-monitoring blood glucose, and being supported by their family and HCPs helped to keep them motivated [18]. However, hindering factors to lifestyle change received more prominence in discussions than facilitating factors. The overriding hindering factors were patients' concerns about changing well-established habits, coupled with negative perceptions and confusion about particular aspects of the recommended diet. Patients also appeared to feel overwhelmed by the number of changes they had to make to their diet.

Poor health behavior places patients with T2DM at an increased risk of disease progression and affects their quality of life [19-21]. Effectively adopting self-management is often challenging and self-management of T2DM is less than optimal, especially regarding lifestyle behaviors [22]. Poor self-management can be a conscious choice ("reasoned behavior"). However, many patients do not see the relevance of the advice to their own health. Others lack the confidence that they will succeed in adopting the changes, often after experiencing several failed attempts. As a result, patients can "burn out" in the long term from trying to follow lifestyle advice, making it difficult to implement it in their daily life [23].

In the following sections, several self-management aspects are discussed that are at the core of this thesis: participation during the consultation, medication adherence, and usage of eHealth applications.

Participation during the consultation

Effective and productive patient–provider interactions are at the heart of the CCM and the key to improving outcomes [13]. Good communication between a PN and a patient can help to properly manage a chronic disease [24,25]. The PN is part of the multidisciplinary team and provides most of the care. The diabetes care provided by a PN is comparable to that provided by a GP in terms of the clinical parameters [26]: both GPs and PNs perform lifestyle counseling according to generally acknowledged criteria and clinical guidelines [26,27]. Thus, the PN acts as a medical expert on diabetes, a diabetes educator, and a lifestyle counselor to support the patient's diabetes self-management. Patients value the fact that the PNs take them seriously, listen carefully, are open, take sufficient time, and provide adequate advice on how to manage complaints [27,28]. An aspect of self-management is patient participation in medical consultations. Participation in medical consultations is defined as the extent to which patients contribute to the consultation by, for example, asking questions, expressing concerns, and stating preferences [29]. Higher levels of patient participation in medical consultations could improve patients' clinical measures and quality of life [24,30,31].

However, many patients with a chronic condition experience at least one barrier to participation during the consultation, such as not wanting to be bothersome, perceiving time pressure, and forgetting to discuss certain topics during the interviews [32]. Therefore, it is important to understand the factors affecting engagement of patients with T2DM and to support patients in dealing with these factors.

Medication adherence

For most patients, T2DM is a chronic, progressive disease that requires adjustments in non-pharmacological and pharmacological interventions. In the early disease phase, changes in lifestyle may lower blood glucose levels; however, over time, insulin secretory capacity decreases. Thus, most people with T2DM will require pharmacotherapy to achieve glycemic control. Typically, blood glucose levels can be adequately managed by blood glucose lowering agents such as metformin, gliclazide, and insulin [33]. In the Netherlands, 800,000 patients were treated with blood glucose–lowering medication in 2014 [34].

The World Health Organization (WHO) defines adherence as "the extent to which a person's behavior—taking medication, following a diet, and/or executing lifestyle changes—corresponds with agreed recommendations from a health care provider" [35]. Medication adherence can be divided into three interrelated yet distinct states: the initiation of the treatment, the implementation of the prescribed

regime, and the persistence of the pharmacotherapy. In any of these phases, medication nonadherence can occur [36]. Medication adherence is a complex behavior with several aspects [37], making it difficult to measure [38]. No gold standard exists for measuring medication adherence. The necessity of medication depends on the extent to which patients follow other lifestyle recommendations (e.g. losing weight, eating healthier, and being more physically active). Improved lifestyle can, particularly in the first few years after diagnosis, lead to patients no longer needing medication.

However, patients with T2DM reported taking diabetes medication as the most burdensome self-management activity [17]. A substantial proportion of people with T2DM—up to 18%—do not take their medication as prescribed [34]. This percentage is probably higher than reported. According to a recent systematic review, nonadherence rates on diabetes pharmacotherapy vary across studies from 7% to 61%, with most reporting rates <20% [39]. This diversity in adherence rates could be attributable to differences in the populations studied, the medication that patients were taking, and the adherence measures used among included studies [39]. In T2DM, poor initiation appeared to be the largest contributor to overall nonadherence [40] with polypharmacy as a risk factor for slower initiation of treatment. Furthermore, T2DM is often asymptomatic, which could also be an important factor explaining treatment nonadherence.

Usage of eHealth applications

eHealth applications can be used to provide self-management support and maintain and/or improve the quality of chronic disease management by engaging patients in their own health care [41]. Studies have shown that an online addition to standard care (i.e., blended care) for people with T2DM can improve their weight, blood cholesterol, quality of life, depression, social support, self-efficacy, physical activity, fasting blood glucose, and HbA1c [42-44]. A systematic review by Bolle et al. (2015) examined the effectiveness of online health information tools for older patients. Their best evidence synthesis provided evidence that online health information tools improve self-efficacy, blood pressure, hemoglobin, and cholesterol by providing information, enhancing information exchange, and promoting self-management [45]. One example of an online tool that could be beneficial for patients with T2DM is an online platform [46]. In general, online platforms are environments with which patients can obtain an overview of their health outcomes, find information on how to set and achieve treatment goals, communicate with their care provider, and gather information regarding their disease. These platforms have the potential to support patients in changing their lifestyle and taking more responsibility for their own health [47].

So far, the effects of online platforms reported in systematic reviews vary [48-50]. According to several systematic reviews, the use of eHealth improves health behaviors and health-related diabetes outcomes in patients with T2DM [51-53]. Nevertheless,

implementation problems, nonadherence, and a low participation rate are common [54-58]. A previous literature review about online care platform use showed that only 29–46% of patients with diabetes (type 1 and 2) registered for a platform account. In addition, of those registered, 27–76% of the patients used the platform at least once [58].

In the Netherlands, an online care platform called e-Vita has been developed to improve patient self-management skills [59]. The e-Vita platform contains information about the patient's health status but also offers patients more engaging options, such as formulating personal goals, participating in educational modules, exchanging messages between patient and care provider, or searching for information in the "library."

Diabetes self-management education

To facilitate the use of self-management support programs within a platform such as e-Vita, patients first need to develop an intention for behavioral change, which can only be achieved if they have sufficient risk awareness, experience a need for behavioral change, and feel confident in making these changes [60]. According to the CCM, behavior change can be encouraged by diabetes self-management education [12]. Engagement in diabetes self-management education results in a decrease in HbA1c levels, as demonstrated by Chrvala et al. (2016) in their systematic review [61]. Self-management education could be helpful for patients to obtain these insights and beliefs [62].

Patients need to be supported in managing their T2DM. Self-management support involves a patient-centered collaborative approach to care, promoting active patient involvement, education, and empowerment [63]. Empowerment is a process through which people gain greater control over decisions and actions affecting their health [64]. Improved empowerment may be achieved by promoting patient knowledge regarding T2DM, thus giving patients more insight into their own health situation. The effectiveness of diabetes management ultimately depends on patient compliance with recommendations and treatment [1]. Therefore, patient education is an important component of diabetes management. By understanding the principles and importance of a healthy lifestyle, patients are more likely to successfully adopt lifestyle changes [65].

Fan & Sidani (2018) explored the associations between patient factors and their preferences for types and features of diabetes self-management education interventions. Patients indicated a preference for a combination of educational (information related to self-management), behavioral (training skills associated with lifestyle changes), and psychological (stress, negative mood states, and coping skills) interventions. In addition, patients value face-to-face sessions that allow discussion with diabetes educators to develop and carry out a care plan [66]. To maximize the effectiveness of interventions,

Fan & Sidani (2018) recommended HCPs remain aware of personal and clinical factors that influence patient preferences; this knowledge could promote the tailoring of interventions to fit each patient [66].

Diabetes self-management education can be delivered individually or in a group of patients. Group-based education has the advantage of providing patient meetings that include discussions and peer motivation while being less costly than individual therapy. Furthermore, group-based education has been found to improve clinical, lifestyle, and psychosocial outcomes of patients with T2DM [53,67,68]. In the Netherlands, an example of group-based education is the group-based Proactive Interdisciplinary Self-Management (PRISMA) training program.

Aim and outline of this thesis

To summarize, the prevalence of T2DM is rapidly increasing. In the Netherlands, the projected growth of patients is expected to exceed the number of available HCPs. Therefore, to lower the risk of cardiovascular complications and manage the burden of diabetes on patients and the system, self-management could be part of the solution. Patients need to be supported in managing their T2DM. A person with T2DM needs to make a multitude of daily self-management decisions and perform complex care activities. One method for improving patient self-management, satisfaction, and glucose control is diabetes self-management education [12]. In addition, online care platforms can help to support patients in managing T2DM [47].

The research described in this thesis focused on the self-management skills of patients with T2DM. By offering the group-based diabetes self-management education PRISMA, the aim was to improve patients' self-management in terms of (1) participating more actively during the consultation with their PN, (2) adhering better to the medication, and (3) using an online platform. The PRISMA program was expected to increase patients' motivation to change their behavior and manage their condition using an online platform. Therefore, the objective of this thesis was to investigate whether the PRISMA training program improved patients' use of the online care platform e-Vita.

Research questions

1. Which factors help and hinder active participation of patients with T2DM in consultations with their primary care PNs?
2. What are the effects of a group-based PRISMA training program on quality of life, self-management behavior and clinical outcomes in patients with T2DM treated in primary care in terms of
   a. patient self-efficacy and participation during PN consultations?
   b. adherence to glucose-lowering medications?

c. the usage of the online care platform e-Vita?

This thesis is divided into eight chapters. Chapter 2 describes a qualitative study into the active participation of patients with T2DM during consultations with their PN. Several helping and hindering factors were identified. Chapter 3 shows the protocol of the study, a randomized controlled trial investigating a multicomponent intervention to increase empowerment in patients with T2DM. Chapter 4, 5, 6, and 7 describe the effects of the PRISMA program on patient self-efficacy and participation during PN consultations, medication adherence, usage of an online care platform, self-management behavior, and clinical parameters. Chapter 8 is the general discussion where the main research questions are answered and discussed.

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Chapter 2

Active participation of patients with type 2 diabetes in consultations with their primary care practice nurses

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Abstract

Background

Patients with type 2 diabetes mellitus (T2DM) receiving primary care regularly visit their practice nurses (PNs). By actively participating during medical consultations, patients can better manage their disease, improving clinical outcomes and their quality of life. However, many patients with T2DM do not actively participate during medical consultations. To understand the factors affecting engagement of patients with T2DM, this study aimed to identify factors that help or hinder them from actively participating in consultations with their primary care PNs.

Methods

Two semi-structured focus groups and 12 semi-structured individual interviews were conducted with patients with T2DM (n = 20) who were undergoing treatment by primary care PNs. All interviews were transcribed verbatim and analyzed using a two-step approach derived from the context-mapping framework.

Results

Four factors were found to help encourage patients to actively participate in their consultation: developing trusting relationships with their PNs, having enough time in the appointment, deliberately preparing for consultations, and allowing for the presence of a spouse. Conversely, four factors were found to hinder patients from participating during consultations: lacking the need or motivation to participate, readjusting to a new PN, forgetting to ask questions, and ineffectively expressing their thoughts.

Conclusion

Patients lacked the skills necessary to adequately prepare for a consultation and achieve an active role. In addition, patients' keen involvement appeared to benefit from a trusting relationship with their PNs. When active participation is impeded by barriers such as a lack of patient's skills, facilitators should be introduced at an early stage.

Background

Type 2 diabetes (T2DM) is a chronic condition associated with adverse lifestyle habits. The rapidly increasing prevalence of T2DM in the Netherlands has reached 65 per 1,000 inhabitants of all ages and 230 per 1,000 inhabitants aged 65 years or older [1]. This rate of occurrence is expected to increase by another 30% by 2030 [1]. The success of T2DM treatment largely depends on the patient's ability and willingness to self-manage the disease in daily life, including following advice and adhering to medication [2].

Patients with T2DM regularly visit health care providers (HCPs). These visits are intended to monitor their medical condition and support self-management. Higher levels of patient participation in these consultations have been shown to stabilize blood glucose and improve quality of life [3-5]. Participation in medical consultations refers to actively contributing to the care process by, for example, asking questions, expressing concerns, and stating preferences [6]. As part of patient-centered care,[7,8] patient participation is also a prerequisite for shared decision-making (SDM), which has been demonstrated to improve clinical, psychosocial, and behavioral outcomes [9]. The complexities of changing behavior in T2DM require a counseling-based approach rather than the traditional approach of providing information and advice [10,11].

In the Netherlands, patients with T2DM are primarily treated in primary care by general practitioners (GPs) and their practice staff, including practice nurses (PNs). PNs conduct routine diabetes consultations, including physical examinations, blood glucose checks, and other laboratory tests, every 3–6 months and discuss the results with patients. PNs also inquire about a patient's well-being, occurrence of hypoglycemia or hyperglycemia, lifestyle issues, and adherence to medication. The diabetes care provided by a PN is comparable to that provided by a GP; both GPs and PNs perform lifestyle counseling according to generally acknowledged criteria [12,13].

Thus far, patients have generally not evolved into proactive health care consumers during medical consultations [14-18]. These consultations frequently do not address the use of medication, medication side effects, and lifestyle issues [15,17]. A recent study by Henselmans et al. (2015) revealed that many patients with chronic conditions expressed an interest in communication support [19]. However, patients were reportedly hindered in their communication because they feared being seen as bothersome, perceived time pressure during the visit, and experienced difficulty remembering topics post-visit [19].

Although some previous research on barriers in communication exists, it specifically focused on patients with other chronic conditions,[20,21] patients with chronic conditions in general,[19,20,22,23] or patients with T2DM in countries outside of the Netherlands [10,24]. Consequently, participation of patients with T2DM during PN consultations was not investigated in the Dutch situation before. Therefore, this study aimed to identify the factors that help and hinder active participation of patients with T2DM in consultations with their primary care PNs.

These findings may provide evidence for designing interventions aimed at improving patient participation.

Methods

This study adopted a qualitative design and was registered with the Medical Ethics Committee of Isala (Zwolle, the Netherlands; METC no. 14.07104). The committee declared that the study did not fall under the scope of the Medical Research Involving Human Subjects Act [25,26].

Participants

Primary care treated patients (18 years and older) diagnosed with T2DM were included in this study. Due to their important role in diabetes care, spouses or relatives of the patients were also invited to participate in the interviews [27-29]. A lifestyle-dependent condition such as T2DM is known to influence the daily lives of a patient's spouse, so PNs often invite them to join consultations [10].

Recruitment

In May 2015, all general practices in the Zwolle region of the Netherlands were informed of the study and asked for permission to recruit patients from their practices. In case of permission, the general practices allowed Medrie Care Group in Zwolle to recruit during retinopathy screenings. These screenings are a part of the annual T2DM checkups. Patients were recruited at the Medrie Care Group using flyers and posters. Since all patients with T2DM in the Zwolle region (approximately 12,000) are usually scheduled for these screenings, this recruitment method was expected to result in a representative sample.

During a four-week recruitment period, two practice assistants with experience in performing the retinopathy screening introduced the study to eligible patients. After the screening, each patient interested in participating was enrolled in the study and signed an informed consent form. Subsequently, these patients, and any partners or relatives, were invited by telephone to a focus group at the Medrie Care Group in Zwolle in July 2015. Those who were unable to travel to the focus group location or did not feel comfortable speaking in a group were invited to participate in individual interviews held at their homes in September and October 2015.

Study design

In this study, a two-step approach[20] derived from the context mapping framework was followed [30].

Step 1: Sensitizing

Sensitizing is a process that triggers, encourages, and motivates patients to think, reflect, wonder, and explore aspects of their personal contexts in their own time and environment [30]. This step was intended to enhance the quality and quantity of the patients' contributions in later individual or focus groups [31]. To encourage patients to consider the interview topics in advance, they were invited to formulate their experiences, preferences, and needs and reflect upon them. One week prior to the interviews, the patients received a small booklet with open-ended questions regarding their consultations with their PNs. The questions were divided into the following themes: T2DM diagnosis, discussion about T2DM, consultation with the PNs, and self-reflection. Table 1 presents the booklet questions, which were based on a booklet used in a previous study [20]. To help patients answer the more abstract questions, example answers and small stickers of relevant pictures and words to use as starting points were included. In addition, patient characteristics (sex, age, level of education [low, middle, or high], diabetes duration, familiarity with their PN [slightly, moderately, or very], and type of treatment [lifestyle only, oral medication, or insulin]) were collected. We asked each patient to bring the completed booklet to the individual or focus group. The main objective of this sensitizing process was to promote self-reflection on the part of the patients.

Table 1. Questions asked in the booklets and during the interviews

Booklets		
	Themes	**Questions**
	Characteristics	Sex, age, education, diabetes duration, familiarity with PN, type of treatment.
	T2DM diagnosis	Can you say something about the moment you heard you have diabetes and what this meant to you?
	Discussing T2DM	Who are the three most important people for you to talk to about your diabetes (including at least one care provider)? How do you experience communicating with them?
	Consultations with the PN	Can you say something about the proceedings of your consultations with the practice nurse? (For example: Is there a clear conversation structure? Do you make notes? Do you ask many questions, not that many, or none? If you bring a companion to the consultation, does this person ask questions?) Can you describe your attitude during the consultations?
	Self-reflection	Are there issues you would like to change for yourself before, during, or after a consultation? Are there issues you have already changed regarding your consultations? (For example: Do you prepare for your consultations differently than in the past? Do you ask more, fewer, or other types of questions now than in the past?)

Interviews		
	Themes	**Questions**
	Preparation	Do you prepare for consultations with your practice nurse? If so, how?
	Asking questions	Do you ask questions during consultations? If so, do you often know which questions you need to ask? After the consultations, do you feel that your questions were answered? If you have not asked your practice nurse everything you wanted to ask, what are your main reasons?
	Problems	Do you sometimes experience problems talking with your practice nurse? Why? Why not?
	Active role	Do you want to participate more actively during the consultations? If so, why? What do you hope to achieve?
	Support	What kinds of support could help you during consultations with your practice nurse? How can the practice nurse help you achieve that support?

Abbreviations: PN, practice nurse; T2DM, type 2 diabetes.

Step 2: Individual interviews and focus groups

In the second step, the patients engaged in semi-structured 45-minute individual interviews or semi-structured 90-minute focus groups. Individual interviews allow for a great amount of time and attention to be devoted to a single patient, which often leads to detailed information [30]. Moreover, focus groups enable patients to react to each other's experiences, convey a global view of the topic, and exchange diverse amounts of information [30]. This is expected to lead to deeper insights than individual interviews, in which the patient is less challenged to consider other perspectives.

Permission was requested to audio record the individual interviews and video record the focus groups. Video recordings were necessary for the focus groups, as they facilitated the transcription of the patients' responses. The audio and video recordings will be stored for up to 15 years at Utrecht University of Applied Sciences.

First, the interviewer (EdP) introduced the study by explaining her interest in patient participation in diabetes consultations with their PNs. She further explained that the patients' experiences could help researchers, HCPs, and other patients better understand factors that help or hinder patient participation. The interviewer also emphasized that the PNs would not be judged, as the aim of the interviews was to share experiences anonymously.

Next, the interview started with general questions concerning patient perceptions about their own role during consultations with their PNs. The interviews continued with questions asking what helped and what hindered their participation in these consultations. The interview themes were adopted from empirical literature (inductive). The same topics were discussed and the same questions were asked for both the individual interviews and the focus groups. Table 1 presents the interview questions.

Data analysis

The framework method developed by Ritchie and Lewis [32] was applied for data analysis. This systematic and flexible approach to analyzing qualitative data is most commonly used for the thematic analysis of semi-structured interview transcripts and produces highly structured summarized data as an output. The framework provides seven clear steps, which are presented below [33,34].

Step 1: Transcription

The video and audio recordings were anonymously transcribed verbatim by three students. The transcripts included large margins and adequate line spacing for subsequent coding and notes.

Step 2: Familiarization with the interviews

This stage was particularly important since students transcribed the individual interviews and focus groups, while EdP was responsible for analyzing the data. EdP familiarized herself with the individual interviews and focus groups by repeatedly listening to and watching the recordings.

Step 3: Coding

EdP read the transcripts carefully and highlighted certain codes, such as salient or frequently mentioned words, sentences, or phrases, in both the transcriptions and the comments from the booklets. Coding was intended to classify all data in order to systematically compare it with other parts of the data set. New codes emerged from the process of data analysis (deductive). The MAXQDA software program (VERBI Software GmbH, Berlin, Germany) facilitated the coding process [35]. MAXQDA is designed for computer-assisted qualitative and mixed methods data, text, and multimedia analysis in academic, scientific, and business institutions [35]. The program was used for the organization and analysis of our data, such as the import of transcriptions; reading, editing and coding data; searching and tagging words; and annotating data. MAXQDA also recognizes different speakers of focus groups automatically. Therefore, we could easily compare their contributions and analyze each speaker separately.

Step 4: Developing an analytical framework

After coding the first transcripts, an analytical framework in which codes were placed within categories (e.g., "support of a spouse" and "attitude during the consultation") was developed. Categories were clearly defined, and several iterations of the analytical framework were required before additional codes no longer emerged.

Step 5: Applying the analytical framework

Next, EdP and a diabetes specialist nurse (AW) applied and refined the coding framework

while independently coding the interviews. When this coding framework was used to define every (sub)code, only fragments of texts concerning the helping and hindering factors associated with the consultation participation were coded.

The MAXQDA program expedited this process and ensured that data were easily retrievable at the later stages [35]. Both researchers coded all interviews to determine interrater reliability, and the researchers also discussed new codes and unclear fragments. Credibility was established by discussing the framework and coding with a senior researcher (SvD). A qualitative study is considered credible if its descriptions of human experience are immediately recognized by individuals who share the same experience [33].

Step 6: Charting data into the framework matrix

Reducing data is a vital aspect of the analytical process, during which the original meanings and "feel" of the respondents' words should remain intact. A spreadsheet was used to generate a matrix into which the data were charted. The data of each transcript were summarized by category and references to quotes were included.

Step 7: Interpreting the data

During this step, EdP and AW noted and discussed interesting ideas, concepts, potential themes, and early interpretations. Since the data seemed complete and useful in answering the research question, particular cases were described to illuminate the patients' perceptions of when active participation occurred and why. Patient quotes that illustrate the results were retrieved from the interviews and translated from Dutch to English by EdP and verified by a native speaker. The respondents' names in this article are all fictitious to protect their privacy.

Results were classified using the Feldman-Stewart framework for patient–professional communication within the health care setting. This framework suggests that the patients' attributes in consultations with their HCPs are influenced by their needs, beliefs, values, skills, and emotions [36]. The communication is directly a function of the attributes, or qualities, of each person involved. The framework can help guide assessing the communication process, in particular how the patient interact in the setting of diabetes consultation.

Results

Respondent and interview characteristics

Forty patients were approached as potential participants, 13 of whom withdrew before the start of the study due to logistic reasons (e.g., illness, moving houses, or a hospital visit), and five did not meet the inclusion criteria (see Section 2.1). Of the remaining

22 patients, two did not attend any interview. In total, 20 patients were included in the study, and the mean age of the patients was 71.5 years. All 20 patients had different PNs. In three cases (one men, two women), a spouse accompanied the patient during the interview. Other patient characteristics are presented in Table 2.

Table 2. Patient characteristics

	Participants (*n* = 20)
Men	11
Woman	9
Age, median (IQR)	71.5 (68.0–77.8)
Education (*n*)[a]	
Low	6
Moderate	11
High	3
Diabetes duration	
< 1 year	2
1-5 years	6
5-10 years	7
> 10 years	5
Familiarity with their PN	
Slightly familiar	3
Moderately familiar	3
Very familiar	14
Type of treatment	
Lifestyle only	5
Oral medication	12
Insulin	3

Abbreviations: IQR, interquartile range; PN, practice nurse.
[a]Low = no education or primary education; moderate = lower secondary education, (upper) secondary education or post-secondary non-tertiary education (including vocational education); high = tertiary education (bachelor's degree or higher).

All 20 enrolled patients completed their booklets before the interview. Of these patients, 12 participated in focus groups, and 8 had individual interviews. One focus group consisted of seven patients plus 2 spouses, and the other consisted of 5 patients plus 1 spouse. As the last three interviews did not provide any new information, it was concluded that data saturation had been reached. This means that we reached a point in our analysis of data that sampling more data would not lead to more information related to the research question [37]. The results concerning helping and hindering factors are presented in Table 3.

Table 3. Helping and hindering factors in participation reported by patients, classified by the Feldman-Stewart framework

	Helping factors	Hindering factors
Need	Trusting relationship with a PN	Readjustment to a new PN
	Presence of a spouse	-
Belief	Availability of time	Insufficient need or motivation to participate
Value	-	-
Skill	Preparation for the visit	Forgetting to ask questions
		Expressing thoughts ineffectively
Emotion	-	-

Factors helping with active participation

Trusting relationship with the PN

Patients perceived a trusting relationship with their PNs as a facilitating factor for active participation. In general, patients experienced their PNs' manners of communication as pleasant and warm, which encouraged them to discuss their emotions and concerns. For example, patients felt welcome to discuss problems with adhering to a diet or fear of dealing with complications in the future. One patient explained this trust with an example:

"I was open to her about my candy-eating habits when my weight was too high. When you know each other well, you start to open up more. This process went smoothly; I trusted her soon enough." (aged 68, very familiar with PN)

In a trusting relationship, patients also felt encouraged to discuss issues unrelated to their T2DM, such as their personal situations.

"We talk about the grandchildren we both have, small talk. That has nothing to do with the disease. It is personal. She told me how happy she was when she first became a grandmother. You continue on that subject, and I liked that as well!" (aged 77, very familiar with PN)

Along with personal situations, emotional events in their lives or in the PNs' lives were discussed. Patients indicated that sharing emotional events led to a trusting relationship, which strengthened over time.

Presence of a spouse

Patients who preferred to visit their PNs together with their spouses indicated that they were supported by their spouses because the latter were already familiar with T2DM.

"We visit the practice nurse together. That's nice because my wife has a longer record of dealing with practice nurses than I do, and she knows how they work." (aged 80, very familiar with PN)

Other patients reported that their spouses were more accurate in asking questions or that they considered their spouses to be more careful and precise when asking questions about the disease. One patient spoke about the benefit of having a spouse at an appointment:

"We always go together, as she needs her blood pressure and COPD checked. So, we combine our visits. I find it convenient that she is there with me because I am messy, and she is more precise. I am lazy; why should I know something if somebody else already knows?" (aged 78, very familiar with PN)

Availability of time

Patients indicated that when they did not experience time pressure, active participation was stimulated. The PNs had sufficient time to discuss all necessary subjects, and the patients felt free to ask questions. Thus, questions arose automatically.

According to the patients, the PNs verified whether patients understood them and stimulated patients to ask additional questions or ask for clarification.

"She checks if you understood; and if not, you can ask again. I certainly do that. I ask something that is unclear to me, and then I will ask again." (aged 73, very familiar with PN)

In addition, when patients felt there was enough time, they usually felt welcome to raise (new) topics, even though these discussions might deviate from the PNs' routines.

"The consultation can turn at any given time. For example, when my weight is too high, you might start a conversation about the possible cause." (aged 77, very familiar with PN)

Preparation for the visit

Patients mentioned personal preparation as beneficial in terms of allowing them to actively participate in consultations with their PNs. Some patients commonly prepared questions prior to their consultations, while others formulated questions only out of fear of forgetting them. One patient spoke about list making:

"Making a list of questions is not only a positive influence on me during the consultation; it is something to go by about things I want to say or ask, things that are important to me. That's why I do it. This way I never get the feeling afterwards I forgot something because the list is my starting point. I would like to discuss several topics, but that list should be addressed anyhow." (aged 75, very familiar with PN)

Factors hindering active participation

Readjustment to a new PN

Patients also expressed a need to readjust to new PNs with whom they did not yet have working relationships. In the beginning, patients reported having a wait- and see attitude and had reservations about questioning their PNs. When they had known one another for a longer period, their attitude became more assertive. A patient reported unease with new PNs:

"It is annoying. You must get acquainted again to see what kind of person she is. See which way the pendulum swings, things like that. During my first consultation with her, I was really quiet. As I visited her more often, I felt more comfortable, and our conversations opened up more. You get to know each other better. I did not feel comfortable at first but did at times. And, when you finally trust her, she is replaced by a colleague." (aged 56, moderately familiar with PN)

Some patients described how their PNs used a tone of voice that annoyed them. One patient explained the importance of this tone:

"My practice nurse first struck me as someone who did not know how to address 'yet another patient with diabetes.' I told her I am not a child anymore, she did not need to patronize me. Such a pedantic tone at first. Now, she is just open." (aged 77, very familiar with PN)

Insufficient need or motivation to participate

Most patients described communication between the PNs and themselves as evenly balanced interactions, while a few patients indicated that the PNs played the leading role. Patients also mentioned that they were satisfied with the division of roles in the consulting room:

"I consider it to be just a professional relationship. It is her job to lead the consultation. I am comfortable with that. You must keep the roles clear. It is her job," (aged 78, very familiar with PN).

This division of roles in the consulting room seemed to develop naturally, and the patients did not feel the need or motivation to participate more actively. The patients did not have to determine the agenda, did not feel the need to take the lead, or did not want to "take all they could get." Some patients blamed this lack of need or motivation on the absence of symptoms of their T2DM; they simply did not feel sick. Other patients blamed the mandatory nature of the consultations:

"I go to the appointments because I have to; if these were not necessary, I would rather not go." (aged 45, very familiar with PN)

Patients reported customarily arriving at the consulting room with a wait-and-see attitude or thinking that they only visited the PNs to hear test results. In addition, patients indicated that positive test results often did not lead to discussions, and the issues on the agenda were usually uncomplicated.

"The conversations are not complicated, so I will not run into difficulties." (aged 75, very familiar with PN)

Forgetting to ask questions

The patients reported that they sometimes forgot to ask their questions and stated that this could be due to memory problems caused by their older age. One patient explained this forgetfulness:

"I tend to forget things, so you talk about different matters. Only afterwards you remember what you had actually wanted to ask." (aged 70, very familiar with PN)

Other reasons given for forgetting to ask questions included being distracted or having the consultation take another turn (e.g., to a more social conversation).

"Then, it actually becomes more pleasant [laughs]. As I said, discussing personal things like becoming a grandmother. And then you sometimes forget your questions, and you later think to yourself, 'oh, well." (aged 77, very familiar with PN)

Expressing thoughts ineffectively

The patients occasionally mentioned having trouble expressing their thoughts, which hindered their active participation in the consultations. Patients blamed this feeling on their age and memory loss. Patients also reported that problems in expressing thoughts appeared to be caused by the confusion of having multiple conditions. The difficulties in communicating about their comorbidities deterred patients from bringing up other topics about diabetes:

"I have several different conditions, and diabetes is one of them. If I start to talk about something, she often replies with 'you should discuss that with the doctor." (aged 50, moderately familiar with PN)

Finally, patients indicated having problems in stating their preferences for a more tailored consultation.

Discussion

This qualitative study revealed four helping factors and four hindering factors that may affect active participation of patients with T2DM in consultations with their primary care PNs. First, having a trusting relationship with their PNs encouraged patients to express their emotions and concerns.

Applying the framework of Feldman-Stewart, this positive element could be considered a need. Second, the presence of a spouse (a need) during the consultation could also support participation. Third, the availability of time (a belief) stimulated patients to ask questions. Lastly, preparing for the visit (a skill) helped patients discuss the topics that are important to them. By contrast, the results indicated that participating in consultations could be hindered by the following factors: readjusting to a new PN (a need), lacking the need or motivation to participate (a skill), forgetting to ask questions (a skill), and expressing thoughts ineffectively (a skill).

Needs

The finding that the presence of a spouse could support participation is not surprising because social support is important in diabetes care,[27-29] and the spouses of patients with T2DM play key roles in adhering to and maintaining a healthy diet [28]. Moreover, the presence of a companion was associated with a more task-focused exchange, particularly by the patient [38].

In addition, the barrier of "familiarizing oneself with a new PN" identified in this study suggests that a trusting relationship with a PN, which patients value greatly, is needed to enhance active participation [24].

Skills

An obstacle identified in the Henselmans et al. study [19] (i.e., difficulty remembering discussion topics after an appointments has ended) is comparable to this study's hindering factor of "forgetting to ask questions." However, the other two barriers identified by Henselmans et al. (the desire to avoid being bothersome and perceived time pressure) were not encountered in this study. The discrepancy with the results of Henselmans et al. may be explained by the differences in the study settings. The sample investigated by Henselmans et al [19] consisted of patients with a variety of chronic conditions who usually had a GP or a medical specialist as the primary HCP. The patients in this study, all of whom had been diagnosed with T2DM and were seen in primary care, were treated by PNs. Previous research indicates that patients are more satisfied with the care delivered by PNs than GPs [12].

The patients in this study were primarily older adults—which was not surprising as T2DM primarily affects older adults—and they mentioned that "forgetting to ask questions" could be caused by memory problems. The patients also indicated that

"having problems expressing their thoughts" interferes with participation. According to the literature, elderly patients appear to ask fewer questions and obtain less medical information than younger patients [16]. While these issues may be age related, health literacy could also play a role because the study primarily included patients with low or middle levels of education. Patients with low literacy levels feel less confident and perceive more barriers in communication [19].

Beliefs

Although patients with T2DM may have concerns and questions that they rarely discussed with GPs,[39] in this study, patients did not report experiencing time pressures and instead felt free to ask questions while interacting with their PNs. This finding could be explained by the fact that consultations with PNs are twice as long as those with GPs[16] and that patient participation is more limited in short consultations [40,41]. In addition, another explanation could be the fact that most patients in our sample were very familiar with their PN. Since the introduction of PNs in the Netherlands in 1999, patients with chronic conditions have become more satisfied with the care delivered [13]. Many patients with diabetes prefer to be supervised by a PN instead of a GP [42]. because PNs have more time for patients and superior knowledge about diabetes [42]. Patients value the fact that the PNs take them seriously, listen carefully, are open, take sufficient time, and provide adequate advice on how to manage complaints [18,42]. This could explain why patients did not mention an issue related to the relationship of authority with their PN.

Considering the age of the population, it is difficult to determine the actual statuses of the patients' health or whether other health problems may be contributing factors. Some patients may view other health problems as graver issues than T2DM. In addition, the absence of disease burden in T2DM, which is particularly relevant for recently diagnosed patients,[43] could lead to a lack of motivation and willingness both to adopt an active role during consultations and to accept lifestyle changes.[30] In a study examining the readiness of patients to discuss psychosocial problems with PNs during diabetes consultations, Van Dijk et al. (2016) showed that patients view a consultation primarily as a biomedical check-up [44]. Thus, they did not expect to talk about psychosocial problems with their PN. Similarly, we found that patients who lacked the need or motivation to participate only visited the PNs to be information about test results.

Patient participation in consultations should always be considered in its context. Most barriers that PNs perceive with respect to lifestyle counseling in general practice are at the patient level, such as a lack of motivation to modify their lifestyles or insufficient discipline to maintain an improved lifestyle [45]. In this study, we aimed to take a closer look at the patient perspective; however, PNs also need the skills to engage patients. General practice staff in diabetes care, such as PNs, express positive views

towards actively engaging their patients,[46] which is an important element of SDM [47]. This attitude may explain why most patients in the present study were satisfied with the current mode of participation in the consulting room. T2DM is a complicated and demanding disease, and improving outcomes requires more than improving patient participation during the consultation with PNs. However, relatively small solutions could significantly contribute to improvements in diabetes care [48].

This study has several strengths. First, a varied sample of patients with T2DM was included; patient demographics varied widely in sex, education level, diabetes duration, and type of treatment. Second, by using more than one interview approach, it was possible to capture a wide variety of information.[49] Although the results of the focus groups and the individual interviews were analyzed separately, the focus groups were particularly useful for cataloguing the range of patients experiences, and individual interviews contributed specific details of these experience [50]. The combination of individual interviews and focus groups methods was used to strive not only for data completeness and confirmation [51,52] but also for practical considerations. Offering individual interviews to patients unable or unwilling to attend a focus group may have led to fewer refusals or withdrawals [53], as individuals could choose the method that is most convenient to them. Third, the patients seemed well-prepared during the research interviews. The sensitizing process may have enhanced their contributions during the interviews by facilitating the expression of their thoughts about helping and hindering factors. In the focus groups, patients referred to the stories they wrote down in their booklets, which demonstrates the reflection effect of the sensitizing phase. Fourth, because patient participation is an abstract topic, interacting with other patients and hearing their ideas seemed to be helpful to stimulate patients to talk about their own experiences. The presence of a spouse may also have improved the patients' willingness to share experiences.

Some limitations must also be mentioned. First, due to the abstract nature of the topic, some patients found the booklet questions difficult to answer. They indicated that they did not have an opinion and had not previously thought about the helping and hindering factors in participation. Second, recall bias might have affected the results because we asked the patients about experiences in the past. Third, although multimorbidity was a contributing factor to the study's findings, no medical health data were collected on these patients. Fourth, because our respondents came from a region in the eastern part of the Netherlands, it is possible that they do not reflect the entire Dutch population with T2DM, which may affect the external validity of this study. Fifth, because patients were recruited during diabetes retinopathy screenings, patients with diabetes retinopathy treated in the secondary care who have probably more complications were not included. The fact that patients could choose between an individual interview or focus group might have introduced bias.

Conclusions

Patients' needs, beliefs, and skills influence their participation during consultations. In particular, patients' skills with regard to taking the lead, expressing thoughts, and preparing for the visits seem to be lacking. However, a trusting relationship with their PNs, which usually develops over time, can help patients to discuss their emotions and concerns. The majority of patients in the study seldom felt the need to participate more actively. This attitude is most likely due to the perceived absence of disease burden and satisfaction with their current roles in the consulting room.

Practical implications

This study can inform HCPs and policymakers about how patients with T2DM and other chronic diseases can benefit from consultations with a PN. Practice nurses should take into account the potential lack of skills of their patients. Apparently, patients are satisfied with the current modus of participation in the consulting room. Trusting relationships with their PNs, which are usually developed over time, help them to participate more actively. The importance of trust was supported by patients who reported playing a passive role in consultations with new PNs, demonstrating the need to search for other methods to improve self-management behavior. When a patient and a PN are not familiar with each other, the new relationship requires an extra investment of time. In addition, particularly in general practices with several PNs, patients have a need for a PN "of their own." Other implications are the potential value of encouraging patients to write down questions in advance of the consultation (using a question prompt sheet) [54] or visiting the PN together with their spouses. Future research should explore how multimorbidity influences active participation during PN consultations. Furthermore, the development of an intervention trial versus usual care could be of interest, where patients in the intervention group receive support to capitalize on helping factors and to handle hindering factors.

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Chapter 3

DESTINE: a multi component intervention to increase empowerment in patients with type 2 diabetes

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Abstract

Background

Self-management plays a central role in diabetes management. However, not all patients are able to translate the health care providers' recommendations for effective self-management in daily life. Diabetes Education and Selfmanagement To INcrease Empowerment (DESTINE) primarily investigates the effects of group education program PRoactive Interdisciplinary Self-MAnagement (PRISMA) in primary care treated people with type 2 diabetes mellitus (T2DM) on the use of an online care platform.

Methods

The DESTINE study has a Randomized Controlled design (1:1). 200 patients with T2DM using an online care platform called e-Vita will receive either PRISMA in addition to usual care or usual care only. The primary endpoint of this study is usage of the e-Vita platform. The secondary endpoints are participation in the consultation with the care provider, adherence to oral diabetes medications, and a selection of self-reported and clinical measures. After six months, both groups will receive PRISMA in a 6 month extension phase.

Discussion

PRISMA focuses on aligning treatment goals from different health care providers while the individual patient remains in the lead. The goal is to shift patients from being an information receiver towards applying self-management and becoming empowered health care participants. Though recognized as important, theoretically based group education is still not routinely offered in the Netherlands. In the future, depending on the study results, e-Vita and PRISMA could be implemented in regular diabetes care.

Background

Worldwide, the prevalence of diabetes mellitus is increasing dramatically. The number of people with diabetes has risen from 108 million in 1980 to 422 million in 2014 [1]. The prevalence in the Netherlands is expected to rise from 830,000 in 2011 to over 1,300,000 in 2025 [2]. Over 90% of this population is estimated to have type 2 diabetes mellitus (T2DM) [3]. In the Netherlands, T2DM is mainly treated in primary care, where the general practitioners (GP) usually see patients once a year to manage their diabetes. In addition to these GP visits, every three to six months, the primary care practice nurse (PN) checks the patients' body weight, blood pressure and (fasting) blood glucose levels. The PNs also inquire about their patients' well-being, hypo- or hyperglycemia, nutrition, exercise and medication, when indicated.

Self-management plays a central role in diabetes management [4]. Influential self-management behaviors are using a healthy diet, being active, acting upon self-measured blood glucose levels when needed, taking medication according to prescription, and problem solving [5]. Unfortunately, not all patients are able to translate the GPs' and PNs' recommendations for effective self-management into appropriate action in daily life [6]. For many people with T2DM, self-management is challenging, since they do not possess adequate knowledge, skills or motivation to initiate and maintain behaviors that can help them control their condition [7]. Furthermore, although good communication between a PN and a patient can help to properly manage their condition [8,9], many patients have not yet evolved into active health care consumers when it comes to medical consultations [9].

In addition, the number of PNs will not keep up with the projected growth in patient numbers. Therefore, diabetes care will be in need of a decrease in the workload per patient for PNs, which eventually will result in a decrease in face-to-face time per patient. The general growth of health care costs will further restrict the possibilities to spend adequate time per patient [10]. Consequently, this implies the necessity of alternative forms of support, treatment, and patient self-management [3].

Improving patient empowerment could not only lead to more/increasingly empowered patients, but could also decrease the workload of PNs. Improved empowerment may be achieved by promoting patient knowledge regarding T2DM and thus giving patients more insights into their own situation. Patients may also obtain these insights using web based self-management programs [11]. In 2012, an online care platform (e-Vita) was developed in the Netherlands. This platform was designed to offer people with T2DM insight into their diabetes-related health data as well as to educate and inform them on their condition and their data [12]. Users of this platform had lower HbA1c levels compared to non-users [13]. Furthermore, users reported higher quality of life and improved medication adherence, and suffered less from diabetes-related distress.

However, offering patients this platform alone did not yield the usage results that were expected; of 633 patients registered for platform use 57% never logged on, 29% logged on once and only 14% logged on for at least two sessions [13]. Even though this platform was designed to be suitable and available for all people with T2DM, the interested patients were primarily men, younger, more often higher educated and had a shorter diabetes duration [14].

In the current study, called Diabetes Education and Self-management To Increase Empowerment (DESTINE), the primary objective is to test the effect of the PRoactive Interdisciplinary Self-MAnagement (PRISMA: a program that aims to specifically increase self-management skills in people with T2DM) group education program on the use of the e-Vita care platform. The secondary objectives are to test the effect of the PRISMA group education program on participation in the consultation with the PN, adherence to oral diabetes medications and a selection of self-reported and clinical measures.

Patients and methods

Study design

The study will be a Randomized Controlled Trial (RCT), as shown in Fig. 1.

Recruitment

We will use a small-scaled implementation strategy. General practices in the region of Zwolle, a city in the east of the Netherlands, will be included. The PNs will all be trained by the author (EdP) in the month prior to the first study activity.

Next, the GPs will make a selection of their patients with T2DM and exclude the patients not matching the inclusion criteria. The selected patients will be recruited by the primary investigator (EdP). This process will be mediated by the GPs. These patients will receive information about the study, including an informed consent form. The patient is encouraged to ask his or her treating PN and/or GP or the investigator any question about the study. After giving informed consent, patients will be included in the study.

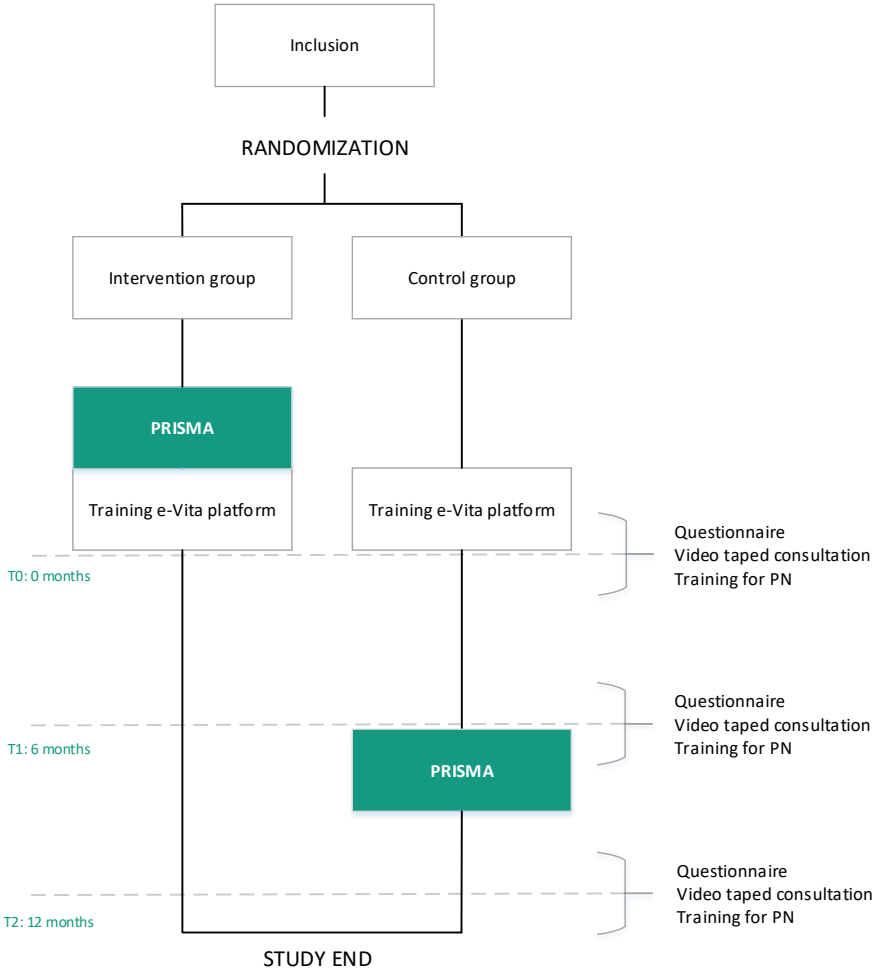

Figure 1. Trial design

Study population

People of 18 years and older, diagnosed with T2DM (ongoing and newly) and treated in one of the participating general practices with the GP defined as their main caregiver will be included.

The following exclusion criteria will apply: 1) insufficient knowledge of the Dutch language to understand the requirements of the study and/or the questions posed in the questionnaires, 2) mental retardation, psychiatric treatment for schizophrenia, 3) mental disorder or bipolar disorder, 4) life expectancy less than one year due to malignancies, 5) and any other condition that according to the investigators may interfere with trial participation or evaluation of results, for example multiple sclerosis or dementia.

Description of the intervention

The PRISMA group education program will be offered in addition to usual care. PRISMA aims to improve self-management skills in patients with T2DM [15,16], and is based on the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) program developed in the UK. The DESMOND programs' curriculum has been described in detail elsewhere [16].

The philosophy of PRISMA is based on patient empowerment. This program is adapted by the VU University Medical Center in Amsterdam specifically for patients [17] and grounded in the following four psychological models: the self-regulation theory [18], the dual process theory [19], the self-determination theory [20], and the social learning theory [21].

In short, the PRISMA program consists of two meetings of 3.5 hours with a group size of maximum 12 patients plus possible partners. Groups are guided by two diabetes professionals, for example a dietician and a PN. These trainers have followed a standardized training program to ensure the quality of information delivery. PRISMA aims to empower patients by using a non-didactic learning approach. Patients are stimulated to consider their own personal risk factors and to choose a specific goal of behavior change.

Usual care

Visits at the GP or PN

In line with clinical guidelines at that time, patients of the participating general practices should have 2 to 4 visits a year with their GP or PN, one of which is an annual check-up.

The e-Vita platform

The current study elaborates on the study performed by Roelofsen et al. (2014). For the present study, an improved version of the e-Vita care platform will be developed. Technical and visual adjustments will be conducted to increase usability. e-Vita offers patients the following four functions: firstly, view and track their lab results of the last three visits at their GP or PN; secondly, formulating and monitoring their health related actions and goals; thirdly, conversing with their PN; and fourthly, taking part in educational modules about T2DM tailored to their actual knowledge.

Training for PNs

We will use the following strategies to involve the PNs of the participating practices in our study. First, the PNs will be trained in using e-Vita as well, in order to be able respond to their patients' messages and questions about the platform and to follow their patients' activity in educational modules. Second, the PNs will be stimulated to take part in one of the PRISMA courses along with their patients to become familiar with the non-didactic learning approach of PRISMA, which they can implement in

their consultations afterwards. Last, the PNs will be invited to participate in trainings to improve their communication skills (motivational interviewing) in interactions with their patients. These trainings will not be linked to the randomization order of the patients and will be organized by EdP in cooperation with a care group.

Outcomes

Baseline and outcome parameters will be measured at the start of the study (T0), and after 6 months (T1) and 12 months (T2), respectively. Table 1 shows a time schedule of the data-collection.

The patient profile includes the following parameters: surname, family name, gender, birth date, home address, and level of education.

Table 1. Time schedule of data-collection

			T0	T1	T2
		Months	**0**	**6**	**12**
	Patient profile		X		
Primary outcome	Use of platform			X	X
Secondary outcomes	Self-reported data (questionnaires)		X	X	X
	Participation in consultation with PN (videos)		X	X	X
	Adherence to diabetes medication		X	X	X
	Clinical measures		X	X	X

Primary outcome

The primary endpoint of this study is usage (number of log-ons and time spent per session) of the e-Vita platform. Log-data will be used to track individual use of the platform over time.

Secondary outcomes

Self-reported data (questionnaires)

The following parameters will be examined through questionnaires (see Appendix 1): Well Being (WHO-5 scale) [22], Health Related Quality of Life (EQ-5D) [23], Self-Reliance (PAM) [24], Quality of Received Care (HowRwe), eHealth Literacy (eHEALS) [25], Diabetes Self-management Behavior (SDSCA) [26], Self-Reported Adherence to Medication Prescriptions (MARS-5) [27], and Self-Efficacy in Patient-Physician Interactions (PEPPI-5) [28].

Participation in consultation with PN (videos)

After providing PRISMA to the intervention group, the participants' consultations (intervention and control group) about their condition with their PN will be recorded

by an unmanned camera at T0, T1 and T2 in order to analyze verbal as well as non-verbal behavior.

- Verbal behavior: the videotaped consultations will be reviewed using relevant communication categories from the Roter Interaction Analysis System (RIAS) to analyse the level of information exchange and the topics discussed (condition, treatment, lifestyle, psychological issues).
- Non-verbal behavior: coding of eye gaze direction, which is a sign of participation, will be done by coding 'patient – PN' directed gaze, 'PN – patient' directed gaze and 'PN – computer' directed gaze.

Adherence to diabetes medication

Information with regards to the amount of prescribed diabetes medication and rates and times of prescriptions will be derived from the pharmacies connected to the participating GPs. We will extract the medication status and medication history out of the pharmacy's information system. Next, we determine adherence using the Medication Possession Ratio, specifically suitable for oral diabetes medication [29].

Clinical measures

Clinical measures described in the national medical guidelines of diabetes parameters (see Appendix 2) will be included in the study to objectify a person's health status. These clinical measures are already being collected by the participants' PN (and GP) during their routine check-ups, and will be sent anonymously to KCK for research purposes.

Participant flow

In the intervention group, participants will start with receiving PRISMA on top of usual care including platform usage (Fig. 1). The control group will continue to receive usual care including platform usage for the duration of 6 months and will be offered PRISMA after 6 months.

In both groups participants will get the option to voluntarily use the platform and its educational content in order to get more control over their health process. Therefore, participants will be registered on e-Vita and will be invited for a training about this platform. They will be introduced to e-Vita and receive login data during the training. After this training participants are able to start using the platform immediately. Consultations between the participants and their PN will be video-recorded and participants are asked to complete a questionnaire at three points during the study (0, 6 and 12 months).

The clinical measures collected by the KCK will be combined with the results of the collected questionnaires to assemble a complete dataset on each included subject.

Randomization

From the start of the study, participants will be included based on the availability of PRISMA training capacity. The PRISMA groups will consist of 10 patients. Participants will be randomized in 10 blocks of each 20 participants at patient level in a general practice (see Fig. 1) using a randomization list. The inclusion period will last 12 months. There will be no blinding for the participant, investigator and PN after assignment to either intervention.

Data

The reliability of the registered data in the IT-system of the GP warrants their use for research purposes. Using a research ID for every patient, all data will be collected and analyzed anonymously. Personal data gathered in this study will be stored encrypted in our database using the Rijndael cryptographic algorithm [30]. The video recordings will be processed and encrypted anonymously, are never used for public display (not for lectures or presentations) and will be stored securely at the Netherlands institute for health services research (Nivel). The video recordings will be stored for a period of up to fifteen years.

Statistical analysis

All analyses will be conducted by using IBM SPSS Statistics version 22. Normally distributed data will be presented as means and standard deviation, abnormally distributed data as median and interquartile range. Dichotomous/categorical data will be presented as numbers and percentage of total. To evaluate differences in target variables (use of the online platform: number of log-ons and time spent per session) over time and between arms, a T-test or Mann-Whitney test will be used.

In addition, we will use (generalized) linear mixed model, depending on the distribution of the target variables, where time will be used as within-subjects variable. Immediate start with the platform or one year later will be used as a between-subjects factor. Relevant variables will be added as a covariate in the analyses. To provide unbiased comparisons among the groups and to avoid the effects of dropouts, an intention to treat analysis will be conducted. Also, per-protocol analysis will be conducted to compare groups including only patients who attended PRISMA.

Sample size calculation

To show a difference on the primary outcome measure 'usage of the e-Vita platform' of 0.15 in the control group versus 0.35 in the intervention group with a two-sided risk alpha of 5% and a power of 80%, in both groups 81 individuals are needed using the unpooled Z-test. With an expected drop-out rate of 20%, we will include 200 patients in our RCT, 100 patients in each group.

Discussion

Strengths/limitations

Our study design attempts to eliminate the following aspects that could affect the results. First, participant's experiences with health information seeking behavior on the Internet could vary before the start of the study. Therefore, we will measure eHealth literacy using 4 items of the eHEALS questionnaire [25]. Second, it could be necessary to make adjustments to the e-Vita platform during the study, for example when technical problems occur. These adjustments will be monitored accurately by EdP. Third, experiences with communication techniques and motivational interviewing could vary between the participating PNs. This will depend on whether or not the PN works as PRISMA trainer.

Because of the nature of the treatments, the study will not be blinded. To limit bias, the randomisation will be conducted under blinded conditions using a randomization list, also analyses will be performed blinded by labelling the groups with nonidentifying terms.

Further implementation

Improving patient empowerment could not only lead to better empowered patients, but may also decrease the workload of diabetes HCPs. The e-Vita platform and the PRISMA program are additional to routine care and focus on aligning treatment goals from different HCPs while the individual patient remains in the lead. The goal is to shift patients from being an information receiver towards applying self-management and becoming empowered. The current study investigates whether our practice-based intervention (e-Vita plus PRISMA) will improve patient empowerment by involving patients in their own treatment, thus resulting in increased quality of life and a reduction of medical care utilization.

Offering patients e-Vita alone did not yield the usage results that were expected [13]. The participation rate and the continuity of e-Vita use by patients appeared to be low. Training patients and HCPs in the use of the online platform seems essential, as well as improving the usability of the platform. In the current study, we will focus on these aspects.

Theoretically based group education, such as PRISMA, can influence health, psychological and lifestyle outcomes [30-32]. In the UK, everyone diagnosed with T2DM is offered theoretically based group education. Though recognized as important, such programs are still not offered routinely in the Netherlands. Nowadays, the most frequently offered program is PRISMA, which is mainly offered in primary care. In the future, depending on the study results, e-Vita and PRISMA could be implemented in regular diabetes care.

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Appendix I: self-reported outcomes (questionnaires)

Well Being (WHO-5 scale)

The five items WHO-5 questionnaire covers positive mood, vitality and general interests [22]. The WHO-5 measures not only the absence of symptoms but also gives a reliable indication of mental well-being. This includes the following dimensions: cheerfulness, calmness, being active, waking up fresh and rested, general interests.

Health Related Quality of Life (EQ-5D)

Health-related quality of life will be tested by using the EQ-5D-3L questionnaire. The EQ-5D-3L is a generic instrument for describing and valuing health. It is based on a descriptive system that defines health in terms of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression [23]. Each dimension has three response categories corresponding to no problems, some problems, and extreme problems. The instrument is designed for self-completion, and respondents also rate their overall health on the day of the interview on a 0–100 hash-marked, vertical visual analogue scale (EQ-VAS). The EQ-5D-3L has been widely tested and used in both general population and patient samples and has also been used in patients with diabetes [23].

Self Reliance (PAM)

Patient's knowledge, skills and confidence for self-management will be measured with the Patient Activation Measure (PAM). The PAM segments people into one of four progressively higher levels of activation [24].

Quality of Received Care (HowRwe)

Patient evaluations of general practice will be measured with the howRwe questionnaire. This questionnaire has four items which focus on waiting time, listening and explanation, care and respect and expectations. Each item is rated using four levels (excellent, good, reasonable, bad). The questionnaire has an aggregate scoring scheme with a range from 0 (worst) to 12 (best).

eHealth Literacy (eHEALS)

eHealth literacy will be determined by an adapted version of the eHealth Literacy Scale (eHEALS) [25]. From this 8-item questionnaire, the 4 most relevant items will be used. This instrument is designed to provide a general estimate of patients' eHealth-related skills. Our version includes the following dimensions: finding helpful health resources on the Internet, how to use the Internet to answer health questions, telling high quality from low quality health resources on the Internet and feeling confident in using information from the Internet to make health decisions.

Diabetes Self-management Behavior (SDSCA)

The Summary of Diabetes Self-Care Activities (SDSCA) measure is a validated self-report questionnaire that includes 11 core items, along with 14 additional questions that may be used, that assess diabetes self-management behavior in relation to general diet, specific diet, exercise, blood glucose testing, foot care and smoking [26]. For example, patients will report how many days in the previous week they engaged in a certain activity. The inclusion of this measure in studies of diabetes self-management is recommended when appropriate [26].

Self-Reported Adherence to Medication Prescriptions (MARS-5)

The Medication Adherence Rating Scale (MARS) will be used to assess self-reported adherence to medication prescriptions. This measure can be administered in any clinical setting and is quick and simple since it only contains 5 questions that require a Yes or No answer [27]. The number of items and range of response options emphasize a continuum of adherence behavior, in contrast to other scales with dichotomous responses. Furthermore, the MARS has been used to assess medication adherence in a variety of health populations, including diabetes [27].

Self-Efficacy in Patient-Physician Interactions (PEPPI-5)

The Perceived Efficacy in Patient-Physician Interactions scale (PEPPI) is a validated measurement of patients' self-efficacy in obtaining medical information, and the attention of physicians to their medical concerns. PEPPI is a 5-item survey, scored on a scale of 1 (not confident at all) to 5 (very confident) [28].

Appendix 2: clinical outcomes measures

- Quetelet index (BMI)
- Systolic blood pressure
- Diastolic blood pressure
- Creatinine
- Cholesterol total
- HDL
- LDL
- Albumin / Creatinine ratio
- Triglycerides
- MDRD (GFR)
- Cockcroft
- Inspection left foot
- Inspection right foot
- Blood circulation left foot
- Blood circulation right foot
- Monofilament test left foot
- Monofilament test right foot
- SIMMS classification
- Date last fundoscopy
- Fundus photo assessment
- Diabetic retinopathy left eye
- Diabetic retinopathy right eye
- Smoking
- Quit smoking advice given
- Use of alcohol
- FiveShot questionnaire
- Diabetes medicine
- Antihypertensiva
- Antilipaemica
- Influenza vaccination (ATC)
- Influenza vaccination (ICPC)
- Additional medication
- Cardiovascular complications / risk facts
- (Micro)-vascular complications
- Mental disorders
- Other relevant history

Chapter 4

Effects of the Proactive Interdisciplinary Self-Management (PRISMA) program on patient self-efficacy and participation during practice nurse consultations

Currently in press:
du Pon, E, van Dooren AA, Kleefstra N, van Dulmen S. Effects of the Proactive Interdisciplinary Self-Management (PRISMA) program on patient self-efficacy and participation during practice nurse consultations: An open randomized controlled trial in type 2 diabetes. J Clin Med Res.

Abstract

Background

Nowadays, patients with chronic conditions such as type 2 diabetes need and want to be more active participants in their health care. This study aimed to investigate the effects of the Proactive Interdisciplinary Self-Management (PRISMA) training program on participation during consultations with practice nurses and self-efficacy of patients with type 2 diabetes mellitus in general practice.

Methods

Within a randomized controlled trial, patients were followed for six months. They received either PRISMA in addition to usual care or usual care only. Self-efficacy was assessed using the Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) scale. Consultations were video-recorded and analyzed using the Roter interaction analysis system. Multilevel analysis was carried out.

Results

No differences in the PEPPI-5 were found between the intervention (n = 101) and control groups (n = 102) (U = 1737.5, z = –0.2, p = 0.8). In addition, the groups did not differ in patient participation. However, patients who attended the PRISMA program expressed more counseling utterances (B = 0.22; SE = 0.09).

Conclusions

PRISMA did not result in higher self-efficacy or patient participation during the consultation with practice nurses at six months. Possibly, two training sessions are insufficient and a more powerful intervention might be needed. However, the study showed indications that patients counseled themselves more frequently during the consultation. Practice nurses could stimulate patients who are already engaged in self-counseling by further specifying their goals of behavior change.

Introduction

Today, patients need and want to be more active participants in their health care. This is especially the case for patients with chronic conditions, such as type 2 diabetes mellitus (T2DM).

In the Netherlands, 51 per 1,000 persons are currently affected by T2DM. This rate is expected to increase to 80 per 1,000 inhabitants by 2025 [1]. Patients with T2DM are primarily treated in general practice where they usually see a general practitioner once a year to manage their diabetes and a practice nurse (PN) once to three times a year for routine assessments. In terms of clinical parameters, the quality of the diabetes care provided by a PN is comparable to that provided by a general practitioner [2]. In most patients with T2DM, the cornerstone of the cause and the management of the disease is lifestyle. Treatment success depends on patients' active involvement in self-management behavior and their willingness to adhere to lifestyle advice and medication changes [3]. Therefore, it is important to fully benefit from the consultations with PNs. Due to the absence of perceived disease burden in T2DM, many patients are not encouraged to change their lifestyle and adhere to their medication regimen [4].

Making informed choices about treatment and discussing them with health care providers (HCPs) is one of the core skills in self-management [5]. Active involvement in self-management can be reflected in, among others, a patient's self-efficacy and participation in medical consultations. Because self-efficacy determines the initiation of coping behavior, it is a very important precondition for behavioral change [6]. In addition, participation in medical consultations is defined as the extent to which patients contribute to the conversation by, for example, asking questions, expressing concerns, and stating preferences [7]. Many patients with a chronic condition experience at least one barrier to participation, and a considerable portion would like to receive support in communicating with their HCP. Reported barriers to participation include (1) not wanting to be bothersome, (2) perceiving time pressure, and (3) forgetting discussion topics during the appointment [8]. Skills necessary to overcome these barriers appear to be insufficient in some patients [9]. However, PNs express positive views toward active engagement of their patients [10], which is an important element of shared decision-making [11]. HCPs consider their role to be advisory and aim for patient centeredness.

In the Netherlands, the group-based Proactive Interdisciplinary Self-Management (PRISMA) training program was developed for patients with T2DM in primary care. It was adapted from the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) program, which was designed in the UK for primary diabetes care [12-14]. One important topic during PRISMA is communication with HCPs; patients are encouraged to prepare for their diabetes consultation and discuss their goals with their HCP. As previous research showed that communication skills training interventions increase patient participation during

medical consultations [15,16], this PRISMA topic was expected to improve self-efficacy and participation during PN consultations. This, in turn, is expected to lead to improved health outcomes [17-19]. PRISMA appears to improve self-management behavior in terms of dietary behaviors, foot care, and action planning [20]. In addition, a pilot study showed that the PRISMA program is promising in decreasing dietary intake in newly diagnosed, overweight patients with T2DM in secondary care [14]. However, empirical studies examining the effects of group education on patient self-efficacy and participation during diabetes consultations are lacking.

The present study aimed to investigate the effects of PRISMA on self-efficacy and participation during PN consultations in patients with T2DM treated in general practice. Because communication with HCPs is an important aspect of self-management, a change in participation due to PRISMA can be expected. The primary research question was as follows: what are the effects of PRISMA on patient self-efficacy regarding the communication with their PNs? The secondary research questions were as follows: what are the effects of PRISMA on patient participation during consultations with PNs in terms of asking questions and providing counseling and information on T2DM-related topics (medical condition, therapeutic regime, lifestyle, psychosocial issues), and which medical and demographic patient characteristics influence patient participation?

Materials and methods

Design

The current study was part of a larger study, which has been described in detail previously [21]. In short, this study had a randomized controlled trial design in which patients were followed for six months. The patients received either PRISMA in addition to usual care or usual care only. A power calculation was carried out on the primary outcome measure (platform use) resulting in 81 participants in both groups [21]. A sample size calculation was not specifically performed for examining effects on self-efficacy and patient participation for the present study. Usual care included a visit to the general practitioner once a year and a visit to their PN one to three times a year to manage their disease. HCPs ask patients about their well-being, hypoglycemia or hyperglycemia, diet, physical exercise and medication use. The current study was a video-observation study. After providing PRISMA to the intervention group, the first consultations between the PNs and the patients were recorded by an unmanned camera to analyze their interactions.

This study was reviewed by the Medical Ethics Committee of Isala Hospital (Zwolle, Netherlands), which decided that, according to Dutch law, formal approval was not necessary (METC no. 14.07104). The study was conducted in accordance with the Declaration of Helsinki and registered at the Dutch Trial Register (no. NTR4693).

All participants gave written informed consent.

Participants

Patients aged ≥18 years or older who were diagnosed with T2DM and treated in one of the participating general practices with the GP defined as their main caregiver were included. Patients with the following conditions that according to the general practitioners may have interfered with trial participation or evaluation of results were excluded [21]: (1) insufficient knowledge of the Dutch language to understand the requirements of the study and/or the questions posed in the questionnaires, (2) intellectual disability or psychiatric treatment for schizophrenia, (3) mental disorder or bipolar disorder, (4) life expectancy less than one year due to malignancies, or (5) any other serious condition that according to the general practitioners may interfere with trial participation or the evaluation of results.

Recruitment

Eight general practices in the eastern part of the Netherlands participated in the larger study, of which six also participated in the video-observation portion. Two general practices withdrew due to a heavy workload. The general practitioners selected all eligible patients who were then informed in detail and recruited by the primary investigator (EdP).

Intervention

The PRISMA program was offered in addition to usual care. PRISMA aims to empower patients by using a nondidactic learning approach. Patients were stimulated to consider their own personal risk factors and choose a specific goal of behavior change. The PRISMA program consisted of two sessions of 3.5 hours each. Groups were guided by a dietician and a PN, both experienced in diabetes care. These trainers had followed a standardized training program to ensure the quality of information delivery.

In the first session, the following aspects were covered: individual experiences with T2DM [14], the effect of insulin or oral blood glucose–lowering medication on blood glucose levels, hyperglycemia or hypoglycemia, the monitoring of blood glucose levels, nutrition (carbohydrates), body weight, and stages of behavior change. At the end of the session, patients self-assessed their perceived stage of change given current nutrition and physical activity factors. The second session involved a review of the first session, discussions on complications and personal risk factors, nutrition (fat), physical activity, and the patients' individual diabetes action plans. For the latter, patients chose a specific behavior change goal, such as "I'll take a walk every morning," "I'll quit smoking," or " I will ask two important questions during my next consultation". The last part of the second session specifically focused on communication with the HCPs. The trainers encouraged the patients to consult their HCPs when necessary and stimulated

them to think about questions to discuss during future consultations. To help them remember, patients were asked to write down their questions beforehand. The patients were also encouraged to discuss their individual action plans with their HCP during their next consultation and bring up the topics important to them.

In the intervention group, the participants received PRISMA on top of usual care (Figure 1).

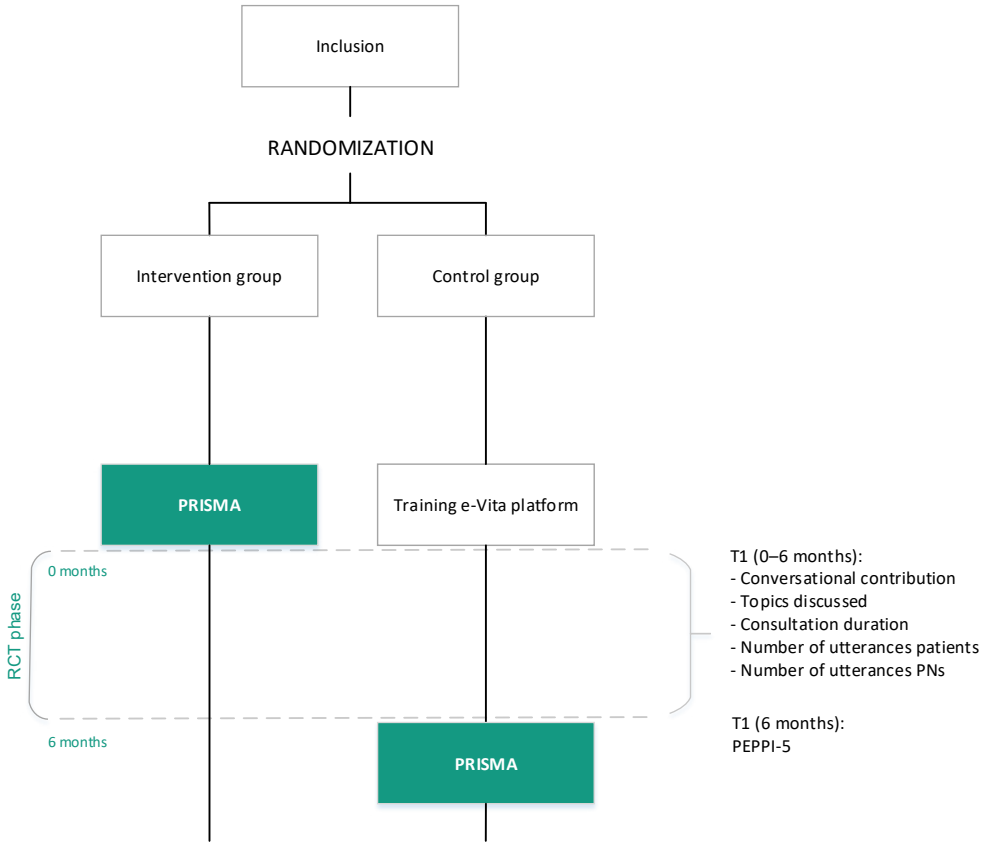

Figure 1. Trial design.

RCT = randomized controlled trial; PRISMA = Proactive Interdisciplinary Self-Management; PEPPI = Perceived Efficacy in Patient-Physician Interactions; PN = practice nurse.

Randomization

The primary investigator (EdP) performed non-stratified block randomization to assign participants to one of the two groups. The participants were randomized over all general practices in 10 blocks of 20 participants each (10 per group). The blocks were generated

by the order of participants' entry (e.g., when 20 participants had applied, they were randomized into two groups). The group assignment was not blinded to participants, the investigator, or the HCP.

Outcomes

The effects of PRISMA were measured by investigating patient self-efficacy and patient participation during consultations with PNs in terms of asking questions, counseling, providing information on T2DM-related topics, and the extent to which these topics were discussed between patients and PNs. Furthermore, the proportion of utterances made by the patients and PNs was used as a global indicator of conversational contribution. The duration of the consultation was also noted.

Patient self-efficacy

Patient self-efficacy has been defined as the belief that patients can successfully take appropriate and meaningful action [22]. The self-efficacy of patients when interacting with PNs was assessed using the 5-item version of the Perceived Efficacy in Patient-Physician Interactions (PEPPI-5) survey [23], a validated and reliable measurement of patient self-efficacy for obtaining medical information and physician attention about their medical concerns that is available in Dutch [24]. The PEPPI survey is scored on a scale of 1 (not confident at all) to 5 (completely confident) and contains the items: (1) Get your PN to answer all of your questions?; (2) Make the most of your visit with the PN?; (3) Get your PN to take your chief health concerns seriously?; (4) Know what questions to ask your PN?; and (5) Get your PN to do something about your chief health concern? The developers of the PEPPI have suggested that the instrument could be useful in measuring the impact of empowerment interventions [23].

Patient participation

Patient participation was subdivided into "conversational contribution" and "topics discussed". To measure conversational contribution, the number of diabetes-specific task-focused verbal utterances made by the patients (questions, counseling, providing information) was determined. To measure the topics discussed, the extent to which T2DM-related topics (medical, lifestyle, therapeutic, psychosocial) were discussed between patients and PNs was determined by calculating the number of diabetes-specific task-focused verbal utterances per topic. Finally, associations with the following medical and demographical characteristics of patients were investigated: sex, age, diabetes duration, and the presence of a spouse during the consultation.

Video recording

The PNs were instructed about the use of the camera. The primary investigator (EdP) installed an unmanned video camera, in line with protocol instructions, in the PNs'

consulting rooms for the study duration. The recording was started before the patient entered the consulting room and switched off after they left.

Coding procedure

EdP coded all videos using the Roter interaction analysis system (RIAS), a widely-used international observation system with proven validity and reliability [25-28]. In the RIAS, every HCP and patient utterance is coded in mutually exclusive categories. According to the 2013 RIAS manual [26,27], "utterances" are defined as the smallest distinguishable speech segment to which a classification may be assigned. The unit may vary in length from a single word to a lengthy sentence. The RIAS distinguishes between affective (socioemotional) and instrumental (task-oriented) behavior. The current study focused exclusively on the latter because we did not expect that PRISMA would influence affective behavior (Table 1). The four primary task-oriented RIAS categories were (1) medical, (2) therapeutic, (3) lifestyle, and (4) psychosocial. For the purpose of this study, the task-oriented categories were further divided into twenty content categories. According to practice guidelines, these topics were considered relevant for patients with T2DM.

At the start of the coding process, EdP and a second researcher experienced in applying RIAS compared the observations of five video recordings, adjusted unclear items, and made a final coding model. To establish inter-rater reliability, 10% of the same consultations were observed by a third experienced researcher. During the coding process, EdP and the second researcher compared their observations regularly and exchanged coding experiences to check and to reach consensus.

Table 1. The RIAS codes applied in the current study

Task-oriented main topic with sub-categories	**Communication behavior (examples)**		
	Asking questions	Informing	Counseling
Medical Information about type 2 diabetes, tests to measure blood glucose levels, tests to measure other health values, other medical information	What is the difference between type 1 and type 2 diabetes?	I have had diabetes for eight years now.	I am working on decreasing my blood glucose levels.
Therapeutic Self-care, the prescription of medicines, usage of medicines, contact with health care providers, other therapeutic information	Is there another pill without side effects that I could try?	I take these pills twice a day, and other pills once a day.	This week I need to make an appointment for a pedicure.
Lifestyle Nutrition, physical activity, alcohol use, smoking, social context, other lifestyle information	How many times a week do you advise to eat fish?	Sometimes we eat nuts in between meals.	Now it is time to diminish our carbohydrate intake.
Psychosocial Mood, stress, coping with alcohol/smoking or diseases, problems with having a chronic disease, other psychosocial information	Do you think I should worry about my forgetfulness?	I feel really desolate all the time.	I said to myself: the stress is gone, so I quit smoking.

Analysis

All video recordings were digitalized and analyzed in direct entry software (Observer XT version 7.0-computer system). This computer system is especially designed for coding behavioral interactions from video recordings [29].

Patient self-efficacy

Patients' self-efficacy in interacting with PNs was assessed at six months.

Patient participation

Video recordings of the first consultation after PRISMA were made. To account for any variation in communication skills between PNs, multilevel models were used which consisted of consultations (level 1) nested within PNs (level 2). Multilevel regression models were used to estimate the frequency of utterances expressed by patients and PNs.

Statistical methods

Descriptive analyses were used to describe patient and consultation characteristics. Multilevel analysis was carried out to control for the clustering of patients in PNs (with patients [Level 1] nested within PNs [Level 2]). The first model included patient participation, compared between groups. The second model included whether the patient attended the PRISMA program. To investigate potential associations with patient characteristics, we added sex, age, diabetes duration, and the presence of a spouse during the consultation. Analyses were performed using IBM SPSS Statistics version 22.

Results

The inclusion period lasted 9 months (June 2014 to February 2015). Video recordings were made in six of the eight participating general practices. Thirteen PNs recorded their diabetes consultations with participating patients.

The patient flow chart is presented in Figure 2. Of 203 enrolled patients, 101 were randomly assigned to the intervention group while 102 were assigned to the control group. No recordings were available for 24 (23.5%) patients in the intervention group and 29 (28.2%) patients in the control group due to withdrawn consent afterwards or failed or missing recordings. In the intervention group, 71 (70.3%) of 101 patients attended at least one of the two PRISMA sessions. The baseline characteristics did not differ between patients of the participating general practices and those of the non-participating practices. The number of consultations per PN in the sample varied between 1 and 33, and 80% of the PNs had five or less consultations included.

The patient and consultation characteristics are presented in Table 2. In both samples, almost two thirds of the patients were men aged approximately 70 years. In addition, most patients were moderately educated and visited the PN alone.

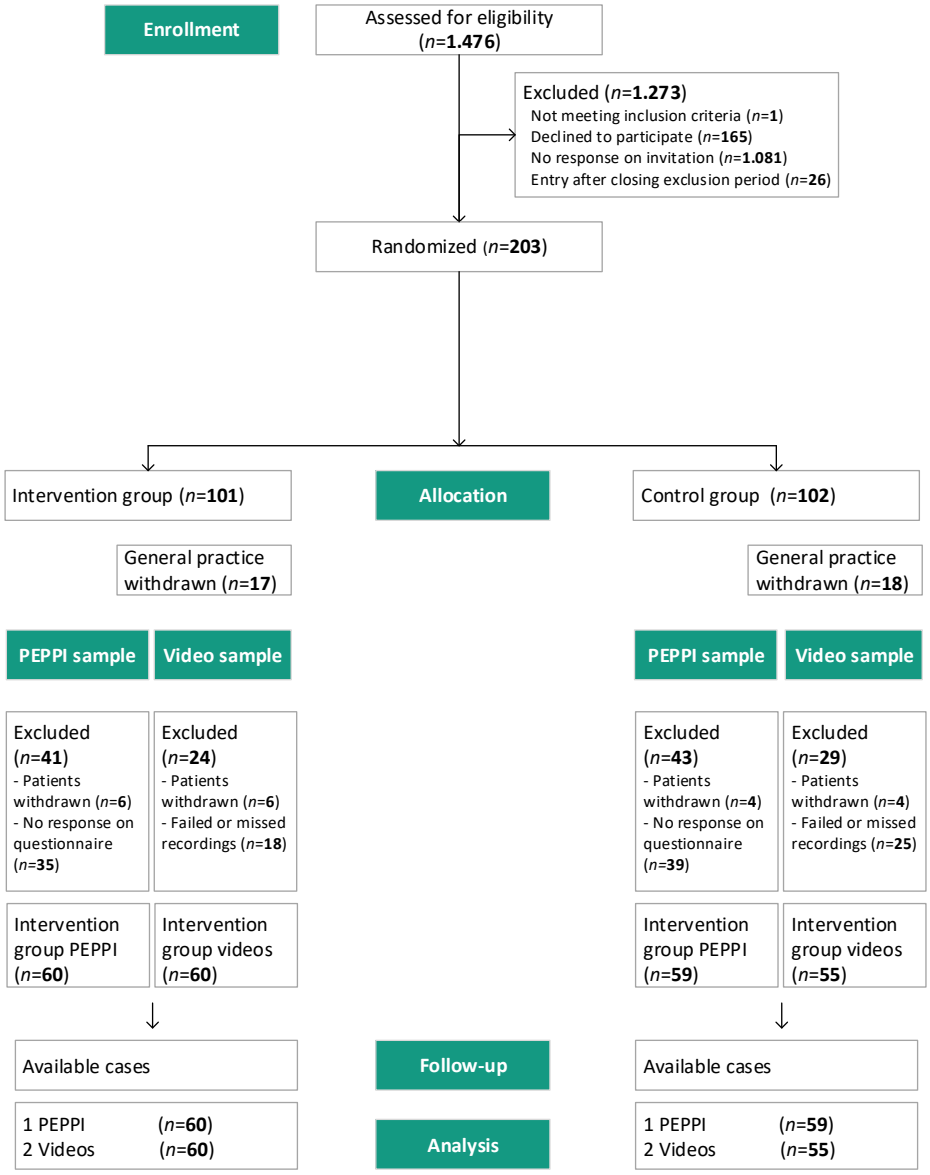

Figure 2. Patient flow chart.

PEPPI = Perceived Efficacy in Patient-Physician Interactions.

Table 2. Patient and consultation characteristics of the PEPPI sample (*n* = 119) and the video sample (*n* = 115).

	PEPPI		**Videos**	
	Intervention group (*n* = 60)	Control group (*n* = 59)	Intervention group (*n* = 60)	Control group (*n* = 55)[a]
Patient characteristics				
Male (%)	38 (63.3)	40 (67.8)	35 (58.3)	34 (61.8)
Age in years (mean, SD)	70.3 (10.0)	71.0 (8.3)	69.9 (10.0)	70.6 (9.4)
Age in categories'				
< 50	1 (1.7)	0 (0.0)	1 (1.7)	1 (1.8)
50–59	6 (10.0)	6 (10.9)	9 (15.0)	6 (10.9)
60–69	18 (30.0)	17 (30.9)	16 (26.7)	16 (29.1)
70–79	25 (41.7)	26 (47.3)	26 (43.3)	21 (38.2)
≥ 80	10 (16.7)	10 (18.2)	8 (13.3)	11 (20.0)
Education level (%)[b]				
Low	2 (3.3)	7 (11.9)	2 (3.3)	4 (7.3)
Moderate	27 (45.0)	32 (54.2)	28 (46.7)	28 (50.9)
High	9 (15.0)	7 (11.9)	9 (15.0)	6 (10.9)
Unknown	22 (36.7)	13 (22.0)	21 (35.0)	17 (30.9)
Visit the PN (%)	N/A	N/A		
Alone			51 (85.0)	46 (83.6)
Not alone			9 (15.0)	9 (16.4)
Use of blood glucose lowering medication (%)				
None	9 (15.0)	7 (11.9)	10 (16.7)	7 (12.7)
Tablets	41 (68.3)	39 (66.1)	50 (83.3)	41 (74.5)
Insulin	1 (1.7)	2 (3.4)	0 (0.0)	1 (1.8)
Unknown	9 (15.0)	11 (18.6)	0 (0.0)	6 (10.9)
Consultation characteristics				
Conversational contribution per patient (average number of utterances)				
Questions			7.0	5.5
Counseling			0.2	0.3
Providing information			116.7	100.6
Total			123.9	106.4
Topics discussed (average number of utterances per consultation per topic)				
Medical			84.5	91.9
Lifestyle			88.8	64.8
Therapeutic			57.8	56.7
Psychosocial			10.6	5.6
Duration of a consultation (in minutes mean, SD)	N/A	N/A	21.5 (9.1)	19.6 (8.3)

[a]The PEPPI sample differed from the video sample by the number of cases. In the PEPPI sample, cases were missing due to non-response to the questionnaires. In the video sample, missing cases were due to withdrawal of general practices and failed or missing recordings. Because we focused on the patient and the PN, the spouses' utterances are left out.

[b]Low, no education or primary education; moderate, lower secondary education, (upper) secondary education or post-secondary non-tertiary education (including vocational education); highl, tertiary education (bachelor's degree or higher).

In total, patients expressed 124.0 instrumental utterances (which were observed for this study) per consultation in the intervention group compared to 106.4 in the control group. For both groups, the most common conversational contribution was "providing information" (intervention: 116.7 utterances; control: 100.6 utterances), and the least common was ''counseling" (intervention: 0.2 utterances; control: 0.3 utterances). Most utterances were made about the topic ''medical" (intervention: 84.5; control: 91.9), and the least utterances were about the topic ''psychosocial" (intervention: 10.6; control: 5.6). Consultations in the intervention group took 21.5 (SD, 9.1) minutes on average compared to 19.6 (SD, 8.3) minutes in the control group.

Patient self-efficacy

At six months, the median sum score of the PEPPI-5 was 20 (19.0–23.0) for the intervention group and 20 (18.0–25.0) for the control group. The median score on all five items for both the intervention and control groups was 4.0 (interquartile range, 4.0–5.0). No significant differences were found between the groups ($U = 1737.5$; $z = -0.2$; $p = 0.8$).

Patient participation

Table 3 shows the results of the multilevel analysis. The groups did not differ in patient participation in terms of their conversational contribution or the topics discussed. In addition, the consultation duration and number of utterances made by patients and PNs did not differ. However, attending PRISMA showed an effect on the conversational contribution of the patients and the topics discussed. Patients who attended the PRISMA program counseled themselves more often ($B = 0.22$; $SE = 0.09$), discussed their medical condition more often ($B = 20.40$; $SE = 9.51$) and discussed their therapeutic regime less often ($B = -25.90$; $SE = 9.88$).

Table 3. Participation during the consultation and associations with medical and demographical characteristics

	Patient contribution to the conversation						**Number of utterances PN**		**Number of utterances patient**	
	Asking questions (B, SE)		Counseling (B, SE)		Providing information (B, SE)		(B, SE)		(B, SE)	
Main outcomes										
Available cases	2.01	1.18	−0.15*	0.09	−3.88	10.78	8.55	13.45	2.97	11.84
Per protocol (attended PRISMA)	−2.20	1.20	0.22	0.09*	13.19	10.96	11.54	13.71	11.32	12.05
Associations with characteristics										
Female	−0.11	1.04	0.10	0.08	11.17	9.66	3.54	12.12	10.15	10.59
Age	0.09	0.05	−0.01	−0.00	0.96	0.50	−0.38	0.62	1.01	0.55
Diabetes duration	0.08	0.12	−0.01	0.01	3.16*	1.17	1.25	1.45	3.18*	1.26
Presence spouse	−2.08	1.44	0.93	0.11	−36.12*	13.25	25.59	16.56	−42.64*	14.53

	Topics discussed								**Consultation duration**	
Available cases	−0.00	9.32	13.90	9.76	13.98	10.57	1.89	3.81	0.94	1.71
Per protocol (attended PRISMA)	20.40*	9:51	−25.90*	9.88	12.94	10.78	3.41	3.85	0.97	1.75
Associations with characteristics										
Female	8.75	8.44	9.15	8.58	7.54	9.55	−4.47	3.37	0.75	1.55
Age	0.07	0.43	0.37	0.45	−0.18	0.49	−0.08	0.18	0.05	0.08
Diabetes duration	1.70	1.01	2.70*	1.02	1.89	1.14	0.26	0.41	0.33	0.19
Presence spouse	22.61*	11.51	3.85	11.89	8.98	13.03	−4.40	4.67	4.55*	2.11

B, regression coefficient; SE, standard error. *p<0.05. PRISMA: Proactive Interdisciplinary Self-Management

Patient participation was subdivided into "patient contribution to the conversation" and "topics discussed". To measure patient contribution to the conversation, the number of diabetes-specific task-focused verbal utterances made by the patients (asking questions, counseling, providing information) was determined. To measure the topics discussed, the extent to which type 2 diabetes related topics (medical, therapeutic, lifestyle, psychosocial) were discussed between patients and practice nurses was determined by calculating the number of diabetes-specific task-focused verbal utterances per topic. Associations with characteristics of patients (sex, age, diabetes duration, and the presence of a spouse during the consultation) were investigated.

In addition, several associations with medical and demographic characteristics were found. First, diabetes duration and the presence of a spouse showed an effect on the conversational contribution. Patients with a longer diabetes duration provided more information (B = 3.16; SE = 1.17), and those who were accompanied by a spouse provided less information (B = –36.12; SE = 13.25). Second, the presence of a spouse and longer diabetes duration showed an effect on the topics discussed. Patients who were accompanied by a spouse discussed their medical condition more often (B = 22.61; SE = 11.51), and those with a longer diabetes duration discussed their therapeutic regime more often (B = 2.70; SE = 1.02). Third, patients accompanied by a spouse had a longer consultation (B = 4.55; SE = 2.11). Fourth, duration and the presence of a spouse showed an effect on the number of utterances of patients. Patients with a longer diabetes duration produced more utterances (B = 3.18; SE = 1.26), while patients accompanied by a spouse produced less utterances (B = –42.64; SE = 14.53)

Discussion

Discussion

In general, PRISMA did not change the self-efficacy of patients with T2DM treated in general practice. Moreover, no effects of PRISMA were found on patient participation in terms of their conversational contribution or the topics discussed during the consultation. In addition, the consultation duration and the number of utterances patients and PNs made did not change. However, patients who attended the PRISMA program counseled themselves more frequently during the consultation and their medical condition was discussed more often while their therapeutic regime was discussed less often. Furthermore, patients with a longer diabetes duration provided more information, and their therapeutic regime was discussed more often. Patients accompanied by a spouse provided less information, and their medical condition was discussed more often.

The patients in our sample did not report better self-efficacy after attending PRISMA. This could be explained by the fact that patients perceived their confidence in medical consultations with their PN as quite high (ceiling effect). In addition, high baseline values are common using the PEPPI-5 [30,31]. According to the literature, improvements on other aspects of self-management behavior (dietary behaviors, foot care and action planning) were found three months after PRISMA [20]. Effects in our study may have faded away during the six-month follow-up period. Health outcomes in diabetes care are usually measured on the longer term. However, the effects of the communication outcomes we were interested in are expected earlier [32]. In addition, effects of diabetes self-management education tend to slowly decline after several months [33]. Therefore, effects on the longer term were not expected.

Our sample consisted primarily of older patients who tend to report greater confidence in interacting with physicians than younger patients [24]. This could be due to their greater experience in communicating with HCPs in general.

In addition, patient participation was not improved by PRISMA. Possibly, two training sessions are insufficient and a more powerful intervention, specifically focused on communication with HCPs, might be needed. An alternative explanation for the lack of effects could be contamination. Generally, PNs in the Netherlands become more and more experienced and follow communication trainings as part of their job. The PNs in our study could also have applied their new mindset to the conversations with the control group. However, there are indications that PRISMA triggered patients to counsel themselves. Examples of self-counseling during the consultation were patient statements such as "I am working on decreasing my blood glucose levels" or "I said to myself: the stress is gone, so I quit smoking". This result is not surprising because during the PRISMA program, patients choose a specific goal of behavior change and were stimulated to discuss their goal(s) with their PN. Patients value the fact that the PNs take them seriously, listen carefully, are open, take sufficient time, and provide adequate advice on how to manage complaints [34,35]. Therefore, the PNs in our study might have stimulated their already self-counseling patients in further specifying their goals. However, in both groups, counseling did not occur frequently, which could be explained by the fact that patients experience barriers to participation [8].

The knowledge about T2DM gained during the PRISMA program could have triggered patients to talk about (how to improve) their medical condition in general and less about the treatment (medication) because that topic was already well-known. In addition, possibly, patients' medical condition was discussed more often due to the encouragements of the PRISMA trainers to discuss their specific goal of behavior change with their PNs. The treatment of patients with a longer diabetes duration and thus more experience with the disease might be more complex, supported by results that they provided more information and longer discussions about their therapeutic regimen. This suggests that, in time, every patient might evolve from marginally participating patients to active participants. However, a study in cancer care indicated that for some patients such an evolvement is hampered by barriers, such as suboptimal health literacy skills, requiring specific attention by HCPs to engage these patients [36].

Patients accompanied by a spouse provided less information, and their medical condition was discussed more often. Consultations with a spouse meant an extra discussion participant. A logical consequence was that patients gave less information themselves. The finding that the presence of a spouse supports participation is positive because social support is important in diabetes care and a patient never has diabetes alone [37-39]. This result is in agreement with the study by Wolff et al. (2012), who investigated whether specific spouse behaviors are helpful in engaging patient participation in medical communication [40]. They found that the presence of a spouse

was associated with a more task-focused exchange, particularly by the patient him- or herself.

A strength of this study was the real-life video observation, which is considered optimal for investigating patient participation during consultations [41]. In addition, the influence of the video recorder on the participants' behavior is considered marginal [41]. In six general practices, many video recordings were collected and analyzed which resulted in an extensive data collection. In the current study, 13 PNs recorded their diabetes consultations. Variations in communication skills between PNs, due to characteristics and experience with shared decision-making, was accounted for by using multilevel models.

This study had some limitations. First, although only the first consultations after PRISMA were recorded, it remains unknown what happened during the subsequent consultations after six months. Second, in this open label study, both PNs and patients knew whether a patient followed the PRISMA program. This could have influenced the PNs' communication behavior. Despite detailed instructions given to the PNs, some recording problems did occur, resulting in missing recordings. In these cases, PNs reported they have forgot to activate the camera or to replace a full memory card. Third, two general practices withdrew from the study; however, the baseline characteristics did not differ between the patients of the participating and those of the non-participating general practices. Fourth, in the statistical analysis, we did not account for a patient's educational background because the educational levels of many patients were unknown. Fifth, the PEPPI questionnaire was completed by the participants after providing the PRISMA program but not before the training sessions. This could have triggered socially desirable answers on the PEPPI. Sixth, the last part of the second session of PRISMA specifically focused on communication with the HCPs, which was recently added at the start of the study. Therefore, it may not have been internalized sufficiently by the trainers, which could have resulted in less attention to HCP communication than planned.

Conclusion

The PRISMA program was originally developed to increase self-management behavior in patients with T2DM, of which patient participation during the consultation is an important aspect. PRISMA did not result in higher self-efficacy or patient participation during the consultation with the PN at six months, despite the focus on preparing diabetes consultations and discussing goals with PNs. Two training sessions may be insufficient and a more powerful intervention, specifically focused on communication with HCPs, may be needed. However, this study showed indications that PRISMA triggered patients to counsel themselves more frequently during the consultation. In addition, their medical condition appeared to be discussed more often, while their therapeutic regime appeared to be discussed less often.

Practice implications

HCPs should be prepared for more of a counseling role in consultations of patients with T2DM. In further specifying patient goals of behavior change, they can encourage patients who are already engaged self-counseling to improve their diabetes management. Future research should investigate the effect of PRISMA on consultations with PNs after six months. Patients may need more time to manage their health goals and participate more actively.

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Chapter 5

Effects of a Proactive Interdisciplinary Self-Management (PRISMA) program on medication adherence

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Abstract

Background

The present study aims to investigate the effect of the group-based Proactive Interdisciplinary Self-Management (PRISMA) training program on medication adherence in patients with type 2 diabetes (T2DM) treated in primary care.

Methods

The current study is a two-arm parallel group randomized open label trial (1:1) of 6-month duration with a 6-month extension period in which both groups received the intervention (wait-list control). People 18 years old or older who were diagnosed with T2DM were included. The intervention consisted of two group meetings about T2DM guided by care providers. The control group received usual care only (visits at the general practice). The primary outcome was adherence based on pharmacy refill data and measured with the medication possession ratio (MPR). The secondary outcomes were the number of drug holidays and self-reported adherence, measured by the 5-item Medication Adherence Rating Scale (MARS-5).

Results

Of the total sample (n = 108), 66.6% were male. The mean age was 69.3 years (standard deviation (SD) = 9.1). In the 6-month period, patients were more adherent in the intervention group (n = 56) ((median MPR = 100.0 (51.1 – 100.0)) than in the control group (n = 52) ((median MPR = 97.7 (54.1 – 100.0)) (U = 1042, z = –2.783, p = 0.005). The intervention group had less drug holidays than the control group (0.55, 95% CI, 0.37 – 0.80). The sum scores of the MARS did not differ between the intervention group (median = 23.98, SD = 0.91) and the control group (median = 24.00, SD = 1.54).

Conclusion

The PRISMA program resulted in a small improvement of MPR and fewer drug holidays, while no improvement has been found in self-reported adherence. However, health care providers and policy makers could take into account that adherence might be influenced by PRISMA.

Introduction

Type 2 diabetes mellitus (T2DM) is a highly prevalent, predominantly lifestyle-related, chronic condition [1]. In the Netherlands, 51 per 1,000 persons are affected by T2DM. This rate is expected to increase to 80 per 1,000 persons in 2025,[2] especially—but not exclusively—among those with unhealthy lifestyles [3]. T2DM is related to an increased risk of developing macro- and microvascular complications, including cardiovascular disease, diabetic retinopathy, neuropathy and nephropathy [1].

In the Netherlands, T2DM is mainly treated in primary care by the general practitioners (GP) and the primary care practice nurse (PN). For patients with T2DM, restoring a healthy lifestyle is the cornerstone of treatment. Self-management is challenging, because the combination of adequate knowledge, skills, perseverance and motivation to initiate and maintain behaviors that can help manage the disease on a daily basis is difficult for many patients to achieve [4]. Influential self-management behaviors involve a healthier diet, more physical activity, self-monitoring of blood glucose levels when needed, and taking medication according to prescription [5].

Most patients with T2DM additionally need to be treated with glucose-lowering medication (oral blood glucose–lowering medication, eventually followed by insulin). In 2014, in the Netherlands, 800.000 patients were treated with glucose-lowering medication and 82% of T2DM patients take their medication as prescribed [6]. Medication adherence has been defined by the World Health Organization as the extent to which a person's medication taking behaviour corresponds with agreed recommendations from a healthcare provider [7]. Although, medication adherence is a crucial factor in the effectiveness of a therapy it is a complex behavior with several aspects, [8] which makes it difficult to measure [9]. Medication adherence can be divided into three interrelated yet distinct phases: the initiation of the treatment, the implementation of the prescribed regime, and the discontinuation of the pharmacotherapy. Medication non-adherence can occur in any of these phases [10]. Non-adherence can be considered a significant healthcare problem, especially for patients with chronic illnesses [11]. In T2DM, glycemic (the levels of blood glucose) control is essential to prevent long-term macro- and microvascular complications.

One way to encourage self-management and lifestyle change is through group-based diabetes self-management education [12,13]. Group-based education possesses the advantages of having patient meetings, discussions and peer motivation [12] Furthermore, group-based education has been found to result in improvements in clinical, lifestyle and psychosocial outcomes [14]. In the Netherlands, the group-based Proactive Interdisciplinary Self-Management (PRISMA) training program was developed. It was adapted from the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) program developed in the UK for primary diabetes care [15-17]. DESMOND was translated into Dutch and adapted to

the Dutch health care system. With PRISMA, patients are challenged to consider their own personal risk factors and to choose a specific goal of behavior change [18]. In the PRISMA sessions, the risk factors for T2DM were discussed, as well as the expected effect of insulin or oral blood glucose–lowering medication on blood glucose levels. In addition, patients were challenged to formulate their own personal risk factors and to choose a specific goal of behavior change, for example "taking medication as prescribed". A better understanding of the ways that medications can affect T2DM, could stimulate patients to be adherent to their medication therapy.

Moreover, because adherence is an important aspect of self-management, a change in medication intake due to PRISMA can be hypothesized. Unfortunately, little is known about the actual effect of these kinds of self-management education programs on medication adherence in patients with T2DM [19]. The present study aims to investigate the effect of PRISMA on medication adherence in patients with T2DM treated in primary care.

Material and methods

Trial design

The current study is part of the Diabetes Education and Self-Management to Increase Empowerment (DESTINE) study, described in detail elsewhere [20].

The current study was performed with data available from DESTINE [20]. A power calculation was carried out on the primary outcome measure (platform use), therefore a sample size calculation was not performed for examining effects on adherence in the present study.

DESTINE had a two-arm parallel group randomized open label trial (1:1) of 6 months. The study investigated sustainability in the intervention group during a 6-month extension period (wait-list control), in which both groups received the intervention. The control group received the intervention as well because of ethical reasons. All patients were given the opportunity to attend the PRISMA program since positive effects were expected. An observational study had already shown some improvements of PRISMA in self-management behavior (dietary behaviors, foot care and action planning) [21].

The patients (n = 203) with T2DM received either PRISMA in addition to usual care or usual care only. The GP saw patients once a year to manage their diabetes. In addition to these GP visits, every three to six months, the PN checked the patients' body weight, blood pressure and (fasting) blood glucose levels. The PNs also inquired about their patients' well-being, hypo- or hyperglycemia, nutrition, exercise and medication, when indicated.

This study was reviewed by the Medical Ethics Committee of Isala, Zwolle, the Netherlands, which decided that according to the Dutch law formal approval was

not necessary (METC no. 14.07104). The study was conducted in accordance with the Declaration of Helsinki, and registered at the Dutch Trial Register (no. NTR4693). All participants gave written informed consent. All criteria of the CONSORT checklist and the minimum criteria of the EMERGE checklist were reported [22,23].

Participants

In DESTINE, people 18 years old or older who were diagnosed with T2DM and treated in primary care were included. Patients with conditions that according to the investigators may have interfered with trial participation or evaluation of results were excluded. In- and exclusion criteria were described in details elsewhere [20].

Recruitment

General practices (n = 8) in the eastern part of the Netherlands participated. The general practitioners selected all eligible patients (see "Participants"). Eligible patients were then informed in detail and recruited by the primary investigator (EdP). There was no blinding for the participants, the investigator or the health care provider (HCP).

Intervention

The PRISMA program was offered in addition to usual care. The philosophy of PRISMA is based on patient empowerment, grounded in the following four psychological models: the self-regulation theory [24], the dual process theory [25], the self-determination theory [26], and the social learning theory [27]. Although PRISMA was not specifically developed with the purpose to increase adherence, it may be improved because it is an important aspect of self-management. PRISMA aims to empower patients by using a nondidactic learning approach. Patients were stimulated to consider their own personal risk factors and to choose a specific goal of behavior change, —for example, "taking a walk every morning," "quitting smoking" or "taking medication as prescribed."

The PRISMA program consisted of two meetings of 3.5 hours each. Groups were guided by a dietician and a practice nurse, both experienced in diabetes care. These trainers had followed a standardized training program to ensure the quality of information delivery.

The first session of the PRISMA program concerned the following topics[17]: patients' individual stories, T2DM, the effect of insulin or oral blood glucose–lowering medication on blood glucose levels, hyper- or hypoglycemia, monitoring of blood glucose levels, nutrition (carbohydrates and body weight) and in which stage of change the patients consider themselves with respect to their nutrition and physical activity. The second session concerned a retrospective of the first session, complications and personal risk factors, nutrition (fat), physical activity and the patients' individual diabetes action plans.

The participants were stimulated to continue discussing their goals and actions

with their HCP after completing the course. In the intervention group, the participants started with receiving PRISMA on top of usual care (Figure 1). The control group participants continued to receive usual care and were offered PRISMA after 6 months. Twenty PRISMA trainings (which consisted of two meetings each) were performed to train all included participants.

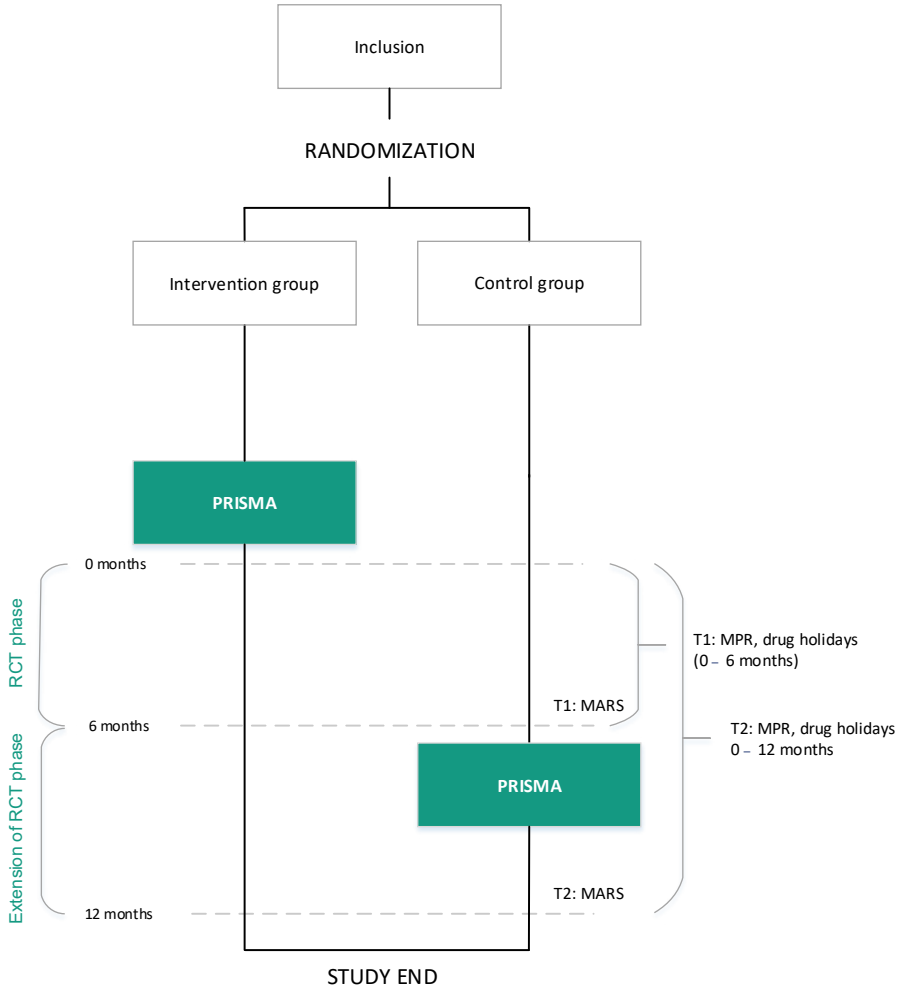

Figure 1. Trial design

PRISMA = Proactive Interdisciplinary Self-Management, RCT = Randomized Controlled Trial, MPR = Medication Possession Ratio, MARS = Medication Adherence Rating Scale.

The control group also received PRISMA after 6 months (wait-list control).

Randomization

To allocate participants to one of the two groups, non-stratified block randomization was used. The researcher performed the randomization over all general practices in a central place were patients' applications were collected. The participants were randomized in 10 blocks of 20 participants each (10 per arm). The blocks were generated by the order of participants' entry, each time 20 participants applied, they were randomized into two groups. After application, patients were matched to a research number which was written on a list in order of participants' entry. The list was used to make blocks of 20 participants. Finally, the researcher allocated closed, transparent envelopes with a note of the patients' research numbers to one of the groups.

Outcomes

In this analysis, two sources were used to measure adherence: 1) pharmacy refill data, and 2) self-reported data. The primary outcome was adherence based on pharmacy refill data and measured with the medication possession ratio (MPR) [28]. The secondary outcomes were the number of times when there was a gap of more than 3 days between the theoretical end date of the administration period and the dispensing date of the next prescription ("drug holidays"), also based on pharmacy refill data, and self-reported adherence, measured by the 5-item medication adherence rating scale (MARS-5) [29]. This study was focused on the adherence phase "suboptimal implementation of the dosing regimen", for example, late, skipped, extra, or reduced doses or drug holidays.

Pharmacy data: MPR

Access to information about the number of dosages dispensed and the dispensing dates was provided by the 11 pharmacies where the participants were registered. In the Netherlands, virtually all patients pick up their medication at a single pharmacy [30]. The medication status and medication history of each patient were extracted from the pharmacies' computer information systems.

Adherence to medication was determined using the MPR [9]. The following three phases describe the process for calculating an adherence percentage.

Phase I: Calculate a measuring period

The measuring period started with the first prescription of medication before the start of the intervention, or with the first medication after the start of the intervention in the case of new users. The measuring period ended with the first medication prescription 6 months (182 days) after the start of the intervention, or—in the case where no medication was used after 182 days—with the last available medication prescription.

Phase 2: Calculate the MPR

In the measuring period, the number of days for which the medication was dispensed was divided by the number of days from the first prescription during that period until the end of the measurement period. The outcome was expressed as a percentage which ranges from 0 to 100%. The higher the MPR, the more adherent the patient is.

Phase 3: Determine how to handle exceptions

For patients who used more than one medication for their T2DM, the adherence for every specific medication was measured separately. If patients used two or three medications simultaneously, the medication with the lowest adherence percentage was analyzed, because the study focused on investigating nonadherence. When patients picked up their medication too early, multiple prescriptions could have overlapped. Such overlaps were corrected by the next prescription as follows: The overlap of two prescriptions was corrected by adding the number of days of overlap in the first prescription date and the theoretical end date of the second prescription.

Drug holidays and self-reported adherence

Dose omissions represented a common form of nonadherence in patients with T2DM. Therefore, drug holidays were a valuable and clinically relevant outcome [31]. As mentioned above, by using the MPR over a period of time, gaps could be corrected by overlaps later. Though, by adding drug holidays as an outcome, it could be detected when patients had no medication in stock. The number of drug holidays was determined by counting the number of times there was a gap of more than 3 days between the theoretical end date of the administration period and the dispensing date of the next prescription. Whether patients had one or more drug holidays (yes/no) was reported, as well as categorized into the following: no drug holiday, one drug holiday, and two or more drug holidays. To assess self-reported adherence to medication prescriptions, participants were asked to complete the MARS-5 questionnaire. This was done at the baseline (i.e., directly after the PRISMA training),after 6 months and 12 months. The MARS-5 consisted of 5 general statements about nonadherent behavior (I forget to take my medicines; I alter the dose of my medicines; I stop taking my medicines for a while; I decide to miss a dose; and I take less than instructed) answered on a 5-point Likert scale (1 = always, 2 = often, 3 = sometimes, 4 = rarely, and 5 = never). The total MARS-5 score was calculated by summing scores from each individual question (range = 5–25). Higher scores indicate lower self-reported adherence. The level of education was also obtained from these questionnaires. The MARS has been validated in Dutch [32].

Analysis

Pharmacy refill data (MPR) and drug holiday data were available over a period of 6 and 12 months, and self-reported data (MARS) at two points in time: 6 and 12 months. The

current study distinguished two phases: a randomized controlled trial (RCT) phase (0–6 months), and an extension of the RCT phase (0–12 months); see Figure 1.

At first, differences between the intervention group and the control group were investigated during the RCT phase over a period of 6 months, and subsequently, during the extension of the RCT phase over a period of 12 months. For the RCT phase, an intention to treat (ITT) analysis and a per protocol (PP) analysis were conducted. The PP analysis consisted of only patients of the intervention group who followed PRISMA.

For both the intervention group and the control group, the MPR was reported in two categories (yes/no), and the drug holidays were reported in two categories (yes/no) and in three categories (no drug holiday, one drug holiday and more than one drug holiday). Also, the scores on the five items and the average score were calculated (MARS).

Statistical methods

Treatment comparisons for efficacy endpoints were assessed with two-sided tests at a significance level of 0.05, including a 95% confidence interval. All efficacy analyses were done in the ITT population. The analyses in the extension phase comprised all patients of the ITT who were randomly assigned in the first phase and received PRISMA in the second phase (between 6 and 12 months). Quantitative variables are described in means and standard deviations, and categorical variables are described in numbers and percentages. Independent samples t-tests were used to test differences between the groups in the case of normally distributed variables; otherwise, the Mann–Whitney test was used. The chi-square tests were utilized for categorical data. When PP analyses are done, this is stated explicitly. Statistical analyses were conducted by using IBM SPSS Statistics version 22.

Results

The inclusion period lasted 9 months (June 2014 to February 2015). Of 1,476 patients, 203 (13.8%) were included in the study and signed the informed consent form; 101 patients were randomized in the intervention group and 102 in the control group. Furthermore, 10 patients (4.9%) withdrew from the study: 6 in the intervention group and 4 in the control group. In addition, 31 patients (15.3%) did not use blood glucose–lowering medication (n = 15 in the intervention group; n = 16 in the control group), and for 54 patients (26.6%) sufficient pharmacy data were not available (n = 24 in the intervention group; n = 30 in the control group). Therefore, they had no adherence data available and could not be included in the analysis. In the intervention group, 46 (82%) of 56 patients attended at least one of the two PRISMA meetings. The patient flow chart is presented in Figure 2.

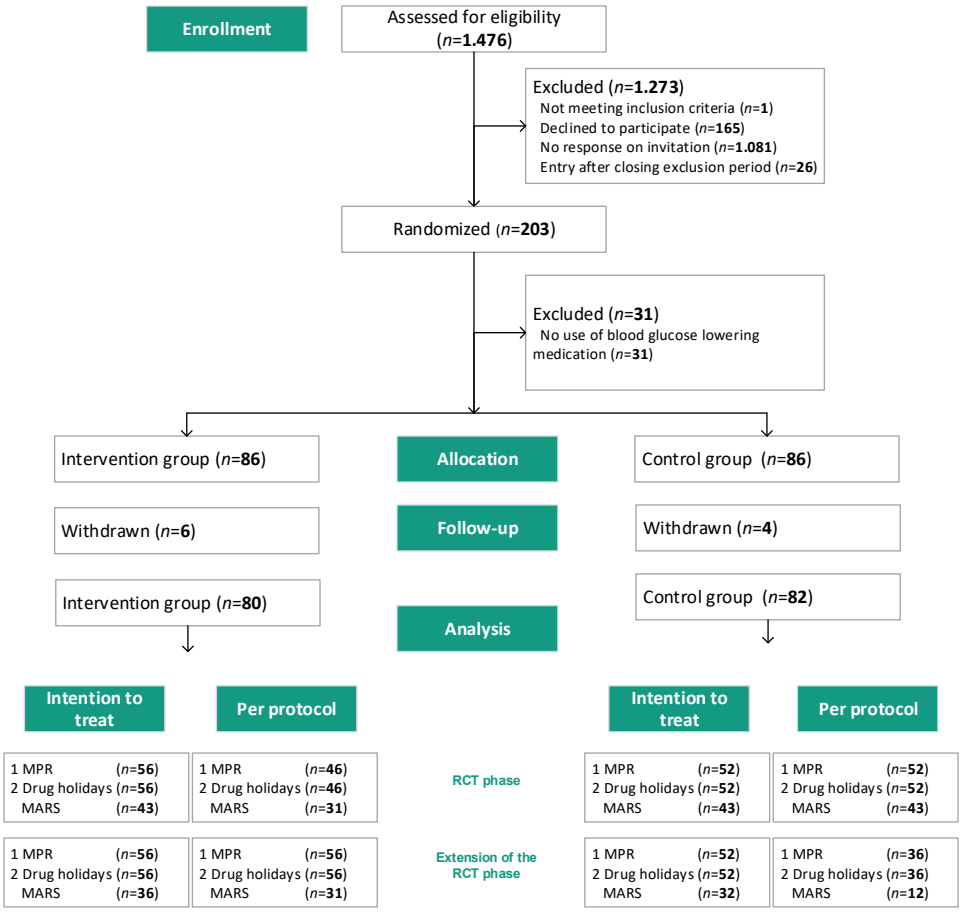

Figure 2. Patient flow chart.

RCT = Randomized Controlled Trial, MPR = Medication Possession Ratio, MARS = Medication Adherence Rating Scale. Patients from the larger trial who did not use blood glucose lowering medication (*n* = 31) were excluded from this study.

MPR and drug holidays

In the 6-month period, for measuring the MPR and drug holidays, 108 (53.2%) of the 203 included patients were analyzed for ITT (n = 56 in the intervention group; n = 52 in the control group). In the PP analysis, patients of the intervention group who did not attend PRISMA were excluded (n = 10). Consequently, 98 (90.7%) of the 108 patients were analyzed.

In the 12-month period, for measuring the MPR and drug holidays, for the PP analysis, patients (n = 16) of the control group who did attend PRISMA between 6 and 12 months were also excluded. Consequently, 92 (85.2%) of the 108 patients were analyzed.

MARS

The 6-month MARS questionnaire was completed by 86 (52.8%) of the 163 patients (n = 43 in the intervention group; n = 43 in the control group). These 86 patients were analyzed for ITT. In the PP analysis, patients (n = 12) of the intervention group who did not attend PRISMA were excluded. Consequently, 74 (86.0%) of the 86 patients were analyzed.

The 12-month MARS questionnaire was completed by 68 (41.7%) of the 163 patients. These 68 patients were analyzed for ITT. In the PP analysis, patients (n = 5) of the intervention group who did not attend PRISMA were excluded, as well as patients (n = 20) of the control group who did attend PRISMA between 6 and 12 months. Consequently, 43 patients (63.2%) were analyzed.

Patient characteristics

The patient characteristics are presented in Table 1. Of the total sample (n = 108), 66.6% were male. The mean age was 69.3 years (SD = 9.1), with a minimum age of 50 and a maximum of 87.

Table 1. Patient characteristics (*n*=108)

	Intervention group (*n*=56)	**Control group** (*n*=52)
Male (%)	**38 (66.7)**	**34 (64.2)**
Age in categories		
50 – 59	12 (21.4)	6 (11.5)
60 – 69	18 (32.1)	15 (28.8)
70 – 79	21 (37.5)	21 (40.4)
≥ 80	5 (8.9)	10 (19.2)
Education level (%)[a]		
Low	2 (3.6)	5 (9.6)
Moderate	26 (46.4)	27 (51.9)
High	11 (19.6)	6 (11.5)
Unknown	17 (30.4)	14 (26.9)
Diabetes duration in years (median, IQR)	6 (4 – 6 – 9)	7 (4 – 7 – 9)
Number of blood glucose lowering medications (%)		
One	36 (64.3)	27 (51.9)
Two	18 (32.1)	24 (46.2)
Three	2 (3.6)	1 (1.9)
Type of blood glucose lowering medication(s) (%)		
Metformin	53 (94.6)	48 (92.3)
Gliclazide	13 (23.2)	18 (34.6)
Tolbutamide	9 (16.1)	9 (17.3)
Other	4 (7.2)	2 (3.8)
Insulin	11 (19.6)	14 (26.9)

[a] Low = no education or primary education; moderate = lower secondary education, (upper) secondary education or post-secondary non-tertiary education (including vocational education); high = Tertiary education (bachelor's degree or higher). IQR = interquartile range

MPR and drug holidays

In the 6-month period, the median MPR was higher in the intervention group (100.0) compared to the control group (97.7) (U = 1042, z = –2.783, p = 0.005 [see Table 2]). Also, the intervention group was more often completely adherent compared to the control group; ($X^2(1) = 8.21$, p = 0.004). In the 6-month period, the relative risk of having one or more drug holidays was lower for the intervention group compared to the control group: (0.55, 95% CI, 0.37 – 0.80).

MARS

The sum scores of the MARS did not differ between the intervention group and the control group: (M = 23.98, SD = 0.91) versus (M = 24.00, SD = 1.54). In the 12-month period, the MPR did not differ between the groups (U = 1187.5, z = –1.752, p = 0.080). Other results did not relevantly change in the 12 months period (data not shown). The results of the PP analysis did not differ from the results above (data not shown).

Table 2. Results of medication possession ratio (MPR), drug holidays and medication adherence rating scale (MARS)

	0 – 6 months	
	Intervention group	**Control group**
	(*n* = 56)	**(*n* = 52)**
MPR[a]		
Median (IQR[b])	100.0 (98.0, 100.0, 100.0)*	97.7 (94.1, 97.7, 100.0)
Range	51.1 – 100.0	54.1 – 100.0
< 100 (*n*, %)	18 (32.1)*	31 (59.6)
100 (*n*, %)	38 (67.9)	21 (40.4)
Drug holidays		
One or more drug holidays (*n*, %)	14 (25.0)	28 (53.8)
Relative risk (95% CI[d])	0.6 (0.4 – 0.8)*	
	6 months	
	Intervention group	**Control group**
MARS[c]	**(*n* = 43)**	**(*n* = 43)**
Median (range)		
Item 1 I forget to take medicines	4 (3 – 5)	4 (3 – 5)
Item 2 I alter the dose of my medicines	5 (3 – 5)	5 (3 – 5)
Item 3 I stop taking my medicines for a while	5 (4 – 5)	5 (4 – 5)
Item 4 I decide to miss out a dose	5 (3 – 5)	5 (3 – 5)
Item 5 I take less than instructed	5 (3 – 5)	5 (3 – 5)
Sum score	24.0 (0.9)	(1.5)

* significant; [a] medication possession ratio; [b] inter quartile range; [c] medication adherence rating scale; [d] confidence interval; [e] randomized controlled trial.
RCT = Randomized Controlled Trial, MPR = Medication Possession Ratio, MARS = Medication Adherence Rating Scale

Discussion

First, PRISMA resulted in a significantly higher MPR in patients with T2DM over a 6-month period. Second, PRISMA also resulted in fewer drug holidays. On the other hand, self-reported adherence (MARS) did not differ between the groups. In the 12-month period no differences between the groups were found in MPR and self-reported adherence

These results show that PRISMA could be promising for improving adherence. Because PRISMA has not specifically been developed to improve adherence, the improvements could be related to the overall increase of self-management behaviors due to PRISMA [17,33]. These improvements may also be attributed to the medication component discussed during PRISMA. PRISMA aims to empower patients. The enhanced knowledge about (advantages of taking) blood glucose lowering medication could have stimulated patients to take their medication as agreed upon with their HCP. In addition, nonspecific effects may play a role, such as increasing patient attention by providing more contact hours with HCPs. The lacking effect of the MPR in the 12-months period could be explained by the fact that between 6 and 12-months both groups received the intervention. In addition, the MPR rates were quite high already. Although, PRISMA resulted in fewer drug holidays, the number of drug holidays was quite low already (the ceiling effect).

These results are in line with previous reports of self-management education programs, which have been shown to improve medication adherence in patients with T2DM [12,13]. Tan et al. (2011) improved medication adherence and the correct timing of intake in patients with poorly managed T2DM through their structured educational face-to-face program. In addition, the pictorial image and teach-back educational strategies of Negrabdeh et al. (2013) seemed to improve medication adherence among patients with T2DM and low health literacy. HCPs often rely on the written word to deal with the lack of time to teach patients about self-management. However, in the study of Negrabdeh et al. (2013), as well as in the PRISMA program, simple educational strategies were used, such as asking definite questions, avoiding medical jargon, encouraging patients to ask questions and utilizing simple pictures with limited content.

Regarding the MARS, the ceiling effect could explain why no significant effects were found on the MARS score: Patients reported themselves to be very adherent. No patients reported stopping taking medicines for a while, and almost no patients took less than instructed. According to Van Vught et al. (2015), primary care patients with T2DM who participated in the PRISMA program showed indications of improvement in illness perceptions, dietary behaviors, foot care and action planning three months after the training [34]. In that study, no effects on medication adherence were found. However, adherence was measured by only one item of the Summary of Diabetes Self-

Care Activities questionnaire, which is of limited reliability. Clearly, the overall increase of self-management behaviors which the PRISMA program was aimed to achieve, combined by the better understanding of the ways that medications can affect T2DM, was not enough to increase the patients' self-reported adherence.

Strengths and limitations

A strength of this study is the multi-measure approach, which was used to measure different adherence aspects. There are numerous tools available for measuring adherence[34]; nonetheless, currently none of them can be considered the gold standard [35,36]. Collecting refill data is an objective and relatively easy process compared to other methods such as pill counts. A main advantage of refill data is that adherence rates can be estimated without the patient being aware of it, which increases the accuracy of the estimates by eliminating any Hawthorne effect [37]. In addition, the validated MARS questionnaire that was used for self-reported adherence can be deployed in any clinical setting and is quick and simple because it contains only five questions [29].

Some limitations need to be mentioned as well. This study was focused on the non-adherence phase suboptimal implementation of the dosing regimen. Late or incomplete initiation or non-initiation was not applicable, because only patients who were already treated by medication for their T2DM were included. In addition, early discontinuation (non-persistence) could not be detected because the patients' reasons of discontinuation of the treatment were unknown. For example, if any drug discontinuation was advised by prescriber verbally, without record, this would be missed out.

Despite the strength of using two measures, none of them measures true medication intake. The results do not absolutely reflect actual patients' drug intake, because patients fill their prescriptions more readily than they take their medicine [38]. By using electronic medication packaging devices, for example, it would be possible to observe each single intake and subsequent deviation from the prescribed regimen [34]. In addition, because the actual medication pickup dates were unavailable in the pharmacy's computer information system, the prescription dates were used, which could have caused overestimation of adherence.

Also, the reliability of medication adherence questionnaires is limited [39]. Several factors could have caused overestimation of the adherence rate. The patients in this study reported themselves to be very adherent. In general, nonadherent patients do not take part voluntarily in studies or do not show up at interventions (the healthy worker effect). Moreover, this study measured adherence through pharmacy refills, and the measuring period only concerns the implementation phase. Furthermore, although self-reporting questionnaires are generally considered as the most cost-effective and time-efficient way to assess medication adherence, they have also been reported to sometimes overestimate adherence [40]. It should be acknowledged that many patients

were lost and could not be followed up with for this study. Originally, the patient sample was selected from a study [20] in which patient selection was based on general criteria (people of 18 years and older, diagnosed with T2DM) instead of their medication intake specifically. Taking blood glucose lowering medication was set as inclusion criteria for the current study. The fact that patients who did not use these medications were excluded after randomization could have affected the results. The study investigated sustainability in the intervention group during the 6-months follow-up. This wait-list control design had the advantage of creating extra data, while a disadvantage was that no effects were expected. In addition, the MARS-5 questionnaire was completed by the participants after providing the PRISMA program instead of before. This could have been resulted in even more socially desirable answers on the MARS-5. Furthermore, despite our efforts to enthuse patients about the PRISMA program, only 12% of the approached patients participated. The year before the start of the study, the PRISMA program was already offered to patients treated by several GPs in the Zwolle region, which could be an explanation. Patients with an incomplete MARS questionnaire were excluded from the analysis because their total MARS score was not comparable with the rest of the study population. Hence, by excluding them, imputation became unnecessary. The large losses to follow-up and the low participation rate could have affected the generalizability of the study. A disadvantage of these kind of trials is the healthy worker effect, which made the results less generalizable over all T2DM patients in the Netherlands.

Conclusion

Although PRISMA was not specifically developed to increase adherence in patients with T2DM, a small improvement has still been found in the MPR over a 6 month period. PRISMA also resulted in fewer drug holidays over a 6- and 12-month period. No effects were found in self-reported adherence. The adherence rates were quite high already. Theoretically based group education such as PRISMA can influence health, psychological and lifestyle outcomes [15,41]. PRISMA was originally developed with the purpose to increase self-management behavior in patients with T2DM. However, HCPs and policy makers could take into account that adherence, as part of diabetes self-management, might be influenced by PRISMA. Nowadays, the most recent version of PRISMA is extended with education about adherence. For future research, it would be of interest to test whether this version has a stronger effect on adherence compared to the former one.

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Chapter 6

Effects of a Proactive Interdisciplinary Self-Management (PRISMA) program on the usage of an online care platform

Currently in press:
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Abstract

Background

Online care platforms can support patients with type 2 diabetes (T2DM) in managing their health. However, in the use of eHealth, a low participation rate is common. The Proactive Interdisciplinary Self-Management (PRISMA) program, aimed to improve patients' self-management skills, was expected to encourage patients to manage their disease through the use of an online platform. Therefore, the objective of the current study was to investigate whether a group education program can improve the use of an online care platform in patients with T2DM treated by primary care providers in the Netherlands.

Methods

In a randomized controlled trial, patients with T2DM received either PRISMA with usual care or usual care only. During a six-month follow-up period in 2014-2015, usage (number of log-ons and time spent per session) of an online care platform (e-Vita) aimed at improving T2DM self-management was assessed. A training about the functionalities of e-Vita was offered.

Results

The sample consisted of 203 patients. No differences were found between the intervention and control groups in the number of patients who attended the platform training (interested patients) ($X^2(1) = 0.58$; $p = 0.45$), and the number of patients who logged on at least once (platform users) ($X^2(1) = 0.46$; $p = 0.50$). In addition, no differences were found between the groups in the type of users-patients who logged on twice or more (active users) or patients who logged on once (non-active users) ($X^2(1) = 0.56$; $p = 0.45$).

Conclusion

The PRISMA program did not change platform usage in patients with T2DM. In addition, only a small proportion of the patients logged on twice or more. Patients probably need other encouragements to manage their condition using an online platform.

Introduction

Worldwide, the prevalence of diabetes mellitus is increasing dramatically. In the Netherlands, 66 per 1,000 persons have type 2 diabetes mellitus (T2DM), and this rate is expected to increase to 80 per 1,000 persons by 2025 [1]. Although patients with T2DM are primarily treated by primary care providers, this projected growth is expected to exceed the number of available providers [2]. Already, diabetes care providers see an increase in patients, which results in a decrease in face-to-face time available per patient. This has partly been tackled by a transfer of tasks, previously performed exclusively by general practitioners (GPs), to other medical professionals including specialized practice nurses (PNs). To deal with the increasing number of patients with T2DM and the burden of diabetes on healthcare, increased patient participation is needed, including more self-management. Self-management includes the active participation of patients in their treatment [3] to minimize the impact of chronic disease on their physical health and functioning and to enable patients to cope with the psychological effects of the illness [4]. Patient participation could be enhanced by offering them the possibility to track their own medical data together with tailored advice through eHealth [5].

eHealth applications, and more specifically online care platforms, provide the opportunity for self-management support and maintaining and/or improving the quality of chronic disease management by engaging patients in their own healthcare [6]. In general, online care platforms are environments in which patients can get an overview of their health outcomes, communicate with their care provider, and/or read information regarding their disease. It has been shown that such platforms are beneficial for people with T2DM [7]. These platforms have the potential to support patients in managing their own health and changing their lifestyle [8].

So far, the effects of online care platforms reported in systematic reviews vary [9-11]. Health behaviors and health-related outcomes have been shown to improve through the use of eHealth [12-15]. Moreover, these platforms were shown to be specifically beneficial for people with T2DM [7]. Therefore, platforms aimed at empowering patients can potentially decrease the workload of diabetes care providers and improve the (cost-)effectiveness of diabetes treatment [16,17]. Nevertheless, implementation problems, non-adherence, and low participation are common [18-23]. A recent literature review of studies reporting online care platform use by patients with diabetes (type 1 and 2) revealed that 29% to 46% of them registered for a platform account; of those registered, 27% to 76% patients used the platform at least once [23]. Platform use was associated with the following factors: patient characteristics (e.g., sociodemographic, clinical characteristics, health literacy), technology (e.g., functionality, usability), and provider engagement. For facilitating the use of self-management support through a platform, patients first need to develop an intention for behavioral change, which can only be achieved if they have sufficient risk awareness, experience a need for behavioral

change, and feel confident in making these changes [24]. In the Netherlands, an online care platform called e-Vita has been developed to improve patients' self-management skills [25].

Group education could be a helpful way for patients to obtain an intention for behavioral change [26]. A recent systematic review suggests that group-based diabetes self-management education is associated with improved clinical and psychosocial outcomes [27]. The PRoactive Interdisciplinary Self-MAnagement (PRISMA) program aims to improve self-management skills in patients with T2DM [26]. PRISMA appeared to improve self-management behavior in terms of dietary behaviors, foot care, action planning, and medication adherence [24,28]. In addition, a pilot study showed that the PRISMA program is promising for decreasing dietary intake in newly diagnosed, overweight patients with T2DM in secondary care [26]. PRISMA helps patients to evaluate their own risk factors, to set personal goals, and to formulate a realistic action plan. Therefore, the PRISMA program is expected to increase the patients' motivation to behavior change and to motivate patients to manage their condition using an online platform.

The objective of the current study was to investigate whether a group education program aimed at empowering and stimulating self-management in patients with T2DM can improve the use of an online care platform.

Material and Methods

Study design

The current study is part of the Diabetes Education and Self-Management to Increase Empowerment (DESTINE) study described in detail elsewhere [29]. DESTINE is a randomized controlled trial that followed enrolled patients for six months (Figure 1). The patients with T2DM received either the PRISMA program with usual care or usual care only. According to the guidelines of the Dutch College of GPs (NHG-Standard), usual care involves two to four visits per year with a PN and one annual check-up with a GP. All patients had access to the online care platform.

In another sub study of DESTINE, the effects of PRISMA on medication adherence were described [28]. Therefore, people 18 years old or older who diagnosed with T2DM and treated in primary care were included. Eight general practices in the eastern part of the Netherlands participated, and eligible patients were selected by GPs. Non-stratified block-randomization was used to allocate participants to one of the two groups [30]. For the current study, we followed the methods of du Pon et al. (2019) [28].

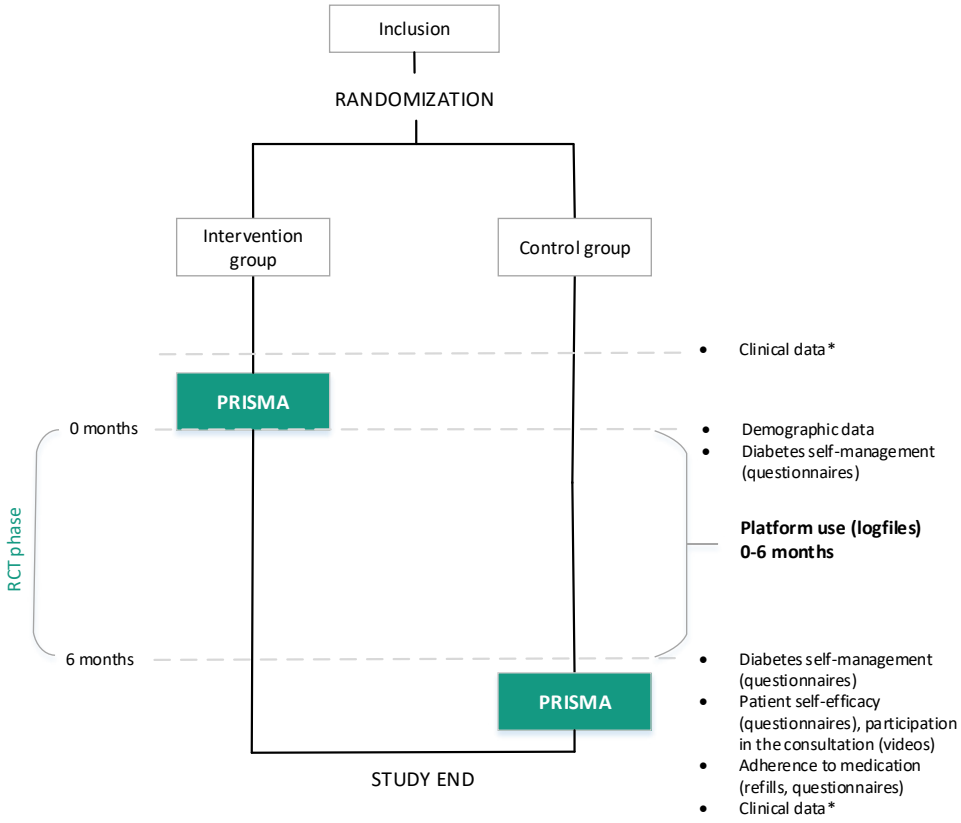

Figure 1: Overview of the complete DESTINE trial of which the current study is part of
PRISMA = PRoactive Interdisciplinary Self-Management; RCT = randomized controlled trial.
*Clinical data includes HbA1c, body mass index (BMI), systolic blood pressure, and cholesterol levels.

Description of the platform

In a previous study, the online care platform used for this study (e-Vita) showed that users of the platform had lower glycated hemoglobin (HbA1c) levels and reported higher quality of life, better well-being, lower diabetes-related distress, and better medication adherence than non-users [5]. However, the usage of this platform has been shown to be minimal in the past [5,31]. Only 11% of the patients who were interested in the use of a care platform logged on at least once [31]. An improved version of the online platform e-Vita was used in our study. First, platform adjustments were conducted to make the platform more user-friendly. Second, the log-on procedure was simplified. Third, a function regarding communication between patients and their PN was added. Finally, a training was offered to patients, their companions, and caregivers about the functionalities of e-Vita, as suggested by Roelofsen et al. (2014) [5].

The use of e-Vita was offered as part of a larger program that aimed to study the effects of an online platform for various chronic illnesses (T2DM, chronic obstructive pulmonary disease and chronic heart failure). The platform (accessible through app.e-vita.nl) contains information about the patient's health status but also offers participants more engaging options, such as formulating personal goals, participating in educational modules, exchanging messages between patient and care provider, or searching for information in the "library." The language of the platform is Dutch. Table 1 shows these items in more detail.

Table 1. Platform items

Health status	View annual checkups for the last three visits. Every outcome was accompanied by an explanation.
Personal goals	Formulate personal goals to reach health-related wishes.
Educational modules	Participate in education presented in text and pictures, followed by a set of simple control questions. This education was patient specific, based on their health data.
Messages	Exchange emails with PN through email program.
"Library"	Look at links to reliable information on T2DM in general, patient associations, and short videos about patient experiences using the platform.

In both groups, participants (and their spouses) had the option to use the platform. Therefore, participants were registered on e-Vita and were invited for a 90-minute training about this platform. In groups of 5–10, patients were introduced to e-Vita and received log-on data. Spouses were also invited due to their important role in supporting patient who wish to access and use the platform [31]. They also became familiarized with the content by completing several exercises on the platform (e.g., 'enter your weight' or 'formulate a health goal'). After this training, participants were able to start using the platform immediately. The PNs also received training about how to use e-Vita to be able to respond to their patients' messages, answer questions about the platform, and follow their patients' activity in the educational modules.

Description of the intervention

The intervention consisted of two group meetings about T2DM guided by care providers. The PRISMA program has been described in detail in du Pon et al. (2019) [29]. During PRISMA, patients were encouraged to set personal goals and formulate a realistic action plan. They could enter these personal goals on e-Vita and pursue their goals using the platform.

Outcomes

The outcome of this study was the change between groups in the usage of the e-Vita platform (number of log-ons and time spent per session), as assessed by user log files.

Usage of the e-Vita platform

Each action performed by the users was logged in a file that was saved to the server and was available for the researcher. Log-in and log-out times of each session of all platform users were registered. First, for all platform users, the number of log-ons, the time spent per session, and the total time spent on the platform were calculated. Then, patients were defined according to what type of platform user they were (Figure 2) [32]. A session included all log-ons to the platform within 30 minutes [33].

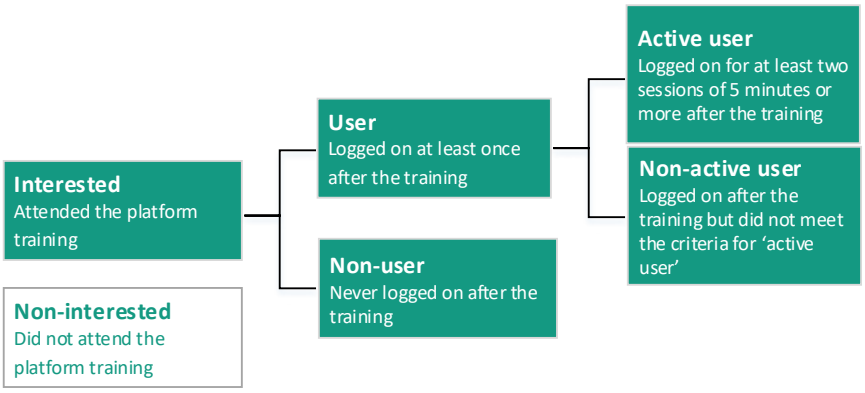

Figure 2. Flowchart of the process of sorting users into categories by log-on behavior.

Baseline demographic and clinical data

Demographic baseline data were obtained from questionnaires, including sex, age, education level, health-related quality of life, emotional well-being, quality of received care, and eHealth literacy. Participants of the intervention group received the paper-based questionnaires immediately after the PRISMA program, whereas those of the control group received them by post.

Health-related quality of life was assessed by the EuroQol Five Dimension (EQ-5D-3L) scale [34]. This questionnaire consists of two parts: the EQ-5D descriptive system and the EQ visual analog scale (EQ-VAS). The EQ-5D-3L comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems, some problems, and extreme problems. The EQ-5D-3L includes a visual analog scale (EQ-VAS) from which an individual rates their own health today from 0 (worst imaginable health) to 100 (best imaginable health). Emotional well-being was assessed by the World Health Organization Well-being Index 5-Item (WHO-5) scale [35]. The WHO-5 covers five items: subjective quality of life based on positive mood (good spirits, relaxation), vitality (being active, waking up fresh and rested), and general interest (being interested in things). Each of the five items is rated on a 6-point Likert scale from 0 (not present) to 5 (constantly present). Higher scores represent higher levels of emotional well-being. Quality of received

care was assessed by the HowRwe [36]. This questionnaire has four items concerning promptness, communication, personal relationship, and general satisfaction. Each item is scored using four levels ranging from "excellent" to "poor," and each level is assigned a score on a scale from 0 (poor) to 3 (excellent), with higher scores indicating a better patient experience.

eHealth literacy was assessed by the eHEALS questionnaire, an 8-item scale measuring perceived skills at finding, evaluating, and applying electronic health information to health problems [37]. For this study, the four most relevant items were used ($\alpha = .90$): (1) "I know how to find helpful health resources on the Internet"; (2) "I know how to use the Internet to answer my health questions"; (3) "I know what health resources are available on the Internet", and (4) "I feel confident in using information from the Internet to make health decisions". The items were measured with a 5-point Likert scale with response options ranging from "strongly disagree" to "strongly agree." Total scores of the eHEALS were summed (possible range, 4–20), with higher scores representing higher self-perceived eHealth literacy.

In addition, baseline clinical data (T2DM duration, HbA1c, body mass index, systolic blood pressure) were obtained from the personal health record systems of the GPs. Only data gathered less than four months before the intervention were used.

Sample size calculation

To show a difference of at least 20% in active users (15% in the control group versus 35% in the intervention group) for the primary outcome measure (usage of the e-Vita platform) with a two-sided risk alpha of 5% and a power of 80%, 81 individuals per group were needed using the unpooled Z-test. With an expected drop-out rate of 20%, we aimed to include 200 patients in our randomized controlled trial.

Analysis

Log files were collected for each patient over a six-month period. An intention to treat (ITT) analysis and a per protocol (PP) analysis were conducted. The PP analysis consisted of all patients of the intervention group who attended at least one session of the PRISMA program.

Statistical analysis

All analyses were conducted using IBM SPSS Statistics version 22. Normally distributed data were presented as the means and standard deviation, whereas skewed data were presented as the medians and interquartile range. Dichotomous/categorical data were presented as numbers and percentage of the total. To evaluate differences in target variables (use of the online platform: number of log-ons and time spent per session) over time and between arms, the chi-square test and median difference scores (95% confidence intervals [CI]) were used. A sub group analysis was conducted to investigate

differences in platform use between male and female patients, younger (<65 years) and older patients (>65 years), and patients with a low eHEALS sum score (12 or less) and patients with a high eHEALS sum score (13 or more).

Ethics

This study was reviewed by the Medical Ethics Committee of Isala, Zwolle, the Netherlands. The committee decided that formal approval was not necessary (METC no. 14.07104).

Results

The inclusion lasted nine months (June 2014 to February 2015). Of 1,476 eligible patients, 203 (13.8%) were included in the study and signed the informed consent form; 101 patients were randomized to the intervention group and 102 were randomized to the control group. After inclusion, 10 patients (4.9%) withdrew from the study: 6 in the intervention group and 4 in the control group. Patients withdrew because of illness, immigration, or personal reasons. In the intervention group, 68 (71.6%) of 95 patients attended at least one of the two PRISMA meetings. The CONSORT patient flow chart is presented in Figure 3 [38].

Patient characteristics

The patient characteristics are presented in Table 2. Of the total sample (n = 193), 60.1% were men. The mean age was 69.9 years (SD, 9.1; range, 35–96). No differences in patient characteristics were found between groups at baseline.

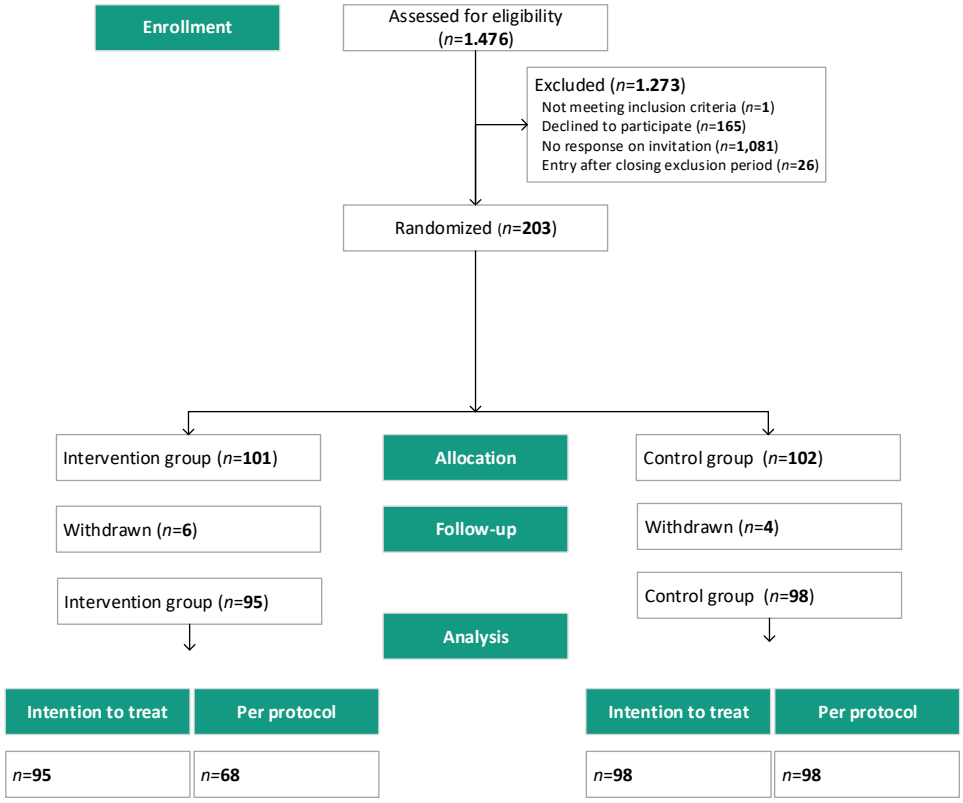

Figure 3. Flow chart of the participant selection process.
Participants in the per protocol analysis attended at least one session of the PRISMA program.

Table 2. Patient characteristics at baseline (*n* = 193)

***n* (%)/mean ± SD/median (25-75 quartiles)**	**Intervention group (*n* = 95)**	**Control group (*n* = 98)**
Male	56 (58.9)	60 (61.2)
Age in years	69.7 ± 9.8	70.1 ± 10.1
Education level[a]		
Low	4 (4.2)	8 (8.2)
Moderate	41 (43.2)	45 (45.9)
High	12 (12.6)	11 (11.2)
Unknown	38 (40.0)	34 (34.7)
T2DM duration (years)	6 (4–8)	6 (4–9)
HbA1c (mmol/mol)	50.7 ± 8.5	54.7 ± 11.7
BMI	28 (26–31)	30 (27–34)
Systolic blood pressure (mmHg)	139 (131–150)	130 (126–148)
Cholesterol (mmol/L)	4.3 (3.5–5.1)	3.9 (3.4–4.9)
EQ-5D index-score	0.9 (0.8–01)	0.9 (0.9–1.0)
WHO-5 index-score	76 (61–80)	80 (72–80)
HowRwe sum score	12 (10–12)	12 (9–12)
eHealth literacy	13 (11–16)	13 (11–16)

[a]Low, no education or primary education; moderate, lower secondary education, (upper) secondary education or post-secondary non-tertiary education (including vocational education); high, tertiary education (bachelor's degree or higher).
T2DM = type 2 diabetes mellitus; HbA1c = glycated hemoglobin; BMI = body mass index; EQ5D = EuroQol Five Dimension; WHO-5 = World Health Organization Well-being Index 5-Item.

Platform usage

The results of the ITT analyses on the platform usage are presented in Table 3.

Table 3. Results of platform usage by interest, user category, and activity.

n **(%)/mean ± SD/median (25-75 quartiles)**			***p*-value / median difference score (95% CI)**
	Intervention group (*n* = 95)	**Control group (*n* = 98)**	
Interested patient[a]	58 (61.1)	65 (66.3)	0.45*
Platform user[b]	33 (34.7)	33 (33.7)	0.50*
Active user[c]	21 (22.1)	18 (18.4)	0.45*
Number of log-ons (all patients)	0 (0–1)	0 (0–1)	0.77#
Number of log-ons (only interested patients)	2 (1–7)	2 (1–5)	0.74#
Range	1–11	1–26	–0.34 (–3.28 to 2.61)
Categories			0.85*
0–1 log-ons	36 (63.2)	46 (70.8)	
2–4 log-ons	9 (15.8)	9 (13.8)	
More than 4 log-ons	12 (21.1)	10 (15.4)	
Time spent per session in hh/mm	00:23 ± 00:09	00:25 ± 00:08	0.09#
Total time spent hh/mm	00:56 (00:27–02:15)	00:53 (00:27–02:14)	0.93#
Range	00:07–09:02	00:06–09:34	0.90 (–50.25 to 52.05)

*Pearson chi-square test.
#Mann-Whitney U test.
[a]Attended the platform training.
[b]Logged on at least once after the training.
[c]Logged on for at least two sessions of 5 minutes or more after the training.

Of the 193 participants in total, 58 (61.1%) patients of the intervention group and 65 (66.3%) patients of the control group registered on the platform during the training (interested patients). At 6 months, 33 (34.7%) patients of the intervention group and 33 (33.7%) patients of the control group had logged on to e-Vita once or more (platform users). Of the intervention group, 12 (12.6%) patients logged on once (non-active users); 15 (15.3%) patients of the control group logged on once. Of the intervention group, 21 (22.1%) patients logged on twice or more (active users); 18 (18.4%) patients of the control group logged on twice or more. No differences were found between the groups in the number of interested patients ($X^2(1) = 0.58$; $p = 0.45$), the number of platform users ($X^2(1) = 0.46$; $p = 0.50$), or the type of users ($X^2(1) = 0.56$; $p = 0.45$).

Males more often were interested patient compared to females ($X^2(1) = 7.70$; $p = 0.01$). However, no association was found between sex and being a platform user ($X^2(1) = 1.41$; $p = 0.24$) or being an active user of the platform ($X^2(1) = 0.83$; $p = 0.36$).

Also no association was found between age and being an interested patient ($X^2(1) = 0.12$; $p = 0.73$), a platform user ($X^2(1) = 0.26$; $p = 0.61$) or active user of the platform ($X^2(1) = 0.10$; $p = 0.92$). In addition, no association was found between self-perceived eHealth literacy and being an interested patient ($X^2(1) = 0.71$; $p = 0.39$) or active user of the platform ($X^2(1) = 0.62$; $p = 0.43$). However, patients with a higher self-perceived eHealth literacy more often were platform users than patients with a lower self-perceived eHealth literacy ($X^2(1) = 5.01$; $p = 0.03$).

Of all patients, the median number of log-ons was 0 (interquartile range, 0–1) for the intervention group and 0 (interquartile range, 0–1) for the control group. Of the interested patients, the median number of log-ons was 2 (interquartile range, 1–7) for the intervention group and 2 (interquartile range, 1– 5) for the control group with a median difference score of –0.34 (95% CI, –3.28 to 2.61). The total time spent on the platform was 56 minutes (interquartile range, 00:27–02:15) for the intervention group and 53 minutes (interquartile range, 00:27–02:14) for the control group with a median difference score of 0.90 (95% CI, –50.25 to 52.05).

The results of the PP analysis do not differ from the ITT results above (data not shown).

Discussion

The PRISMA group program, which aimed to improve T2DM patients' self-management skills, was expected to increase patient motivation for behavior change and encourage them to manage their disease through the use of an online platform. However, PRISMA did not result in a higher platform usage of patients with T2DM over a six-month period. No differences were found between the groups regarding the number of log-ons, the length of time spent per session, and the total time spent on the platform. In addition, attending the PRISMA intervention did not increase the chance of becoming a user of the platform nor enhanced patient activity on the platform. Clearly, consideration of their own personal risk factors and choice of a specific behavior change goal during PRISMA did not encourage patients (enough) to actually use the platform.

Previous results on the effect of e-Vita usage on clinical outcomes were promising [32]. However, our study showed that usage of this platform was minimal. Even offering the PRISMA program coupled with a training to introduce the platform did not remove the threshold for patients to use the platform. Most of the patients who were registered for platform use and attended the training never logged on. Going online indeed requires extra effort for which the added value in view of self-managing a chronic disease using eHealth may not be automatically apparent for patients [39]. An explanation could be either a lack of worry about their future health [40,41], resulting in an insufficient intrinsic motivation, and no intention to change behaviors. In addition, the absence

of disease burden in early stage T2DM could lead to a lack of patient motivation to use an online health platform. Most complications of T2DM arise on longer term. It would be easier to motivate patients if they could already see results of their self-management behaviour in the short term. In addition, the mean age of the patient group was 70 years and we did not find an association between age and platform use, however, according to another study younger age is associated with platform use [23]. Although the Netherlands is a country with high levels of general Internet diffusion even among older adults, [42] these new techniques may be not suitable for older generations who have not mastered the required computer skills [43]. We showed that male patients more often were interested in platform use compared to female patients, which corresponds to the findings of Roelofsen et al. [5]. Our finding that high eHealth literate patients used the platform more often than low eHealth literate patients corresponds to the literature [44,45]. The improvement of eHealth literacy in patients with T2DM needs attention. A recent literature review revealed the lack of data accuracy as the most important barrier to using eHealth for patients with T2DM [45]. This was often a result of manually reporting or the input of monitoring data. In our study, we recognized this problem. Patients probably need other encouragement to manage their T2DM through a platform, for example by follow-up meetings, counsel sessions, or reminders. Otherwise, a platform might not be the most appropriate solution to improve self-management skills in patients with T2DM. The day-to-day management of T2DM can be complex and challenging and requires major responsibility of patients. The use of an online platform would be an extra activity and, as a result, patients could become overwhelmed. In addition, T2DM often affects people with a lower socioeconomic status [46], who could experience other problems considered more important than their chronic condition.

In our study, 34% of the patients logged on, which was an improvement from the 11% found in the study by Roelofsen et al. (2014) on the former version of e-Vita. The trainings about the functionalities of the platform seemed necessary to familiarize patients with the platform [45,47,48]. This may also have decreased the threshold for patients to visit this platform and may have helped patients and PNs to feel the gains of using it. According to Sieverink (2014), PNs understand the importance of stimulating self-management skills of patients with chronic conditions via a platform. Other possible causes for the increase in platform usage could be the visual and technical improvements of the platform. In addition, bended care, where digital health and usual care are integrated, is likely to lead to increased use of an online program for patients with COPD [48]. Patients with diabetes log on to platforms for various reasons. According to the literature, frequently used features are viewing laboratory results [44], sending and reading messages, [49] and participating in educational modules [50]; setting personal goals is the least popular feature [50].

Strengths and limitations

To our knowledge, this is the first study that focuses on the extent to which patients use an online diabetes care platform after attending a group education program. The training offered about the functionalities of e-Vita helped patients to start their first session on the platform. In addition, communication between healthcare providers and patients, a new function on e-Vita, may have encouraged the use of the platform. Another strength of the study was that the participants were randomized over all general practices. This prevented influences from the general practices on the results. In addition, the study has pragmatic character, which means that it was designed to test PRISMA in the full spectrum of everyday usual care to maximize applicability and generalizability. Therefore, the study determined whether PRISMA actually increased the platform usage in real life. In 2017, the platform was renewed, extended with an app, and used by twenty care groups in the Netherlands.

Some limitations of this study need to be mentioned as well. The eight participating general practices diverged by inclusion rate: of the 1,476 invited patients, most were registered in three general practices. In addition, despite the instructions given during the training, the steps to gain access to the platform were considered complex. These factors posed a considerable barrier to visiting the platform, especially for those who were less able to handle computers. In the beginning of the project, technical problems appeared on the platform and, as a result, outcomes of patient annual checkups were not displayed. Furthermore, despite our efforts to enthuse patients about the PRISMA program, only 12% of the approached patients participated. Our target group might not be interested in this type of intervention, which could explain this low participation rate. In addition, most participants in our study were moderately or highly educated and reported a moderate or high eHealth literacy. Lower educated patients, in whom T2DM is most common [51], may not be interested in interventions such as PRISMA and e-Vita because of its complexity. Despite the randomized design, whether a patient becomes a (active) user of e-Vita could thus depend on caregiver attitudes toward participation, online platforms, and eHealth in general (selection bias).

Conclusions

The PRISMA program did not result in a higher online healthcare platform usage in patients with T2DM and also the continuity of use was low. The added value of self-managing a chronic disease may not be automatically apparent for patients. In addition, platforms may not be suitable for the older adults with lower eHealth literacy. There is a need to invest in developing online skills, particularly for older adults with lower eHealth literacy. Otherwise, these patients probably need other encouragements to help them manage T2DM using an online platform. Future research should explore other sources for patients to develop intentions to behavior change for facilitating the use of self-management support programs within a platform. Further development of the platform is ongoing.

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Chapter 7

Effects of a Proactive Interdisciplinary Self-Management (PRISMA) on self-management behavior and clinical parameters

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Abstract

Background

Diabetes self-management education can be helpful for patients with type 2 diabetes in managing their condition. We aimed to study the effects of the group-based PRoactive Interdisciplinary Self-MAnagement (PRISMA) training program on self-reported and clinical outcomes in patients with type 2 diabetes treated in general practice.

Methods

Persons aged 18 years or older diagnosed with type 2 diabetes and treated in primary care were included. In a randomized controlled trial design (1:1), patients were followed for 6 months with an extension phase of 6 months. Block randomization was used. The patients with type 2 diabetes received either PRISMA in addition to usual care or usual care only. All patients completed a range of validated questionnaires (including knowledge, skills, and confidence for self-management [PAM], diabetes self-care behavior [SDSCA], health-related quality of life [EQ-5D], and emotional well-being [WHO-5]). In addition, clinical outcomes (HbA1c, body mass index, systolic blood pressure, and cholesterol levels) were collected during the routine diabetes checkups.

Results

Of the total sample (n = 193), 60.1% were men. The mean age was 69.9 years (SD = 9.1). No significant differences were found on self-reported outcomes between the groups at 0, 6, and 12 months. The clinical outcomes were not reported due to a large number of missing values.

Conclusion

PRISMA did not improve self-reported outcomes in patients with type 2 diabetes treated in primary care. It was not possible to make a statement about the clinical effects.

Background

In the Netherlands, 66 in 1,000 persons were diagnosed with type 2 diabetes mellitus in 2017 [1]. This rate is expected to increase to 80 in 1,000 persons by 2025 [2]. There will be no comparable increase of health care providers, which compromises the availability of face-to-face time between patients and health care providers. In the Dutch health system, 95% of patients with type 2 diabetes are treated in primary care by a general practitioner (GP) and a practice nurse (PN) [3]. To lower the risk of cardiovascular complications and manage the increasing number of type 2 diabetes patients, encouraging self-management could be part of the solution. Self-management can be defined as the active participation of patients in their treatment [4] to minimize the impact of type 2 diabetes on their physical health and functioning and help them to cope with the psychological effects of their illness [5]. In the Netherlands, the quality of care for patients with type 2 diabetes has improved considerably in recent decades [6]. In 1998, 55% of patients with type 2 diabetes younger than 75 years had an HbA1c higher than 53 mmol/mol. In 2013, this decreased to 29% [5]. For patients of 75 years and older, similar trends were found for HbA1c. Poor health behavior places patients with type 2 diabetes at an increased risk of disease progression, impacting their quality of life and increasing their risk of additional health problems and premature death [7-9].

The effectiveness of diabetes self-management ultimately depends on patients' adherence with lifestyle recommendations and treatment [10]. Patients need to understand the principles and importance of self-management activities [11], which makes diabetes self-management education a key component of diabetes care. Diabetes self-management education can be helpful for patients with type 2 diabetes in managing their condition [12]. It aims not only to enhance the patients' medical understanding but also to improve their intrinsic motivation, belief in their innate ability to achieve goals (self-efficacy), illness perception, self-management skills, and behavior [13]. Moreover, a recent systematic review showed that diabetes self-management education resulted in improved HbA1c [14]. Group-based diabetes self-management education seems to be more effective than usual care and individual education at improving clinical, lifestyle, and psychosocial outcomes [15].

One example of an evidence-based diabetes self-management education program is the group-based Proactive Interdisciplinary Self-MAnagement (PRISMA) training program. This program is based on the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) program, which was developed and tested in the UK [12,16,17]. DESMOND has proven to be (cost-)effective in patients newly diagnosed with type 2 diabetes [16,17]. PRISMA was adapted for use in type 2 diabetes in primary care in the Netherlands and, in a previous study, seemed to improve self-management behavior in terms of dietary behaviors, foot care, and action planning three months posttraining [18]. However, the effects of PRISMA on self-

reported and clinical outcomes in a controlled setting are still unknown. Therefore, the present study aimed to investigate the effects of PRISMA on self-reported (knowledge, skills and confidence for self-management, diabetes self-care behavior, health-related quality of life, and emotional well-being) and clinical outcomes in patients with type 2 diabetes treated in general practice.

Methods

Study design

The current study is part of the Diabetes Education and Self-Management to Increase Empowerment (DESTINE) study, described in detail elsewhere [19]. DESTINE has a randomized controlled trial (RCT) design (1:1) in which patients are followed for 6 months with an extension phase of another 6 months. The study has a pragmatic character, as it was carried out in daily practice. More details about the DESTINE study can be found in a previous article [20]. Persons of 18 years and older diagnosed with type 2 diabetes and treated in primary care were included. Eight general practices in the eastern part of the Netherlands participated, and eligible patients were informed and asked to participate by GPs. Block randomization was used to allocate participants to one of the two groups. The participants were randomized in 10 blocks of 20 participants each. All criteria of the CONSORT checklist were reported [21].

Description of the intervention

Patients with type 2 diabetes received either PRISMA in addition to usual care or usual care only. According to the guidelines of the Dutch College of GPs (NHG-Standaard), usual care involves two to four visits per year with the PN and at least one annual check-up with the GP. In addition, all patients had access to an online care platform (e-Vita), which aimed to support patients' self-management skills. The PRISMA program consisted of two group meetings about type 2 diabetes, guided by different PNs and a dietician specialized in diabetes care. These trainers strictly adhered to the PRISMA protocol. In short, the following topics were discussed: blood glucose levels, medication, nutrition, physical activity, complications, and personal risk factors. The PRISMA program has been described in detail previously [20]. The PRISMA philosophy is to actively involve patients and support them with the regulation of the disease. PRISMA aims to support patients by making them aware of their specific risk profile regarding the development of complications and providing information about methods to decrease their risks. Through a constructive approach, a learning process is initiated that helps patients to (continue to) work on promoting and monitoring their health. The trainers encouraged the patients to discuss their individual action plans with their health care provider during their next consultation and bring up the topics important to them. The

two PRISMA meetings should therefore be seen as a starting point to motivate/activate patients, with behavior change as the final objective.

Outcomes

The outcomes of the study included self-reported data (questionnaires), as well as clinical data retrieved from the GP information systems.

Self-reported data

All patients completed a range of validated questionnaires at T0 (0 months, at the end of two PRISMA meetings), T1 (6 months) and T2 (12 months). The following questionnaires were used:

1. The Patient Activation Measure (PAM). The PAM is a validated 13-item instrument used to assess the knowledge, skills, and confidence for self-management [22]. Each item has four response categories with scores from 1 (strongly disagree) to 4 (strongly agree). Higher scores represent higher levels of patient activation.
2. The Summary of Diabetes Self-Care Activities (SDSCA) scale. This scale assesses diabetes self-care behavior over the previous 7 days in six domains: diet, exercise, self-monitoring of blood glucose, foot care, adherence and smoking [23]. The mean score of each item was reported [24].
3. The EuroQol Five Dimension (EQ-5D-3L) scale. This questionnaire assesses health-related quality of life and consists of two parts: the EQ-5D descriptive system and the EQ visual analog scale (EQ-VAS) [25]. The EQ-5D-3L comprises five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels: no problems, some problems, and extreme problems. The EQ-5D-3L includes a visual analog scale (EQ-VAS) where individuals rate their own health today on a scale from 0 (worst imaginable health) to 100 (best imaginable health).
4. The World Health Organization Well-being Index 5-Item (WHO-5) scale. The WHO-5 assesses emotional well-being and covers five items: subjective quality of life based on positive mood (good spirits, relaxation), vitality (being active and waking up fresh and rested), and general interest (being interested in things) [26]. Each of the five items is rated on a 6-point Likert scale from 0 (not present) to 5 (constantly present). Higher scores represent higher levels of emotional well-being.

Additional demographics (gender, age, education level, and type 2 diabetes duration) were included as patient characteristics.

Clinical outcomes

The clinical outcomes described in the national primary care guideline for diabetes treatment were included in the study: HbA1c, body mass index (BMI), systolic blood pressure, and cholesterol levels (total cholesterol, high-density lipoprotein [HDL], and low-density lipoprotein [LD]). These clinical outcomes were collected during the routine diabetes checkups as part of usual care. These data were individually linked to our own database and anonymized. The data were collected at T0 (0 months), T1 (6 months), and T2 (12 months). For T0, only data available no more than 4 months before the intervention were used. For T1 and T2, only data 6 weeks before and 6 weeks after the measuring moment were used. Using a research identification number for every patient, all data were collected and analyzed anonymously.

Sample size calculation

A power calculation was carried out on the primary outcome measure (usage of the e-Vita online care platform), resulting in 81 participants needed per group [19]. The usage of e-Vita was investigated by du Pon et al. (2019 – in press) in another study.

Statistical analysis

All analyses were conducted using IBM SPSS Statistics version 22. Normally distributed data are presented as the means and standard deviation, while skewed data are presented as the median and interquartile range. Dichotomous/categorical data are presented as the numbers and percentage of the total. To evaluate differences in target variables between groups, a t-test was used if the data were normally distributed; if not, a Mann-Whitney U test was used. An intention to treat analysis was conducted.

Results

The inclusion period lasted 9 months (June 2014 to February 2015). Of 1,476 invited patients with type 2 diabetes treated at participating general practices, 203 (13.8%) were included in the study and signed the informed consent form: 101 patients were randomized in the intervention group; and 102, in the control group. After inclusion, 10 patients (4.9%) withdrew from the study: 6 in the intervention group and 4 in the control group. Patients withdrew because of illness, immigration, or personal reasons. Therefore, 95 patients in the intervention group and 98 patients in the control group were analyzed. In the intervention group, 68 (71.6%) of 95 patients attended at least one of the two PRISMA meetings in the RCT phase. The patient flow chart is presented in Figure 1 [21].

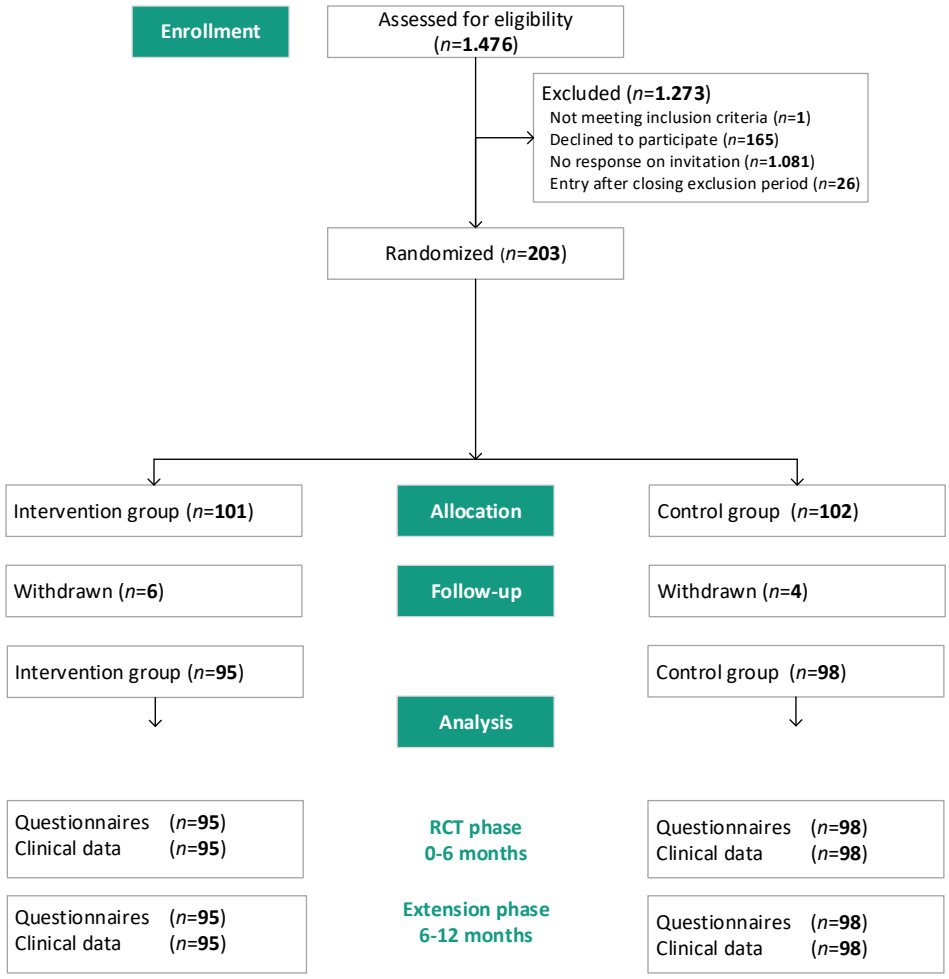

Figure 1. Flow chart of the randomized controlled trial
RCT = randomized controlled trial

Patient characteristics

The patient characteristics are presented in Table 1. Of the total sample (n = 193), 60.1% were men. The mean age was 69.9 ± 9.1 years (range, 35-96).

Table 1. Baseline patient characteristics (*n* = 193)

***n* (%)/mean ± *SD*/median (25-75 quartiles)**	**Intervention group (*n* = 95)**	**Control group (*n* = 98)**
Male	56 (58.9)	60 (61.2)
Age, years	69.7 ± 9.8	70.1 ± 10.1
Education level[a]		
Low	4 (4.2)	8 (8.2)
Moderate	41 (43.2)	45 (45.9)
High	12 (12.6)	11 (11.2)
Unknown	38 (40.0)	34 (34.7)
Type 2 diabetes duration, years	6 (4–8)	6 (4–9)

[a]Low = no education or primary education; moderate = lower secondary education, (upper) secondary education or post-secondary non-tertiary education (including vocational education); high = tertiary education (bachelor's degree or higher

Self-reported outcomes

Table 2 shows the scores on knowledge, skills, and confidence in self-management (PAM), diabetes self-care behavior (SDSCA), health-related quality of life (EQ-5D), and emotional well-being (WHO-5) of the intervention and control groups at 0, 6, and 12 months. No significant differences were found between the groups.

Table 2. Scores on self-reported outcomes of the intervention and control groups at 6 and 12 months.

n **(%)/mean ± SD/median (25–75 quartiles)**	**Baseline–0 months**				**RCT phase–6 months**						**Extension phase–12 months**					
	Intervention group (*n* = 95)		Control group (*n* = 98)		Intervention group (*n* = 95)		Control group (*n* = 98)				Intervention group (*n* = 95)		Control group (*n* = 98)			
		Analyzed (*n*)		Analyzed (*n*)		Analyzed (*n*)		Analyzed (*n*)	Mean / median[a] difference (95% CI)	p-value		Analyzed (*n*)		Analyzed (*n*)	Mean / median[a] difference (95% CI)	p-value
PAM sum score higher scores represent higher levels of patient activation (range 13–52)	40.88 ± 5.48	57 (60)	41.95 ± 5.08	64 (65.3)	40.07 ± 5.76	59 (62.1)	41.78 ± 5.38	59 (60.2)	0.63 (-1.77–3.03)	0.60	40.53 ± 5,36	47 (49.5)	41.20 ± 5.27	44 (44.9)	0.019 (–2.23–2.28)	0.99
SDSCA diabetes self-care behavior in days a week (range 0–7)																
General diet	6.00 (4.75 – 7.00)	57 (60)	5.50 (4.75 – 6.75)	57 (58.2)	6.00 (5.00 – 7.00)	59 (62.1)	6.00 (5.00 – 7.00)	57 (58.2)	-0.08[a] (-0.84 – 1.00)	0.61	6.00 (5.00 – 7.00)	46 (48.4)	6.00 (5.00 – 7.00)	43 (43.9)	0.03[a] (-0.63 – 0.74)	0.20
Specific diet	5.50 (4.50 – 6.00)	60 (63.2)	6.00 (5.00 – 6.50)	60 (61.2)	5.50 (4.60 – 6.00)	60 (63.2)	5.50 (4.50 – 6.30)	58 (59.2)	-0.06[a] (-0.63 – 0.74)	0.55	5.50 (4.50 – 6.00)	49 (51.6)	5.5 (5.00 – 6.50)	45 (45.9)	-0.09[a] (-0.67 – 0.86)	0.92
Exercise	5.00 (3.00 – 6.00)	59 (62.1)	4.50 (2.90 – 6.00)	62 (63.3)	4.00 (3.00 – 5.40)	60 (63.2)	4.00 (3.00 – 6.00)	57 (58.2)	0.13[a] (-1.09 – 0.83)	0.17	4.50 (2.50 – 6.00)	49 (51.6)	5.00 (3.50 – 6.50)	43 (43.9)	-0.21[a] (-1.28 – 1.20)	0.21
Blood glucose control	0.00 (0.00 – 0.50)	59 (62.1)	0.00 (0.00 – 0.50)	62 (63.3)	0.00 (0.00 – 0.50)	61 (64.2)	0.00 (0.00 – 0.50)	59 (60.2)	0.11[a] (-2.70 – 0.97)	0.49	0.00 (0.00 – 0.88)	48 (50.5)	0.00 (0.00 – 0.50)	44 (44.9)	0.00[a] (-0.06 – 0.06)	0.30
Foot care	1.00 (0.00 – 3.50)	57 (60)	1.00 (0.00 – 3.30)	61 (62.2)	1.00 (0.00 – 3.50)	58 (61.1)	1.75 (0.00 – 3.50)	58 (59.2)	0.31[a] (-2.58 – 0.46)	0.78	1.50 (0.00 – 4.13)	50 (52.6)	1.25 (0.00 – 3.50)	44 (44.9)	-0.26[a] (-1.20 – 2.21)	0.04
Medication	7.00 (7.00 – 7.00)	58 (61.1)	7.00 (7.00 – 7.00)	59 (60.2)	7.00 (7.00 – 7.00)	56 (58.9)	7.00 (7.00 – 7.00)	55 (56.1)	-0.18 (-0.53– 0.16)	0.30	7.00 (7.00 – 7.00)	48 (50.5)	7.00 (7.00 – 7.00)	39 (39.8)	–0.51 (–1.11 –0.09)	0.07
Smoking number of patients who smoked in the last 7 days	7 (14.2)	49 (51.6)	4 (7.1)	60 (61.2)	9 (15.5)	59 (62.1)	6 (11.8)	51 (52.0)	0.02 (-0.06– 0.10)	0.62	7 (14.9)	47 (49.5)	4 (8.9)	45 (45.9)	0.06 (–0.02– 0.14)	0.16

Table 2. Scores on self-reported outcomes of the intervention and control groups at 6 and 12 months.

n **(%)/mean ± SD/median (25–75 quartiles)**	**Baseline–0 months**				**RCT phase–6 months**						**Extension phase–12 months**					
	Intervention group (*n* = 95)		Control group (*n* = 98)		Intervention group (*n* = 95)		Control group (*n* = 98)				Intervention group (*n* = 95)		Control group (*n* = 98)			
		Analyzed (*n*)		Analyzed (*n*)		Analyzed (*n*)		Analyzed (*n*)	Mean / median[a] difference (95% CI)	p-value		Analyzed (*n*)		Analyzed (*n*)	Mean / median[a] difference (95% CI)	p-value
EQ-5D index score higher scores represent higher levels of health-related quality of life (range 0–1)	0.89 (0.84 – 1.00)	58 (61.1)	0.89 (0.84 – 1.00)	62 (63.3)	0.84 (0.77 – 1.00)	63 (66.3)	0.84 (0.78 – 1.00)	61 (62.2)	-0.00 (-0.06– 0.05)	0.92	0.89 (0.81 – 1.00)	48 (50.5)	0.88 (0.79 – 1.00)	46 (46.9)	0.01 (–0.68– 0.09)	0.76
EQ-VAS higher scores represent higher levels of health-related quality of life (range 0–100)	80.00 (71.30 – 90.00)	56 (58.9)	80.00 (70.00 – 90.00)	56 (57.1)	80.00 (65.00 – 90.00)	57 (60)	80.00 (70.00 – 86.30)	44 (55.1)	-8,11 (-15.01– -1.22)	0.02	80.00 (70.00 – 90.00)	43 (45.3)	80.00 (79.50 – 90.00)	42 (42.9)	-6.65 (-15.27– -1.21)	0.13
WHO-5 index score higher scores represent higher levels of emotional well-being (range 0–100)	76.00 (61.00 – 80.00)	56 (58.9)	80.00 (72.00 – 80.00)	57 (58.2)	76.00 (57.00 – 80.00)	56 (58.9)	72.00 (64.00 – 80.00)	55 (56.1)	-3.90[a] (-.07 – 15.87	0.93	78.00 (65.00 – 80.00)	42 (44.2)	76.00 (68.00 – 80.00)	39 (39.8)	–5.21 (–13.88– 3.47)	0.23

SD = standard deviation; RCT = randomized controlled trial; PAM = patient activation measure; SDSCA = summary of diabetes self-care activities; EQ-5D = euroqol five dimension; EQ-VAS = euroqol visual analog; WHO-5 = world health organization well-being index 5-item.

Clinical outcomes

The clinical outcomes (HbA1c, BMI, systolic blood pressure, and cholesterol [total, HDL, LDL]) were not reported in this article due to a large number of missing values. The missing values varied from 41.8% to 88.8%. Therefore, it is not possible to make a statement about the clinical effects. The clinical outcomes are available in an appendix.

Discussion

We hypothesized that offering the PRISMA program would result in better self-reported and clinical outcomes in patients with type 2 diabetes treated in primary care. However, no effects were found on the following self-reported outcomes: knowledge, skills and confidence for self-management, diabetes self-care behavior, health-related quality of life, and emotional well-being. In addition, it was not possible to make a statement about the clinical effects.

Previous observational research showed that PRISMA appeared to improve self-management behavior in terms of dietary behaviors, foot care, and action planning after 3 months [18]. The lack of effects in self-reported outcomes in our study may be explained by the already high scores at baseline. These high scores indicated that the patients included in our study had generally well managed type 2 diabetes, so there was limited room for improvement. In addition, Van Vught et al. (2016) observed patients for only 3 months. Changes in outcomes could have been diminished after 6 or 12 months. However, PRISMA was expected to change self-management skills by achieving personal goals (e.g., losing weight), which usually would be visible in clinical measures in the intermediate term or longer. Therefore, in our study, 6 and 12 months were logical terms. Diabetes self-management education interventions appear most effective when group and individualized interventions are combined [27]. Therefore, patients probably need additional encouragement to change their behavior, such as with follow-up education in either group or individual settings.

Some evidence also suggests that contact exceeding 10 hours for diabetes self-management education interventions are more likely to result in additional decreases in HbA1c [14]. However, PRISMA consisted of two interactive group meetings totaling 7 hours [12]. Thus, additional meetings may have been needed. However, the day-to-day management of type 2 diabetes requires major responsibility from patients. Group education (combined with access to an online care platform) would be an extra activity and, as a result, patients could become overwhelmed. Moreover, our target group might not be interested in this type of interventions, which is the reality of usual care.

A strength of this study was that it was embedded in routine primary diabetes care, which means that it was designed to test PRISMA in the full spectrum of everyday usual care to maximize applicability and generalizability. Furthermore, randomization

was performed at a patient level, which generally decreases influences of health care providers. Some limitations of this study must be mentioned as well. First, the eight participating general practices diverged in the inclusion rate: of the 1,476 invited patients, most were registered in three general practices. Thus, the extent to which the health care providers motivated their patients to participate could have played a role. However, the characteristics of the patients (sex, age, education) do reflect the general Dutch population with type 2 diabetes. Second, in spite of the expected positive effects, in other studies about 30–50% of the eligible patients do not participate in diabetes education [28,29]. In our study this rate was even lower. Despite our efforts to enthuse patients about the PRISMA program, only 12% of the approached patients participated. Therefore, selection bias was very likely. Patients who experience difficulties with self-management behavior probably do not voluntarily take part in studies or do not show up at interventions. Moreover, recruiting from a clinical sample may exclude the patients in greatest need of self-management, i.e. people who actually do not visit a general practice. Our target group may have been uninterested in this type of intervention, which could explain our low participation rate. If especially motivated patients participated, this could also explain why the self-reported and clinical measures were already quite good. However, despite their motivation, 28% of the patients from the intervention group who agreed to participate in the study did not attend at least one meeting of PRISMA. Patients changed their mind because were persuaded to enroll by their healthcare provider despite lack of interest. Patients were invited for PRISMA per letter signed by their own GP. Possibly, more personal attention in terms of reminding patients by telephone a couple of days before PRISMA would have prevented dropouts. Third, in an attempt to avoid a type III error, we monitored as many process factors as possible during the implementation of PRISMA. A type III error occurs when evaluating a program that has not been adequately implemented [30]. Such low intervention fidelity could decrease the interpretability of the data collected. As mentioned, PRISMA was guided by different PNs and dieticians, and their work experience in the diabetes field varied. However, all trainers used the same protocol and reported deviations from this protocol after the training. Notable deviations were not reported. In an ideal situation, the researcher would personally attend or record all training sessions in order to check intervention fidelity, however, this was not possibly due to a lack of time. Fourth, the great number of missing values in the clinical outcomes should be acknowledged. As a result, it is not possible to make a statement about the clinical effects. This could be explained by the fact that the study was carried out in daily practice. The clinical outcomes were collected annually during the routine diabetes checkups as part of usual care, and no extra laboratory tests were done. As a result, we were dependent on the data delivered as part of usual care. The missing values in the self-reported data were due to non-responses on the questionnaires. Sending reminders may have been a solution for this problem but would have interfered with the restricted time frame in which

questionnaires had to be completed. Fifth, because of organizational reasons, the patients completed the baseline questionnaire at the end of the two PRISMA meetings rather than at the start. We realize this is inconsistent with RCTs, however, the two PRISMA meetings should be seen as a starting point to motivate/activate patients, with behavior change as the final objective. Because we were primarily interested in the outcomes during the months, the influence of the intervention on completing questionnaires before or after the intervention was less relevant. Sixth, a sample size calculation was not specifically performed for examining effects on the secondary outcomes for the present study [19].

Conclusion

In previous observational research, the diabetes self-management education program PRISMA seemed to improve self-management behavior after 3 months. However, in this study, PRISMA did not improve self-reported outcomes (knowledge, skills and confidence for self-management, diabetes self-care behavior, health-related quality of life, and emotional well-being) after 6 or 12 months. In addition, it was not possible to make a statement about the clinical effects given the large number of missing values. The lack of effects on the outcomes in the current study does not automatically mean that PRISMA is not effective in improving self-management skills. Our target group may have been uninterested in this type of intervention, which is the reality of usual care. Therefore, additional research is necessary. In pragmatic trials such as the current study, it is essential to monitor all possible information during the implementation phase of the intervention. This will improve the reliability of the data collected.

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Appendix

Clinical outcomes (HbA1c, BMI, systolic blood pressure, cholesterol (total, HDL, LDL]) of the intervention and control group at 6 and 12 months

	Baseline – 0 months				**RCT phase – 6 months**					**Extension of the RCT phase – 12 months**				
Clinical parameters *n* (%)/mean ± SD/median (25–75 quartiles)	Intervention group (*n* = 95)		Control group (*n* = 98)		Intervention group (*n* = 95)		Control group (*n* = 98)			Intervention group (*n* = 95)		Control group (*n* = 98)		
	Value	Missing	Value	Missing	Value	Missing	Value	Missing	Mean difference (95% CI)	Value	Missing	Value	Missing	Mean difference (95% CI)
HbA1c in mmol/mol	50.7 ± 8.5	70 (73.7)	54.7 ± 11.7	75 (76.5)	51.1 ± 11.0	71 (74.7)	58.2 ± 14.3	74 (75.5)	-7.08 (-14.49–0.33)	53.91 ± 7.72	73 (76.8)	56.2 ± 10.3	82 (83.7)	-2.28 (-8.29–3.63)
BMI	28.5 ± 4.3	64 (67.4)	30.8 ± 5.1	66 (67.3)	28.5 ± 4.3	58 (61.1)	30.7 ± 5.3	44 (44.9)	-2.17 (-4.25–-0.09)*	29.9 ± 4.7	48 (50.5)	31.2 ± 6.3	50 (51.0)	-1.29 (-3.56–0.98)
Systolic blood pressure in mmHG	139.35 ± 15.0	58 (61.1)	135.59 ± 14.93	61 (62.2)	142.19 ± 17.56	59 (62.1)	139.54 ± 18.74	41 (41.8)	2.65 (-5.09–10.39)	138.51 ± 13.35	50 (52.6)	137.94 ± 13.68	48 (49.0)	0.57 (-4.95–6.09)
Cholesterol in mmol/L	4.47 ± 1.45	78 (82.1)	4.08 ± 1.21	80 (81.6)	4.10 ± 0.97	77 (81.1)	3.92 ± 0.81	77 (78.6)	0.18 (-0.40–0.76)	4.09 ± 0.90	80 (84.2)	4.26 ± 0.98	87 (88.8)	-0.18 (-0.94–0.59)
HDL in mmol/L	1.25 ± 0.3	78 (82.1)	1.06 ± 0.3	80 (81.6)	1.11 ± 0.31	77 (81.1)	1.26 ± 0.30	77 (78.6)	-0.15 (-0.34–0.05)	1.24 ± 0.39	80 (84.2)	1.10 ± 0.44	87 (88.8)	0.14 (-0.2–0.48)
LDL in mmol/L	2.19 ± 1.7	78 (82.1)	2.27 ± 2.1	80 (81.6)	2.23 ± 0.92	77 (81.1)	2.01 ± 0.70	77 (78.6)	0.23 (-0.31–0.77)	2.10 ± 0.56	80 (84.2)	2.17 ± 0.68	87 (88.8)	-0.07 (-0.58–0.43)

* Significant

Chapter 8

Summary and discussion

Summary of the main findings

This thesis investigated how self-management skills in patients with T2DM can be improved. To this purpose, two overarching research questions were examined.

The first question refers to the factors that help and hinder active participation of patients with T2DM in consultations with their primary care PNs. The participation of patients with T2DM during the consultation with their PN appears to be influenced by their needs, beliefs, and skills. Overall, the patients in our study seemed satisfied with their current mode of participation in the consulting room and did not feel the need to participate more actively. These results can inform health care providers and policymakers about how patients with T2DM can be encouraged to participate more actively in consultations with a PNs.

The second question focuses on the effects of the group-based PRISMA training program in patients with T2DM treated in primary care. The effects of the PRISMA program were assessed by (1) usage of an online care platform, (2) patient self-efficacy and participation during PN consultations, (3) adherence to glucose lowering medications, and (4) health outcomes. The PRISMA program aims to help patients consider their own risk factors and choose a specific goal of behavior change. This personal goal can be entered on an online platform (e-Vita) and pursued while using the platform. No major effects of PRISMA on the above-mentioned outcomes were found. The added value of self-managing T2DM may not be automatically apparent for patients. Possibly, additional group or individual meetings are needed. Moreover, the management of T2DM already requires major effort and responsibility from patients. Group education (combined with access to an online care platform) may be considered yet another obligation. As a consequence, patients could become overwhelmed.

Discussion

Group education and eHealth combined

With the intention to support and improve the self-management of T2DM, this thesis reports the results of two interventions: the PRISMA training program and the e-Vita online care platform (Chapter 6). Originally, these were two separate interventions which, for the purpose of the current study, were connected in a logical way [1]. During the PRISMA program, patients evaluate their own risk factors, set personal goals, and formulate a realistic action plan. Subsequently, patients can manage their personal goals using the online platform. Both interventions were promoted to participants in the current study as one self-management program aiming to help them to manage their condition.

The platform was designed with emphasis on making it suitable and available for

all patients with T2DM. From the start, focus groups of caregivers and caretakers were actively involved in designing and testing this platform [2]. Therefore, the content of the platform seemed to fit to the patients' needs and perceptions. The PRISMA trainers mentioned the added value of the platform to their patients to encourage patients in the intervention group to visit the platform after the PRISMA training. The developers of PRISMA attached great importance to the philosophy behind the program. A philosophy determines the theoretical perspective, the attitude of the care provider, and the content and style of the program, as well as the interaction between the caregiver and the patient [3]. The philosophy of PRISMA is based on patient empowerment, grounded in the following four psychological models: the self-regulation theory [4], the dual process theory [5], the self-determination theory [6], and the social learning theory [7]. In short, the PRISMA philosophy is to actively engage patients and support them in managing T2DM. From a constructive approach, a learning process is initiated that helps patients to (continue to) work on promoting and monitoring their health. PRISMA aims to support patients by making them aware of their specific risk profile regarding the development of complications and providing information about methods to decrease their risks. In addition, PRISMA aims to give patients valuable tools for decision-making by offering information about the causes, effects, and self-management of T2DM. The following sections discuss the absence of effects of the PRISMA program on the outcomes assessed in this thesis.

Self-efficacy and participation during the consultation

As mentioned previously, the core skills in self-management are making informed choices about treatment and discussing them with HCPs. As a first step, the current study investigated factors that help and hinder active participation of patients with T2DM in consultations with their PNs. We showed that patients were hindered by barriers to participate during PN consultations, such as lacking skills to take the lead in the discussion, express thoughts, and prepare for the visit (see Chapter 2). Suggestions to overcome these barriers are encouraging patients to write down potential valuable questions in advance of the consultation or to visit the PN together with their spouse. Three factors were found to help patients actively participate in consultations: developing trusting relationship with their PNs, preparing for consultations, and allowing for the presence of a spouse. In addition, particularly in general practices with several PNs, patients have a need for a PN "of their own" [8]. This increases the chance that patients can develop a trusting relationship with their PNs, helping them discuss their emotions and concerns. Nevertheless, patients in our study seldom felt the need to participate more actively. This attitude may be explained by the perceived absence of disease burden and satisfaction with their current roles in the consulting room. Self-management support is a dynamic process in which the patient and caregiver are equal partners. Together, they determine how a health problem is tackled in a process of shared decision-making, of

which active patient participation during consultations is a prerequisite.

Chapter 4 reported the effects of PRISMA on patient self-efficacy and participation during the consultation with the PN. The first finding was that PRISMA did not increase patient self-efficacy [9]. An explanation could be that patients perceived their confidence in medical consultations with their PN as quite high already. Second, our results also showed that PRISMA did not change patient participation during the consultation (see Chapter 4). Possibly, two training sessions are insufficient, and a more powerful intervention specifically focused on communication with HCPs may be needed. Otherwise, a more powerful intervention may have no added value.

Contamination could also play a role. PNs may have applied the lessons learned from communication trainings in their consultations with patients in the control group. For example, courses about motivational interviewing could have positively influenced patient outcomes. We also found that patients who attended the PRISMA program counseled themselves more frequently during the consultation. This result is not surprising because patients were encouraged to discuss their goal(s) with their PN.

When patients with T2DM fail to exercise sufficient self-management behaviors and attain glycemic control [10,11], PNs are faced with the challenge of effectively supporting their patient's self-management activities to make improvements. However, PNs also experience barriers in communication with their patients. Mulder et al. (2015) conducted a structured literature review to investigate communication between PNs and patients with T2DM [12]. They categorized common communication barriers for PNs such as lacking communication skills and self-efficacy, losing motivation, experiencing a role conflict when adopting a patient-centered perspective, and moving to the physical examination (because the patient's role may shift from an active discussion into a passive, silent object undergoing examination). PNs need to communicate with patients in such a way that patients change their behavior, thus resulting in improved clinical outcomes. For example, PNs can apply motivational interviewing skills to encourage behavior change. A recent systematic review supported the potential effectiveness of motivational interviewing in patients with T2DM. However, nurses found motivational interviewing difficult to perform in daily practice [13]. Although PNs appear to be sensitive to patients' concerns when providing information, when the patient talks about behavior change, PNs fail to use empathic statements and do not always acknowledge the challenges of implementing changes. In addition, PNs often forget to summarize the patients' story and ask patients about their willingness to talk about their behavior. Nevertheless, PNs generally express positive views toward active engagement of their patients [14]. They consider their role to be advisory and aim for patient centeredness.

Medication adherence

Chapter 5 reported the effects of PRISMA on adherence to glucose-lowering medication. The PRISMA program resulted in a small improvement of medication possession rate

(MPR) (median MPR intervention group, 100.0 [51.1–100.0]; median MPR control group, 97.7 [54.1–100.0]) and fewer drug holidays. No improvement was found in self-reported adherence [15]. The positive effects may be attributed to the overall increase of self-management behaviors due to the PRISMA program and, in particular, the medication component discussed during the PRISMA training. The enhanced knowledge about the advantages of taking blood glucose–lowering medication could have spurred patients to take their medication more regularly as prescribed. The self-reported adherence rates in our study were quite high for both outcome measures but are likely to be overestimated. Self-reporting questionnaires have been found to sometimes overestimate adherence.

Our results are in line with previous reports of self-management education programs, which have been shown to improve medication adherence in patients with T2DM [16,17]. Group education can be a valuable method for informing patients about the importance of taking their medication and encouraging them to set targets. The asymptomatic early stages of T2DM could make it difficult for patients to understand the added value of their medication therapy. Therefore, this topic should be emphasized during PRISMA and also during conversations with HCPs. In this study, only patients who used oral glucose-lowering medications participated. Lifestyle changes can alter the need for long-term medications, and sometimes it is no longer necessary to take medication.

Usage of an online care platform

Chapter 6 first reports the effects of PRISMA on the usage of the e-Vita online care platform. The PRISMA program did not increase platform usage in patients with T2DM. Despite the given support and the promising results in previous studies about the effect of e-Vita usage on clinical outcomes [18], only a small proportion (20.3%) of the patients logged on twice or more. However, PRISMA also did not decrease platform usage. Lie et al. (2017) investigated reasons why participants withdrew from an eHealth self-management support intervention for adults with T2DM in general practice. They identified an overall theme of participants losing motivation to participate. This theme was illustrated by four categories related to participant experiences with the eHealth intervention: (1) being frustrated by the technology, (2) perceiving the content as irrelevant and incomprehensible, (3) choosing other activities and perspectives, and (4) lacking face-to-face encounters [19]. At the beginning of our project, patients' annual checkups at the GP office could not be uploaded due to technical issues. This could have decreased patient motivation to further explore the platform. In addition, the day-to-day management of T2DM can be complex and challenging and requires major responsibility of patients. Consequently, self-management may be perceived as burdensome, frustrating, and even overwhelming [20]. The time required for recommended self-management is already substantial [21]. For experienced patients

with T2DM under blood glucose medication, recommended self-management requires more than 2 hours every day [21]. Older adults, patients who are newly diagnosed, and those who are physically limited need even more time. Adhering to exercise and diet [21] recommendations are the most time-consuming tasks. Moreover, the results of self-management are not always immediately clear [22]. The use of an online platform would be an extra self-management activity and, as a result, patients could become overwhelmed.

To help patients start their first session on e-Vita, a training about the functionalities of the platform was organized. This training seemed to help patients to start their first session on the platform. During this training, patients were, among other things, supported by creating an account to obtain access to the platform. This task was considered complex and posed a considerable barrier to visiting the platform. Therefore, the given support was essential, especially for those who had not mastered the required computer skills. In case of problems, patients could contact a help desk, which 35 patients utilized. This service was provided by "Care Within Reach" (Stichting Zorg Binnen Bereik). Yet, this initiative again asked for active patient behavior.

We found that high eHealth literate patients used the platform more often than low eHealth literate patients. eHealth literacy can be defined as the ability to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving a health problem [23]. There is a correlation between eHealth literacy and health literacy [24], which is defined as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health" [25]. Lower health literacy is associated with poorer self-management skills [26]. In addition, health literacy may affect behaviors necessary for the development of self-management skills. Given that self-management strategies are core components for effective treatment of T2DM, low health literacy poses a considerable health concern. Because platform use is also associated with health literacy [27], platforms may not be suitable for older adults with lower eHealth literacy. There is a need to invest in developing online skills, particularly for older adults with lower eHealth literacy. Otherwise, these patients probably need other encouragements to help them manage their condition by means of an online platform.

Health outcomes

Finally, Chapter 6 reported the effects of PRISMA on patient and health outcomes. Results show that PRISMA did not improve knowledge, skills, and confidence for self-management; diabetes self-care behavior; health-related quality of life; and emotional well-being. These findings may be explained by the already high scores at baseline. There was limited room for improvement (ceiling effect) because the patients included in our study had generally well-managed T2DM. Possibly, in our sample, improvement of

health outcomes was not necessary, or otherwise there is a need to focus on a specific subgroup of patients who have problems self-managing their disease. This group may benefit more from the advantages of group education. Because a combination of group and individualized interventions appear to be most effective [28], patients probably need additional encouragement to change their behavior, such as follow-up education in either group or individual settings. In addition, it was not possible to make a statement about the clinical effects.

Unfortunately, the effects of group education tend to slowly decline over time [29]. This is common for most behavioral interventions, and thus, patients need periodic refresher courses to sustain the effects over time [28,30]. Patient motivation to sustain their newly learned self-management behaviors could be kept up with booster sessions or additional exposure to the course [31].

Studying patient care interventions in clinical practice

Methodological reflection

Our study has several strengths. First, our study had a randomized controlled trial design. We randomized the patients to an intervention or a control group. Randomization is considered to be the most powerful experimental design in clinical trials: by keeping other variables equal between groups any differences in outcome can be attributed to the intervention [32]. The primary advantage of randomization is the reduction of allocation bias, which derives from baseline variables that may influence outcome(s). Randomization ensures that baseline characteristics not known to be related to the outcome of interest are equally distributed among the groups [33]. We used block-randomization and the participants within each block were randomly assigned to treatment conditions. The second strength of our study was that the participants were randomized over all general practices, which reduced the risk of influences by general practice on the results. Third, we investigated several self-management–related outcomes: usage of an online care platform, self-efficacy, participation during the consultation, medication adherence, and health outcomes. This led to a rich data collection of platform log files, video recordings of patient-PN visits, pharmacy refill data, and health outcomes. Fourth, our study reflected daily practice, and the results found are ecologically valid and applicable in usual care.

However, because this pragmatic study was carried out in daily practice, it is impossible to have full control. Therefore, our study also has some limitations: (1) selection bias, (2) ethics of randomization, (3) low response rate or high drop-out rate, and (4) accuracy of adherence measures. First, selection bias was likely because the actual population with T2DM may be less healthy than the patients included in our study. Patients who experience difficulties with self-management behavior probably do

not voluntarily take part in studies or show up at interventions. This could have made the results less generalizable to all patients with T2DM in the Netherlands. On the other hand, the characteristics of the patient sample (sex, age, education) did reflect the general Dutch population with T2DM. Second, an obstacle was receiving agreement from health care organizations to expose certain patients (i.e., those allocated to the control group) to a potential intervention later in time. When the study was introduced, participants seemed to be motivated to receive the intervention. The health care organizations' concern was that this motivation could vanish after a couple of months. Our first plan was to follow the participants in the intervention group for 12 months, but in the end, all involved parties agreed to only 6 months. Therefore, we designed a randomized, two-arm, parallel-group, open-label trial of a 6-month duration with a 6-month extension period in which both groups received the intervention (wait-list control). Third, only 12% of the approached patients participated, and the drop-out rate varied from 41.8% to 88.8% for the clinical outcomes. This could have affected the generalizability of the study. For the clinical outcomes (registered annually during the routine diabetes checkups), we were dependent on the data delivered as part of usual care. Due to a large number of missing values, we decided not to report the clinical outcomes, as it was not possible to make a statement about the clinical effects. Unfortunately, imputation could not solve this high drop-out rate because then more data would be imputed than measured, making the data and results too unreliable. Possibly, patients were not interested in an online intervention, and moreover, such an intervention needs to be tailored more to patient preferences and abilities specifically. Fourth, adherence could have been measured more accurately compared to the MPR using electronic medication packaging (EMP) devices. EMP devices provide precise data on the manner in which the patient uses the medication. A widely used EMP device in medication adherence studies is the medication events system (MEMS). The MEMS had advantages over other adherence measures in providing continuous, reliable data on medication use [34]. It determines the precision with which the patient adheres to a prescribed diabetes regimen. The MEMS helps identify whether the nonadherence is sporadic, consistent, or any other abnormal medication-taking pattern. Although the accuracy of MEMS is undeniable, due to the large costs of the equipment, it is not the preferred measure in larger clinical trials such as our study [35].

Complex intervention

Several aspects of the study were considered complex. First, the intervention we studied meets the definition for complex interventions according to the Medical Research Council guideline [36]. The following factors make an intervention complex: a number of interacting components within the experimental and control interventions, number and difficulty of behaviors required by those delivering or receiving the intervention, a number of groups or organizational levels targeted by the intervention, a number and

variability of outcomes, and the degree of flexibility or tailoring of the intervention permitted. An intervention with different components could also be (too) complex for patients. They were asked to attend three meetings, one of which was a platform training with computers. Handling the computer turned out to be difficult for most of the older participants. Therefore, the complexity of the intervention itself probably caused drop-outs. Third, T2DM is a complex condition. As mentioned before, T2DM differs from other chronic conditions by the relative demanding self-management requirements and self-management activities to control the condition on a daily basis. Therefore, patients could have become overwhelmed by a platform as extra self-management activity.

Furthermore, we used a relatively simple methodology for a complex phenomenon, which could have led to other limitations. PRISMA was embedded in routine primary diabetes care, so it was tested in the full spectrum of everyday usual care to maximize applicability. We took several steps to minimize the risk of a type III error, which occurs when evaluating a program that has not been adequately implemented [37]. Such low intervention reliability could decrease the interpretability of the collected data. For example, we had to account for different implementers (trainers), differences in intensity of training [33], and patients who did not attend PRISMA meetings.

First, PRISMA was guided by different PNs and dieticians, and their work experience in the diabetes field varied. To compensate, all trainers used the same protocol and were trained to report any deviations from this protocol after the training; however, no deviations from the study protocol were reported. Second, differences in training intensity should have been prevented by the study design. Every topic of PRISMA was accurately registered in the protocol, including time and depth of discussion. However, the trainers had to anticipate and respond to their patients' needs, which could have differed between trainings. This may have led to other questions and shorter or longer discussions about specific topics. Trainers reported that generally all topics were discussed, but the extent may have varied. Third, although 72% of the patients from the intervention group who agreed to participate in the study attended at least one meeting of PRISMA, the number of patients who visited both PRISMA meetings is unknown. Several people were involved in the process of monitoring the presence of the patients. This turned out to be too complex. In an ideal situation, one of the researchers or an assistant would personally attend all training sessions.

The implementation phase of the study can also be considered complex. During the implementation phase, a high degree of organization was expected from all participating parties. For example, the Medrie care group planned the PRISMA trainings, the PNs were responsible for the video recordings of their consultations, Care Within Reach acted as a platform helpdesk, and the researcher was responsible for coordinating all processes. Especially during the start of the study, all parties were enthusiastic and involved in the project. However, there were also difficulties. In a partnership, every party participates from its own perspective, and what works in

practice is not always useful for research purposes and vice versa. To make decisions about practical issues, detailed discussions usually were needed. Over the months, we noticed better mutual understanding of each other's points of view, and we became a team with the same mission: helping to improve the self-management skills of patients with T2DM. Together, we found an appropriate balance between the rules of science and the applicability in practice. We aspired to establish ''blended care" by using a small-scaled implementation strategy: only eight general practices were included. This helped us to focus on changing the attitude of caregivers toward active patient participation. The researcher was available for the PNs and visited them regularly, which the PNs highly appreciated; personal attention seemed the best way to enthuse general practices.

In conclusion, in pragmatic clinical studies, it is simply not possible to completely control all variables. This should not be the goal either.

Inclusion

Despite our efforts to enthuse patients about the PRISMA program, only 12% of the approached patients participated. We can conclude that many patients are not interested in our intervention as offered, and the patients who attended the platform training barely used the platform later on. Some patients were persuaded by their HCP to participate in this project initially but later dropped out. This could have been prevented by involving the patients in terms of personal attention at the beginning of the project. We sent a package of information material about the project, which could have been too noncommittal. While this was indeed our intention because attending our project was voluntary, explaining the information as received and answering questions by telephone could have helped patients to decide to continue on the study. However, this procedure may be too time-consuming and, therefore, a challenge in usual care and can also affect the external validity.

Regardless of the lack of effects found in the current study, the fact that the majority of patients did not seem very interested in an intervention is enough of a reason to consider it ineffective in the given setting. However, our intervention is not an exception in diabetes care concerning a lack of effects. The lack of interest in diabetes education was also found by Gorter et al. (2010). They investigated preferences and opinions of patients with T2DM on education and found that most patients preferred not to receive diabetes education by means of a special diabetes course. More than 80% of the patients preferred to receive diabetes education during their regular diabetes check-ups. Only 3% preferred a special diabetes course [38]. However, we had expected that patients would be open to receive the PRISMA program because it enabled patients to discuss all aspects of their T2DM with trainers and other patients.

The literature also shows that many diabetes self-management education programs are underused, with a significant proportion of patients choosing to not attend despite classes being readily available [39,40]. In a recent systematic review [41],

two broad categories of non-attenders were identified: (1) those who could not attend for logistical, medical, or financial reasons (e.g. timing, costs, or existing comorbidities) and (2) those who did not attend because they perceived no benefit from doing so, felt they had sufficient knowledge already, or had emotional and cultural reasons (e.g. no perceived problem, denial or negative feelings toward education). Moreover, the attenders seemed to be often those who already used the methods taught in the course [42]. Similarly, our sample consisted of patients who controlled their T2DM relatively well. This could have resulted in missing the more complex patients who need such a program most. In addition, the general practices who participated in our study probably are pioneers in diabetes care.

In our study, we applied the traditional opt-in methodology in which patients were asked to actively signal their willingness to participate. Recruitment requiring patients to opt in is associated with a sample of healthier participants [43] and a lower participation rate [43,44] than the opt-out method. In an opt-out methodology, patients are contacted repeatedly unless they signaled unwillingness to participate. Opt-out is generally well accepted by HCPs and patients and results in high participation rates [45,46]. Another option is studying the platform as integral (joint) component of the consultations. In our study, some of the PNs showed the platform to their patients during their consultations. They answered their patients' questions or explained functionalities. However, the use of the platform was still noncommittal. When there is a need to use the platform as part of usual care (e.g. to enter or to check patient data), patients and PNs may become accustomed to it. However, it is probably a matter of time, and in a few years, eHealth and platforms may be part of usual care.

Implications for daily practice and future research

According to our study results, the following implications for daily practice and future research are suggested.

First, our study can inform HCPs and policymakers about how patients with T2DM can benefit from consultations with a PN. PNs should take into account the attitude and the potential lack of skills of their patients because these factors could affect the process of shared decision-making. Trusting relationships with their PNs, which are usually developed over time, help them to participate more actively [8]. Therefore, patients have a need for a PN "of their own." Encouraging patients to write down questions in advance of the consultation or visiting the PN together with their spouses could also be valuable to participate actively. Our findings may provide evidence for designing interventions aimed at improving patient participation. In addition, as a result of the PRISMA program, HCPs should be prepared for a more counseling role in consultations with patients with T2DM. In further specifying patient goals of

behavior change, they can encourage patients who are already engaged in self-counseling to improve their diabetes management. Future research should investigate the effect of PRISMA on consultations with PNs after six months. Patients may need more time to manage their health goals and participate more actively.

Second, the PRISMA program was originally developed with the purpose of increasing self-management behavior in patients with T2DM. However, HCPs and policy makers could take into account that medication adherence, as part of diabetes self-management, might be influenced by PRISMA. Our study was focused on suboptimal implementation of the dosing regimen, which is one of the phases of nonadherence. Since in T2DM nonadherence of the medication therapy mostly occurs during the initiation phase [47], HCPs should provide group education at an early stage (e.g. directly after diagnosing T2DM). Moreover, future research regarding adherence in patients with T2DM should focus on all three adherence phases: the initiation, the implementation, and the persistence of the pharmacotherapy. In addition, patients with T2DM are usually older adults in whom polypharmacy is common, and polypharmacy is a risk factor for slower initiation of medical treatment [47]. Therefore, this patient group needs extra attention. By doing so, patients might fully benefit from the advantages of group education. To date, the most recent version of PRISMA is extended with education about adherence. For future research, it would be of interest to test whether this version has an effect on adherence to prescribed medications and lifestyle recommendations.

Finally, in the future, due to the burden on diabetes health care, the care provided in general practice will be less intensive. However, it is important to uphold or improve the current level of quality of diabetes care. Therefore, it will be of interest to compare current usual care to a less intensive version of usual care (e.g., less contact moments between patient and PN) plus an intervention (e.g., an online care platform). Future research should also explore other sources for patients to develop intentions to behavior change for facilitating the use of self-management support programs within a platform. In addition, online care platforms may not be suitable for the older adults with lower eHealth literacy. There is a need to invest in developing online skills, particularly for this patient group. Otherwise, these patients probably need other encouragements to help them manage T2DM using an online platform.

Conclusion

This research aimed to investigate how self-management skills in patients with T2DM can be improved. We did not find an added value of the PRISMA program in improving the use of an online care platform. Our target group may have been uninterested in this type of intervention, which is the reality of usual care. It appeared to be difficult

to engage patients in the PRISMA program, which resulted in a low inclusion rate and a large number of patients who did not attend (both) meetings. The management of T2DM already requires major effort and responsibility from patients, and group education may be considered yet another obligation. Therefore, other sources need to be explored for patients to develop intentions to behavior change for facilitating the use of an a online care platform.

To deal with the increasing number of patients with T2DM and the burden of diabetes on health care, increased patient participation is needed, including more self-management. An improved online platform could be part of a solution. We observed that technical issues on the platform decreased patients' motivation to further explore it, so the platform must be ready for use. In addition, a training to help patients use the platform seems essential. Older adults with lower eHealth literacy need extra support in using a platform. Moreover, we noticed a lack of enthusiasm in patients using the platform; however, embedding the platform in usual care is expected to make implementation easier. Nevertheless, in a few years eHealth and platforms could be part of usual care.

To date, the quality of clinical care for patients with T2DM in the Netherlands is already good. In the future, it is important to uphold this current level of quality of diabetes care or improve it with less intensive care from general practice (e.g., less face-to-face contacts with HCPs). Nevertheless, if the quality of care remains the same, we can regard it as profit.

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Chapter 9

Nederlandstalige samenvatting

Diabetes type 2 en zelfmanagement

Sinds de tweede helft van de jaren negentig is het aantal patiënten met diabetes type 2 (DM2) toegenomen. Deze toename is het gevolg van bevolkingsgroei, hogere levensverwachting en de obesitas-epidemie. DM2 is een chronische, progressieve aandoening die wordt gekenmerkt door verhoogde niveaus van bloedglucose. Het wordt veroorzaakt door een combinatie van insulinetekort en insulineresistentie wat kan leiden tot ernstige complicaties. Belangrijke risicofactoren voor het ontwikkelen van DM2 zijn overgewicht of obesitas, lichamelijke inactiviteit en slechte voedingsgewoonten, waarbij genetische aanleg ook een rol speelt.

Mensen met DM2 worden voornamelijk behandeld in de eerstelijnszorg. Naast jaarlijkse huisartsenbezoeken controleert een praktijkondersteuner (POH) om de drie tot zes maanden het lichaamsgewicht, de bloeddruk en de (nuchtere) bloedglucosespiegels. Naast een gezonde leefstijl bestaat de behandeling van DM2 vaak uit langdurige therapie met bloedglucose verlagende medicijnen.

In de nabije toekomst zal het aantal huisartsen en POH'ers niet in staat zijn om de verwachte groei van patiënten met DM2 te realiseren. Ter compensatie moet de werklast per patiënt voor zorgverleners afnemen, uiteindelijk resulterend in minder contacttijd per patiënt. Bovendien zal de algemene groei van de kosten voor gezondheidszorg de mogelijkheden om voldoende tijd met elke patiënt door te brengen verder beperken. Daarom zijn alternatieve vormen van ondersteuning, behandeling en zelfmanagement van de patiënt nodig.

Achtergrond

Tegenwoordig worden patiënten met chronische aandoeningen aangemoedigd om actieve deelnemers aan hun eigen gezondheidszorg te zijn. In tegenstelling tot veel andere chronische aandoeningen vereist DM2 relatief veeleisende zelfmanagementactiviteiten om de aandoening dagelijks te beheersen. Zelfmanagement kan worden gedefinieerd als de actieve deelname van patiënten aan hun behandeling met als doel het effect van de chronische aandoening op de lichamelijke gezondheid en de dagelijkse activiteiten te minimaliseren en patiënten in staat te stellen om te gaan met de psychologische effecten van de aandoening. Daarom moeten mensen met DM2 dagelijkse beslissingen nemen als reactie op hun ziektetoestand. Als gevolg hiervan richten de zorgconcepten van vandaag zich op zelfmanagement. Zelfmanagementgedrag omvat bloedglucosemeting thuis (voor insulinegebruikers), gezonde voeding, dagelijkse lichamelijke activiteit, voetverzorging en medicijngebruik. Van al deze factoren is aangetoond dat ze de incidentie en progressie van complicaties geassocieerd met DM2 aanzienlijk verminderen.

In Nederland is op protocol gebaseerde diabeteszorg overigens goed georganiseerd. In de afgelopen decennia is de kwaliteit van klinische zorg voor patiënten

met DM2 zelfs aanzienlijk verbeterd. Desondanks is het voor veel patiënten moeilijk om zich aan een DM2-behandeling te houden. Het effectief toepassen van zelfmanagement is vaak een uitdaging en zelfmanagement van DM2 is minder dan optimaal, vooral met betrekking tot leefstijlgedrag. Slecht zelfmanagement kan een bewuste keuze zijn. Sommige patiënten zien de relevantie van het leefstijladvies voor hun eigen gezondheid niet in, terwijl anderen het vertrouwen missen dat ze erin zullen slagen om de veranderingen door te voeren.

In dit proefschrift staan de volgende aspecten van zelfmanagement centraal: participatie tijdens het consult, therapietrouw en gebruik van een online zorgplatform.

Participatie tijdens het consult

Goede communicatie tussen een POH'er en een patiënt kan helpen om een chronische aandoening goed te managen. Een aspect van zelfmanagement is daarom patiëntparticipatie in medische consulten. Participatie in medische consulten wordt gedefinieerd als de mate waarin patiënten bijdragen aan het consult, bijvoorbeeld door vragen te stellen, zorgen te uiten en voorkeuren te vermelden. Hogere niveaus van patiëntparticipatie in medische consulten kunnen klinische waarden en kwaliteit van leven verbeteren. Echter, veel patiënten met een chronische aandoening ervaren barrières voor participatie tijdens het consult, zoals tijdsdruk of de zorgverlener niet "tot last" te willen zijn.

Therapietrouw

De noodzaak van medicatie hangt af van de mate waarin patiënten andere leefstijladviezen opvolgen (bijv. afvallen, gezonder eten en lichamelijk actiever zijn). In Nederland werden in 2014 800.000 patiënten behandeld met bloedglucose verlagende medicijnen. De Wereldgezondheidsorganisatie (WHO) definieert therapietrouw als "de mate waarin het gedrag van een persoon - medicatie nemen, een dieet volgen en/of leefstijlveranderingen doorvoeren - overeenkomt met overeengekomen aanbevelingen van een zorgverlener". Echter, patiënten met DM2 benoemen inname van diabetesmedicatie als meest belastende zelfmanagementactiviteit en een aanzienlijk deel van de patiënten - tot 18% - neemt de medicatie niet zoals voorgeschreven.

Gebruik van een online zorgplatform

eHealth applicaties kunnen worden gebruikt om zelfmanagementondersteuning te bieden. Een voorbeeld van een online tool die zinvol kan zijn voor patiënten met DM2 is een online zorgplatform. Deze platforms kunnen patiënten ondersteunen bij het veranderen van hun leefstijl en het nemen van meer verantwoordelijkheid voor hun eigen gezondheid. Het gebruik van eHealth kan gezondheidsgedrag en klinische waarden bij patiënten met DM2 verbeteren. Desondanks komen implementatieproblemen en een lage participatiegraad veel voor.

In Nederland is een online zorgplatform genaamd "e-Vita" ontwikkeld om de zelfmanagementvaardigheden van patiënten met DM2 te verbeteren. Het e-Vita-platform bevat informatie over de gezondheidstoestand van de patiënt, maar biedt patiënten ook opties voor het formuleren van persoonlijke doelen, deelname aan educatieve modules, uitwisseling van berichten tussen patiënt en zorgverlener en zoeken naar informatie over DM2.

Diabetes zelfmanagementeducatie

Om het gebruik van een online zorgplatform zoals e-Vita te vergemakkelijken, moeten patiënten eerst een intentie voor gedragsverandering ontwikkelen. Dit kan alleen worden bereikt als ze voldoende risicobewustzijn hebben, behoefte aan gedragsverandering ervaren en er vertrouwen in hebben hun gedrag te kunnen veranderen. Het volgen van diabetes zelfmanagementeducatie kan nuttig zijn voor patiënten om deze inzichten en overtuigingen te verkrijgen. Voorlichting aan patiënten is een belangrijk onderdeel van diabetesmanagement, want de effectiviteit van diabetesmanagement hangt uiteindelijk af van de naleving door de patiënt van aanbevelingen en behandeling. Door de principes en het belang van een gezonde leefstijl te begrijpen, hebben patiënten meer kans om veranderingen in leefstijl succesvol aan te nemen. Diabetes zelfmanagementeducatie kan individueel of in een groep patiënten worden gegeven. Groepseducatie heeft onder meer het voordeel dat het patiëntbijeenkomsten biedt met discussies en peer motivatie.

In Nederland is een voorbeeld van diabetes groepseducatie het PRoactive Interdisciplinary Self-MAnagement (PRISMA) programma. PRISMA is gebaseerd op het in het VK ontwikkelde DESMOND-programma (Diabetes Education and Self-Management for Continuous and New Diagnosed). Het PRISMA-programma bestaat uit twee bijeenkomsten van 3,5 uur met een groepsgrootte van maximaal 12 patiënten plus mogelijke partners. Groepen worden begeleid door twee diabetesprofessionals, bijvoorbeeld een diëtist en een POH'er. Tijdens PRISMA worden patiënten gestimuleerd om hun eigen persoonlijke risicofactoren te overwegen en een specifiek doel van gedragsverandering te kiezen. Tevens worden zij gemotiveerd om na het voltooien van de training hun doelen en acties met hun zorgverleners te blijven bespreken.

Onderzoeksdoelen

Het onderzoek beschreven in dit proefschrift richtte zich op de zelfmanagementvaardigheden van patiënten met DM2. Het aanbieden van het PRISMA-programma had als doel zelfmanagement van patiënten te verbeteren door actiever deel te nemen aan het consult met hun POH'er, het trouwer innemen van hun

medicatie, en het gebruik van een online zorgplatform. Verwacht werd dat het PRISMA-programma de motivatie van patiënten zou vergroten om hun gedrag te veranderen en hun gezondheidstoestand te beheren met behulp van een online zorgplatform. Het doel van dit proefschrift was daarom onderzoeken of het PRISMA-programma het gebruik van het online zorgplatform e-Vita door patiënten met DM2 verbeterde.

De hoofdvragen van het proefschrift zijn:

1. Welke factoren helpen en belemmeren de actieve participatie van patiënten met DM2 in consulten met hun POH'ers in de huisartsenpraktijk?
2. Wat zijn de effecten van het PRISMA-programma op kwaliteit van leven, zelfmanagement en klinische waarden bij patiënten met DM2 die in de huisartsenpraktijk worden behandeld in termen van
   a. eigen-effectiviteit en participatie tijdens POH-consulten?
   b. therapietrouw aan het gebruik van glucose verlagende medicijnen?
   c. het gebruik van het online zorgplatform e-Vita?

Zelfmanagement verbeteren

Participatie van patiënten tijdens het consult

In hoofdstuk 2 wordt de participatie van patiënten met DM2 tijdens het consult besproken. Om inzicht te krijgen in de factoren die de participatie van patiënten met DM2 beïnvloeden, heeft deze studie onderzocht wat hen helpt of belemmert actief deel te nemen aan consulten met hun POH'ers. Uit de resultaten blijkt dat de behoeften, overtuigingen en vaardigheden van patiënten hun participatie beïnvloeden tijdens consulten. Met name de vaardigheden van patiënten met betrekking tot het nemen van de leiding, het uiten van gedachten en het voorbereiden van de consulten lijken te ontbreken. Een vertrouwensrelatie met hun POH'er, die zich meestal in de loop van de tijd ontwikkelt, kan patiënten echter helpen hun emoties en zorgen te bespreken. De meerderheid van de patiënten in de studie voelde zelden de noodzaak om actiever deel te nemen. Deze houding is waarschijnlijk te wijten aan de waargenomen afwezigheid van ziektelast en tevredenheid met hun huidige rol in de spreekkamer.

Studieopzet

In hoofdstuk 3 wordt de opzet van de studie gepresenteerd. Deze studie onderzocht de effecten van groepseducatieprogramma PRISMA bij patiënten met DM2 die worden behandeld in de huisartsenpraktijk op het gebruik van een online zorgplatform. De studie had een randomized controlled trial (RCT) design met een interventie- en controlegroep. Mensen van 18 jaar of ouder die waren gediagnosticeerd met DM2 onder behandeling waren in de huisartsenpraktijk konden deelnemen. Tweehonderd patiënten met DM2

die waren uitgenodigd om online zorgplatform e-Vita te gebruiken, ontvingen PRISMA naast de standaardzorg (interventiegroep) of enkel de standaardzorg (controlegroep). Het primaire eindpunt van deze studie was het gebruik van het e-Vita-platform. De secundaire eindpunten waren eigen-effectiviteit en participatie tijdens het consult met de POH'er, therapietrouw aan het gebruik van medicatie, zelfmanagementgedrag en klinische waarden. Na zes maanden ontvingen beide groepen PRISMA in een follow-up van zes maanden. Het doel van deze studie was om de instelling van patiënten te veranderen van het vrij passief ontvangen van informatie naar het meer actief toepassen van zelfmanagement.

PRISMA en eigen-effectiviteit en participatie tijdens het consult

In hoofdstuk 4 wordt het effect van PRISMA op de eigen-effectiviteit van patiënten met DM2 en hun participatie tijdens het consult met de POH'er onderzocht. PRISMA resulteerde niet in een hogere eigen-effectiviteit of participatie tijdens het consult met de POH'er na zes maanden, ondanks de focus op het voorbereiden van het diabetesconsult en het bespreken van doelen met POH'ers. Twee trainingssessies kunnen onvoldoende zijn en een krachtiger interventie, specifiek gericht op communicatie met zorgverleners, is mogelijk nodig. Deze studie toonde echter aanwijzingen dat PRISMA patiënten ertoe aanzette zichzelf tijdens het consult vaker te adviseren. Voorbeelden hiervan zijn uitingen zoals "Ik ben bezig met het verlagen van mijn bloedglucosewaarden". Dit resultaat is niet verrassend omdat patiënten tijdens het PRISMA-programma een specifiek doel van gedragsverandering kiezen en werden gestimuleerd om hun doel met hun POH'er te bespreken. Verder leek de medische toestand patiënten vaker te worden besproken na PRISMA, terwijl hun therapeutische behandeling juist minder vaak aan bod kwam.

PRISMA en therapietrouw aan medicatie

In hoofdstuk 5 wordt het effect van PRISMA op therapietrouw aan orale bloedglucose verlagende medicatie onderzocht bij patiënten met DM2 in de huisartsenpraktijk. Hoewel PRISMA niet specifiek is ontwikkeld om de therapietrouw bij patiënten met DM2 te verbeteren, is er binnen een periode van zes maanden toch een kleine verbetering gevonden. PRISMA resulteerde ook in minder medicijnonderbrekingen over een periode van zes en twaalf maanden. Er werden geen effecten gevonden bij zelf-gerapporteerde therapietrouw. De therapietrouw was al behoorlijk hoog.

PRISMA en het gebruik van een zorgplatform

In hoofdstuk 6 wordt het effect van PRISMA op het gebruik van een zorgplatform (e-Vita) besproken bij patiënten met DM2 in de huisartsenpraktijk. Een online zorgplatform kan patiënten met DM2 ondersteunen bij het managen van hun gezondheid. Het PRISMA-programma resulteerde niet in een hoger gebruik van online zorgplatform e-Vita bij patiënten met DM2 en ook de continuïteit van het gebruik was laag. Wellicht

is de meerwaarde van zelfmanagement van een chronische aandoening niet automatisch zichtbaar voor patiënten. Bovendien zijn platforms mogelijk niet geschikt voor ouderen met een lagere e-gezondheidsgeletterdheid.

PRISMA en zelfmanagement en klinische waarden

In hoofdstuk 7 wordt het effect van PRISMA op zelfmanagement en klinische waarden besproken. In deze studie verbeterde PRISMA het zelfmanagement (kennis, vaardigheden en vertrouwen voor zelfmanagement, diabetes zelfzorggedrag, gezondheid gerelateerde kwaliteit van leven en emotioneel welzijn) na zes of twaalf maanden niet. Bovendien was het niet mogelijk om een uitspraak te doen over de klinische waarden (HbA1c, BMI, systolische bloeddruk en cholesterolspiegels) gezien het grote aantal ontbrekende waarden in de dataset.

Implicaties voor de praktijk en toekomstig onderzoek

Naar aanleiding van de onderzoeksresultaten worden de volgende implicaties voor de dagelijkse praktijk en toekomstig onderzoek gesuggereerd.

Ten eerste kan ons onderzoek zorgverleners en beleidsmakers informeren over hoe patiënten met DM2 kunnen profiteren van consulten met een POH'er. Zorgverleners kunnen rekening houden met de houding en het potentiële gebrek aan vaardigheden van hun patiënten, omdat deze factoren het proces van gedeelde besluitvorming kunnen beïnvloeden. Vertrouwensrelaties met hun POH'er, die meestal in de loop van de tijd worden opgebouwd, helpen patiënten om actiever deel te nemen aan het gesprek. Daarom hebben patiënten behoefte aan een 'eigen' POH'er. Patiënten aanmoedigen om vragen op te schrijven voorafgaand aan het consult of de POH'er samen met hun partner te bezoeken, kan ook waardevol zijn om actief deel te nemen. Onze bevindingen kunnen bewijs leveren voor het ontwikkelen van interventies gericht op het verbeteren van participatie van patiënten. Als gevolg van het PRISMA-programma moeten zorgverleners bovendien worden voorbereid op een meer adviserende rol in overleg met patiënten met DM2. Bij het verder specificeren van patiëntdoelen van gedragsverandering, kunnen ze patiënten die al bezig zijn zichzelf te counselen aanmoedigen om hun diabetesmanagement te verbeteren. Toekomstig onderzoek zou het effect van PRISMA op het consult met POH'ers na zes maanden moeten onderzoeken. Patiënten hebben mogelijk meer tijd nodig om hun gezondheidsdoelen te beheren en actiever deel te nemen.

Ten tweede kunnen zorgverleners en beleidsmakers er rekening mee houden dat therapietrouw, als onderdeel van zelfmanagement van DM2, mogelijk wordt beïnvloed door PRISMA. Overigens zijn patiënten met DM2 meestal ouderen bij wie

polyfarmacie veel voorkomt en polyfarmacie is een risicofactor voor een langzamere start van een medische behandeling. Daarom heeft deze patiëntengroep extra aandacht nodig. Hierdoor kunnen patiënten volledig profiteren van de voordelen van groepseducatie. Onlangs is PRISMA uitgebreid met voorlichting over therapietrouw. Voor toekomstig onderzoek zou het interessant zijn om te testen of deze versie aanvullend effect heeft op therapietrouw aan medicijngebruik en leefstijladviezen.

Ten slotte zal de zorg in de huisartsenpraktijk in de toekomst minder intensief zijn vanwege de belasting op de diabeteszorg. Het is daarom interessant om de huidige gebruikelijke zorg te vergelijken met een minder intensieve versie van de gebruikelijke zorg (bijv. minder contactmomenten tussen patiënt en POH'er) plus een interventie (bijv. een online zorgplatform). Toekomstig onderzoek zou ook andere interventies voor patiënten moeten onderzoeken om intenties voor gedragsverandering te ontwikkelen om het gebruik van zelfmanagementprogramma's zoals een platform te vergemakkelijken. Bovendien zijn online zorgplatforms mogelijk niet geschikt voor ouderen met lagere digitale gezondheidsvaardigheden. Er moet worden geïnvesteerd in het ontwikkelen van online vaardigheden, met name voor deze patiëntengroep.

Conclusies

We hebben geen toegevoegde waarde van het PRISMA-programma gevonden bij het verbeteren van het gebruik van een online zorgplatform. Onze doelgroep was mogelijk niet geïnteresseerd in dit soort interventies, wat de realiteit is van de huidige zorg. Het bleek moeilijk om patiënten bij het PRISMA-programma te betrekken, wat resulteerde in hoge non-respons en een groot aantal patiënten die niet beide bijeenkomsten bijwoonden. Het managen van DM2 vereist al grote inspanning en verantwoordelijkheid van patiënten, groepseducatie kan worden beschouwd als nóg een extra verplichting.

Om het toenemende aantal patiënten met DM2 en de druk van diabetes op de gezondheidszorg aan te pakken, is een grotere participatie van patiënten nodig, inclusief meer zelfmanagement. Een verbeterd online zorgplatform zou onderdeel kunnen zijn van een oplossing. We hebben namelijk vastgesteld dat technische problemen op het platform de motivatie van patiënten om het verder te verkennen hebben verminderd. Bovendien lijkt een training om patiënten te helpen het platform te gebruiken essentieel.

Oudere volwassenen met minder kennis van eHealth hebben extra ondersteuning nodig bij het gebruik van een platform. We zagen een gebrek aan enthousiasme bij patiënten die het platform gebruikten. Naar verwachting zal inbedding van het platform in de standaardzorg de implementatie ervan vergemakkelijken. Desondanks kunnen eHealth en platforms over een paar jaar deel uitmaken van de gebruikelijke zorg.

Vandaag de dag is de kwaliteit van de klinische zorg voor patiënten met DM2 in Nederland al goed. In de toekomst is het belangrijk om dit huidige kwaliteitsniveau

van diabeteszorg hoog te houden of te verbeteren met minder intensieve zorg uit de huisartspraktijk (bijv. minder face-to-face contactmomenten met zorgverleners). Echter, ook als de kwaliteit van de zorg hetzelfde blijft, kunnen we dat als winst beschouwen.

About the author

Biografie
Dankwoord
List of publications

Biografie

Biografie

Esther du Pon werd op 11 oktober 1985 geboren in Zwolle (Overijssel). In 2006 behaalde zij haar mbo-diploma Sociaal Cultureel Werk – Kunst & Cultuur aan het Deltion College in Zwolle. Vervolgens begon ze in 2006 met de Bachelor Farmakunde aan de Hogeschool Utrecht, gecombineerd met een Minor Journalistiek. Voor de Bachelor Farmakunde volgde Esther stages bij Jellinek in Amsterdam en het Trimbos-instituut in Utrecht. In 2009 begon zij met de Master Communicatiestudies aan de Universiteit Utrecht. Voor deze Master volgde zij een stage bij TNO in Zeist. Tijdens haar masterscriptie verdiepte zij zich in het ontmoedigen van rookgedrag bij jongvolwassenen. Eind 2012 ging Esther werken bij de Hogeschool Utrecht, waar zij in 2014 officieel startte met haar promotietraject bij Radboudumc. Het promotieonderzoek zoals beschreven staat in dit proefschrift is uitgevoerd onder leiding van Prof. Dr. Sandra van Dulmen (Nivel, Radboudumc), Dr. Ad van Dooren (Hogeschool Utrecht) en Dr. Nanno Kleefstra (GGZ Drenthe Geestelijke Gezondheidszorg). Sinds oktober 2019 werkt Esther bij het Rijksinstituut voor Volksgezondheid en Milieu (RIVM).

Esther du Pon was born on October 11, 1985 in Zwolle (Overijssel). In 2006, she obtained her secondary education certificate in Social Cultural Work - Art & Culture at the Deltion College in Zwolle. In 2006, she started with a Bachelor in Pharmaceutical Business Administration at Utrecht University of Applied Sciences, combined with a Minor Journalism. For the study Pharmaceutical Business Administration, Esther followed internships at the Jellinek in Amsterdam and the Trimbos Institute in Utrecht. In 2009, she started the Master in Communication Studies at Utrecht University.
For this Master she did an internship at TNO in Zeist. During her master's thesis she studied discouraging smoking behavior among young adults. At the end of 2012, Esther started working at Utrecht University of Applied Sciences, where she officially started her PhD project in 2014 at Radboudumc. The PhD research as described in this thesis was conducted under the supervision of Prof. dr. Dr. Sandra van Dulmen (Nivel, Radboudumc), Dr. Ad van Dooren (Hogeschool Utrecht) and Dr. Nanno Kleefstra (GGZ Drenthe Mental Health Services). In October 2019, Esther started working at the National Institute for Public Health and the Environment (RIVM).

Dankwoord

Dankwoord

Sommige momenten leek het einde dichtbij, andere momenten leek ik juist in het duister te tasten… en nu is het af! Enkel mijn naam staat op de voorkant, maar mijn proefschrift had nooit bestaan zonder de hulp van vele anderen. Ik wil daarom graag een aantal mensen in het bijzonder bedanken.

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Naast mijn promotieteam hebben er nog andere coauteurs bijgedragen aan de totstandkoming van de artikelen. Bedankt Anita Wildeboer, Siham El Azzati, Henk Bilo en Frits Cleveringa voor jullie doorgaans verfrissende wetenschappelijke bijdrage.

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Studenten die een rol hebben gespeeld in dit onderzoek, jullie bijdrage was meer dan welkom. In het kader van stage of afstuderen hebben jullie onder meer geholpen met trainingsbijenkomsten organiseren, interviews coderen en data analyseren. Ik ben dankbaar dat ik jullie van dichtbij heb mogen zien groeien als onderzoekers.

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Lectoraatcollega's, ik begon bij het lectoraat IZF als eerste promovenda, maar naar mate de jaren verstreken volgden velen. We startten als een klein clubje hechte collega's, ik denk met veel plezier terug aan die tijd. Bedankt voor de inspirerende overleggen, praktische hulp en bijzondere uitjes. Erg boeiend om zijdelings betrokken te zijn (en blijven) bij al jullie onderzoeken.

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Esther

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