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A web-based program to improve treatment adherence in patients with type 2 diabetes: Development and study protocol

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ABSTRACT

Background: Many patients with type 2 diabetes mellitus (T2DM) sub-optimally adhere to core treatment recommendations, such as healthy diets, sufficient physical activity and pharmacological support. This paper describes the development of the web-based computer-tailored program My Diabetes Profile (MDP), incorporating identified success factors of web-based interventions, and the protocol for testing the effectiveness of this program in a randomized multicentre trial.

Methods: Formative research - including the input of a program committee, qualitative and quantitative studies with patients and health professionals and a literature search - yielded input for the development of the MDP program. MDP provides video and text tailored advice, based on determinants and salient beliefs derived from the I-Change Model, on decreasing unhealthy snack intake, increasing physical activity, and improving adherence to both oral blood glucose lowering drugs and self-administered insulin therapy. Patients with T2DM recruited by practice nurses and diabetes nurses across the Netherlands fill in online questionnaires at baseline and six-months follow-up. Participants are randomized on patient level to the intervention group (access to the MDP program) or control group (receiving care as usual).

Discussion: The formative research using co-creation principles proved essential in the development of the MDP program and involved various disciplines in T2DM management including target group representatives. Co-creation revealed clearly that patients needed short and attractive messages. Consequently, a mix of video and short text messages were chosen for the ultimate program format. Pilot testing was useful to further shape the program to needs of patients and professionals.

Trial registration: Dutch Trial Register NTR6840; Archived program website: http://www.webcitation.org/6xXz01S7X

1. Introduction

Type 2 diabetes mellitus (T2DM) is a progressive disease characterized by hyperglycemia and the body's inability to maintain a normal glucose metabolism [1]. Worldwide over 400 million people live with diabetes, with expectations of almost 650 million people being affected by 2040 [1]. Core T2DM treatment recommendations concern lifestyle modifications such as improving dietary patterns and increasing physical activity (PA) as well as pharmacological support such as oral blood glucose lowering drugs and/or (self-administered) insulin therapy [2,3]. Unfortunately, patients' adherence to each of these separate recommendations is suboptimal [4–8]. The majority does not consistently meet dietary or PA recommendations [4,7,8], and most studies on adherence to pharmacological support, report adherence prevalences below 80% (range 38.5–93.1%) [6]. Suboptimal adherence not only attenuates positive treatment effects [9], but is also associated with disease worsening, an increase in cardiovascular events, quality of life reduction, increased healthcare expenditures and hospitalizations, as well as early mortality [10–16]. Clearly, new avenues need to be sought to improve treatment adherence in patients with T2DM.

Patients' (non)-adherence to specific treatment recommendations can partly be explained by socio-cognitive determinants, such as a person's knowledge, attitudes, self-efficacy and intention [17]. Salient personal beliefs about a certain treatment recommendation, underlying these socio-cognitive determinants, are considered important in predicting treatment adherence [18,19]. For instance, patients often lack

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knowledge and motivation to modify lifestyles, as well as clear goals and coping plans to persist in these changes [3,20,21]. Therefore, these determinants need to be addressed in interventions that aim to improve treatment adherence [18].

The Internet offers novel opportunities to improve treatment adherence in chronic diseases such as T2DM [22]. *E*-Health interventions have shown to be (cost)-effective, easy in use, have fewer availability restrictions than regular medical consultations, and can temper pressure on healthcare systems [23–30]. Moreover, these interventions can apply computer-tailoring technology; a methodology to provide patients with personalised advice based on unique answers given during an online assessment [31]. Yet, a recent general review on Internet interventions supporting diabetes management [32] concluded that only one of the nine included studies reported significant improvements in dietary patterns and PA, with small to modest effect sizes of 0.19 and 0.32 respectively [33]. Furthermore, none of the studies focussing on improving medication adherence yielded significant results. However, existing web-based support programs often include little interactive content, are mainly text-based, make little use of theoretical substantiation, and focus on separate behaviors which play a role in the management of T2DM instead of combining behaviors [32,34]. As success factors of web-based interventions include using a theoretical framework, providing interactive tailored information, applying goal setting principles, using tracking tools, identifying risk behaviors, making use of visual support and focussing on various phases of health behavior change (i.e. awareness, motivation and action planning) [22,32–34], web-based diabetes treatment adherence interventions effects might be significantly improved by incorporating these factors. First, this paper describes the development of the new web-based computer-tailored program (My Diabetes Profile), aiming to improve patients' adherence to core T2DM treatment recommendations, by incorporating previously identified intervention success factors. Subsequently, it describes the protocol for the assessment of its effectiveness in a randomized multicentre trial.

2. Methods/design

2.1. My diabetes profile program

As preparation for the development of the My Diabetes Profile (MDP) program, formative research was conducted. Firstly, both qualitative [35] and quantitative studies were conducted to identify the scope of treatment (non)-adherence and to elicit salient personal beliefs involved in treatment recommendation adherence [19]. Findings indicate that patients' adherence to treatment recommendations was suboptimal and therefore subject to improvement. Moreover, many patients incorrectly perceived themselves as adherent to distinct treatment recommendations. With regard to non-adherence to dietary recommendations, patients were most likely to engage in unhealthy snack intake [35]. Secondly, knowledge was accumulated from previously developed computer-tailored programs targeting improvements in treatment recommendation adherence [36–38]. Thirdly, a program committee was formed to foster co-creation, following the principles of Havelock's linkage approach [39]. The committee met three times during the 18-months program development phase and included members from various disciplines involved in T2DM management: practice nurses (PNs), diabetes nurses (DNs), a dietician, an internist, a general practitioner, health scientists, an e-Health expert, and patients with T2DM. Based on the input of the formative research and co-creation, the MDP program was developed. The content of the MDP program is theoretically grounded in the I-Change Model (ICM) [17]. The ICM integrates different well-known socio-cognitive theories [19,40,41] and is used often to identify salient beliefs of health behavior (change) and develop interventions accordingly [42]. The ICM differentiates between three phases; an awareness phase, a motivation phase and an action planning phase, which are influenced by preceding factors and information factors (see Fig. 1). The model assumes that behavior change is a result of becoming aware of the necessity of behavior change by activating risk perceptions and increasing knowledge of the behavior and its consequences. Moreover, a person's cognizance level indicates if a person is (in)correctly aware of carrying out the recommended behavior. For instance, a person could perceive to be sufficiently physically active, while in fact recommended levels sufficient PA are not met. Contrary, a person could correctly perceive that s/he is not sufficiently physically active, which indicates awareness of the discrepancy between what is recommended and actual behavior. In sum, first one needs to be aware of the necessity of behavior change. Subsequently, if sufficient awareness of behavior change is present, a weighing of the pros and cons of the desired behavior, perceptions of social influences, and the level of one's own belief to successfully carry out the desired behavior in certain difficult situations (self-efficacy), determines the motivation a person has to change a behavior. The strength of the intention to change a behavior a person has, is determined by motivational factors and awareness factors. The ICM assumes that people who express a low intention towards behavior change, can increase their intention to change by increasing their motivation and awareness of a specific health behavior. Contrary, people who express a high intention towards behavior change have a higher likelihood of successful translation of this intention into practice, by making and enacting action and coping plans. In this phase, again self-efficacy plays a major role in carrying out action plans. It is well known that expressing a high intention towards behavior change, does not necessarily guarantee successful behavior change [43]. Hence, the action phase facilitates the translation of intention into actual action.

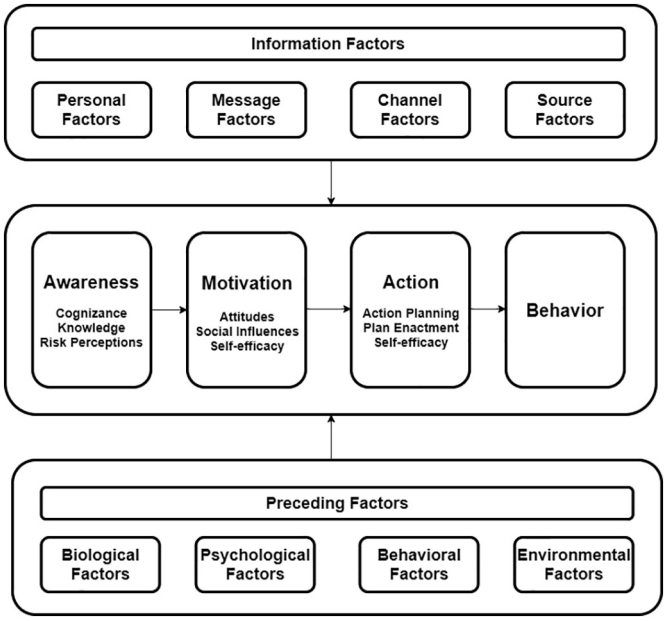

Fig. 1. The I-Change Model.

2.1.1. Program content

The MDP program starts with a baseline assessment consisting of demographic questions, questions on comorbidity, patient's perceived adherence (cognizance) to separate treatment recommendations, and an objective treatment recommendation adherence assessment regarding PA, unhealthy snack intake, medication adherence (adherence to oral blood glucose lowering drugs and/or self-administered insulin therapy), and smoking. The objective treatment recommendation adherence assessment will serve as outcome measure and is described in more detail in section 2.3. The program lasts a total of six months, and consists of two practically identical blocks of three months. In each block of three months, participants can select a single treatment

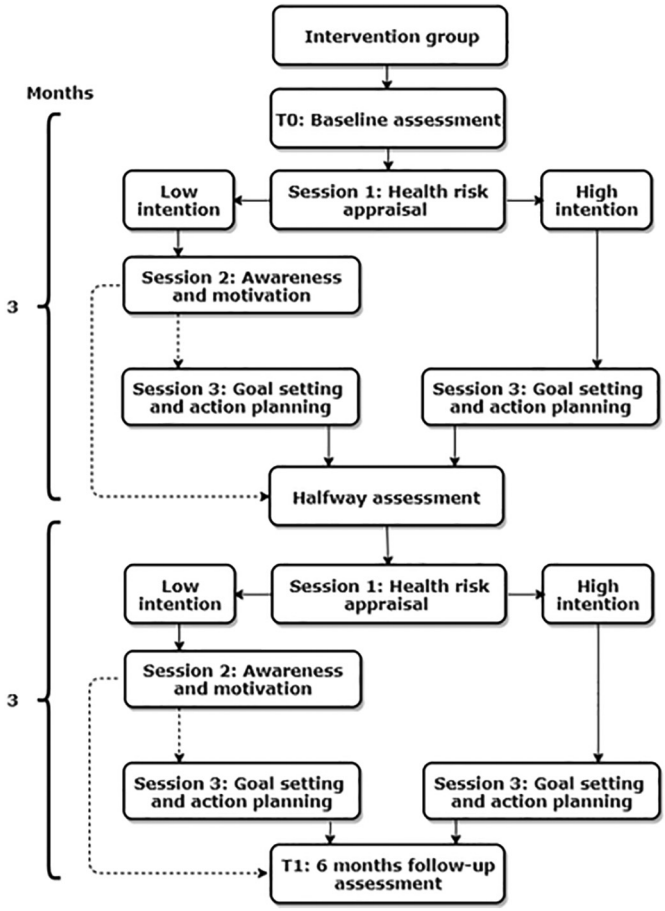

Fig. 2. schematic overview of program course.

recommendation to improve. For instance, it might be that a participant selects unhealthy snack intake to improve in the first three months, and physical activity in the second three months. However, participants are able to select the same behavior again in the second three months if they believe this particular recommendation needs further improvement relative to others. In turn, every three-month block consists of three sessions; 1) health risk appraisal, 2) awareness and motivation, and 3) goal setting and action planning, which guide the behavior change process. All sessions last on average 20–30 min and can be continued any time where someone left off (Fig. 2).

2.1.2. Session 1: health risk appraisal

In the first session, participants receive a tailored health risk appraisal based on the answers given to the baseline assessment. The health risk appraisal provides information on whether their perceived adherence to treatment recommendations matches with objective guideline targets. For those behaviors that the participant is not yet adherent to, their intention to change that behavior is assessed. As the last parts of session one, participants are prompted to self-select a single behavior that can be improved and which will be their focus for the coming three months while working with the program. The approach of selecting a single improvable behavior at a time was chosen because on the one hand patients are more successful in achieving behavior change in one treatment element, when compared to two [44]. On the other hand, improving behaviors sequentially rather than simultaneously, might work better if patients are permitted to self-select a behavior to work on first and which aligns best with their willingness to change [45]. Although smoking status is assessed and followed-up with tailored advice in the health risk appraisal, it is not considered a core T2DM treatment recommendation [2,3]. Hence, participants are not able to select this behavior within the MDP program. Instead, all smokers receive a brief advice to quit and are directed to their general practitioner for further information and support. In case participants meet all recommendations they are recommended to select PA, as current Dutch guidelines state that any physical activity beyond the weekly recommended 150 min is desirable [46]. A participant who has selected a behavior for which s/he has a low intention to change (i.e. not motivated to change, or motivated to change but not within the next three months) is directed to session two (i.e. awareness and motivation). This session particularly aims to increase this motivation or raise awareness for the need to make improvements, with the ultimate goal to achieve a high intention to change. Therefore, session two is designed for participants to keep on working with the program procedure, even while they express a low intention to change an improvable behavior. If a behavior is selected for which the participant has a high intention to change (i.e. motivated to change within three months), the participant is directed to session three (i.e. Goal Setting and Action Planning). This strategy was chosen to optimally tailor the intervention to the behavior change state of the participant as assumed by the I-Change Model [17].

2.1.3. Session 2: awareness and motivation

The second session consists of two sub-sessions and is specifically designed for participants who chose to work on a behavior for which they have a low intention to change. The goal of sub-session 2a is to increase a participant's motivation to change behavior by providing tailored advice the motivational determinants ‘attitudes’ (i.e. pros and cons) and ‘perceived social influences’ (i.e social support, social modeling and social norm). First, salient beliefs with regard to motivational determinants are assessed on a 5-point Likert scale (totally disagree – totally agree), after which tailored feedback is provided. Session 2a ends with again an assessment of the intention to change the behavior. If a participant now has a high intention to change the behavior, the participant will be directed to session 3. If a participant still holds a low intention to change, s/he continues to session 2b. The goal of sub-session 2b is to increase a participant's awareness to change behavior by providing tailored advice on the awareness determinants ‘knowledge’ and ‘risk perception’. Salient beliefs with regard to risk perception are assessed on a 5-point Likert scale; knowledge items are answered on a dichotomous scale (true, false). Session 2b ends with a final assessment of the intention to change the behavior. If a participant now has a high intention, the participant is directed to session 3. If a participant again has a low intention to change the behavior, the program advises to wait for the second block of three months. Participants are then able to select a different behavior to work on or to use the time in between to contemplate changing the initial selected behavior. The approach to start with increasing motivation and if necessary raising awareness was chosen to keep the program as proximate to behavior as possible according to the ICM. At the same time, the aim was to offer only the most relevant feedback and content to patients, in order to keep the total time to use the program low and feedback tailored to the individual user's needs.

2.1.4. Session 3: goal setting and action planning

In the third session, participants are primarily prompted to set specific goals for their selected behavior. For instance, participants who wish to increase their level of PA can select how many more minutes/week they want to be physically active. The program facilitates goal setting by providing several pre-formulated options varying in difficulty, but also provides an option to construct their own goal. Participants are encouraged to set small, realistic and achievable goals [44]. Next, participants select pre-formulated action plans or construct their own. For instance, if a person wants to become more physically active, the program facilitates goal achievement likelihood by formulating specific plans on how to become more physically active, e.g. *taking the stairs more often* or *cycling to work*. Subsequently, self-efficacy is assessed, i.e. participants are asked to identify pre-formulated or

individual situations in which they might find it difficult to carry out the intended goal, e.g. *being physically active when it rains.* Self-efficacy is assessed on a 5-point Likert scale (very difficult – very easy). This is followed by tailored advice on why particularly these situations are considered difficult and how to deal with them. Last, participants are prompted to formulate specific pre-formulated or individual coping plans for their difficult situations. Session 3 ends by providing patients with an overview of the advice they received and the goals and plans they made. Participants can now revisit their advice at any time, as well as the general program modules in the main menu.

2.1.5. Forms of computer-tailoring

The MDP program offers two forms of tailored advice, video and text tailoring, throughout all sessions. First, participants receive segment-tailored information messages via video, to generate attention and to help process information [34]. Tailoring based on segmentation entails that participants who score high, medium or low on a specific determinant receive different video content. For instance, a participant that scores high on pros of PA (i.e. seeing many advantages to being physically active) receives a video that reinforces the advantages a participant sees and provides additional advantages. Contrary, a video for participants who score low on pros of PA (i.e. perceiving few advantages to being physically active) includes arguments to persuade participants of the most salient advantages of PA. All videos are animated video's created with Go Animate software [47]. Animated videos were preferred by the program committee over real life videos because they were perceived as more exciting and potentially less confronting to patients with T2DM. After a video, participants receive a brief text advice, which generally consists of five to ten text lines with more in-depth tailored information. For instance, the health risk appraisal text on PA provides accurate numbers of minutes a participant is physically active. Keywords in the text messages are either underlined or highlighted by color or font to generate additional attention [48].

2.1.6. Ipsative advice

The health risk appraisal (session 1) at three month follow-up (i.e. the start of the second three-month block) uses both the answers given to the baseline assessment and the answers given to the halfway assessment to provide ipsative advice [49]. Ipsative advice can be offered in interventions with multiple feedback sessions in time and can provide insights in the direction and extend of changes over time in relevant behaviors [49]. The advice is displayed in tailored text messages, which provide the participant information on whether s/he significantly improved, deteriorated or did not change a certain treatment element.

2.1.7. General modules

In addition to tailored behavioral modules, the MDP program also includes three general modules; My Care, My Values and My Profile. These general modules were incorporated to make the program a more complete self-management tool, to facilitate consultation preparation, and to stimulate program revisits. My Care facilitates participants in preparing their consultations and stimulates participants to proactively formulate questions, provide a brief health update, and to learn how to be an active collaborator in consultations. My Values gives participants the opportunity to enter and visually keep track of their blood glucose levels, blood pressure, weight, and body mass index. My Profile provides a clear overview of the participant's most recent entered values, their medication, and their next appointment with their healthcare professional. Fig. 3 displays the main menu of the MDP program.

2.1.8. Health report

In order to facilitate discussion of respondents' health goals during regular medical consultations, the healthcare professional will have access to the patients' individual health report summary. The health report visually displays the behavior the respondent has selected to improve, the goals s/he has set, and the information from the My Care and My Values modules.

2.1.9. Usability testing

To identify potential program bugs, to assess participants' satisfaction with the program, and to make pre-trial improvements, usability tests were conducted with healthcare professionals ($n = 5$) and T2DM patients ($n = 17$). Recruitment occurred pragmatically in one outpatient clinic, where healthcare professionals and patients were deliberately recruited, taking into account profession, age, gender, education level, medication use, to strive for heterogeneity. Healthcare professionals were provided with login-data and program instructions, and were asked to visit the program website. Patients were provided with login-data and program instructions and were asked to use the program. While reading the instructions and visiting the program, healthcare professionals and patients were instructed to express their thoughts and opinions using the thinking aloud method [50]. Usability tests were conducted at the research department in the presence of a researcher and were audio recorded. Expressed thoughts and opinions were used as input to improve the program. Healthcare professionals and patients reported that they were very satisfied with the program and its usability. Only minor changes had to be made, which included instructions on how to navigate in the program, on how to answer questions on PA adherence, and on how to thoughtfully read questions and information.

2.1.10. Prompts to promote program use

The My Diabetes Profile program includes periodic email prompts to persuade participants to (re-)log in and to enhance usage. Periodic prompts are considered promising in enhancing effectiveness [51] and short timing prompts (two weeks after their first visit) seem to be most effective in encouraging computer-tailored program revisits [52]. The prompts used in our program are tailored to the participants' gender and last name. Participants receive a maximum of two email reminders, within two weeks after their most recent visit, to prompt completion of a yet uncompleted session, or when new sessions or assessments become available.

2.2. Study design effectiveness trial

A multicenter randomized trial with a waiting list control group design will be used to assess the effectiveness of the developed MDP program in patients with T2DM. After recruitment, registration and informed consent procedure, all participants will be randomly assigned to either an intervention group or control group. Group allocation takes place on patient level by means of computer randomization which allocates 50% of the participants to either group. Respondents of both groups are then prompted to fill in an identical baseline assessment (T0). Intervention group participants then gain access to the MDP program for six months. Control group participants are made aware that they will not receive access to the program at this stage, but are eligible for delayed access, after completion of the effectiveness trial (waiting list control group). Six months after baseline completion, all participants are prompted to fill in the follow-up assessment (T1). Afterwards, control group participants will receive instructions on how to request program access. The study is approved by the Medical Ethics Committee of the Maastricht University Medical Centre (16–4-171). The study is registered in the Dutch Trial Register (NTR6840).

2.2.1. Recruitment of T2DM participants

In the Netherlands, T2DM patients are predominantly treated by practice nurses (PNs) and diabetes nurses (DNs) in the general practice and hospital outpatient setting respectively, who are in turn supervised by physicians [3]. Most T2DM patients visit their PN or DN quarterly, and in case of no direct risk factors of health complaints every semester [3], hence these healthcare professionals are in an ideal position to

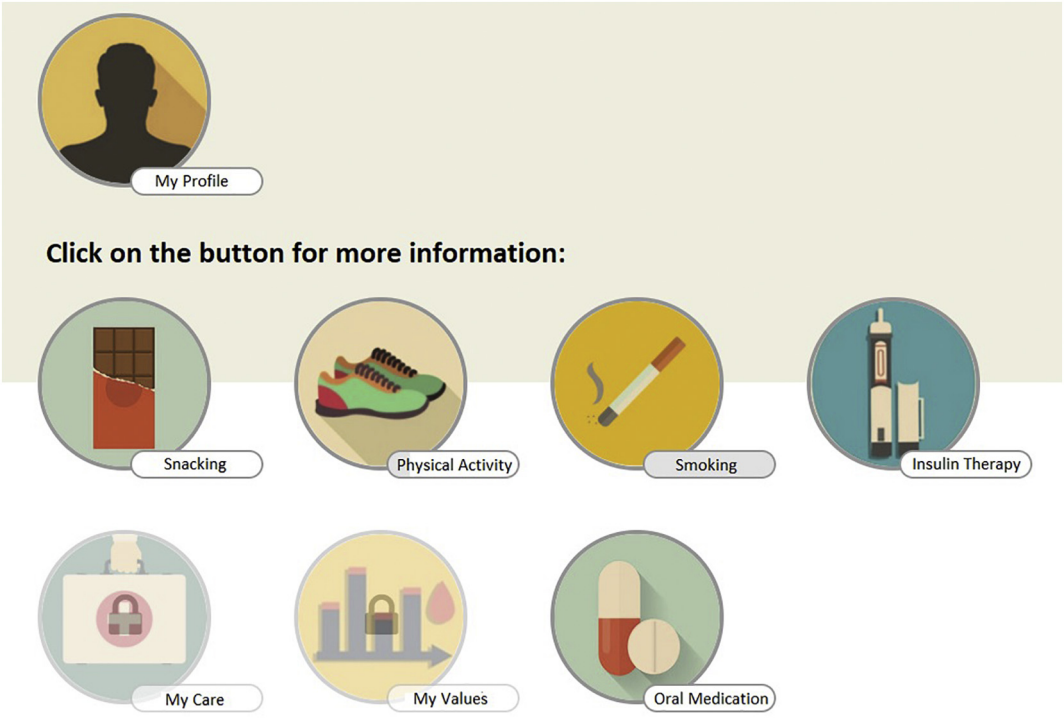

Fig. 3. main menu of the My Diabetes Profile program.

recruit patients for our trial. Trial inclusion criteria are: 1) T2DM diagnosis for at least one year, 2) 40–70 years old, 3) using at least one form of diabetes pharmacological support, and 4) having no walking disability. Exclusion criteria are: 1) not speaking or understanding the Dutch language, 2) having no access to the Internet, and 3) insulin pump therapy. People on insulin pump therapy will be excluded because of the distinct adherence nature of insulin pump therapy compared to self-administered insulin therapy. Given this recruitment strategy, patients are nested in the general practice and hospital outpatient settings. PNs and DNs across the Netherlands will be approached through email (with an invitation and brochure that explained study details), telephone calls, letters to their work address and social media platforms. PNs and DNs can register for the study by contacting the research team directly, or by registering via the project website. PNs and DNs are asked to recruit T2DM patients during regularly occurring medical consultations, through telephone calls or through email for a period of six-months. Prior to the start of the effectiveness trial, participating healthcare professionals are provided with detailed information about the study and the MDP program. A recruitment checklist can be used during consultations to facilitate recruitment and graphically depicts the study's inclusion criteria. The checklist also includes the healthcare professional's unique username and password, and instructions on how to register a participant. Following registration by their PN or DN, patients immediately receive an email from the research team including login instructions and an invitation to fill in the online baseline assessment. After logging into the system, patients are provided with extended study information and an online informed consent form. After signing for informed consent, participants are directed to the baseline assessment.

2.3. Power calculation and data collection

2.3.1. Primary outcome measure and power calculation

To assess the effectiveness of this multiple behavior intervention program as a whole, changes in adherence to PA, unhealthy snack intake, oral blood glucose lowering drugs and self-administered insulin therapy will be standardized and summed into a composite lifestyle index score as primary endpoint. As proposed by Prochaska and colleagues [53], an option to create standardized change scores is to subtract baseline scores for each behavior separately from follow-up scores and subsequently divide this by the standard deviation of the difference of the specific behavior. This way, effect sizes can be calculated for all behavior separately. Subsequently, to create the index score, separate effect sizes for all behaviors were summed. The effect size for unhealthy snack intake was reverse coded since the intervention aimed to decrease this behavior. To assess significant change between the intervention and control condition, a two-tailed *t*-test was applied with an α of 5%. Our power calculation is based on the primary outcome measure and aims for a near medium MDP program effect size of 0.4. Assuming an intraclass correlation coefficient of 0.02, an α of 5%, and power of 0.80, 116 patients per group are required at the end of the trial (232 in total). Considering an attrition percentage of 50%, our aim is to include a minimum of 464 patients at baseline. We expect that each PN/DN can recruit eight patients, hence we aim to recruit a minimum of 58 healthcare professionals.

2.3.2. Data collection

The data obtained from the first entry into the program, as described earlier in section 2.1.1 (Program Content), will be used as baseline assessment. These measurements will be repeated at a six-months follow-up assessment except for the comorbidity questions. Socio-cognitive determinants are assessed with four to six items on a five point Likert scale (totally disagree – totally agree). We use the following instruments to measure our primary outcomes.

2.3.3. Physical activity

The level of PA is assessed using the validated Short Questionnaire to Assess Health-Enhancing Physical Activity (SQUASH) [54]. The SQUASH assesses physical activities in the area of commuting, leisure time and sports, household, and work and/or school. Activities can be reported in average hours and minutes per day, and the frequency of weekdays these activities are carried out. A total number of weekly minutes of physical activity will be calculated based on the SQUASH.

2.3.4. Unhealthy snack intake

A food frequency questionnaire (FFQ) developed for this trial is used in which participants are asked to recall their last week's unhealthy snack intake. The FFQ lists unhealthy snacks identified by earlier research supplemented with unhealthy snacks which are commonly consumed in the Netherlands [55,56]. All listed unhealthy snacks account for a specific amount of caloric intake which will be summed to create a total number of weekly calories consumed from unhealthy snacks.

2.3.5. Oral blood glucose lowering drugs adherence

Oral drug adherence will be measured with the ProMAS questionnaire [57], a self-report instrument which has been recently developed in response to flaws in existing and frequently used self-report adherence measures such as the MARS-5 and Morisky Medication Adherence Scale [57,58]. It consists of eighteen items that assess a variability of adherence behaviors, e.g. forgetting, stopping, changing dosages, or taking medication too late (range 0–18). A higher score indicates a better adherence. In close collaboration with the developers, we translated the original English ProMAS questionnaire to Dutch which fits the use in this intervention study. To be able to compare changes over time, we further added a time period to every single items to assess adherence of the past three months. Based on the eighteen items, a sum score will be calculated as outcome for adherence to oral blood glucose lowering drugs.

2.3.6. Insulin therapy adherence

Adherence to insulin therapy is measured with a self-administered questionnaire, adapted from the ProMAS questionnaire [57]. Non-relevant items were removed, resulting in a measure with nine times. Items were considered not relevant if they did not distinguish between adherence and non-adherence for insulin therapy (e.g. the item 'I sometimes take fewer medicines than prescribed by my doctor' was removed as patients using insulin should adjust their dosage in case of hypoglycemia or illness). In line with the assessment of oral blood glucose lowering drugs adherence, a time period was added to every single item to assess adherence of the past three months. Based on the nine items, a sum score will be calculated as outcome for adherence to insulin therapy, ranging from 0 to 9 where higher scores indicate better adherence.

2.4. Data analysis

Complete case analyses will be conducted for participants who completed both the baseline and follow-up assessment. Sensitivity analyses will be carried out for those who did not complete the follow-up assessment, i.e. for participants of which no primary outcome is available at follow-up. For incomplete assessments, multiple imputation on the outcome measure will be applied using both an optimistic and pessimistic scenario. Descriptive statistical methods and frequencies will be used to describe sample characteristics. A logistics regression analysis will be conducted to identify potential selective attrition of participants between baseline and follow-up with regard to demographics. The effect analyses will be conducted for the primary outcome measure which will consist of a combined index of individual behavior z-scores. Given the hierarchical structure of the data, multilevel linear regression analyses will be conducted. Besides the repeated measures structure, patients are nested within healthcare providers, and two types of healthcare providers will recruit the participants, i.e. practice nurses and diabetes nurses. Therefore, these levels will be included in the analyses as random factors. Both adjusted and un-adjusted analyses will be provided and analyses will be adjusted for potential confounders (i.e. baseline adherence, predictors of attrition, and demographics). All statistical analyses will be executed using SPSS version 24.0.

3. Discussion

This paper presented the design, course and content, and proposed effect evaluation protocol for a newly developed web-based computer-tailored program named My Diabetes Profile. The program aims to improve patients' adherence to core T2DM treatment recommendations and incorporates previously identified success factors to successfully influence patients' adherence rates. Because patients' adherence to treatment recommendations is frequently suboptimal, interventions are needed to support treatment adherence and to support the persistence of behaviour over time. The Internet offers promising opportunities to intervene given a variety of advantages including the potential to reach out to the rapidly growing population of patients with T2DM, the potential (cost)-effectiveness of Internet based interventions, the application of computer-tailoring technology and the tempering of pressure on healthcare systems. The MDP program combines various success factors such as using a theoretical framework, providing interactive tailored information, applying goal setting principles, using tracking tools, identifying risk behaviors, making use of visual support and brief text advice, and focussing on various phases of health behavior change. Hence, we hypothesize that the MDP program can effectively improve treatment recommendation adherence in patients with T2DM, which will be tested in a randomized trial.

3.1. Potential strengths of the study

Several potential strengths of the MDP program and the study are worth mentioning. First, the program's design, course and content are based on extensive formative research including co-creation by a variety of key persons involved in diabetes care. Secondly, the MDP program incorporates previously identified success factors and uses salient personal beliefs in changing behavior, i.e. improving treatment recommendation adherence. Third, in order not to further burden health care professionals, the program is run completely independent of healthcare professionals in the trial. Fourth, the trial will be conducted nationwide, in both primary and secondary care, which increases generalization of the results obtained. Fifth, the program was comprehensively pilot tested among the target group which yielded useful input for pre-implementation improvements. Last, randomization will occur on patient level which means that healthcare professionals include patients which will randomly be assigned to either the intervention or control group. Contrary to randomization on healthcare professional level, this procedure attempts to minimize the potential influence of healthcare professionals.

3.2. Potential limitations of the study

The present study (design) and program is also subject to some limitations. A first potential limitation concerns high attrition rates of participants in online interventions [34,59]. Various factors might positively contribute to attrition rates, e.g. a high workload and limited usability of the intervention, and the ease of ending program and trial participation [59]. In the program, workload was limited by creating fairly short sessions (20–30 min) and allowing participants to access and continue the program at any time where they left off. Moreover, we tried to minimize usability issues by comprehensively testing the intervention prior to the start of the effect evaluation in which participants indicated their satisfaction and by using prompts to pursue program revisits and continued use once a patient is registered. Although these measures are likely to limit the drop-out rate, we still expect considerable drop-put and adjusted our power calculation accordingly (i.e. 50% drop-out rate at the time of last follow-up). A second potential limitation is the relatively short follow-up assessment of six months following intervention start. This way, it is not possible to assess if potential program effects sustain over time after program completion. Future studies should, if possible, apply study designs with extended

follow-up periods to assess whether potential effects sustain over a longer period of time after intervention completion. Last, as our recruitment period will last for six months, and our intervention duration is six months, this might lead to seasonal variation in our outcome measures. Indeed, Ma and colleagues [60] showed that caloric intake was higher in autumn compared to spring and that PA levels were lowest during winter whereas they were highest in springtime. However, seasonal differences in this particular study were considered generally small.

3.3. Lessons learned

As advocated in Havelock's linkage approach [39], the involvement of relevant stakeholders was an essential element in the development of our computer-tailored program and the subsequent design of the trial. Based on our positive experiences we suggest that the program committee should be a representation of all relevant disciplines involved. Selecting one or two individuals, however, does not guarantee that all the relevant viewpoints that are current in a specific discipline are expressed. Therefore, we suggest that in future projects the representatives should, if possible, consult a larger group of colleagues, to seek input on the topics discussed and decisions made by the program committee. This requires not only the formation of a program committee, but also the formation of a number of stakeholder-specific panels. Moreover, our program committee met three times during the formative research and program development phase which lasted for eighteen months. However, it is unclear what the optimal frequency of such gatherings should be and which disciplines should always be involved. We suggest that future projects should properly investigate which disciplines to include and internally assess the necessity and frequency of gatherings.

4. Conclusion

This paper offers detailed insight into the design and protocol for the effectiveness trial of the newly developed My Diabetes Profile program. The effectiveness trial's data collection is expected to be available from the end of 2018. If the MDP program is effective in improving treatment adherence in patients with T2DM, adaptation of the intervention to other chronic diseases might have potential value for other patient groups.

Conflict of interest

None declared.

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