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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.

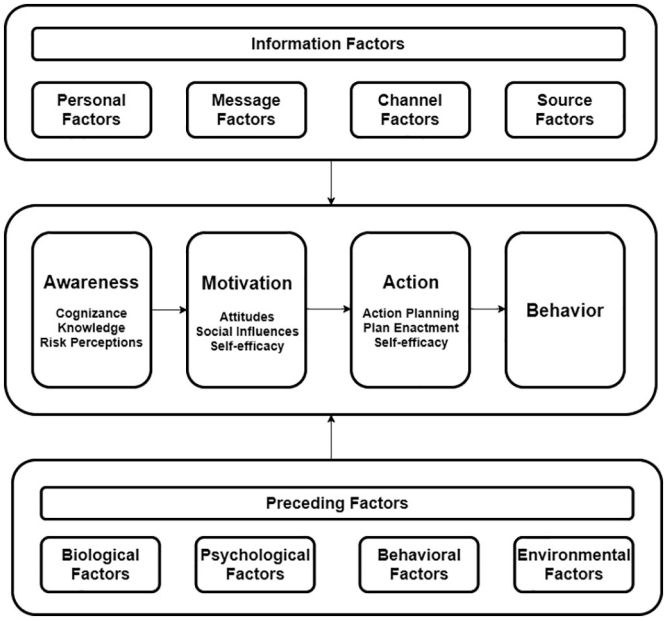

Fig. 1. The I-Change Model.

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