



# Self-regulation-based eHealth promoting an active lifestyle in adults

A focus on users with type 2 diabetes

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## Summary

In Europe 58 million people are diagnosed with diabetes. Type 2 diabetes accounts for 90% of all diabetes cases. The disease is associated with a large number of negative health outcomes, including cardiovascular disease and kidney failure. Research shows that increasing physical activity and decreasing sedentary behaviour are important health behaviours for the prevention and management of type 2 diabetes. Nevertheless, the majority of adults with type 2 diabetes does not reach the guidelines regarding physical activity and accumulates high levels of sitting time. These findings call for cost-effective interventions targeting physical activity and sedentary behaviour in adults with type 2 diabetes.

Interventions delivered via the Internet (eHealth) or mobile phones (mHealth) can reach many people in a cost-effective way. E- and mHealth interventions targeting physical activity in the population of adults with type 2 diabetes usually show mixed results. Furthermore, to date, there are no e- or mHealth interventions targeting sedentary behaviour in this target group.

The effectiveness of e- and mHealth interventions can be increased in two ways. First, online interventions show stronger effects when they are underpinned by a solid behaviour change theory. For example, self-regulation theory describes how people alter their behaviour by making a distinction between motivational processes targeting the development of an intention and volitional processes translating this intention to actual behaviour change. Second, the high rates of attrition characterizing e- and mHealth interventions highlight the need to involve users in the development process. To summarize, it is of major importance to adopt a top-down (theory-based) as well as a bottom-up (user-based) approach.

'MyPlan 1.0' is a self-regulation-based eHealth intervention, developed by the department of Movement and Sports Sciences and the department of Experimental Clinical and Health Psychology, targeting physical activity and the intake of fruit and vegetables. The programme was found to be effective to alter these health behaviours in the general population as well as in recently retired adults. However, similar to other Internet-based interventions, 'MyPlan 1.0' was challenged by high rates of attrition.

The research conducted for this doctoral thesis had two aims. The first aim was to identify the reasons for attrition in 'MyPlan 1.0' and to develop 'MyPlan 2.0', a self-regulation-based e- and mHealth intervention targeting physical activity and sedentary behaviour in adults with type 2 diabetes. However, considering the promising effects of 'MyPlan 1.0' in the general population, it was decided to also ameliorate the programme for adults from the general population. The second aim was to test the effectiveness of 'MyPlan 2.0' via a randomized controlled trial.

Two studies were conducted to gain insight in the reasons for the high levels of attrition detected in 'MyPlan 1.0'. First, by analysing the website usage data, we found that a high number of users quit during the first session of the programme, especially in the components during which users received minimal feedback from the programme (e.g. when completing questionnaires). Furthermore, the results indicated that men and younger users were less likely to complete the intervention. Second, by asking users from the general population as well as users with type 2 diabetes to go through the intervention while verbalizing their thoughts, we found that many users perceived the intervention as time-consuming and did not understand how to use some of the implemented behaviour change techniques. Based on these findings, we created 'MyPlan 2.0'.

To investigate users' perception regarding 'MyPlan 2.0', semi-structured interviews were conducted with adults having type 2 diabetes and adults from the general population who had completed the intervention. Participants liked the time-efficiency of the website and felt supported by the action planning component. However, both samples found it difficult to identify barriers and select solutions to overcome these barriers. These results guided the further adaptations to 'MyPlan 2.0'.

Before testing the effectiveness of 'MyPlan 2.0', a study protocol describing the intervention as well as the randomized controlled trial, was created. 'MyPlan 2.0' was tested in two samples: a sample having type 2 diabetes and a sample of adults aged 50 years or older. In the sample having type 2 diabetes, intervention effects favouring the intervention group were found for the personal determinants 'action planning' ( $p = .08$ ) and 'monitoring' ( $p < .01$ ). However, intervention effects favouring the control group were detected for the personal determinants 'self-efficacy' ( $p = .01$ ) and 'risk perception' ( $p = .03$ ). To analyse the behavioural outcomes, a distinction was made between the intervention group receiving the version of 'MyPlan 2.0' targeting physical activity and the group receiving the version aiming to reduce sedentary behaviour. In comparison with the control group, the intervention group targeting physical activity showed a decrease in self-reported daily time spent sedentary ( $p = .09$ ) and an increase in self-reported moderate ( $p = .05$ ) and moderate-to-vigorous ( $p = .05$ ) physical activity. The intervention group targeting a reduction in sedentary behaviour showed an increase in accelerometer-assessed daily breaks from sedentary bouts ( $p < .01$ ) in comparison with the control group. In the sample of adults aged 50 or older, intervention effects favouring the intervention group were found for the personal determinants 'self-efficacy' ( $p = .05$ ), 'coping planning' ( $p < .01$ ), 'intention' ( $p = .07$ ) and 'monitoring' ( $p = .09$ ). In the intervention group targeting physical activity an increase in self-reported total physical activity ( $p < .01$ ) in comparison with the control group was found. Finally, the sample targeting a reduction in sedentary behaviour showed a decrease in self-reported daily sitting time ( $p = .08$ ) and an increase in self-reported moderate ( $p = .06$ ) and moderate-to-vigorous ( $p = .07$ ) physical activity.

The results of the studies undertaken in this doctoral thesis highlight the need to involve users in the development process of eHealth interventions. Furthermore, the results of the randomized controlled trial in the sample with type 2 diabetes indicate that further research and adaptations to the programme are needed to more effectively support this target group in adopting an active way of living.

## Samenvatting

In Europa zijn er 58 miljoen mensen gediagnosticeerd met diabetes. In 90% van de gevallen gaat het om diabetes type 2. Deze aandoening gaat gepaard met een groot aantal negatieve gezondheidsuitkomsten waarvan cardiovasculaire aandoeningen en nierfalen slechts een paar voorbeelden zijn. Onderzoek toont aan dat het verhogen van de fysieke activiteit en het verminderen van het sedentair gedrag belangrijke gezondheidsgedragingen zijn om diabetes type 2 te voorkomen en te behandelen. Het merendeel van de patiënten beweegt echter te weinig en zit te veel. Deze bevindingen vragen om kosteneffectieve interventies die volwassenen met diabetes type 2 ondersteunen om meer te bewegen en minder te zitten.

Interventies aangeboden via het internet (eHealth) of via smartphones (mHealth) kunnen veel mensen op een kosteneffectieve manier bereiken. E- en mHealth interventies gericht op het verhogen van de fysieke activiteit bij volwassenen met diabetes type 2 tonen echter gemengde resultaten. Verder zijn er tot nog toe geen e- of mHealth interventies ontwikkeld die zich specifiek richten op het beperken van het sedentair gedrag van deze doelgroep.

De effectiviteit van e- en mHealth interventies kan op twee manieren verhoogd worden. Ten eerste blijkt uit voorgaand onderzoek dat online interventies sterkere effecten vertonen wanneer ze gebaseerd zijn op een theorie die uitlegt hoe de gedragsverandering tot stand komt. Bijvoorbeeld, de zelfregulatietheorie beschrijft hoe mensen hun gedrag veranderen door een onderscheid te maken tussen motivationele processen gericht op het ontwikkelen van een intentie en wilsgerichte processen die ervoor zorgen dat de intentie wordt omgezet in een daadwerkelijke gedragsverandering. Ten tweede, de hoge mate van uitval die karakteristiek is aan e- en mHealth interventies geeft aan dat de eindgebruikers meer moeten betrokken worden in de ontwikkeling van deze programma's. Het is dus belangrijk om het probleem zowel top-down (via het gebruik van gedragsveranderingstheorieën) als bottom-up (door het betrekken van mogelijke eindgebruikers) te benaderen.

'Mijn Actieplan 1.0' is een op zelf-regulatie-gebaseerde eHealth interventie ontwikkeld door de vakgroep Bewegings- en Sportwetenschappen en de vakgroep Experimenteel-klinische en Gezondheidspsychologie die zich richt op het verhogen van de fysieke activiteit en de consumptie van fruit en groenten. Het programma bleek effectief te zijn om deze gezondheidsgedragingen te verbeteren in de algemene populatie alsook in recent gepensioneerden. Echter, zoals veel andere eHealth interventies, had 'MyPlan 1.0' te kampen met een hoge mate van uitval.

Het onderzoek uitgevoerd in het kader van deze doctoraats thesis had twee doelen. Het eerste doel was het in kaart brengen van de oorzaken van de uitval in 'Mijn Actieplan 1.0' en het ontwikkelen

van 'Mijn Actieplan 2.0', een op zelf-regulatie-gebaseerde e- en mHealth interventie gericht op het verhogen van de fysieke activiteit en het beperken van het sedentair gedrag bij volwassenen met diabetes type 2. Echter, rekening houdend met de veelbelovende effecten van 'Mijn Actieplan 1.0' in de algemene populatie, werd er besloten om het programma ook voor volwassenen uit de algemene populatie te verbeteren. Het tweede doel was om de effectiviteit van 'Mijn Actieplan 2.0' te testen aan de hand van een gerandomiseerde en gecontroleerde studie.

Twee studies werden uitgevoerd om zicht te krijgen op de redenen voor de hoge mate van uitval in 'Mijn Actieplan 1.0'. In de eerste studie werden de gebruikersdata geanalyseerd. De resultaten gaven aan dat een groot deel van de gebruikers het programma al tijdens de eerste sessie verliet en dit vooral bij de componenten waarin de gebruikers weinig feedback van het programma ontvingen (bijvoorbeeld bij het invullen van vragenlijsten). Verder toonde deze studie aan dat vooral mannen en jongere gebruikers minder geneigd waren om de interventie af te werken. In de tweede studie vroegen we gebruikers uit de algemene populatie en gebruikers met diabetes type 2 om het programma te doorlopen terwijl ze hun gedachten luidop verwoordden. De resultaten van dit onderzoek gaven aan dat veel gebruikers de interventie als tijdrovend ervoeren en vaak niet begrepen hoe ze de aangeboden gedragsveranderingstechnieken konden gebruiken. Op basis van de bevindingen van deze twee studies werd 'Mijn Actieplan 2.0' ontwikkeld.

De percepties omtrent 'Mijn Actieplan 2.0' werden onderzocht aan de hand van semigestructureerde interviews bij volwassenen met diabetes type 2 en volwassenen uit de algemene populatie die het programma doorlopen hadden. Participanten gaven aan dat ze de website als tijdsefficiënt ervoeren en dat ze zich gesteund voelden door de component waarin hen gevraagd werd om hun acties concreet in te plannen. Echter, beide groepen vonden het moeilijk om hindernissen te identificeren en oplossingen te selecteren die hen konden helpen om met deze hindernissen om te gaan. Deze resultaten bepaalden de verdere aanpassingen aan 'Mijn Actieplan 2.0'.

Voor het daadwerkelijke testen van 'Mijn Actieplan 2.0' werd een studieprotocol ontwikkeld. Dit studieprotocol beschreef de interventie alsook de gerandomiseerde en gecontroleerde studie die de effectiviteit van het programma zou testen. De effectiviteit van 'Mijn Actieplan 2.0' werd getest in twee groepen: een groep gediagnosticeerd met diabetes type 2 en een groep van volwassenen die 50 jaar of ouder waren. In de groep gediagnosticeerd met diabetes type 2 werden er interventie-effecten gevonden voor de persoonlijke determinanten 'actieplanning' ( $p = .08$ ) en 'monitoren' ( $p < .01$ ). Echter, in vergelijking met de interventiegroep, toonde de controlegroep een toename in 'zelf-effectiviteit' ( $p = .01$ ) en 'risicoperceptie' ( $p = .03$ ). Om de gedragsveranderingen te analyseren werd een opsplitsing gemaakt tussen de interventiegroep gefocust op een toename van fysieke activiteit

en de interventiegroep gericht op het verminderen van het sedentair gedrag. In vergelijking met de controlegroep, vertoonde de interventiegroep die zich richtte op het verhogen van de fysieke activiteit een afname in zelf-gerapporteerde zittijd ( $p = .09$ ) en een toename in zelf-gerapporteerde matige ( $p = .05$ ) en matig-tot-zware ( $p = .05$ ) fysieke activiteit. De interventiegroep gericht op het verminderen van het sedentair gedrag vertoonde, in contrast met de controlegroep, een toename in het objectief gemeten aantal onderbrekingen van de zittijd ( $p < .01$ ). In de groep van participanten van 50 jaar of ouder werden er interventie-effecten in het voordeel van de interventiegroep gevonden voor de persoonlijke determinanten 'zelf-effectiviteit' ( $p = .05$ ), 'plannen van oplossingen voor problemen' ( $p < .01$ ), 'intentie' ( $p = .07$ ) en 'monitoren' ( $p = .09$ ). In de interventiegroep gericht op het verhogen van de fysieke activiteit werd, in vergelijking met de controlegroep, een toename in zelf-gerapporteerde totale fysieke activiteit ( $p < .01$ ) gedetecteerd. Ten slotte vertoonde de interventiegroep gericht op het verminderen van het sedentair gedrag, in vergelijking met de controlegroep, een afname in zelf-gerapporteerde zittijd ( $p = .08$ ) en een toename in zelf-gerapporteerde matige ( $p = .06$ ) en matig-tot-zware ( $p = .07$ ) fysieke activiteit.

De resultaten van de studies die werden uitgevoerd in het kader van dit doctoraatsonderzoek onderschrijven het belang van het betrekken van de gebruikers in het ontwikkelingsproces van eHealth interventies. Verder geven de resultaten van de gerandomiseerde en gecontroleerde studie in de steekproef met diabetes type 2 aan dat verder onderzoek en aanpassingen aan het programma nodig zijn om deze doelgroep beter te ondersteunen in het aannemen van een actieve levensstijl.



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## PART 1 – GENERAL INTRODUCTION

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## 1. Introduction

The prevalence of diabetes increases: in Europe 58 million people are diagnosed with the disease and this number is estimated to rise to 66.7 million by 2045. The accelerated growth of diabetes is mainly driven by type 2 diabetes, accounting for 90% of all cases [1]. Besides causing many deaths, type 2 diabetes is associated with a large number of health problems including cardiovascular disease, kidney failure, neuropathy and depression. Furthermore, the disease causes high costs for society: in 2017 23% of Europe's total health expenditure was spent on diabetes management [1].

Adopting an active way of living by increasing physical activity and reducing sedentary time is considered a cornerstone in type 2 diabetes management [2, 3]. Unfortunately, the majority of adults with type 2 diabetes does not meet the guidelines regarding physical activity [4] and shows high levels of sedentary time [5]. Consequently, cost-effective interventions supporting adults with type 2 diabetes to become more physically active and to reduce their sedentary time are urgently needed.

Interventions delivered via the Internet (eHealth) have the potential to reach large populations and still offer a personalized approach by tailoring the intervention content to the user's specific needs. Mobile Health or mHealth refers to interventions delivered via mobile phones. Internet-delivered interventions have been applied to alter a wide range of health behaviours in the general population as well as in adults with type 2 diabetes, and usually produce significant, but small effects [6-8].

There are two ways in which the effectiveness of online interventions can be increased. First, online interventions show stronger effects when they are informed by a theoretical framework [9]. Internet-delivered interventions are therefore often grounded in social-cognitive theories describing how a person develops an intention for behaviour change [9]. Unfortunately, intentions are often not readily transformed into behaviour [10]. This problem is called the 'intention-behaviour gap' and highlights the need to support people in effectively translating behavioural intentions to actual behaviour change. Self-regulation theory proposes the motivational processes through which the individual develops an intention, and the volitional processes describing the translation of intentions into actions. Creating interventions based on self-regulation frameworks, such as the Health Action Process Approach (HAPA) [11], might thus help the target populations to actually convert their intentions into actions. Second, the potential effect of online interventions is often diminished by the high levels of attrition characterizing this kind of interventions. Indeed, low levels of intervention usage seem to be the norm rather than the exception in Internet-based interventions [12]. Consequently, it is of utmost importance to adopt a top-down theoretical as well as a bottom-up

user-based perspective on the development of e- and mHealth in order to create effective interventions that meet the needs and interests of the end-users [13].

MyPlan 1.0 is a HAPA-based eHealth intervention targeting physical activity and the intake of fruit and vegetables developed by the department of Movement and Sports Sciences and the department of Experimental Clinical and Health Psychology. The programme can be easily adapted to different populations, and has been applied in adults visiting general practice [14] and recently-retired older adults [15]. Previous research shows the effectiveness of the programme, but also highlights the well-known attrition-problem: the majority of MyPlan 1.0-users (72% - 75%, depending on the chosen behaviour) does not complete the intervention [15-17].

This doctoral thesis describes the development and evaluation of MyPlan 2.0, a HAPA-based e- and mHealth intervention targeting physical activity and sedentary behaviour in adults with type 2 diabetes. However, considering the promising effects found with MyPlan 1.0 in the general population, it was decided to adapt MyPlan 2.0 to users from the general population as well. The first part of the original research includes the analysis of the attrition problem in MyPlan 1.0 and the qualitative studies performed with MyPlan 2.0 to improve the programme. The second part provides the protocol of the study assessing the effectiveness of MyPlan 2.0 and the results of this study.

In this general introduction, we first describe the concepts 'type 2 diabetes', 'physical activity' and 'sedentary behaviour' and discuss the importance of increasing physical activity and decreasing sedentary behaviour in the target population. The following sections are dedicated to e- and mHealth research in the general population as well as in adults with type 2 diabetes, behaviour change theories with a specific focus on the self-regulation framework, and MyPlan 1.0. The last section of the general introduction will outline the problem analysis and the aims of the thesis.



## 2. Definitions

This thesis mainly focuses on the promotion of an active lifestyle in adults with type 2 diabetes. It is therefore important to define type 2 diabetes, as well as the behaviours constituting an active lifestyle, namely increasing physical activity and decreasing sedentary behaviour.

### 2.1 Type 2 diabetes

The International Diabetes Federation defines 'diabetes' as "a chronic condition that occurs when there are raised levels of glucose in the blood because the body cannot produce any or enough of the hormone insulin or use insulin effectively" (page 17). Insulin is a hormone responsible for the uptake of glucose from the bloodstream into the body's cells. Insulin-related problems will result in high levels of blood glucose or hyperglycaemia. Long periods of hyperglycaemia can lead to several health complications such as cardiovascular disease and neuropathy. In Belgium, 6.1% of adults aged between 20 and 79 are diagnosed with diabetes [1].

There are two main types of diabetes: type 1 and type 2, of which the latter accounts for 90% of all diabetes cases. Type 1 diabetes mostly occurs in children and adolescents. The exact mechanisms of this disease are not yet fully understood, although research shows that it is caused by a combination of genetic and environmental factors. People with type 1 diabetes produce none to very little amounts of insulin. Consequently, the treatment mainly consists of taking daily insulin injections [1]. In type 2 diabetes, hyperglycaemia is caused by a lack of production of insulin and decreased responsiveness of the body's cells to insulin. Although type 2 diabetes has a hereditary component and is related to increasing age, lifestyle factors such as being physically inactive, accumulating high levels of sitting time, smoking and having an unhealthy diet have shown to be risk factors for developing the disease [1, 18, 19]. Consequently, the management of this disease is based on lifestyle changes and medication. This thesis focusses on adults with type 2 diabetes.

### 2.2 Physical Activity

'Physical activity' has been defined as "any bodily movement produced by skeletal muscles that requires energy expenditure" (page 126) [20]. The level of energy expenditure is expressed in metabolic equivalents (METs). One MET corresponds to an average oxygen use of 3.5 ml per kilogram of body weight per minute. Based on these METs, three levels of physical activity intensity are defined. Activities with a MET-value between 1.5-3, such as tooth brushing or ironing, are

considered 'light-intensity physical activities' [21, 22]. Activities with a MET-value between 3-6, such as playing the drums or painting walls, are defined as 'moderate-intensity physical activities' [21]. 'Vigorous-intensity physical activities' are defined as activities with a MET-value of >6, such as running or chopping wood [21]. The examples above show that physical activity encompasses more than 'exercise', which is "a subcategory of physical activity that is planned, structured, repetitive, and purposeful in the sense that the improvement or maintenance of one or more components of physical fitness is the objective" (page 128) [20].

The WHO recommends adults aged 18 to 64 to accumulate each week a minimum of 150 minutes of moderate-intensity aerobic physical activity or a minimum of 75 minutes of vigorous-intensity aerobic physical activity, or an equivalent combination of both. These activities should be performed in bouts of at least 10 consecutive minutes. Furthermore, muscle-strengthening activities involving major muscle groups should be performed on at least 2 days a week. The same recommendations apply to adults aged 65 and older. However, older adults with mobility impairments are additionally advised to perform physical activity enhancing balance and preventing falls on a minimum of 3 days per week. Older adults who cannot follow these guidelines due to health problems should be as physically active as their abilities allow [23]. The recommendations regarding physical activity for adults aged 18 to 64 provided by the Flemish Institute of Healthy Living are the same as the ones provided by the WHO for this target group. Furthermore, the Flemish Institute of Healthy Living advises all adults aged  $\geq 65$  to perform activities targeting strength, balance and agility on 3 days per week. A person is then considered physically inactive when he or she does not meet the recommendations regarding physical activity.

### 2.3 Sedentary Behaviour

'Sedentary behaviour' can be defined as "any waking behaviour characterized by an energy expenditure  $\leq 1.5$  METs while in a sitting, reclining or lying posture" (page 9) [22]. Based on this definition activities such as watching television or driving a vehicle are considered sedentary behaviours, but sleeping is not. The total time spent in those sedentary behaviours has been defined as sedentary time.

Accumulating high levels of sedentary time has been associated with adverse health-related changes (e.g. increased waist circumference, blood pressure, glucose levels and cardio-metabolic risk) relatively independent of physical activity [24-26]. This indicates that, unless people show high levels of moderate intensity physical activity (60-75 min/day) [27], increasing physical activity does not

counterbalance the detrimental effect of high levels of sedentary behaviour [28]. Consequently, sedentary behaviour and physical activity are regarded as distinct behaviours with different physiological mechanisms rather than opposing behaviours.

In contrast to physical activity, no international guidelines about sedentary behaviour have yet been formulated. This might be due to the fact that sedentary behaviour is a relatively novel research domain and more research will be needed to identify its working mechanisms. However, several public health institutes already provide recommendations regarding sedentary behaviour in adults. For example, the Australian Department of Health recommends to limit the amount of time spent in prolonged sitting and to break up sitting times whenever possible [29]. These guidelines are very similar to the guidelines formulated by the Flemish Institute of Healthy Living, which state that periods of sitting should be limited and interrupted every 30 minutes [30]. An active lifestyle represents a healthy balance between the daily time spent physically active versus sedentary. The Flemish Institute of Healthy Living visualized the recommendations regarding both health behaviours in the Physical Activity Triangle (see figure 1).



Figure 1: Physical Activity Triangle (Flemish Institute of Healthy Living)

### 3. Health benefits of adopting an active lifestyle in adults with type 2 diabetes

#### 3.1 Health benefits of increasing physical activity

When left untreated, type 2 diabetes results in hyperglycaemia. Consequently, the treatment of type 2 diabetes is focused on reaching a healthy level of blood glucose. As the skeletal muscles are responsible for 75% of the insulin-mediated uptake of glucose, physical activity plays an important role in this treatment. Glucose can enter the skeletal cells via two distinct pathways: an insulin-mediated pathway and a contraction-mediated pathway. In people with type 2 diabetes the first pathway is problematic (see section 2.3), but the second one is not [31]. As a consequence physical activity offers acute as well as chronic benefits. A single bout of physical activity results in three acute effects (i.e. effects occurring immediately after the physical activity) lowering the chances on hyperglycaemia. First, as the body will need energy to perform the physical activity, there will be an immediate decline in the blood glucose level. Second, glucose will enter the skeletal cells via the contraction-mediated pathway. Third, the uptake of glucose via the insulin-mediated pathway will be improved for a period until three days after the physical activity. Engaging in regular physical activity (i.e. repeating the physical activity sessions) will result in chronic effects. First, mainly due to aerobic physical activity, the insulin sensitivity will increase. Second, due to hypertrophy, the uptake of glucose via the contraction-mediated pathway will be more efficient.

Type 2 diabetes patients who engage in regular physical activity will also benefit from its general effects. Several studies describe the inverse relation between physical activity and chances on developing cardiovascular disease [32, 33], osteoporosis [34] and colon and breast cancer [33, 35]. Furthermore, research shows that physical activity can reduce feelings of depression and anxiety in both clinical [36] and non-clinical populations [37].

Despite these clear benefits, the majority of adults with type 2 diabetes does not meet the guidelines regarding physical activity. For example, a survey conducted in 15 462 Swedish adults with type 2 diabetes showed that only 55% reached 150 minutes per week of physical activity at a moderate to vigorous intensity [38]. A nationally representative survey with 23 283 US adults showed that only 39% of patients with diabetes engaged in regular physical activity [4]. As 90% of US adults with diabetes have type 2 diabetes, no differentiation between both types was made in this study. The results of these two studies are based on self-reports. In the Look AHEAD trial physical activity levels of 1980 overweight or obese adults with type 2 diabetes were measured using accelerometers. At baseline less than 20% of the participants met the guidelines regarding physical activity [39].

Some studies compared the physical activity levels of people with type 2 diabetes with those of healthy controls. For example, Hamer and colleagues (2013) conducted a case-control study in which each of the 122 participants with type 2 diabetes were matched with two healthy controls based on age, sex and income [5]. Daily physical activity and sedentary time were measured with an Actigraph accelerometer. The results showed that the participants with type 2 diabetes, in comparison with the healthy controls, showed less daily light-intensity physical activity (186 vs. 208 minutes). However, no significant difference was found for daily moderate-to-vigorous physical activity. Van der Berg et al. (2016) measured levels of physical activity and sedentary behaviour with ActivPal accelerometers and found a large difference for moderate-to-vigorous physical activity between people with type 2 diabetes (14.7 minutes/day) and people with a normal glucose metabolism (26.8 minutes/day) [40].

### 3.2 Health benefits of decreasing sedentary behaviour

There are two ways to limit sedentary behaviour. The first way is by minimizing the periods spent sitting (e.g. by cycling instead of driving a car to work). Research in the general population shows that people who display low levels of sedentary time show more insulin sensitivity [41], have less psychological distress [42] and have a lowered risk on having metabolic syndrome [43] and cardiovascular disease [18] in contrast with people displaying high levels of sedentary behaviour. The second way to limit sedentary behaviour is by interrupting periods of prolonged sitting (e.g. by taking active breaks during TV commercials). Interrupting sedentary time is associated with a lower waist circumference and a smaller body mass index (BMI) independent of total sedentary time in the general adult population [44].

Although research regarding the benefits of limiting sedentary behaviour is relatively novel, there is cross-sectional, longitudinal and experimental evidence demonstrating the beneficial effects of this health behaviour in people with type 2 diabetes. A cross-sectional study with 528 adults with newly diagnosed type 2 diabetes showed that each hour of sedentary time was associated with a higher waist circumference independent of patients' levels of moderate-to-vigorous-intensity physical activity [45]. A longitudinal study using accelerometry and continuous glucose monitoring demonstrated that more sedentary time predicted significant increases in time spent in hyperglycaemia independent of patients' levels of low physical activity [46]. A cross-sectional study conducted by Falconer et al. (2015) showed that displacing 30 minutes of uninterrupted sedentary time with 30 minutes of short bout sedentary time, light-intensity physical activity or moderate-to-vigorous-intensity physical activity was associated with a lower BMI and waist circumference in

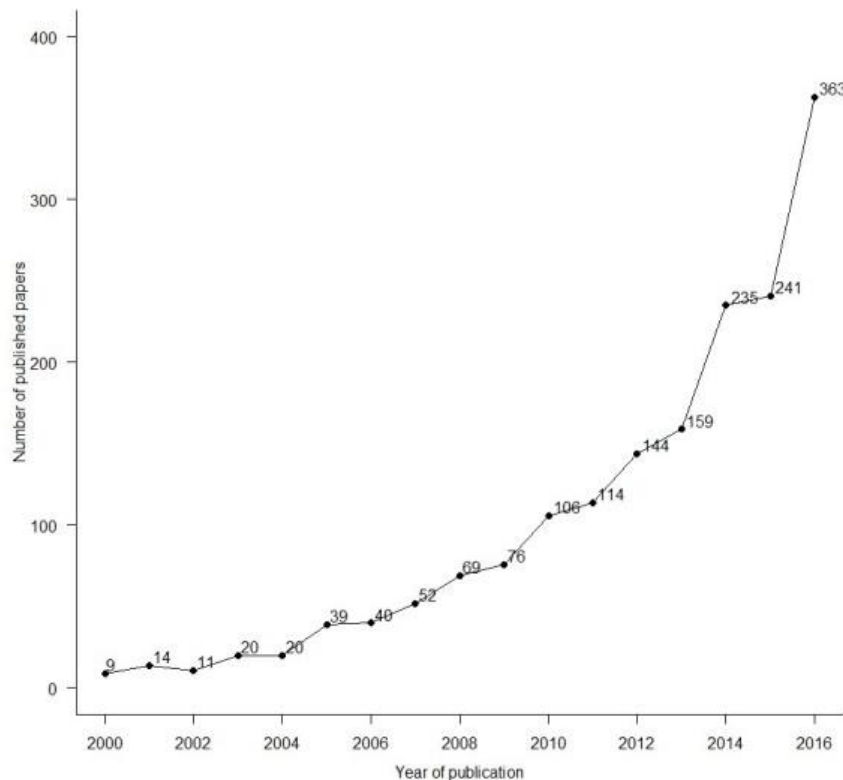
adults with type 2 diabetes [47]. Dempsey et al. (2016) conducted a randomized crossover trial with 24 adults with type 2 diabetes. The three 8-hour conditions were: uninterrupted sitting, sitting with 3-minute bouts of walking at a light intensity every 30 minutes and sitting with 3-minute bouts of simple resistance activities every 30 minutes. The results showed that breaking up periods of prolonged sitting with brief periods (i.e. 3 minutes) of light-intensity walking or simple resistance activities reduced resting blood pressure and attenuated postprandial glucose in adults with type 2 diabetes [48, 49]. Finally, a meta-analysis of Chastin et al. (2018) showed that the beneficial effect of performing light-intensity physical activity, which is often performed when reducing sedentary behaviour [50], on blood glucose is stronger in people with a metabolic impairment, such as adults with type 2 diabetes [51]. Indeed, previous research has shown that the beneficial effect of replacing sedentary time with light-intensity walking is stronger in adults with a lower cardiorespiratory fitness compared with adults with a high cardiorespiratory fitness [52].

Research shows that people with type 2 diabetes show high levels of sedentary behaviour and tend to sit more than people from the general population. For example, in their randomized controlled trial testing STAND, an intervention targeting sedentary behaviour in young adults with type 2 diabetes, Biddle et al. (2015) found that the mean time spent sedentary at baseline was >10 hours a day [53]. Similar results were found in a prospective cohort study with 326 people with type 2 diabetes: mean daily sedentary time was 10.5 hours at baseline and 11.1 hours at the follow-up four years later [54]. The previously mentioned case-control study of Hamer and colleagues (2013) showed that patients had significantly higher levels of objectively assessed daily sedentary time in comparison with the matched controls (636 vs. 662 minutes) [5]. Similar results were found in the case-control study of Cichosz et al. (2013) in which 100 adults with type 2 diabetes were matched with 100 controls based on age and sex. Even after correcting for differences in BMI between the two groups, the patients showed higher levels of daily sedentary time than the matched controls (926 vs. 898 minutes) [55]. Finally, the previously discussed study of Van der Berg and colleagues (2016) showed that people with type 2 diabetes accumulated significantly higher levels of daily sedentary time in comparison with people with a normal glucose metabolism (9.71 hours vs 9.28 hours) [40].

## 4. e- and mHealth

### 4.1 Definition

The problems outlined above call for effective approaches that can be implemented in the growing group of people diagnosed with type 2 diabetes. Interventions delivered via the Internet offer several advantages. First, in contrast to one-on-one counselling sessions, these kind of interventions can reach many people simultaneously and in a cost-effective way [6]. Furthermore, as the content of the intervention can be tailored to the user's specific situation, the personalized approach characterizing one-on-one sessions can be retained [56]. Second, the number of Internet users is increasing [57]. This trend is also visible in older adults [58] (e.g. 57% of Belgian adults aged  $\geq 65$  use the Internet at least once a week [59]), making the use of online interventions in this group feasible. However, it should be noted that Internet usage in older adults is also determined by age, education and income. Indeed, male older adults and older adults with a higher level of education or income are more likely to use the Internet [60]. Finally, online interventions offer a fast and efficient transfer of information. As a result, the interest in online interventions is rising and research regarding this type of interventions shows an exponential growth (see figure 2) [61].



*Figure 2. Number of published papers on online interventions targeting physical activity, sedentary behaviour or diet in function of year of publication. (Müller et al., 2018)*

There are two key terms in the field of online interventions, namely “eHealth” and “mHealth”. The WHO defines eHealth or “electronic health” as “the use of information and communication technology (ICT) for health” (page 1) [62]. Mobile health or mHealth is defined as “the use of mobile and wireless technologies to support the achievement of health objectives” (page 9) and is thus considered as a component of eHealth [63].

#### 4.2 Effectiveness of e- and mHealth in the general population

Systematic reviews and meta-analyses combine the results of multiple studies to identify the common effect of a specific type of intervention. The mean effect is often reported with a Cohen’s  $d$  or Hedges  $g$  statistic allowing us to interpret the effect size (trivial =  $<0.20$ , small =  $0.20-0.50$ , moderate =  $0.50-0.80$ , large =  $>0.80$ ) [64]. It is important to note that an effect size on its own does not reflect the potential public health impact of an intervention. Indeed, one should examine which patterns are found in the data and carefully consider whether upscaling an intervention would be beneficial. For example, if a small effect size is caused by a strong effect in a particular subpopulation and no change in the rest of the group, one might consider to upscale the intervention for this subgroup. On the other hand, if the small effect size represents a change that is not clinically relevant in all members of the group or reflects a combination of negative and positive effects, upscaling the intervention might be discouraged. As the field of e- and mHealth is rapidly evolving [61], only reviews and meta-analyses published in 2010 or later will be discussed.

A meta-analysis by Krebs and colleagues (2010) examined the effectiveness of computer-tailored interventions for several health behaviours including physical activity. The overall mean effect size was  $g = 0.17$ , whereas the mean effect size for interventions targeting physical activity was  $g = 0.16$  (both significant). Furthermore, dynamically tailored interventions were found to be more effective than interventions of which the feedback was based on one assessment. However, the authors highlighted that studies should more clearly describe how the methods of assessment and feedback are implemented in the programme [65]. A similar meta-analysis was carried out by Webb and colleagues (2010). The combined effect of 85 online interventions targeting a range of health behaviours resulted in a significant weighted average effect size of  $d = 0.16$ . For Internet-based interventions specifically targeting physical activity a weighted effect size of  $d = 0.24$  was found. Furthermore, the authors showed that online interventions incorporating more behaviour change techniques tend to have stronger effects than those incorporating a smaller number of behaviour change techniques [9]. Laplante and Peng (2011) conducted a systematic review on eHealth for physical activity and highlight the poor quality of the study designs. The authors recommended to



use objective physical activity measurements and to create control groups not receiving any health-related information as doing so helps the synthesis of research [66]. Davies et al. (2012) conducted a meta-analysis with 34 studies and found that Internet-delivered interventions produce a trivial, but significant positive effect (overall mean effect of  $d = 0.14$ ) on participants' level of physical activity. This effect was larger ( $d = 0.37$ ) in studies only including insufficiently active participants [67]. However, the authors endorsed the call for well-designed randomized controlled trials with an adequate sample size and long-term follow-up measures to assess the overall effectiveness. A review by Joseph and colleagues (2013) found 72 Internet-based interventions targeting physical activity of which 61.1% significantly increased the participants' level of physical activity. The authors recommended to test online interventions in more varied samples (i.e. minority and male populations) and to include follow-up measurements [68]. Finally, a systematic review of reviews examining the effectiveness of Internet-based interventions targeting several health behaviours showed that reviews examining online interventions to increase physical activity report trivial and small effect sizes. Furthermore, the effect of online interventions targeting this health behaviour seemed to decrease at follow-up. The authors therefore highlighted the need for strategies to increase adherence and to use the opportunities offered by the Internet to gain insight in intervention usage (e.g. page views) [69].

Meta-analyses and reviews assessing the effectiveness of mHealth physical activity interventions report similar results. As this thesis focuses on mHealth interventions delivered via smartphone, studies examining the effect of text-message interventions (see for example [70-72]) will not be discussed. Bort-Roig et al. (2014) conducted a systematic review on the use of smartphones for physical activity promotion. Of the 5 studies assessing intervention effects, 4 studies reported an increase in physical activity and in one study physical activity maintenance over 3 months was found. The authors highlighted the need for more rigorous study designs [73]. A review by Coughlin and colleagues (2016) included 8 randomized controlled trials examining the effect of smartphone applications for increasing levels of physical activity. The authors indicated that the efficacy of these apps is still modest and provide several points for improving study quality including the use of randomized controlled trials, recruiting larger study samples and implementing longer study periods [74]. Schoeppe et al. (2016) assessed the effect of apps targeting diet, physical activity and sedentary behaviour. Of the 23 studies targeting adults 17 reported significant health-related improvements. The authors show that effective apps often include goal-setting, self-monitoring and feedback on performance. However, further research is needed to define the optimal number and combination of behaviour change techniques to maximise the effect of mHealth interventions [75]. A meta-analysis by Direito and colleagues (2017) examined whether, in comparison with usual or minimal care,

mHealth interventions (including SMS, smartphones/apps, PDA, biosensors, tablet computers and websites) are effective in altering participants' level of physical activity or sedentary behaviour. The summary effects for total physical activity, moderate-to-vigorous physical activity nor walking reached statistical significance [7]. The authors indicated that the individual studies found small-to-moderate sized effects (standardised mean differences ranged between 0.01 and 0.69) and that lack of significant summary effects might be due to the active control groups receiving manuals or print-based materials regarding the importance of physical activity. Finally, the need for better reporting of the interventions' active ingredients is endorsed [7].

The number of reviews and meta-analyses assessing the effect of e- or mHealth interventions targeting sedentary behaviour is limited. The previously mentioned meta-analysis by Direito (2017) and colleagues reported a significant standardised mean difference of -0.26 in favour of mHealth interventions targeting sedentary behaviour versus usual care. However, solely 5 of the 21 studies reported outcomes regarding sedentary behaviour [7]. Stephenson et al. (2017) conducted a systematic review and meta-analysis with 17 randomized controlled trials assessing the effect of interventions delivered via computer, mobile and wearable technology on sedentary behaviour. Fifteen of the 17 studies reported a significant reduction in sedentary time in the intervention group resulting in a mean reduction of 41 minutes per day. The authors noted that stronger reductions in sedentary time were found in studies using self-report data in comparison with studies using objective measurements. Provided points for improvement were better reporting of the incorporated behaviour change techniques, conducting more rigorously controlled studies with longer-term follow-ups, using objective methods to assess sedentary behaviour and implementing strategies to reduce attrition [76].

To summarize, research examining the common effect of e- or mHealth interventions targeting physical activity or sedentary behaviour reports trivial-to-small and short-termed effects. Important points for improvement are (1) better reporting the active ingredients (i.e. the implemented behaviour change techniques), (2) developing rigorous study designs with longer-term follow-up measurements, (3) adopting objective measures to assess physical activity and sedentary behaviour and (4) implementing strategies to reduce the high levels of attrition.

#### 4.3 Effectiveness of e- and mHealth in adults with type 2 diabetes

To date, no online interventions targeting sedentary behaviour have been tested in adults with type 2 diabetes. However, a number of reviews and one meta-analysis assessed the common effect of

online interventions on the level of physical activity in this population. Cassimatis and colleagues (2012) conducted a systematic review investigating the effect of telehealth interventions (i.e. telephone counselling, videoconferencing or educational telephone-based interventions) on glycaemic control and diabetes self-management (including physical activity). Of the 8 studies assessing changes in physical activity, 5 showed significant intervention effects. The authors argued that telehealth is a promising avenue for patient care, but that the methodology of telehealth studies should be ameliorated and that follow-up assessments of more than 6 months post baseline are needed [77]. Pal and colleagues (2013) performed a review assessing the effect of computer-based interventions on health status and health-related quality of life in adults with type 2 diabetes. Physical activity was considered a secondary outcome. Five studies reported changes in physical activity, but only one study found a statistically significant intervention effect in favour of the intervention group. Furthermore, the authors showed that changes in personal determinants such as knowledge and self-efficacy are not often translated into behavioural changes. Points for improvement included creating interventions informed by theory and evidence and providing protocols describing the theoretical basis, active ingredients and 'dose' of the intervention [8].

Connelly et al. (2013) conducted a systematic review assessing the effect of technology-based interventions targeting physical activity in adults with type 2 diabetes. The included interventions were delivered via mobile phone and text messages or computer-based technology, but did not include counselling via telephone. In 9 of the 15 included studies a significant intervention effect was found. The authors recommended to foresee additional support to increase adherence to online interventions and highlighted the importance of conducting research with high methodological quality [78]. Cotter and colleagues (2014) examined whether Internet-based interventions can promote lifestyle modifications in adults with type 2 diabetes. Of the 8 included studies measuring changes in physical activity, only one study found a significant difference in favour of the web-based intervention group versus the non-web-based control group. Furthermore, in all studies website use decreased over time. The authors indicated that more research investigating website utilization patterns and engagement is needed [79]. Rollo et al. (2016) argued in their narrative review that text messages, apps and web-based programmes can show beneficial effects in altering diet and physical activity behaviours for diabetes self-management. Furthermore, the authors recommended to tailor the provided information to the needs of the participant [80]. Finally, Kongstad and colleagues (2017) conducted a review and meta-analysis with 27 randomized controlled trials examining whether remote feedback (i.e. interventions delivered via telephone counselling, text messages or computer programmes) can increase physical activity in adults with type 2 diabetes. The authors concluded that, in this target population, remote feedback can result in a small increase in physical activity

(Cohen's  $d = 0.33$ ). However, more research is needed to determine how and when feedback is best provided [81].

To summarize, studies testing the effect of e- and mHealth interventions targeting physical activity in adults with type 2 diabetes provide mixed results and highlight the importance of (1) creating research protocols describing the active ingredients as well as the theoretical basis of the intervention, (2) achieving a higher methodological quality and (3) investigating patients' engagement with the online programmes. Furthermore, no online interventions specifically targeting sedentary behaviour have yet been tested in adults with type 2 diabetes.

## 5. Theories of behaviour change

Behaviour change interventions should depend on theory and theories should be adapted based on the results derived from behaviour change interventions [82]. A theory is “an integrated summary of the hypothesised causal processes involved in behaviour change” (page 662) [83]. Theories can thus guide intervention developers as they describe which causal determinants should be targeted in order to establish behaviour change [83]. This theory-based approach is supported by research showing that online interventions elicit stronger effects when they are informed by a solid behaviour change theory [9]. The beneficial effect of theory-based interventions is reciprocal: testing these interventions will allow theorists to refine and ameliorate our current theoretical frameworks [82].

Theories can be categorized by their explanatory level. Some theories focus on the individual or interpersonal level, whereas others describe how behaviour is shaped by determinants located at the organizational or even societal level [84]. Online interventions are able to offer personalised information. Consequently, eHealth interventions are mostly informed by theories focussing on personal and psychosocial determinants at the individual level [9]. Examples of behaviour change theories focusing on the individual level are the theory of reasoned action/planned behaviour [85], social-cognitive theory [86] and the health belief model [87]. These theoretical models consider intention as the best and most important predictor of behaviour change [88]. Consequently, they mainly predict changes in an individual’s intention or motivation for behaviour change rather than the actual behaviour change [89]. Contrary to popular belief, intentions are not readily translated to actual behaviour [10]. For example, Rhodes and Dickau (2012) conducted a meta-analysis to assess the experimental evidence for the intention-behaviour relationship in the physical activity domain. The results indicated that an experimentally induced increase in intention ( $d = 0.45$ ) resulted in a rather trivial increase in physical activity ( $d = 0.15$ ). The authors therefore highlight the need to apply models incorporating action control variables to overcome the intention-behaviour gap [90]. There is also a more practical reason to not solely focus on increasing people’s intention for change. People participating in an intervention targeting physical activity are likely to show high levels of intention at baseline, but low levels of physical activity [91]. This poses a challenge for interventions based on motivational models as they consider the participants’ intention as the most proximal variable to target. Indeed, the arguments outlined above might help us understand why interventions based on motivational models often fail to produce behavioural effects [88, 92]. Models for altering health behaviours should therefore not only describe how an intention is created (i.e. the motivational phase) but also show how this intention can be translated to actual behaviour change (i.e. the volitional phase) [93]. The integration of the motivational phase with the volitional phase of

behaviour change is reflected in the theoretical framework of self-regulation [94].

## 5.1 Self-regulation

Self-regulation has been defined as “a goal-guidance process, occurring in iterative phases, that requires the self-reflective implementation of various change and maintenance mechanisms that are aimed at task- and time-specific outcomes” (page 269) [94]. The self-regulation framework emphasizes the active rather than passive role of the individual and is therefore embedded in a collaborative rather than prescriptive care approach [94, 95].

Maes and Karoly (2005) describe the self-regulation process via three phases of which the first phase is ‘goal selection’ [94]. This phase highlights the cognitive determinants (e.g. outcome expectancies or risk perception) needed to create an intention and thus reflects the motivational phase of behaviour change. Indeed, the causal processes described by the before-mentioned motivational theories are hypothesised to take place in this phase of the self-regulation process. For example, Plotnikoff et al. (2010) used the theory of planned behaviour to predict physical activity in adults with type 2 diabetes and found that the constructs attitude, subjective norm and perceived behavioural control explained 40% of the variance in intention [96].

The second phase is characterized by planning and active goal pursuit, and highlights the volitional processes of the behaviour change process, such as action planning, barrier identification, problem solving and creating implementation intentions. Implementation intentions link the goal-directed behaviour with a specific situational cue (e.g. “If I come home from work, I will go running for 30 minutes”) [97]. This strategy has found to be effective to promote health-related behaviours such as increasing physical activity [98] and healthy eating [99]. The volitional processes are supposed to take place within a feedback loop: an individual sets a specific goal, compares his/her behaviour with the set goal and tries to reduce the discrepancy between both [94, 100].

The third phase consists of goal attainment, maintenance and, if necessary, disengagement. This phase highlights the importance of an individual’s satisfaction regarding the obtained outcomes for long-term behaviour change. Goal disengagement is considered an essential element in self-regulation theory as holding on to unrealistic goals might negatively affect an individual’s mental well-being and decrease the chances on reengaging in a more realistic goal [101].

Rhodes and colleagues (2015) conducted a review to provide an overview of the models incorporating pre- as well as post-intentional processes for behaviour change. Sixteen models were identified, including the Health Action Process Approach (HAPA) [102], the I-Change model [103] and

Action Control Theory [104]. The sixteen models showed considerable overlap in the proposed factors to overcome the intention-behaviour gap; 14 of the 16 models included volitional self-regulation techniques such as self-monitoring, planning, problem-solving and prioritizing [91]. The results of the review furthermore showed that only two of these models were frequently used in the context of increasing physical activity. The most often used model was the HAPA, followed by the multi-process action control (M-PAC) framework. Within the context of increasing levels of physical activity, the HAPA has had more independent assessments outside of the studies performed to develop the model [105]. Furthermore, the HAPA has been applied to alter physical activity levels in clinical (including adults with type 2 diabetes [106]) as well as non-clinical populations. The following section will therefore describe the HAPA in more depth.

5.1.1 The Health Action Process Approach (HAPA)

The HAPA (see figure 3) explains health-related behaviour change within the framework of self-regulation [102]. The model has been found useful to predict and alter health behaviours such as physical activity, dietary behaviour and sunscreen use [107-109]. The HAPA proposes a distinction between pre-intentional motivational processes contributing to a behavioural intention and post-intentional volitional processes leading to the actual behaviour.

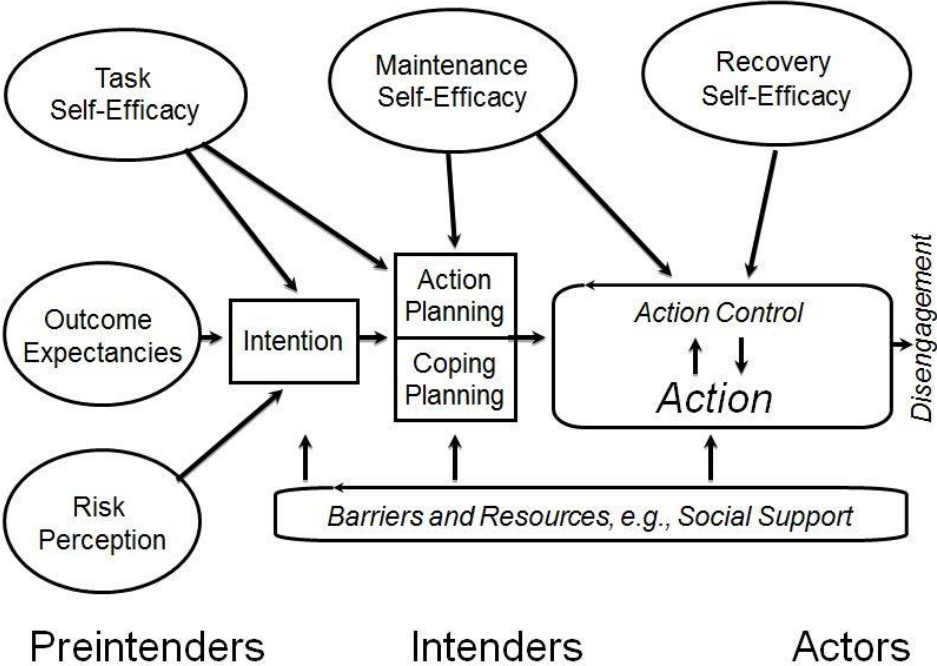


Figure 3: The Health Action Process Approach

Within the initial motivational phase, risk perception (e.g. "I am at risk for having a stroke") is considered a distal antecedent. Therefore this determinant might contribute to, but does not suffice for creating an intention. Positive outcome-expectancies about performing the behaviour (e.g. "Being physically active reduces my risk on having a stroke") and task/perceived self-efficacy (e.g. "I am capable to go for a walk even if it rains") are regarded as the major predictors of developing an intention for change. It is argued that the level of influence of these two determinants depends upon the level of experience an individual has with the behaviour. When a person already has experience with the target behaviour, task/perceived self-efficacy might be more influential than outcome-expectancies and vice versa for little experience. After creating an intention, the volitional phase is entered.

In the volitional phase intention is translated to actual behaviour via self-regulatory strategies (i.e. action planning and coping planning). For example, a person who wants to be more physically active needs to convert her general intention to proximal and specific goals (e.g. "I will go swimming for half an hour on Mondays") and decide how she will deal with barriers, such as lack of time, tiredness or other temptations (e.g. "I will prepare my swimming bag on Sunday to save time on Monday"). These self-regulatory strategies are influenced by volitional self-efficacy, referring to maintenance as well as recovery self-efficacy [11]. Maintenance self-efficacy reflects how confident a person is that he or she will be able to cope with barriers. People with higher maintenance self-efficacy will show more persistence in coping with barriers to reach their behavioural goals than people who show lower levels of maintenance self-efficacy. Recovery self-efficacy refers to how confident a person is that he or she will be able to recover after a setback. People with higher recovery self-efficacy are more likely to restart their actions after a relapse than people with lower recovery self-efficacy. Finally, the determinant barriers and resources, such as social support, acknowledges the influence of contextual factors on our behaviour. For example, a person who would like to reduce her sedentary time will have a higher chance to actually do so when she feels supported by her colleagues.

Based on their progress in behaviour change, three groups of people can be identified [110]. 'Pre-intenders' are people who do not yet have an intention for behaviour change. These individuals will benefit most from behaviour change techniques targeting motivational determinants for developing an intention (i.e. risk perception, outcome expectancies and task/perceived self-efficacy). People who already have an intention without acting on it are labelled as 'intenders'. According to the model these persons need support to translate their intentions into specific plans for action. Finally,



people who are acting on their intentions are called 'actors'. Actors might benefit from identifying risk situations and planning appropriate coping responses to deal with these kind of situations.

## 6. MyPlan 1.0

'MyPlan 1.0' is a HAPA-based eHealth intervention (i.e. a website) targeting physical activity and a healthy diet in adults. The following sections will discuss the development of 'MyPlan 1.0', describe the content of the programme and provide an overview of the results of the studies testing its effectiveness.

### 6.1 Development of MyPlan 1.0

The eHealth intervention 'MyPlan 1.0' was systematically developed using the six steps described by the intervention mapping protocol [14, 111]. In the first step a planning group (i.e. six researchers from different health disciplines and leading GPs from the Belgian association of GPs) discussed the core theories, methods, practical implications, implementation options and evaluation strategies. It was decided to focus on physical activity as well as the intake of fruit and vegetables. In step 2, performance objectives (e.g. 'Adults recognize the importance of increasing physical activity levels') were created. Based on the HAPA model pre- as well as post-intentional determinants for change (e.g. 'outcome expectancies') were identified and combined with the performance objectives in order to create change objectives (e.g. 'Adults describe that changing their physical activity levels will help to be healthy, feel better and to prevent chronic diseases in the long term'). In step 3, methods that can alter the determinants in order to achieve the performance objectives were selected. This process was guided by the results of systematic reviews assessing the effect of behaviour change techniques, the taxonomy of behaviour change techniques compiled by Abraham and Michie (2008) [112] and the overview of techniques provided by Bartholomew and colleagues (2011) [111]. By consulting the study protocols of effective interventions, the intervention developers translated the selected methods into practical applications. In step 4, the programme was created and tested for acceptability and feasibility in a pilot study [113]. In step 5, the plan to implement 'MyPlan 1.0' in general practice was created and discussed with general practitioners via focus group interviews [114]. Finally, in step 6, the programme was tested via a quasi-experimental trial [16, 17].

### 6.2 Content of MyPlan 1.0

MyPlan 1.0 consists of three sessions. During the first session users select which health behaviour they would like to change (i.e. their level of physical activity, fruit intake or vegetable intake). After

doing so, users complete a validated questionnaire assessing the current level of the chosen behaviour and receive feedback on their results (providing tailored feedback). Based on this feedback users are asked to indicate self-perceived barriers to be more physically active or to increase their fruit or vegetable intake (depending on their choice of behaviour) (barrier identification). Potential solutions, based on the selected barriers, are shown and users are asked to select solutions that seem feasible to them (problem solving). Users are then guided to create an if-then plan (e.g. If I don't feel like spending much time on preparing fruit, I will select pieces of fruit that do not require much preparation such as a banana or grapes) (creating implementation intentions). After doing so, users create an action plan (e.g. "On weekdays I will eat a piece of fruit during lunchtime at work") (action planning). Users' action and coping plan are then combined in an overview that they can print and send to friends or family (stimulating social support). Finally, users select how they will monitor their behavioural change (e.g. using their diary, a booklet, etc.) (prompting self-monitoring) [14].

After one week users receive an e-mail inviting them for the first follow-up session. During this session users are asked to fill-out the questionnaire assessing their current level of the chosen behaviour and received tailored feedback about whether or not they were able to reach their goal (prompting review of behavioural goal). Thereafter users can maintain or adapt their action plan and/or their barriers and solutions. The action and coping plan are then again combined in a printable overview that can be send to friends or family. Finally, users reselect how they will monitor their behaviour. One month after the first session, users receive an e-mail inviting them for the second and last follow-up session which is identical to the first follow-up session [14].

### 6.3 Effectiveness of MyPlan 1.0

The effectiveness of 'MyPlan 1.0 was first tested in adults visiting general practice [16, 17]. Based on focus groups with general practitioners (GPs), a plan for implementation was developed for this specific setting [114]. The implementation plan provided the GPs with a flowchart containing different methods (i.e. a flyer directing patients to the website or a tablet containing the website) and moments (i.e. before or after consultation) for delivering the intervention (see figure 4). Patients were offered the opportunity to discuss their plan with their GP during their next consultation.

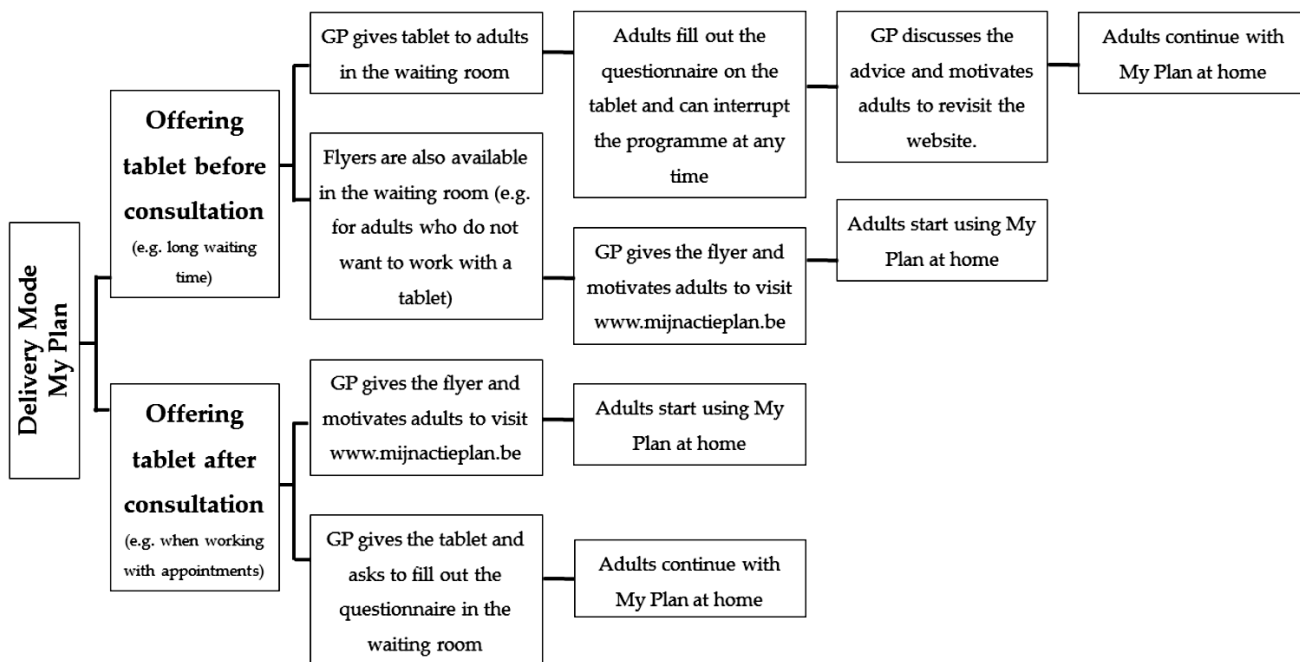


Figure 4: Flow-chart with delivery options for the general practitioners (Poppe et al., 2018)

Nineteen general practices participated in the cluster quasi-experimental trial testing the effectiveness of 'MyPlan 1.0'. In each general practice participants were recruited by the researchers as well as by the GPs. Alternating between morning and evening consultations researchers allocated patients to the control group or the intervention group (researchers' intervention group). GPs solely recruited patients for the intervention group (GPs' intervention group). Participants allocated to the control group received general feedback after completing the questionnaires assessing physical activity, fruit intake and vegetable intake and were informed that they would receive access to 'MyPlan 1.0' after study completion. After one month intervention effects for fruit as well as vegetable intake in favour of the researchers' intervention group ( $d = 0.91$  for fruit intake and  $d = 0.90$  for vegetable intake) and the GPs' intervention group ( $d = 0.82$  for fruit intake and  $d = 0.59$  for vegetable intake) were found [17]. Furthermore, patients recruited by the researchers showed a stronger increase in self-reported total ( $d = 0.41$ ) and moderate-to-vigorous ( $d = 0.45$ ) physical activity compared to the control group [16]. As there were only four GP-recruited patients who selected physical activity and completed the intervention, these participants were discarded from the analysis.

Van Dyck et al. (2016) conducted a randomized controlled trial to examine the effectiveness of 'MyPlan 1.0' to increase self-reported physical activity levels of recently retired adults both on short (i.e. baseline to 1 week) and intermediate term (i.e. baseline to 1 month) [15]. Of the 5000 contacted 58- to 65-year-old adults, 289 eligible individuals agreed to participate. On short term, an intervention effect favouring the intervention group was found for walking for transport ( $d = 0.14$ ). On intermediate-term, intervention effects favouring the intervention group were found for walking for transport ( $d = 0.21$ ), voluntary work-related vigorous physical activity ( $d = 0.04$ ), leisure-time walking ( $d = 0.32$ ), leisure time vigorous physical activity ( $d = 0.14$ ) and moderate intensity gardening ( $d = 0.07$ ).

In both studies a number of participants stopped using the intervention. In the effectiveness study with the general practitioners, 72% of the patients who selected intake of fruit or vegetables as their target behaviour did not complete the intervention [17]. Similarly, 75% of the patients who selected physical activity as their target behaviour dropped-out [16]. Attrition rates were lower in the study with the recently retired older adults: 75% of the participants allocated to the intervention group completed the intervention. These findings are in line with previous research showing that older users tend to show higher levels of adherence to online interventions [115].

#### 6.4 Attrition

As quitting is only a mouse click away, attrition seems to be the norm rather than the exception in e- and mHealth research [12, 115]. Two types of attrition can be distinguished: non-usage attrition, referring to lack of use of the online intervention, and drop-out attrition, referring to study-related drop-out [12]. Eysenbach (2005) argues that the drop-out attrition curve will follow the non-usage attrition curve because people who lose interest in the online programme might also lose interest in the study examining its effectiveness (see figure 5) [12]. The reduced exposure to intervention content caused by this "law of attrition" diminishes the potential effects of online interventions [116]. In order to tackle this problem it is important to investigate why non-usage attrition occurs and how increased engagement with online interventions can be achieved.

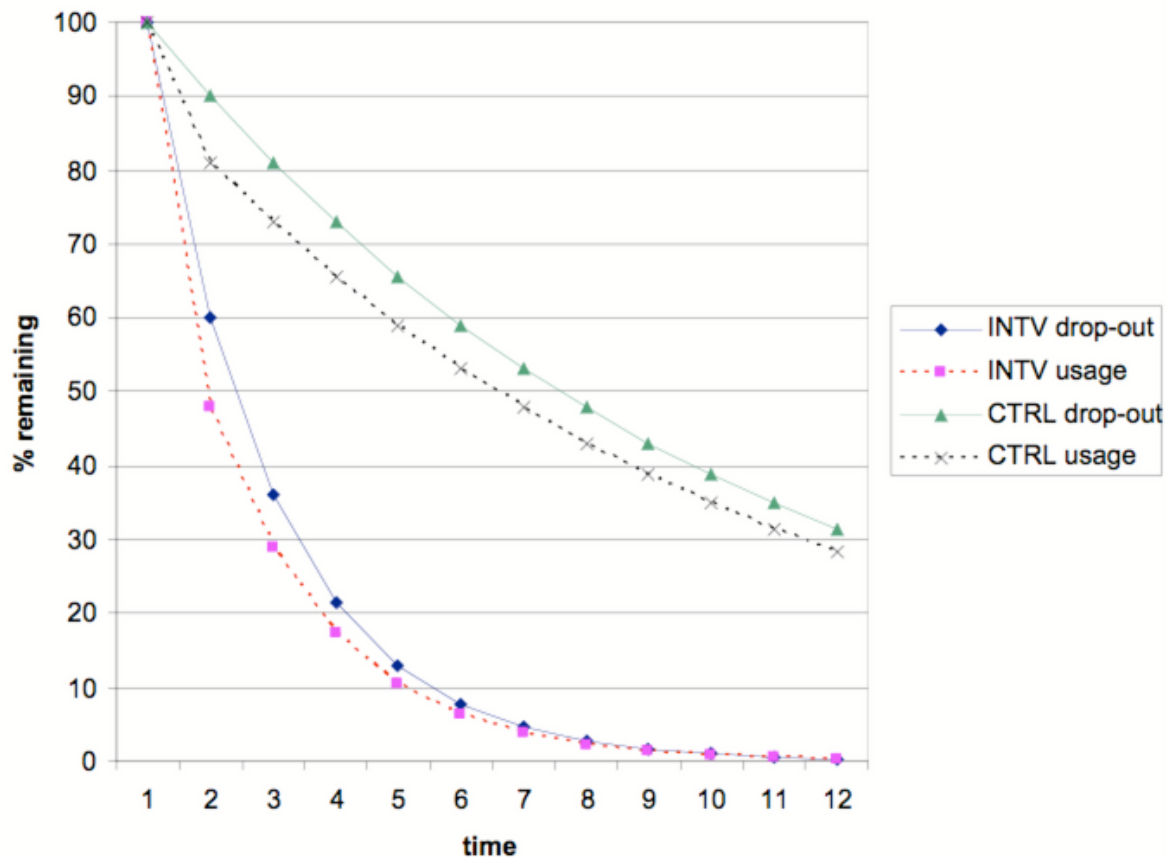


Figure 5. Attrition curves in a hypothetical eHealth trial (Eysenbach, 2005)

Engagement with an online intervention has been defined as “(1) the extent (e.g. amount, frequency, duration, depth) of usage and (2) a subjective experience characterised by attention, interest and affect”(page 258) and can be measured using subjective (e.g. questionnaires and interviews) as well as objective (e.g. number of logins and usage patterns) methods [117]. Several authors argue that engagement with an online intervention can be ameliorated by taking into account users’ needs and experiences regarding the programme [118-121]. For example, the person-based approach advocated by Yardley and colleagues (2015) advises to conduct in-depth qualitative research (e.g. interviews, think aloud studies, panel discussions, etc.) at every stage of the intervention process in order to create a profound understanding of the users’ characteristics and needs [13]. Consequently, the developmental process of an intervention is considered an iterative cycle between user feedback and programme adaptation [13, 118].

## 7. Problem analysis, aims and outline of the thesis

### 7.1 Problem analysis

The majority of adults with type 2 diabetes does not meet the recommendations regarding physical activity [4, 38, 39] and shows high levels of sedentary time [5, 53-55]. Delivering interventions via the Internet has shown to be a promising method to alter health behaviours in large populations [6]. However, current online interventions targeting an active lifestyle in adults with type 2 diabetes show mixed results [8, 77-81] and offer room for further improvement.

First, online interventions are often based on theories describing how an individual develops an intention (e.g. theory of planned behaviour) [9]. As previous research has shown that intentions are not readily translated to goal-directed behaviour [10], it might be beneficial to create interventions targeting motivational (e.g. outcome expectancies) as well as volitional (e.g. action planning) determinants of behaviour [11].

Second, the high levels of attrition characterizing online interventions [12] call for studies investigating patterns of attrition and in-depth qualitative research during each phase of the development process [13].

Third, despite the effectiveness of online interventions targeting sedentary time in the general population [7, 76] and the clear benefits of reducing sitting time in adults with type 2 diabetes [3, 48], no online interventions targeting sedentary behaviour in people with type 2 diabetes have yet been tested. As reducing sedentary time might be a feasible start for patients who are unable or reluctant to perform structured exercise [3], targeting reduced sitting times might be a fruitful avenue for Internet-based interventions focussing on an active lifestyle in a clinical population.

Finally, meta-analyses and reviews regarding e- and mHealth research often highlight the poor methodology and lack of clarity in effectiveness studies [8, 66, 68, 73]. Only a minority of studies examining the effectiveness of online interventions in adults with type 2 diabetes provides a protocol describing the study design and the online intervention (i.e. the content, its theoretical basis and the assumed active ingredients) [8]. Furthermore, several authors emphasize the need for objective measures of physical activity or sedentary behaviour and longer follow-up assessments [8, 66, 68].

## 7.2 Aims and outline of the thesis

Based on the problems described above, the aim of this doctoral thesis was twofold. The first objective was to develop a theory-based eHealth intervention (i.e. a website) targeting physical activity and sedentary behaviour in adults with type 2 diabetes accompanied by a mobile application (mHealth) providing daily support. The second objective was to test the effect of the e- and mHealth intervention in adults with type 2 diabetes via a randomized controlled trial.

To reach the first objective a theory-based e- and mHealth intervention targeting an active lifestyle in adults with type 2 diabetes needed to be created. This e- and mHealth intervention would be considered a working tool to answer scientific research questions rather than a health-promoting programme to be implemented on a large scale which would require the input of experts from different domains (e.g. engineering, marketing, communication sciences, ...) [122]. Taking into account the intention-behaviour gap, the online programme needed to target volitional determinants of behaviour change. As 'MyPlan 1.0' explicitly targets these determinants, the programme was considered a solid base to develop the e- and mHealth intervention for adults with type 2 diabetes. Considering the promising effects found with 'MyPlan 1.0' in the general population, it was decided to also create an improved version for adults from the general population. Consequently, adults with type 2 diabetes as well as adults from the general population were involved in the research performed to create an improved version of 'MyPlan 1.0'. Similar to other eHealth interventions, 'MyPlan 1.0' faces high rates of attrition. Consequently, the programme offered us the opportunity to gain more insight in users' reasons for quitting an online intervention. The first sub aim of this thesis was therefore to investigate when and why users did not complete 'MyPlan 1.0'. Chapter 1.1 of the thesis describes the study investigating which user and website characteristics are related to non-usage attrition in 'MyPlan 1.0'. Chapter 1.2 presents a qualitative study assessing how adults with type 2 diabetes and adults from the general population perceive 'MyPlan 1.0'. The second sub aim was to create 'MyPlan 2.0'. A first version of 'MyPlan 2.0' was developed based on the findings of the two studies described in chapters 1.1 and 1.2. Potential users (i.e. adults with type 2 diabetes and adults from the general population) tested this first version and final adaptations were made based on their feedback. Chapter 1.3 describes the experiences of adults with type 2 diabetes regarding 'MyPlan 2.0'. Recommendations regarding how behaviour change techniques should be implemented in the online format to suit the needs of adults from the general population are provided in chapter 1.4.

The second objective of this doctoral thesis was to test the effect of MyPlan 2.0 in adults with type 2 diabetes via a randomized controlled trial. Chapter 2.1 provides the protocol in which the study



design and the intervention are described in depth. As the recruitment of participants with type 2 diabetes was slow, it was decided to recruit another sample from a similar age cohort of people with type 2 diabetes. Consequently, chapter 2.2 describes the results and learned lessons of the randomized controlled trials testing the effect of 'MyPlan 2.0' in adults with type 2 diabetes and in adults aged 50 or older.

## 8. Overview of the original research studies

### **CHAPTER 1 – Identifying reasons for attrition in ‘MyPlan 1.0’ and developing ‘MyPlan 2.0’**

#### ***Chapter 1.1 – A self-regulation-based eHealth intervention to promote a healthy lifestyle: investigating user and website characteristics related to attrition***

Van der Mispel C, Poppe L (joint first author), Crombez G, Verloigne M, De Bourdeaudhuij I: A Self-Regulation-Based eHealth Intervention to Promote a Healthy Lifestyle: Investigating User and Website Characteristics Related to Attrition. *Journal of Medical Internet Research* 2017, 19:e241. DOI: 10.2196/jmir.7277

#### ***Chapter 1.2 – Users’ thoughts and opinions about a self-regulation-based eHealth intervention targeting physical activity and the intake of fruit and vegetables: a qualitative study***

Poppe L, Van der Mispel C (joint first author), De Bourdeaudhuij I, Verloigne M, Shadid S, Crombez G: Users’ thoughts and opinions about a self-regulation-based eHealth intervention targeting physical activity and the intake of fruit and vegetables: A qualitative study. *PloS one* 2017, 12:e0190020. DOI: 10.1371/journal.pone.0190020

#### ***Chapter 1.3 – Experiences and opinions of adults with type 2 diabetes regarding a self-regulation-based eHealth intervention targeting physical activity and sedentary behaviour***

Poppe L, Crombez G, De Bourdeaudhuij I, Van der Mispel C, Shadid S, Verloigne M: Experiences and Opinions of Adults with Type 2 Diabetes Regarding a Self-Regulation-Based eHealth Intervention Targeting Physical Activity and Sedentary Behaviour. *International Journal of Environmental Research and Public Health* 2018, 15:954. DOI: 10.3390/ijerph15050954

#### ***Chapter 1.4 – How users experience and use an eHealth intervention based on self-regulation: mixed-methods study***

Poppe L, Van der Mispel C, Crombez G, De Bourdeaudhuij I, Schroé H, Verloigne M: How Users Experience and Use an eHealth Intervention Based on Self-Regulation: Mixed-Methods Study. *Journal of Medical Internet Research* 2018, 20. DOI: 10.2196/10412

### **CHAPTER 2 – Testing the effectiveness of ‘MyPlan 2.0’**

#### ***Chapter 2.1 – A self-regulation-based eHealth and mHealth intervention for an active lifestyle in adults with type 2 diabetes: Protocol for a randomized controlled trial.***

Poppe L, De Bourdeaudhuij I, Verloigne M, Degroote L, Shadid S, Crombez G: A self-regulation-based eHealth and mHealth intervention for an active lifestyle in adults with type 2 diabetes: Protocol for a randomized controlled trial. *JMIR Research Protocols*, 2019; 8(3): e12413. DOI: 10.2196/12413

#### ***Chapter 2.2 – Effectiveness of a self-regulation-based e- and mHealth intervention targeting an active lifestyle in adults aged 50 or older and in adults with type 2 diabetes: two randomized controlled trials***

Poppe L, De Bourdeaudhuij I, Verloigne M, Shadid S, Van Cauwenberg J, Compernelle S, Crombez G. Effectiveness of a self-regulation-based e- and mHealth intervention targeting an active lifestyle in adults aged 50 or older and in adults with type 2 diabetes: two randomized controlled trials. *Submitted to Journal of Medical Internet Research.*





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## PART 2 – ORIGINAL RESEARCH

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## CHAPTER 1

Identifying reasons for attrition in 'MyPlan 1.0' and developing 'MyPlan 2.0'





## CHAPTER 1.1

A self-regulation-based eHealth intervention to promote a healthy lifestyle:  
investigating user and website characteristics related to attrition

Van der Mispel C, Poppe L (joint first author), Crombez G, Verloigne M, De Bourdeaudhuij I: A Self-Regulation-Based eHealth Intervention to Promote a Healthy Lifestyle: Investigating User and Website Characteristics Related to Attrition. *Journal of Medical Internet Research* 2017, 19:e241. DOI: 10.2196/jmir.7277



Original Paper

# A Self-Regulation-Based eHealth Intervention to Promote a Healthy Lifestyle: Investigating User and Website Characteristics Related to Attrition

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## Abstract

**Background:** eHealth interventions can reach large populations and are effective in increasing physical activity (PA) and fruit and vegetable intake. Nevertheless, the effects of eHealth interventions are overshadowed by high attrition rates. Examining more closely when users decide to leave the intervention can help eHealth developers to make informed decisions about which intervention components should be reshaped or simply removed. Investigating which users are more likely to quit an intervention can inform developers about whether and how their intervention should be adapted to specific subgroups of users.

**Objective:** This study investigated the pattern of attrition in a Web-based intervention to increase PA, fruit, and vegetable intake. The first aim was to describe attrition rates according to different self-regulation components. A second aim was to investigate whether certain user characteristics are predictors for start session completion, returning to a follow-up session and intervention completion.

**Methods:** The sample consisted of 549 adults who participated in an online intervention, based on self-regulation theory, to promote PA and fruit and vegetable intake, called “MyPlan 1.0.” Using descriptive analysis, attrition was explored per self-regulation component (eg, action planning and coping planning). To identify which user characteristics predict completion, logistic regression analyses were conducted.

**Results:** At the end of the intervention program, there was an attrition rate of 78.2% (330/422). Attrition rates were very similar for the different self-regulation components. However, attrition levels were higher for the fulfillment of questionnaires (eg, to generate tailored feedback) than for the more interactive components. The highest amount of attrition could be observed when people were asked to make their own action plan. There were no significant predictors for first session completion. Yet, two subgroups had a lower chance to complete the intervention, namely male users (OR: 2.24, 95% CI=1.23-4.08) and younger adults (OR: 1.02, 95% CI=1.00-1.04). Furthermore, younger adults were less likely to return to the website for the first follow-up after one week (OR: 1.03, 95% CI=1.01-1.04).

**Conclusions:** This study informs us that eHealth interventions should avoid the use of extensive questionnaires and that users should be provided with a rationale for several components (eg, making an action plan and completing questions). Furthermore, future interventions should focus first on motivating users for the behavior change before guiding them through action planning. Though, this study provides no evidence for removal of one of the self-regulation techniques based on attrition rates. Finally, strong efforts are needed to motivate male users and younger adults to complete eHealth interventions.

**KEYWORDS**

physical activity; healthy diet; eHealth; attrition; self-regulation

## Introduction

eHealth is defined as “the use of information and communications technology, especially the Internet, to improve or enable health and health care” [1]. Compared with traditional face-to-face health interventions, eHealth interventions have the potential to reach large populations in a time-efficient way. Furthermore, these interventions can be tailored to users’ needs and have shown to be effective in changing health behavior, such as increasing physical activity (PA) [2-4] and fruit and vegetable intake [5]. Despite the promising results, the effects of eHealth interventions are often plagued by high attrition rates. With attrition rates reaching 60-80%, loss of participants during the intervention seems to be the rule rather than the exception in eHealth research [6]. Possible effects of the intervention may then be compromised due to low exposure to the intervention content [7]. That way, high attrition rates are a threat for the internal and external validity of the intervention results [8].

According to Eysenbach [9], 2 types of attrition in eHealth can be identified. The first type, called nonusage attrition, refers to attrition from the intervention and occurs when participants stop using the eHealth intervention. This problem can arise at any given moment, for example, when participants do not complete a website session or when they do not return to the website anymore. The second type of attrition refers to participants withdrawing from the study itself. The phenomenon of participants not returning for follow-up assessment sessions is described by the term dropout attrition. Both types of attrition can challenge eHealth research. Nonusage attrition can undermine the potential effect of an intervention (due to low exposure to the intervention content), whereas dropout attrition might influence the power and the results of the study that evaluates the intervention [10].

Investigating patterns of nonusage attrition can provide valuable information for the development of eHealth interventions [9]. By examining when users discontinue the intervention, possible obstacles can be identified. Researchers often describe attrition rates at the end of the intervention and investigate predictors of intervention completion [8,11-13]. However, attrition can occur at all stages of the intervention. To our knowledge, no study has examined nonusage attrition early on in the intervention, that is, during an intervention program. Examining more closely when users decide to leave the intervention can help eHealth developers to make informed decisions about which parts or components of the intervention tool should be redesigned or simply removed. Attrition should thus be investigated as a function of different meaningful intervention components.

Many eHealth interventions require participants to fill out questionnaires for either providing tailored feedback or research purposes. However, it is not known whether this affects the attrition rates of the eHealth program. Furthermore, self-regulation techniques (eg, action planning, coping planning,

and monitoring) play an important role in many behavior change theories [14-16] and are therefore often implemented in eHealth interventions (eg, see [17-19]). These techniques are theory-based and elicit behavior change [20]. However, there is a lack of research that investigates whether participants easily adopt using these techniques, or rather whether the implementation of these techniques in eHealth interventions is related to attrition. Thus, identifying critical components in an intervention, that is, moments during which nonusage attrition peaked, can provide useful information.

Of further importance is to identify who is less likely to complete the eHealth intervention. For example, research shows that the utilization of eHealth tools depends upon the age of its users, with younger adults being more likely to show higher levels of nonusage attrition than older adults [6,21,22]. Also, men and users with a lower level of education have higher chances to show low levels of eHealth utilization [21,23,24]. However, to our knowledge, attrition according to age, sex, or education level has not been thoroughly investigated in self-regulation-based eHealth interventions. Finally, body mass index (BMI) could be predictive for the completion of eHealth interventions, although previous research on the predictive value of BMI in completing weight-loss interventions shows inconsistent results [25-29]. Identifying groups of users who are more likely to quit a Web-based program can inform developers about whether and how an intervention should be adapted to specific subgroups of users. Further research can then help us define the unaddressed needs of these subgroups. By doing so, the reach and effectiveness of future eHealth interventions can be ameliorated.

This paper investigates nonusage attrition from the eHealth intervention “MyPlan 1.0”. MyPlan 1.0 is a website that aims to increase PA and the intake of fruit and vegetables in the adult population [30]. This intervention is based on self-regulation theory [14], which is the process of goal selection, goal pursuit, and goal maintenance. MyPlan 1.0 thus includes different self-regulation techniques that can be investigated for their likelihood of increasing or decreasing attrition. The first technique included in MyPlan 1.0 is providing tailored feedback. Therefore, participants complete questionnaires regarding their current behavior and receive advice that compares their behavior with the guidelines and provides examples on how they could improve their behavior. A second technique is coping planning, in which users identify possible obstacles and solutions. The program also contains action planning. Here users define what they want to achieve and when and where exactly they are planning to do so. Also included is self-monitoring of behavior, which is facilitated by prompting users to reflect upon how they will keep track of their behavior (eg, in their diary or via cellphone). Finally, the use of social support is encouraged by providing users the opportunity to email their personal plan to a friend or family member. More information on how the techniques were implemented in the website is described in the

**Multimedia Appendix 1.** These techniques were carefully selected based on their potential effectiveness, described in the current literature. Previous research demonstrated the effectiveness of MyPlan 1.0 as a whole to increase PA and the consumption of fruit and vegetables in adults [31-33]. However, like many eHealth interventions, MyPlan 1.0 is challenged by high rates of attrition: at the end of the intervention a loss of 64.0% (235/367) of the participants was observed [32]. In this program, participants that caused nonusage attrition were automatically causing dropout attrition since participants completed all measures in the Web-based program. In this article, we focus on nonusage attrition and aim to identify the components that make people stop using an intervention in which they initially showed interest.

The aim of this paper is two-fold. First, we aim to identify critical moments of attrition in the eHealth intervention MyPlan 1.0 using an explorative and quantitative approach. Therefore, we will describe the rates of website utilization according to the different self-regulation-based intervention components (namely providing feedback, action planning, coping planning, self-monitoring, and social support) and the general components (namely filling in demographic information and filling in a questionnaire). This may help us understand which components in an eHealth intervention discourage users to continue with the program. For this aim, we will also report the usage half-life of MyPlan 1.0, which is the moment where 50% of the users have stopped using the tool [9]. Our second aim is to investigate if certain user characteristics (ie, sex, education, age, and BMI) are predictors of start session completion, returning to a follow-up session, and intervention completion. This may provide information about whether the intervention distinguishes between certain subpopulations of users.

## Methods

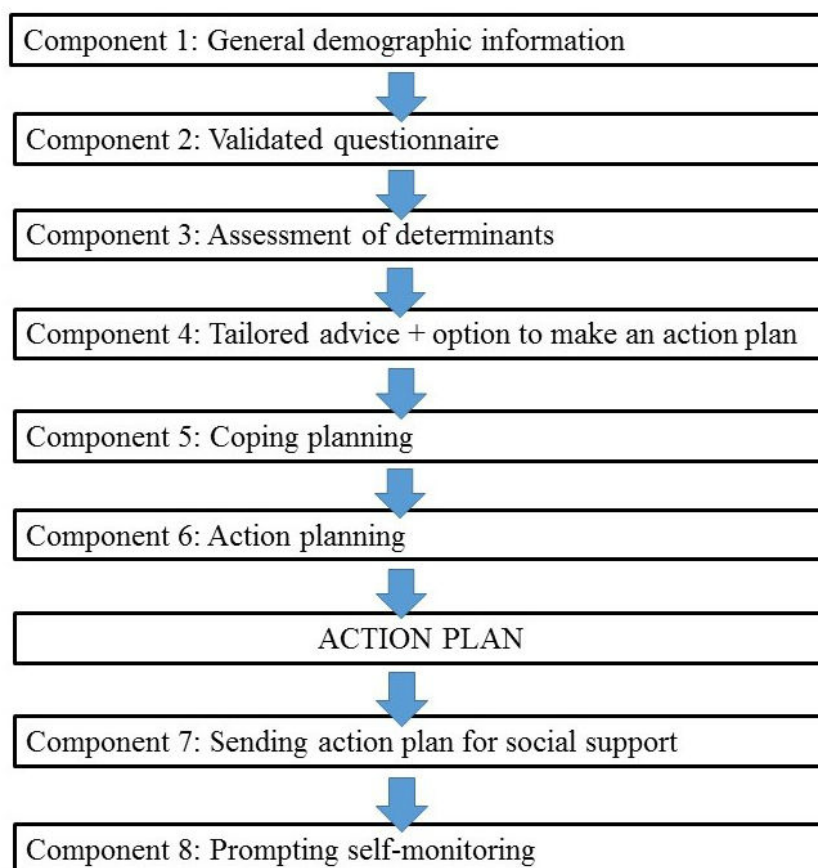
### Participants and Design

The sample consisted of adults who participated in a Web-based intervention to promote a healthy lifestyle, called MyPlan 1.0, from November 2014 to September 2016. Participants were recruited via the general practice setting. Both researchers in the waiting room and general practitioners provided the participants with a flyer that directed them to the intervention website. There were also tablets available in the waiting room, where participants could start to fill in the intervention program. When they were not able to finish the program in the waiting room, they received a link to complete the intervention program at home. The inclusion criterion was a minimum age of 18 years. All data entered by participants were, just as the information about website use, collected and stored in LimeSurvey (LimeSurvey Project Hamburg, Germany). Participants did not

receive any kind of incentive. The study was approved by the Ghent University Hospital Ethics Committee.

### Intervention

The Web-based intervention website MyPlan 1.0 was developed using the intervention mapping protocol [30] and has proven to be effective and feasible [32]. The intervention targets behavior change in three domains: PA, fruit intake, and vegetable intake. In a first step, participants choose which behavior they prefer to change. Thereafter, the structure of the intervention is identical for the three behaviors. The intervention consists of 3 sessions: one start session, and two follow-up sessions. In the start session, participants are making personal health action plans for the first time. After 1 week, they get an invitation by email to complete the second session of the intervention (follow-up 1, FU1). In this follow-up session they get feedback on their behavior change and can choose to keep or adapt their personal action plan according to their success or failure. One month after the first session, the third and last session (follow-up 2, FU2) is activated, in which they evaluate their behavior change a second time. The intervention is based upon self-regulation theory [14,34] and guides participants in their behavior change through different mandatory components based on self-regulation techniques (namely providing feedback, action planning, coping planning, self-monitoring, and social support). **Figure 1** illustrates the flow of the start session, in which all self-regulation techniques are incorporated. Within this first session, participants start by filling in general demographic information. Thereafter, they complete a validated questionnaire regarding the chosen behavior (International Physical Activity Questionnaire [IPAQ] [35]; The Flemish Fruit Test and Vegetable Test, [36]) and get tailored feedback on their current level of PA or fruit or vegetable intake. For study purposes, participants also fill out an assessment of determinants of behavior change such as self-efficacy and motivation. After the tailored advice, participants can choose to make an action plan or to leave the website. In order to make an action plan, participants complete a coping planning and an action planning component, respectively. In the coping planning component, they identify possible difficulties and make a plan to overcome these barriers. In the action planning component, they are guided to define where, when, and in which way they would like to be physically active or eat more fruit or vegetables. Participants also get the option to state implementation intentions [37,38], that is, to formulate an if-then plan (eg, if I come home from work, I go walking in the neighborhood for half an hour). This information is collected and shown in a comprehensive action plan. Participants can choose to send their action plan to family or friends in order to get social support. At the end, the website asks participants how they are going to keep track of their activity or fruit or vegetable intake in order to prompt self-monitoring of behavior change.

**Figure 1.** Overview of the start session components.

## Measures and Statistical Analysis

### Description of the Nonusage Attrition Pattern

To analyze the nonusage attrition during the intervention (aim 1), the start session was divided into 8 components according to the different self-regulation techniques and the general information part, as described previously and depicted in [Figure 1](#). If the last question of the component was answered or the last choice option was filled in, the component was considered as completed. If not, nonusage attrition occurred during that specific component. Attrition as a function of the different components was described in terms of absolute and relative numbers. Critical components during the follow-up sessions were not analyzed because the self-regulation techniques included in these sessions were very similar to the ones in the start session.

### Predictors of Intervention Completion

Besides nonusage attrition in the start session, predictors (ie, users' demographic information) of intervention completion were also investigated (aim 2). Demographic characteristics were obtained from the answers given in the start session of the website intervention. Demographic measures included sex, educational level, age, height, and weight. Regarding educational level, a college degree was considered as high educational level, whereas no education, primary school, and secondary school

were considered as low educational level. BMI was calculated by dividing weight (in kilogram) by height (in meter) squared. Participants were classified as not overweight if they had a BMI under 25 kg/m<sup>2</sup> and as overweight if their BMI was 25 kg/m<sup>2</sup> or higher.

Completion was defined as follows: if the last question of the start session was filled in, the session was considered as completed. Returning to the website was defined as accessing FU1, or more specifically, "filling in the first question of FU1." If the last question of the last session (FU2) was filled in, the whole intervention was considered as completed. To investigate aim 2, three logistic regression analyses were conducted in SPSS version 23 (IBM Corporation): (1) to identify predictors of start session completion, (2) to investigate predictors of a first return to the website after start session completion (ie, accessing FU1), and (3) to examine predictors of FU2 completion (ie, intervention completion). After checking for multicollinearity, all demographic variables (ie, sex, educational level, age, and BMI) were entered together into the regression as possible predictors. The level of significance was set at  $P < .05$ .

## Results

### Participant Characteristics

In total, 549 adults visited the intervention website and were therefore defined as "potential users". However, 127 of them

only visited the home page and did not register (ie, fill in their name and email address). They were excluded from the analyses since no information about them was available. The remaining 422 were considered as “actual users”; 39.1% (165/422) of them chose to focus on PA, 41.0% (173/422) on fruit intake, and 19.9% (84/422) on vegetable intake. All participants that registered were included in the study, although it has to be noted that some people registered but did not complete (all) demographic measures.

An overview of the participant characteristics can be found in [Table 1](#). In the total sample, 55.7% (235/422) were female and 28.2% (119/422) were male. Furthermore, 41.7% (176/422) of the people had a low educational level, whereas 42.2% (178/422) had a high educational level. The mean age of the sample was 43.92 years (SD 14.23), ranging from 18-81 years. Finally, 48.3% (204/422) of the sample was overweight, whereas 48.6% (205/422) had a normal weight. The mean BMI was 25.96 (SD 5.39) kg/m<sup>2</sup>.

**Table 1.** Overview of participant’s demographic characteristics (N=422).

Characteristics	n (%)	Mean (SD)
<b>Sex</b>		
Male	119 (28.2)	
Female	235 (55.7)	
Missing	68 (16.1)	
<b>Education</b>		
Low	176 (41.7)	
High	178 (42.2)	
Missing	68 (16.1)	
<b>BMI (kg/m<sup>2</sup>)</b>		25.96 (5.39)
Overweight	204 (48.3)	
Not overweight	205 (48.6)	
Missing	13 (3.1)	
<b>Age (years)</b>		43.92 (14.23)
Missing	68	

### Description of the Nonusage Attrition Pattern

In total, 55.7% (235/422) of the participants completed the start session. Only 43.1% (182/422) of the total sample returned to the first follow-up session. Therefore, the usage half-life is situated between the start session and FU1. Of the total sample, 21.8% (92/422) completed FU2. Hence, at the end of the intervention program, there was a nonusage attrition rate of 78.2% (330/422).

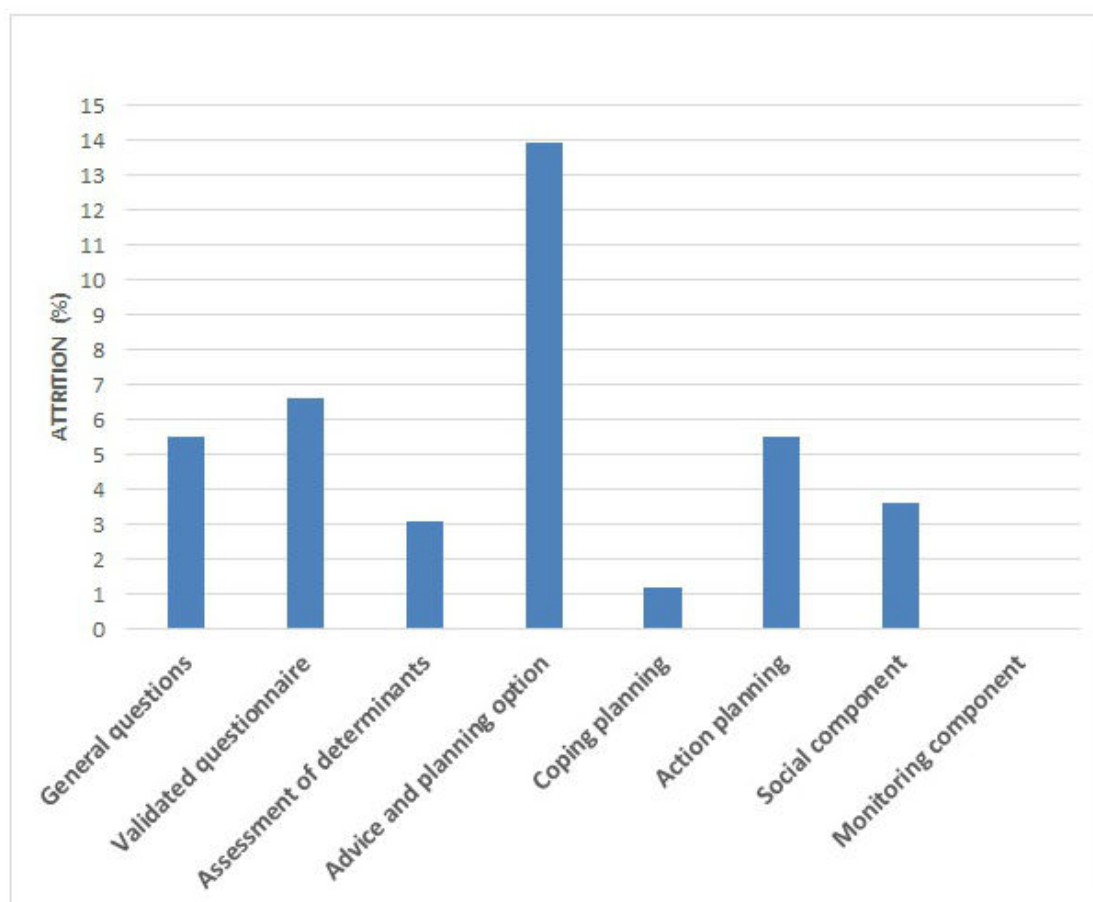
To identify components (eg, action planning and coping planning) in which nonusage attrition is the highest, the start

session was divided into eight components, as described in the methods section. The critical moments were defined separately for the three target behaviors (PA, fruit intake, and vegetable intake) in order to get a more detailed insight in possible obstacles during intervention fulfilment. The extent to which attrition occurred per component can be found in [Table 2](#). Results are also visualized in [Figures 2-4](#) for the PA, fruit, and vegetable module, respectively. All components show attrition rates of less than 5%. The only component for which attrition rates are higher than 5% in all three modules is the advice and planning option.

**Table 2.** Attrition rates per website component.

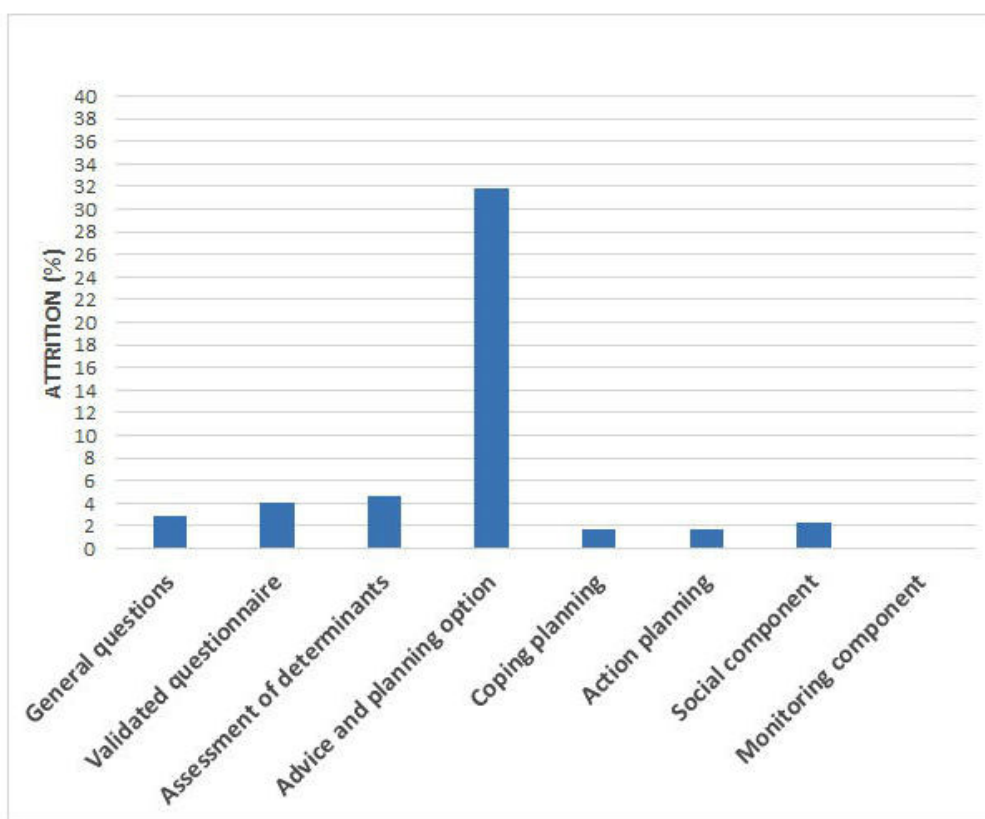
Session	Website component	Physical activity (n=165)		Fruit intake (n=173)		Vegetable intake (n=84)	
		n	% (cumulative %)	n	% (cumulative %)	n	% (cumulative %)
<b>Start session</b>		65	39.4 (39.4)	85	49.1 (49.1)	37	44.0 (44.0)
	General questions	9	5.5 (5.5)	5	2.9 (2.9)	0	0 (0)
	Validated questionnaire	11	6.6 (12.1)	7	4.0 (6.9)	5	6.0 (6.0)
	Assessment of determinants	5	3.1 (15.2)	8	4.7 (11.6)	5	5.9 (11.9)
	Advice and planning option	23	13.9 (29.1)	55	31.8 (43.4)	22	26.2 (38.1)
	Coping planning	2	1.2 (30.3)	3	1.7 (45.5)	2	2.4 (40.5)
	Action planning	9	5.5 (35.8)	3	1.7 (46.8)	1	1.2 (41.7)
	Social component	6	3.6 (39.4)	4	2.3 (49.1)	2	2.3 (44)
	Monitoring component	0	0 (39.4)	0	0 (49.1)	0	0 (44)
<b>Follow-up 1</b>		57	34.5 (73.9)	40	23.2 (72.3)	27	32.2 (76.2)
<b>Follow-up 2</b>		7	4.3 (78.2)	4	2.3 (74.6)	8	9.5 (85.7)

**Figure 2.** Attrition percentage per website component in the start session of the physical activity module.

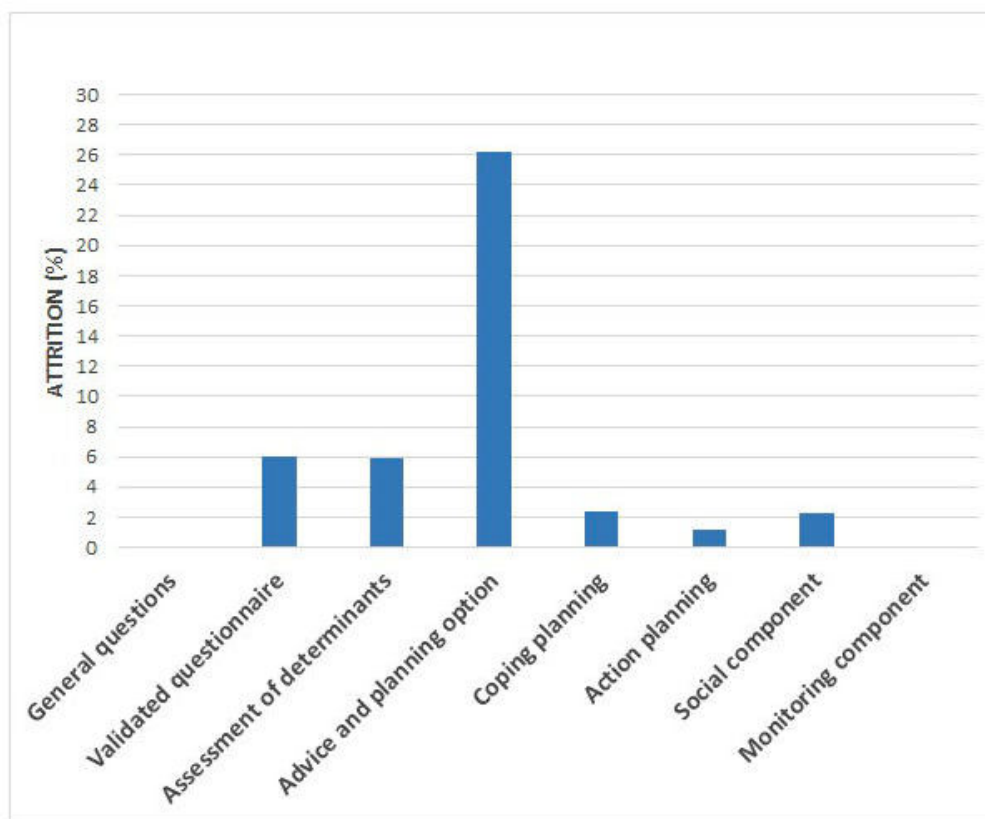




**Figure 3.** Attrition percentage per website component in the start session of the fruit module.



**Figure 4.** Attrition percentage per website component in the start session of the vegetable module.



**Table 3.** Predictors for start session completion, returning after start session completion, and intervention completion.

Session	Exp (B) <sup>a</sup>	SE <sup>b</sup>	95% CI
<b>Start session completion</b>			
Sex	1.35	0.23	0.85-2.12
Education	1.10	0.22	0.72-1.68
Age	1.01	0.01	0.99-1.02
Overweight or not	1.15	0.23	0.74-1.79
<b>Returning to FU1<sup>c</sup></b>			
Sex	1.22	0.24	0.77-1.94
Education	1.07	0.22	0.69-1.64
Age	1.03	0.01	1.01-1.04
Overweight or not	1.41	0.23	0.90-2.20
<b>Intervention completion</b>			
Sex	2.24	0.31	1.23-4.08
Education	1.15	0.26	0.69-1.92
Age	1.02	0.01	1.00-1.04
Overweight or not	1.28	0.27	0.75-2.16

<sup>a</sup>Exp(B): exponential function of the coefficient B. This indicates the odds ratio for the predictor.

<sup>b</sup>SE: standard error.

<sup>c</sup>FU1: follow-up 1.

## Predictors of Intervention Completion

There were no significant predictors for start session completion (see Table 3). However, there was one significant predictor for returning after start session completion (see Table 3). Age group significantly predicted whether participants would return to the website after 1 week (Odds ratio [OR]=1.03, 95% CI 1.01-1.04), with older participants being more likely to return than younger participants. There were two significant predictors for FU2 completion as well (see Table 3). Both age (OR=1.02, 95% CI 1.00-1.04) and sex (OR=2.24, 95% CI 1.23-4.08) could predict intervention completion, with older participants and women being more likely to complete the intervention.

## Discussion

### Principal Findings

This paper investigated both website and user characteristics related to nonusage attrition levels from a self-regulation-based eHealth tool (MyPlan 1.0). First, possible obstacles were identified by exploring attrition rates for the self-regulation techniques and general components of the start session. Second, we investigated which user characteristics predicted whether users finished the start session, returned to the website (ie, logged in for the second session), and completed the whole intervention (ie, the third session). Results show an overall attrition rate of 78.2%. Although attrition rates were similar for the various components, attrition levels were higher for filling out questionnaires (eg, to generate tailored feedback) than for the more interactive components (such as action planning, coping planning, etc). The highest amount of attrition could be observed when people were shown the advice and asked to make

their own action plan. There were no significant predictors for first session completion. Yet, younger adults were less likely to return to the website for the follow-up after 1 week. Furthermore, male users and younger adults had a lower chance to complete the intervention.

A notable finding is that a large amount of users did not register when visiting the website. Previous research has already indicated that a registration procedure can be a barrier for starting an intervention [39]. This could be due to the loss of anonymity: people might be concerned about their privacy or afraid of spam mail. Providing information about the necessity to register and how personal data will be used, could overcome this problem [39]. This result further shows that not only piloting the active components (ie, behavior change techniques such as action planning), but also the more technical components (eg, registration procedure) of eHealth programs in the population of interest is very important to investigate the acceptability and feasibility of the whole intervention.

The attrition rates were similar for the various health behaviors, which may indicate that our findings are not limited to one particular behavior. Furthermore, we found that attrition levels were higher during the first components than during the later ones. This might be due to the fact that the first three components included questionnaires, whereas the latter components contained self-regulation techniques that allowed more interaction between the website and the user (eg, the user indicates possible barriers and the website offers possible solutions). Moreover, a lot of questions were added for research purposes without immediate value for the users of the intervention. Completing long questionnaires without knowing the specific purpose might have discouraged users and

consequently made them stop using the intervention. Previous research already indicated that including lengthy questionnaires in an eHealth tool should be discouraged [39]. Although questionnaires are needed to enable tailored feedback, which has shown to be more effective than generic [40], the length of these questionnaires should be kept to a minimum. Furthermore, it might also be important to inform users about the necessity of providing information in order to make the tailoring possible. Tailoring could be made explicit by explaining how users' answers shape the advice they get. Another possible explanation for higher attrition rates during the first components could be that users tend to discontinue an intervention mostly at the beginning of an intervention. When already further advanced in the intervention, users might be more motivated and have invested more, so they are less likely to quit. For example, we could observe that users who completed the first follow-up session were highly likely to complete the second follow-up session (attrition rates for FU2<10%).

The most critical moment (ie, the component for which attrition levels were the highest) occurred when users were shown the tailored advice and were asked whether they would like to create an action plan. Since previous research indicated that most users experienced the advice as personally relevant, interesting, and clear [32], we assume that users were rather discouraged by the question to make a plan than by seeing the advice. A possible explanation for attrition at this moment could be that users have gained what they needed from the intervention (eg, see [41]). From this perspective, attrition is not necessarily detrimental. When people are reaching the health norms, no intervention to change their behavior is needed. The fact that people are shown feedback on their behavior and potentially realize that they are reaching the norms might result in attrition at that moment. An additional analysis showed indeed that many of the users that were already physically active or eating enough fruit and vegetables at baseline, quitted the intervention at this point. For PA, 20 of the 113 users who met the guidelines, quitted at this moment, whereas in the fruit and vegetable module this was 28 of the 29 and 7 of the 7 users, respectively. Providing users with feedback regarding whether or not they reach the health norms can thus be beneficial as the original sample is narrowed down to a sample mainly consisting of users that the intervention aims to target.

However, other participants who did not meet the guidelines stopped using the intervention: for PA, 3 out of 32 users; for fruit, 27 out of 136 users; and for vegetables, 16 users out of 77. There are several possible reasons for attrition at this moment (ie, the choice option to make a personal action plan) in the target population. First, since the website was openly accessible, many users might not have been motivated enough to actually improve the chosen health behavior. Previous research has already indicated that people who are not motivated to change their health behavior will be reluctant to make specific plans to do so [42]. Open-access eHealth tools might attract a subgroup of users who are still ambivalent toward change (contemplators) (Stages of Change; [43]). These users are likely to explore the website without actually making specific plans for behavior change. According to the Stages of Change theory, these users should not be pushed toward immediate behavior

change but provided with information and persuasive arguments to increase their motivation to change [43]. This could be implemented in eHealth interventions by giving users tailored information in relation to the stage they are in (eg, providing knowledge vs helping to plan change) and by providing the opportunity to easily return to the website, when they feel ready. Second, users might perceive the creation of an action plan as a more demanding task than answering multiple choice questions. Third, users might not have been aware of the advantages of making a specific plan to increase their PA, fruit or vegetable intake, and might have had the idea that the information and tailored advice were sufficient to put their newly elicited intentions into action. To overcome the latter two problems, it will be important that eHealth tools clearly explain why creating a specific action plan is beneficial during behavior change. Furthermore, not only highlighting the importance of creating an action plan but also communicating this component to the users in an engaging way is required. Components that cause high attrition rates should not immediately be thrown overboard, but they demand a process of reshaping. Researchers should search for a way to present theoretical components in an attractive way, for example, by minimizing the cognitive effort involved in component-specific tasks. Further qualitative research with possible users can help us understand why this component elicited high levels of attrition and can provide valuable information for reshaping the intervention.

We also explored which user characteristics predict returning to the website and completing the first and last module. We found that 2 subgroups had a lower chance to complete the intervention, namely male users and younger adults. Younger adults were also less likely to return to the website after 1 week. Male users were less likely to start with the intervention as well (28.2% male users in comparison with 55.7% female users in the sample). The phenomenon of younger users and male users being more likely to discontinue an intervention has been described as a recurring problem in eHealth [6,11,21,22]. Furthermore, previous research with MyPlan 1.0 showed that older users found the personal advice more interesting, informative, and motivating than the younger users did [32]. New opportunities to motivate younger adults and male users to use eHealth for an extended period of time need to be explored. Specifically involving these subgroups during the development of an eHealth intervention could help to make the intervention more acceptable. For example, Vandelanotte et al [44] conducted focus groups with middle-aged men regarding website and mobile-phone delivered PA and nutrition interventions and found that men are willing to use Web-based interventions provided that these interventions are quick and easy to use. Remarkably, education or BMI did not predict attrition in this eHealth intervention. This indicates that the intervention does not distinguish between low and high educated users and can be applied in an overweight population. Previous qualitative research already showed that the intervention was well accepted for high and low educated users [32].

### Strengths and Limitations

This study has several strengths. To our knowledge, this is the first study to investigate nonusage attrition during users' first use of an eHealth intervention. Many articles have investigated

attrition in eHealth but most of them focused on attrition related to the follow-up sessions [6,24]. Furthermore, this study was also the first to investigate attrition according to different website self-regulation components. Second, this study was conducted with a relatively large group of users with a balanced distribution in age, educational level, and BMI. Third, MyPlan 1.0 always offers users the possibility to log out and save their answers. So when users discontinue using the intervention because they are disturbed, they always had the possibility to continue on a later moment in time. Therefore, nonusage attrition here is most likely caused by the program itself rather than by external events.

This study has also some limitations. First, there was a disproportion in men versus women (28.2% vs 55.7%, respectively, cf. Table 1). Second, nonusage attrition was calculated based on the last mandatory question of each component. Therefore, no conclusions regarding specific questions within a certain component can be made. Third, the intervention only targeted PA, fruit intake, and vegetable intake

for behavior change. More research is needed to investigate attrition in interventions targeting other behaviors (eg, smoking and weight loss). Fourth, we do not know why people stopped using the intervention during the specific intervention components. Therefore, further qualitative research might reveal why people struggle with certain components and provide insight in how the implementation of self-regulation techniques can be improved.

## Conclusions

In conclusion, this study indicates that eHealth developers should be aware that attrition already occurs during the first contact with the program and that lessons can be learned by analyzing attrition patterns. Besides investigating website characteristics, also exploring the predictive value of user characteristics is important to gain insight in the users' needs. Combining these findings with qualitative research can help developers make informed decisions when adapting and optimizing intervention programs.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Implementation of the self-regulation techniques in MyPlan 1.0.

[[PDF File \(Adobe PDF File\), 730KB - jmir\\_v19i7e241\\_app1.pdf](#)]

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## Abbreviations

- PA:** physical activity  
**BMI:** body mass index  
**FU1:** follow-up 1  
**FU2:** follow-up 2  
**IPAQ:** International Physical Activity Questionnaire

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## Supplementary file 1:

### Implementation of the self-regulation techniques in MyPlan 1.0

#### Providing tailored feedback

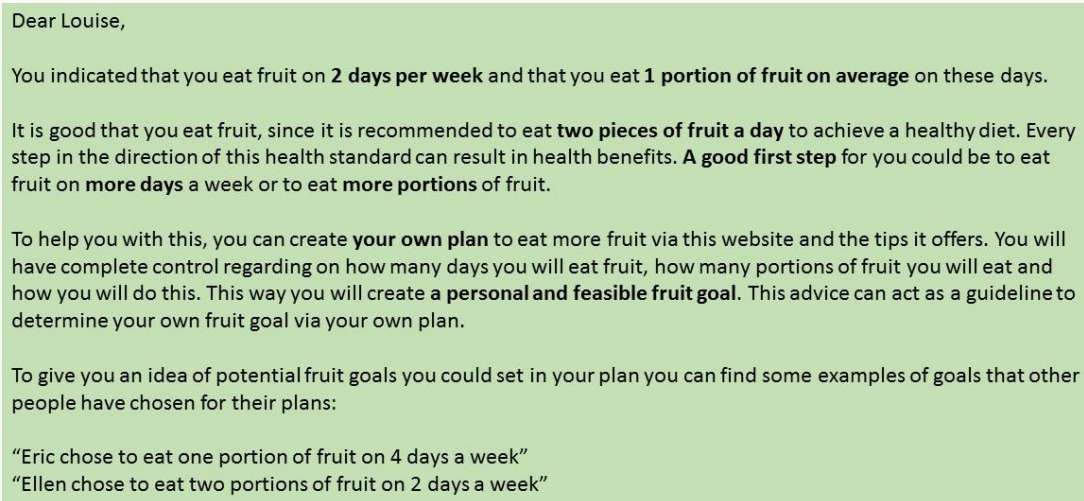
##### Definition:

Providing information related to the outcome of interest and based on a personal assessment [1].

##### Implementation in 'MyPlan 1.0':

Users complete the International Physical Activity Questionnaire (IPAQ), the Flemish Fruit Test or the Flemish Vegetable Test in order to gain insight in their current behaviour. After doing so, they receive personal feedback in which their behaviour is compared with the guidelines. Domains in which they can improve are explained (e.g. being physically active via active transport, eating fruit during breakfast, eating vegetables as a snack) and examples on how they could improve are given.

##### Screenshot:



Dear Louise,

You indicated that you eat fruit on **2 days per week** and that you eat **1 portion of fruit on average** on these days.

It is good that you eat fruit, since it is recommended to eat **two pieces of fruit a day** to achieve a healthy diet. Every step in the direction of this health standard can result in health benefits. **A good first step** for you could be to eat fruit on **more days** a week or to eat **more portions** of fruit.

To help you with this, you can create **your own plan** to eat more fruit via this website and the tips it offers. You will have complete control regarding on how many days you will eat fruit, how many portions of fruit you will eat and how you will do this. This way you will create a **personal and feasible fruit goal**. This advice can act as a guideline to determine your own fruit goal via your own plan.

To give you an idea of potential fruit goals you could set in your plan you can find some examples of goals that other people have chosen for their plans:

“Eric chose to eat one portion of fruit on 4 days a week”  
“Ellen chose to eat two portions of fruit on 2 days a week”

#### Coping planning

##### Definition:

Identifying possible hindrances in the goal attainment process and deciding how to overcome these [2].

##### Implementation in 'MyPlan 1.0':

Users are provided with a list of possible hindrances, which they have to place in order of importance. They also have the opportunity to add their own barrier. After selecting the most applicable hindrance, they get to see predefined solutions for the hindrance. Users should select a solution that they consider feasible.



## Screenshots:

Please indicate which option describes best your most important barrier to eat more fruit.

If none of the options listed below fit, you can choose "other" and describe your barrier. If you do not experience any hindrances or barriers to eat more fruit, you can choose the last option.

Select one of the following options.

- I think many fruits are unappetizing
- I do not know many fruits
- I find fruit expensive
- I experience a lack of encouragement of my partner, family, friends, ... to eat more fruits
- I find that fruits have a short shelf life
- I do not like to prepare fruit (washing, peeling, cutting, ...)
- I do not know where I can eat fruits
- I find that there is not much fruit available at my workplace
- I find that there is not much fruit available at my home
- I often forget to eat fruit
- I often feel like eating something else than fruit
- None of the options listed above or other hindrances fit
- Other:

How would you like to eat more fruit?

You indicated that your most important barrier to eat more fruits is that **you do not like to prepare food (washing, peeling, cutting, ...)**. Therefore, some methods are presented that might help you to eat more fruit. Select the method you would like to apply to eat more fruit. Choose a method that you perceive feasible to apply. You can also think up another method than the ones listed below and describe your method in the option "other".

Select one of the following answers

- By also eating precut frozen fruit
- By also eating canned fruit (without added sugars)
- By preparing fruit in advance for several days (for example preparing a large bowl of fruit salad and keep it in the refrigerator)
- By selecting fruits that you do not have to prepare or that are easy to prepare (an unpeeled apple/pear, a kiwi cut in half, a banana, berries such as grapes, raspberries and cherries)
- Other:

## Action planning

### Definition:

Specifying concretely when, where, and how you are going to achieve your goal. [2].

### Implementation in 'MyPlan 1.0':

Users choose which behaviour they are going to perform and when and where exactly they are planning to do this. Users choose activities (e.g. certain sports), places (e.g. at work, at home) and moments (e.g. after work, during breakfast, ...) from an extensive list of options, which they can extend with their own ideas. Thereafter, they have to state their plan in an implementation intention, formulated as an if-then sentence.

### Screenshot:

You chose to eat fruit on more days a week. You indicated that you now eat fruit on one day a week. Now you can set a goal by indicating on how many days you would like to eat fruit:

Select one of the following answers.

- On 1 day a week
- On 2 days a week
- On 3 days a week
- On 4 days a week
- On 5 days a week
- On 6 days a week
- On 7 days a week

During which moments would you like to eat fruit?  
(If you prefer another moment than the ones listed below, you can describe this in the option "other")

Multiple answers are possible.

- During breakfast
- As a snack in the morning
- During lunch time
- As a snack in the afternoon
- During dinner
- As a snack in the evening
- Other:

## Self-monitoring of behaviour

### Definition:

Keeping track of the specified goal behaviour [3].

### Implementation in 'MyPlan 1.0':

At the end of each session users are suggested to monitor their behaviour change. Users can select different options to keep record of their behaviour (for example: in their diary, via cellphone, ...), but can also tick the option that they prefer not to monitor their behaviour.

### Screenshot:

**We advise you to monitor whether you follow your plan or not.**

You can do this by writing down whether you have reached your goal and when you did so. Below you can find some proposals to do so.

Select the method you would like to apply to keep track of your goal on a daily basis. You can also think up your own method and describe it in the option "other".

- I will monitor my goal via a booklet
- I will monitor my goal via my calendar
- I will monitor my goal via my diary
- I will monitor my goal using my computer (Excel, Word, online diary, ...)
- I will monitor my goal using my mobile phone (notes, calendar)
- I will monitor my goal using an application on my smartphone or tablet
- I would rather not monitor my goal
- Other:

## Social support

### Definition:

Information that makes a person believe that he is liked, valued and part of a social network [4].

### Implementation in 'MyPlan 1.0':

The feeling of social support is elicited by giving users the opportunity to e-mail their personal plan, not only to themselves, but also to a friend or family member.

### Screenshot:

**Would you like to show your plan to a family member, a colleague, a friend or someone else?**

If you would like to show your plan to someone, then your plan will be send to this person. In the e-mail sent to this person we will ask him/her to support you in achieving your goal.

Below you can fill out the e-mail address of the person you would like to show your plan. If you would like to show your plan to several people, you can fill out several e-mail addresses.

The e-mail address of the first person I would like to send my plan:

The e-mail address of the second person I would like to send my plan:

The e-mail address of the third person I would like to send my plan:

The e-mail address of the fourth person I would like to send my plan:

The e-mail address of the fifth person I would like to send my plan:

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## CHAPTER 1.2

Users' thoughts and opinions about a self-regulation-based eHealth intervention targeting physical activity and the intake of fruit and vegetables: a qualitative study

Poppe L, Van der Mispel C (joint first author), De Bourdeaudhuij I, Verloigne M, Shadid S, Crombez G: Users' thoughts and opinions about a self-regulation-based eHealth intervention targeting physical activity and the intake of fruit and vegetables: A qualitative study. *PloS one* 2017, 12:e0190020



RESEARCH ARTICLE

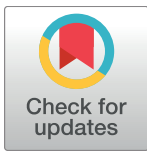
# Users' thoughts and opinions about a self-regulation-based eHealth intervention targeting physical activity and the intake of fruit and vegetables: A qualitative study

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**Data Availability Statement:** All relevant data are within the paper and its Supporting Information files.

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## Abstract

### Purpose

EHealth interventions are effective in changing health behaviours, such as increasing physical activity and altering dietary habits, but suffer from high attrition rates. In order to create interventions that are adapted to end-users, in-depth investigations about their opinions and preferences are required. As opinions and preferences may vary for different target groups, we explored these in two groups: the general population and a clinical sample.

### Methods

Twenty adults from the general population (mean age = 42.65, 11 women) and twenty adults with type 2 diabetes (mean age = 64.30, 12 women) performed 'MyPlan 1.0', which is a self-regulation-based eHealth intervention designed to increase physical activity and the intake of fruit and vegetables in the general population. The opinions and preferences of end-users were explored using a think aloud procedure and a questionnaire. During a home visit, participants were invited to think aloud while performing 'MyPlan 1.0'. The thoughts were transcribed verbatim and inductive thematic analysis was applied.

### Results

Both groups had similar opinions regarding health behaviours and 'MyPlan 1.0'. Participants generally liked the website, but often experienced it as time-consuming. Furthermore, they regularly mentioned that a mobile application would be useful to remind them about their goals on a daily basis. Finally, users' ideas about how to pursue health behaviours often hindered them to correctly use the website.

BOF.24J.2015.0007.01). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**Competing interests:** The authors have declared that no competing interests exist.

## Conclusions

Although originally created for the general population, 'MyPlan 1.0' can also be used in adults with type 2 diabetes. Nevertheless, more adaptations are needed to make the eHealth intervention more convenient and less time-consuming. Furthermore, users' ideas regarding a healthy lifestyle should be taken into account when designing online interventions.

## Introduction

The prevalence of many chronic diseases, such as type 2 diabetes, cardiovascular diseases and cancer, is high and still rising [1]. A healthy lifestyle, including sufficient physical activity (PA) and fruit and vegetable intake, can prevent these diseases, or alter their negative consequences [2–6]. However, only 35% of the Western adult population follows the guidelines of 30 minutes moderate- to vigorous PA on 5 days per week (and preferably every day), whereas 24% meets the norm of eating 5 or more servings of fruit and vegetables per day [6–8]. Even people for whom having a healthy lifestyle is key in the management of their disease, such as patients with type 2 diabetes, often fail to be physically active on a regular basis and fail to conform to a disease-specific dietary regime [9–11]. Consequently, there is a strong need for effective and easy-to-implement interventions that target a healthy lifestyle.

Internet-based interventions have the potential to reach a large part of the population, while still being able to offer a personal approach. Indeed, via computer tailoring e- (electronic) health features can be adapted to the user's specific needs. Such interventions are promising in changing health behaviours [12], such as increasing PA levels and altering dietary habits [13–18], especially when interventions are informed by solid theory and use behaviour change techniques that are evidence-based [16, 19–21]. However, even when eHealth interventions are theory- and evidence-based, attrition is often high and affects the potential effect of these programmes [22, 23]. In order to address this challenge, it has been recommended to involve users in the design and testing of eHealth tools [24]. The experience and opinion of end-users about core elements of online interventions may further guide eHealth development and understand eHealth usage [25]. As eHealth interventions are often used in various target groups [26], it is important to investigate possible differences in perceptions, opinions and preferences between user groups. Only by doing so the needs of different target populations can be taken into account.

In this paper, we investigate the perspectives of users on a web-based programme (the web-site 'MyPlan 1.0') that aims to increase PA and fruit and vegetable intake. 'MyPlan 1.0' is grounded in self-regulation theory [27, 28], and guides users through the processes of behaviour change via different evidence-based techniques, such as setting specific goals (goal-setting), deciding how these goals can be reached (action planning), foreseeing barriers and possible solutions (coping planning) and monitoring the behaviour change process. These behavioural targets and self-regulation techniques are relevant for the general population as well as for individuals with chronic diseases [29]. The potential use of 'MyPlan 1.0' by patients with type 2 diabetes was also suggested by general practitioners who reflected upon the usefulness of that intervention for their practice [30]. Indeed, disease management of patients with type 2 diabetes also includes alterations in PA and diet [31]. Developing an inclusive tool may then be non-stigmatizing and more cost-effective than creating an intervention specifically designed for adults with type 2 diabetes.



'MyPlan 1.0' is effective in increasing PA and the intake of fruit and vegetables (trial registration on ClinicalTrials.gov: NCT02211040) [32, 33]. Adults of the general population perceive the intervention as feasible and acceptable [32, 34]. Notwithstanding, only 24% of the users completed the entire intervention [34]. Such high attrition rates may indicate that 'MyPlan 1.0' was designed too much from a top-down perspective (i.e. from a theoretical point of view) and highlights the need for more in-depth research regarding the users' perspectives. Assessing users' experiences while performing the online programme may guide further adaptations to the programme, and may also inform other researchers about how possible end-users experience online programmes and how programmes can be adapted to better meet the users' needs.

The aim of this paper is to understand the experience of potential users, both adults from the general population and individuals with type 2 diabetes, via a think aloud procedure and a self-report questionnaire. Because self-report questionnaires only allow general inferences and are sensitive to recall bias, we also used a think aloud procedure to assess users' thoughts while performing each step of the programme. In so doing, users provide more immediate reactions in comparison with the opinions expressed in retrospective focus groups and interviews.

## Methods

### Participants

We wanted to include twenty participants from the general population and twenty participants with type 2 diabetes. The intended sample size was based on a similar study using a think aloud interview [35]. Furthermore, the meta-analysis of Hwang and Salvendy (2010) indicated that  $10 \pm 2$  participants is sufficient for usability tests such as the think aloud method [36].

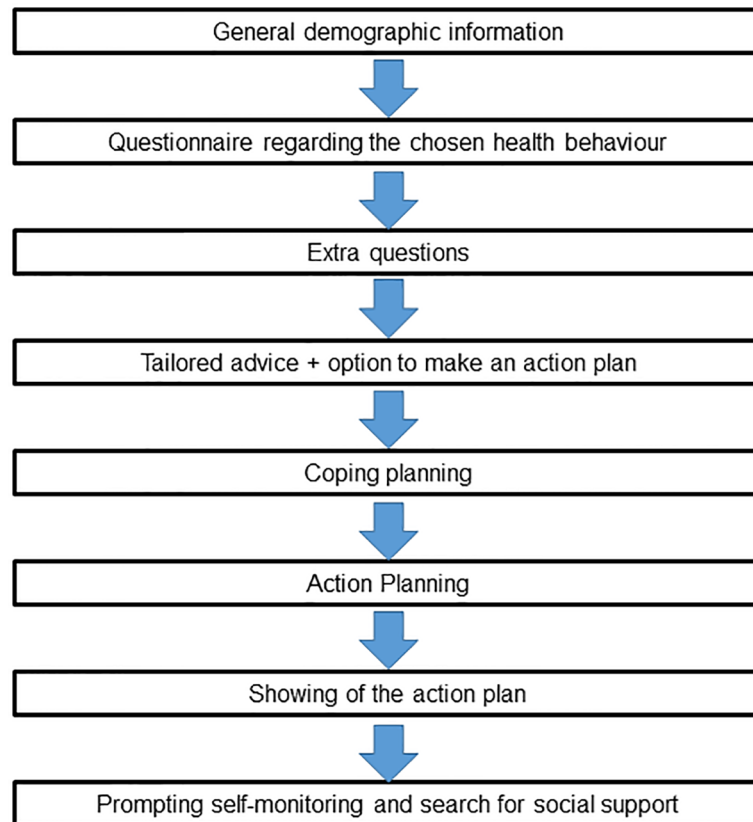
The participants from the general population were recruited via an available database, consisting of individuals who had expressed their interest to participate in studies of the Ghent Health Psychology Research Group via a website (<http://www.healthpsychology.ugent.be/vrijwilligers>), and via the snowball sampling technique. Participants were purposively sampled to have an equal distribution of men versus women, participants with low versus high education level and younger versus older persons. Inclusion criteria were being  $\geq 18$  years old and Dutch speaking. Participants with type 2 diabetes were recruited via advertisements distributed by the Diabetes Association Flanders and the Ghent University Hospital and via the snowball sampling technique. For this group, we aimed to create an equal distribution in men versus women. Patients had to be  $\geq 18$  years old, Dutch speaking and being  $\geq 1$  month post-diagnosis to be eligible for participation in the study.

Six persons from the general population were not willing to take part in the study. One person with type 2 diabetes could not participate because she did not have a computer. Consequently, another person with type 2 diabetes was recruited. Some of the participants were acquaintances of the interviewers.

The study was approved by the Committee of Medical Ethics of the Ghent university hospital (B670201526613) and written informed consent was obtained. There was no reimbursement for participation in the study.

### The intervention 'My Plan 1.0'

'MyPlan 1.0' is an eHealth tool designed to increase PA and the intake of fruit and vegetables in the general population [37]. The fully-automated and freely accessible website ([www.mijnactieplan.be](http://www.mijnactieplan.be)) incorporates several self-regulation techniques [27] and consists of three modules: a start module, a first follow-up module (one week after the start module) and a second follow-up module (one month after the start module).



**Fig 1. Overview of the start module.**

<https://doi.org/10.1371/journal.pone.0190020.g001>

Fig 1 displays an overview of the components of the start module and the order in which they appear. First, users choose whether they would like to increase their PA, their intake of fruit, or their intake of vegetables, and answer questions assessing demographic information. Thereafter, they fill out a questionnaire to assess the baseline level of their selected health behaviour. PA is assessed by the International Physical Activity Questionnaire (IPAQ-L) [38]. Fruit and vegetable intake is assessed by the Flemish Fruit Test and Vegetable Test [39]. Users also answer questions about personal determinants for behaviour change, such as outcome-expectancies and self-efficacy. This is done for research purposes. Next, users receive tailored feedback based on their answers on the questionnaire assessing the chosen health behaviour, and are asked whether they would like to make a plan to change this behaviour. Users can decide to make a plan or leave the website. By going through the coping and action planning components, users respectively look for solutions to tackle possible barriers (e.g. “I will put my running shoes at the door so I don’t forget about my plan”) and create their own specific plan to be more physically active, to eat more fruit or to eat more vegetables (e.g. “Every Tuesday I will run for 30 minutes”). During this process, users have the opportunity to create implementation intentions in the form of an if-then plan (e.g. “If I come home from work, I will run for 30 minutes in the neighbourhood) [40]. Their specific plans together with possible barriers and solutions are then shown in a printable format. Finally, the website invites users to monitor their behaviour change and to send their plan to friends and family in order to receive social support.

During the follow-up modules (one week and one month after the start module), users complete questions to assess whether they have been able to change the health behaviour of their choice and to receive tailored feedback on their change. Thereafter users have the possibility to adapt their plan based upon the success or failure of their previous plan.

## Protocol and procedures

The protocol of the think aloud procedure was based on a think aloud study by Yardley and colleagues (2010) [35]. Two female researchers (LP and CVDM) and two female master students in Clinical Psychology (ED and VVH) performed the think aloud procedure. LP has a Master's degree in Experimental and Theoretical Psychology. CVDM has a Master's degree in Clinical Psychology. The master students were trained by LP and CVDM. Participants were visited at home by one of the researchers. They first completed a questionnaire assessing demographic information. Participants with type 2 diabetes also reported the time since their diagnosis. Participants received the following instructions for the think aloud procedure:

*“MyPlan’ helps people to live a healthier life. Via this tool you can choose whether you like to eat more vegetables, consume more fruit or increase your physical activity. ‘MyPlan’ will give you advice about your current health behaviours and help you with making a plan to change these behaviours step by step. Currently, we try to improve the programme, and you can help us with this. We will require you to perform the programme and develop your own plan. When going through the programme, please state out aloud what comes to your mind. Please do not refrain from giving critical remarks, as we can learn a lot from these comments. Also positive experiences can be stated.”*

To let participants become acquainted with verbalizing their thoughts, a short exercise was provided. Participants were instructed to imagine their house and count the windows. They had to state out aloud how they imagined walking through each room and counting the windows. After the exercise, participants went through the website on their own computer at their own pace. Verbalizations were voice-recorded and the computer screen was filmed via a tablet. In contrast to the standard intervention, participants were instructed to start the first follow-up module immediately after completing the start module. Participants did not perform the second follow-up session, because it is similar to the first follow-up session.

When participants forgot to verbalize their thoughts, prompts such as “please try to say out aloud what comes to your mind” or “what comes to your mind when you see this?” were given by the researcher. When participants completed the second module of the programme, the researcher asked them how they generally perceived the website and what they liked or disliked.

Finally, participants filled out the Dutch version of the Website Evaluation Questionnaire [41]. This questionnaire consists of three subscales, each having three items. The first subscale assesses users' perceptions regarding the personal relevance of the eHealth tool. The second subscale measures the extent to which users experience the tool enjoyable and attractive (i.e. their engagement with the tool). The third subscale assesses whether users feel like the tool helped them with self-assessment and goal-setting. All items are rated on a Likert-scale, ranging from 1 (strongly disagree) to 5 (strongly agree).

The home visits were carried out from March 2016 until May 2016, and lasted approximately 75 minutes.

## Data analysis

For the Website Evaluation Questionnaire, sum scores for each scale were calculated by adding the scores for each item of a subscale (minimum = 1; maximum = 5), resulting in a possible maximum score of 15 for each scale.

Inductive thematic analysis was conducted in order to identify recurring patterns in participants' perceptions about 'MyPlan 1.0'. Thematic analysis has been defined as "a method for identifying, analysing and reporting patterns (themes) within data" ([42] page 6). Inductive or "bottom-up" thematic analysis codes the data without a pre-existing framework to do so [42]. This technique was chosen for two reasons. First, by using a data-driven way of coding we maximally explore users' perceptions instead of framing their ideas according to a specific theory. Second, we wanted to explore whether different themes would emerge as a function of group, i.e. the participants from the general population and the type 2 diabetes group. In order to code the data we followed the analysis process described by Braun and Clarke (2006).

In a first step, all the recordings were transcribed verbatim. None of the transcripts were returned to the participants for comments. Two researchers (CVDM and LP) read the transcripts to get acquainted with the data. While reading, some general findings were written down. In the second step, the data were read again, and initial codes were generated using qualitative data analysis software nVivo 11 (QSR International Pty. Ltd. Version 11, 2015). During this phase, no limit was set on the amount of generated codes. CVDM and LP each coded the data of 10 randomly selected participants from the general population and 10 participants with type 2 diabetes. In the third step, codes related to different opinions or experiences (e.g. codes expressing opinions regarding lay-out versus codes expressing experiences of awareness) identified in more than one participant's transcript were brought together in different themes and a first differentiation between main and subthemes was established (e.g. opinions regarding lay-out and user-friendliness are both related to the design of the website, but not to the usefulness of the website). The codes were now classified under the themes according to the principles of internal homogeneity and external heterogeneity. Themes with a low number of codes were removed or integrated within other themes. This phase was carried out by CVDM for the data of the participants from the general population, whereas LP did the same for the data of the participants with type 2 diabetes. Next, all data was read again but with the identified themes in mind. This was done to check whether the data was well captured by the themes. Finally, CVDM and LP discussed and defined the final themes for both groups. If no consensus was reached, a third researcher (LD) was consulted. The participants did not provide feedback on the findings. The completed version of the consolidated criteria for reporting qualitative research (COREQ) checklist is added as [S1 File](#).

## Results

### Participants

Twenty adults from the general population and twenty adults with type 2 diabetes participated in the study. Demographic information for both groups is shown in [Table 1](#).

### Website Evaluation Questionnaire

[Table 2](#) shows the results from the Website Evaluation Questionnaire for both the general sample and the individuals with type 2 diabetes. A fairly good score was given for each of the subscales by both groups.

**Table 1. Demographic information.**

	General Sample (n = 20)	Diabetes Sample (n = 20)
<b>Mean age (SD, range)</b>	42.65 years (14.47, 20–60)	64.30 years (15.30, 18–83)
<b>Women</b>	11 (55%)	12 (60%)
<b>Level of education</b>		
Primary school	0 (0%)	1 (5%)
Lower secondary education	1 (5%)	3 (15%)
Higher secondary education	13 (65%)	3 (15%)
College	3 (15%)	9 (45%)
University	4 (20%)	3 (15%)
<b>Marital status</b>		
Single	11 (55%)	3 (15%)
Married	8 (40%)	15 (75%)
Cohabiting	1 (5%)	0 (0%)
Widowhood	0 (0%)	2 (10%)
<b>Mean reported time since diagnosis (SD, range)</b>	NA	145.80 months (95.21, 6–324)

<https://doi.org/10.1371/journal.pone.0190020.t001>

### Think aloud procedure

The content of the remarks from the general sample and the adults with type 2 diabetes was very similar. No group-specific themes were identified. Consequently, the results of both groups are discussed together. Table 3 gives an overview of the themes and shows the importance of each subtheme in the dataset by displaying the number of participants who endorsed the subtheme.

**Knowledge.** Many participants stated their opinion about a healthy lifestyle (i.e. the positive effects of sufficient PA and the intake of fruit and vegetables). Some users agreed that having a healthy lifestyle has a positive effect on their physical and mental wellbeing, whereas others disagreed. Below some quotes of participants are provided. Underlined text indicates that the participant was reading the content from the website out aloud.

**Table 2. Results from the Website Evaluation Questionnaire.**

Questions according to subscales	Scale Range	General Sample Mean (SD, range)	Diabetes Sample Mean (SD, range)
<b>Personal Relevance</b>	3–15	10.45 (2.16, 6–14)	10.85 (1.93, 6–14)
The information and advice provided by the website were of personal relevance to me	1–5	3.70 (0.73, 2–5)	3.65 (0.75, 2–5)
The website addressed my specific problems	1–5	3.10 (0.91, 1–4)	3.45 (0.83, 2–5)
The information and advice provided by the website were appropriate for me	1–5	3.65 (0.99, 1–5)	3.75 (0.72, 2–5)
<b>Engagement</b>	3–15	10.90 (2.97, 5–14)	11.35 (2.03, 8–15)
The website kept my attention	1–5	3.85 (0.99, 2–5)	4.05 (0.83, 2–5)
The website was engaging	1–5	3.45 (1.15, 1–5)	3.80 (0.70, 3–5)
I found the website enjoyable to use	1–5	3.60 (1.23, 1–5)	3.50 (1.00, 1–5)
<b>Goal-setting</b>	3–15	11.10 (2.02, 7–13)	11.65 (1.93, 7–15)
The website helped me to plan	1–5	3.60 (0.75, 2–4)	3.80 (0.83, 2–5)
The website helped me to think about my own behaviour	1–5	4.00 (0.79, 2–5)	4.00 (0.79, 2–5)
The website helped me to set goals regarding my PA / fruit intake/ vegetable intake	1–5	3.50 (1.15, 1–5)	3.85 (0.81, 2–5)

<https://doi.org/10.1371/journal.pone.0190020.t002>

**Table 3. Number of participants that addressed a subtheme.**

Theme	General Sample (N = 20)	Diabetes Sample (N = 20)
<b>Knowledge</b>		
Perceptions regarding a healthy lifestyle	16 (80%)	13 (65%)
Perceptions regarding behaviour change	18 (90%)	15 (75%)
<b>Design of the intervention</b>		
General appreciation of the website	14 (70%)	14 (70%)
User friendliness	19 (95%)	20 (100%)
Time-efficiency	15 (75%)	18 (90%)
Lay-out	8 (40%)	4 (20%)
<b>Usefulness of the website</b>		
Opinion on the motivational value of the website	16 (80%)	10 (20%)
Opinion on the informative value of the website	10 (50%)	9 (45%)
Feelings of awareness elicited by the website	14 (70%)	10 (50%)
Personal relevance	15 (75%)	19 (95%)
Recommendations	10 (50%)	6 (30%)

<https://doi.org/10.1371/journal.pone.0190020.t003>

*“Then I will have a smaller chance on getting diseases (cf. when eating more vegetables). . . I hope so, but I don't think it has much to do with it.”*

(Female, 57)

*“If I eat more fruit, then I will have a smaller chance on getting diseases. I do think that eating fruit might indeed be healthy.”*

(Male, 23)

*“My mental wellbeing will be better (cf. when being more physically active). . . yeah, since I will exercise and lose weight.”*

(Male, 49)

*“My mental wellbeing will be better. . . those things (cf. mental wellbeing and eating fruit) are poorly related, it hardly affects your mental state.”*

(Male, 78, type 2 diabetes)

Users often expressed their uncertainty about which actions actually are health-related.

*“I make fresh soup. Does that also count?”*

(Female, 83, type 2 diabetes)

*“I once read that eating fruit after a meal is not healthy because of the fermentation process. . . I will practically never eat it after a meal.”*

(Female, 64, type 2 diabetes)

*“I often eat yogurt with fruit, but I guess that does not count?”*

(Female, 48)

Some users shared their opinion about behaviour change and stated that creating action plans was unnecessary. In addition, users often believed that creating specific plans is difficult due to changes in their week schedules.

*"I have a specific goal: completely disagree. I don't have a plan! I think it's weird to plan when you will eat fruit."*

(Female, 20)

*"I don't want an action plan, if I would like to eat it (cf. fruit) then I will do it, otherwise I won't. It doesn't have to be planned. I just eat when I want and what I want. No plan."*

(Male, 33)

*"It's difficult because everything depends from day to day and from week to week, because not every day or week is the same. . ."*

(Female, 21)

*"On how many days would you like to do your first activity? Three days a week. You do not know in advance, right? How can I plan this? I have a busy schedule, so it is unpredictable."*

(Male, 65, type 2 diabetes)

Users often stated that they did not need or want any social support when trying to have a healthy lifestyle. Consequently, many people were reluctant to send their plans to friends or family.

*"Do you think other people will support you? What has that to do with it? I think it has nothing to do with each other."*

(Male, 23)

*"I'm not going to send it, I'm doing this for myself"*

(Female, 73, type 2 diabetes)

Furthermore, many users stated that they did not want to monitor their behaviour change.

*"I'm not going to monitor this, I have my brain. I don't want to monitor it. I'll remember it, I don't need a book or diary, no. I'm not going to do this, I'm not a child."*

(Female, 48)

*"In my case, it's hard to define whether I have reached my goal and if I reached it, then I don't have to write it down. I don't really see the point to start counting how many times I took the stairs. I would rather not keep track of this every day."*

(Male, 58, type 2 diabetes)

**The design of the intervention.** Participants also verbalized their general appreciation of the website and often described 'My Plan' as a questionnaire rather than an interactive tool that may help users with behaviour change.

*"I don't like to fill in questionnaires, I think it's a waste of time and it's not useful for me. I don't think I would fill it in a second time."*

(Female, 20)

Almost all users had complaints regarding user-friendliness. Generally, there were four types of remarks. First, participants reported difficulties to fill out the questionnaires to assess PA, or intake of fruit or vegetables.

*"I don't really know how much vegetables weigh. A tomato, how much does it weigh? The recommendation is 300 grams, but I don't know how I should envision 300 grams. And one vegetable weighs more than another one. . ."*

(Female, 57)

Second, most participants found it hard to know how to answer questions, and doubted whether they were actually doing what the website requested them to do.

*"The advice gives you a recapitulation and then you think "I didn't answer the questions well", maybe because I didn't understand them, I don't know."*

(Female, 69, type 2 diabetes)

Third, participants often reported difficulties with making the 'if-then plan'.

*"I find "if-then" difficult. . . It's hard to put it into words, because well. . . I am an economist, but you can't say three or five or seven, "if-then" just gives you too much freedom."*

(Male, 47)

Finally, the website offered users the possibility to send their plans to friends and family. However, users often did not know the email address of the persons they wanted to send it to.

*"Would you like to show your plan to someone. . . yeah, why not. Email address, I don't know by heart. . ."*

(Male, 78, type 2 diabetes)

Many participants had remarks about the time-efficiency and stated that it took too much time to go through the website. Furthermore, filling out the questionnaires was often perceived as a waste of time.

*"But it does take some time and you need to read it carefully too. And now we are lucky, but if you fill it out during the evening and the phone rings or at the office and someone walks in, you could be distracted, maybe it should be formulated more concisely."*

(Male, 58, type 2 diabetes)

*"I think it's—well not for me, because I have time—I think it takes too long and beats around the bush. It's too long, I would have forgotten about it!"*

(Female, 76, type 2 diabetes)

Participants who had remarks about the lay-out. They often disliked how the website looked, but appreciated the large font of the text.



*"I really don't find it an attractive website. . . Look at it. It is ugly as sin, it is not attractive, it is not interactive, it's nothing. . . It's for old people."*

(Female, 45)

*"It's good that the text has a large font, it invites you to read it, if it would be smaller, it would be difficult to read."*

(Male, 58, type 2 diabetes)

**Usefulness of the website.** Opinions about the motivational value of the website were mostly positive. Participants found it stimulating to make specific plans to be more physically active or to increase their intake of fruit or vegetables.

*"I think it is nice that it (cf. the action plan) is well-defined, that you see that you can actually do more. The non-compulsory nature is gone"*

(Male, 47)

*"I think that making a plan helps you stick to the goal. If you really have a plan, I think you believe that you. . . otherwise you wouldn't make it! So, I will do it."*

(Female, 31)

Nevertheless, participants who did not like the idea of making specific plans, were not motivated by the action planning component of the intervention.

*"I don't really think it's necessary. I don't think people will need the website to fill-in what they have done. I don't need it. I also don't think it will have a large influence on whether or not I will reach my goals, to eat fruit five times a week. That's my opinion."*

(Female, 20)

*"If this would go together with a dietician or a doctor or do it in a hospital, then I can imagine that it will be followed, but people on their own, they fill it in and forget about it."*

(Female, 76, type 2 diabetes)

Participants often verbalized their opinion about the informative value of the website and stated that they had learned something. These statements were mostly evoked when participants read the guidelines regarding PA and the intake of fruit and vegetables or when the website displayed their BMI.

*"Two pieces of fruit a day, interesting!"*

(Male, 56)

*"Eating olives also counts? It's strange that it's a fruit, it surprises me!"*

(Male, 60)

*"I find this (cf. the action plan) informative"*

(Male, 78)

Participants often expressed feelings of awareness when reading the guidelines about PA and the intake of fruit and vegetables, or when filling out the questionnaire regarding these behaviours.

*"Damn, that's not much. Horrible. . ."*

(Female, 56, type 2 diabetes)

*"I think it's good that you are getting confronted with it and they highlight it and that they really inculcate it."*

(Male, 78, type 2 diabetes)

Perceptions regarding personal relevance were also stated. Although the website was created for adults in the general population, some participants felt like they did not belong to the target group and believed that the website was poorly tailored to their situation.

*"It really depends on your age. You will not work in the garden when your back is starting to hurt. And if you are young, you will do more household chores, you will paint and perform renovations, but if it is done then it's done."*

(Male, 72, type 2 diabetes)

*"Physical activity during work. . . Well, first you need to have work!"*

(Male, 57)

Participants with type 2 diabetes often stated that the suggestions for fruit did not fit within their dietary scheme.

*"I shouldn't eat apples, it's all sugars they say. . . Mangos. . . I also don't eat it."*

(Male, 78, type 2 diabetes)

While going through the website, some people shared their ideas about how 'MyPlan 1.0' could be adapted. Most recommendations involved creating a mobile application so people would be easily reminded to their goals.

*"If you really want to do it well, then you have to monitor it. But I am not good at doing this, so an app would be really ideal to do this."*

(Male, 47)

*"With an app you will be able to reach much more since you can send messages"*

(Male, 60)

*"It would be nice if the website showed graphs and if you could create your own tables."*

(Male, 49)

*"I find it non-committal. I would rather send stuff on a daily basis. I would observe it more closely and react rapidly to people following a plan. You would get an automatic email saying "Have you eaten two pieces of fruit, yes or no?" and then they have to fill in which ones."*

(Female, 41, type 2 diabetes)

## Discussion

This study investigated the perspectives of users on a self-regulation-based eHealth tool labelled 'MyPlan 1.0' via a self-report questionnaire and a think aloud procedure. Noteworthy, the results of the Website Evaluation Questionnaire and the think aloud procedure indicate that participants from the general population and patients with type 2 diabetes had similar perceptions about health behaviours and 'MyPlan 1.0', except regarding the suggestions proposed by the website for fruit intake. This difference is appropriate. The norms for the amount of fruit during the day are different for people with type 2 diabetes than for the general population. Several participants with type 2 diabetes stated to avoid some types of fruit because of the potential impact upon their sugar level. Notwithstanding, research shows that the consumption of fresh fruit, when limiting the portions based on the choice of fruit and adjusting the insulin amounts to these choices, should be encouraged rather than discouraged in this population [10, 43, 44]. Hence, eHealth tools targeting adults with type 2 diabetes may also provide users with correct and up to date information about dietary guidelines. For example, when users with type 2 diabetes create a plan to replace unhealthy snacks by a piece of fruit the programme may explain why consuming snacks marketed specifically for people with type 2 diabetes should be discouraged and why it is beneficial to consume fresh fruit [44]. The same holds for guidelines regarding PA. For example, when users with type 2 diabetes create a plan to go hiking, information regarding the importance of regular blood glucose checks could be shown [45].

Nevertheless, it is promising that similar comments and remarks were stated by the sample with type 2 diabetes and the sample from the general population. This may indicate that there is a large overlap between the needs and expectations of both groups regarding an eHealth tool targeting a healthy lifestyle. If specific adaptations (e.g. adding information about the beneficial effects of fruit intake or about the importance of foot care) are made, 'MyPlan 1.0' has the potential to be a suitable tool for this clinical group as well. These findings may encourage other researchers to adapt existing interventions to new target populations as it may be more cost-effective and less stigmatizing than creating new condition-specific interventions.

According to the Website Evaluation Questionnaire users experienced 'MyPlan 1.0' as engaging. This finding is further corroborated by the think aloud procedure. Users reported that the website provided new information and raised awareness about the selected behavioural target. The results of the questionnaire furthermore show that the participants perceived the website as being personally relevant. However, the think aloud procedure revealed that personal relevance can still be improved: some participants stated that the website was poorly tailored to their specific situation. The effectiveness of offering a personalised approach by using tailored feedback and showing information (such as for example success stories) based on the user's characteristics is well-established in research [18, 46–48] and should therefore be included as a standard element in all behaviour change interventions.

The results of the Website Evaluation Questionnaire indicate that users valued the website as helpful for goal-setting and self-assessment. This finding was also corroborated by the think aloud results: most of the users found it useful to make a tangible and concrete plan. Literature has shown that action planning can indeed be an effective technique for behaviour change [28, 49]. Nevertheless, action planning strategies should be offered in a way that is understandable for users. For example, although implementation intentions have shown to be effective in facilitating behaviour change [40, 50–52], users experienced great difficulties in creating their own implementation intentions. Consequently, implementation intentions should be accompanied by clear instructions and examples. Important to note however is that a fair amount of users reported that they did not see the point of making a specific plan for PA, fruit or vegetable

intake. Likewise, some users did not understand why they should monitor their behaviour change or why they would seek for social support. This can be due to a lack of knowledge about how behavioural change is achieved. Therefore, future interventions should include the rationale for these components and give information to users about behaviour change and the self-regulation techniques that can be of aid. Even more, one could give the users more autonomy regarding which behaviour change techniques they want to apply in a specific situation.

An important finding of our study is that the Website Evaluation Questionnaire did not reveal the frustrations of users about the design of the website. This was better captured by the think aloud procedure: users described the tool rather as a long questionnaire than an intervention. They stated that it took too much time to go through the website and answer all the questions. Furthermore, they described that some questions were difficult and confusing. Although researchers are probably well aware that users prefer short and easy interventions [53], it remains an issue to specifically address. For example, Yardley and colleagues [35] also found that pages with extensive questions from their health-care website were often perceived as excessive by the users.

In order to overcome this problem, researchers should check with users whether interventions are sufficiently short and do not contain too much text, and adapt when deemed necessary. It is clear from our findings that extensive questionnaires should be avoided in online interventions, and kept to a minimum. Evidently, research on the efficacy of interventions may require multiple questionnaires at baseline, during and after intervention, and at follow-up moments. When this is the case, we recommend that participants are explicitly informed that these questionnaires are only for research purposes and are not part of the intervention. Another possibility to reduce the length of the online intervention is to only include the necessary components of behavioural change. Therefore, more research is warranted to identify the optimal combination of self-regulation techniques. Apart from frustrations regarding time efficiency, some users stated that they disliked the lay-out of 'MyPlan 1.0'. This problem can be tackled by involving members of the target population early on in the developing process. Several authors have provided guidelines to adapt the lay-out of websites to specific target populations (for example see [54, 55]).

Finally, many users suggested that a mobile application would be useful for monitoring their behaviour and helping them remind about their goal. Indeed, self-monitoring has proven to be one of the most effective techniques for behaviour change [56]. A mobile application targeting a healthy lifestyle (mHealth) could indeed be a more convenient tool for self-monitoring and lead to a more sustained behaviour change by providing daily reminders and support. Furthermore, mHealth has shown to be promising in altering health behaviours [57, 58].

This study has several strengths. First, the think aloud method allows us to grasp immediate thoughts and reactions of users, not compromised by recall bias or researcher suggestions. Second, the perceptions of two different groups were investigated and found to be similar. As such, 'MyPlan 1.0' seems to have potential in clinical samples, such as patients with type 2 diabetes. Finally, the sample was heterogeneous and there was an equal distribution regarding sex, age and education. This study has also some limitations. First, a shortcoming of the think aloud method is that performing the intervention website interferes with thinking out aloud. Some users reported difficulties to simultaneously read text and to think aloud. Furthermore, users were more likely to elaborate on the things they found difficult or superfluous than highlighting the aspects they appreciated. Second, there are no norms available for the Website Evaluation Questionnaire. Therefore, the interpretation of low or high scores is arbitrary. Moreover, one should be cautious when interpreting results of the Website Evaluation Questionnaire, because users tend to give higher scores on the questionnaire compared

to their actual experience [59]. Furthermore, although the calculated means of the Website Evaluation Questionnaire show that the intervention was perceived as engaging, relevant and helpful, a large range was found on all three subscales. This suggests that a certain group of users did not evaluate the intervention positively. Third, the fact that users went through the follow-up module immediately after filling out the start module compromises the ecological validity of the comments regarding the follow-up. Fourth, there is always the potential that results are biased. The—even unintended— influence of researchers (e.g. training, profession) may result in a confirmation bias [60]. However, we used a strict protocol for the think aloud procedure (e.g. the use of predefined prompts) and for the analyses of the data (e.g. the use of double coding). Furthermore, the interviewers were not involved in the development of 'MyPlan 1.0'. Bias may also result from social desirability, especially because the researcher was sitting next to the participant [61]. In so doing, participants may have provided a more positive view about 'MyPlan 1.0' by neglecting the problems of the programme. However, we explicitly asked participants not to refrain from remarks, and stressed the constructive nature of these remarks for the further optimization of the programme. Finally, we did not assess specific characteristics of the clinical sample such as their treatment options or the presence of late-complications. This information might have given us more in-depth knowledge regarding our study population.

To conclude, this study used a think aloud procedure and a questionnaire to gain insight in the perceptions and preferences of the users of a self-regulation-based eHealth intervention. The presented study showed that the intervention, providing small adaptations, can also be used in tertiary prevention of type 2 diabetes. We thus argue that 'MyPlan 1.0' might be able to help adults with type 2 diabetes to adopt a healthier way of living which in turn will have a positive impact on the further development of their disease (i.e. better glycemic control [45] and a reduced risk of diabetic complications [62]). Furthermore, we found that there are still strong efforts needed to make eHealth interventions more convenient and less time-consuming. Finally, users' ideas regarding health and behaviour change can form possible hindrances and should be taken into account. This study could be a first step in the development of an engaging eHealth intervention, but more research is needed to investigate how behaviour change techniques can be more conveniently implemented in eHealth. The use of mHealth can contribute to this process. Adaptations made to 'MyPlan 1.0' based on this study are described in [S2 File](#). In further developmental phases, perspectives of users should again be explored in order to make constant improvements regarding personal relevance and user-friendliness.

## Supporting information

### **S1 File. Completed COREQ checklist.**

(PDF)

**S2 File. Adaptations made in 'MyPlan 2.0'.** This file describes how 'MyPlan 2.0' was adapted based on users' remarks and frustrations discussed in this study.

(PDF)

**S3 File. Think aloud Interviews.** This file contains the transcribed interviews.

(ZIP)

**S4 File. Website Evaluation Questionnaire data.** This file contains the data from the Website Evaluation Questionnaire.

(SAV)

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# Supplementary File 1: Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups

## **Domain 1: Research team and reflexivity**

### **Personal characteristics**

1. Interviewer/facilitator. Which author/s conducted the interview or focus group?  
LP, CVDM and two Master students (trained by LP and CVDM) conducted the interviews.
2. Credentials. What were the researcher's credentials? E.g. PhD, MD  
LP: PhD candidate in Health Sciences and Psychology  
CVDM: PhD candidate in Psychology and Health Sciences  
IDB: PhD in Psychology  
MV: PhD in Physical Education  
SS: MD and PhD in Clinical Physiology and Metabolism.  
GC: PhD in Psychology
3. Occupation. What was their occupation at the time of the study?  
LP and CVDM are PhD students performing research; MV is a postdoctoral researcher in health promotion, IDB is full professor in health promotion. GC is full professor in Health Psychology. SS is practicing endocrinologist at the university hospital and lecturer in endocrinology, diabetology and obesity.
4. Gender. Was the researcher male or female?  
LP, CVDM, IDB, MV and SS are female researchers, whereas GC is a male researcher.
5. Experience and training. What experience or training did the researcher have?  
LP has a Master's degree in Experimental and Theoretical Psychology.  
CVDM has a Master's degree in Clinical Psychology.  
IDB has a Master's degree in Clinical Psychology and a PhD in Health Psychology  
MV has a Master's degree and PhD in Physical Education and Movement Sciences  
SS is an MD and has a PhD in Clinical Physiology and Metabolism.  
GC has a Master's degree in Clinical psychology and a PhD in Psychology. He has extensive experience with empirical research on the psychosocial aspects of somatic illnesses.

### **Relationship with participants**

6. Relationship established. Was a relationship established prior to study commencement?  
No relationship with most of the participants was established before the commencement of the study. However, some of the participants were acquaintances of the interviewers.
7. Participant knowledge of the interviewer. What did the participants know about the researcher?  
e.g. personal goals, reasons for doing the research  
The participants knew that the interviewers did not create 'MyPlan 1.0', but were trying to improve the programme.
8. Interviewer characteristics. What characteristics were reported about the interviewer/facilitator?  
e.g. Bias, assumptions, reasons and interests in the research topic  
We report that the specific characteristics of the researchers (e.g. training, profession) might have an influence on data collection and analysis. Nevertheless, we created strict protocols to carry-out the interviews and to analyse the data to minimize bias. Also, none of the

interviewers played a role in creating 'MyPlan 1.0'. We mention these features in the manuscript.

## **Domain 2: study design**

### **Theoretical framework**

#### 9. Methodological orientation and Theory

What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis

Inductive thematic analysis was conducted in order to identify recurring patterns in participants' perceptions about 'MyPlan 1.0'.

### **Participant selection**

#### 10. Sampling. How were participants selected? e.g. purposive, convenience, consecutive, snowball

The sample from the general population was recruited via an available database, consisting of individuals who had expressed their interest to participate in studies of the Ghent Health Psychology Research Group via a website and via the snowball sampling technique. Participants with type 2 diabetes were recruited via advertisements distributed by the Diabetes Association Flanders and the Ghent University Hospital as well as by the snowball sampling technique.

#### 11. Method of approach. How were participants approached? e.g. face-to-face, telephone, mail, email

Participants were recruited in different ways: face-to-face, telephone and email.

#### 12. Sample size. How many participants were in the study?

In total twenty adults from the general population and twenty adults with type 2 diabetes participated in the study.

#### 13. Non-participation. How many people refused to participate or dropped out? Reasons?

Six persons from the general population were not willing to participate. One person with type 2 diabetes could not participate because she did not have a computer. Consequently, another person with type 2 diabetes was recruited for the study.

### **Setting**

#### 14. Setting of data collection. Where was the data collected? e.g. home, clinic, workplace

The data were collected during home visits.

#### 15. Presence of non-participants Was anyone else present besides the participants and researchers?

We asked participants to conduct the interview in a room where they would not be disturbed. However, in some cases we could not prevent that a family member occasionally disturbed the interview.

#### 16. Description of sample. What are the important characteristics of the sample? e.g. demographic data

The demographic information of both samples is provided in table 1 of the manuscript.

### **Data collection**

#### 17. Interview guide. Were questions, prompts, guides provided by the authors? Was it pilot tested?

All questions and prompts are provided in the manuscript. These prompts were not pilot tested, but were based upon previous research by Yardley and colleagues (2010).

18. Repeat interviews. Were repeat interviews carried out? If yes, how many?  
There were no repeat interviews carried out.
19. Audio/visual recording. Did the research use audio or visual recording to collect the data?  
All verbalizations were voice-recorded and the computer screen was filmed.
20. Field notes. Were field notes made during and/or after the interview or focus group?  
Yes, each interviewer made field notes of the interview.
21. Duration. What was the duration of the interviews or focus group?  
The duration of a home visit was approximately 75 minutes.
22. Data saturation Was data saturation discussed?  
Yes. After identifying the different themes the transcripts containing all data were read again with these themes in mind. This was done to check whether the data was well captured by the themes.
23. Transcripts returned. Were transcripts returned to participants for comment and/or correction?  
No.

### **Domain 3: analysis and findings**

#### **Data analysis**

24. Number of data coders. How many data coders coded the data?  
Two data coders (LP and CVDM) coded the data.
25. Description of the coding tree. Did authors provide a description of the coding tree?  
Yes. This is provided in table 3.
26. Derivation of themes. Were themes identified in advance or derived from the data?  
The themes were derived from the data.
27. Software. What software, if applicable, was used to manage the data?  
The qualitative data analysis software nVivo 11 (QSR International Pty. Ltd. Version 11, 2015) was used to manage the data.
28. Participant checking. Did participants provide feedback on the findings?  
No.

#### **Reporting**

29. Quotations presented Were participant quotations presented to illustrate the themes / findings?  
Was each quotation identified? e.g. participant number  
Yes.
30. Data and findings consistent. Was there consistency between the data presented and the findings?  
Yes.
31. Clarity of major themes. Were major themes clearly presented in the findings?  
Yes. Table 3 gives an overview of the number of participants that addressed each theme and subtheme.
32. Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?  
Yes.

## Supplementary file 2: Adaptations made to ‘MyPlan 2.0’

The table below describes the problems and frustrations regarding ‘MyPlan 1.0’ discussed by the participants and the adaptations that were made in ‘MyPlan 2.0’ to overcome these issues.

Problems in ‘MyPlan 1.0’	Adaptations made in ‘MyPlan 2.0’
Participants stated that ‘MyPlan 1.0’ was <b>poorly tailored</b> to their situation.	‘MyPlan 2.0’ offers a more personalised approach. For example, success stories based on the participant’s age and gender were added to the intervention. (see fig. 1)
Participants did not understand <b>the usefulness of several behaviour change techniques</b> implemented in ‘MyPlan 1.0’.	‘MyPlan 2.0’ gives a rationale for each proposed behaviour change technique. For example, the website explains why coping planning is important and how it can help users in the behaviour change process. (see fig. 2)
Participants stated that ‘MyPlan 1.0’ <b>was not time-efficient</b> and described the programme as a long questionnaire rather than an intervention.	Questions solely asked for research purposes were deleted. Furthermore, information is given via quizzes instead of lengthy text pages. (see fig. 3) Going through one session now only requires 10 minutes of the users’ time.
Participants stated that they did not like the <b>lay-out</b> of the website.	‘MyPlan 2.0’ has a different lay-out than ‘MyPlan 1.0’. Lengthy text pages were deleted and more images were added. (see fig. 1-3)
Participants stated that <b>a mobile application</b> would be useful in their behaviour change process.	A mobile application accompanying the website was created. Via this application users can monitor their behaviour (see fig. 4), do quizzes (see fig. 5), revise and adapt their plan (see fig. 6) and find solutions for hindrances (see fig. 7).



Figure 1. Success stories (website)

The text in red is a success story.

Translation: "Fleur (26 years old) tells: I consider it important to be more physically active, but I am not a sporty person. Since I do all my groceries by foot, I feel less tired during the day!".



Figure 2. Rationale for coping planning (website)

Translation: "Living up to a new plan is not always easy. Research shows that it is really important to consider potential hindrances in advance. When this hindrance appears, you will have an immediate solution at hand!"



Figure 3. Example of a quiz question (website)

Translation: "Is the following statement true or false? I you are more physically active, you have a lower chance on developing a depression."

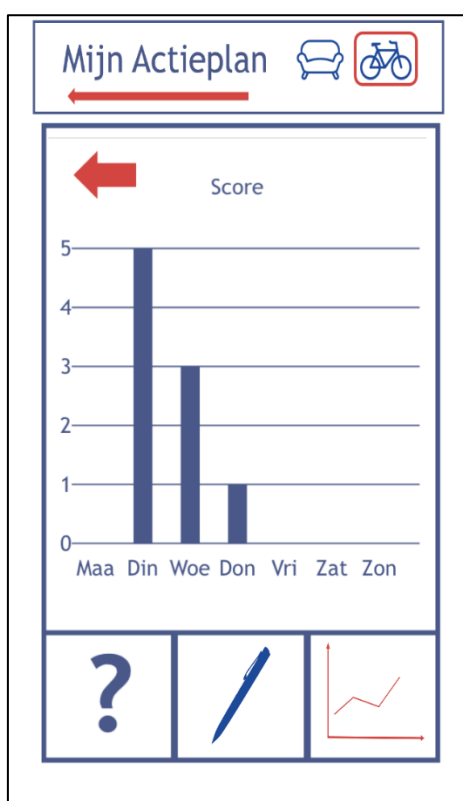


Figure 4. Monitoring health behaviours (mobile application)



Figure 5. Quizzes (mobile application)

Translation: “In general, the more people are physically active, the more happy they are with their lives.” Blue boxes: “True” and “False”.



Figure 6. Revising and adapting plans (mobile application)

Translation: “Below you can find your goals to be more physically active during leisure time. You can adapt your goals by tapping on the pencil icon.”





Figure 7. Coping planning (mobile application)

Translation: "Tap on a hindrance to find solutions".



## CHAPTER 1.3

Experiences and opinions of adults with type 2 diabetes regarding a self-regulation-based eHealth intervention targeting physical activity and sedentary behaviour

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Article

# Experiences and Opinions of Adults with Type 2 Diabetes Regarding a Self-Regulation-Based eHealth Intervention Targeting Physical Activity and Sedentary Behaviour

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**Abstract:** *Background:* Online interventions targeting a healthy lifestyle in adults with type 2 diabetes are more effective when informed by behaviour change theories. Although these theories provide guidance in developing the content of an intervention, information regarding how to present this content in an engaging way is often lacking. Consequently, incorporating users' views in the creation of eHealth interventions has become an important target. *Methods:* Via a qualitative interview study with 21 adults with type 2 diabetes who had completed an online self-regulation-based intervention ('MyPlan 2.0'), we assessed participants' opinions regarding the usefulness of the implemented self-regulation techniques, the design of the programme as well as their knowledge regarding physical activity and sedentary behaviour. A directed content analysis was performed to synthesize the interview data. *Results:* Participants experienced difficulties completing the coping planning component. The simple design of the website was considered helpful, and most participants were aware of the beneficial effects of an active lifestyle. *Conclusions:* 'MyPlan 2.0' was well-accepted by the majority of participants. However, the coping planning component will need to be adapted. Based on these findings, recommendations on how to tailor eHealth interventions to the population of adults with type 2 diabetes have been formulated.

**Keywords:** type 2 diabetes; eHealth; physical activity; sedentary behaviour; content analysis; interview

## 1. Introduction

Type 2 diabetes (T2D) is associated with numerous health complications and health care visits, resulting in high costs for the patient and society [1]. Consequently, the worldwide exponential growth of T2D has become a major issue [1]. Adopting an active lifestyle, i.e., being more physically active and less sedentary, is considered to be vital in the management of this disease [2,3]. Nevertheless, an active lifestyle is not easily adopted by the majority of patients [4]. Thus, there is a need for the development of various and innovative strategies to promote healthy lifestyle choices in this clinical population [5,6].

One strategy is to provide electronic (e-) health interventions. These interventions can reach many individuals in a cost-effective way and are effective in changing behaviour [7]. They may also prove to be a fruitful avenue to reduce the burden of T2D [8]. Indeed, meta-analyses have shown that online interventions result in modest benefits for T2D management, but larger effects were observed when these interventions were grounded in a behaviour change theory [8,9].

Nevertheless, internet-delivered interventions pose some challenges. Quitting is just a mouse-click away. Hence, many eHealth interventions are subject to high levels of attrition undermining their large potential [10]. This challenge is not adequately addressed by behaviour change theories. These theories provide guidance in developing the content of an intervention, but not in presenting the intervention in an engaging way [7]. For example, providing tailored feedback is an important behaviour change technique, but it requires participants to complete long questionnaires, which may result in high levels of attrition [11]. Consequently, identifying the experiences, opinions and preferences of users regarding theory-based interventions has become increasingly important in the eHealth field [12].

The goal of this paper is to explore how users with T2D experience 'MyPlan 2.0', a theory-based eHealth intervention targeting physical activity and sedentary behaviour. 'MyPlan 2.0' is informed by self-regulation theory and includes several behaviour change techniques, such as providing information and feedback, creating specific action plans and prompting coping planning [13]. These techniques help people to translate vague goals (e.g., "being more physically active") to specific actions (e.g., "taking a walk for one hour on each Sunday morning") [13]. To do so, a qualitative interview study was carried-out. Semi-structured interviews were conducted with participants with T2D after completing 'MyPlan 2.0'. Based on the results, recommendations can be formulated on how to tailor online interventions promoting an active lifestyle to the population of adults with T2D.

## 2. Materials and Methods

### 2.1. Participants

Participants were recruited via the Diabetes Association Flanders, the Ghent University Hospital and—as some patients brought the researchers into contact with other interested patients—snowball sampling. Eligibility criteria were (1) having T2D; (2) being  $\geq 18$  years old; (3) Dutch-speaking; and (4) not having participated in earlier studies with 'MyPlan'. The study was approved by the Committee of Medical Ethics of the Ghent University hospital (B670201629995), and written informed consent was obtained for all participants. Each participant received a reimbursement of 20 euros for their participation in the study.

### 2.2. MyPlan 2.0

'MyPlan 2.0' is based on 'MyPlan 1.0', a self-regulation-based eHealth intervention aimed at promoting a healthy lifestyle in the general population. Previous research revealed that 'MyPlan 1.0' was effective in changing users' health behaviours, but faced high levels of attrition [14]. By examining and addressing the features causing attrition (e.g., shortening the programme and applying an easier layout), 'MyPlan 2.0' was created. 'MyPlan 2.0' is not meant to be a fixed programme, but allows for specific adaptations when targeting particular behaviour and/or particular groups. Here, we discuss the further adaptation for adults with T2D.

'MyPlan 2.0' is a self-regulation-based eHealth intervention (i.e., a website) targeting physical activity and sedentary behaviour. Users of 'MyPlan 2.0' can choose between the modules "increasing physical activity" and "decreasing sedentary behaviour". The website offers five sessions during which users can learn more about the beneficial effects of being less sedentary or more physically active via tips and quizzes (providing knowledge), get feedback on their current levels of physical activity or sedentary behaviour by means of a questionnaire (providing feedback), set their own goals for the coming week (action planning), search solutions for potential barriers (coping planning), think about possible ways to keep track of their behaviour change (monitoring), read optional pages with

tips and tricks to become more physically active or less sedentary and evaluate their behaviour change process each week. After an interval of one week, the user receives an email reminding him or her to start the following session. Figure 1 shows the flow of the first session, whereas Figure 2 shows the flow of session 2 to 5.

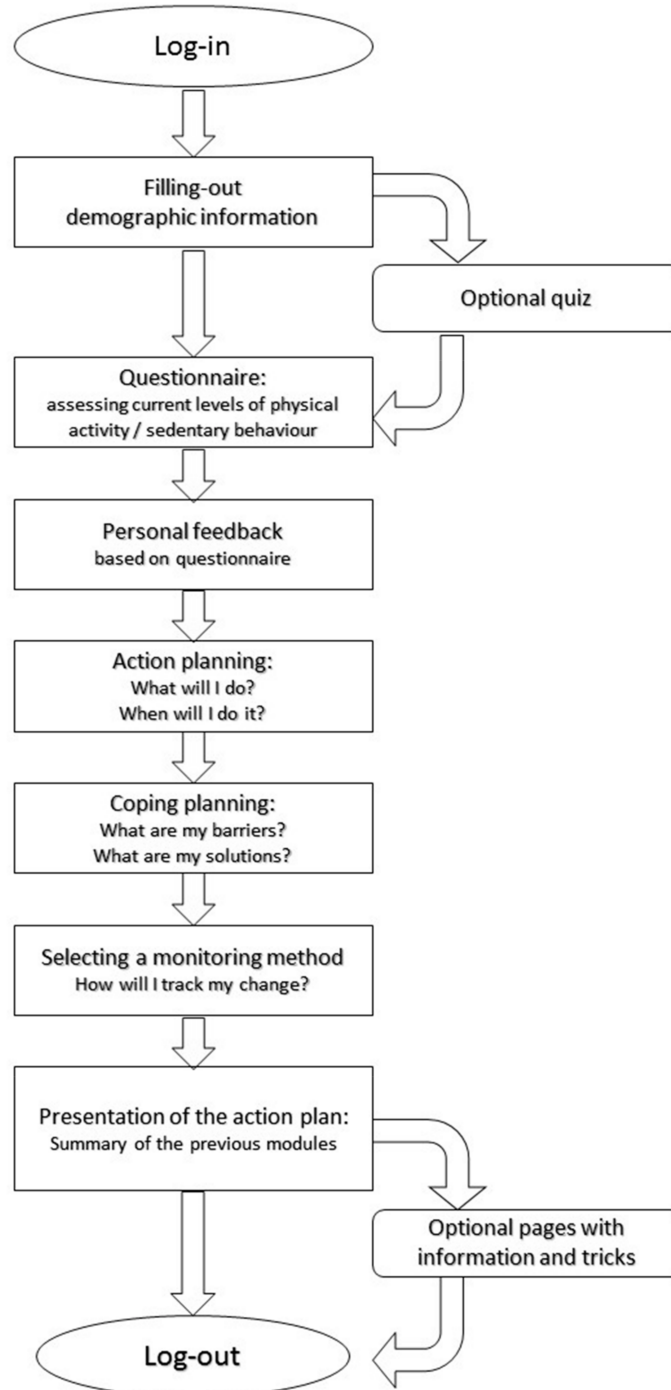


Figure 1. Flow of the first session.

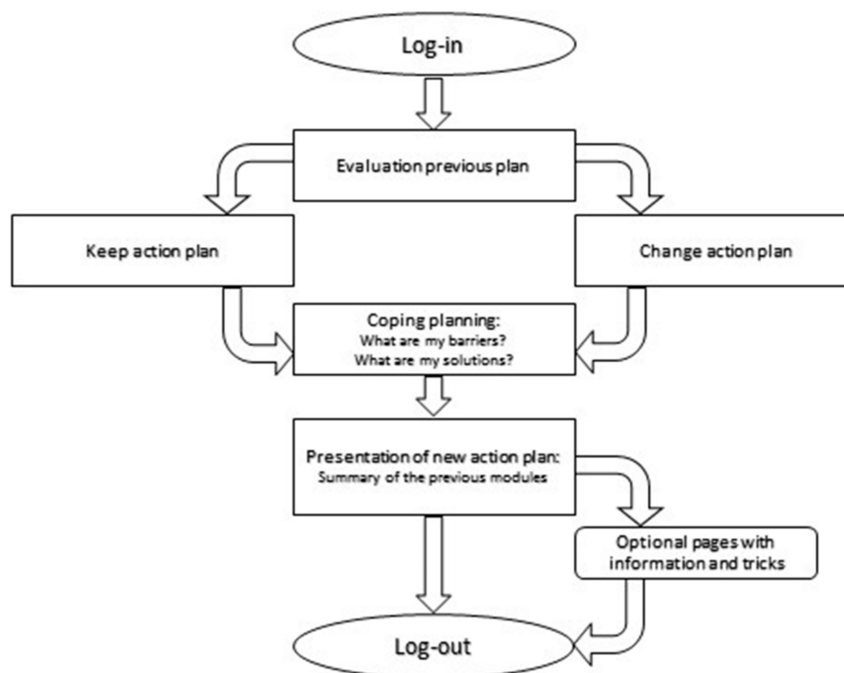


Figure 2. Flow of sessions 2 to 5.

### 2.3. Procedures

Patients eligible to participate filled out a questionnaire assessing demographic information and were invited to use ‘MyPlan 2.0’ over a period of five weeks (i.e., to go through all sessions of the intervention). If participants forgot to log-in for a next session, they were phoned by a researcher to remind them about the session. After these five weeks, a semi-structured interview took place, which was audio recorded. The interviews took place between January and March 2017, had a duration of approximately 20 min, and were carried out either at the participant’s home, at the university or via telephone depending on each participant’s preference. Supplementary file contains the completed COREQ checklist.

### 2.4. Interview Guide

The interview guide (see Supplementary file) consisted of open-ended questions relating to three main themes. The first theme was “usefulness of the website”, which consisted of several subthemes: (1) personal relevance of the website; (2) stimulating nature of the website; (3) informative value of the website; (4) increased awareness by using the website and (5) recommendations offered by users. The second theme was “design of the website”. This theme consisted of the following subthemes: (1) general perception of the website; (2) user-friendliness; (3) layout and (4) time-efficiency. The third theme was “knowledge”, which relates to the opinions and perceptions of users regarding health behaviours and behaviour change. The themes for the semi-structured interview were based on the results of think aloud interviews with users going through an earlier version of the programme, namely ‘MyPlan 1.0’.

### 2.5. Data-Analysis

A directed content analysis was performed to synthesize the interview data [15]. First, all recordings were transcribed verbatim. Second, a coding scheme was developed, which consisted of the three main themes and nine subthemes from the interview guide and their inclusion and exclusion criteria. Third, two researchers (CVD and LP) independently coded all interviews using nVivo 11 software (QSR International Pty. Ltd., Melbourne, Australia, Version 11, 2015). Themes not captured



by the coding scheme were added to the coding template. A Cohen's K (weighted for source size) of 0.62 was obtained, indicating fair to good agreement between both coders.

### 3. Results

#### 3.1. Participants

Twenty-six participants with T2D volunteered for the study. Five participants dropped out during the study process: two participants never started using the programme, two participants only completed the first session and one participant completed all sessions but could not be reached for the interview. Consequently, there were interviews from 21 participants. One participant only finished four sessions. All other participants completed the whole intervention (i.e., five sessions). Demographic information is shown in Table 1.

**Table 1.** Demographic information.

Demographics	N (%)	Mean	SD	Range
Age in years		65.86	5.6	57–81
Women	8 (38.1)			
Level of education				
• Primary school	2 (9.5)			
• Secondary education	9 (42.9)			
• College	10 (47.6)			
Marital status				
• Married	15 (71.4)			
• Unmarried	2 (9.5)			
• Divorced	2 (9.5)			
• Widowhood	2 (9.5)			
Time since diagnosis in months		183.3	155.1	4–480
BMI * in kg/m <sup>2</sup>		30.8	6.1	22.1–42.5

\* BMI = Body Mass Index.

#### 3.2. Website Usage

In total, participants spent, on average, 48.8 min (SD = 23.1; range = 17–111) on the website. All participants filled out the optional quiz presented during the first session. Table 2 gives an overview of the time that participants spent per session and the number of participants who visited the optional pages at the end of each session.

**Table 2.** Time spent on the website expressed in minutes.

Session Number	Mean Time Spent (SD; Range)	Number of Participants Visiting Optional Pages (%)
Session 1	22.2 (10.8; 9–46)	15 (71.4)
Session 2	7.1 (4.4; 2–19)	13 (61.9)
Session 3	6.8 (4.3; 2–21)	18 (85.7)
Session 4	6.0 (3.8; 1–15)	13 (61.9)
Session 5	6.5 (6.3; 1–30)	17 (81.0)

#### 3.3. Interviews

##### 3.3.1. Usefulness of the Website

In response to the question of whether the website provided new information about the importance of increasing physical activity and decreasing sedentary time, many participants responded

negatively. Most participants indicated that they were already well-informed by their general practitioner or dietician.

“No, I knew the advantages for your heart, veins and sugar levels.” (Female, 66 years old)

“I already knew it. Move more often, eat less sweets, those are the basics of diabetes management.” (Male, 66 years old)

Nevertheless, many participants stated that the website raised their awareness regarding their sedentary behaviour or lack of physical activity, and the fact that they needed to change this behaviour.

“Sometimes I do not think about the fact that I am diabetic but then you receive an e-mail that you need to fill out the website. It awakes the subconscious idea that you need to move more. I feel like they are reminders that keep you awake.” (Male, 61 years old)

“On each occasion I think about the fact that I should get up and walk a little. I am more aware of this than I used to be.” (Male, 73 years old)

The questionnaire assessing participants’ current levels of physical activity or sedentary behaviour was considered especially eye-opening. Participants often indicated that they were not aware of the amount of sitting time they accumulated during the day and considered it interesting to gain insight into these patterns.

“I was surprised, I said “ow, I am still sitting a lot”. I often work standing, I iron standing, I prepare meals standing . . . but still . . . ” (Female, 67 years old)

“You get confronted with the fact that you do not move very often. And we know it is one of the things you should do as a diabetic. Drink water and move more often. Those are two things that are hard for me and currently lacking.” (Male, 67 years old)

Almost all participants perceived the website as personally relevant and stated that the website could be used by a broad spectrum of users.

“Yes, yes, absolutely, because being physically active is very important for us!” (Male, 70)

“I think it fits for every age, even for younger people it would be good.” (Female, 57)

Participants not considering the website as personally relevant indicated that they were already having an active lifestyle.

“I must say that we already move a lot, so we already did as much as possible.” (Female, 66)

To explore the extent to which participants adopted the self-regulation-techniques, we asked them whether and how they were helped by specific components of the website. Many stated that creating action plans helped them to actually perform the behaviour because the proposed actions could be easily adopted in everyday life. Some participants stated that they would like to see even more options in the action planning component.

“Yes, that is good! Also because it is not much, well, you do not ask a lot from people. They are small steps that you should take. So each week there are one or two steps and that is achievable. It is not a list of ten things making you say “I need to do all of this!”. No, you do it by yourself, you make your own choices and you get tips and that helps. But you, you do not overwhelm people with it and make it achievable.” (Male, 61)

“Otherwise I put everything near me: water, the remote, a piece of fruit, it is near me. How many times do I get up then? Not once. Now I leave it here and get it when I need it.” (Female, 67)

Furthermore, the action planning module motivated participants because they felt they had to keep their promises as they would be evaluated in the next session.

“It was good and I felt a bit obliged, in a friendly way, to get off the couch or off my bed and to do groceries by foot.” (Male, 69)

“I knew that it (the website) would contact me again, so I had to do something about it!” (Female, 62)

However, when asking whether participants were helped by reflecting on their barriers and searching for solutions, we obtained mixed answers. Some participants liked the fact that they had to actively reflect on their problems and search for solutions. Nevertheless, most participants felt confused when completing the coping planning component as they found it hard to identify problems and stated that some barriers cannot be easily solved.

“Well, I think it was good that I had to ask myself what is wrong, why are you not coming out of the couch, why are you not walking around, why am I not doing groceries . . . So, I think that was good.” (Male, 70)

“Well, there are always barriers, but the solutions are not logic or easy to find.” (Male, 58)

The website encouraged people to monitor their changes and helped them to evaluate their plan weekly. Many participants liked the fact that they could print the plans as it helped them to remember their promises to the website. Furthermore, participants appreciated that the plan was evaluated at the beginning of each new session.

“I printed it and put it next to my computer. If I forgot it, I could review it.” (Female, 67)

“I liked the fact that I could evaluate my plans on a weekly basis. I liked this goal-oriented way of working with moments of evaluation.” (Female, 66)

However, some people believed that monitoring the behaviour change process was superfluous as they could keep it in their mind without additional tools.

“I did not keep track of it, but I kept it in my mind.” (Male, 70)

### 3.3.2. Design of the Website

The overall perception of the website was good. Many participants stated that they liked the personal approach. Some participants mentioned that going through the website sometimes still felt like filling out a questionnaire.

“You get the feeling that someone else is taking care of you, individually, you get this feeling.” (Male, 70)

“I cannot say it is fun, because filling out a questionnaire is not fun.” (Male, 68)

Generally, participants were satisfied regarding the user-friendliness of the website. They mentioned that the questions were brief and understandable, and that the website was easy to navigate through.

“Yes, it is easy to use and that is nice. You only need to read one thing, not a whole text that you need to go through. These are short things, short questions and it goes well.” (Male, 73)

“Well yes, I thought it was easy because I told you I do not do anything else (with the computer) and this was very easy that I had to fill out something and go to the next page.” (Female, 66)

Similarly, participants were also satisfied with the layout of the website. Participants stated that the simple layout helped them to easily navigate through the website without many distractions.

“It is simple and in fact I do not think that is bad, because we are constantly overwhelmed with websites with colours and commercials and other things, I liked it, it was simple but good.” (Male, 70)

“I really liked this! Yes, yes, very good, simple and it has a positive and playful character . . . It was not presented as a purely scientific thing . . . something of which you think “what are they sending me?” No, it is nicely made and remains attractive.” (Male, 61)

Furthermore, almost all participants stated that they were satisfied with the time-efficiency of the website. Participants liked the short duration of each session as they would be likely to postpone sessions that took more time.

“I think the length was good. It should not be too long, because then you will be less interested of course. Succinctly like they say and that is how it was.” (Male, 69)

“The time? Oh, that is very doable! You don’t need to spend much time going through the website and then you are finished and you print your plan then it is done. No, no, initially you need to spend a little time on it, but is not worth to talk about that.” (Male, 73)

### 3.3.3. Knowledge

Whereas most participants were well aware of the beneficial effects of an active way of living, some questioned whether it was also applicable to them as they did not feel any changes in themselves by being more active.

“Healthy body, healthy mind, it goes together. Because if you feel well, then you will not worry about things that are not good. So if you feel good, by letting your blood circulate by standing up and those things, for example taking the stairs, than you will also feel better on the mental level. That is absolutely true.” (Male, 61)

“On a mental level it absolutely does (have an effect). On the physical level I have not . . . I have not really experienced it yet.” (Male, 73)

### 3.3.4. Social Support

An additional theme was identified. Several participants mentioned that they went through the website with a family member and experienced social support by doing so.

“I showed it to my husband and told him that I need to move more, because he is of course more physically active than me.” (Female, 66)

“Yes, sometimes he watched along . . . I found it interesting. I got a lot of support from that. Yes, by filling it out together. And well . . . when I had to do something he stimulated me. “It is evening, you need to cycle now” he said. Sometimes I did not feel like doing it, but he said “Come on, you made a promise, you made a deal, you need to do it.”” (Female, 57)

## 4. Discussion

This study assessed the experiences and opinions of adults with T2D regarding a self-regulation-based eHealth intervention targeting physical activity and sedentary behaviour. Investigating whether the target population is ready for an eHealth intervention is an important step before implementing the intervention on a large scale and assessing its effectiveness. Overall, the feedback on ‘MyPlan 2.0’ was positive and highlighted two important issues. First, adults with T2D are a suitable population for

eHealth interventions. Second, self-regulation techniques which emphasize patients' autonomy [13] are appreciated by this population as they feel the need to be in charge of their own behaviour change process. Based on this study, several recommendations on how to further adapt eHealth interventions to adults with T2D can be formulated.

First, although it is tempting to create detailed and elaborated modules for behaviour change techniques, this may come with a cost in terms of time-efficiency. Because the precursor of 'MyPlan 2.0', 'MyPlan 1.0', was considered too time-consuming, we shortened the programme without omitting any of the implemented behaviour change techniques. This was achieved by providing key messages instead of lengthy texts, creating short questionnaires and making more optional pages. This study shows that many participants appreciated the time-efficiency of 'MyPlan 2.0', highlighting the beneficial effect of this endeavour. Similarly, the interview data regarding the user-friendliness and the layout of the website show that our efforts to create an easier and more simple version than 'MyPlan 1.0' were appreciated. As the prevalence of T2D peaks in older age [16], users from this population might even favour less complex website designs [17].

Second, the implementation of self-regulation techniques, such as action planning and tailored feedback, was found to be an acceptable method to increase users' motivation to change their behaviour. Nevertheless, Pall and colleagues found that eHealth interventions in which adults with T2D state specific goals were likely to be ineffective [8]. However, as the authors also note, only five interventions implemented this technique, and of these five interventions, only one intervention gave feedback on patients' goals. This might be a critical combination. In line with this interpretation, we observed that the action planning component in 'MyPlan2.0' prompted participants to live up to their promises because they knew they would be evaluated in the next session. This indicates that eHealth interventions should encourage patients to set specific goals and provide feedback based on their process.

Third, foreseeing future problems and selecting appropriate solutions (i.e., the coping planning technique) has shown to be effective in promoting behaviour change [18]. However, we found that participants experienced difficulties in completing the open answer questions regarding their future problems and solutions, and were not readily convinced of the usefulness of this technique. It may be better to reflect on the barriers of past attempts and then think about barriers to future attempts. Coping planning has been implemented in previous interventions by sending coping strategies via e-mail or SMS to the user [19,20]. Offering potential coping techniques might ease the cognitive process and be a better way of implementing this technique in online interventions targeting adults with T2D. Gradually reducing the pre-built coping plans throughout the sessions might be an option to increase patients' self-reliance regarding behaviour change.

Finally, several participants wanted to involve their partner when going through the intervention. This is a surprising finding as the feature to send action plans to friends and family was under-used in 'MyPlan 1.0', and for that reason, it was deleted in the current version. As social support is a facilitator of behaviour change in adults with T2D [21,22], it might be interesting to explore other ways to involve partners in online interventions targeting an active way of living. For example, based on the patients' action plan, a page informing the partner regarding how he or she can help the patient to live up to the plan could be created.

To our knowledge, this is the first study to examine the experiences and opinions of adults with T2D regarding a self-regulation-based eHealth intervention. Evidently, our study has some limitations. First, selection bias may hamper the generalizability of our results. Consequently, it might be possible that the patients who were willing to participate in the study differed in some aspects from the general population of adults with type 2 diabetes, such as readiness for behaviour change or computer literacy. Similarly, it is possible that the two participants who only completed the first session and could not be contacted for the interview had different opinions than the participants who were interviewed. These opinions might have given us interesting information about how we could adapt the intervention to individuals who are not yet motivated to complete the programme. Furthermore, 21 patients with T2D

might seem a small sample for this study. However, this sample size is in accordance with previous qualitative studies in the eHealth field [12,23,24]. Second, interview data can be distorted by social desirability. Consequently, the participants might have been more positive about the intervention than they actually were. However, as the usage data show, the majority of the participants visited the optional pages of each session indicating a high engagement with the website. Finally, 'MyPlan 2.0' consists of five sessions. This number was based on a study of Vandelanotte and colleagues showing that a minimum of five sessions is needed to establish an effect [25]. However, this short intervention period might not be able to establish long-term effects. More research will be needed to assess how users respond to longer versions (i.e., more sessions) of the programme.

## 5. Conclusions

To conclude, we found that adults with T2D are a suitable population for eHealth interventions. The easy and simple design of the programme was appreciated by many participants. Furthermore, this population showed interest in the implemented self-regulation techniques, which were designed to help them to gain autonomy in their behaviour change process. However, the current implementation of the coping planning technique (i.e., searching for possible barriers and solutions) was difficult for the users and should be adapted. Furthermore, several patients liked to involve their partners while going through the intervention. Finally, the effectiveness of 'MyPlan 2.0' to increase physical activity and decrease sedentary behaviour in adults with T2D needs to be tested.

**Supplementary Materials:** The following are available online at <http://www.mdpi.com/1660-4601/15/5/954/s1>, Consolidated criteria for reporting qualitative research (COREQ): A 32-item checklist for interviews and focus groups and the interview guide.

**Author Contributions:** I.D.B., G.C., C.V.d.M. and L.P. conceived and designed the study; L.P. and C.V.d.M. performed the interviews; L.P. and C.V.d.M. analyzed the data; L.P. wrote the paper with significant input from I.D.B., G.C., M.V. and S.S.

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## Supplementary file 1:

# Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups

### **Domain 1: Research team and reflexivity**

#### **Personal characteristics**

1. Interviewer/facilitator. Which author/s conducted the interview or focus group?  
LP, CVDM and two Master students (trained by LP and CVDM) conducted the interviews.
2. Credentials. What were the researcher's credentials? E.g. PhD, MD  
LP: PhD candidate in Health Sciences and Psychology  
CVDM: PhD candidate in Psychology and Health Sciences  
IDB: PhD in Psychology  
MV: PhD in Physical Education  
GC: PhD in Psychology  
SS: MD and PhD in Clinical Physiology and Metabolism
3. Occupation. What was their occupation at the time of the study?  
LP and CVDM are PhD students performing research; MV is a postdoctoral researcher in health promotion, IDB is full professor in health promotion. GC is full professor in Health Psychology. SS is practicing endocrinologist at the university hospital and lecturer in endocrinology, diabetology and obesity.
4. Gender. Was the researcher male or female?  
LP, CVDM, IDB, SS and MV are female researchers, whereas GC is a male researcher.
5. Experience and training. What experience or training did the researcher have?  
LP has a Master's degree in Experimental and Theoretical Psychology.  
CVDM has a Master's degree in Clinical Psychology.  
IDB has a Master's degree in Clinical Psychology and a PhD in Health Psychology  
MV has a Master's degree and PhD in Physical Education and Movement Sciences  
SS is an MD and has a PhD in Clinical Physiology and Metabolism  
GC has a Master's degree in Clinical psychology and a PhD in Psychology

#### **Relationship with participants**

6. Relationship established. Was a relationship established prior to study commencement?  
No relationship with the participants was established before the commencement of the study.
7. Participant knowledge of the interviewer. What did the participants know about the researcher?  
e.g. personal goals, reasons for doing the research  
The participants knew that the interviewers created 'MyPlan 2.0' and conducted the study in order to ameliorate the programme.
8. Interviewer characteristics. What characteristics were reported about the interviewer/facilitator?  
e.g. Bias, assumptions, reasons and interests in the research topic



Specific characteristics of the researchers (e.g. training, profession) can always have an influence on data collection and analysis. Nevertheless, we created strict protocols to carry-out the interviews and to analyse the data to minimize bias.

## **Domain 2: study design**

### **Theoretical framework**

9. Methodological orientation and Theory. What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis

A directed content analysis was conducted. This type of analysis was considered best suited for our purpose because our coding scheme was based upon previous research with 'MyPlan 1.0'

### **Participant selection**

10. Sampling. How were participants selected? e.g. purposive, convenience, consecutive, snowball

Participants were recruited via the Diabetes Association Flanders, the Ghent University Hospital and snowball sampling.

11. Method of approach. How were participants approached? e.g. face-to-face, telephone, mail, email

Participants were recruited in different ways: face-to-face and via advertisements.

12. Sample size. How many participants were in the study?

Twenty-six participants with T2D volunteered for the study. Five participants dropped out during the study process: 2 participants never started using the programme, 2 participants only completed the first session and one participant completed all sessions but could not be reached for the interview. Consequently, there were interviews from 21 participants.

13. Non-participation. How many people refused to participate or dropped out? Reasons?

Five participants dropped out during the study process: 2 participants never started using the programme, 2 participants only completed the first session and one participant completed all sessions but could not be reached for the interview.

### **Setting**

14. Setting of data collection. Where was the data collected? e.g. home, clinic, workplace

The interviews took place at the research department or via a telephone call. The interviews were audio-recorded with permission of the participants.

15. Presence of non-participants. Was anyone else present besides the participants and researchers?

We asked participants to conduct the interview in a room where they would not be disturbed. However, in some cases we could not prevent that a family member occasionally disturbed the interview.

16. Description of sample. What are the important characteristics of the sample? e.g. demographic data

The demographic information of the sample is provided in table 1 of the manuscript.

### **Data collection**

17. Interview guide. Were questions, prompts, guides provided by the authors? Was it pilot tested?

All questions are provided in additional file 2.

18. Repeat interviews. Were repeat interviews carried out? If yes, how many?  
There were no repeat interviews carried out.
19. Audio/visual recording. Did the research use audio or visual recording to collect the data?  
All verbalizations were voice-recorded.
20. Field notes. Were field notes made during and/or after the interview or focus group?  
No.
21. Duration. What was the duration of the interviews or focus group?  
The average duration of an interview was 30 minutes.
22. Data saturation. Was data saturation discussed?  
When a text fragment of the interview did not fit any of the predefined categories, a new category was created. Themes that did not contain enough data were not withheld. Coding was done independently by two researchers (CV and LP). A weighted kappa was calculated and showed fair to good inter-rater agreement (weighted kappa: 0.62).
23. Transcripts returned. Were transcripts returned to participants for comment and/or correction?  
No.

### **Domain 3: analysis and findings**

#### **Data analysis**

24. Number of data coders. How many data coders coded the data?  
Two data coders (LP and CVDM) coded the data.
25. Description of the coding tree. Did authors provide a description of the coding tree?  
Yes.
26. Derivation of themes. Were themes identified in advance or derived from the data?  
The themes were identified in advance. This was based on previous research with "MyPlan 1.0".
27. Software. What software, if applicable, was used to manage the data?  
The qualitative data analysis software nVivo 11 (QSR International Pty. Ltd. Version 11, 2015) was used to manage the data.
28. Participant checking. Did participants provide feedback on the findings?  
No.

#### **Reporting**

29. Quotations presented. Were participant quotations presented to illustrate the themes / findings?  
Was each quotation identified? e.g. participant number  
Yes.
30. Data and findings consistent. Was there consistency between the data presented and the findings?  
Yes.
31. Clarity of major themes. Were major themes clearly presented in the findings?  
Yes.
32. Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?  
Yes.

# Supplementary file 2: Interview Guide

- Which module did you select, “sitting less” or “being more physically active”?

## Design of the website

### Perception of the website

- In general, how do you feel about the website?
- How did you experience using the website?
- To what extent, did you perceive the website as engaging?
- To what extent, did you think using the website was a fun thing to do?
- Could you easily keep your attention to the website?
- Which parts of the website did you like the most?
- Which parts of the website did you like the least?
  - Did you like the questionnaire and its accompanying feedback?
  - Did you like creating an action plan?
  - Did you like searching for barriers and solutions?
  - Did you like reading the tips (e.g. regarding social support)?
  - Did you like monitoring your goal?

### User-friendliness

- In general, was the website easy or difficult to use?
- Which parts of the website did you experience as easy?
- Which parts of the website did you experience as difficult?
- How do you think about the user-friendliness of the website?
  - Could you easily find what you needed?
  - Where there moments that you were stuck?
  - Could you easily read all the text?
- Was the questionnaire and its accompanying feedback easy/difficult?
- Did you perceive creating your own action plan as easy/difficult?
- Did you perceive searching for barriers and solutions as easy/difficult?
- Were the tips easy/difficult?
- Did you perceive monitoring your goal as easy/difficult?

### Time efficiency

- What do you think about the time you needed to complete the sessions?

### Lay-out

- What do you think about the lay-out and the design of the website?

## Usefulness of the website

### Recommendations

- Do you suggest any adaptations to the website?
- Are there things you would recommend us to change regarding the website?

### **Stimulating value of the website**

- To what extent did the website help you to change your behaviour?
- Which parts of the website helped you the most?
- Which parts of the website helped you the least?
  - Was it helpful to create an action plan?
  - Was it helpful to search for barriers and solutions?
  - Was it helpful to read the tips (e.g. regarding social support)?
  - Was it helpful to monitor your goal?

### **Awareness**

- To what extent did the website make you more aware?

### **Personal relevance**

- Did you perceive the website as personal relevant?
- Did you perceive the questionnaire and its accompanying feedback as personal relevant?

### **Informing value of the website**

- To what extent did you learn new things by using the website?
- To what extent did you learn new things regarding behaviour change?
- To what extent did you learn new things regarding being less sedentary or more physically active?

### **Knowledge**

- Do you think sitting less/being more physically active has an influence on how you feel physically/mentally?
- Do you think sitting less/being more physically active has an influence on your health?





## CHAPTER 1.4

How users experience and use an eHealth intervention based on self-regulation:  
mixed-methods study

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Original Paper

# How Users Experience and Use an eHealth Intervention Based on Self-Regulation: Mixed-Methods Study

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## Abstract

**Background:** eHealth interventions show stronger effects when informed by solid behavioral change theories; for example, self-regulation models supporting people in translating vague intentions to specific actions have shown to be effective in altering health behaviors. Although these theories inform developers about which behavioral change techniques should be included, they provide limited information about how these techniques can be engagingly implemented in Web-based interventions. Considering the high levels of attrition in eHealth, investigating users' experience about the implementation of behavior change techniques might be a fruitful avenue.

**Objective:** The objective of our study was to investigate how users experience the implementation of self-regulation techniques in a Web-based intervention targeting physical activity and sedentary behavior in the general population.

**Methods:** In this study, 20 adults from the general population used the intervention for 5 weeks. Users' website data were explored, and semistructured interviews with each of the users were performed. A directed content analysis was performed using NVivo Software.

**Results:** The techniques "providing feedback on performance," "action planning," and "prompting review of behavioral goals" were appreciated by users. However, the implementation of "barrier identification/problem solving" appeared to frustrate users; this was also reflected by the users' website data—many coping plans were of poor quality. Most users were well aware of the benefits of adopting a more active way of living and stated not to have learned novel information. However, they appreciated the provided information because it reminded them about the importance of having an active lifestyle. Furthermore, prompting users to self-monitor their behavioral change was not sufficiently stimulating to make users actually monitor their behavior.

**Conclusions:** Iteratively involving potential end users offers guidance to optimally adapt the implementation of various behavior change techniques to the target population. We recommend creating short interventions with a straightforward layout that support users in creating and evaluating specific plans for action.

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**KEYWORDS**

eHealth; self-regulation; behavioral change theory; interview; usage data

## Introduction

eHealth, or "the use of technology to improve health care" [1] is effective in changing health behaviors, such as increasing

physical activity, altering dietary habits, and smoking cessation [2-4]. Furthermore, eHealth programs have the potential to reach large populations in a cost-effective way [5-7]. They may also enable a personalized and interactive approach, for example,

by computer tailoring, without the practical considerations of face-to-face contacts [7-9].

There are strong indications that eHealth interventions should be informed by sound theories. Research has shown that applying a theoretical basis to eHealth interventions increases their effectiveness [10,11]; for example, self-regulation models [12] have identified several techniques that may help users to engage in behavioral change. Self-regulation is the process of goal selection, pursuit, and maintenance [13]; it focuses not only on eliciting an intention to change behavior but also on bridging the gap between intention and behavior [13-15]. Using the self-regulation perspective, individuals may learn how to initiate change effectively and how to maintain health behavior over changing conditions. "Action planning," for example, comprises the detailed planning of what a person will do, whereas "barrier identification/problem solving" helps individuals to identify and solve difficult situations for performing the health behavior [16]. Furthermore, research has shown that self-regulation strategies are, indeed, effective in changing behavior [17-21].

Although behavioral change theories inform us about which behavioral change techniques should be included, they provide limited information about how these techniques can be implemented in an engaging way [10]; this might explain why Web-based and mobile interventions often suffer from high attrition rates (60%-80%) [22-24]. The use of behavioral change theories may be necessary but not sufficient to guarantee efficacious interventions. Equally important is the involvement of potential users during various stages of the development process. Such an approach has been advocated by many and is known as cocreation [25], person-based approach [26], or user-centered development [27].

Involving the target population has given researchers insight into what motivates users to start and adhere to a Web-based intervention; for example, Bardus et al. found that the expectation of receiving reminders regarding physical activity was an important reason to start with a Web-based physical activity intervention [28]. Time efficiency, a clear navigation structure, and professional design of the eHealth intervention have been shown to be important factors to make users stay in the program [29,30]. Finally, providing users with a sense of control motivates them to complete the eHealth program [31]. These findings act as a guide to further fine-tune eHealth interventions to the target population [26].

This study aims to investigate how users experience self-regulation techniques implemented in an eHealth intervention. For this purpose, we used the eHealth intervention "MyPlan 2.0," which supports users to be more physically active or less sedentary in a step-by-step manner. This intervention is informed using self-regulation theory and considers users as their own expert in the behavioral change process. Through a semistructured interview and an examination of users' website data, information was obtained about the appreciation of the website and intervention in general and the experience of users with various self-regulation techniques (ie, goal setting, providing information, providing feedback on performance, action planning, barrier identification/problem solving,

prompting self-monitoring, planning social support, and reviewing behavioral goals). The findings derived from this study might help other eHealth developers on how (not) to implement self-regulation techniques in Web-based interventions.

## Methods

### Participants

In this study, 20 adults from the general population volunteered to participate; this number was based on previous qualitative research about eHealth by Yardley et al. [32]. Participants were recruited via acquaintances of the researchers and a database of the research group. The database contained the names of persons who expressed interest in participating in studies of the Ghent Health Psychology Research Group. The exclusion criteria were as follows: not having internet access, aged <18 years, diagnosed with a chronic disease, and non-Dutch speaking. To maintain an equal distribution over age, gender, and educational level, we preselected participants based on these characteristics. The study was conducted between November 2016 and May 2017. As soon as a participant was enrolled in the study, he or she could start the intervention. The first participant started in November 2016, and the last participant started in April 2017. The study was approved by the Committee of Medical Ethics of the Ghent University Hospital (Belgian registration number: B670201629995), and all participants provided a written informed consent.

### Intervention

"MyPlan 2.0" is a self-regulation-based intervention consisting of 5 weekly Web-based sessions. It aims to increase physical activity and decrease sedentary behavior in adults and is designed and created by our research group. "MyPlan 2.0" is based on a previous version named "MyPlan 1.0" [33], which was effective in changing health behaviors [21,33-35]. However, the quantitative research with "MyPlan 1.0" revealed high levels of nonusage attrition [36]. The qualitative research revealed that users felt frustrated about the length and complexity of the program [30]. Hence, the intervention was iteratively transformed according to this feedback. In particular, the intervention was shortened, the text was limited, information sheets were substituted by a quiz, and the layout was changed. Furthermore, rationales were provided for the implementation of different self-regulation techniques, specific instructions were given during action planning and barrier identification/problem solving, and general tips and tricks were provided. Moreover, success stories of other users were added.

In the first session, participants started by creating a profile and provided general information (eg, gender, age, and working status) to enable personalized messages during the intervention. In addition, they chose which behavior, physical activity or sedentary behavior, they wanted to change during the intervention (ie, "goal setting"). The website offers the option to take a quiz regarding the chosen health behavior (ie, "providing information on the consequences of the behavior"). Thereafter, participants completed a short questionnaire regarding the selected health behavior, that is, a shortened version of the International Physical Activity Questionnaire

(IPAQ) [37] or a last 7-days sedentary behavior questionnaire [38] and received tailored feedback, that is, “providing feedback on performance.” After receiving feedback, participants were guided to the “action planning” technique. During this component, users specified their actions in terms of what, where, and how by answering open- and multiple-choice questions. Several tips were provided to make the action plan feasible (eg, “Choose for one goal instead of multiple goals, this increases the chance of goal attainment”). Next, “barrier identification/problem solving” was introduced by asking users which barriers they could perceive and which solutions were possible to overcome these barriers. In addition, examples of barriers and related solutions were provided, which could be selected by users. Next, “prompting self-monitoring of behavior” was introduced. Users chose from a list how they would monitor their behavior (eg, via their calendar, in a notebook, and so on). During the action planning, barrier identification/problem solving, and self-monitoring component, success stories from fictitious users were shown; these were incorporated to elicit motivation further and provide inspiration. At the end of the first session, “planning social support” was introduced; users read about how to elicit social support, how to talk about behavioral change to significant others, and how to find opportunities to engage in behavioral change together with other people. [Figure 1](#) depicts the flowchart of the first session. [Multimedia Appendix 1](#) shows the exact implementation of the techniques through screenshots.

After 1 week, users received an email to return to the eHealth program to revise their plan. According to the technique “Prompt review of behavioral goals,” they were asked how well the behavioral change was going and whether they wanted to adapt or maintain their plan. If they wanted to adapt their plan, action planning was again completed. In all cases, users were prompted for barrier identification and problem solving. To motivate users to think about more personally relevant barriers and solutions, users now answered an open-ended question instead of selecting an option from a predefined list. A summary of their answers was shown in the action plan, and users were prompted to self-monitor their behavior. In addition, users could again read the information about social support and receive extra tips and tricks, and this illustrated the use of different self-regulation techniques, such as “prompting rewards,” “prompting focus on past success,” “providing instructions,” “teaching to use prompts/cues,” and “prompting self-talk;” this cycle was the same for each of the 4 follow-up sessions. [Figure 2](#) displays the flowchart of the follow-up sessions.

The effect of “MyPlan 2.0” will be tested by a randomized controlled trial. If the intervention is effective, it will be disseminated and implemented by the “Flemish Institute for Healthy Living,” which is the Flemish center of expertise regarding health promotion and illness prevention.

## Procedure

Participants were contacted by telephone and informed about the study. When participants decided to take part in the study, they received an email with a website link to the intervention and the documents to provide their informed consent.

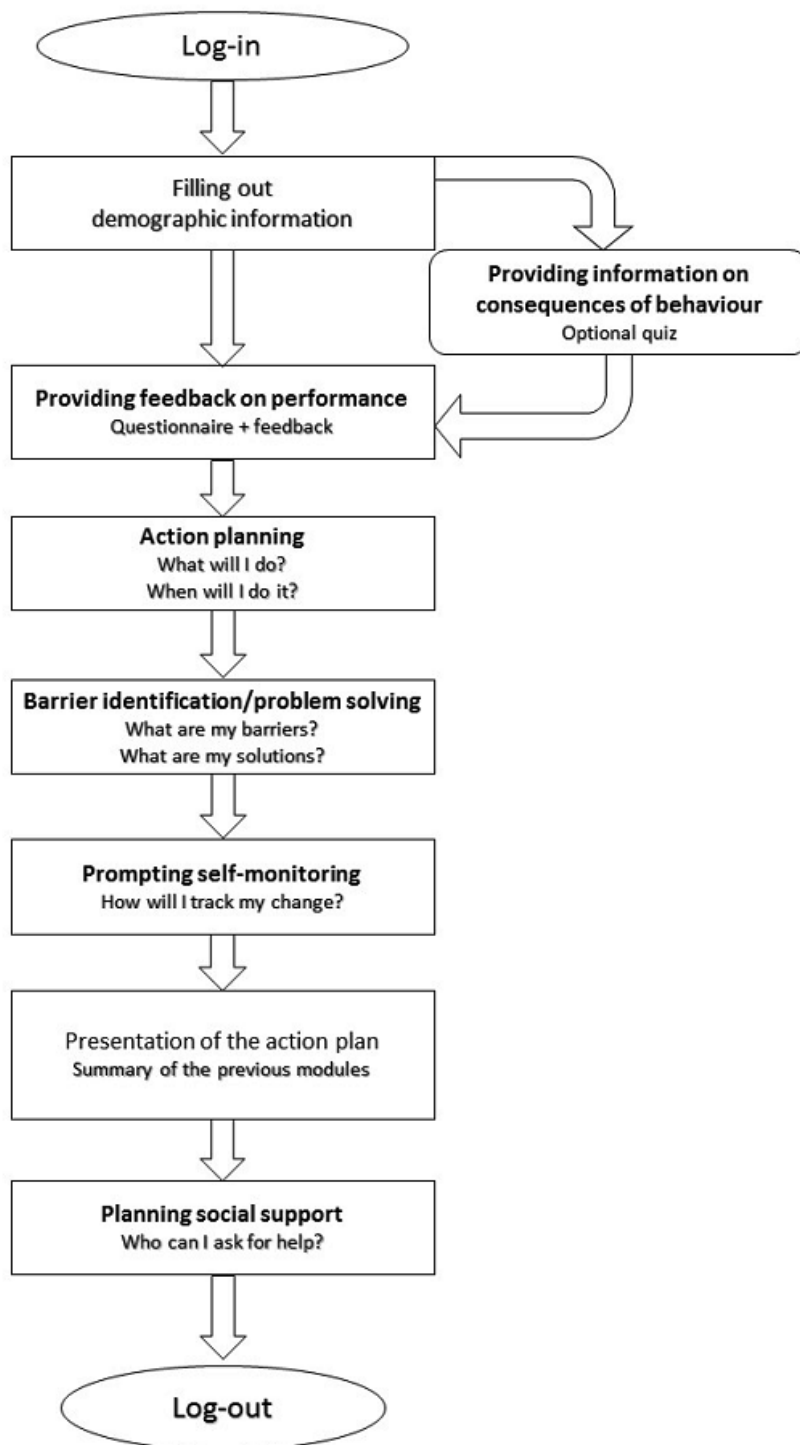
Participants were instructed to complete the intervention on their own. When researchers noted that participants forgot to log in at the scheduled time, they were reminded of doing so by a telephone call. After completing 5 intervention sessions, users’ website data were downloaded, and a date to perform a semistructured interview was scheduled. Before the start of the interview, participants completed questions about demographic characteristics (ie, age, gender, educational level, height, and weight). The interviews took place at the research department or via a telephone call. The interviews were audiorecorded with permission of participants.

The questions and content of the semistructured interview were based on the results of the previous qualitative research with the intervention “MyPlan 1.0” [30]. The 3 main topics that were addressed during the interview were as follows: design of the intervention (ie, general appreciation, user-friendliness, time efficiency, and layout); usefulness of the website (ie, opinion about the motivational value of the website, opinion about the informative value, feelings of awareness elicited by the website, personal relevance, and recommendations); and views about the benefits of being more physically active or less sedentary. During the discussion of each topic, researchers explicitly focused on how users had experienced each of the self-regulation techniques implemented in “MyPlan 2.0” (eg, “How did you experience the component in which you were asked to formulate personal barriers and solutions?”). The interview guide can be found in [Multimedia Appendix 2](#). In the Results section, we will focus on perceptions’ regarding the website in general and the implementation of the behavioral change techniques. The average duration of an interview was 30 minutes, and participants received a reimbursement of €20.

## Data Analysis

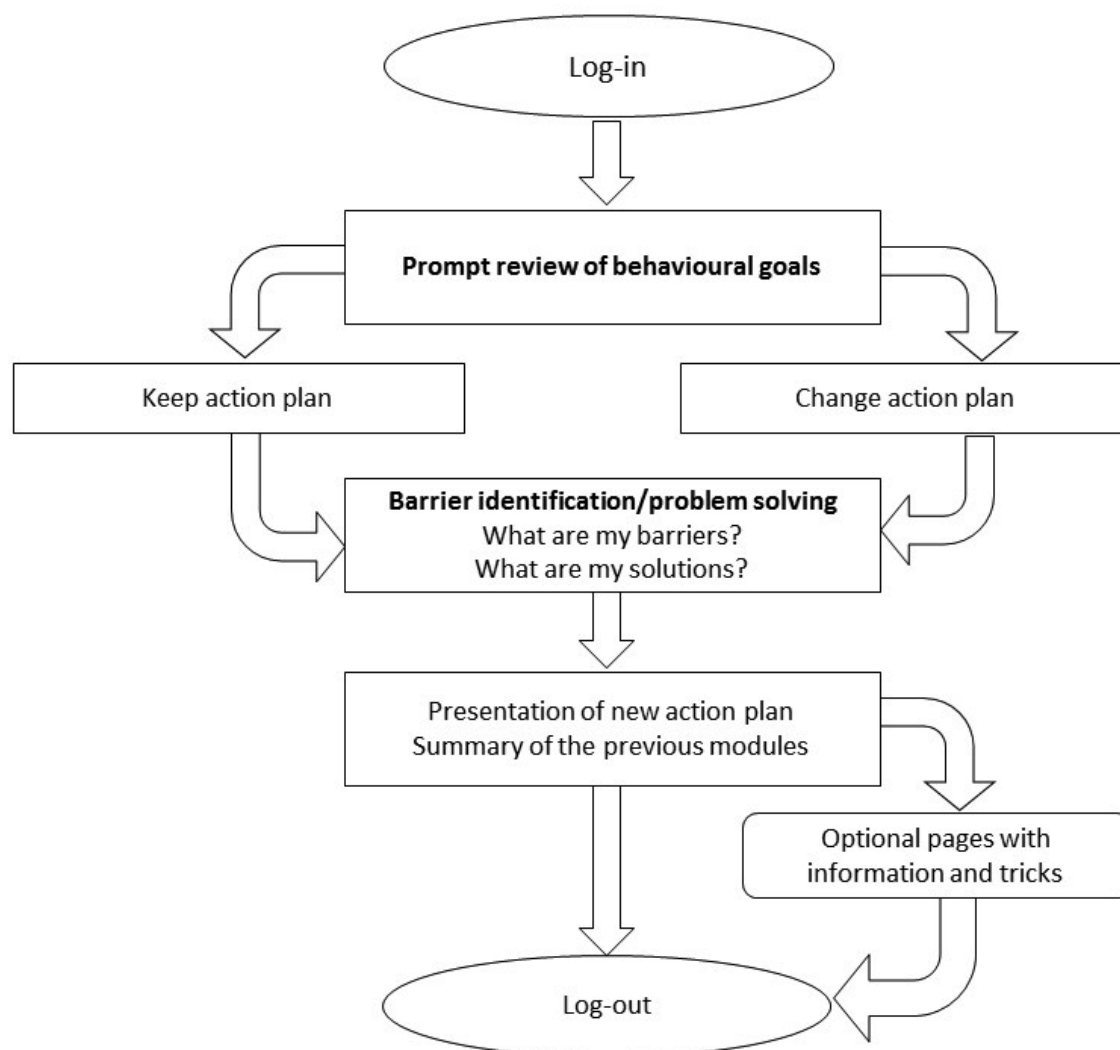
The following information was derived from the users’ website data. First, we identified how many users selected sedentary behavior and physical activity as their target behavior and how many received the tailored feedback that they did not meet the respective health norm (ie, 30 minutes of, at least, moderate physical activity a day [39] or accumulating <8 hours of sitting time a day [40]). Second, time spent on the website and clicks on optional pages were calculated. Optional pages included the quiz, page about social support, and the extra tips describing techniques such as “prompting rewards,” “prompting a focus on past success,” “providing instructions,” “teaching to use prompts/cues,” and “prompting self-talk.” In addition, the average score on the quiz was calculated. Third, users’ action plans were checked by CVdM for achievability and instrumentality toward the chosen behavior [41,42]. Fourth, we calculated how many users were able to (partially) reach their goals and how many times the goals were adapted. Finally, barrier identification/problem solving was checked for achievability (ie, is it possible to execute the solution?) and instrumentality (ie, does the solution actually solve the identified problem?) by CVdM; for example, the solution “scheduling a moment in my diary” was coded as instrumental and achievable for the problem “I do not have enough time,” whereas this solution was considered achievable but not instrumental for the problem “I do not like to do it.”

Figure 1. Flowchart of the first session.



Interviews were transcribed verbatim, and a directed content analysis was performed using NVivo Software (QSR International, Melbourne, Australia, Version 11, 2015) [43]. Content analysis is a way to comprise text into categories based on explicit coding rules [44-47]. In the directed content analysis, theory or prior research guides the coding. Directed content analysis is different from other strategies to analyze qualitative data in which codes most often emerge from the data [48]. Directed content analysis was considered best suited for our purpose because our coding scheme was based on previous research with “MyPlan 1.0” [30], and we were particularly

interested in how participants precisely experienced the practical application of self-regulation techniques. Nevertheless, when a text fragment of the interview did not fit any of the predefined categories, a new category was created. Themes that did not contain enough data were not withheld. Coding was performed independently by two researchers (CVdM and LP). Furthermore, a weighted kappa was calculated, and it showed fair to good interrater agreement (weighted kappa=.67). [Multimedia Appendix 3](#) shows an overview of the themes and subthemes. [Multimedia Appendix 4](#) contains the completed CONSOLIDATED criteria for Reporting Qualitative research checklist [49].

**Figure 2.** Flowchart of the follow-up sessions.

## Results

### Demographic Characteristics

When contacted via telephone, 30 participants were willing to participate. However, 6 participants dropped out before the intervention period, and 4 participants did not respond to the researchers' telephone calls. Recruitment was continued until 20 participants fully completed the 5 intervention sessions. Table 1 shows the demographic characteristics of 20 participants.

### Users' Website Data

Table 2 shows the users' website data according to both behaviors separately. Most users also visited the free-choice components, such as the quiz and additional pages regarding the social support. Only a small number of users indicated that they did not reach their goal or did not want to adapt their goal during the follow-up sessions. Almost all plans (38 of 40) were achievable and instrumental (eg, "On Monday and Wednesday I will perform my workout schedule at home"). The 2 exceptions were plans about sedentary behavior. In these plans, users

indicated that they would perform a physical activity-related activity. During the first session, users had to select barriers and solutions from a list, which made all coping plans instrumental.

### Interviews

#### Website in General

In general, users stated that participating in the study and being involved in the intervention program raised awareness of their own behavior.

*You are also made more aware, and that's where it all starts.* [Woman, >45 years, high educational level, normal weight]

*It was just the fact that I was more aware because I had to take a moment for it.* [Woman, 18-45 years, high educational level, normal weight]

Overall, the intervention website was perceived as user friendly and easy in use. Users highlighted the fact that it was clear and straightforward. In addition, the layout of the website was experienced as positive; it was simple and clear. Yet, some users would have liked a more colorful design.

**Table 1.** Demographic characteristics of participants.

Characteristics	Participants (N=20)
<b>Gender, n (%)</b>	
Men	10 (50)
Women	10 (50)
<b>Age in years, mean (SD), range</b>	46.65 (16.65), 21-74
18-45 y, n (%)	10 (50)
>45 y, n (%)	10 (50)
<b>Educational level, n (%)</b>	
Primary education	1 (5)
Lower secondary education	1 (5)
Higher secondary education	8 (40)
College or university	10 (50)
<b>Body mass index (kg/m<sup>2</sup>), mean (SD), range</b>	25.42 (4.99), 18.47-37.81
Not overweight, n (%)	11 (55)
Overweight, n (%)	9 (45)

**Table 2.** Users' website data according to the 2 target behaviors (sedentary behavior and physical activity).

Website Data	Total (N=20)	Sedentary behavior (n=8)	Physical activity (n=12)
Number of users receiving feedback of not reaching the health norm, n (%)	7 (35)	6 (75)	1 (8)
Time spent per session (min)	6.67	6.74	6.59
Number of users reading the extra tips, n (%)	16 (80)	6 (75)	10 (83)
Number of users reading more about social support, n (%)	14 (70)	4 (50)	10 (83)
Number of users taking the quiz, n (%)	20 (100)	8 (100)	12 (100)
Mean score on the quiz (out of 5)	4.4	4.71	4.08
Number of users willing to monitor their behavioral change, n (%)	15 (75)	4 (50)	11 (92)
Number of plans not achievable or instrumental, n (%)	2 (2)	2 (2)	0 (0)
<b>Indication of...during goal review, n (%)</b>			
Total achievement	39 (49)	20 (63)	19 (40)
Partial achievement	37 (46)	11 (34)	26 (54)
Failure	4 (5)	1 (3)	3 (6)
<b>Choice to...their plan, n (%)</b>			
Adapt	11 (14)	5 (16)	6 (12)
Maintain	69 (86)	27 (84)	42 (88)
<b>Number of solutions not achievable or instrumental, n (%)</b>			
Session 2	8 (40)	2 (25)	6 (50)
Session 3	4 (20)	2 (25)	2 (17)
Session 4	7 (35)	1 (13)	6 (50)
Session 5	4 (20)	2 (25)	2 (17)

*I thought it was a very good website. Very clear. I always knew what to do, where to click. [Woman, 18-45 years, high educational level, normal weight]*  
*It provided overview and was very clear. Nothing negative to mention. It was very easy, very simple.*

*Yes, you could not do anything wrong I think. [Man, >45 years, high educational level, normal weight]*  
*I thought the layout was simple, but that didn't bother me. I think it contributed to the clarity. [Man, 18-45 years, high educational level, normal weight]*

In line with that, users also stated that they would have liked more interaction on the website and more new content per session. For some users, the website was too repetitive and could have been more appealing. Yet, most of the participants were positive about the website and the initiative in general.

*I think, if people will visit the website regularly, they will want to see something new every time though.* [Woman, >45 years, low educational level, overweight]

*It is useful that you try to let people be physically active. You can think about it yourself, everything comes from you. There is no one telling you: 'You have to do this if that happens'. You give yourself feedback.* [Woman, 18-45 years, low educational level, overweight]

Almost all participants experienced the intervention as personally relevant and appropriate. However, the website seemed less fitting for persons who considered themselves as being physically active or for individuals with a lack of motivation.

*It is developed generation-independently, from 7 until 77 in a manner of speaking.* [Man, >45 years, low educational level, overweight]

*Normally, I am already physically active. In that way, the added value for me was minimal. Maybe the intervention is too restricted because it is assumed that people experience difficulties in being physically active.* [Man, >45 years, high educational level, normal weight]

Most users appreciated the time efficiency of the website. Some users would have liked a little more content and for other users, content could have been shown in even less internet pages.

*That (cf. the length) was very reasonable. Certainly not too long. However, not too short either. I had expected a lot more questions and other things.* [Man, >45 years, high educational level, overweight]

In addition, the intervention was perceived as motivating and stimulating for behavioral change by most users. However, some users experienced problems putting their intention into action. Other users were not motivated enough to change their behavior.

*It is stimulating to initiate behavior.* [Man, >45 years, low educational level, overweight]

*The website totally helped me, because I wasn't exercising anymore at all and now I am exercising again. So it did work.* [Man, 18-45 years, low educational level, overweight]

*It is a very good initiative, but it is still difficult to translate it into action and actually move more or sit less. It seems evident, but it is not.* [Man, 18-45 years, high educational level, normal weight]

### **Goal Setting**

Users often mentioned that the difference between physical activity and sedentary behavior was not clear for them, which made the intervention more complex.

*For me there was little difference. If you sit less, then you automatically move more, and if you move more, then you sit less. So I didn't think it was clear.* [Woman, >45 years, high educational level, normal weight]

### **Providing Information on the Consequences of the Behavior**

All participants stated that being more physically active or less sedentary has benefits for both physical and mental health. Some participants believed in the benefits but indicated that they had not experienced the benefits because of the intervention.

*I think it has an influence. I really believe it has, but I have not experienced it.* [Woman, 18-45 years, high educational level, normal weight]

Accordingly, most users indicated that they did not learn new things through the intervention. They already knew the consequences of their behavior. They only had to be reminded to do something about it.

*Learned new things? No. But it gave new insights, you take a moment to think about it.* [Man, >45 years, high educational level, normal weight]

### **Providing Feedback on Performance**

The tailored feedback was highly appreciated by users. They recommended such feedback as the first step toward behavioral change. According to users, the feedback was personally tailored and made them aware that they had to change their behavior. Some users found that the feedback stimulated them actually to alter their behavior. Other users did not remember the feedback from the first session.

*It was good to know where you are because you really don't have a clue.* [Woman, 18-45 years, high educational level, overweight]

*I thought it (cf. the feedback) was good. That way, you know where you are and where you can improve. And it is different for every person. So, it is more personal.* [Woman, 18-45 years, high educational level, normal weight]

### **Action Planning**

Action planning was experienced as highly motivating. Users appreciated the fact that they could plan their personal goals in a structured way by questions. Many users indicated that they actually performed their goal as planned.

*I think it is important to plan this. Because everyone is busy and otherwise there is always something else coming up. If you don't make it a goal or plan in your week, it will not occur or it will fade with time.* [Woman, >45 years, high educational level, normal weight]

*So putting my mobile phone further away (cf. in order to decrease sedentary time) is something that I do now.* [Man, 18-45 years, low educational level, normal weight]

Some users reported problems with action planning. They thought it was difficult to plan behavioral change a week in advance, especially when they had changing work hours. Furthermore, they preferred planning using a calendar rather than by questions. Other users found it difficult to plan behavioral change because they lacked the knowledge and inspiration about what to do. They wanted ready-to-use activity programs.

*If you know what you want to do, but you do not put the words into action, then you fill this in. However, if someone knows he wants to be more physically active, but he does not know how exactly, then I think he will ask himself: "What should I do now?"* [Man, 18-45 years, high educational level, normal weight]

*At the beginning I found it difficult to set up goals for myself.* [Woman, 18-45 years, high educational level, normal weight]

### **Barrier Identification/Problem Solving**

Most users found it a good idea to think about barriers in advance and try to find solutions. However, many indicated that it was difficult to anticipate what could go wrong and how to overcome problems. Users expected the website to provide more guidance for this component.

*What I really appreciated, is the fact that you were obliged to write down at least one barrier and how to cope with it. I had to take a bit of time to think about it, but in the end I always found one. The barrier component is the most powerful of the intervention.* [Man, 18-45 years, high educational level, normal weight]

*Sometimes it was difficult. Because experiencing barriers is not difficult, but finding solutions is not always easy. Most of the time, the same barriers arose.* [Woman, 18-45 years, high educational level, normal weight]

*Barrier identification really was something else (cf. in comparison to action planning). You have to be able to think immediately about what hinders you. That was more difficult. And maybe there could have been more guidance from the website.* [Woman, >45 years, low educational level, overweight]

### **Prompting Self-Monitoring of Behavior**

Many users misunderstood the purpose of self-monitoring and wrote down their plan in advance to remind them about it, but did not keep track of whether they executed the planned behaviors or not.

*I always wrote it down in my diary, in color. That is definitely useful, otherwise you forget about it.* [Man, 18-45 years, high educational level, normal weight]

*I had expected that I would be assisted to monitor my goals myself, to see how my sitting time changes. But*

*I was not asked to write down my sitting time.* [Man, 18-45 years, high educational level, normal weight]

### **Plan Social Support**

There were a few users who commented on the social support component. Some users found it very useful to involve others, whereas other users preferred to keep their behavioral change more private.

*I also appreciated the more practical tips such as inviting neighbors or not exercising alone. I found it nice to read and I often took it into account.* [Women, 18-45 years, high educational level, normal weight]

*I did not really like the social parts. I prefer to do this on my own.* [Woman, >45 years, low educational level, normal weight]

### **Prompt Review of Behavioral Goals**

The largest group of users found it useful to review their goals. Many users indicated that having to log in again was the most motivating part of the intervention.

*The good thing was that it repeated itself every week. Another program ends after one session and then you have the tendency to put it aside. Since you had to log back in for five weeks, you wanted to do what they asked because they would ask if you did it.* [Woman, >45 years, low educational level, overweight]

### **Tips**

Most users expressed their interest in the extra tips and found them very useful. The tips were experienced as feasible and inspiring. Especially, the tip regarding "using prompts or cues" was often implemented. Some users indicated that more new tips during the sessions were needed. Reading success stories of other possible users was also perceived as of added value to the website, although some stated that the stories were too predictable.

*The tips were very interesting because they were practically feasible. It were simple tips that were achievable.* [Woman, >45 years, high educational level, normal weight]

*It is always motivating to see (cf. read) how someone else does it, then you also want to motivate yourself to do it.* [Woman, >45 years, low educational level, overweight]

*The most helping was the note on the fridge. It made you aware to not forget about your plans that day.* [Man, >45 years, low educational level, normal weight]

## **Discussion**

Web-based interventions are increasingly used to alter health behaviors [10] and have shown to be more effective when grounded in a solid behavioral change theory [11]. However, the high levels of attrition highlight the importance to also target user engagement [36]. User engagement has been defined and measured in many ways [50]. According to Perski et al., engagement with a Web-based intervention is influenced by



context (eg, the demographic characteristics of the population) and intervention (eg, the complexity of the intervention) variables [51]. This study focuses on the latter by investigating how users experienced a self-regulation-based eHealth intervention targeting physical activity and sedentary behavior. Users' website data were analyzed, and 20 semistructured interviews were performed.

Besides investigating users' opinions about self-regulation techniques, we also explored how they perceived the intervention in general. In comparison with the users of "MyPlan 1.0" [30], those of the 2.0-version appreciated the time efficiency and user-friendliness of the program; this is encouraging because it proves that an iterative approach in which users are consulted during the development of the intervention pays off [26]. Intervention developers should keep an eye on the user-friendliness of their intervention. We found that a simple but agreeable layout enhanced user-friendliness. Likewise, previous research has indicated that professional design and simple navigation can increase engagement [52]. Some users suggested that the development of a similar mobile app may further increase user-friendliness and interactivity; this suggestion is in line with research showing that the use of mobile apps might increase the adherence [53]. Most users perceived the sessions' duration of approximately 5 minutes as a perfectly reasonable length. Intervention developers are already aware that eHealth interventions should be kept short and to the point [32,52] but reducing length while still implementing different self-regulation techniques has not been an easy endeavor.

This study revealed that most users were well aware of the benefits of increasing physical activity or reducing sedentary behavior; this was reported in the interviews. Users often mentioned that the intervention did not substantially increase their knowledge about the beneficial effect of a more active lifestyle, and this finding was corroborated by the high scores on the quiz, which aimed to provide information engagingly. Notwithstanding, users were interested in information and all completed the optional quiz. The findings indicate that further tailoring and offering more advanced information is recommended in this target population. In addition, previous research highlights the importance of providing new information tailored to the users' needs [32]; for example, Short et al. stated that offering personalized information could increase men's engagement in a Web-based intervention targeting physical activity and nutrition [54]. Of further interest, reading information and receiving personal feedback on the questionnaires seemed to function as a prompt to behavioral change; it reminded users about the importance of adopting a more active way of living.

Of particular interest to this study were the experiences and opinions of users about the self-regulatory strategies to bridge the intention-behavior gap. Key to our eHealth intervention were action planning and problem solving. Action planning consisted of formulating specific actions and planning about when and how they will conduct these behaviors. Action planning seemed to be feasible. Few users stated unachievable plans and many were able to reach their goals, at least, partially. However, thinking in advance about actions was experienced as difficult and effortful by users. Some stated that it was

difficult to come up with specific actions or plan these actions a week in advance, and this is a good remark. An improvement may be to allow users to create and evaluate specific plans on a daily basis. Implementing such microcycles might offer users more guidance in creating instrumental and achievable plans on a daily basis.

The implementation of the technique "barrier identification/problem solving" was less feasible. Many users struggled with identifying barriers and finding solutions in advance, especially in the follow-up sessions in which they had to answer an open-ended question; this was communicated in the interviews and further corroborated by the analysis of the provided barriers and solutions at the website. Our results seem to be at odds with those of other studies. Sniehotta et al. [55] successfully implemented this technique in their intervention to increase physical activity in cardiac rehabilitation patients; their implementation of the technique was very similar to ours—participants were asked which barriers could interfere with their plans and how they could successfully cope with these barriers. However, an important difference with our study is that trained consultants helped users with problem solving in face-to-face contact. Indeed, self-regulation techniques have mostly been used in face-to-face settings [13]. It may well be that counselors are better able to adapt to the implementation of these techniques to the context and needs of an individual. To date, Web-based interventions do not easily offer such an opportunity, and this is an issue worth further consideration and follow-up. Effective techniques may become useless (or even counterproductive) when their implementation is or remains suboptimal. Based on these findings, we recommend offering sufficient guidance when implementing the "barrier identification/problem solving" technique; for example, a button saying "need help?" was added in "MyPlan 2.0" When clicking on this button, users are shown an extensive list of potential barriers and solutions, which can guide them to answer the open-ended question.

In the interviews, some participants mentioned that the intervention may be of lesser use for individuals who are not ready for change yet, and this view is in line with various theoretical models of behavioral change, such as the Stages of Change Theory [56] and the Health Action Process Approach [57]. According to these models, individuals who are not ready to change will not engage in action programs. Indeed, studies investigating engagement according to user characteristics show that users' level of motivation is an important factor for the eHealth uptake [58]. Interventions targeting these individuals might then better include techniques such as motivational interviewing [59], focusing on raising awareness, and eliciting change talk. Such motivational techniques were largely absent in our intervention. We reasoned that eHealth interventions were relatively inadequate for participants with low motivation to change behavior in the short term. Perhaps, more intensive interventions, including face-to-face contact, may be more suited for these individuals [60].

In addition, users indicated that the intervention might be of lesser use for individuals who already have a habit of being active. Inadvertently, many of our participants already had an active way of living. Their personal feedback on the

questionnaire stated that they reached the health norm. We had opted not to exclude participants who reached the health norms. First, research has demonstrated that individuals often overestimate their activity levels when self-report measures of physical activity are used [61]. We reasoned that participants may become more accurate of their estimations of physical activity by engaging in the intervention. Second, we reasoned that the eHealth intervention might also help in maintaining the behavior of those who are already habitually active, but this might not be the case. These individuals may experience the action and coping plan as needlessly effortful, frustrating, and cumbersome. Consequently, informing users explicitly about the target group of the intervention might be worth considering.

One of the strengths of this study was the diversity of the sample with an equal distribution of gender, age, educational level, and body mass index. Furthermore, having both users' website data, as well as interview data, strengthened our conclusions. Finally, the perspective of users on the specific implementation of self-regulation techniques has not been often investigated. The most important limitation of this study was the fact that we did not investigate the participants' actual levels of physical activity and sedentary behavior using validated methods. Consequently,

we do not know whether our sample was more active than the general population. In addition, we were unable to assess the experiences of 4 users who quit the intervention. It may well be that their experience with the intervention was less positive. Furthermore, participants who were acquaintances of researchers might have had a more positive perception of the eHealth intervention. However, to limit this impact, these participants were always interviewed by a trained researcher they did not know.

In conclusion, this study reveals that behavioral change theories may be necessary but not sufficient to guarantee the efficacy in designing interventions. Equally important is the involvement of end users [25-27] because they can inform intervention developers on how self-regulation techniques should (or should not) be integrated. To ameliorate users' engagement with a Web-based intervention, we have the following recommendations: create short (5-6 minutes) interventions with a straightforward layout; provide novel and tailored information regarding the benefits of the health behavior; make users create specific action plans and review these plans in the follow-up sessions; and provide guidance and practical examples when adding a problem solving module.

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## Conflicts of Interest

None declared.

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## Multimedia Appendix 1

Implementation of the behavior change techniques in the website.

[PDF File (Adobe PDF File), 599KB - [jmir\\_v20i10e10412\\_app1.pdf](#)]

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## Multimedia Appendix 2

The Interview Guide.

[PDF File (Adobe PDF File), 39KB - [jmir\\_v20i10e10412\\_app2.pdf](#)]

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## Multimedia Appendix 3

Overview of the themes and subthemes.

[PDF File (Adobe PDF File), 28KB - [jmir\\_v20i10e10412\\_app3.pdf](#)]

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## Multimedia Appendix 4

Completed COREQ checklist.

[PDF File (Adobe PDF File), 45KB - [jmir\\_v20i10e10412\\_app4.pdf](#)]

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## Abbreviations

**IPAQ:** International Physical Activity Questionnaire

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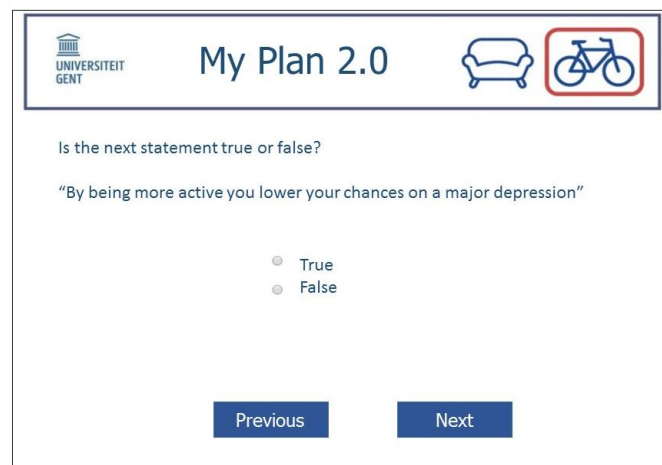
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# Supplementary file 1: Implementation of the self-regulation techniques in MyPlan 2.0

## Providing information on the consequences of behaviour

The website offers the option to take a quiz regarding the chosen health behaviour (i.e. increasing physical activity or decreasing sedentary behaviour). The quiz consists of five statements about the positive effects of the chosen behaviour. Each solution is accompanied by a short and easy text describing the scientific research that has been carried out to answer the question.

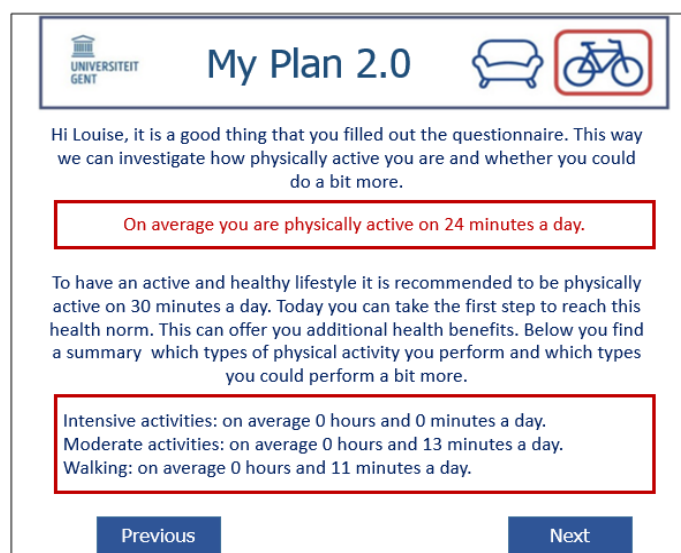


The screenshot shows the 'My Plan 2.0' interface. At the top left is the 'UNIVERSITEIT GENT' logo. The title 'My Plan 2.0' is centered, with icons of a sofa and a bicycle to its right. Below the title, the question asks: 'Is the next statement true or false?' followed by the statement: 'By being more active you lower your chances on a major depression?'. There are two radio button options: 'True' and 'False'. At the bottom, there are two blue buttons labeled 'Previous' and 'Next'.

Figure 1. Example of a quiz question

## Providing feedback on performance

Participants complete a short questionnaire regarding the selected health behaviour (i.e. a shortened version of the International Physical Activity Questionnaire (IPAQ) or a last 7-days sedentary behaviour questionnaire) and receive tailored feedback.



The screenshot shows the 'My Plan 2.0' interface displaying feedback. At the top left is the 'UNIVERSITEIT GENT' logo. The title 'My Plan 2.0' is centered, with icons of a sofa and a bicycle to its right. Below the title, the feedback text reads: 'Hi Louise, it is a good thing that you filled out the questionnaire. This way we can investigate how physically active you are and whether you could do a bit more.' A red-bordered box contains the text: 'On average you are physically active on 24 minutes a day.' Below this, the text continues: 'To have an active and healthy lifestyle it is recommended to be physically active on 30 minutes a day. Today you can take the first step to reach this health norm. This can offer you additional health benefits. Below you find a summary which types of physical activity you perform and which types you could perform a bit more.' Another red-bordered box contains the following summary: 'Intensive activities: on average 0 hours and 0 minutes a day. Moderate activities: on average 0 hours and 13 minutes a day. Walking: on average 0 hours and 11 minutes a day.' At the bottom, there are two blue buttons labeled 'Previous' and 'Next'.

Figure 2. Example of the tailored feedback

## Action planning

During this component, users specify their actions in terms of what, where and when by answering open and multiple choice questions. Several tips are provided to make the action plan feasible (e.g. “Choose for one goal instead of multiple goals, this increases the chance of goal attainment”).



UNIVERSITEIT GENT My Plan 2.0

What will I do? When will I do it? Where will I do it?

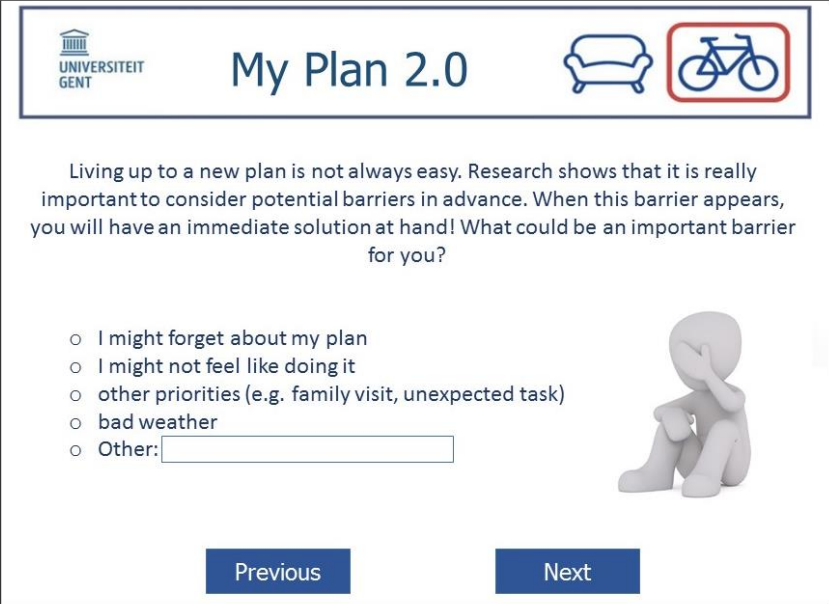
What would you like to do to be more physically active in your spare time (e.g. jogging, cycling, swimming, walking, ...)?

Previous Next

Figure 3: Example of a question in the action planning component

## Barrier identification / Problem solving

‘Barrier identification/problem-solving’ is implemented by asking users which barriers they can perceive and which solutions are possible to overcome these barriers.



UNIVERSITEIT GENT My Plan 2.0

Living up to a new plan is not always easy. Research shows that it is really important to consider potential barriers in advance. When this barrier appears, you will have an immediate solution at hand! What could be an important barrier for you?

- I might forget about my plan
- I might not feel like doing it
- other priorities (e.g. family visit, unexpected task)
- bad weather
- Other:

Previous Next

Figure 4. Barrier identification / problem solving

## Prompting self-monitoring

Self-monitoring is prompted by letting users choose from a list how they will monitor their own behaviour (e.g. via their calendar, in a notebook, ...).

 **My Plan 2.0**  

It is often recommended to monitor your actions. This way you can see how it is going and if you are actually becoming more physically active. How will you do this?

- a booklet
- my calendar or my diary
- my computer
- my mobile phone
- the calendar of MyPlan
- I would rather not keep track of this every day



[Previous](#) [Next](#)

Figure 5: Prompting self-monitoring

## Planning social support

At the end of the first session 'planning social support' is introduced: users read about how to elicit social support, how to talk about behaviour change to significant others, and how to find opportunities to engage in behaviour change together with other people.

 **My Plan 2.0**  

Adopting a healthier way of living is not always easy... Your environment can play an important role. Some people receive a lot of support from their partner, family or friends. For others this is not the case. It might be that your environment has little interest in your lifestyle or they are not aware of the advantages of adopting a healthy way of living. This might make you less motivated as well. If you are looking for ways to get more social support from you environment you might read some of the advices below. Here we describe ways to discuss your plans with others or how you can find other people to be physically active with.

- My Partner
- Friends/Family
- Unknowns
- Colleagues



[Previous](#) [Next](#)

Figure 6: Planning social support



# Supplementary file 2: Interview Guide

- Which module did you select, “sitting less” or “being more physically active”?

## Design of the website

### Perception of the website

- In general, how do you feel about the website?
- How did you experience using the website?
- To what extent, did you perceive the website as engaging?
- To what extent, did you think using the website was a fun thing to do?
- Could you easily keep your attention to the website?
- Which parts of the website did you like the most?
- Which parts of the website did you like the least?
  - Did you like the questionnaire and its accompanying feedback?
  - Did you like creating an action plan?
  - Did you like searching for barriers and solutions?
  - Did you like reading the tips (e.g. regarding social support)?
  - Did you like monitoring your goal?

### User-friendliness

- In general, was the website easy or difficult to use?
- Which parts of the website did you experience as easy?
- Which parts of the website did you experience as difficult?
- How do you think about the user-friendliness of the website?
  - Could you easily find what you needed?
  - Where there moments that you were stuck?
  - Could you easily read all the text?
- Was the questionnaire and its accompanying feedback easy/difficult?
- Did you perceive creating your own action plan as easy/difficult?
- Did you perceive searching for barriers and solutions as easy/difficult?
- Were the tips easy/difficult?
- Did you perceive monitoring your goal as easy/difficult?

### Time efficiency

- What do you think about the time you needed to complete the sessions?

### Lay-out

- What do you think about the lay-out and the design of the website?

## Usefulness of the website

### Recommendations

- Do you suggest any adaptations to the website?
- Are there things you would recommend us to change regarding the website?

### **Stimulating value of the website**

- To what extent did the website help you to change your behaviour?
- Which parts of the website helped you the most?
- Which parts of the website helped you the least?
  - Was it helpful to create an action plan?
  - Was it helpful to search for barriers and solutions?
  - Was it helpful to read the tips (e.g. regarding social support)?
  - Was it helpful to monitor your goal?

### **Awareness**

- To what extent did the website make you more aware?

### **Personal relevance**

- Did you perceive the website as personal relevant?
- Did you perceive the questionnaire and its accompanying feedback as personal relevant?

### **Informing value of the website**

- To what extent did you learn new things by using the website?
- To what extent did you learn new things regarding behaviour change?
- To what extent did you learn new things regarding being less sedentary or more physically active?

### **Knowledge**

- Do you think sitting less/being more physically active has an influence on how you feel physically/mentally?
- Do you think sitting less/being more physically active has an influence on your health?

## Supplementary file 3: Overview of the themes and subthemes

<b>Self-regulation technique</b>	<b>Number of participants mentioning it positively</b>	<b>Number of participants mentioning it negatively</b>
<b>Website in general</b>		
Awareness	19	5
User-friendliness	20	16
Lay-out	17	12
General perception	19	16
Personal relevance	17	11
Time-efficiency	20	11
Motivational value	19	14
<b>Goal setting</b>	0	6
<b>Providing information on the consequences of the behaviour</b>		
Informing value	11	16
Knowledge	20	7
<b>Providing feedback on performance</b>		
Awareness	9	1
Personal relevance	11	1
Motivational value	9	7
<b>Action planning</b>		
Motivational value	19	7
User-friendliness	17	10
<b>Barrier identification/problem-solving</b>		
Motivational value	14	11
User-friendliness	9	13
<b>Prompting self-monitoring of behaviour</b>		
User-friendliness	7	9
Motivational value	15	15
<b>Plan social support</b>		
Motivational value	4	3
<b>Prompt review of behavioural goals</b>		
Motivational value	8	0
<b>Tips: prompting rewards, prompting focus on past success, providing instructions, teaching to use prompts/cues and prompting self-talk</b>		
User-friendliness	12	9
Motivational value	18	13

## Supplementary file 4:

### Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups

#### **Domain 1: Research team and reflexivity**

##### **Personal characteristics**

1. Interviewer/facilitator. Which author/s conducted the interview or focus group?  
LP, CVDM and two Master students (trained by LP and CVDM) conducted the interviews.
2. Credentials. What were the researcher's credentials? E.g. PhD, MD  
LP: PhD candidate in Health Sciences and Psychology  
CVDM: PhD candidate in Psychology and Health Sciences  
IDB: PhD in Psychology  
MV: PhD in Physical Education  
GC: PhD in Psychology
3. Occupation. What was their occupation at the time of the study?  
LP and CVDM are PhD students performing research; MV is a postdoctoral researcher in health promotion, IDB is full professor in health promotion. GC is full professor in Health Psychology.
4. Gender. Was the researcher male or female?  
LP, CVDM, IDB, and MV are female researchers, whereas GC is a male researcher.
5. Experience and training. What experience or training did the researcher have?  
LP has a Master's degree in Experimental and Theoretical Psychology.  
CVDM has a Master's degree in Clinical Psychology.  
IDB has a Master's degree in Clinical Psychology and a PhD in Health Psychology  
MV has a Master's degree and PhD in Physical Education and Movement Sciences  
GC has a Master's degree in Clinical psychology and a PhD in Psychology.

##### **Relationship with participants**

6. Relationship established. Was a relationship established prior to study commencement?  
No relationship with most of the participants was established before the commencement of the study. However, some of the participants were acquaintances of the interviewers.
7. Participant knowledge of the interviewer. What did the participants know about the researcher?  
e.g. personal goals, reasons for doing the research  
The participants knew that the interviewers created 'MyPlan 1.0' and conducted the study in order to ameliorate the programme.
8. Interviewer characteristics. What characteristics were reported about the interviewer/facilitator?  
e.g. Bias, assumptions, reasons and interests in the research topic  
Specific characteristics of the researchers (e.g. training, profession) can always have an influence on data collection and analysis. Nevertheless, we created strict protocols to carry-out the interviews and to analyse the data to minimize bias.

#### **Domain 2: study design**

## **Theoretical framework**

9. Methodological orientation and Theory. What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis

A directed content analysis was conducted. This type of analysis was considered best suited for our purpose because our coding scheme was based upon previous research with 'MyPlan 1.0'

## **Participant selection**

10. Sampling. How were participants selected? e.g. purposive, convenience, consecutive, snowball

The sample from the general population was recruited via an available database, consisting of individuals who had expressed their interest to participate in studies of the Ghent Health Psychology Research Group via a website and via the snowball sampling technique.

11. Method of approach. How were participants approached? e.g. face-to-face, telephone, mail, email

Participants were recruited in different ways: face-to-face, telephone and email.

12. Sample size. How many participants were in the study?

When phoned, thirty participants were willing to participate. However, six participants dropped out before the intervention period, and four participants did not respond to the researchers telephone calls. Recruitment was continued until twenty participants fully completed the five intervention sessions.

13. Non-participation. How many people refused to participate or dropped out? Reasons?

Six participants dropped out before the intervention period, and four participants did not respond to the researchers telephone calls.

## **Setting**

14. Setting of data collection. Where was the data collected? e.g. home, clinic, workplace

The interviews took place at the research department or via a telephone call. The interviews were audio-recorded with permission of the participants.

15. Presence of non-participants. Was anyone else present besides the participants and researchers?

We asked participants to conduct the interview in a room where they would not be disturbed. However, in some cases we could not prevent that a family member occasionally disturbed the interview.

16. Description of sample. What are the important characteristics of the sample? e.g. demographic data

The demographic information of the sample is provided in table 1 of the manuscript.

## **Data collection**

17. Interview guide. Were questions, prompts, guides provided by the authors? Was it pilot tested?

All questions are provided in additional file 2.

18. Repeat interviews. Were repeat interviews carried out? If yes, how many?

There were no repeat interviews carried out.

19. Audio/visual recording. Did the research use audio or visual recording to collect the data?

All verbalizations were voice-recorded.

20. Field notes. Were field notes made during and/or after the interview or focus group?  
No.
21. Duration. What was the duration of the interviews or focus group?  
The average duration of an interview was 30 minutes.
22. Data saturation. Was data saturation discussed?  
When a text fragment of the interview did not fit any of the predefined categories, a new category was created. Themes that did not contain enough data were not withheld. Coding was done independently by two researchers (CV and LP). A weighted kappa was calculated and showed fair to good inter-rater agreement (weighted kappa: 0.67).
23. Transcripts returned. Were transcripts returned to participants for comment and/or correction?  
No.

## **Domain 3: analysis and findings**

### **Data analysis**

24. Number of data coders. How many data coders coded the data?  
Two data coders (LP and CVDM) coded the data.
25. Description of the coding tree. Did authors provide a description of the coding tree?  
Yes. This is provided in additional file 3.
26. Derivation of themes. Were themes identified in advance or derived from the data?  
The themes were identified in advance. This was based on previous research with “MyPlan 1.0”.
27. Software. What software, if applicable, was used to manage the data?  
The qualitative data analysis software nVivo 11 (QSR International Pty. Ltd. Version 11, 2015) was used to manage the data.
28. Participant checking. Did participants provide feedback on the findings?  
No.

### **Reporting**

29. Quotations presented. Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. participant number  
Yes.
30. Data and findings consistent. Was there consistency between the data presented and the findings?  
Yes.
31. Clarity of major themes. Were major themes clearly presented in the findings?  
Yes. Additional file 3 gives an overview of the amount of positive and negative references per theme.
32. Clarity of minor themes. Is there a description of diverse cases or discussion of minor themes?  
Yes.







## Behaviour change techniques included in 'MyPlan 1.0'

Behaviour change technique	Practical application
Motivational Phase	
Providing general information	General information is provided in the form of short texts and slogans. In these texts and slogans, physical activity guidelines and health benefits of reaching these guidelines are highlighted. Users can select the information that they are interested in on the website.
Monitoring, tailored feedback, and personal risk information	After filling out a questionnaire assessing users' physical activity levels, personal feedback is provided in which users' levels of physical activity are provided, as well as how these compare to the recommended level.
Tailored feedback and modelling	The tailored feedback includes stories about peers who succeeded in increasing physical activity levels, also in difficult situations. For example, "Eric (40 years old) decided to be more physically active in his free time, by walking in the local park for 30 minutes, three times per week. When it was raining, Eric decided to go swimming instead of walking."
Prompting identification of barriers and problem solving, and tailored feedback	A predefined list of possible difficulties (barriers and risk situations) to increase physical activity levels is provided and users can select these difficulties that are applicable to them. Based on their answers, tailored information and tips for solutions to overcome the indicated barriers and risk situations are provided; users can select those solutions to apply which they are confident about.
Volitional Phase	
Selecting hindering factors/barriers and solutions, and implementation intentions	Users can first select hindering factors and barriers out of a predefined list. When applicable hindering factors and barriers are not available in the list, users also have the possibility to write down another factor or barrier in an open-ended format. Next, users can select solutions out of a predefined list or write down another solution. Afterwards, users are stimulated to make action plans and coping plans by formulating if-then plans (i.e. "implementation intentions"). After the "if," a situation or the previously selected difficult situations or barriers are stated and after the "then" the selected action or solutions to overcome the difficult situations and barriers are stated (e.g., If it is Monday evening and I am not in the mood for sports, then I call my friend to go to the aerobic lessons together). Users can formulate this implementation intention plan in an open-ended question format on the website.
Goal setting	A list with personal and relevant goals is formed based on previous answers; users can select the goals that they are confident about.
Stating SMART goals	Users are guided by questions to make a specific, measurable, attainable, relevant, and time-bound (SMART) action plan. For example, users can formulate answers to questions on what they want to do (e.g., increasing their level of physical activity by biking 20 minutes to work), how often (e.g., three times per week), when (e.g., Monday, Wednesday, and Friday), and when they want to start (e.g., starting on Monday, July 7). After answering all the questions, the personal action plan and the if-then plan are automatically generated and sent by email to the user.

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Public commitment	Users can send their action plan to others (e.g., family and friends) to obtain social support and invite them to also create an action plan.
Prompt self-monitoring of behaviour and prompt review of behavioural goals	Users are asked to keep a record of their physical activity levels or fruit and vegetable intake by one of the given suggestions (i.e., personal paper agenda, mobile phone, Excel sheet, or online agenda). After the active goal pursuit is started, users are also invited by email to report their behaviour on the website. Periodic email reminders are sent to invite users to fill out a questionnaire about the target behaviour and their goals on the website. The results are compared with their previous behaviour and goals, and iterative feedback is provided on the progress of behaviour change.
Set tasks on a gradient of difficulty	When users have attained their goals, they are invited to change the goal by reformulating a more attainable or more difficult goal or by setting additional goals.
Planning coping responses	Users are asked whether they experienced barriers while pursuing their goals. If so, they are invited to identify solutions to cope with the identified situations or barriers. Users can again select solutions from a list that is generated based on the selected difficulties.
Prompt review of behavioural goals and personal feedback	When users do not achieve their goals, they get personal feedback that informs them that relapse is normal. They are also advised to try again, to choose other strategies, or to adapt their goals to more attainable goals.

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Based on Plaete et al. (2015)

## Overview of the adaptations in 'MyPlan 2.0' based on the results of the studies described in Chapters 1.1 to 1.4

Studies	Lessons Learned	Implementation of the findings in 'MyPlan 2.0'
<b>Studies performed with 'MyPlan 1.0'</b>		
Attrition Study (Chapter 1.1)	<p>High levels of attrition already occur at the first session of 'MyPlan 1.0'.</p> <p>Potential users of 'MyPlan 1.0' are reluctant to create an account.</p>	<p>The sign-up page of 'MyPlan 2.0' indicates that users' email address will only be used to send the four follow-up emails.</p> <p>Besides adding diabetes-specific information regarding the importance of checking blood glucose levels when being physically active no components were added or removed for the version targeting adults with type 2 diabetes.</p>
Think Aloud Study (Chapter 1.2)	<p>The remarks of the sample with type 2 diabetes were similar to those of the sample from the general population.</p> <p>Participants stated that 'MyPlan 1.0' was poorly tailored to their situation.</p> <p>Participants did not understand the usefulness of several behaviour change techniques implemented in 'MyPlan 1.0'.</p> <p>Participants stated that 'MyPlan 1.0' was not time-efficient and described the programme as a long questionnaire rather than an intervention.</p> <p>Participants were reluctant to send their plans to friends and family.</p> <p>Participants experienced difficulties to create implementation intentions (i.e. 'if-then plans').</p> <p>Participants stated that they did not like the lay-out of the website.</p> <p>Participants stated that a mobile application would be useful in their behaviour change process.</p>	<p>In order to offer a more personalised approach, success stories based on the user's age and gender were added to the intervention.</p> <p>Rationales for each proposed behaviour change technique were added. For example, the website explains why coping planning is important and how it can help users in the behaviour change process.</p> <p>Research-related questions (e.g. questions assessing participants' personal determinants for change) were removed and lengthy text pages providing information on the benefits of adopting an active lifestyle were replaced by quizzes.</p> <p>Instead of asking participants to send their plan to friends or colleagues optional pages providing information on how social support can be obtained from friends, family or colleagues were created.</p> <p>Participants are no longer required to create implementation intentions. The plan is now made more specific by asking users questions such as when, where and how many times they will perform the selected behaviour (e.g. being physically active during leisure</p>

		<p>time).</p> <p>Questions assessing participants' level of physical activity/sedentary behaviour were not removed as these were needed to provide tailored feedback. However, the number of these questions was restricted to a minimum.</p> <p>To create a more enjoyable interface, lengthy text pages were deleted and more images were added.</p> <p>A mobile application providing daily support was created.</p>
<b>Studies performed with 'MyPlan 2.0'</b>		
<p>Interview Study (Chapter 1.3)</p>	<p>Participants appreciate the time-efficiency and user-friendliness of 'MyPlan 2.0'.</p> <p>Participants did not learn new information by going through the quiz, but became more aware of the importance of increasing physical activity/decreasing sedentary behaviour.</p> <p>Participants experience the website as personally relevant.</p> <p>Participants felt motivated by the action planning component as they knew they would receive feedback in the next session.</p> <p>Participants experienced problems to complete the coping planning component.</p> <p>Participants liked to go through the programme together with their partner.</p>	<p>Users no longer need to indicate whether they selected physical activity or sedentary behaviour at each of the follow-up sessions. They are immediately guided to the correct version.</p> <p>A button saying "need inspiration?" was added to open-ended questions of the coping planning component. After clicking on this button participants are guided to a page with an extensive list of potential barriers and feasible solutions to overcome these barriers.</p> <p>A printable weekly overview was added to the component prompting users to self-monitor their behaviour change. Furthermore, the mobile application offers a specific component to help users monitor their changes.</p> <p>The mobile application allows people to alter the goals created on the website.</p>
<p>Mixed Methods Study (Chapter 1.4)</p>	<p>Participants indicated that the website is user-friendly and time-efficient.</p> <p>The difference between physical activity and sedentary</p>	<p>To achieve a higher level of interaction, an additional page with recommendations was created for people who indicated that they were not able to reach their goal.</p>

	<p>behaviour was unclear to many users</p> <p>Users would like to see new content per session and more interaction.</p> <p>Almost all users experienced the website as personally relevant.</p> <p>The implementation of action planning was feasible: users liked the specific questions, few users stated unachievable plans and many stated that they were able to reach their goals, at least partially. However, some users found it difficult to create plans a week in advance.</p> <p>Users experienced difficulties to complete the coping planning component and many coping plans were of poor quality.</p> <p>Although prompted to self-monitor their changes, many users did not keep track of their behaviour change.</p>	
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CHAPTER 2  
Testing the effectiveness of 'MyPlan 2.0'





## CHAPTER 2.1

A self-regulation–based ehealth and mhealth intervention for an active lifestyle in adults with type 2 diabetes: protocol for a randomized controlled trial

Poppe L, De Bourdeaudhuij I, Verloigne M, Degroote L, Shadid S, Crombez G: A self-regulation-based eHealth and mHealth intervention for an active lifestyle in adults with type 2 diabetes: Protocol for a randomized controlled trial. *JMIR Research Protocols*, 2019; 8(3): e12413. DOI: 10.2196/12413



Protocol

# A Self-Regulation–Based eHealth and mHealth Intervention for an Active Lifestyle in Adults With Type 2 Diabetes: Protocol for a Randomized Controlled Trial

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## Abstract

**Background:** Adoption of an active lifestyle plays an important role in the management of type 2 diabetes. Online interventions targeting lifestyle changes in adults with type 2 diabetes have provided mixed results. Previous research highlights the importance of creating theory-based interventions adapted to the population's specific needs. The online intervention "MyPlan 2.0" targets physical activity and sedentary behavior in adults with type 2 diabetes. This intervention is grounded in the self-regulation framework and, by incorporating the feedback of users with type 2 diabetes, iteratively adapted to its target population.

**Objective:** The aim of this paper is to thoroughly describe "MyPlan 2.0" and the study protocol that will be used to test the effectiveness of this intervention to alter patients' levels of physical activity and sedentary behavior.

**Methods:** A two-arm superiority randomized controlled trial will be performed. Physical activity and sedentary behavior will be measured using accelerometers and questionnaires. Furthermore, using questionnaires and diaries, patients' stressors and personal determinants for change will be explored in depth. To evaluate the primary outcomes of the intervention, multilevel analyses will be conducted.

**Results:** The randomized controlled trial started in January 2018. As participants can start at different moments, we aim to finish all testing by July 2019.

**Conclusions:** This study will increase our understanding about whether and how a theory-based online intervention can help adults with type 2 diabetes increase their level of physical activity and decrease their sedentary time.

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**KEYWORDS**

protocol; randomized controlled trial; eHealth; mHealth; type 2 diabetes; self-regulation; physical activity; sedentary behaviour; mobile phone

## Introduction

Diabetes is associated with various health problems including kidney failure, retinopathy, and cardiovascular disease [1]. By

2035, it is estimated that one in ten adults will have diabetes [1]. This exponential growth of diabetes is largely accounted for by type 2 diabetes, which is responsible for 85%-95% of the disease cases [1]. Adopting an active lifestyle (ie, being

physically active and limiting sedentary behavior) has shown to play an important role in both the prevention and management of type 2 diabetes [2,3]. Consequently, cost-effective approaches that help adults with type 2 diabetes in increasing their physical activity and reducing their sedentary behavior are needed.

Electronic health (eHealth) and mobile health (mHealth) interventions have the potential to reach large populations in a cost-effective way and are effective in promoting an active lifestyle in the general population [4]. Nevertheless, research about the effectiveness of online interventions targeting adults with type 2 diabetes reveals mixed results [5-7]. Based on these findings, several proposals have been formulated to better design and implement eHealth and mHealth interventions for adults with type 2 diabetes. First, interventions should be grounded in and informed by theoretical models [5,7,8]. Research revealed that online programs that are developed using theoretical models result in larger effect sizes [9]. A useful perspective may well be the self-regulation framework, which focuses on both preintentional (such as increasing knowledge) and postintentional (such as action and coping planning) processes of behavior change [10]. This framework describes behavior change as a goal-guidance process starting from personal determinants for change until goal maintenance or, if necessary, disengagement [11]. Second, online interventions should take into account the perspective and needs of the users. This can be accomplished by involving end users during the entire developmental process of the online program [12,13]. Third, developers should address the high levels of attrition that are negatively affecting many online interventions [14]. Combining a website with a reminder system, such as automated emails or text messages, may be one of the ways to reinforce website use [7].

There are many papers discussing the effects of online interventions. Nevertheless, a clear and thorough description of the interventions themselves is often missing. This impedes research, as researchers often start from scratch when creating an intervention. The publication of study protocols that clearly describe the active ingredients and the “dose” of the interventions are therefore needed [5]. This study describes the protocol for a randomized controlled trial examining how a self-regulation-based eHealth and mHealth intervention (“MyPlan 2.0”) targeting sedentary behavior and physical activity influences the behavior-change process of adults with type 2 diabetes. The needs of adults with type 2 diabetes were taken into account, as they were actively involved in the development of the program [15,16]. “MyPlan 2.0” consists of a website that motivates users to create, follow, and maintain their own goals for physical activity or sedentary behavior in combination with an optional mobile app offering daily support. The aim of this paper is to describe “MyPlan 2.0” and provide the study protocol that will be used to investigate the website’s effectiveness and underlying mechanisms. The items addressed in this protocol paper are based on the 2013 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement [17]. [Multimedia Appendix 1](#) presents the completed SPIRIT checklist.

## Methods

### Ethical Approval

This study was approved by the Committee of Medical Ethics of the Ghent University Hospital (Belgian registration number: B670201732566) and registered as a clinical trial (Clinicaltrials.gov NCT03291171). Written informed consent from each participant will be obtained. Precautions will be taken to ensure participants’ privacy during data analysis.

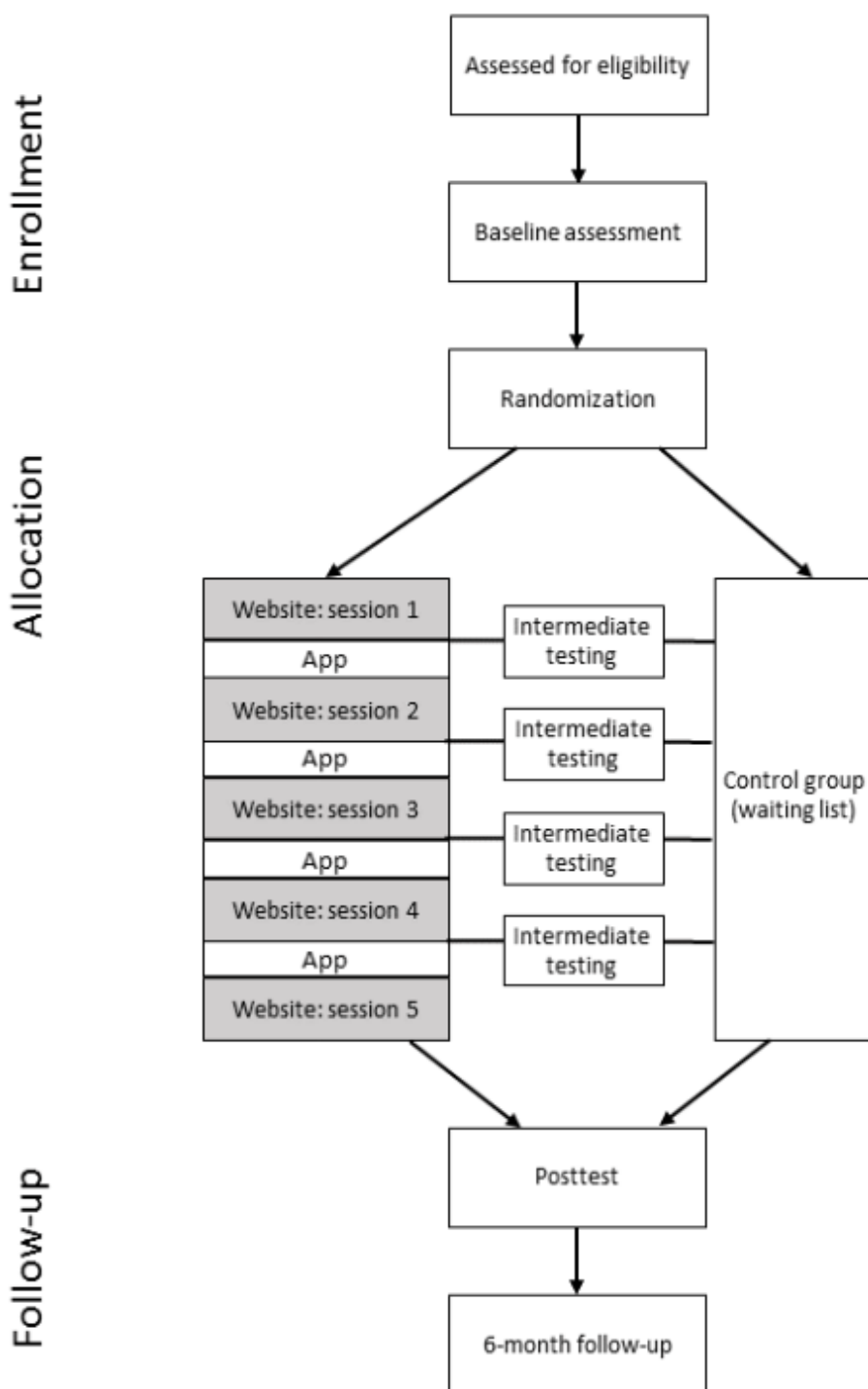
### Study Design

A two-arm superiority randomized controlled trial will be performed. The study flow is depicted in [Figure 1](#). Data will be collected during three home visits. During the first home visit, written informed consent will be obtained from the participants, and the participants will be asked whether they would like to increase their physical activity or decrease their sitting time. Participants will then complete questionnaires on physical activity, sedentary behavior, personal determinants for change (eg, self-efficacy), and health-related outcomes. Furthermore, participants’ weight and waist circumference will be assessed. Finally, participants from both groups will wear an accelerometer for a period of 10 days and fill out a morning and evening diary on each of these days. The diaries will assess participants’ daily goals and possible person-related barriers (ie, fatigue, stress, depressed mood, pain, nausea, and feelings of numbness or tingling in limbs).

After this period, LP will randomly allocate participants to the waiting list control group or the intervention group in a 1:2 allocation ratio by using an automated randomizer [18]. This will be done independent from patients’ choice to increase their physical activity or decrease their sitting time. Participants allocated to the intervention group who chose to increase their physical activity will be directed to the website targeting physical activity, whereas participants who chose to decrease their sitting times will be directed to the website targeting sedentary behavior. Participants owning a smartphone will be asked to download the mobile app. The website part of the intervention consists of five consecutive modules (a start module and four follow-up modules) spread over a 5-week period. Each week, participants from both groups will be phoned by a researcher. During these phone calls, questions regarding participants’ personal determinants for behavior change (eg, self-efficacy) will be repeated. In doing so, we will achieve the temporal separation needed to investigate causal pathways [19]. Furthermore, the phone calls will be used to check whether patients had hypoglycemia or made changes to their medication.

One week after completing the program (for the intervention group) or 6 weeks after finishing the baseline measures (for the control group), a second home visit will be scheduled during which the posttest will be carried out. In this phase, questions regarding process evaluation will be added to the questionnaires of the intervention group. Finally, 6 months after the baseline test, the intervention group will be visited a third time by the researchers to perform the follow-up test in order to examine whether the potential effects of the intervention are sustainable.

Figure 1. Study flow.



**Hypotheses**

Our primary hypotheses for this study are as follows: (1) The intervention group allocated to the module “Physical Activity” will show an increase in total physical activity from pre- to posttest compared to no change in the control group. This effect will be sustained in the intervention group from the posttest to the follow-up test. (2) The intervention group allocated to the module “Sedentary Behaviour” will show a decrease in

sedentary behavior from pre- to posttest compared to no change in the control group. This effect will be sustained in the intervention group from the posttest to the follow-up test.

Our secondary hypotheses are as follows: (1) Positive changes in physical activity or sedentary behavior will be mediated by increases in the personal determinants self-efficacy, action planning, and coping planning. (2) The intervention group will have more positive health outcomes (ie, a lower weight; smaller waist circumference; and lower levels of fatigue, anxiety, and

depression) from pre to follow-up test. (3) The negative effect of daily stressors (ie, fatigue, stress, depressed mood, pain, nausea, and feelings of numbness or tingling in limbs) on physical activity and sedentary behavior will be smaller in the intervention group from pre- to posttest compared to no change in the control group. This effect will be sustained in the intervention group from posttest to follow-up test.

As moderation analyses for online interventions targeting adults with type 2 diabetes are not usually performed [5], no hypotheses regarding the moderation effects are made. The following factors will be examined as potential moderators: age, sex, education, and chosen behavior (ie, physical activity or sedentary behavior).

### Participants

The required sample size was calculated using the software GPower 3.1.9.2 [20]. This program requires the following input: effect size, alpha, power, number of groups, and number of measurements. To our knowledge, there is no meta-analysis documenting the effect sizes of online interventions targeting physical activity or sedentary behavior in adults with type 2 diabetes. As people with type 2 diabetes tend to be overweight and physically inactive, we decided to focus on these characteristics for our effect-size estimation [21]. A meta-analysis by Davies et al (2012) showed that eHealth interventions targeting physical activity levels of overweight or sedentary adults reached effect sizes of 0.37 [22]. Most of the studies included in the meta-analysis used questionnaires rather than accelerometers to measure participants' level of physical activity. Assuming an effect size of 0.37, alpha of .05, beta of .90, two groups (intervention group and control group), and three measurements (pretest, posttest, and follow-up test), the *a priori* power analysis suggests a sample size of 96 (64 participants in the intervention group and 32 in the control group).

Therefore, 96 participants with type 2 diabetes will be recruited via the Ghent University Hospital, the Sint-Lucas General Hospital (Ghent), the Maria Middelaers General Hospital (Ghent), and the Damiaan General Hospital (Ostend). To be eligible for participation, participants should have type 2 diabetes, have been diagnosed for at least 1 month, be 18 years or older, speak Dutch, be computer literate, have internet access, and not have participated in previous studies on "MyPlan 2.0." Participants receiving concomitant care and interventions will not be excluded. Potential participants with type 2 diabetes will be recruited via the endocrinologists of the collaborating hospitals. The endocrinologists will check whether visiting patients meet the inclusion criteria, provide eligible patients with a flyer, and ask these patients if the researchers are allowed to contact them. If the patient agrees, the researchers will receive the patient's contact details. The recruitment procedures will continue until the proposed number of participants is reached. Except during the pretest, neither the participants nor the researchers assessing the outcome variables will be blinded.

### Description of the Intervention

"MyPlan 2.0" is an eHealth and mHealth intervention targeting physical activity and sedentary behavior. The program is based

on "MyPlan 1.0," a self-regulation-based eHealth intervention (ie, a website) originally designed to be used by general practitioners in order to increase the levels of physical activity and the intake of fruit and vegetables in the general population [23]. Although "MyPlan 1.0" was shown to be effective, the high levels of attrition indicated that there was room for improvement [24-27]. Moreover, the general practitioners indicated that the program should also be made available to people with type 2 diabetes, as health self-regulation is of great importance in this population [28]. For "MyPlan 2.0," we decided to focus on physical activity and sedentary behavior. Two studies were performed to guide the adaptations to the program. First, user and website characteristics related to attrition were explored [29]. Second, think-aloud interviews were performed with 20 adults with type 2 diabetes and 20 adults from the general population [15]. We instructed users to verbalize their thoughts while using "MyPlan 1.0." Based on the findings of both studies, a new version—"MyPlan 2.0 version T2D"—was developed. Using semistructured interviews with 21 adults with type 2 diabetes who had completed "MyPlan 2.0," this version was further adapted to users with type 2 diabetes [16].

"MyPlan 2.0" consists of a website and a mobile app. The website, created using LifeGuide [30], is the basis of the intervention and has five consecutive parts. The first time a user logs into the website, (s)he can choose whether (s)he would like to be more physically active or less sedentary. The further structure of the website is independent of the chosen health behavior. First, in order to provide tailored feedback and personalized information (eg, the age and sex of the persons in the success stories are tailored to the user's age and sex), all users answer questions assessing demographic information. Subsequently, users have the option to take a quiz regarding the benefits of the selected health behavior. Next, users fill in a questionnaire to assess their current levels of physical activity or sedentary behavior and receive feedback regarding the time they spend being physically active or sitting. Thereafter, users create a specific plan for increasing their physical activity (eg, "On Monday morning I will walk 10 minutes in the neighbourhood") or decreasing their sedentary behavior (eg, "I will stand when talking on the phone"). Users will then state possible barriers for the selected goal, search for solutions, and decide how they will monitor their goal. Offered choices are a calendar, a booklet, the mobile app, etc. Next, users will see an overview of their goals, barriers, and solutions and how they will monitor their behavior change: This is called the action plan. Finally, users will be offered additional information about how they can receive social support from their environment.

The intervention lasts for 5 weeks. Each week, the users receive an email to go back to the website to evaluate and adapt their goal based on the successes and failures of the past week. In these follow-up sessions (four in total), users can actively reflect on their behavioral change. Each follow-up session has the same structure. First, users see the goal(s) they have set the week before and are asked whether they reached their goal. Feedback based on success or failure is given. Second, users choose to keep or adapt their goal. Third, users think about possible barriers that might come up in the following week and search

for solutions. Fourth, users see an overview of their (new) goal, barriers, and solutions. Fifth, users can read additional tips and tricks to be more physically active or less sedentary. [Table 1](#) gives an overview of the behavior change techniques that are covered by the website. The techniques are labelled according to the taxonomy of behavior change techniques compiled by Michie and colleagues [31].

The mobile app offers daily support during the entire behavior change process. Through the app, users can review their goals, monitor their progression, search for possible coping techniques, and take quizzes regarding physical activity or sedentary behavior. By visiting the website, completing quizzes, and monitoring their behavior change, users can collect points in the mobile app. This gaming element was added to increase engagement with the intervention. The techniques implemented in the mobile app can be found in [Table 2](#). The techniques are labelled according to the taxonomy of behavior change techniques compiled by Michie and colleagues [31]. [Multimedia Appendix 2](#) presents screenshots from the website and the mobile app.

## Measurement instruments

### Questionnaires

#### Demographic Variables

Participants' age, sex, height, civil status, education, profession, and the time since diagnosis will be assessed using a questionnaire in the pretest.

#### Physical Activity and Sedentary Behavior

The Dutch version of the long International Physical Activity Questionnaire (IPAQ-L) [32] and the Longitudinal Aging Study Amsterdam (LASA) sedentary behavior questionnaire [33] will be used to assess the context-specific physical activity and sedentary behavior. The interview version of the IPAQ-L and the LASA questionnaires will be conducted, as previous research showed that participants tend to overreport their levels of physical activity when using self-administered questionnaires [34]. This will be done during each of the three testing waves.

#### Health Outcomes

Participants' feelings of depression, anxiety, and fatigue will be assessed during each testing wave using scales of the Patient-Reported Outcomes Measurement Information System [35]. Feelings of depression and anxiety will be measured via the Dutch version of the depression short-form scale (version 1.0) and anxiety short-form scale (version 1.0), both of which contain six items with five answer options: "never," "seldom," "sometimes," "often," and "always." Participants' fatigue will be measured using the subscale "fatigue" of the Dutch version of the 29-profile scale (version 2.01). The subscale contains

four items with five answer options: "not at all," "a bit," "somewhat," "to a fairly high degree," and "to a high degree."

#### Personal Determinants

Personal determinants for behavior change (ie, self-efficacy, risk perceptions, outcome expectations, motivation, intention, action planning, coping planning, and self-monitoring) will be measured in both groups during each testing wave and the weekly phone calls. These determinants will be assessed using multiple items (minimum three items per determinant) that were selected by presenting a large number of items measuring Health Action Process Approach (HAPA) determinants to 11 experts in the self-regulation framework. All experts indicated whether each item measured the presented HAPA determinant and how sure they were of their answer [36]. Based on these responses, discriminant content validity was assessed using the method described by Johnston et al [36], and the best scoring items were selected. Each item has 10 answer options, ranging from "completely disagree" to "completely agree."

#### Accelerometry

Participants' sedentary time and total, moderate-to-vigorous, and light physical activity will be assessed for a period of 10 days during each of the three testing waves using ActiGraph accelerometers (model GT3X+; Pensacola, FL), which have been shown to be reliable and valid [37-40].

#### Anthropometry

Anthropometry will be carried out on each of the three testing waves (ie, during each home visit). The visiting researcher will assess participants' weight using a Seca weighing scale (model 813; Benson Avenue, CA), whereas waist circumference will be measured at the lowest rib margin and the iliac crest at the midaxillary line using Seca measuring tape.

#### Diary

#### Mental and Physical Well-Being

Each morning and evening, participants will rate the extent of fatigue, stress, depressed mood, pain, nausea, and feelings of numbness or tingling in the limbs experienced by using a 10-point scale, ranging from "absolutely not" to "very much."

#### Action Planning

Each morning, participants will report their planned actions for that day by indicating which type of goals they planned (eg, social activities, work, and physical activity). Each evening, participants will report the level to which they reached their listed goals by using a 10-point scale, ranging from "did not work out" to "worked out very well." An overview of the measures and the time points during which they will be assessed is shown in [Table 3](#).

**Table 1.** Overview of the self-regulation techniques implemented in the website.

Self-regulation technique	Implementation mode
Providing information on the consequences of behavior, in general	During session 1, users have the option of taking a quiz. The quiz contains questions regarding the benefits of the chosen health behavior (ie, increasing physical activity or reducing sedentary behavior). Each answer is followed by a clear explanation.
Exploring social support	During session 1, users can read more information about how they can obtain social support from their partner, friends, family, or colleagues.
Providing feedback on performance	During session 1, users complete a short questionnaire regarding their current levels of physical activity or sedentary behavior. Thereafter, they can see for how much time they are physically active or sedentary and in which domains (eg, transport or leisure time).
Action planning	In each session, users have the option to create their own goals to increase their physical activity or decrease their sedentary behavior. By answering different questions, the goals are made as specific as possible (eg, "On Monday and Wednesday morning I will walk 10 minutes in the neighbourhood").
Barrier identification/problem solving	In each session, users are prompted to think about possible barriers regarding their plans and search for potential solutions (eg, "I might forget my plan to take a walk in the evening, so I will stick a note on the fridge").
Prompting self-monitoring of behavior	In each session, the website encourages users to monitor their behavior change and presents options to do so.
Prompting review of behavioral goals	During each follow-up session, users are asked to review the extent to which the goals set in the previous session were achieved.

**Table 2.** Overview of the self-regulation techniques implemented in the mobile app.

Self-regulation technique	Implementation mode
Providing information on the consequences of behavior, in general	Users have the option to take several quizzes on the benefits of the chosen health behavior (ie, increasing physical activity or reducing sedentary behavior).
Prompting self-monitoring of behavior	Every evening, users receive a notification to fill in whether they were more active today than they used to be before. The entries of each week are shown in a graph visible to the user.
Action planning	Users can review their goals and make adaptations, if necessary. In the mornings of days during which users should live up to their goal, a notification is sent to remind them about the goal.
Barrier identification/problem solving	Users can see an overview of common barriers and solutions for these barriers.

Cognitive interviews, usually performed in small samples [41], were used to assure the comprehensibility of the diary and questionnaire assessing personal determinants for behavioral change [42,43]. We purposively selected participants aged  $\geq 50$  years, because the prevalence of type 2 diabetes peaks in older age [1]. The participants were instructed to read and complete the diary and questionnaire. For each item, the interviewer (LP) asked the participant whether (s)he considered the item to be difficult, how (s)he came to an answer, and which time period (s)he took into account when providing an answer. Based on the results of these interviews, adaptations to the items were made. The mean (SD) age of the participants was 58.3 (6.5) years (range, 52-67 years). Demographic information of the participants is provided in Table 4.

### Data Quality Assurance

The data-collection process will be guided and monitored by the researchers. As this study is part of a postgraduate doctoral degree project, no specific data trial steering or data monitoring committee was assigned. However, the study progress will be discussed monthly with the research team. Only accelerometer data from participants who had 4 valid days including 1 weekend day ("valid" defined as  $\geq 10$  hours of wear time) will be included in the analysis [44]. Furthermore, responses to the IPAQ-L and

LASA questionnaires will be checked for plausibility. For the IPAQ, we will use the method described by Dubuy et al [45] to truncate the data. For the LASA questionnaire, we will truncate the data to a maximum total score of 16 hours a day [46].

### Statistical Analysis

Statistical analysis will be performed after completing the data-collection phase. No interim analysis will be executed. Descriptive statistics and independent samples *t* tests will be carried out to explore and identify potential differences between the intervention and the waiting-list control group. To evaluate the primary outcomes of the intervention, three-level (hospital, patient, and time) analyses will be conducted. Intention-to-treat analyses will be performed. As the drop-out rate is usually high in eHealth research [14], it is likely that a per protocol analysis will not be feasible. Furthermore, participants of the intervention group will only be included in the analysis if they complete four of five sessions on the website. Moderating effects will be identified via interaction terms (including the possible moderator). For the secondary outcomes, mediating effects will be investigated using structural equation modelling. Changes in health outcomes and the effect of daily stressors on patients' activity levels will be assessed using multilevel analysis. Data analysts will not be blinded to participants' group allocation.



**Table 3.** Overview of the measures.

Measures	Baseline	Intermediate test	Posttest	Follow-up test
Demographic information using the general questionnaire	✓			
<b>Physical activity and sedentary behavior</b>				
Accelerometer	✓		✓	✓
IPAQ-L <sup>a</sup>	✓		✓	✓
LASA <sup>b</sup> sedentary behavior questionnaire	✓		✓	✓
<b>Health outcomes</b>				
Weight	✓		✓	✓
Waist circumference	✓		✓	✓
PROMIS <sup>c</sup> fatigue	✓		✓	✓
PROMIS depression	✓		✓	✓
PROMIS anxiety	✓		✓	✓
Personal determinants - single items	✓	✓	✓	✓
<b>Daily stressors and goals</b>				
Fatigue	✓		✓	✓
Stress	✓		✓	✓
Feelings of depression	✓		✓	✓
Pain	✓		✓	✓
Nausea	✓		✓	✓
Numbness/tingling in limbs	✓		✓	✓
Goals	✓		✓	✓
Evaluation of goals	✓		✓	✓

<sup>a</sup>IPAQ-L: long International Physical Activity Questionnaire.

<sup>b</sup>LASA: Longitudinal Aging Study Amsterdam.

<sup>c</sup>PROMIS: Patient-Reported Outcomes Measurement Information System.

**Table 4.** Demographic information of the participants from the cognitive interviews (N=4).

Demographics	N
Women	3
<b>Level of education</b>	
Primary school	1
Secondary education	1
College	2
Diagnosed with type 2 diabetes	2

## Process Evaluation

### Contextual Factors

Individuals live in certain contexts that inevitably shape their lifestyle. As the design of the environment plays an important role in developing and maintaining an active way of living [47], patients' perception of the environment will be examined during the pretest. This will be done via the short version of the

Assessing Levels of Physical Activity questionnaire, which has shown to be valid and reliable [48]. Furthermore, we will check for physical conditions that may have hindered the participant from being active. This will be examined during the posttest and the follow-up tests using the question, "In the past six weeks, were there physical factors (e.g. sickness or injury) making it hard for you to be physically active?" In case the participants give a positive answer, they will be asked to describe the physical factor.

**Textbox 1.** Overview of the questions assessing participants' satisfaction with the website and the mobile app.

**Satisfaction with the website (scale: 1 - very poor to 10 - outstanding):**

1. Overall, to what extent did you like the website of 'MyPlan 2.0'?
2. To what extent did you like the quiz?
3. To what extent did you like the questionnaire and the accompanying feedback?
4. To what extent did you like the action planning module?
5. To what extent did you like the coping planning module?
6. To what extent did you like the tips and tricks section?
7. To what extent did you like the feedback in the follow-up sessions?

**Satisfaction with the mobile app (scale: 1 - very poor to 10 - outstanding):**

1. Overall, to what extent did you like the mobile application of 'MyPlan 2.0'?
2. To what extent did you like the quizzes?
3. To what extent did you like the monitoring module?
4. To what extent did you like the action planning module?
5. To what extent did you like the coping planning module?
6. To what extent did you like the points collection module?

**Satisfaction with "MyPlan 2.0" as a whole (scale: 1 - not at all to 5 - very much):**

1. Was the information and support delivered by 'MyPlan 2.0' comprehensible ?
2. Was the information and support delivered by 'MyPlan 2.0' useful?
3. Was the information and support delivered by 'MyPlan 2.0' personally relevant to you?
4. Was the information and support delivered by 'MyPlan 2.0' motivating?
5. Did you enjoy using 'MyPlan 2.0'?

### ***Usage of the Website and the Mobile App***

LifeGuide allows researchers to monitor website usage and time spent on the website. Participants from the intervention group who do not return to the website after receiving the reminder email will be contacted by phone by one of the researchers. The time point and number of these calls will be monitored for each participant.

### ***Satisfaction With the Website and the Mobile App***

Users' satisfaction with both the website and the mobile app will be assessed using questionnaires during the posttest and by analyzing the usage data. [Textbox 1](#) gives an overview of the questionnaire items and response categories. The questions are

based on items used in other studies examining the appreciation of online interventions [49,50]. Participants who did not use the mobile app will not receive the questions regarding appreciation of the mobile app. Time spent on the website and the number of optional pages visited will be assessed by analyzing the website usage data.

### **Dropout**

To gain insight into participants' reasons for attrition, several questions will be asked in case participants decide to quit using the program. [Textbox 2](#) gives an overview of the questions and their accompanying scale. These questions are created by the research team based on a viewpoint article regarding attrition in eHealth by Eysenbach [14].

**Textbox 2.** Overview of the questions about participants' reasons for attrition. Scale for all questions was 1 (not at all) to 5 (very much), except question number 17 (response options: yes/no).

1. 'MyPlan 2.0' lived up to my expectations.
2. The website of 'MyPlan 2.0' is userfriendly.
3. The mobile application of 'MyPlan 2.0' is userfriendly.
4. My diabetes educator reacted positively regarding my participation in 'MyPlan 2.0'.
5. My GP reacted positively regarding my participation in 'MyPlan 2.0'.
6. My friends and family reacted positively regarding my participation in 'MyPlan 2.0'.
7. 'MyPlan 2.0' helped me to be more physically active/to sit less.
8. The personal contact with the researchers of 'MyPlan 2.0' were an additional reason for me to participate.
9. Going through 'MyPlan 2.0' took a lot of my time.
10. Filling out the questionnaires took a lot of my time.
11. I did not like wearing the accelerometer.
12. I did not like being weighed and measured.
13. I doubted to participate in this study.
14. While taking part in the study drastic changes in my life occurred (e.g. death of a family member, had a (grand)child, new job, etc.).
15. I can work well with a computer.
16. When I have computer problems, I can rely on others to help me.
17. I also took part in other programmes targeting a healthy way of living.

## Informed Consent

All participants will be required to provide written informed consent before starting the study (ie, during the first home visit). Each participant will be informed about the design of the study, its purpose, confidentiality of data, and the fact that (s)he has the right to leave the study at any time without stating any reason.

## Adverse Effects

Adverse effects are defined as negative outcomes related to participation in the study. Possible adverse effects in this study might be injury or severe hypoglycemia resulting from increased physical activity. The occurrence of adverse effects will be recorded and evaluated for both the intervention and control groups.

## Data Storage

All data will be stored on a password-protected computer and central disk space. Data from the website will additionally be stored on password-encrypted servers. Only persons who are part of the research team will have access to the data. [Multimedia Appendix 3](#) presents the data-management plan.

## Incentives

To encourage participants to fill out their diaries, draw lots will be given based on the number of questions answered. The intervention group and the waiting-list control group will have equal chances to win prizes (ie, gift vouchers of popular supermarkets).

## Results

Development of the website and the mobile app is complete. The randomized controlled trial started in January 2018. As participants can start the study at different times, we aim to complete all testing by July 2019. Important protocol modifications will be reported on [Clinicaltrials.gov](#). The results of the study will be communicated via publications. For these publications, the American Psychological Association guidelines for authorship eligibility will be followed.

## Discussion

### Overview

Adopting an active lifestyle is key in the management of type 2 diabetes [3]. As the prevalence of adults with type 2 diabetes is increasing [1], self-management interventions that can be applied to large groups are welcomed. Online interventions have the possibility to reach many users at the same time and have shown to be effective in altering health behaviors, especially when they are theory based [4,9]. "MyPlan 2.0" is a theory-based website and mobile app for motivating and supporting adults with type 2 diabetes to be more physically active and less sedentary.

### Study Implications

This study will test the effectiveness of "MyPlan 2.0" for each phase of the behavior change process using a randomized controlled trial. More specifically, this trial will investigate whether the program can increase patients' physical activity and decrease their sitting time. Furthermore, we will determine whether these potential changes are mediated by alterations in

personal determinants for change and result in positive health outcomes. Through the diaries, we will gain more insight into patients' daily struggles to adopt an active way of living. Finally, potential differences based on participants' characteristics will be explored. Consequently, the implications of this study will contribute to the literature of both the theoretical and practical domain of eHealth and mHealth, targeting self-management in adults with type 2 diabetes.

This study design has several limitations. First, as the resources for this study are limited, we will not be able to collect a large sample size. Consequently, it might be more difficult to identify statistically significant intervention effects. This issue highlights the importance of preventing dropout from the intervention. Dropout will be prevented by sending reminders to participants who are not logging in for follow-up sessions on the website via emails and phone calls. Second, considering the important role of creating a feeling of "goal-ownership" in self-regulation theory, participants can freely choose between the components increasing physical activity and decreasing sedentary behavior. We can therefore not ensure that the two components will have the same number of users. As a result, it might be more difficult

to detect an effect for sedentary behavior if a large group selects physical activity as their target behavior and vice versa. As the structure of the intervention and the implemented behavior change techniques are exactly the same for both target behaviors, we decided to perform the analysis with one, rather than two, intervention groups. However, the selected behavior will be added as a moderator to the analysis. Third, in order to test our hypotheses, participants will need to fill out many questionnaires. This might cause higher levels of attrition. Fourth, participants are called weekly by the researchers to check for hypoglycemia or alterations in medication and to assess participants' personal determinants for change via an interview. Due to these weekly phone calls, participants might show higher levels of engagement with the intervention than they normally would. However, as we will also implement these weekly calls in the control group, we believe that the calls will have a limited impact on the intervention effects. Finally, as the researcher who will analyze the data will also be involved in the data-collection process, blinding of the data analyst is not possible. To account for this issue, a strict protocol has been developed for processing and analyzing the data.

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## Conflicts of Interest

None declared.

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## Authors' Contributions

LP, MV, IB, and GC designed the project. LD and SS provided additional input for the study design. LP wrote the original draft. GC, MV, IB, and LD edited the manuscript and provided feedback. All authors read and approved the final manuscript.

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## Multimedia Appendix 1

Completed SPIRIT checklist. SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials.

[[PDF File \(Adobe PDF File\), 182KB - resprot\\_v8i3e12413\\_app1.pdf](#)]

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## Multimedia Appendix 2

Screenshots from the website and the mobile app.

[[PDF File \(Adobe PDF File\), 693KB - resprot\\_v8i3e12413\\_app2.pdf](#)]

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## Multimedia Appendix 3

Data management file.

[[PDF File \(Adobe PDF File\), 450KB - resprot\\_v8i3e12413\\_app3.pdf](#)]

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## Abbreviations

**eHealth:** electronic health

**HAPA:** Health Action Process Approach

**IPAQ-L:** long International Physical Activity Questionnaire

**LASA:** Longitudinal Aging Study Amsterdam

**mHealth:** mobile health

**PROMIS:** Patient-Reported Outcomes Measurement Information System

**SPIRIT:** Standard Protocol Items: Recommendations for Interventional Trials

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents\*

Section/item	Item No	Description	Addressed on page number
<b>Administrative information</b>			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	Yes, clinicaltrials.gov
Protocol version	3	Date and version identifier	2
Funding	4	Sources and types of financial, material, and other support	22
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	22 and metadata file
	5b	Name and contact information for the trial sponsor	Metadata file
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	22
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	14

**Introduction**



Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	2,3
	6b	Explanation for choice of comparators	3-5
Objectives	7	Specific objectives or hypotheses	5
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	3

**Methods: Participants, interventions, and outcomes**

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	Not applicable
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	4
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	5, 11-15 and table 1
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	6
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	6

### **Methods: Assignment of interventions (for controlled trials)**

#### Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	4
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	4
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	4

Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6, 15, 21
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	Not applicable

**Methods: Data collection, management, and analysis**

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-13
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14, 15 and supplementary file 3
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14, 15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14, 15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14, 15

**Methods: Monitoring**

Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	14, 15
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	15
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	19
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	22
<b>Ethics and dissemination</b>			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	21
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	19
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	3, 19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	Not applicable
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	19 and supplementary file 3

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	22
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	19 and supplementary file 3
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	19
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	19, 20
	31b	Authorship eligibility guidelines and any intended use of professional writers	20
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Supplementary file 3

## Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available on request
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

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\*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.

# Data Management Plan

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## 1 Information about the data that will be collected or used

### 1.1 Description of the data that will be collected

A randomised controlled trial will be executed to test the effectiveness of 'MyPlan 2.0' to alter the levels of physical activity and sedentary behaviour of adults with type 2 diabetes. The data will be collected before, during and after the intervention. Furthermore, to investigate long term effects, a final testing phase will be performed six months after the first testing phase. We will use questionnaires to assess self-reported physical activity, sedentary behaviour and participants' psychosocial determinants for change (e.g. attitude, intention, etc.), in combination with motion sensors to assess objective physical activity/sedentary behaviour. Furthermore, via the use of diaries patients' daily stressors and goals to adopt an active lifestyle will be investigated. Participants' weight and waist circumference will be assessed via a weighing scale and a tape measure. Finally, other health outcomes such as lowered levels of fatigue will be assessed via questionnaires.

### 1.2 File formats that will be used

Website data (collected via LifeGuide software) and data from the mobile application will be extracted in Excel files and stored in one SPSS file. The physical activity and sedentary behaviour data will be retrieved from the accelerometers using ActiLife software. The format of the data will be '.AGD'. The SPSS file will be completed with the essence of these data. The diary data will be added to the same SPSS file. All data collected during each of three testing waves will be stored in three SPSS documents, one document per measurement time. After finalization of the data collection, data will be grouped in one SPSS file. Statistical analysis will be performed using R Studio.

### 1.3 Documentation of the data

- **Study level documentation:**

All contextual information, such as background, information about the research design, context of data collection, etc. will be documented in a study protocol, that will be updated regularly.

- **Data level documentation:**

An excel file inventory of the datasets will be made to list all the datasets and to document the relationships between the different datasets. Names of the SPSS files, containing the different datasets, will also be documented in this inventory.

Variable labels will be defined and stored in SPSS itself, where the data is stored and analyzed. All information about the variables included in these datasets will also be gathered in an excel codebook. The codebook will contain variable names, labels, codes, classification, abbreviations, item information, missing data codes, etc.

The steps that were taken to structure and analyze these data will be documented in a logbook.

## **1.4 Risks and potential difficulties during data collection and processing**

It is important to have enough data to conduct the analyses. To avoid drop out users not logging in for following sessions will be phoned by one of the researchers. To make sure that the measures are reliable and valid, we will make use of validated motion sensors and questionnaires. All data collected will be checked for missing values (e.g. a missing day in the motion sensor data) and loss of information.

## **1.5 Data storage**

To prevent loss, all data will be stored at the provided central storage infrastructure ("central share") of Ghent University, where the data are secure. Once retrieved, data will be deleted from recording devices and survey servers. Questionnaires will be stored in the foreseen cupboards in the department or in the archive of the faculty after scanning them and thus making the information digitally available.

## **1.6 Back-up of the data**

The central share of Ghent University, where all data will be stored, provides daily automated back-ups. On the share "snapshots" of the data are made. Snapshots allow you to retrieve (older versions of) files. To retrieve previous versions you can go back 15 weeks in total, based on 5 weeks of daily snapshots and 15 weeks of weekly snapshots.

## **1.7 Data security**

All cupboards (that store questionnaires and informed consents) are locked and can only be accessed by the researchers from our research group. All computers are provided with personal passwords and are weekly scanned for malware. Digital files will be coded, using participant codes instead of names. Only the researcher and the promoters will have access to a file containing the links between the codes and the personal data of the participants (name, address, etc.). All data will be stored at the central storage infrastructure of Ghent University and are therefore automatically protected. When destroying files after digitalizing them, we will make sure this is done properly by a shredder. Paper documents can also be collected and destroyed at university level.

## **1.8 Data access**

All researchers from our research team (two PhD students, one post-doctoral researcher and two promoters) will have access to the data. During this study master students will be involved in the data collection and will get access to (part of) the data as well. Therefore they will sign a declaration of confidentiality.

# **2 Ethical Issues**

## **2.1 Data collection, storage, processing and archiving**

Participants will be informed on every aspect of the study that concerns their participation (e.g. data collection and storage, anonymization, etc.) and give written informed consent for their participation. All the data will be stored and processed confidentially, in accordance with the Belgian Law of 8 December 1992 on the protection of privacy in relation to the processing of personal data, the Belgian law of 22 August 2002 on the rights of patients, and the European regulation of 14 April 2016 on data protection. This study was approved by the Committee of Medical Ethics of the Ghent University

hospital (Belgian registration number: B670201732566) and registered as clinical trial on <https://register.clinicaltrials.gov> (ID number: NCT03291171).

## **2.2 Data sharing**

All participants receive an information letter in which ethical and privacy consequences will be explained. Data will only be accessible to the persons described above. If (parts of) datasets are shared with other researchers, all shared data will be anonymized. Only the researcher and the promoters (and research assistants when they recruited the participants) will have the rights to link the data to the participants.



## Additional remarks

### ❖ The power analysis

The power analysis described in the protocol is based on a meta-analysis of Davies et al. (2012). This meta-analysis only included (quasi-) randomized controlled trials with a non-Internet comparison group. The results indicated that three types of control groups were used: care-as-usual (76%), minimal care (12%) or alternative care (12%).

### ❖ Cognitive interviews

The cognitive interviews assessing the clarity of the items of the diary and the items measuring personal determinants for change were conducted between 29/09/2017 and 03/10/2017.

### ❖ Gamification in 'MyPlan 2.0'

Users can collect points to win virtual prize cups (see figure 1). The “Intelligence cup” can be won by achieving high scores on the quizzes (see figure 2). The “Perseverance cup” is connected to the module in which the user can keep track of his/her behaviour (see figure 3). If the user monitors his/her behavioural changes on a daily basis he/she wins this cup. The last cup is het “Finishing cup”. After each session on the website users receive a point. After completing each of the five sessions the user wins this cup.



Figure 1. Overview of the virtual prize cups.



Figure 2. Collecting points to win the “Intelligence cup”.



Figure 3. Collecting points to win the “Perseverance cup”.



Figure 4. Collecting points to win the “Finishing cup”.





## CHAPTER 2.2

Effectiveness of a self-regulation-based e- and mHealth intervention targeting an active lifestyle in adults aged 50 or older and in adults with type 2 diabetes: two randomized controlled trials

Poppe L, De Bourdeaudhuij I, Verloigne M, Shadid S, Van Cauwenberg J, Compernelle S, Crombez G. Effectiveness of a self-regulation-based e- and mHealth intervention targeting an active lifestyle in adults aged 50 or older and in adults with type 2 diabetes: two randomized controlled trials. Submitted to Journal of Medical Internet Research.



# Effectiveness of a self-regulation-based e- and mHealth intervention targeting an active lifestyle in adults aged 50 or older and in adults with type 2 diabetes: two randomized controlled trials

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## **Abstract**

### **Background**

Adopting an active lifestyle plays a key role in the prevention and management of chronic diseases such as type 2 diabetes (T2D) and cardiovascular disease. Internet-delivered interventions are promising, especially if they are informed by a sound behaviour change theory. 'MyPlan 2.0' is a fully-automated e- and mHealth intervention targeting physical activity (PA) and sedentary behaviour (SB), based upon self-regulation theory. The programme was iteratively adapted based on users' feedback.

### **Objective**

Our objective was to test the short-term effects of 'MyPlan 2.0' in adults aged  $\geq 50$  and in adults with T2D.

### **Methods**

The study consisted of two randomized controlled trials in two samples: (1) adults aged  $\geq 50$  (N=63) and (2) adults with T2D (N=54). The primary outcomes were changes in objectively-measured and self-reported PA and SB, and changes in personal determinants for change. Linear mixed models were performed to analyse the effects of 'MyPlan 2.0' in the two samples.

### **Results**

In the RCT with adults aged  $\geq 50$  an intervention effect favouring the PA intervention group was found for self-reported total PA. Furthermore, intervention effects favouring the SB intervention group were found for self-reported time spent sitting as well as accelerometer-assessed moderate and moderate-to-vigorous PA. Intervention effects in favour of the intervention group were detected for the personal determinants 'self-efficacy', 'coping planning', 'intention' and 'monitoring'. In the RCT with adults with T2D, intervention effects favouring the PA intervention group were found for self-reported time spent sitting as well as accelerometer-measured moderate and moderate-to-vigorous PA. An intervention effect in favour of the SB intervention group was found for accelerometer-assessed breaks from sedentary time. Intervention effects favouring the intervention group were found for the personal determinants 'action planning' and 'monitoring'. However, intervention effects favouring the control group were detected for the personal determinants 'self-efficacy' and 'risk perception'.

### **Conclusions**

The self-regulation-based e- and mHealth intervention 'MyPlan 2.0' is promising in changing levels of



PA and SB in adults aged  $\geq 50$  and in adults with T2D. However, further research with larger samples is needed to confirm the consistency of these findings.

**Keywords**

eHealth; mHealth; physical activity; type 2 diabetes; older adults, HAPA; self-regulation

## Background

The increasing prevalence of chronic diseases, such as type 2 diabetes (T2D), cardiovascular disease and cancer, is considered a global threat as it challenges human, social as well as economic development [1, 2]. Adopting an active lifestyle (i.e. increasing physical activity (PA) and reducing sedentary behaviour (SB)) plays an important role in the prevention and management of these diseases [3, 4]. However, the majority of adults does not meet the guidelines considering PA and accumulates high levels of sitting time [4]. Even people with T2D, for whom adopting an active lifestyle is considered a cornerstone in the management of their disease, show high levels of physical inactivity and sedentary time [5, 6]. Consequently, interventions targeting alterations in PA and SB in adults from the general populations as well as in adults with T2D are needed. As the number of Internet and smartphone users increases, interest in e(electronic)- and m(mobile)Health interventions is growing [7]. E- and mHealth interventions offer several advantages as they can deliver fast and tailored information to large groups of individuals in a cost-effective way. The effectiveness of online interventions has been demonstrated for a wide range of health behaviours, including PA and SB [8, 9].

Interventions delivered via the Internet show stronger effects when they are grounded in sound behaviour change theories [10], of which self-regulation theory is one such framework. Self-regulation models, such as the Health Action Process Approach (HAPA), describe how people create and achieve personal goals, and which techniques can help them to do so [11, 12]. Whereas previous models mainly focus on how to strengthen an individual's intention for change [13, 14], the HAPA describes also how this intention can be transformed into a specific behaviour. For example, the self-regulation technique 'action planning' offers guidance in how to set up specific plans for action, whereas the technique 'barrier identification/problem solving' helps people to foresee and solve potential barriers to perform these plans [12]. The HAPA has been used to predict and alter a wide range of behaviours in a large variety of populations [15, 16]. During the last years, this theoretical framework has also been used for developing online interventions [17-20]. For example, 'SmartMobiel', an eHealth intervention informed by the HAPA-model was found to be effective in increasing PA in adults [21].

'MyPlan 2.0' is a HAPA-based e- and mHealth intervention supporting adults to increase PA or to reduce SB. The intervention consists of (1) a website offering weekly sessions to create and evaluate personal goals, and (2) an optional mobile application providing daily support. Its precursor, 'MyPlan 1.0', was found effective in increasing PA [22], but showed high attrition rates [23]. To improve adherence, qualitative studies were performed in adults from the general population and in adults

with T2D. Results were used to improve the content and the design of the intervention [24-26]. For example, many users did not fully understand particular self-regulation techniques and considered the programme as time-inefficient. These problems were addressed by simplifying the implementation of the techniques, providing a rationale for the use of the self-regulation techniques, and shortening texts. Taking into account that many people had difficulties to navigate through the website, the interface was also simplified. We also added diabetes-specific information.

The aim of this study was to investigate the effectiveness of 'MyPlan 2.0' in adults from the general population and in adults with T2D via two randomized controlled trials (RCTs). It was decided to recruit adults from the general population from a similar age cohort as people with type 2 diabetes. Consequently, participants of RCT 1 were adults from the general population aged 50 years or older [27, 28]. Participants of RCT 2 were adults diagnosed with T2D.

## **Methods**

### **Study design and procedure**

Two RCTs with a parallel group design were conducted to investigate the effectiveness of 'MyPlan 2.0' on PA, SB, and on HAPA-based determinants. The protocol was preregistered [29]. The sample of adults aged  $\geq 50$  years was recruited via advertisements in local newspapers and via snowball sampling. The inclusion criteria were (1) being  $\geq 50$  years of age, (2) being Dutch-speaking, (3) being computer literate, (4) having Internet access and (5) not having participated in the qualitative study about 'MyPlan 2.0'. Adults with T2D were recruited via the Ghent University Hospital and the Damian General Hospital (Ostend). However, recruitment via the hospitals was slow. Therefore, in contrast with the recruitment process described in the protocol, we also advertised the study via the Flemish Diabetes Association and in adults with T2D who participated in previous research of the involved research groups. To be eligible, patients with T2D had to (1) have their diagnosis since at least one month, (2) be 18 years or older, (3) be Dutch-speaking, (4) be computer literate, (5) have Internet access, and (6) not have participated in the qualitative study about 'MyPlan 2.0'.

After enrolment, participants were visited by one of the researchers. During the home visit, the researcher explained the difference between PA and SB and asked the participants to select a target behaviour (i.e. increasing PA or decreasing SB). They completed questionnaires assessing (1) demographic information, (2) their current level of PA and SB and (3) HAPA-based personal determinants to change the selected health behaviour. Participants' weight and waist circumference were assessed. Participants were instructed to wear an ActiGraph (type GT3X+) accelerometer for ten consecutive days starting the day after the home visit. After these ten days, participants were

allocated by LP to the intervention or the waiting-list control group using a 2:1 ratio. This was done via the website [randomization.com](http://randomization.com). Participants allocated to the waiting-list control group were informed about their allocation, and instructed to continue with their life as usual. Participants allocated to the intervention group received access to the MyPlan 2.0 website and the mobile application. Participants who selected to focus on their level of PA were guided to the version targeting PA (PA intervention group; url: [www.mijnactieplan.be/meerbewegen](http://www.mijnactieplan.be/meerbewegen)), whereas participants who selected to alter their level of SB were guided to the version targeting SB (SB intervention group; url: [www.mijnactieplan.be/minderzitten](http://www.mijnactieplan.be/minderzitten)). They were instructed to go through each of the weekly sessions (five in total) offered by the website. Participants who forgot to log in were contacted by a researcher via e-mail and informed about the next session. If the participant did not respond, he or she was contacted via telephone. As having a smartphone was not an inclusion criterion, it was not obligatory to use the mobile application. To monitor any adverse effects (e.g. hypoglycaemia), all participants were weekly phoned by a member of the research team.

After completing all sessions (PA and SB intervention groups) or the five-week waiting period (control group), a second home visit was arranged. During this second home visit participants completed the same assessments as at baseline. Participants who decided to leave the study were contacted by one of the researchers and asked if they were willing to complete a questionnaire assessing potential reasons for attrition. Except during the pre-test, participants, nor researchers assessing the outcome variables were blinded.

All data were collected between January and September 2018. The RCTs were approved by the Committee of Medical Ethics of the Ghent University hospital (Belgian registration numbers: BE670201731996 (RCT 1) and B670201732566 (RCT 2)).

### **MyPlan 2.0**

'MyPlan' 2.0 is a fully-automated HAPA-based e- and mHealth intervention consisting of a website and an optional mobile application. The used techniques are mentioned below and labelled according to the taxonomy of behaviour change techniques of Michie and colleagues [30].

#### The website

The website-part of 'MyPlan 2.0' offers five sessions with a period of one week between each session. The two versions of the programme (one targeting PA and one targeting SB) have an identical structure and offer the same self-regulation techniques. During the first session users create a profile, complete an optional quiz regarding the benefits of the chosen health behaviour (i.e. increasing PA or reducing SB) (*providing information on consequences of behaviour*), fill out a questionnaire assessing their current level of PA/SB and receive tailored feedback (*providing*

*feedback on performance*), create a personal action plan to alter the chosen health behaviour (*action planning*), foresee potential barriers and search for solutions (*barrier identification/problem solving*) and select how they will monitor their behaviour (*prompting self-monitoring of behaviour*). At the end of the first session, users' answers are summarized in a printable action plan and users are offered optional information about how they can obtain support from their partner, friends, family or colleagues (*exploring social support*). Figure 1 shows the flow of the first session.

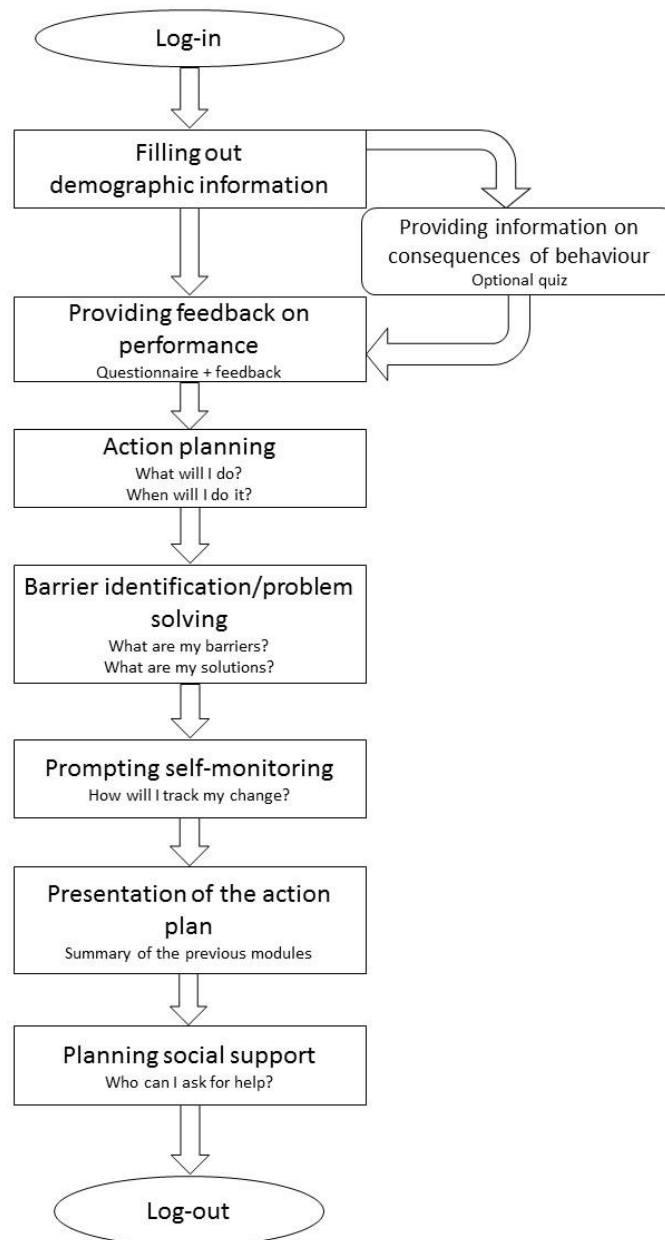


Figure 1. Flow of the first session

After one week users receive an email to start the second session. The follow-up sessions (i.e. sessions two to five) have a similar structure. After logging in, users are asked to what extent they reached the goal set in the previous session (*prompting review of behavioural goals*) and asked

whether they would like to keep or adapt this goal. When choosing the latter, the user is guided to the action planning section. All users again foresee potential barriers to reach the goal and search for solutions. Finally, their answers are summarized in a printable action plan and users are optionally offered additional tips and tricks (e.g. “Try to take the stairs instead of using the elevator”) to become more physically active or less sedentary. Figure 2 depicts the flow of the follow-up sessions.

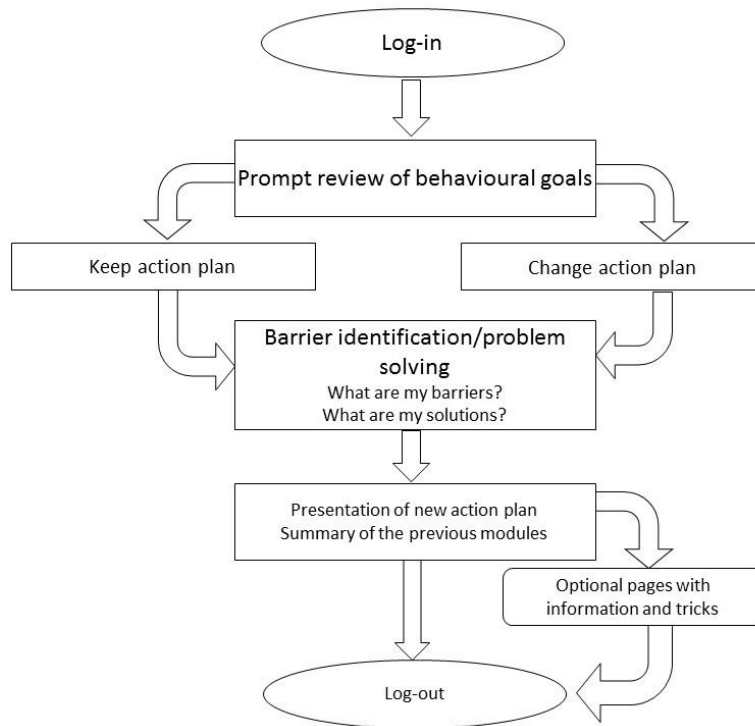


Figure 2. Flow of the follow-up sessions

### The mobile application

The mobile application consists of five modules through which users can freely navigate. The first module supports users in monitoring their behaviour (*prompting self-monitoring of behaviour*). Every evening, users receive a notification to report the extent to which they were able to be more physically active, or to sit less (“not at all”, “not”, “a little”, “well”, “very well”). These entries are then shown in a graph displaying all responses of the week. The second module allows users to review their weekly goals (created on the website) and make adaptations to these goals (*action planning*). The option to review potential problems and their solutions is offered in the third module (*barrier identification/problem solving*). In the fourth module users can perform quizzes on the benefits of being more physically active or less sedentary (*providing information on the consequences of behaviour*). Finally, users can collect points by visiting the website, completing quizzes and monitoring their behaviour. By collecting these points users could earn the victory cups implemented

in the mobile application. This gamification element was added in order to increase engagement with the mobile application.

## **Measurements**

### Questionnaires

An ad hoc questionnaire assessed age, sex, height, civil status, level of education and time since diagnosis (only for participants with T2D). Participants who completed college or university were considered highly-educated.

The Dutch, long version of the International Physical Activity Questionnaire (IPAQ) [31] assesses self-reported PA of the past week in four domains (work, transport, household and leisure time) and provides indicators for work-related PA, transport-related PA, household-related PA, leisure-related PA, total PA, vigorous-intensity PA (VPA) and moderate-to-vigorous-intensity PA (MVPA) per week. The IPAQ has good reliability (intra-class range from 0.46 to 0.96) and a fair-to-moderate criterion validity (Spearman's rho between 0.30 and 0.37) [31]. Because the IPAQ overestimates PA [32], the data was truncated according to the method described by Dubuy et al. [33]. The LASA Sedentary Behaviour Questionnaire [34], which has moderate reliability (intra-class = 0.71) and moderate validity (Spearman's rho = 0.35), was used to assess usual total sedentary time on weekdays. Data were truncated at a maximum of 16 hours of sitting time a day [35]. Both questionnaires were conducted via an interview by the visiting researcher.

Participants' determinants for behaviour change (i.e. self-efficacy, risk perceptions, outcome expectations, intention, action planning, coping planning and self-monitoring) were measured using multiple items with a minimum of three items per determinant. To select these items a large number of items measuring HAPA-determinants were presented to 11 experts in the self-regulation framework. All experts indicated for each item whether or not it measured the presented HAPA determinant and how certain they were of their answer [36]. Based on their responses a discriminant content validity method was used [36] and the best scoring items were selected. To assure comprehensibility of these items cognitive interviews were conducted with four adults (mean age: 58.3 (SD = 6.5), three women, two having T2D and two with college degree or higher). Based on the results of these interviews the final items were selected and adapted. Each item was assessed using ten answer options ranging from "completely disagree" to "completely agree". For each personal determinant a mean score (potential range: 1-10) was calculated.

### Accelerometry

ActiGraph accelerometers (type GT3X+), shown to be reliable and valid [37-40], were used to assess participants' number of breaks in sedentary time, average length of the sedentary bouts, total

sedentary time, number of steps, light PA (LPA), moderate PA (MPA), VPA, MVPA and total PA. Participants were instructed to wear the accelerometer on the right hip during waking hours, but to remove it for water-based activities (e.g. showering). Actilife 6.13.3 software was used to initialize the accelerometers and to process the data. The epoch was set at 60 seconds and non-wear time was calculated as  $\geq 60$  minutes of consecutive zero counts. Participants' accelerometer data were included in the study when they had at least four valid days including one weekend day (with valid defined as  $\geq 10$  hours of wearing time) [41]. Using the cut points described by Freedson and colleagues [42] each minute of wear time was categorised as sedentary (0 – 99 counts per minute (CPM)), LPA (100 – 1951 CPM), MPA (1952-5724), VPA (5725 – 9498) or MVPA ( $\geq 1952$  CPM). Total PA was calculated by combining LPA and MVPA. A bout of sedentary time was considered a period of at least ten consecutive minutes  $< 99$  counts with zero tolerance allowed. A break from a sedentary bout was defined as a transition from  $< 99$  CPM to  $> 99$  CPM between two sedentary bouts.

### Antropometry

A Seca weighting scale (type 813) and a Seca measuring tape were used to assess participants' weight and waist circumference. Waist circumference was measured at the lowest rib margin and the iliac crest at the midaxillary line. During each testing wave, participants' weight and waist circumference was measured twice. In case the difference between the two measurements was  $> 100$  grams or  $> 1$  cm, the measurement was performed a third time. The mean of the measurements was calculated as the final score.

### **Hypotheses**

Similar hypotheses were formulated for both RCTs. Regarding physical activity, we hypothesized that 'MyPlan 2.0' would have a positive effect on the levels of total and MVPA in the PA intervention group compared to the control group. We expected to find this effect in the data from the self-report questionnaire (i.e. the IPAQ) and from the accelerometer. Regarding sedentary behaviour, we hypothesized that 'MyPlan 2.0' would reduce total sitting time, measured via the LASA questionnaire and the accelerometer, in the SB intervention group compared to the control group. Furthermore, as the intervention focuses on limiting sedentary time as well as interrupting periods of prolonged sitting, we expected to find an increase in breaks from sedentary time and a decrease in the length of the sedentary bouts in the intervention group targeting SB compared to the control group. Regarding the personal determinants for change, we expected that 'MyPlan 2.0' would increase participants' self-efficacy, outcome expectations, intention, action planning, coping planning and self-monitoring. No hypotheses regarding participants' risk perception were made as 'MyPlan 2.0' does not specifically target this personal determinant.



## Statistical analysis

The data from both RCTs were analysed separately using R version 3.2.5 [43]. Nevertheless, the analyses are similar for both RCTs.

Group comparability at baseline between the two intervention groups (PA intervention group and SB intervention group) and the control group was investigated using one-way ANOVA (for the quantitative variables) and chi-square tests (for the qualitative variables). T-tests and  $\chi^2$ -tests were used to perform the dropout analysis. Linear mixed models (two levels: repeated measures clustered within participants) were performed using the 'lme4-package' [44] to investigate the effect of 'MyPlan 2.0' on levels of PA, SB and personal determinants for change [45]. In contrast to multivariate analysis of variance (MANOVA), the linear mixed model can easily handle missing data in repeated measures [46]. In the protocol we stated that we would consider participants' choice of target behaviour (i.e. PA or SB) as moderator. However, because we were not able to recruit large enough samples, we decided to perform the analyses on the behavioural outcomes with a group variable (i.e. the PA intervention group, the SB intervention group, and the control group).

All participants filled out one version of the HAPA-based determinants (i.e. the version focusing on PA or the version focusing on SB). As described in the protocol, we planned to account for this issue by considering the choice of target behaviour (i.e. PA or SB) as moderator. However, considering the small sample size, we decided to combine the PA intervention group and the SB intervention group as one intervention group for analysing the effect on the personal determinants. By doing so, we considered these outcome variables as personal determinants regarding the chosen health behaviour rather than personal determinants regarding increasing PA or decreasing SB.

Due to the low prevalence of accelerometer-based VPA (no VPA at baseline was detected in 67.69% of the sample in RCT 1 and in 94.23% of the sample in RCT 2), self-reported VPA (no self-reported VPA at baseline was detected in 73.44% of the sample in RCT 1 and in 79.63% of the sample in RCT 2) and self-reported work-related PA (no self-reported work-related PA at baseline in 65.63% of the sample in RCT 1 and in 68.52% of the sample in RCT 2) in both samples, these specific outcome variables were not analysed.

Distribution of the dependent variables was first checked using Shapiro-Wilk tests. Normally distributed dependent variables were analysed using the 'lmer' function of the 'lme4'-package [44]. For non-normally distributed variables we compared models with different variance and link functions (i.e. Gaussian with Identity; Gamma with Log; Gamma with Identity; Poisson with Log; Negative binomial with Log) using the Bayesian Information Criterion (BIC). For each dependent

variable we selected the model providing the lowest BIC-value. By exploring the interaction between time and condition (i.e. intervention versus control) the effect of the intervention on the dependent variable was assessed. The beta-values for 'Time\*Condition' reported in the results section describe the difference between the change in the intervention group and the change in the control group. Consequently, these values represent the intervention effect for each dependent variable. P-values <.05 were considered statistically significant, whereas *p*-values between .05 and .10 were considered borderline significant.

Effect sizes were calculated for each of the dependent variables in both groups [47]. As recommended by Morris [48], the pooled pretest standard deviation was used to estimate the effect sizes.

## **Results**

The results of the two RCTs are reported separately. The first section will describe the results of the RCT with the sample aged ≥50 years, whereas the second section will describe the results of the RCT with the sample with T2D.

### **RCT with the sample aged ≥50 years**

Figure 3 shows the flow of the participants. Sixty-five participants agreed to participate in the study. As we do not know how many people saw the advertisements, the response rate could not be calculated. Two participants dropped-out before completing the baseline measurements. Consequently, the data of 63 participants was analysed. Of the 8 participants who dropped out before completing 4 sessions only one participant was willing to complete the questionnaire assessing specific reasons for attrition. The participant indicated that 'MyPlan 2.0' did not meet her expectations and that her friends or family did not respond positively to her participation in the study. Furthermore, she indicated that the high number of research-related questionnaires frustrated her.

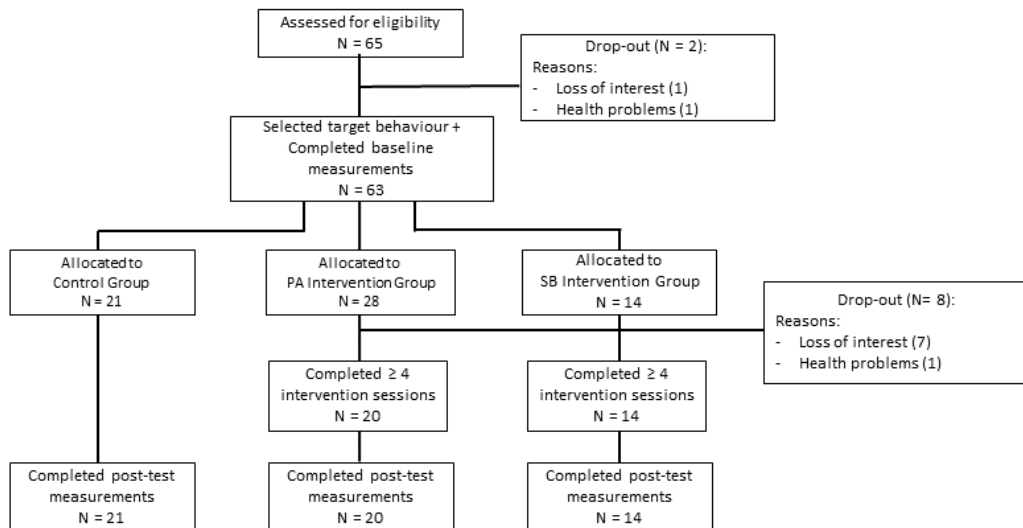


Figure 3. Flow of the sample aged  $\geq 50$  years

Participants' characteristics are provided in Table 1. At baseline, 46 participants decided to focus on PA (28 of these participants were later allocated to the PA intervention group) and 17 participants chose to focus on SB (14 of these participants were later allocated to the SB intervention group). Consequently, the PA intervention group consisted of 28 participants and the SB intervention group consisted of 14 participants. No significant baseline differences in sociodemographic characteristics were found between the PA intervention group, the SB intervention group and the control group. Five participants used the optional mobile application. The dropout analyses indicated that participants with a lower level of education (i.e. no college or university degree) [ $\chi^2(1) = 3.23$ ,  $P = 0.07$ ] and participants allocated to the intervention group [ $\chi^2(1) = 3.02$ ,  $P = 0.08$ ] were more likely to dropout. No significant dropout effects were found for age, sex, BMI, total PA at baseline (accelerometer-measured) or sedentary time at baseline (accelerometer-measured).

Table 1. Characteristics of the sample aged  $\geq 50$  years.

	<b>Total Sample (n = 63)</b>	<b>CG (n = 21)</b>	<b>IG – PA (n = 28)</b>	<b>IG – SB (n = 14)</b>	<b>F/<math>\chi^2</math></b>	<b>P-value</b>
<b>Age (mean <math>\pm</math> SD years)</b>	58.68 $\pm$ 7.76	57.67 $\pm$ 7.18	59.00 $\pm$ 7.98	59.57 $\pm$ 8.55	0.29	.75
<b>Sex (% male)</b>	25.40	28.57	14.29	42.86	4.19	.12
<b>Level of education (% high = university/college)</b>	60.32	61.90	50.00	78.57	3.22	.20
<b>BMI (mean <math>\pm</math> SD kg/m<sup>2</sup>)</b>	25.91 $\pm$ 3.86	25.29 $\pm$ 4.07	26.14 $\pm$ 3.94	26.34 $\pm$ 3.55	0.40	.68
<b>Waist circumference (mean <math>\pm</math> SD cm)</b>	89.08 $\pm$ 12.89	89.03 $\pm$ 14.69	89.26 $\pm$ 11.22	91.51 $\pm$ 13.93	0.48	.62

CG = Control Group, IG = Intervention Group

Table 2 displays the results of the mixed models testing the intervention effect on the behavioural outcomes. A significant intervention effect favouring the PA intervention group was identified for self-reported total PA ( $P = .003$ ). Borderline significant intervention effects favouring the SB intervention group, were found for self-reported daily sitting ( $P = .08$ ), MPA ( $P = .06$ ) and MVPA ( $P = .07$ ). No intervention effects were detected for the outcome variables self-reported total transport-related PA, self-reported total household-related PA, self-reported total leisure-related PA, accelerometer-assessed MVPA, accelerometer-assessed number of breaks per day, accelerometer-assessed length of the sedentary bouts, accelerometer-assessed sedentary time, accelerometer-assessed LPA, accelerometer-assessed total PA or accelerometer-assessed daily steps.

Table 2. Intervention effects (time by group interactions) on the behavioural outcomes in the sample aged ≥50.

Behavioural outcomes	CG mean ± SD	IG – PA mean ± SD	IG – SB mean ± SD	Time * Group PA (Ref: pre * CG) B(SE)	d (IG-PA vs. CG)	Time * Group SB (Ref: pre * CG) B(SE)	d (IG-SB vs. CG)
<b>LASA questionnaire</b>							
Total sitting time (min/day) <sup>c</sup>	Pre: 414.21 ± 187.08 Post: 421.52 ± 189.29	Pre: 378.39 ± 182.25 Post: 335.25 ± 167.12	Pre: 615.00 ± 195.46 Post: 549.69 ± 175.37	-0.06 (0.07)	-0.27	<b>-.14 (.08)*</b>	-0.37
<b>IPAQ</b>							
Total transport-related PA (min/day) <sup>c</sup>	Pre: 13.30 ± 15.29 Post: 11.29 ± 12.93	Pre: 16.17 ± 35.33 Post: 17.89 ± 13.32	Pre: 28.98 ± 40.10 Post: 12.40 ± 15.48	0.26 (0.77)	0.13	-0.69 (0.88)	-0.43
Total household-related PA (min/day) <sup>c</sup>	Pre: 38.01 ± 41.71 Post: 58.88 ± 70.27	Pre: 35.08 ± 36.66 Post: 75.00 ± 78.41	Pre: 42.40 ± 51.65 Post: 50.56 ± 37.63	0.32 (0.65)	0.49	-0.26 (0.75)	-0.26
Total leisure-related PA (min/day) <sup>c</sup>	Pre: 45.99 ± 68.62 Post: 39.08 ± 39.40	Pre: 19.24 ± 27.66 Post: 28.04 ± 31.95	Pre: 26.58 ± 31.16 Post: 36.33 ± 37.84	0.54 (0.76)	0.32	0.48 (0.87)	0.35
Total PA (min/day) <sup>a</sup>	Pre: 134.57 ± 96.05 Post: 117.55 ± 86.04	Pre: 109.39 ± 107.99 Post: 168.93 ± 99.52	Pre: 98.42 ± 94.30 Post: 104.18 ± 48.76	<b>73.85 (25.80)**</b>	0.74	22.79 (28.92)	0.24
MVPA (min/day) <sup>c</sup>	Pre: 65.20 ± 73.66 Post: 64.25 ± 75.19	Pre: 63.88 ± 81.80 Post: 106.39 ± 78.42	Pre: 36.12 ± 39.59 Post: 60.61 ± 38.70	0.52 (0.66)	0.55	0.53 (0.76)	0.48
<b>Accelerometer</b>							
Number of breaks per day <sup>a</sup>	Pre: 13.61 ± 3.60 Post: 12.81 ± 3.27	Pre: 13.01 ± 2.19 Post: 12.02 ± 2.43	Pre: 15.02 ± 2.22 Post: 14.10 ± 2.76	-0.30 (0.63)	-0.07	-0.36 (0.71)	-0.04
Length of sedentary bouts (min/day) <sup>a</sup>	Pre: 20.78 ± 2.50 Post: 20.60 ± 3.02	Pre: 20.77 ± 2.08 Post: 20.42 ± 2.50	Pre: 22.19 ± 2.19 Post: 21.95 ± 2.66	-0.12 (0.59)	-0.08	-0.11 (0.66)	-0.03
Sedentary time (min/day) <sup>a</sup>	Pre: 482.41 ± 76.11 Post: 460.11 ± 75.94	Pre: 472.52 ± 65.42 Post: 450.09 ± 64.09	Pre: 512.94 ± 50.07 Post: 486.94 ± 73.86	-4.76 (16.97)	-0.002	-8.90 (19.08)	-0.06
LPA (min/day) <sup>a</sup>	Pre: 306.08 ± 89.43 Post: 316.74 ± 74.81	Pre: 337.39 ± 80.84 Post: 348.74 ± 81.03	Pre: 262.25 ± 53.62 Post: 270.39 ± 61.93	2.12 (12.79)	0.008	0.70 (14.29)	-0.04

MPA (min/day) <sup>b</sup>	Pre: 29.13 ± 21.70	Pre: 24.35 ± 11.37	Pre: 26.26 ± 21.29	2.36 (2.76)	-0.05	<b>7.85 (4.17)*</b>	0.40
	Post: 22.70 ± 14.56	Post: 17.14 ± 10.40	Post: 28.27 ± 17.09				
MVPA (min/day) <sup>b</sup>	Pre: 29.33 ± 22.07	Pre: 24.96 ± 12.26	Pre: 28.96 ± 23.40	1.64 (2.78)	-0.11	<b>7.50 (4.21)*</b>	0.34
	Post: 23.51 ± 14.75	Post: 17.23 ± 10.53	Post: 30.94 ± 17.62				
Total PA (min/day) <sup>a</sup>	Pre: 335.41 ± 91.72	Pre: 362.36 ± 82.76	Pre: 291.20 ± 66.53	1.71 (14.43)	-0.02	7.23 (16.14)	0.07
	Post: 340.25 ± 73.81	Post: 365.98 ± 87.64	Post: 301.33 ± 73.21				
Daily steps <sup>a</sup>	Pre: 7929.68 ± 2976.07	Pre: 8271.67 ± 2464.25	Pre: 7809.16 ± 3231.18	-91.16 (553.35)	-0.17	763.22 (619.53)	0.26
	Post: 7779.78 ± 2147.86	Post: 7663.54 ± 2797.72	Post: 8479.68 ± 3343.09				

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CG = Control Group, IG = Intervention Group

\*\*\* p<.001 \*\*p<.01 \*p<.05 \*p<.10

<sup>a</sup> Gaussian (identity), <sup>b</sup> Gamma (identity), <sup>c</sup> Gamma (log)

Table 3 displays the results of the mixed models testing the intervention effect on participants' personal determinants for change. As described above, the PA intervention group and the SB intervention group were considered as one group to analyse the effect on the personal determinants. For coping planning a significant intervention effect favouring the intervention group was found ( $P < .001$ ). Furthermore, borderline significant intervention effects favouring the intervention group were found for intention ( $P = .07$ ), self-efficacy ( $P = .05$ ) and monitoring ( $P = .09$ ). No intervention effect was found for outcome expectancies, risk perception or action planning.

Table 3. Intervention effects (time by group interactions) on personal determinants for change in the sample aged  $\geq 50$ .

Personal Determinants	CG mean $\pm$ SD	IG mean $\pm$ SD	Time * Group (Ref: Pre * CG) B(SE)	d
Self-efficacy <sup>b</sup>	Pre: 5.84 $\pm$ 2.67 Post: 5.66 $\pm$ 2.08	Pre: 6.13 $\pm$ 1.82 Post: 6.71 $\pm$ 1.71	<b>0.76 (0.39)<sup>*</sup></b>	0.37
Outcome expectancies <sup>b</sup>	Pre: 7.27 $\pm$ 1.32 Post: 7.32 $\pm$ 1.59	Pre: 7.31 $\pm$ 1.41 Post: 7.30 $\pm$ 1.21	0.30 (0.27)	-0.04
Risk perception <sup>c</sup>	Pre: 2.64 $\pm$ 1.82 Post: 2.57 $\pm$ 1.84	Pre: 3.79 $\pm$ 2.09 Post: 3.83 $\pm$ 2.30	-0.07 (0.08)	0.05
Action planning <sup>b</sup>	Pre: 5.49 $\pm$ 2.27 Post: 5.40 $\pm$ 2.29	Pre: 5.63 $\pm$ 2.24 Post: 5.25 $\pm$ 2.16	0.05 (0.65)	-0.13
Coping planning <sup>b</sup>	Pre: 3.84 $\pm$ 2.69 Post: 3.32 $\pm$ 1.78	Pre: 3.32 $\pm$ 2.30 Post: 5.65 $\pm$ 2.04	<b>2.59 (0.50)<sup>***</sup></b>	1.19
Intention <sup>b</sup>	Pre: 7.19 $\pm$ 2.11 Post: 6.81 $\pm$ 2.57	Pre: 7.83 $\pm$ 1.88 Post: 7.78 $\pm$ 1.70	<b>0.93 (0.51)<sup>*</sup></b>	0.17
Monitoring <sup>b</sup>	Pre: 2.46 $\pm$ 2.40 Post: 2.16 $\pm$ 1.69	Pre: 2.65 $\pm$ 1.77 Post: 3.60 $\pm$ 2.36	<b>0.57 (0.34)<sup>*</sup></b>	0.65

CG = Control Group, IG = Intervention Group

\*\*\*  $p < .001$  \*\*  $p < .01$  \*  $p < .05$  <sup>\*</sup>  $p < .10$

<sup>a</sup> Gaussian (identity), <sup>b</sup> Gamma (identity), <sup>c</sup> Gamma (log)

### RCT with the sample with T2D

Figure 4 shows the flow of the participants with T2D. Fifty-eight participants agreed to participate in the study. Of this sample, 18 participants were recruited via the Ghent University Hospital, 8 via the

Damian General Hospital, 24 via the Flemish Diabetes Association and 8 via previous studies. As we do not know how many patients saw the advertisements, the response rate could not be calculated. Four participants dropped-out before completing the baseline measurements. Consequently, the data of 54 participants was analysed. Of the 14 participants who dropped out before completing four sessions only 3 participants (all belonging to the control group) were willing to complete the questionnaire assessing specific reasons for attrition. One participant indicated that he doubted to participate at the beginning of the study, two participants indicated that drastic changes in their life occurred while participating. Finally, one participant indicated that the high number of research-related questionnaires frustrated her.

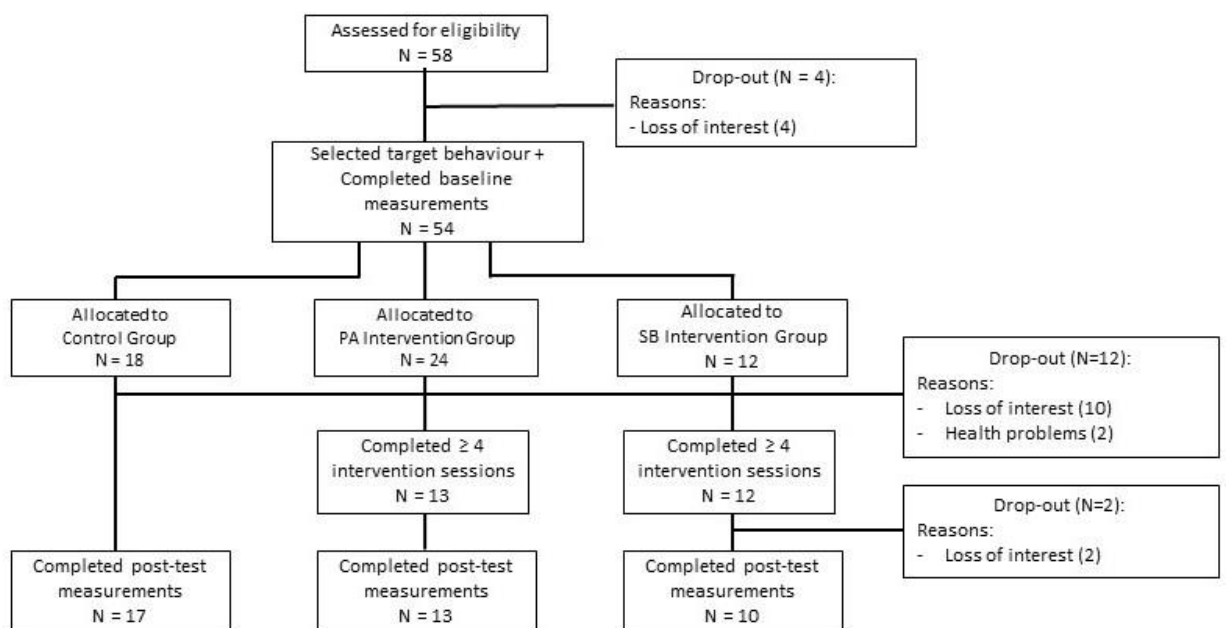


Figure 4. Flow of the sample with T2D

Participants' characteristics are provided in Table 4. At baseline, 32 participants decided to focus on PA (24 of these participants were later allocated to the intervention group) and 22 participants chose to focus on SB (12 of these participants were later allocated to the intervention group). Consequently, the PA intervention group consisted of 24 participants and the SB intervention group consisted of 12 participants. No significant baseline differences in sociodemographic characteristics were found between the PA intervention group, the SB intervention group and the control group. Seven participants used the optional mobile application. The dropout analyses indicated that participants allocated to the intervention group [ $\chi^2(1) = 4.35, P = .04$ ] were more likely to dropout. No significant differences between completers and drop-outs were found for age, sex, level of



education, BMI, time since diagnosis, total PA at baseline (accelerometer-measured) or sedentary time at baseline (accelerometer-measured).

Table 4. Characteristics of the sample having T2D

	<b>Total Sample (n = 54)</b>	<b>CG (n = 18)</b>	<b>IG – PA (n = 24)</b>	<b>IG – SB (n = 12)</b>	<b>F/<math>\chi^2</math></b>	<b>P-value</b>
<b>Age (mean <math>\pm</math> SD years)</b>	62.67 $\pm$ 8.40	64.89 $\pm$ 8.62	62.91 $\pm$ 7.16	58.92 $\pm$ 9.52	1.90	.16
<b>Sex (% male)</b>	62.96	50.00	70.83	66.67	2.01	.37
<b>Level of education (% high = university/college)</b>	53.70	66.67	41.67	58.33	1.85	.40
<b>BMI (mean <math>\pm</math> SD kg/m<sup>2</sup>)</b>	30.84 $\pm$ 5.66	30.51 $\pm$ 6.86	30.86 $\pm$ 5.35	31.25 $\pm$ 4.73	0.06	.94
<b>Waist circumference (mean <math>\pm</math> SD cm)</b>	109.23 $\pm$ 14.08	108.14 $\pm$ 18.38	109.16 $\pm$ 11.09	110.99 $\pm$ 13.06	0.14	.87
<b>Time since diagnosis (mean <math>\pm</math> SD months)</b>	129.78 $\pm$ 83.09	157.69 $\pm$ 67.08	100.18 $\pm$ 87.25	146.83 $\pm$ 82.94	2.73	.08

CG = Control Group, IG = Intervention Group

Table 5 displays the intervention effects on the behavioural outcomes. Borderline significant intervention effects favouring the PA intervention group were found for self-reported total daily sitting time ( $P = .09$ ) and accelerometer-assessed MPA ( $P = .052$ ) and MVPA ( $P = .05$ ). A significant intervention effect favouring the SB intervention group was found for accelerometer-assessed daily breaks from sedentary time ( $P = .005$ ). No intervention effects were found for self-reported total transport-related PA, self-reported total household-related PA, self-reported total leisure-related PA, self-reported total PA, self-reported MVPA, accelerometer-assessed length of the sedentary bouts, accelerometer-assessed sedentary time, accelerometer-assessed LPA, accelerometer-assessed total PA or accelerometer-assessed daily steps.

Table 5. Intervention effects (time by group interactions) on the behavioural outcomes in the sample with T2D.

Behavioural outcomes	CG mean ± SD	IG – PA mean ± SD	IG – SB mean ± SD	Time * Group PA (Ref: Pre * CG) B(SE)	d (IG-PA vs. CG)	Time * Group SB (Ref: pre * CG) B(SE)	d (IG-SB vs. CG)
<b>LASA questionnaire</b>							
Total sitting time (min/day) <sup>a</sup>	Pre: 553.06 ± 174.05 Post: 567.94 ± 211.84	Pre: 592.83 ± 232.52 Post: 470.38 ± 185.23	Pre: 599.17 ± 133.58 Post: 579.44 ± 188.84	<b>-102.50 (59.32)*</b>	-0.65	-4.61 (66.59)	-0.22
<b>IPAQ</b>							
Total transport-related PA (min/day) <sup>c</sup>	Pre: 18.02 ± 24.61 Post: 31.30 ± 36.60	Pre: 13.90 ± 25.70 Post: 29.34 ± 24.61	Pre: 35.54 ± 35.30 Post: 26.50 ± 23.16	0.19 (0.92)	0.09	-0.85 (1.05)	-0.76
Total household-related PA (min/day) <sup>c</sup>	Pre: 45.28 ± 71.89 Post: 46.89 ± 62.34	Pre: 63.33 ± 71.60 Post: 62.96 ± 56.18	Pre: 44.17 ± 78.15 Post: 67.29 ± 92.89	-0.04 (0.96)	-0.03	0.39 (1.10)	0.29
Total leisure-related PA (min/day) <sup>c</sup>	Pre: 16.35 ± 18.76 Post: 38.45 ± 59.88	Pre: 19.08 ± 25.59 Post: 30.61 ± 41.58	Pre: 38.63 ± 46.27 Post: 49.86 ± 74.39	-0.38 (0.99)	-0.46	-0.60 (1.13)	-0.33
Total PA (min/day) <sup>c</sup>	Pre: 86.07 ± 70.54 Post: 124.50 ± 96.02	Pre: 113.81 ± 90.52 Post: 143.83 ± 91.48	Pre: 137.98 ± 99.89 Post: 150.07 ± 100.48	-0.14 (0.52)	0.23	-0.29 (0.60)	-0.31
MVPA (min/day) <sup>c</sup>	Pre: 17.86 ± 24.37 Post: 61.98 ± 75.83	Pre: 53.19 ± 72.03 Post: 48.67 ± 41.35	Pre: 47.26 ± 67.18 Post: 63.57 ± 76.93	-1.33 (0.85)	-0.85	-0.95 (0.97)	-0.60
<b>Accelerometer</b>							
Number of breaks per day <sup>b</sup>	Pre: 16.63 ± 2.25 Post: 15.65 ± 2.87	Pre: 15.51 ± 3.08 Post: 14.64 ± 2.39	Pre: 16.88 ± 1.69 Post: 17.50 ± 1.45	0.28 (0.63)	0.04	<b>1.93 (0.69)**</b>	0.77
Length of sedentary bouts (min/day) <sup>b</sup>	Pre: 22.90 ± 2.70 Post: 23.46 ± 2.01	Pre: 22.34 ± 2.44 Post: 22.82 ± 2.64	Pre: 22.80 ± 1.57 Post: 23.22 ± 1.14	-0.50 (0.59)	-0.03	-0.46 (0.62)	-0.06
Sedentary time (min/day) <sup>b</sup>	Pre: 544.52 ± 56.24 Post: 537.77 ± 81.01	Pre: 528.09 ± 80.79 Post: 498.09 ± 43.81	Pre: 551.39 ± 56.66 Post: 555.21 ± 44.39	-19.71 (23.92)	-0.32	19.91 (25.00)	0.19

LPA (min/day) <sup>a</sup>	Pre: 239.34 ± 73.14 Post: 231.51 ± 76.84	Pre: 238.13 ± 67.23 Post: 244.46 ± 71.05	Pre: 218.87 ± 54.49 Post: 215.69 ± 37.91	7.02 (14.70)	0.20	-5.07 (14.94)	0.07
MPA (min/day) <sup>c</sup>	Pre: 23.14 ± 12.93 Post: 19.36 ± 14.77	Pre: 17.02 ± 15.70 Post: 25.50 ± 15.77	Pre: 20.15 ± 13.92 Post: 19.13 ± 14.06	<b>0.37 (0.19)*</b>	0.86	0.02 (0.92)	0.21
MVPA (min/day) <sup>c</sup>	Pre: 23.20 ± 12.92 Post: 19.36 ± 14.77	Pre: 17.07 ± 15.68 Post: 25.50 ± 15.77	Pre: 20.23 ± 13.87 Post: 19.38 ± 13.81	<b>0.37 (0.19)*</b>	0.84	0.06 (0.19)	0.39
Total PA <sup>a</sup>	Pre: 262.54 ± 78.58 Post: 267.17 ± 83.11	Pre: 255.19 ± 69.00 Post: 269.95 ± 78.24	Pre: 239.10 ± 48.83 Post: 235.07 ± 33.89	11.09 (15.47)	0.002	-4.54 (15.73)	-0.13
Daily steps <sup>a</sup>	Pre: 6203.10 ± 2284.41 Post: 6292.05 ± 2480.44	Pre: 5364.39 ± 2219.28 Post: 6549.71 ± 2313.67	Pre: 6083.88 ± 1343.30 Post: 6001.03 ± 1107.26	499.46 (543.12)	0.49	-302.11 (555.83)	-0.09

CG = Control Group, IG = Intervention Group

\*\*\* p<.001 \*\*p<.01 \*p<.05 \*p<.10

<sup>a</sup> Gaussian (identity), <sup>b</sup> Gamma (identity), <sup>c</sup> Gamma (log)

Table 6 displays the results of the mixed models testing the intervention effect on participants' personal determinants for change. Significant intervention effects favouring the control group were found for self-efficacy ( $P = .01$ ) and risk perception ( $P = .03$ ). A borderline significant intervention effect favouring the intervention group was found for action planning ( $P = .08$ ). Finally, a significant Time\*Group interaction effect favouring the intervention group was found for self-monitoring ( $P = .008$ ). No intervention effects were found for the personal determinants outcome expectancies, coping planning or intention.

Table 6. Intervention effects (time by group interactions) on personal determinants for change in the sample with T2D.

Personal Determinants	CG mean $\pm$ SD	IG mean $\pm$ SD	Time * Group (Ref: Pre * CG) B(SE)	d
Self-efficacy <sup>b</sup>	Pre: 5.68 $\pm$ 1.98 Post: 6.88 $\pm$ 1.22	Pre: 6.35 $\pm$ 1.81 Post: 7.23 $\pm$ 1.61	<b>-1.24 (0.48)*</b>	-0.17
Outcome expectancies <sup>b</sup>	Pre: 7.03 $\pm$ 1.51 Post: 8.01 $\pm$ 1.10	Pre: 7.62 $\pm$ 1.63 Post: 8.04 $\pm$ 0.96	-0.09 (0.42)	-0.35
Risk perception <sup>a</sup>	Pre: 4.46 $\pm$ 1.81 Post: 5.10 $\pm$ 1.71	Pre: 5.16 $\pm$ 2.19 Post: 4.74 $\pm$ 2.05	<b>-1.17 (0.53)*</b>	-0.51
Action planning <sup>a</sup>	Pre: 5.41 $\pm$ 1.99 Post: 5.29 $\pm$ 2.21	Pre: 5.19 $\pm$ 2.32 Post: 6.09 $\pm$ 2.05	<b>1.18 (0.65)<sup>x</sup></b>	0.46
Coping planning <sup>b</sup>	Pre: 3.52 $\pm$ 2.43 Post: 4.69 $\pm$ 2.22	Pre: 3.95 $\pm$ 2.66 Post: 5.77 $\pm$ 2.32	0.79 (0.54)	0.25
Intention <sup>a</sup>	Pre: 6.87 $\pm$ 2.83 Post: 7.88 $\pm$ 1.26	Pre: 7.82 $\pm$ 2.11 Post: 8.06 $\pm$ 1.81	-0.87(0.76)	-0.32
Monitoring <sup>c</sup>	Pre: 4.65 $\pm$ 3.21 Post: 4.84 $\pm$ 2.98	Pre: 3.46 $\pm$ 2.61 Post: 5.17 $\pm$ 2.41	<b>0.47 (0.18)**</b>	0.54

CG = Control Group, IG = Intervention Group

\*\*\*  $p < 0.001$ , \*\*  $p < 0.01$ , \*  $p < 0.05$ , <sup>x</sup>  $p < 1.10$

<sup>a</sup> Gaussian (identity), <sup>b</sup> Gamma (identity), <sup>c</sup> Gamma (log)

## Discussion

This paper investigated the effect of a self-regulation-based e- and mHealth intervention ('MyPlan 2.0') targeting an active lifestyle in two samples: adults aged  $\geq 50$  and adults having T2D. 'MyPlan 2.0' is informed by self-regulation theory. In line with this theory, the online intervention does not prescribe a normative goal, but instead emphasizes the creation of personally relevant and feasible goals. As a result, users are allowed to adapt their goals based on the failure or success of their actions to reach the set goal. Two randomized controlled trials with an identical design were

conducted. In both RCTs, 'MyPlan 2.0' changed personal determinants and the related target behaviour. Although the pattern of results was overall in line with our hypotheses, the analyses revealed that the intervention was only significant for some indicators, probably due to a lack of statistical power.

The HAPA describes a number of personal determinants influencing the behaviour change process. 'MyPlan 2.0' affected various of these determinants. In the RCT with adults aged  $\geq 50$ , intervention effects favouring the intervention group were detected for self-efficacy (borderline), intention (borderline), coping planning and self-monitoring (borderline). In the RCT with the sample with T2D, an intervention effect in favour of the intervention group was found for action planning (borderline) and self-monitoring, but significant intervention effects favouring the control group were detected for the personal determinants risk perceptions and self-efficacy.

Some of these findings require additional attention. First, although targeted in the intervention, no intervention effect was found for outcome expectancies. This finding might be explained by a ceiling effect caused by the high levels of positive outcome expectancies at baseline in both RCTs. Indeed, our qualitative studies indicated that users often have an extensive knowledge of the benefits of adopting an active way of living [25, 26]. Second, although 'MyPlan 2.0' does not provide users with a pedometer or wearable automatically tracking users' behaviour change, both RCTs identified intervention effects favouring the intervention group for monitoring. Avery et al. found a negative effect of pedometer use on physical activity in people with type 2 diabetes and older adults, indicating that, without additional support, these populations find it difficult to effectively reflect on the information provided by this self-monitoring tool [49]. Our results indicate that prompting users to monitor their change and reviewing this change in the following session might be a feasible alternative to target self-monitoring in these samples. Third, the lack of effect for action planning in the RCT with adults aged  $\geq 50$  was unexpected, as this determinant was targeted in each session. Sniehotta and colleagues argue that action planning might play an important role for individuals who just started to put their intentions into actions, whereas coping planning will support individuals who have moved further in the behaviour change process to maintain their change under challenging conditions [50]. As the baseline levels of PA and SB of the RCT with the sample aged  $\geq 50$  are quite close to the health norms [51], it is possible that this group already knew how to plan their actions and consequently did not benefit from the action planning component. Similarly, considering the low levels of PA and high levels of SB in the RCT with adults with T2D at baseline, the lack of evidence for coping planning in the RCT with adults with T2D could be explained by the fact that this group was not yet ready to optimally benefit from the coping planning component.

'MyPlan 2.0' focused on altering users' level of PA and SB. In the RCT with the sample aged  $\geq 50$  an intervention effect favouring the PA intervention group was found for self-reported total PA. This effect is in line with previous research with 'MyPlan 1.0' in recently retired older adults [52]. In the RCT with adults with T2D borderline significant intervention effects favouring the PA intervention group were found for self-reported daily sitting and accelerometer-assessed MPA and MVPA. This is a promising result as a previous study by Silfee and colleagues testing a self-regulation-based intervention targeting PA in adults with T2D did not show behavioural effects despite the positive effect on personal determinants for change (including self-monitoring) [53]. The reduction we found in self-reported sedentary time might indicate that users preferred to perform MPA or MVPA on moments that were usually spent sitting (e.g. cycling instead of driving to work). The lack of evidence for self-reported domain-specific PA is in line with our hypotheses and can be explained by the fact that 'MyPlan 2.0' allows users to select each session a different PA-domain that is at that moment most relevant to them rather than imposing a specific domain.

In the RCT with adults aged  $\geq 50$  an intervention effect favouring the SB intervention group was detected for self-reported daily sitting time (borderline). This finding is in line with research by Stephenson and colleagues indicating that technology enhanced interventions are able to reduce sedentary behaviour [9]. Although it is assumed that sedentary behaviour will be replaced by LPA rather than MVPA [54], intervention effects favouring the SB intervention group were found for MPA (borderline) and MVPA. Similarly, Gardiner et al. found that their intervention to reduce and break-up sedentary time in older adults resulted in changes in sedentary time, breaks from sedentary time, LPA as well as MVPA [55]. Finally, in the RCT with adults with T2D an intervention effect favouring the SB intervention group was found for accelerometer-assessed daily breaks from sedentary time. To our knowledge, 'MyPlan 2.0' is the first e- and mHealth intervention targeting sedentary behaviour in adults with type 2 diabetes. Considering the health effects of breaking-up periods of prolonged sitting in adults with T2D [56], this result is promising for further research.

Overall, the lack of intervention effects reaching statistical significance could be interpreted as disappointing. However, one has to keep in mind the following issues that may have led to an underestimation of our effects. First, in keeping with the self-regulation literature, 'MyPlan 2.0' motivated participants to set and pursue their own goals. Consequently, the set goals could differ strongly between as well as within participants (i.e. each session participants could select a different goal) on four aspects: chosen behaviour (e.g. MVPA versus LPA), ambitiousness (e.g. reaching 500 versus 5000 additional steps), setting (e.g. leisure time versus transport) and time-frame (e.g. every day of the week versus in the weekend). This will have lowered the chance of finding an effect. However, this approach was believed to be better and more sustainable. It would lead to more

success experiences, and a greater willingness to continue with the process of behavioural change. Second, as accelerometers are not able to capture posture, these devices tend to have problems to distinguish between sedentary time and light-intensity PA [57]. This could imply that some of the accelerometer-assessed breaks do not automatically reflect posture change from sitting to standing. Furthermore, previous research already indicated that the agreement between self-reported and objective measurements of PA is limited [58]. Indeed, instead of creating a hierarchy of preferred measures, objective and self-report measures should be considered distinct rather than interchangeably [59]. Finally, although not reaching statistical significance, intervention effects for domain-specific PA in the sample aged  $\geq 50$  years are promising. Indeed, our limited power caused by the small samples might have hindered these effects to reach statistical significance.

Online interventions are characterized by high levels of attrition [60]. More than 70% of 'MyPlan 1.0'-users did not complete the intervention [22, 61]. In the RCT with the sample aged  $\geq 50$  years 19% of participants receiving 'MyPlan 2.0' did not complete the intervention. In the RCT with adults with T2D this was 33%. These massive reductions in attrition might be explained by the iterative adaptations that were made to the programme to increase engagement and by the fact that participants were phoned on a weekly basis. However, in both RCTs we found that participants receiving the intervention were still more likely to quit compared to those in the control group. Furthermore, in the sample aged  $\geq 50$  years, we found that drop-out was higher in users with a lower level of education. These findings were disappointing as we, being aware of this issue, purposefully conducted a series of studies to adapt the intervention's content to this target population [24-26]. Yardley argues to make a distinction between the micro (engagement with intervention itself) and macro (engagement with the behaviour change process to reach the set goals) level of engagement in order to create effective engagement (i.e. "sufficient engagement with the intervention to reach the desired outcomes" (page 833) [62]) rather than simply more engagement. This idea is in line with the hypothesis of Eysenbach stating that users need to experience the added value of using the online intervention in order to prevent attrition [60]. Consequently, not only investigating whether users like the programme itself, but also identifying how users put the learned techniques into practice and which variables (e.g. level of education) moderate this process might be a fruitful avenue to (1) decrease the level of attrition and (2) increase the effectiveness of online interventions in the future.

This study has several strengths. First, several studies have assessed the effect of Internet-based interventions on sedentary behaviour in the general population [9, 63]. To our knowledge, this is the first study testing an online intervention targeting sedentary behaviour in adults with T2D. Second, by also assessing the HAPA-based determinants for change, we were able to check whether the

implemented behaviour change techniques effectively altered users' personal determinants for change. Third, by using self-report as well as objective measurements a more nuanced view of the effects was presented. However, it should be acknowledged that the self-report and objective measures did not represent the same timeframe. This study also has a number of limitations. First, the small sample sizes make it difficult to detect statistical effects. Second, we decided to consider the HAPA-based personal determinants as personal determinant for the chosen behaviour rather than personal determinants for PA or SB. Consequently, it was not possible to investigate whether the intervention effects for the personal determinants altered according to the chosen behaviour. Finally, the effects reported here reflect short-term changes. However, a third wave of data collection at 10 months post-baseline will be performed.

To conclude, this study suggests that a self-regulation-based online intervention has the potential to alter levels of PA and SB in adults aged  $\geq 50$  and adults with T2D. However, further research with larger samples is needed to confirm the consistency of these findings.

### **Trial registration**

The protocols for the randomized controlled trials were registered as clinical trials on <https://register.clinicaltrials.gov> (NCT03799146 (RCT 1); NCT03291171 (RCT 2)).

### **Supplementary files**

Supplementary file 1: CONSORT checklist

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### **Conflicts of Interest**

None declared.

### **Abbreviations**

T2D: type 2 diabetes

PA: physical activity

SB: sedentary behaviour

BMI: body mass index



IG: intervention group

CG: control group

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# CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1, 2
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	3,4
	2b	Specific objectives or hypotheses	4, 11
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4, 5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4, 12
Participants	4a	Eligibility criteria for participants	4, 5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9, 10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	see protocol
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
<b>Randomisation:</b>			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	6
Statistical methods	11b	If relevant, description of the similarity of interventions	NA
	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13, 19
	13b	For each group, losses and exclusions after randomisation, together with reasons	13, 19
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	29
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14, 20
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14, 20
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14-18 and 20-24
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	29
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	25-29
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	25-29
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	29
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	29

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).







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## PART 3 – GENERAL DISCUSSION

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## 1. Main findings and overall discussion

This doctoral thesis had two objectives. The first objective consisted of two sub aims, of which the first was to identify the underlying reasons for the high rates of attrition found in 'MyPlan 1.0'. The second sub aim was to create 'MyPlan 2.0' based on these findings and to adapt the programme to adults with type 2 diabetes. 'MyPlan 2.0' is based on the Health Action Process Approach (HAPA) [11] and consists of a website and mobile application targeting physical activity and sedentary behaviour. The second objective of this thesis was to test the effectiveness of 'MyPlan 2.0' in adults with type 2 diabetes. However, as the recruitment of participants with type 2 diabetes was slow, the effect of 'MyPlan 2.0' was also tested in adults aged 50 or older.

This part of the thesis will first provide an overview of the main findings of the research followed by a critical discussion. The subsequent sections will describe the strengths and limitations of the research project and provide directions for further research. Finally, this part will be closed with an overall conclusion.

### 1.1 Main findings

#### *1.1.1 Identifying reasons for attrition in 'MyPlan 1.0' and developing 'MyPlan 2.0'*

Two studies were performed to identify the underlying reasons for the high rates of attrition found in 'MyPlan 1.0', the precursor of 'MyPlan 2.0'. The first study – *described in chapter 1.1* – examined the usage data of 549 'MyPlan 1.0' users. The results showed that many potential participants refused to register for the intervention, and that only 21.8% of the registered participants went through all three sessions with male users and younger users being less likely to complete the intervention. Furthermore, the study showed that attrition was higher during less interactive components (e.g. filling out a questionnaire assessing participants' current level of physical activity) and peaked after users received feedback on their current behaviour and were asked if they wanted to create a personal plan for action. Importantly, the users who left at this point were not limited to those who received the feedback that they met the guidelines regarding the chosen health behaviour: 18.8% of users who could benefit from the intervention (i.e. users who did not reach the guidelines) also quit at this point in the intervention.

Whereas the first study showed when users left the programme, the second study – *described in chapter 1.2* – aimed to define why users quit. Twenty adults from the general population and 20 adults with type 2 diabetes went through 'MyPlan 1.0' while verbalizing their thoughts. Afterwards,

all participants completed a questionnaire assessing users' experiences with an online intervention. The expectations and remarks of the sample with type 2 diabetes were very similar to those of the sample from the general population. The results indicate that participants found it useful to create specific plans for actions, but considered 'MyPlan 1.0' as too time-consuming. Furthermore, we found that the implementation of several behaviour change techniques needed to be adapted as participants often experienced difficulties to complete the implemented techniques, or did not understand their usefulness. Finally, many users suggested that a mobile application would help them remember about their goals.

The above-mentioned findings guided the creation of 'MyPlan 2.0', a website providing five weekly sessions targeting physical activity or sedentary behaviour. For example, the time-efficiency of the programme was ameliorated by shortening the text, reducing the length of the questionnaires assessing participants' current level of physical activity or sedentary behaviour, and selecting an easier interface. Furthermore, the implementation of the behaviour change techniques was simplified and rationales together with clear examples were added. Finally, an optional mobile application was created to provide daily support.

To investigate whether the website of 'MyPlan 2.0' (i.e. the main part of the intervention) was now well-adapted to the target population, a third study – *described in chapter 1.3* – was performed. Twenty-one adults with type 2 diabetes went through the five sessions of the renewed programme. Afterwards, participants' experiences were assessed using semi-structured interviews and the website usage data (i.e. time spent on the website and number of optional pages visited) were explored. Participants spent on average 9.76 minutes per session and appreciated the time-efficiency of the programme. Each session, more than 61% of the participants visited the optional pages indicating their interest in the website. Participants stated that they already knew the provided information regarding the benefits of an active lifestyle. Nevertheless, it reminded them about the importance of being more physically active and limiting the time spent sedentary. Furthermore, participants felt supported by the action planning component as they knew their goals would be revised in the next session. The majority of participants experienced difficulties to identify potential barriers and solutions to overcome these barriers. Finally, participants experienced the design of the website as straightforward.

A fourth study – *described in chapter 1.4* – using the same methodology as study 3 was carried out with a sample from the general population. However, in this study, participants' usage data were analysed in depth. The goal of this study was to specifically investigate whether the self-regulation techniques were well implemented in the website. We found that users appreciated the techniques

‘providing feedback on performance’ and ‘prompting review of behavioural goals’. Participants experienced the action planning component as highly motivating and were able to create achievable and instrumental plans for action. Similar to the results of the third study, participants reported difficulties to go through the coping planning component. This finding was reflected by the website usage data: across the four follow-up sessions we found that many coping plans were of poor quality. Finally, the technique ‘prompting self-monitoring’ did not stimulate participants to actually keep track of their behaviour change.

Based on the results of study 3 and 4 the website of ‘MyPlan 2.0’ was further adapted. For example, a list of specific barriers and solutions was added to the coping planning component. Furthermore, a printable weekly overview was provided in the component prompting users to self-monitor their behaviour change. The next objective was then to test the effectiveness of ‘MyPlan 2.0’.

### *1.1.2 Effectiveness of ‘MyPlan 2.0’*

Before actually conducting the randomized controlled trial a study protocol – *described in chapter 2.1* – was made. The protocol discussed the active ingredients (i.e. the implemented behaviour change techniques) of ‘MyPlan 2.0’, their theoretical underpinnings, and how the randomized controlled trial would be conducted. The randomized controlled trials – *described in chapter 2.2* – tested the effectiveness of ‘MyPlan 2.0’ to alter the levels of physical activity (10 outcome measures), sedentary behaviour (4 outcome measures) and HAPA-based personal determinants for change (7 outcome measures) in a sample of 63 adults aged  $\geq 50$  (RCT 1) and in a sample of 54 adults with type 2 diabetes (RCT 2). In the RCT with the sample aged  $\geq 50$  (RCT 1), intervention effects favouring the intervention group were found for the personal determinants self-efficacy ( $p = .05$ ), coping planning ( $p < .01$ ), intention ( $p = .07$ ) and monitoring ( $p = .09$ ). To analyse the behavioural outcomes, a distinction was made between the intervention group receiving the version of ‘MyPlan 2.0’ targeting physical activity (PA intervention group) and the group receiving the version aiming to reduce sedentary behaviour (SB intervention group). In the PA intervention group an increase in self-reported total physical activity ( $p < .01$ ) in comparison with the control group was found. In the SB intervention group, a decrease in self-reported daily sitting time ( $p = .08$ ) and an increase in self-reported moderate ( $p = .06$ ) and moderate-to-vigorous physical activity ( $p = .07$ ) was found. In the RCT with the sample with T2D (RCT 2), intervention effects favouring the intervention group were found for the personal determinants action planning ( $p = .08$ ) and monitoring ( $p < .01$ ). However, intervention effects favouring the control group were detected for the personal determinants self-efficacy ( $p = .01$ ) and risk perception ( $p = .03$ ). In comparison with the control group, the PA

intervention group showed a decrease in self-reported daily time spent sedentary ( $p = .09$ ) and an increase in self-reported moderate ( $p = .05$ ) and moderate-to-vigorous physical activity ( $p = .05$ ). The SB intervention group showed an increase in accelerometer-assessed daily breaks from sedentary bouts ( $p < .01$ ) in comparison with the control group.

## 1.2 Overall discussion

The randomized controlled trials testing the effectiveness of 'MyPlan 2.0' showed significant effects for only some of the outcomes. Considering previous research [8, 78], these findings are not surprising. For example, Pal and colleagues (2013) conducted a review assessing the effect of computer-based interventions on health outcomes in adults with type 2 diabetes. The results of the review indicate that only 1 of the 5 included computer-based interventions targeting physical activity found a significant intervention effect favouring the intervention group [8]. Similarly, the systematic review by Connelly et al. (2013) showed that 9 of the 15 included studies assessing the effect of technology-based interventions targeting physical activity in adults with type 2 diabetes detected significant intervention effects favouring the intervention group [78]. Both reviews indicate that the level of physical activity in the intervention group tends to increase, but this difference is often not significant in comparison with the changes in the control group. The following paragraphs will first provide a number of factors that might have contributed to the (borderline) significant interventions effects of 'MyPlan 2.0' and suggest recommendations for further research. Consequently, we will discuss how stronger effects could have been achieved.

A first factor that might have contributed to the (borderline) significant intervention effects of 'MyPlan 2.0' is the fact that the intervention is grounded in a sound theoretical framework (i.e. self-regulation theory [94]). Indeed, previous research shows that Internet-based health-promoting interventions with a more extensive use of theory tend to have stronger effects [9]. Furthermore, in contrast with interventions mainly focusing on increasing participants' intention for change [92], 'MyPlan 2.0' applied the HAPA [110] to bridge the intention-behaviour gap. Consequently, motivational (e.g. creating positive outcome expectancies in order to develop an intention for change) as well as volitional determinants (e.g. supporting users in developing feasible plans for action in order to translate the intention into the desired behaviour) of behaviour change were targeted.

The strong efforts made to adapt the intervention to the target population might be considered a second factor contributing to the (borderline) significant effects. Four studies adopting a user-based

approach were performed to create and improve 'MyPlan 2.0'. The results of these studies allow us to provide a number of practical recommendations on how to implement theory-based behaviour change techniques in the online format. First, in line with previous research [123], the results of the think aloud and semi-structured interviews clearly highlight the need to develop time-efficient interventions providing sufficient interaction with the user. To be more specific, sessions taking 5 to 10 minutes to complete were considered time-efficient. The time needed to complete an online intervention can be shortened by (1) providing key messages rather than lengthy texts, (2) reducing the length of questionnaires used to provide users with tailored feedback and (3) selecting an easy and straightforward lay-out. Second, previous research highlights the importance of targeting participants' ability to identify barriers and to select solutions to overcome these barriers [124]. However, the studies included in the thesis show that implementing this behaviour change technique in the online format is not an easy endeavour. Participants often did not see the advantage of using the technique and experienced difficulties to create a feasible coping plan. Based on these experiences, we recommend to provide a clear rationale before presenting the coping planning technique, to offer specific examples of feasible coping plans and to highlight the learning process (e.g. "this might be a difficult task to do, but next session you might have a better idea of what your personal barriers are and how you can overcome them"). Third, users often highlighted the importance of setting specific goals and reviewing these goals in the following session. Indeed, the HAPA assumes that the volitional processes of behaviour change take place within a feedback loop: people set a goal, try to live up to this goal and compare their behaviour change with the set goal [110]. Consequently, prompting users to review their behavioural goals might be an indispensable component when implementing behaviour change techniques such as goal setting or action planning.

A third factor contributing to the intervention effects of 'MyPlan 2.0' might be the iterative nature of the programme. In each of the five sessions users are asked to review their goals and receive feedback based on their performance. A meta-analysis by Krebs et al. (2010) showed that computer-tailored interventions with dynamic tailoring show stronger effect sizes than tailored interventions providing feedback based on only one assessment [65]. Furthermore, research by Avery and colleagues (2015) indicates that the use of follow-up prompts is a successful behaviour change technique to increase physical activity in adults with type 2 diabetes [125].

A fourth and final factor contributing to the detected intervention effects might be the considerable efforts made to provide users a sense of goal-ownership: users were allowed to create personal goals for the health behaviour of their choice (i.e. increasing physical activity versus decreasing sedentary behaviour). Indeed, self-regulation theory highlights the importance of goal-ownership for the adoption [126] as well as maintenance [94] of health behaviours.

As stated above, 'MyPlan 2.0' was able to affect only some of the outcomes. The following paragraphs will therefore provide a number of reflections on which aspects might have contributed to the limited effects and how stronger effects could have been obtained with the programme.

First, the HAPA was selected as theoretical basis for 'MyPlan 2.0'. Considering the limited effects of the intervention, a critical analysis of this theoretical framework and its application in 'MyPlan 2.0' is warranted. The critical analysis will discuss the following aspects of the model: (1) the stage versus continuum layer, (2) the role of action and coping planning, (3) the cognitive nature of the model and (4) its applicability in eHealth interventions.

The HAPA can be considered a hybrid model as it can be applied as a continuum model or as a stage model [11]. Continuum models, such as the theory of reasoned action [127], assume that individuals can be located on a range representing the likelihood of behaviour change. We based 'MyPlan 2.0' on the continuum model of the HAPA and therefore included motivational as well as volitional behaviour change techniques. However, assuming that individuals willing to use an online intervention already have an elevated level of intention for behaviour change, a higher emphasis was put on the volitional rather than motivational behaviour change techniques. Consequently, it is possible that participants with a lower intention for change felt less supported by the intervention. Another approach is offered by stage models, such as the transtheoretical model of behaviour change [128]. Stage models hypothesize that there are qualitatively different stages that individuals must go through in order to achieve behaviour change. The HAPA can be considered a stage model by making a distinction between individuals based on whether or not they have an intention for behaviour change. Consequently, individuals who do not yet have an intention for change are identified as 'pre-intenders', individual who have an intention but who do not yet act on these intentions are considered 'intenders' and individuals already acting on their intentions are categorized as 'actors' [110]. Some researchers argue that interventions informed by the stage version of the HAPA might be more effective than interventions informed by the continuum version [108, 129, 130]. Lippke et al. (2010) tested whether interventions matched to the stage of the participant are more successful than mismatched interventions [130]. The authors found that only the volitional intervention provided to intenders (i.e. the stage-matched intervention) was able to move participants further in the process of behaviour change. However, assessing a persons' stage is not an easy endeavour [131]. Consequently, stage-based interventions can easily misclassify people and provide users with techniques that are not supporting their needs. Furthermore, it is important to consider how people categorized as pre-intenders (i.e. people with a low level of intention for change) are best supported and whether eHealth is the best medium to do so.



Although many individuals show no intention for behaviour change, research regarding the creation of effective interventions for unmotivated people is scarce [132]. One way to target an individual's level of intention is by integrating Motivational Interviewing which is defined as "a collaborative conversation style for strengthening a person's own motivation and commitment to change" (page 12) [133]. Motivational interviewing adopts a client-centred approach to evoke a client's personal reasons for change and explicitly targets low levels of intention or even resistance regarding behaviour change. Motivational Interviewing stems from one-on-one counselling sessions, but has been implemented in eHealth interventions as well. For example, Friederichs et al. (2014) created two eHealth interventions based on Motivational Interviewing to increase Dutch adults' levels of physical activity. One intervention was purely text-based, whereas the other included an avatar mimicking a human counsellor. When comparing the two interventions with a control condition receiving no intervention, the results indicated that both interventions were able to increase self-reported physical activity at one month post-baseline and no difference between the two versions was found. Furthermore, process evaluations of the two interventions were quite positive and comparable [134]. However, it is important to note that participants were selected from a pool of individuals who expressed their interest to take part in online research. Consequently, it is very likely that these participants already showed an intention for change [91]. Indeed, considering the importance of the relational style in people with low motivation for change [132], eHealth might not be the best platform to target unmotivated people. Another perspective is offered by dual-process frameworks indicating that our behaviour is steered by conscious (e.g. active consideration of pros and cons) as well as unconscious processes (e.g. habits). For example, Maher et al. (2016) found that habit strength for sedentary behaviour positively predicted older adults' objectively monitored sitting time [135]. Indeed, identifying when and where unhealthy habits take place offers important information for interventions aiming to provide healthy substitutions for these habits [135]. For example, people are more likely to take the stairs in stair-centric compared to elevator-centric buildings [136].

The HAPA puts a strong emphasis on the volitional processes translating an intention into actual behaviour. Key determinants within this phase are 'action planning' and 'coping planning'. Consequently, in each session of 'MyPlan 2.0' users were prompted to create a specific plan for action and to select solutions that might help them overcome potential barriers to their plan. A recent meta-analysis by Zhang and colleagues (2019) shows that, although action and coping planning mediate the effect of intention on behaviour, the direct effect is substantially larger than the planning-mediated effect [137]. The authors provide three potential explanations for this effect. First, individuals might rely on previously-created behavioural scripts for action and do not need to

consciously form plans for action. Second, action and coping planning might act as moderators rather than mediators in the intention-behaviour relationship. Finally, the mediation of planning depends on the level of self-efficacy in the volitional phase. The authors argue that further research is needed before ruling-out action and coping planning as potential intervention targets. However, these findings warrant research regarding other processes involved in closing the intention-behaviour gap.

The HAPA strongly relies on the cognitive capacities of the individual. People are expected to weigh up pros versus cons, develop an intention to alter their behaviour, create specific plans for action, foresee barriers and solutions and monitor their behaviour change process. Focusing on these deliberative processes might create a blind spot for non-conscious processes (e.g. habits or implicit beliefs). For example, Maher and Conroy (2016) argue to take into account multilevel influences and added 'habit strength' to the HAPA [135]. Similarly, an individual's behaviour can be influenced by a wide variety of contextual factors ranging from the interpersonal to the policy level [84]. For example, individuals living in neighbourhoods with a higher level of walkability show higher levels of physical activity than individuals living in areas with a lower level of walkability [138]. Consequently, it is possible that self-regulation based interventions are more successful in environments supporting people to be physically active than in environments with limited possibilities to engage in physical activity. One can argue that these contextual factors could be categorised under the 'barriers and resources' component of the model. However, considering the recent technological advancements allowing intervention developers to offer behaviour change techniques based on contextual factors (e.g. weather, location, time of the day, etc.) [139], gaining insight in how these contextual factors influence the effect of behaviour change techniques might be a fruitful avenue. For example, one could investigate whether users create more effective action or coping plans when they are provided with information regarding the weather (e.g. "Going for a walk on Monday evening might be a bad idea as heavy rain is predicted") or their online agenda (e.g. "You could cycle to your lunch meeting with Anna instead of going by bus"). Similarly, GPS-derived information allows intervention developers to send notifications depending on the location of the user. For example, notifications to take a break from prolonged sitting might be more effective when they are sent when the user is at home than when he or she is at the movie theatre.

Finally, similar to the majority of behaviour change theories, the HAPA has a predominantly static and linear nature. Indeed, the HAPA assumes that by altering personal determinants for change (e.g. outcome expectancies) individuals will move further up in the behaviour change process (e.g. non-intender becomes an intender). These static and linear models provide limited information for the development of online interventions providing dynamic support [140]. For example, in 'MyPlan 2.0' prompts for action planning, coping planning and monitoring are repeated in each session rather

than adjusted to the users' current and past behaviour. Riley and colleagues (2012) argue to use control systems engineering to transform linear and static theories into dynamic theories that can inform eHealth interventions [140]. The authors argue to perceive behaviour change as a time-varying process in which variables can be manipulated (e.g. level of self-efficacy) to reach changes in outcomes of interest (e.g. daily steps) adjusting for exogenous variables (e.g. level of walkability of the environment).

Second, stronger effects might have been achieved by not only investigating whether users like the programme, but also identifying whether and how users apply the lessons taught by the programme into practice. Yardley and colleagues (2016) argue to promote 'effective engagement', which is defined as "sufficient engagement with the intervention to achieve intended outcomes" (page 833) rather than simply more engagement [141]. The authors make a distinction between the micro and the macro level of engagement. The micro level of engagement reflects the moment-to-moment interaction with the programme itself [141]. Quantitative as well as qualitative methods can be used to investigate this level of engagement [142]. By investigating when, by whom and why non-usage attrition occurs, our studies strongly focused on understanding this micro level of engagement. However, to establish behavioural change users should not only engage with the online intervention, but also apply the learned skills in their daily lives. The macro level of engagement therefore reflects users' involvement in the behaviour change process to reach the intervention goals [141]. In the interview-study we specifically asked participants which behaviour change techniques had helped them to be more physically active or to sit less. For example, users with type 2 diabetes stated that the behaviour change technique "action planning" in combination with "feedback based on performance" supported them to live up to their weekly goals. Nevertheless, it is possible that stronger effects could be found if we paid more attention to the extent to which and how users were able to put the learned techniques into practice. Short et al. (2018) provide an overview of methodologies to investigate engagement and show that quantitative as well as qualitative methods can be used to explore the macro level [142]. For example, participants of our qualitative studies indicated that they found it difficult to select barriers and solutions to overcome these barriers on the website. Consequently, it would have been interesting to ask users if they actually applied the solutions they had selected. Taking into account the cyclic nature of behaviour change, Short and colleagues recommend to measure changes in personal determinants and/or behaviour at different time points. For example, one can ask users to complete a questionnaire assessing behavioural outcomes and personal determinants for change after each session to investigate the effect of the specific behaviour change techniques implemented in that session. Finally, Short et al. indicate that sensor data allow intervention developers to check whether users actually alter their behaviour

when using the intervention [142]. For example, if a user indicates that he or she will walk for 30 minutes during her lunch break at work, combining information from global positioning systems (GPS) and a wearable with an in-built accelerometer would allow intervention developers to know whether the user was able to meet this specific goal rather than solely detect a change in behaviour.

Third, 'MyPlan 2.0' might have produced stronger effects by increasing the number of sessions of the programme and decreasing the length of the interval between each of these sessions. The number of sessions (i.e. 5 sessions) was based on previous research indicating that a minimum of 5 sessions is needed to establish an effect [143]. In line with self-regulation theory [94], 'MyPlan 2.0' motivates users to start with small and feasible goals and to perceive behaviour change as a stepwise process. Consequently, it is possible that after five weeks users' goals were still too small (e.g. "I will walk to my colleague instead of sending him/her an e-mail") to result in big behavioural changes. For example, 'MyPlan 1.0' showed stronger effects on physical activity on the intermediate versus short term in recently retired older adults [15]. Between each of the five sessions of 'MyPlan 2.0' there was an interval of one week. Consequently, each session users of 'MyPlan 2.0' were asked to set a goal for the following week. It is possible that stronger effects would be found by shortening this interval. Sniehotta and colleagues (2012) asked participants to create a daily step goal and found that mean step counts were higher on goal setting days than on days on which no specific step goal was set [144]. Similar results were found by Nyman and colleagues (2016) who replicated the study in older adults [145]. Indeed, implementing these microcycles might help users to create feasible plans taking into account the daily context in which the behaviour is performed (e.g. rainy days, busy schedule, etc.).

Finally, providing users with a sense of goal-ownership came with a price at the methodological level. In both RCTs we found that 67% of the intervention group focused on physical activity, whereas 33% focused on sedentary behaviour. Consequently, detecting significant intervention effects for physical activity as well as sedentary behaviour was challenging as this was not the target behaviour for a number of participants. Furthermore, each session we allowed users to create time and context specific goals (e.g. On Monday morning I will do the grocery shopping by bike instead of by car). Consequently, between as well as within participants, the set goals could differ strongly regarding selected behaviour (e.g. walking versus swimming), setting (e.g. transport-related versus household related physical activity), ambitiousness (e.g. running five versus ten kilometres) and timeframe (e.g. every day versus on Wednesday). From a methodological level, we might therefore recommend to focus on one type of behaviour (e.g. decreasing sedentary time) that can be performed in a wide variety of settings. This approach will allow (1) users to select their own goals (i.e. create a sense of goal-ownership) and (2) researchers to select the most appropriate measurement methods to

capture alterations in the targeted behaviour. As previous research has shown that breaking up sedentary time might be more beneficial for some groups of people in comparison to others [51, 52], it would be innovative to adapt the target behaviour based on the needs and capacities of the targeted population.

To analyse the effect of the intervention we conducted multiple statistical tests. In biomedical and social sciences it is a common practice to adjust the cut-off score (i.e.  $\alpha$ ) categorizing p-values as 'significant' or 'nonsignificant' when performing multiple tests [146]. The idea behind this practice is that the chance of mistakenly accepting the null hypothesis increases with the number of tests performed. For example, the Bonferroni correction rejects the null hypothesis in case the p-value is smaller than  $\frac{\alpha}{n}$  with n being the number of tests performed. However, several researchers argue against this approach by stating that the presumptions on which these corrections are based are flawed [146, 147]. For example, these multiple comparison adjustments are guided by the 'universal null hypothesis' [146, 147]. In our study this premise implicates that we assume that there is no intervention effect for each of the dependent variables and that randomness causes the variability in all observations. Consequently, when rejecting the null hypothesis for one or more of the tests, we know that there was an intervention effect, but we cannot say for which of the dependent variables. Second, the interpretation of individual effects will differ according to the number of tests performed. This premise does not only defy common sense (i.e. the results differ according to the number of tests performed), but is also impractical to follow. This requires that researchers know at the start of a study how many tests will be performed based on the collected data. Several researchers therefore argue that transparently describing the statistical tests performed and discussing the potential interpretations for each of the results will allow the reader to make conclusions without the help of multiple comparison adjustments [147].

The paragraph above discussed whether  $\alpha$  should be corrected depending on the number of tests performed. For reporting the results of the randomized controlled trials we considered p-values smaller than .05 as statistically significant whereas p-values smaller than .10 and larger than .05 were considered borderline significant. However, although often applied, there is no real scientific reason for choosing the .05 cut-off score [148]. Similarly, the decision to consider p-values between .05 and .10 as 'borderline significant' or 'showing a trend towards significance' is arbitrary. Indeed, the p-value provides a continuous measure of the strength of evidence against the null hypothesis [148]. A growing group of researchers therefore argues to leave behind the categorisation of p-values into 'significant' or 'nonsignificant' and to report the exact p-values instead [149].

Considering the potentially important differences (e.g. recruitment method) between the two samples (i.e. the sample aged  $\geq 50$  and the sample with type 2 diabetes) and the small sample sizes, we decided not to perform analyses with the combined data. Consequently, it is not possible to determine whether the intervention was more effective in one group than the other for each of the dependent variables. However, in general we can see that the results of the randomized controlled trials tend to be more positive in the sample aged  $\geq 50$  than in the sample with type 2 diabetes. This is especially the case for the personal determinants and the direction of the effects for self-reported physical activity. A first potential explanation for this finding might be related to the methods that were used to recruit the two samples. Adults with type 2 diabetes were mainly recruited via hospitals after talking to a researcher, whereas adults from the general population aged  $\geq 50$  were recruited via advertisements. Consequently, it is possible that the sample aged  $\geq 50$  was more autonomously motivated to alter their lifestyle and experienced stronger feelings of 'goal-ownership' than the sample with type 2 diabetes. Second, there were significantly more women in the sample aged  $\geq 50$  than in the sample with type 2 diabetes. Previous research already indicated that women are more likely than men to follow an eHealth intervention as recommended [150]. Third, although we aimed to minimize the age difference between the two samples, the sample with type 2 diabetes is significantly older than the group aged  $\geq 50$ . It is therefore possible that the sample with type 2 diabetes experienced more difficulties to engage with the website than the sample aged  $\geq 50$ . Finally, people with type 2 diabetes are assumed to make multiple lifestyle-related changes (i.e. adopting a healthy diet, monitoring the blood glucose levels and taking medication on a regular basis), each requiring high levels of self-control [151]. Adhering to an eHealth intervention promoting an active lifestyle might therefore have been more challenging for this group than for a sample that is not ought to make multiple health-related changes.

The randomized controlled trials furthermore showed that, in the sample with type 2 diabetes as well as in the sample aged  $\geq 50$  years, only a minority of the intervention group used the mobile application. This finding was unexpected as providing a mobile application was a recommendation suggested by participants in the think aloud study. A first explanation might be that, as the mobile application was offered as an optional tool, users did not expect it to provide any added value and were therefore reluctant to download the application. Second, it is possible that users in general prefer to receive health-promoting interventions via a website rather than a mobile application. Quiñonez and colleagues (2016) delivered the same online intervention via a website and a mobile application and found that drop-out levels were higher in the group who received the intervention via a mobile application in comparison with users receiving the website-version [152]. The authors argue that using a mobile phone is a more automatic behaviour than using a computer.

Consequently, when people decided to go to the website delivering the intervention, they autonomously chose to do so. In contrast, receiving a notification from the mobile application might make people feel forced to engage with the intervention. Finally, considering the mean age of the sample aged 50 or older ( $58.68 \pm 7.76$  years) as well as the sample having type 2 diabetes ( $62.67 \pm 8.40$  years), it is possible that participants had limited experience with using a mobile application. In Belgium, 84% of adults aged 25 to 54 use their mobile phone to access the Internet. In adults aged 55 to 74 this percentage drops to 52% [153].

In the sample with type 2 diabetes intervention effects favouring the control group were detected for the personal determinants outcome expectancies and self-efficacy. As yet we do not have an explanation for this finding and we can only speculate about possible reasons. For example, it is possible that by taking part in the study members of the control group became more aware of the facts that they (a) were having an inactive lifestyle and (b) were not altering their level of physical activity or sedentary behaviour. Consequently, this group might have become more aware of their risks to develop chronic diseases. Furthermore, the timing of the pre- and post-test might have influenced the results for self-efficacy. Indeed, for 29 of the 54 participants (12 of 18 participants in the control group) the pre-test took place in the period January-March. Consequently, it is possible that the weather conditions at the post-test were better in comparison with the pre-test. This might have influenced self-efficacy levels of the members of the control group (e.g. “the weather is getting better now, so I will be able to work in the garden again”), whereas members of the intervention group realised that behaviour change might require considerable effort and therefore showed little change in their levels of self-efficacy. However, these are just hypotheses that require further investigation. Furthermore, it is important to note that the increases in these personal determinants were not associated with changes in the behavioural outcomes. Consequently, we can conclude that being part of the control group of a health-promoting intervention might alter pre-intentional determinants for change, but will not lead to an actual change in behaviour. This finding is in line with previous research showing that an increased intention for behaviour change is not readily translated to actual behaviour change [10].

## 2. Strengths and limitations

In this section the strengths and limitations of the original research included in the thesis will be briefly discussed.

### 2.1 Strengths of the thesis

A first important strength of the thesis is that we created 'MyPlan 2.0' by adopting a top-down (theoretical) as well as bottom-up (person-based) approach. Health-promoting interventions are more effective when the selection of the behaviour change techniques is based on a sound theoretical framework [8, 9, 82]. However, the often linear and static nature of these theories limits their potential to guide the creation of interactive online interventions [6, 140]. By performing four studies investigating how users use and experience both versions of 'MyPlan', we developed a profound understanding of how theory-based behaviour change techniques can be implemented in an understandable and feasible way in the online format.

Second, taking into account the complex nature of engagement in online interventions, e- and mHealth researchers highlight the need to combine different methods to better understand this concept [142]. This thesis complied with this call, by using quantitative (i.e. usage data and self-report questionnaires) as well as qualitative (i.e. think aloud and semi-structured interviews) methods to gain insight in why people stopped using 'MyPlan 1.0' and to guide the creation of 'MyPlan 2.0'. By doing so, we were able to identify (1) which groups of users were more likely to quit 'MyPlan 1.0', (2) which components of 'MyPlan 1.0' demotivated users, (3) how users perceived 'MyPlan 2.0' and (4) how 'MyPlan 2.0' could be further ameliorated. These insights can be of great value for other researchers planning to develop a theory-based eHealth intervention.

Third, few studies examining the effect of online interventions in adults with type 2 diabetes provide a study protocol clearly describing the intervention's theoretical basis and its active ingredients [8]. This impedes research aiming to replicate findings. Therefore, before conducting the randomized controlled trial examining the effectiveness of 'MyPlan 2.0' in this population, we created a study protocol. This protocol did not only describe how the randomized controlled trial would be conducted, but also provided a clear overview of the intervention, its theoretical underpinning and the implemented behaviour change techniques (i.e. the active ingredients of the intervention).

Fourth, in randomized controlled trials examining the effect of e- and mHealth interventions, the use of objective methods to assess physical activity or sedentary behaviour is limited [66]. Taking into



account the often detected differences between objective and self-report measures [76, 154], applying both measures is needed to create a better understanding of the effectiveness of e- and mHealth interventions. In the randomized controlled trial assessing the effect of 'MyPlan 2.0' both accelerometers and questionnaires were used. Furthermore, as previous research has shown that people overestimate their levels of physical activity in self-report questionnaires [155], the questionnaire assessing participants' physical activity and sedentary behaviour was assessed via an interview.

Fifth, in contrast to previous research with 'MyPlan 1.0' [15-17], behavioural outcomes as well as changes in personal determinants were measured and evaluated in the randomized controlled trials. Strong efforts were put in the creation of the items assessing participants' personal determinants for change. Eleven experts indicated for a large number of HAPA-based determinants whether or not the item measured the presented HAPA-based determinant and rated their certainty of the answer [156]. Based on the responses a discriminant content validity method was performed [156] and the best scoring items were selected. To check the comprehensibility of these items cognitive interviews were conducted with four adults (mean age:  $58.3 \pm 6.5$  years). Based on the results of these interviews the final items were selected and adapted. Incorporating these items in the randomized controlled trials allowed us to check whether the intervention was able to actually alter the HAPA-based personal determinants.

Sixth, in contrast to multivariate analysis of variance (MANOVA), the linear mixed model can easily handle missing data in repeated measures [157]. Consequently, to analyse the intervention effect, these sophisticated statistical analyses were applied to maximally use the collected data.

A final, but very important strength is the fact that 'MyPlan 2.0' targets also sedentary behaviour in adults with type 2 diabetes. E- and mHealth interventions are often used to target physical activity in adults with type 2 diabetes [78, 81], whereas the use of Internet-based interventions to alter sedentary time in this population is limited. Nevertheless, there are strong indications that reducing sedentary behaviour in people with type 2 diabetes results in important health benefits [3, 49]. To our knowledge, 'MyPlan 2.0' is the first e- and mHealth intervention targeting sedentary behaviour in this target group.

## 2.2 Limitations of the thesis

First, despite our efforts, the final sample sizes of the randomized controlled trials were small (54 participants in the sample having type 2 diabetes and 63 participants in the sample aged  $\geq 50$  years).

Indeed, conducting two randomized controlled trials requires considerable time and resources, especially in a clinical population [158, 159]. In line with previous research [160], many potential participants refused to participate. From an ethical as well as practical point of view, it was impossible to monitor their reasons for doing so. It is therefore likely that people participating in the study differed from people who refused to participate (e.g. age or severity of diabetes-related complications). As self-selection might have occurred, one should be cautious to extrapolate the results of the randomized controlled trials to the overall population of adults with type 2 diabetes or adults aged 50 or older. Furthermore, it is likely that participants had a higher level of intention for behaviour change than people who refused to participate [91]. However, as 'MyPlan 2.0' was designed for users aiming to translate their intentions into actual behaviour change, this should not be considered a limitation. The limited samples of the randomized controlled trials have several negative implications. First, as the randomized controlled trials were underpowered, our chances to detect statistically significant intervention effects were lowered. Consequently, it is difficult to estimate the actual effect of 'MyPlan 2.0' in the two samples. Second, although planned in the study protocol, it was not feasible to perform mediation analyses testing the working mechanisms of the HAPA-based determinants. Consequently, drawing theory-based conclusions based on the results of the randomized controlled trials is challenging. Third, the small sample sizes hindered us to conduct moderation analyses investigating whether the effect of the intervention differed according to demographic variables such as age, sex or education or personal determinants for change (e.g. level of intention). Nevertheless, as there are more differences between the two samples besides whether or not participants have been diagnosed with type 2 diabetes (e.g. recruitment method), we decided not to combine the two samples for the analysis of the intervention effects.

Second, no power analysis was conducted to calculate the required sample size for the group aged 50 or older. As described in the protocol, we calculated the required sample size for the group with type 2 diabetes based on an effect size of 0.37. However, this effect size was based on studies with overweight or sedentary participants. Indeed, eHealth interventions targeting physical activity levels in adults of the general populations tend to show smaller effects (e.g.  $d = 0.24$  [9] or  $d = 0.14$  [67]). Performing the required sample size calculation based on this information would have shown us that that a much larger sample of adults aged 50 or older was needed to perform the randomized controlled trial.

Third, in the randomized controlled trial the GT3X accelerometer was used to assess physical activity as well as sedentary behaviour. This accelerometer has, in contrast to for example the ActivPal activity monitor [161], limited ability to capture posture, such as sitting or standing still. Consequently, periods of standing might have been misclassified as sitting time and vice versa.

Nevertheless, the GT3X accelerometer shows a high correlation ( $\rho = 0.76$ ) with the ActivPAL activity monitor [162].

Finally, based on practical and ethical reasons, a waiting-list rather than a placebo control group was used. Consequently, we are not certain whether the detected intervention effects were actually caused by the active ingredients of the intervention (i.e. the implemented behaviour change techniques). Furthermore, informing a participant that he or she is allocated to a waiting-list control group might have influenced his/her behaviour.

### 3. Directions for further research

The field of e- and mHealth is growing rapidly [61]. The swift advancements in technology do not only provide us with new and innovative ways to deliver health-promoting interventions, but also raise questions on how we can most effectively benefit from these advancements. Several gaps therefore need further consideration. The following sections are dedicated to recommendations for further research.

First, behaviour change techniques are considered the active ingredients of an intervention [163]. Examples of behaviour change techniques included in 'MyPlan 2.0' are 'providing feedback based on performance', 'action planning' and 'prompting review of behavioural goals'. Previous research using meta-regression [164, 165] and meta-CART analysis [166, 167] already provided some insights in the single and combined effects of behaviour change techniques. However, as these methods are based on correlation, the studies might neglect a number of important confounders (e.g. sample characteristics, behavioural domain or active ingredients of the control group's usual care) [168]. Consequently, experimental research is needed to investigate the single as well as synergistic effects of behaviour change techniques. Performing these experiments will help research about e- and mHealth interventions in two ways. First, by identifying the most effective (combination of) behaviour change techniques it becomes possible to minimize intervention content and reduce the burden on participants. Second, it will increase researchers' understanding of why an intervention did (not) work [82].

Second, Internet-delivered interventions can now provide support at any location and at each moment of the day. Consequently, intervention developers have started to create 'Just In Time Adaptive Interventions' (JITAI) [139]. A JITAI is defined as "an intervention design that adapts the provision of support (e.g. the type, timing, intensity) over time to an individual's changing status and contexts, with the goal to deliver support at the moment and in the context that the person needs it most and is most likely to be receptive" (page 446) [139]. For example, 'HeartSteps', a mobile application providing suggestions to be physically active tailored to the time of the day, the weather, day of the week and the user's location, was found to be effective to increase walking in adults from the general population [169, 170]. Similarly, the B-MOBILE JITAI, a mobile application suggesting users to walk after periods of prolonged sitting, was effective to increase the number of breaks from sedentary behaviour in overweight/obese individuals [171]. Taking into account the importance of managing the blood sugar level on a daily basis in people with type 2 diabetes, JITAI might offer additional benefits in this population. For example, the timing of notifications prompting patients to take a walk could be adapted in order to optimally regulate the blood sugar level. Indeed, in people

with type 2 diabetes, postprandial walking has shown to be more effective to counter the dinner-induced increase in glucose in comparison with pre-meal walking or no physical activity [172]. Similarly, the JITAI could continuously measure the blood sugar level and provide warning messages in case of a steep decrease in blood glucose during high-intensity exercise. Considering the ability of JITAIS to support people in their natural environment, exploring the potential applications and gaining insight in the working mechanisms of this type of interventions might be a fruitful avenue for health promotion [173].

Finally, for developing health-promoting interventions delivered via a mobile application, a growing number of mHealth researchers now argues to explore other strategies beyond the traditional between-subject randomized controlled trials (RCTs) [174, 175]. Traditional between-subject randomized controlled trials compare differences between participants and calculate the average effect of an intervention. Consequently, participants are considered interchangeable (i.e. the working mechanisms for behaviour change in person A are the same as in person B). However, inferences made on group level rarely hold on the individual level [176]. Furthermore, due to their time-inefficient nature ( $\pm 5.5$  years from enrolment to publication) randomized controlled trials cannot keep up with the fast-paced advancements in technology [175, 177]. Results based on randomized controlled trials might thus be obsolete by the time they get published [175]. Consequently, the results of randomized controlled trials might be less informative for the development of swiftly developing tools providing highly individualized support [174]. Experiments using within-subject designs test interventions or their components by randomly allocating the intervention within a certain period of time in a number of subjects. This type of design allows researchers to investigate (1) the effect of an intervention (component) within participants and (2) between-participant moderators of within-participant processes (e.g. which contextual factors influence within-person effectiveness). Consequently, conducting experiments using a within-subjects design might be a valid method to create Internet-based interventions offering personalized and daily support [169, 174, 178]. For example, considering the effectiveness of the behaviour change technique 'self-monitoring' [144, 145] and the fact that walking is a well-accepted form of physical activity [179], it might be interesting to test which volitional behaviour change technique might be most effective in combination with step monitoring. To do so, a full factorial randomized within-subject experiment (see figure 6) could be performed to identify the single and synergistic effects of the volitional behaviour change techniques 'goal setting', 'coping planning' and 'feedback based on performance' in the context of step monitoring. Participants can be asked to wear a wearable (e.g. a Fitbit Charge) for step monitoring and use a mobile application providing the behaviour change techniques. The eight potential combinations (i.e. the independent variables) will then be randomly provided over a

fixed number of days within each of the subjects. Number of daily steps could be considered as the dependent variable. Although within-subject designs offer a wide variety of interesting opportunities for research, the use of these designs in health promotion has been scarce [169, 175].

Feedback on Performance				No Feedback on Performance			
Coping Planning		No Coping Planning		Coping Planning		No Coping Planning	
Goal setting	No Goal Setting	Goal setting	No Goal Setting	Goal setting	No Goal Setting	Goal setting	No Goal Setting
1	2	3	4	5	6	7	8

Figure 6. Design of the full-factorial within-subject experiment

#### 4. Overall conclusion

'MyPlan 2.0', a HAPA-informed e- and mHealth intervention targeting physical activity and sedentary behaviour, was developed by iteratively consulting potential end-users. Based on these user-based studies a number of practical recommendations to ameliorate online health-promoting interventions can be provided. For example, we found that users value time-efficient and interactive eHealth interventions. Based on these findings we suggest to create interventions requiring 5 to 10 minutes of the user's time and to minimize lengthy texts or the implementation of research-related questionnaires. Furthermore, by assessing users' experiences, we gained insight in how the implementation of behaviour change techniques can be adapted to the online format. For example, as users often underestimate the usefulness of coping planning and find it difficult to create helpful coping plans, we suggest to provide a rationale for this technique accompanied by clear examples of potential barriers and feasible solutions to overcome these barriers. Furthermore, users considered it useful to create specific plans for action because they knew these plans would be reviewed in the next session. We therefore recommend to also provide the technique 'review of behavioural goals' when implementing an action planning component.

The effectiveness of 'MyPlan 2.0' to alter users' levels of physical activity, sedentary behaviour and personal determinants for change was tested using two randomized controlled trials in two samples: a sample with type 2 diabetes and a sample aged  $\geq 50$  years. In both RCTs, the programme showed significant effects for only some of the outcomes. There are a number of factors that might have contributed to the (borderline) significant intervention effects of 'MyPlan 2.0'. First, 'MyPlan 2.0' is based on a theoretical framework targeting motivational as well as volitional personal determinants for change. Second, strong efforts were made to gain insight in the experiences of end-users and to adapt the intervention based on these findings. Third, 'MyPlan 2.0' provides dynamic tailoring allowing users to review their goals based on success or failure of their plans. Finally, strong efforts were made to provide users with a sense of goal-ownership by allowing users to select a target behaviour and to create personally relevant goals. The following points of improvement might increase the effectiveness of 'MyPlan 2.0'. First, it might be fruitful to consider automatic and contextual factors influencing the behaviour change process. Second, the original research presented in this thesis strongly focused on increasing participants' engagement with the programme itself. However, investigating how users implement the lessons taught in the programme into their daily lives might help intervention developers to create more effective interventions. Third, the programme consisted of five weekly sessions. It is possible that stronger behavioural changes could be obtained by increasing the number of sessions and decreasing the length of the interval between

each session. Finally, users were allowed to select their target behaviour (i.e. increasing physical activity or decreasing sedentary behaviour) and create time and context related personal goals. Considering the limited sample size and the wide variety of potential goals, detecting significant intervention effects was challenging. From a methodological point of view, it might be better to target one behaviour that can be performed in a wide variety of settings in order to select the most appropriate method to measure changes in the targeted behaviour.

Taken together, this doctoral thesis created a profound understanding on how online interventions can be adapted to better meet the needs of end-users. Furthermore, the results of the randomized controlled trial in the sample with type 2 diabetes indicate that further research and adaptations to the programme are needed to more effectively support this target group in adopting an active way of living.



## 5. Publication List

### 5.1 First authorship

- Poppe, L., De Bourdeaudhuij, I., Verloigne, M., Degroote, L., Shadid, S., & Crombez, G. A self-regulation-based eHealth and mHealth intervention for an active lifestyle in adults with type 2 diabetes: Protocol for a randomized controlled trial. *JMIR Research Protocols*, 2019; 8(3).
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