Research Protocol

In Control: Can self-control training (SCT) improve the effectiveness of interventions?

Single-case experimental designs on physical activity in people with mental illness

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

AE	**Adverse Event**
AR	**Adverse Reaction**
DSMB	**Data Safety Monitoring Board**
GDPR	**General Data Protection Regulation; in Dutch: Algemene Verordening Gegevensbescherming (AVG)**
METC	**Medical research ethics committee (MREC); in Dutch: medisch-ethische toetsingscommissie (METC)**
PA	**Physical Activity**
(S)AE	**(Serious) Adverse Event**
SCED	**Single Case Experimental Design**
SCRIBE	**Single-Case Reporting Guideline in BEhavioural Interventions**
SCT	**Self-control Training**
SMI	**Severe Mental Illness**
Sponsor	**The sponsor is the party that commissions the organisation or performance of the research, for example a pharmaceutical company, academic hospital, scientific organisation or investigator. A party that provides funding for a study but does not commission it is not regarded as the sponsor, but referred to as a subsidising party.**
SUSAR	**Suspected Unexpected Serious Adverse Reaction**
WMO	**Medical Research Involving Human Subjects Act; in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen**

SUMMARY

Rationale: Improving physical activity (PA) through eHealth can promote health and wellbeing of people with severe mental illness (SMI). Most existing interventions suffer from a behaviour-intention gap and require high level of cognitive skills which people with SMI do not fully possess. Complementary interventions that focus on automatic processes, such as self-control training (SCT), can be used to bolster effectiveness of PA interventions in this vulnerable population.

Objective: to assess the effect of offering SCT as an addition to an existing physical activity intervention (Google Fit), on physical activity and self-control.

Study design: A series of two single-case experimental designs (SCEDs). SCED I is a concurrent multiple baseline of 49 days, SCED II is an introduction-withdrawal of approximately 42 days, depending on optimal intervention length as determined in SCED I.

Study population: 12 adult psychiatric patients from clinics from two Dutch mental healthcare organizations.

Intervention: a) SCT app: a mobile app to train self-control. In this new app, which is based on an existing, evidence-based intervention, users receive daily challenges to perform everyday tasks (such as drinking or writing) using their non-dominant hand for two weeks to practice repeatedly overriding dominant responses, resulting in improved self-control.
b) Google Fit app: a freely downloadable app that motivates the user to make small changes in PA throughout the day by incorporating evidence-based behaviour change techniques (BCTs) such as goal-setting and self-monitoring.

Main study parameters/endpoints: The primary outcome is physical activity, measured daily by ActiGraph GTX+ accelerometers worn at least 6 hours a day during the study period. The secondary outcome is self-control, measured through short, validated items designed for frequent sampling, the Brief Self-Control Scale, and cognitive tasks (Go/No-Go Task).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is no risk associated with participation in the study or use of either mobile intervention. Participation is on a voluntary basis and does not interfere with treatment as usual, and patients will be clearly instructed that they can stop participation at any time. In addition, while inclusion and data collection will be closely coordinated with healthcare providers at both sites, an independent researcher who is not the patient's primary care provider will provide practical assistance to patients to avoid any role conflict. The SCT app has been co-designed with people with SMI to specifically meet their preferences and capabilities and is based on an existing, evidence-based intervention. Efficacy and user-friendliness of the app has been established in usability tests. Google Fit is freely available to health consumers and has been positively evaluated on user friendliness, reliability, and privacy. Neither apps collect personal data. We estimate that the burden of

responding to questionnaires is no more than 2 hours in total (2 questionnaires a day x 1 minute x 49 days).

1. INTRODUCTION AND RATIONALE

A lack of physical activity (PA) and increasing sedentary behaviour has a broad range of detrimental consequences for physical and mental health. It has an especially negative impact on the quality of life, risk of cardiovascular disease, and symptom severity of 210.000 Dutch people with severe mental illness (SMI), such as schizophrenia and major depression [1–4]. Specifically psychiatric inpatients lead an alarmingly sedentary life: they spent 84% of their day sedentary, and only 6% in moderate to vigorous PA [5]. Fortunately, even minor improvements in PA can prevent problems with physical health and deterioration of psychiatric symptoms in people with SMI [6].

Clearly, there is an urgent need to improve PA in this extremely vulnerable target group. However, existing PA interventions have several limitations when used in the SMI population. Most interventions are delivered by professionals, requiring additional time from already overworked staff [7,8]. On top of that, most PA interventions are underpinned by cognitive models that only target the reflective route of behaviour change. Consequently, these models are suboptimal in explaining and changing behaviour, partly due to the intention-behaviour gap [9]. This is not merely a limitation in PA interventions for people with SMI, but for goal-directed interventions in general. Still, cognitively underpinned interventions are specifically hard to use for people with SMI due to cognitive deficits (e.g. memory and attention), low literacy rates, and apathy [10]. This highlights the need for new types of interventions that target the automatic route of behaviour change.

A very promising focus for these new types of interventions is training the automatic part of self-control: the ability to prevent or override unwanted thoughts or behaviours [11]. Studies have shown that self-control has a positive impact on a broad range of topics, such as academic success, aggression regulation and physical health [11]. According to the strength model of self-control, it can be seen as a muscle, implying that it can be trained [12]. A large body of research has confirmed this surprisingly straightforward hypothesis: self-control training (SCT) can indeed strengthen self-control [13–15].

In SCT, participants are asked to perform tasks that require self-control for a predetermined period, often two weeks. An often-used example is using one's non-dominant hand for daily tasks, such as writing or opening doors. By repeatedly overriding dominant responses, self-control is trained, which in turn is expected to help put PA behaviour into practice. SCT has been shown to increase self-control [13–15]. Self-control, in turn, is a predictor of goal-directed behaviours such as physical activity. To illustrate: when self-control is high, participants are more likely to get off the couch and go for a walk, as opposed to remaining sedentary – in other words, they are more likely to bring their intention of walking into practice. In this way, bolstering self-control by means of SCT can support people in bridging the intention-behaviour gap. Our previous study, in which we evaluated a functional prototype of the SCT app in a factorial design, showed that 14 days of mobile SCT can increase self-control [16]. This suggests that SCT could be added to many existing, cognitively underpinned interventions to increase participants' self-control and thus to

decrease the intention-behaviour gap and bolster the effectiveness of interventions. Surprisingly, despite the large body of evidence that shows SCT's potential [13–16], it has hardly been applied and studied in psychiatric clinical practice and for preventive purposes.

This project aims to evaluate an SCT app to improve self-control in people with SMI and bolster the effectiveness of existing PA interventions. It will do so in a series of two single case experimental designs (SCEDs). SCEDs are high-quality experimental designs in which a limited number of patients function as their own control. SCEDs are especially suitable for extremely heterogeneous populations that are hard to involve in larger trials such as RCTs, such as psychiatric patients [17]. To achieve sufficient power, a RCT study should including a large number of homogeneous participants, which is extremely challenging in the psychiatric context. Consequently, SCEDs seem to be a better fit to evaluate interventions in this hard-to-involve and thus understudied population. Additionally, SCEDs cannot just be used to answer questions regarding if, but also how, when and for how long an intervention works.

In SCED I, patients will first use Google Fit, an existing PA intervention, after which SCT is added to determine if the addition of SCT leads to an increase in PA & self-control, and to determine how long effects remain. In SCED II, SCT will be systematically introduced and withdrawn from patients to validate the findings from SCED I. In both experiments, self-control will be measured using short questionnaires and physical activity using accelerometers.

This study can be considered very low in risk. It makes use of mobile interventions directed at lifestyle change that have been validated and are already available to the public and collects data either automatically or through very short questionnaires. Additionally, the focus on the intervention lies on lifestyle and not on treatment- or disorder-related variables. Participation in the lifestyle intervention is on a voluntary basis and does not interfere with care as usual. Both Google Fit and the SCT app are merely used as prevention, to support patients in increasing their physical activity and thus overall quality of life.

2. OBJECTIVES

Primary objective: To assess the effect of adding SCT to an existing PA intervention (Google Fit) on PA in psychiatric inpatients with SMI.

Secondary objectives: The secondary objectives are to:

- To examine the effect of SCT on self-control in psychiatric inpatients with SMI;
- To optimize SCT training, by examining how long SCT effects persist over time and how long SCT should be delivered to be most effective.

3. STUDY DESIGN

People with SMI are a target group that suffer from poor physical health yet are barely targeted in preventive and health promotion research, leading to large systemic inequality [18]. In general, people with SMI are understudied because they are considered difficult to involve in larger trials such as RCTs [19]. In addition, assembling a homogeneous target group which is often necessary for controlled trials, is difficult or even impossible to achieve due to relatively high number of patients with co-morbidity. Consequently, there is an urgent need for more suitable research designs to study interventions in this understudied patient population. A design that fits these requirements is a Single Case Experimental Design (SCED).

SCED is a family of high-quality experimental designs in which individual patients function as their own control. In a SCED, the intervention is systematically manipulated across multiple phases of introduction and withdrawal while the outcome variable is measured repeatedly and frequently [17,20,21]. A relatively common misconception is that SCEDs are case reports, which is not the case: SCEDs are rigorous experimental research designs that are carefully designed prior to the evaluation of an intervention and can be used to draw causal inferences about the relationship between the intervention and the outcome [17,20].

There are several reasons to use SCED to evaluate lifestyle interventions in the psychiatric population. First, SCEDs require only a small number of participants – typically 3 to 6. This makes it more feasible to recruit sufficient participants and requires less time and financial resources from both staff and patients. Furthermore, SCEDs can handle heterogenous samples, as participants function as their own control. This makes it possible to involve the diverse population of people with SMI who may present with co-morbidity. Overall, this makes SCEDs very suitable for the evaluation of lifestyle interventions [22,23] and an excellent and feasible alternative to classical experimental designs such as the RCT.

The current project employs two SCEDs: a multiple-baseline design (SCED I) and an introduction/withdrawal design (SCED II). SCED I is used to examine to what extent adding SCT to a PA intervention improves the effectivity of the PA intervention and to explore how long effects persists to determine an optimal intervention length. SCED II is used to validate the effectiveness of the optimized intervention. An overview of both experiments according to the Single-Case Reporting Guideline in BEhavioural Interventions (SCRIBE) criteria is provided in Table 1 and both experiments are visualized in Figures 1 & 2.

SCED I

SCED I is a concurrent multiple baseline design across participants [24,25]. In SCED I, 6 participants' physical activity and self-control is assessed continuously for 49 days (7 weeks). During this period, participants start with a baseline (phase A), during which their physical activity and self-control is monitored but no intervention is provided. After a randomly determined period of 5 to 7 days, each participant will move to a subsequent phase of using Google Fit one by one, until all participants use Google Fit (phase B). After another period of

7 to 9 days, participants move to Google Fit + SCT (phase C) and use both apps for 28 days. Finally, all interventions are withdrawn, and participants are followed for the remaining period as follow-up. Since participants use the intervention for 28 days (4 weeks) we will be able to explore intervention effects over time and determine an optimized intervention length for SCED II. In addition, once the study is complete, patients' perspectives and experiences will be gathered during post-design interviews to provide input to further improve the intervention.

SCED II

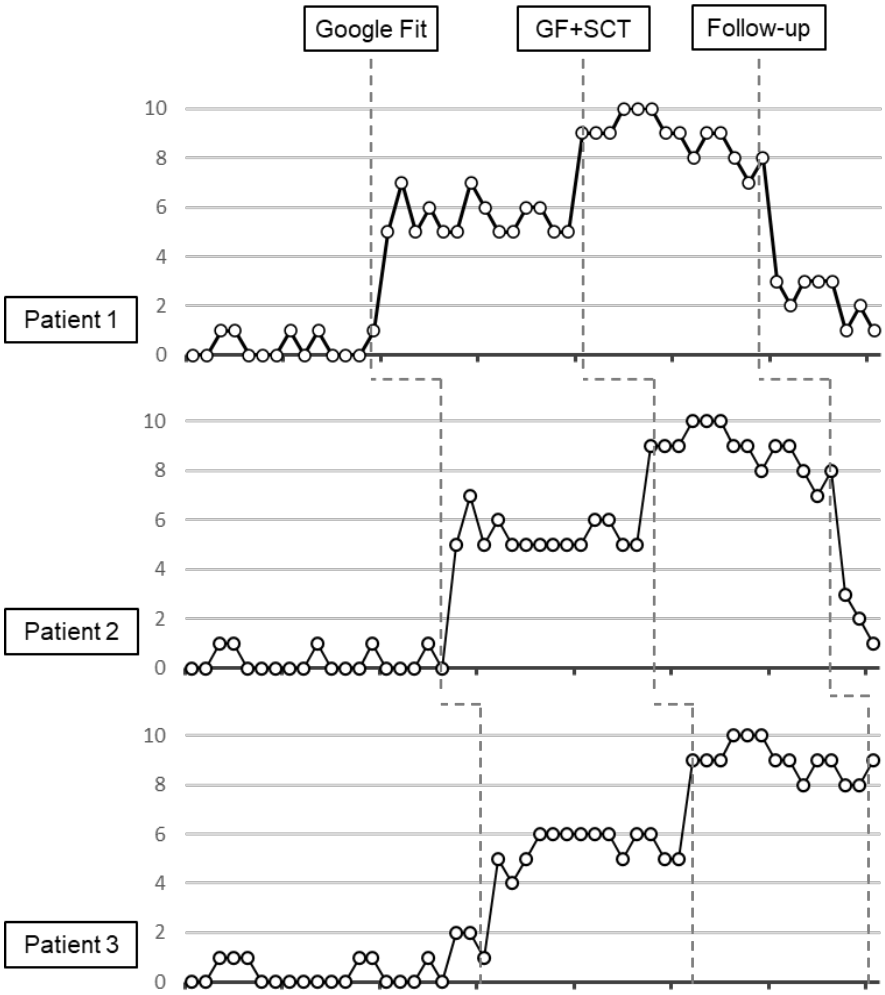
SCED II is a ABAB introduction-withdrawal design. In SCED II, 6 patients will be enrolled and participate in the experiment for approximately 42 days, depending on the optimized intervention length as determined in SCED I. During the first 7 days, patients use only Google Fit (phase A). After 7 days, SCT is introduced in addition to Google Fit, and patients use both interventions for 14 days (phase B), unless SCED I showed that a different intervention length (between 7 to 28 days) is more appropriate. The exact duration of this phase will be determined using the information gathered during SCED I. For example, if we find that effects of SCT stabilize after 14 days, a 14-day phase B will be used in SCED II. After this period, SCT is withdrawn, and patients will again use only Google Fit for 7 days. In the final phase, SCT is reintroduced, and patients will use both interventions for the remainder of the experiment.

Table 1: SCRIBE design elements of SCED I & II

	SCED I	**SCED II**
Design	Multiple baseline across 6 patients.	Introduction-withdrawal across 6 patients.
Duration	49 days	~42 days (28-70 days)
Sequence of phases	ABCD	ABAB
Description of phases	Baseline (A): 5 days minimum No intervention, only monitoring of physical activity	Google Fit (A): 7 days Only Google Fit intervention is used.
	Google Fit (B): 7 days minimum Only Google Fit intervention is used.	Google Fit + SCT (B): 7-28 days minimum. Optimal phase length is determined from findings of SCED I. Google Fit & SCT intervention are used simultaneously.
	Google Fit + SCT (C): 28 days minimum Google Fit & SCT intervention are used simultaneously.	
	Follow-up (D): 5 days minimum No intervention, only monitoring of physical activity	

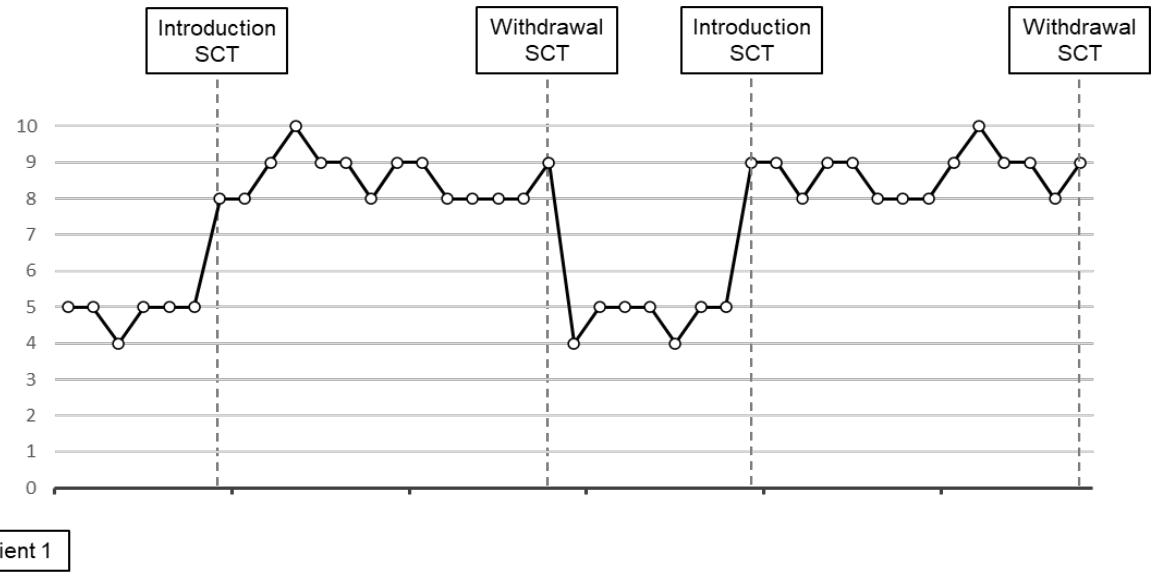
Measures	Physical activity, measured daily and continuously throughout the trial (at least 5 measures per phase)	Physical activity, measured daily and continuously throughout the trial (at least 5 measures per phase)
	State self-control, measured daily throughout the trial (at least 5 measures per phase)	State self-control, measured daily throughout the trial (at least 5 measures per phase)
	Trait self-control, measured weekly throughout the trial (at least 1 measure per phase)	Trait self-control, measured weekly throughout the trial (at least 1 measure per phase)
	Inhibition (Go/No-Go task), measured weekly throughout the trial (at least 1 measure per phase)	Inhibition (Go/No-Go task), measured weekly throughout the trial (at least 1 measure per phase)
Randomization	Phase length is randomized with restriction to have at least 5 measures (= 5 days) per phase.	Not randomized.
Blinding	Patients, practitioners and researchers are not blinded to phase to offer sufficient support to participants.	Patients, practitioners and researchers are not blinded to phase to offer sufficient support to participants.

Figure 1: Potential visualization of SCED I using hypothetical data



SCED I: Hypothetical data illustrating data collection in three patients for 49 days. Dotted lines indicate transitions between phases of baseline (A), Google Fit only (B), Google Fit + Self Control Training (C), and follow-up (D). Data illustrate expectations regarding GF & SCT: limited PA prior to intervention, a medium effect of GF only on PA and an optimized effect of GF + SCT on PA which rapidly declines when all interventions are removed.

Figure 2: Potential visualization of SCED II using hypothetical data



SCED II: Hypothetical data illustrating data collection in one patient for 42 days, with a 14 day SCT intervention phase. Dotted lines indicate transitions between phases of Google Fit only (A) and Google Fit + Self Control Training (B). Data illustrate expectations regarding GF & SCT: a medium effect of GF only on PA and an optimized effect of GF + SCT on PA.

STUDY POPULATION

3.1 Population

12 participants with SMI (6 for each SCED) will be recruited from randomly selected clinics of two Dutch large mental healthcare organizations.

We follow the Dutch consensus definition of severe mental illness in defining the SMI population [26]. A severe mental illness (including substance use and addiction):

- requires treatment (i.e. no symptomatic remission);
- is associated with severe limitations in social and/or societal functioning (i.e. no functional remission) that result in and are caused by a psychiatric disorder;
- is not transient (i.e. is structural, chronic, or long-term, at least several years);
- requires coordinated care from professional caregivers in care networks to realize the treatment plan.

The study will be introduced to all selected clinics' patients by the researchers via short presentations and flyers. We specifically decided to do the initial introduction via researchers to avoid any (perceived) role conflicts between healthcare providers and patients, for example, when the healthcare provider also makes decisions about patients' leave in a forensic psychiatric context. Instead, patients will be able to sign-up themselves, after which we will discuss with the healthcare provider responsible for the patient ('persoonlijk begeleider') whether participation is safe, appropriate, and feasible for this patient. If the number of eligible patients exceeds the number of participants needed, up to 8 participants will be randomly selected. Only 1 patient from each clinic will be selected. This ensures that SCT is tested in different types of patients, disorders, staff and clinics, and prevents social comparison effects as patients from the same clinic could challenge each other to take more steps per day. Patients not selected will be invited to participate in SCED II, or, if not possible, are offered to use the intervention after the study.

3.2 Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:

- 18 years or older.
- Have a severe mental illness, including but not limited to schizophrenia, bipolar disorder, addiction, and major depression, following the definition above and as evaluated by the staff member responsible for the patient ('persoonlijk begeleider').
- Are expected to reside at the clinic for at least the data collection period.[1]
- Voluntary consent to participation, following the voluntary informed consent procedure described in Section 8.2.

[1] The criterium should not impede early discharge or necessary transitions to other type of care or care facilities. Healthcare professionals involved in the study will be informed that the study should not be used to consider discharge or transitions. If such a transition will take place, the patient will be offered to continue with the study if desired and possible.

- The staff member that is responsible for the patient indicates that the patient is physically and mentally able to participate in the study and that participating will not be in any way harmful for the patient.
- The patient has an intention of improving PA. This is due to the nature of the SCT intervention: SCT supports putting an existing goal into practice (i.e. tackling the intention-behaviour gap), but does not support patients who are unwilling to improve PA. In a similar vein, SCT is also not expected to be effective for people who already meet their PA goals. Readiness to improve PA will be assessed during screening using the single-item assessment of Stages of Change adapted for healthy behaviour (including PA) based on the transtheoretical model of behaviour change [27,28]. Only patients who are in contemplation, preparation, or action stages (reflecting intentions for, first steps in, and short-term changes towards the behavioural goal respectively) will be included.

3.3 Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:

- Participants are excluded when they have no intention to improve PA (i.e. in pre-contemplation stage of behaviour change).
- Participants are excluded when repetitive behaviour may potentially aggravate the patient's disorder or symptoms (e.g. obsessive-compulsive disorder) as evaluated by the healthcare provider or patient.

3.4 Sample size calculation

SCED can be used to test the efficacy of an intervention using only a small sample of 1 to 3 patients [17]. It does not use a traditional sample size or power calculation to evaluate whether the design is able to demonstrate effect. Instead, power to determine effect is evaluated by calculating the number of data points per phase [20,29,30]. To meet quality standards, a SCED should include at least 3 participants, who are monitored for at least 1 baseline phase and 1 intervention phase, with each phase lasting at least 5 data points. Given that PA is measured continuously and self-control is measured two times a day, this will result in at least 28 datapoints in SCED I, and 14 in SCED II. To account for high drop-out rates common in the psychiatric population, we will include 6 participants in both SCEDs.

4. TREATMENT OF SUBJECTS

4.1 Intervention: Self-Control Training App + Google Fit

The intervention consists of two mobile applications designed to improve physical activity. The first is the Self-Control Training (SCT) app which was specifically designed for this study and the second is the Google Fit app, an existing mobile lifestyle intervention. All interventions are delivered on the participants' own mobile smartphone. If patients do not have a smartphone or own a smartphone that is not compatible with the applications, a smartphone will be provided to them for the duration of the study.

The SCT app is based on an evidence-based intervention [13–16] to train self-control. The SCT app was specifically redesigned with and for people with SMI (see 4.2 *Summary of findings*). The SCT app is available on Android and provides users with a new daily challenge for 14 days. The daily challenge concerns an assignment in which the user is asked to perform an everyday activity (such as opening the door or turning on the light) with their non-dominant hand (e.g. the left hand), allowing users to repeatedly practice overriding dominant responses. After accepting the challenge, users are reminded of the daily challenge 4 times a day. At the end of the day, users report whether they have done the challenge and how well the challenge went. If a challenge is performed, users see a reward screen featuring the app's mascot. After the first successful day and halfway through the challenge, users are also encouraged to tell their environment, e.g. friends, family or healthcare provider, about their progress in the app. Users can monitor their process on the overview page. After 14 days, the app notifies the user that the training is concluded. Users are presented their initial goal and the total number of challenges succeeded. By restarting the intervention, the app can be used up to 4 weeks (28 days). All screens and components of the SCT app can be found in Appendix A 'Wireframe' (Dutch).

Google Fit is a freely available mobile health tracking platform developed by Google in collaboration with the World Health Organisation and the American Heart Association. It is available on Android and iOS operating systems but in this study, only the Android version will be used. Google Fit uses sensors from the user's mobile device or external activity trackers to record physical fitness activities. It translates each minute of moderately intense activity into a Heart Point, and more intense activities result in more points. In addition, the number of steps is tracked. Google Fit incorporates various behaviour change techniques to motivate the user to be more active. These include the ability to set a personal activity and step count goal, to self-monitor activities in a personal dairy, and to receive customized coaching based on health and activity history. It is used by people with poor mental health [31] which makes it a suitable intervention to examine the proposed booster-effect of SCT on. The current study does not use Google Fit as a means for data collection, nor asks patients to submit personal (health) data to the app.

Participants will receive help in installing and registering both apps from a trained researcher prior to the start of the intervention. After the apps are installed, participants will use the apps independently. The researcher will also support the participant in the transition to a new

phase of the study (for example, by uninstalling the GF app). During the whole study period, this researcher will also visit participants frequently (see Section 5.3) to check on progress, provide technical support, and answer questions.

4.2 Summary of findings from non-clinical studies

Efficacy study SCT

Research on paper-based version of SCT consistently report that training self-control by repeatedly overriding dominant responses results in a small-to-medium increase in self-control [13–15].

A previous study using a digital, functioning prototype of the SCT app among 204 young adults confirmed earlier findings by demonstrating that 10 days of app based SCT significantly increases self-control, while participants in a control and email condition showed no improvement [16]. Participants in this study also positively noted the usability and visual design of the app and liked performing the tasks. They also wanted to receive more than one daily reminder of the challenge, which was incorporated into the new version of the app.

Design study SCT

To redesign the app specifically for use with people with SMI, we conducted a participatory design and usability study involving 7 patients, 2 care providers with lived experience as patients (*ervaringsdeskundigen*) and 4 care providers. The study consisted of creative workshops, informal interviews, and usability tests and was aimed at identifying the specific eHealth needs, preferences, and capabilities of people with SMI.

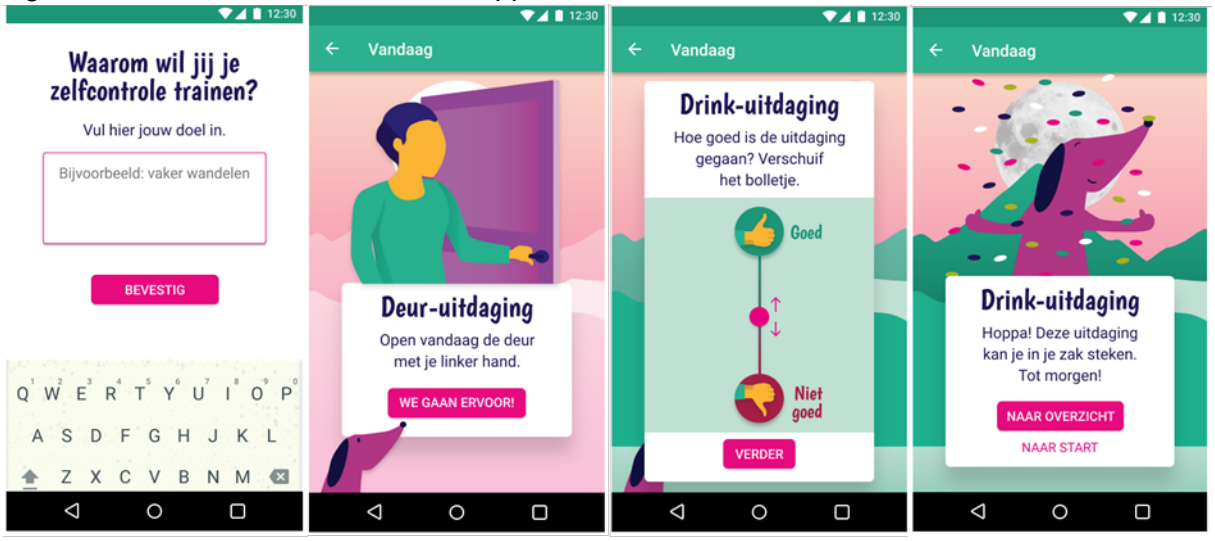
4 patients were enrolled in a series of three co-creative design workshops. Each workshop guided patients through creative exercises that explored their perspective on self-control, their experiences with eHealth, and their preferences for the design and functionality of the self-control training app. The full protocol and ethical approval for this study are attached in Appendix B ‘Protocol and ethical approval design study’.

Findings from the study were summarized in the following design requirements:

1. SCT should accommodate various lifestyle related goals, including diet, alcohol, smoking, hygiene, and interpersonal relationships.
2. SCT should foster collaboration and team spirit.
3. SCT should consider that the trajectory towards new behaviour is not linear and may involve ups and downs.
4. SCT should motivate users by using recognizable, visual, and varied rewards.
5. SCT should use visuals to explain challenges but should not be too busy or distracting.
6. SCT should use short, easy-to-read, hip Dutch text.
7. SCT should not use many numbers and instead use functional descriptions (e.g. Door-challenge rather than Challenge 4).
8. SCT should provide simple opportunities for feedback.

These recommendations were incorporated into the app by developing a mascot (Figure 3). This is a dog-like character that guides patients throughout the intervention. In return, users take care of the dog and help him climb a mountain by completing challenges. The dog reminds users that even if they do not complete a challenge, they can always try again (in line with req. 3). He also invites users to share their progress and accomplishments (in line with req. 2). When challenges are completed, users are rewarded with a picture of the dog in a funny pose. These visuals incorporate symbols (thumbs up, muscle, confetti) recognizable from other apps often used by the target group such as Whatsapp (in line with req. 4) and are accompanied with a short, easy-to-read motivational message (in line with req. 6). Recommendations 1, 5, 7 and 8 were met by asking users to provide their personal goal at the start of the intervention and removing explicit references to (only) PA as a behavioural goal; using a neutral figure to explain challenges; using functional descriptions for challenges; and incorporating a positive-to-negative slider with a thumbs-up/thumbs-down symbol to help users provide feedback easily.

Figure 3: Screenshots from the SCT app



The SCT app involves a mascot who guides patients through the simple, easy-to-read and recognizable interface.

Usability tests were conducted with 3 patients who had not been involved in the interviews or workshops. Findings showed that patients found the app “funny” and “clear”, enjoyed the inclusion of the mascot, and were motivated to work on self-control following his coaching. They were also able to independently navigate through the major functions of the app including registering an account, reading the explanation, accepting the daily challenge, providing feedback on the daily challenge, and retrieving their process from the overview screen. They suggested minor adaptations to the lay-out, including removing failed challenges from the overview screen, which were incorporated in the final version of the app.

Studies Google Fit

Google Fit has been successfully used in recent research related to physical activity, for example in one study aimed at monitoring physical activity during the COVID-19 pandemic

[32]. It also provides a recognizable interface, as Google Fit is a popular app among people with symptoms of depression and anxiety [31]. This may be partly due to Google Fit's user friendliness, reliability, strong theoretical justification, and clear privacy regulations. For these reasons, the GGD AppStore has given Google Fit an overall positive evaluation [https://www.ggdappstore.nl/Appstore/PubApp/-N263, accessed 17-09-2021], making it into a well-substantiated, accessible, and reliable intervention to monitor and coach PA in a broad range of target groups, among which people with SMI.

4.3 Summary of known and potential risks and benefits

Both the SCT app and Google Fit pose no risks for mental or physical health of users. No personal data is collected or used in the study. Potential benefits include insight in physical activity behaviour and higher self-control and higher physical activity after two weeks.

NON-INVESTIGATIONAL PRODUCT

4.4 Name and description of non-investigational product(s)

The ActiGraph GT3X+ (*ActiGraph*, Pensacola, Florida, VS), see Appendix C 'Actigraph GT3X+', and ActiLife 6.8.0 software (same manufacturer) will be used to measure and analyse PA. The accelerometer is worn on the right hip and is held in place with an elastic strap between two belt loops. Patients without belt loops will use a pouch pinned at the same place.

Mobile survey distribution platform Ethica Data [https://ethicadata.com/, accessed 30-09-2021] will be used to distribute (daily) questionnaires on self-control. Ethica is an online platform which is designed for researchers to create, modify and distribute momentary surveys. It allows researchers to obtain and view the data of the participant in real-time, to identify possible errors while the study is still running. Further, it amplifies ecological validity, possibilities, and reliability of frequent data collection [33].

Participants use their smartphone to complete surveys. This reduces strain on participants, as they do not have to carry additional study related material. Finally, trigger logistics help reduce participant burden by sending automatic reminders to fill out surveys [34].

4.5 Summary of findings from non-clinical and clinical studies

The ActiGraph GT3X+ has a high inter- and intra-instrumental reliability [35] and validity [36]. It has been used successfully in previous studies with people with SMI to examine physical activity and sedentary behaviour [5,37,38]. None of these studies have reported usability, safety, or other issues related to the use of the ActiGraph GT3X+ in this population, which makes it a reliable, valid, and appropriate choice for measuring PA in the current study.

Ethica has produced reliable data in many previous studies, e.g. [39,40]. It will be used in the current study under the Faculty of Behavioural, Management and Social Sciences data progressing agreement to warrant participant safety and privacy in accordance with the GDPR and other applicable laws and regulations concerning the processing of personal data.

4.6 Summary of known and potential risks and benefits

The ActiGraph GT3X+ does not pose additional risks, including no risks of violation of privacy, addiction, or physical or mental injury as the accelerometer is small, lightweight, and worn externally on the hip. This is an unobtrusive way of collecting physical activity data, which reduces participants' burden as they do not have to fill out the data manually nor need to be reminded to do so. Additionally, extended use of the accelerometer provides insight into patterns of physical activity and trajectories of behaviour change in this vulnerable population, which may be essential in developing and evaluating lifestyle interventions.

5. METHODS

5.1 Study parameters/endpoints

The primary study parameters are daily physical activity and self-control which are measured through a combination of objective and self-reported data. Objective measurements of daily physical activity are measured with a wearable accelerometer: the ActiGraph GTX+. Self-reported data on state self-control will be retrieved from participants twice daily using the State Self-Control Scale (SSCS) [41]. Data on trait self-control will be measured through the validated Brief Trait Self-Control Scale (BSCS; [11]) and an objective measure of self-control will be obtained using the go/no-go task. Finally, we will also collect qualitative data through semi-structured interviews. Interviews will focus on participants' experiences with the app, possible points of improvements, and their perceived effectiveness of SCT.

5.1.1 Main study parameter/endpoint

Physical activity is operationalized as average total activity counts per hour (TAC/h), which is a continuous and detailed outcome variable of PA [37]. More counts indicate a higher level of PA. Together with percentage of valid wear time, TAC/h can also be used to classify physical activity in sedentary behaviour (< 150 counts/min), light intensity physical activity (151–3207 counts/min) and moderate to vigorous physical activity (≥3208 counts/min) [5,42].

The ActiGraph GT3X+ (*ActiGraph*, Pensacola, Florida, VS) and ActiLife 6.8.0 software (same manufacturer) will be used to measure and analyse PA. Following existing procedures for valid measurement of PA using this device in this population, a wear time of more than six hours/day for at least three days will be used as the criterion for sufficient measurement [5,37]. Once a day, patients will also be asked how satisfied they are with their amount of PA.

5.1.2 Secondary study parameters/endpoints (if applicable)

Daily state self-control will be measured using the 3-item State Self-Control Scale (SSCS) [41]. Participants use a 100-point slider ranging from 0 (*not at all*) to 100 (*very much*) to reflect on recent self-control experiences. All questions start by "*In the past couple of hours*…". Participants answer questions about decision making ("*it's hard to make up my mind about even simple things"),* intensified frustration due to depletion ("*things are bothering me more than they usually would*"), and subjective feelings of depletion ("*I had less mental and emotional energy than I normally have*"). We have previously used this questionnaire to measure daily state self-control in students. Prior to the current study, we will also discuss the items with people with SMI to improve phrasing for clarity and brevity if necessary.

5.1.3 Other study parameters

To describe the characteristics of the target group we will only collect information about participants' age and gender. We will also describe the type of care they receive in general terms, without asking for specific diagnoses or treatment objectives. To explore possible covariates or moderators of the intervention effect, we will collect body weight, height, stage of change, and monitor intervention usage (number of completed challenges, self-reported success of each challenge). In addition, we will measure trait self-control and cognitive

control using two different types of measures since this is in line with the multifaceted nature of self-control [43].

Trait self-control is measured using the Brief Self-Control Scale (BSCS; [11]) and a web-based go/no-go task. The BSCS is a validated, brief, and psychometrically sound measure of individual differences in self-control that consist of 13 items [11,43,44]. The BSCS measures several aspects of trait self-control, including inhibitory and initiating control [45]. Participants rate the extent to which a statement, for example "*I am good at resisting temptation*", matches them on a 5-point Likert scale ranging from 1 (*not at all*) to 5 (*very much*). A total score of self-control can be created by taking the sum of all items after recoding negatively phrased items (α=.83-85 [46]). Higher scores indicate higher levels of self-control which has a medium effect on behavioural outcomes, showing criterion validity [47].

The go/no-go task is a well-studied measure of cognitive control and has been used in previous research to assess self-control [36]. In the go/no-go task, participants are instructed to respond to target stimuli, but must refrain from responding to nontarget stimuli, which requires suppressing a behavioural response. In this study, we will use reaction time [16,48] as secondary parameters of cognitive control.

5.2 Randomisation, blinding and treatment allocation

In RCT trials, randomization exclusively refers to random treatment allocation. In comparison, several elements of SCED studies can be randomised, including phase order and phase length [17].

In SCED I, phase length of baseline, phase A (Google Fit only) and follow-up will be randomised with restriction to have at least five measures per phase. In SCED II, phase length will not be randomised as the optimal intervention length will be derived from findings from SCED I. Phase order will not be randomized in both experiments, as we are interested in the additive effect of SCT over GF only.

Due to the nature of the intervention (e.g. using 1 versus 2 apps), it is not possible to blind participants to the phase. The researcher(s) responsible for supporting participants in transferring between phases will not be blinded to phase for the same reason. Where possible, researchers only involved in data entry, processing, and analysis will be blinded to phase to improve reliability of the findings [17].

5.3 Study procedures

Patients will be recruited and enrolled according to the procedures described in Section 8.2. One day before the start of the experiment, both the patient and primary healthcare provider are visited by the researcher responsible for patient contact. The researcher will help the patient install all necessary apps (Google Fit, SCT, and Ethica) on the patient's mobile phone.

Next, the researcher will fit the accelerometer to the patients' hip or belt and demonstrate how to take it off when changing clothes to both patient and healthcare provider. During the experiment, the involved health care provider will help patients to take of the accelerometer at the end of each day if necessary. Health care providers will receive written instructions to also support them to do so. These instructions will also include the researcher's contact information and a form to fill out if patients unexpectedly cannot wear the accelerometer with time and reason. Finally, the researcher will help patients fill out the baseline questionnaires (BSCS & Go/No-Go task) on Ethica, for example by the questionnaires out loud, supervising the tasks, or any other type of support necessary for the specific patient.

During baseline phases (day 1-5 of SCED I) physical activity and self-control will be monitored but no interventions will be used. To monitor physical activity, the patient will wear the accelerometer each day from 09:00 to 23:59, except when sleeping or during activities that involve water. They will also receive one daily prompt at 22:00 (with reminders at 22:30 and 23:00) to fill out their daily step count in Ethica as self-reported measure of physical activity that acts a safeguard should the accelerometer data not be usable. To measure self-control, they will receive a prompt at 09:00 on the first day of baseline to fill out the baseline instruments (demographics, BSCS & Go/No-Go task). A reminder will be sent at 09:30 and 10:00. Next, patients will receive two daily prompts at 09:00 and 22:00 (again, with two reminders) to fill out the state self-control items.

During Google Fit phases (day 6-12 of SCED I, day 1-7 & day 22-28 of SCED II[2]) physical activity and self-control will be monitored and Google Fit will be used. Monitoring of physical activity and self-control follows the same procedure as above. To help patients get started with Google Fit, the researcher will visit the patient and help set-up the app by entering their activity goals (number of steps and number of Heart Points), wake-sleep schedule, weight and height. Next, the researcher will demonstrate where to find and how to use the primary functions of Google Fit. This will enable patients to self-monitor activity and to receive personalised coaching. During the third phase of SCED II (withdrawal of SCT app), the researcher will also deactivate the SCT app and explain to the patient that this app will not be used for the next phase.

During Google Fit + SCT phases (day 13-40 of SCED I, day 8-21 & day 29-42 of SCED II[3]) physical activity and self-control will be monitored and Google Fit & the SCT app will be used. Monitoring and use of Google Fit follows the same procedure as above. To help patients get started with the SCT app, the researcher will visit the patient one day prior to the start of the SCT phase and help set-up the app by entering their participant number, personal goal, and dominant hand. The researcher will also enquire about their experiences with

[2] Approximate days are provided. Exact days depend on randomization of phase length and results of SCED I regarding optimal SCT intervention length.
[3] Approximate days are provided. Exact days depend on randomization of phase length and results of SCED I regarding optimal SCT intervention length.

participation so far, and provide additional instruction regarding Google Fit, the accelerometer, and/or Ethica if required. The next day, the patient will receive the first self-control challenge and will continue receiving and completing challenges throughout the phase. The researcher will return every 7 days to answer questions and if necessary, reset the app to extent use up to 28 days, until the phase is completed.

Finally, follow-up follows the same procedure as baseline phases. The researcher will visit the patient to disable all applications on the patient's phone except Ethica (which is used for data collection). Once the study is completed, the researcher will make one final visit to conduct the post-intervention interview, collect the accelerometer, and reactivate any applications the patient wishes to continue using.

5.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. As described earlier, this will not have any consequences for care, leave, discharge or transitions. The healthcare professional involved in the study and the investigator can also decide to withdraw a subject from the study for urgent medical reasons, including situations of acute psychiatric crisis.

5.5 Replacement of individual subjects after withdrawal

Not applicable.

5.6 Follow-up of subjects withdrawn from treatment

Participants withdrawn from the intervention will continue to be monitored on physical activity and self-control for the duration of the study period unless the participant wishes to withdraw from the study completely.

5.7 Premature termination of the study

During the study, we will keep close contact with the patient and their primary healthcare provider through frequent visits. Both will also receive contact details of the researcher responsible for patient contact to contact the researcher outside these visits. If either the patient or the healthcare professional suggests that the study should be paused or stopped for any reason, this patient will be withdrawn from the study. Given the nature of SCEDs, the study will be able to continue as long as one patient remains enrolled. Should all six patients have withdrawn from the study, the study will be terminated.

6. SAFETY REPORTING

6.1 Temporary halt for reasons of subject safety

In accordance to section 10, subsection 4, of the WMO, the sponsor will suspend the study if there is sufficient ground that continuation of the study will jeopardise subject health or safety. The sponsor will notify the accredited METC without undue delay of a temporary halt including the reason for such an action. The study will be suspended pending a further positive decision by the accredited METC. The investigator will take care that all subjects are kept informed.

6.2 AEs, SAEs and SUSARs

6.2.1 Adverse events (AEs)

Adverse events are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the investigational product, trial procedure or the experimental intervention. All adverse events reported spontaneously by the patient or observed by the involved health care professional or their staff or the researchers will be recorded.

6.2.2 Serious adverse events (SAEs)

A serious adverse event is any untoward medical occurrence or effect that

- results in death;
- is life threatening (at the time of the event);
- requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect; or
- any other important medical event that did not result in any of the outcomes listed above due to medical or surgical intervention but could have been based upon appropriate judgement by the investigator.

An elective hospital admission will not be considered as a serious adverse event.

If SAEs occur, the sponsor will report the SAEs through the web portal *ToetsingOnline* to the accredited METC that approved the protocol, within 7 days of first knowledge for SAEs that result in death or are life threatening followed by a period of maximum of 8 days to complete the initial preliminary report. All other SAEs will be reported within a period of maximum 15 days after the sponsor has first knowledge of the serious adverse events.

6.3 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached.

6.4 Data Safety Monitoring Board (DSMB) / Safety Committee

A DSMB is not considered necessary for this study given the very limited safety risks of using the lifestyle related mobile applications.

7. STATISTICAL ANALYSIS

Data analysis will be performed in R 1.4. [49]. To prepare data for analysis, we will score the primary outcome of physical activity as total activity counts per hour (TAC/h) using the accelerometer data. The secondary outcomes of state self-control will be scored as the average score on the State Self-Control Scale per day. Finally, sum scores on the Brief Self-Control Scale and average reaction time to the Go/No-Go task are calculated to derive trait self-control and cognitive control scores.

Next, we will use median average deviation (MAD) to identify and remove outliers. MAD uses the median to identify scores that deviate 3.5 times from the median as outliers, using a 95% confidence interval. It is specifically recommended for use in small sample studies, including SCEDs [50]. [Iglewicz & Hoaglin, 1993].

As both experiments collect continuous data that is averaged on the daily level, our missing data approach primarily consists of making full use of data that is available. To illustrate, state self-control will be measured morning and evening. If the morning data is missing, only afternoon data will be used to calculate the level of self-control for that day. If no data is available on a given day, we will use multiple imputation to impute missing data. Multiple imputation methods have recently been developed specifically for use in SCED studies and show several advantages over other missing data approaches, including retainment of collected data, maintenance of the design structure of a SCED, reduction of bias, and providing the ability to capture and communicate uncertainty around imputed scores [51].

7.1 Primary study parameter(s)

SCED data are primarily interpreted visually [17]. To do so in this study, physical activity and state self-control data will be presented as a time series graph, with days on the horizontal axis, physical activity/self-control on the vertical axis, and phase changes presented as vertical lines, similar to Figure 1. As recommended by the What Works Clearinghouse guidelines on SCED analysis, we will consider six features to examine within- and between phase data patterns: level, trend, and variability, and overlap, immediacy, and consistency [29,30].

Within phases, level is the mean of all data points in one phase and is used to compare change between phases [17]. Trend is the slope of the best fitting trend line for all data in a phase and is used to determine trends towards (spontaneous) improvement or decline. Variability expresses the standard deviation of data about the trend line and is used to calculate the percentage of overlap between data collected in different phases.

Between phases, overlap is the proportion of overlap between data from two phases, where less overlap indicates stronger intervention effects. The specific non-overlap index we will use is TAU-U summary index [52] which is a family of four indices that calculate nonoverlap in relation to trend. It is expressed by “the percent of data that improve over time considering both phase nonoverlap and Phase B trend, after control of Phase A trend.” [52]. This allows

us to explore, for example, by how much physical activity of a patient has increased after using the SCT app while taking into account a possible increase in physical activity levels that may have already been initiated by Google Fit during the previous phase. Immediacy compares the extent to which level, trend and variability of the last and first three data points of subsequent phases are discriminably different. In SCED I, immediacy is used to examine whether SCT effects are immediate or cumulative, and to make decisions about appropriate phase length in SCED II. Finally, consistency involves examining whether data patterns (level, trend) are consistent in phases with the same condition, where more consistent patterns provide greater certainty for a causal relation between the intervention and outcome. This will be used in SCED II to examine whether physical activity reaches similar level and trend effects in both A phases (Google Fit only) and both B phases (Google Fit + SCT).

To supplement the visual analysis, we will conduct piecewise linear regression analyses (PLM). Piecewise linear regression analyses are an approach to analyzing time series data which is segmented into phases, including SCEDs [53,54]. The PLM model calculates four parameters (intercept, trend, level, and slope) separately for data from each phase, allowing for comparison between phases. Here, intercept refers to the performance at the start of the study, trend effects refer to the continuous increase in the behaviour over time, level effects refer to the constant and instant effect of the intervention, and slope effects refer to the change in continuous increase initiated by the intervention.

Using the PLM, we will construct a linear model for each individual patient, including a p-value and R^2 effect size and beta-weights for trend, level, and slope effects. We will use a cut-off of $p < .05$ to determine significant effects. To explore possible covariates of the intervention effect, we will conduct PLM both without covariates and with the covariates discussed earlier (body weight, height, stage of change, intervention usage, trait self-control, and cognitive control).

In SCED I, we will also construct a multilevel PLM to aggregate single case findings the 6 patients included. Aggregation improves the external validity of the findings by providing overall trend, level and slope effects and allows for exploration and quantification of moderation effects using random slopes [Wilbert, 2021]. In a first step, we will include random slopes in the multilevel PLM to examine whether trend, level and slope effects significantly differ between participants. If this is the case, we will subsequently consider interactions between body weight, height, stage of change, intervention usage, trait self-control and cognitive control as potential moderators of the effect. Since there are no existing hypotheses about moderation, we will not use confirmatory p-values in this analysis but merely report any findings as preliminary and exploratory.

7.2 Secondary study parameter(s)

The analysis of the secondary study parameter (state self-control) follows the same procedure as described above.

7.3 Other study parameters

As described in section 7.1, we will consider moderation effects of trait self-control and cognitive control on the relationship between SCT, physical activity, and state self-control. In addition, we will also explore potential direct effects of SCT on trait self-control and cognitive control. As the study includes a limited sample for such between-subjects analyses, these will only be explored through descriptive statistics and visualisations.

7.4 Interim analysis (if applicable)

Not applicable.

8. ETHICAL CONSIDERATIONS

8.1 Regulation statement

The study will be conducted according to the principles of the Declaration of Helsinki 2013 and in accordance with the Medical Research Involving Human Subjects Act (WMO).

8.2 Recruitment and consent

To recruit participants, the study will be introduced to all selected clinics' inpatients by the researchers via posters and presentations. We specifically decided to do the initial introduction via researchers to avoid any (perceived) role conflicts between healthcare providers and patients, for example, when the healthcare provider also makes decisions about patients' leave in a forensic psychiatric context or discharge from a psychiatric inpatient clinic.

Interested patients will be informed of the goal, duration, and procedure of the study using the patient information sheet. When informing patients, we will stress that participation is voluntary, that they may withdraw at any time, and that their participation will not affect the care or support that they receive, nor will be used to make decisions about leave, discharge, or other transitions. We will also inform patients about the benefits and role of the accelerometer specifically, accounting for any concerns that may be prevalent in the target group (e.g. anxiety, suspicion, delusions) surrounding this device. The healthcare provider will not be present during this initial meeting, again to avoid any role conflicts that may influence the voluntary decision of the patient to participate in the study. However, they will receive the same information written beforehand, so that they are equipped to answer questions if the patient approaches them.

After this initial meeting the patient will be visited by the researcher one week later to discuss their continued interest and answer questions. If the patient wishes to participate in the study, we will discuss their potential participation with the primary healthcare provider responsible for the patient ('persoonlijk begeleider') to check whether participation is safe, appropriate, and feasible for this patient according to the inclusion criteria.

If this is the case, we will return to the patient to answer any questions that may have come up. If everything is clear and the patient wishes to participate, we will obtain written informed consent, using the informed consent form. We will also notify the healthcare provider of the patient's participation so that they can monitor the patient's well-being during study. Over the course of the study, we will frequently visit both the patient and healthcare provider to monitor progress and answer any questions (see section 5.3). If the healthcare provider, patient, and/or researcher responsible for patient contact notices any reason why the participation in the study should be paused or terminated, this will be discussed with the relevant parties. Of course, patients are also free to decline or stop participation without stating a reason at any moment.

8.3 Benefits and risks assessment, group relatedness

The study will be conducted with people with severe mental illness, who may be committed involuntarily to an inpatient clinic as part of their (forensic) psychiatric treatment. As a consequence of this, they might feel obliged to participate in this study as well. In order to deal with this potential conflict, we will communicate clearly, in multiple ways and in a way that is in line with the cognitive skills of the patient about the nature and goal of this study. We will clearly explain that participation is focused on lifestyle, in no way related to their treatment, and that not participating will not affect their treatment progress in any way.

While studies in people with severe mental illness may come with several barriers, it is essential to conduct research for and with this vulnerable target group. As discussed earlier in this proposal, people with SMI are a target group that suffer from poor physical health yet are barely targeted in preventive and health promotion research, leading to large systemic inequality [18]. People with SMI face a number of social, cognitive, physical, psychological, and sensory impairments, which may make regular mobile lifestyle interventions less accessible [57,58]. Therefore, it is imperative to develop and evaluate interventions specifically designed for people with SMI, as is done in this study. An additional potential benefit for participating individuals, is that use of the intervention(s) may increase physical activity and self-control, which is associated with health benefits [6]. As SCEDs represent the highest level of evidence to make treatment decisions for individuals [59], the findings from this study may also be used to inform evidence-based decisions to continue or discontinue use of the apps to improve lifestyle.

To mitigate potential risks when evaluating the novel intervention in this vulnerable population, we work with the Single Case Experiment Design, which allows as to draw valid conclusions about the effectivity of the intervention even with a very small sample of just six patients. In addition, this design allows us to monitor patients very closely in collaboration with their health care provider. This ensures that patients have one familiar contact person from the research and clinical team, who can support them, halt the study if necessary, and overall make sure that participation is safe and enjoyable for patients. In conclusion, by selecting SCEDs as research design, we do not only use a design that is appropriate for answering the main research questions in a complex, heterogeneous target group but also allows for close monitoring the patients to ensure that participation does not have a negative influence on their wellbeing.

8.4 Compensation for injury

Since there are no risk associated with the study, the University of Twente has asked for an exemption of the liability insurance in accordance with article 7 of the WMO.

8.5 Incentives

Participants will receive €50,00 for their participation. To promote continued commitment to the longitudinal design, participants will receive €10,00 at the start, €20,00 midway, and €20,00 at the end of the study.

9. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

9.1 Handling and storage of data and documents

All data generated during screening and the study itself (see Table 2) will be handled confidentially and anonymously in accordance with the EU General Data Protection Regulation and the Dutch Act on Implementation of the General Data Protection Regulation. Personal data will be coded with an individual ID-code, which is not relatable to the participant. A list will be created, which contains the ID-codes, stored on a separate drive on a computer and maintained by the principal investigator at her office in the Department of Psychology, Health and Technology of the University of Twente. Both the office, the drive, the computer, and the file containing the ID-codes will be locked with a key and password. All collected data will be stored in a file containing only the identification code to be able to match the data of the same person across different measurement points. These data will be stored and collected on a shared drive that is password protected and only accessible to the researchers.

The coded research data will be stored at the University of Twente for a period of 15 years. After the period of 15 years, data will be stored in long time storage at Data Archiving and Networked Services (DANS) by the Royal Dutch Academy of Sciences (KNAW) after which the ID codes key file ownership and maintenance is transferred to the secretary of the department of Psychology, Health and Technology of the University of Twente.

Participants who want to be informed about their personal data or who want their data deleted can send a request to the principal investigator. For this, no reason is needed, since participants always have the right to be informed about their personal data. After the personal data is deleted, informing participants about their personal data is no longer possible.

Table 2. Data types, format, and storage.

Data type	Data format	Storage
ID codes key file	.xls (Excel)	PI
Signed consent forms	.pdf (Adobe)	PI
Screening data	.xls (Excel)	Researchers
Accelerometer data	.csv (Excel)	Researchers
Daily questionnaire data	.csv (Excel)	Researchers
Weekly questionnaire data	.csv (Excel)	Researchers
Intervention usage data	.csv (Excel)	Researchers
Interview recordings	.mp3	PI
Interview transcriptions	.docx (Word)	Researchers
Coded dataset	.csv (Excel, R, SPSS)	Researchers
Syntax	.rproj, .sps (R, SPSS)	Researchers

9.2 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be notified to the METC that gave a favourable opinion.

9.3 Annual progress report

The sponsor/investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions, other problems, and amendments.

9.4 Temporary halt and (prematurely) end of study report

The University of Twente will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last measurement. The sponsor will notify the METC immediately of a temporary halt of the study, including the reason of such an action.

In case the study is ended prematurely, the University of Twente will notify the accredited METC within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the University of Twente will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

9.5 Public disclosure and publication policy

We aim to publish three articles about the study. One article will describe the research protocol. A second article will focus on the effectiveness of the intervention and the third will focus on the merit of SCED as a methodology for evaluating eHealth interventions in vulnerable populations. Prior to any publications, the trial will be registered in the Netherlands National Trial Register (NTR) (TrialRegister.nl). All articles will be submitted to open access, scientific peer- reviewed journals.

10. STRUCTURED RISK ANALYSIS

10.1 Potential issues of concern

a. Level of knowledge about mechanism of action

Improving physical activity (PA) can promote health and wellbeing of people with severe mental illness (SMI). Intentions for physical activity can be set using self-monitoring, a technique embedded in many interventions that focus on the reflective route of behaviour change, including Google Fit [60,61]. Various trials suggest that high levels of self-control help people enact intentions to improve physical activity, i.e. through an automatic route of behaviour change [62,63]. Finally, large scale systematic reviews and meta-analyses have demonstrated that SCT increases self-control [13–15]. Together, these findings imply that SCT and Google Fit may be valuable interventions to improve physical activity in people with SMI, specifically when SCT is used to boost the effect of Google Fit by translating intentions to actual behaviour.

b. Previous exposure of human beings with the test product(s) and/or products with a similar biological mechanism

Paper versions of SCT have been used successfully and safely since 1999 [13]. The specific mobile application version used in this study has also been used safely by 204 university students [16]. Three usability tests with people with SMI similarly showed that the app is also safe to use by this vulnerable population due to its tailored design, which incorporates recognizable, clear, and non-distracting visualizations, short and easy-to-read Dutch text, and is less numerical than comparable interventions. Finally, Google Fit is one of the most popular physical activity apps that is safely used by 100 million users worldwide, including in people with poor mental health [31,64].

c. Can the primary or secondary mechanism be induced in animals and/or in *ex-vivo* human cell material?

Not applicable to lifestyle interventions.

d. Selectivity of the mechanism to target tissue in animals and/or human beings

Not applicable to lifestyle interventions.

e. Analysis of potential effect

Given the safe use of SCT and Google Fit over several years we expect no harmful effects or adverse effects to occur as a result of these mobile lifestyle interventions. Patients may experience the benefit of more self-control and physical activity.

f. Pharmacokinetic considerations

Not applicable to lifestyle interventions.

g. Study population

The study will be conducted with people with severe mental illness, who may be admitted (involuntarily) to an inpatient clinic as part of their (forensic) psychiatric treatment. People

with SMI are a target group that suffer from poor physical health yet are barely targeted in preventive and health promotion research, leading to large systemic inequality [18]. Despite promising results in other target groups, many existing cognitively-oriented physical activity mobile interventions are not suitable for people with SMI given the number of social, cognitive, physical, psychological, and sensory impairments they face [57,58]. Therefore, it is imperative to develop and evaluate interventions specifically designed for people with SMI, as is done in this study. The single case experimental design is specifically suitable for this endeavor, since only a limited number of patients need to be recruited to draw valid conclusions about the interventions' effectiveness and the design can inherently handle heterogeneous populations since patients function as their own control.

h. Interaction with other products
Not applicable to lifestyle interventions.

i. Predictability of effect
Not applicable to lifestyle interventions.

j. Can effects be managed?
Not applicable to lifestyle interventions.

10.2 Synthesis

To mitigate potential risks when evaluating the novel SCT intervention in the vulnerable population of people with SMI, we work with the Single Case Experiment Design, which allows as to draw valid conclusions about the effectivity of the intervention with a sample of six patients. This design ensures that we can draw valid conclusions without having to include a large number of patients, which can be both hard to achieve and even undesirable in the heterogeneous target group. All data will be collected automatically or using very brief, simple questionnaires, requiring limited effort of the patient. In addition, this design allows us to monitor patients very closely in collaboration with their health care provider (*persoonlijk begeleider*). This ensures that patients have one familiar contact person from the research and clinical team, who can support them, halt the study if necessary, and overall make sure that participation is safe and enjoyable for patients. Patients will be fairly reimbursed for participation and may decline or stop participation in the study at any time for any reason if they wish to do so without any consequences. Neither participation nor withdrawal will have any consequences for leave, discharge, or care transitions, which will be communicated multiple times and in via multiple different approaches (verbal explanation and information flyers for patients and care providers). Furthermore, our study is not part of psychiatric treatment, but focuses on lifestyle – an important yet underrepresented topic in psychiatric patients. In conclusion, this study can be considered low-risk, low-effort and may have benefits both for individual patients and the vulnerable target population of people with SMI as a whole in improving physical and mental health by facilitating a healthy lifestyle.

11. REFERENCES

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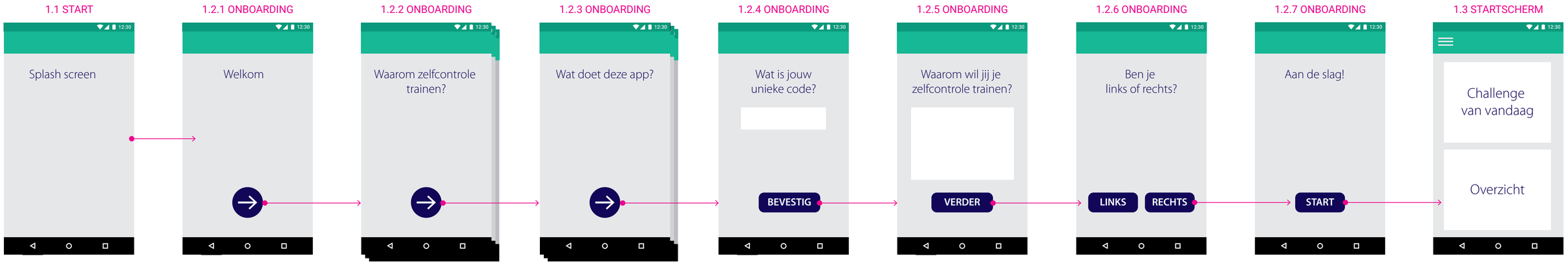
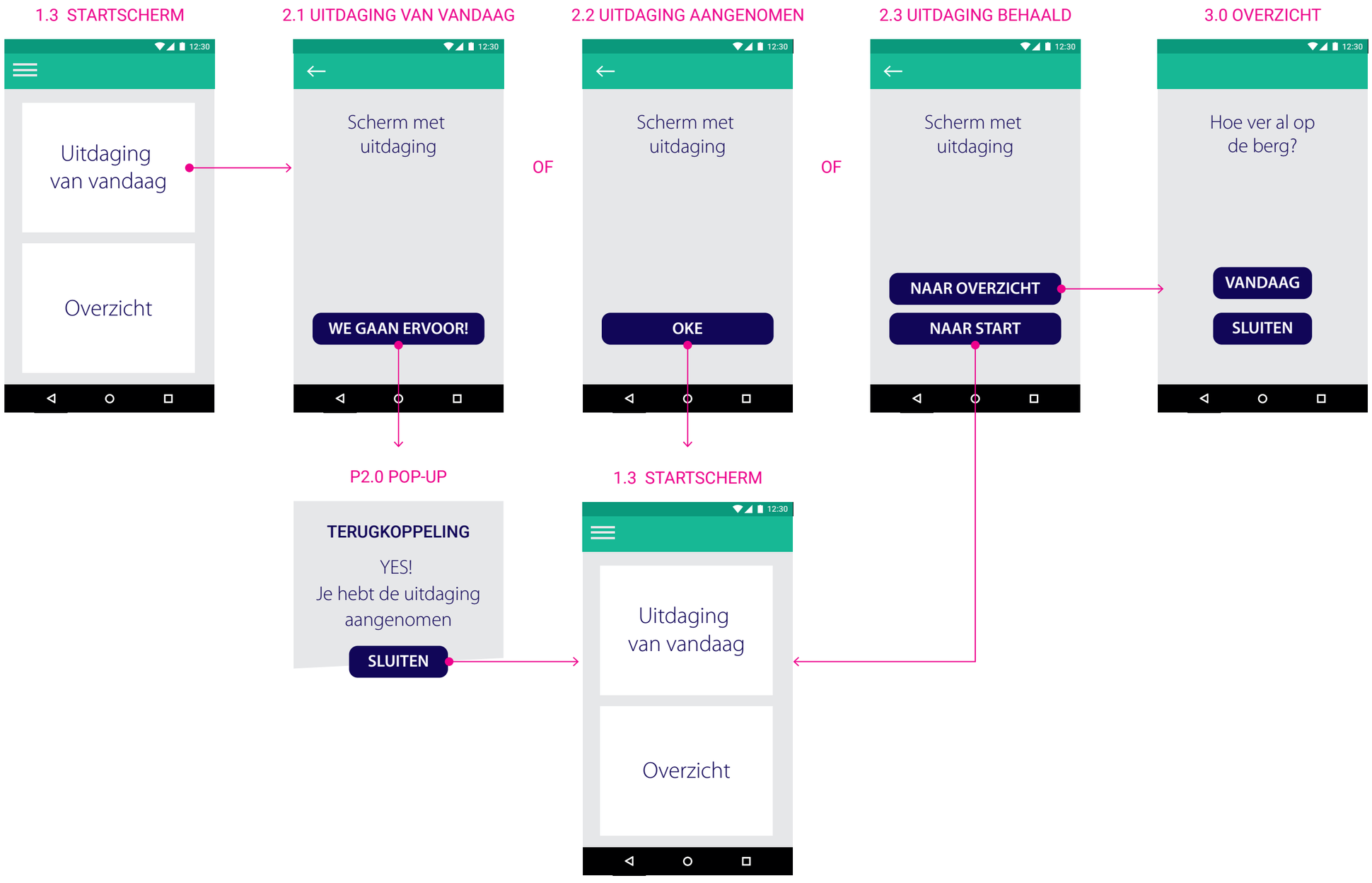
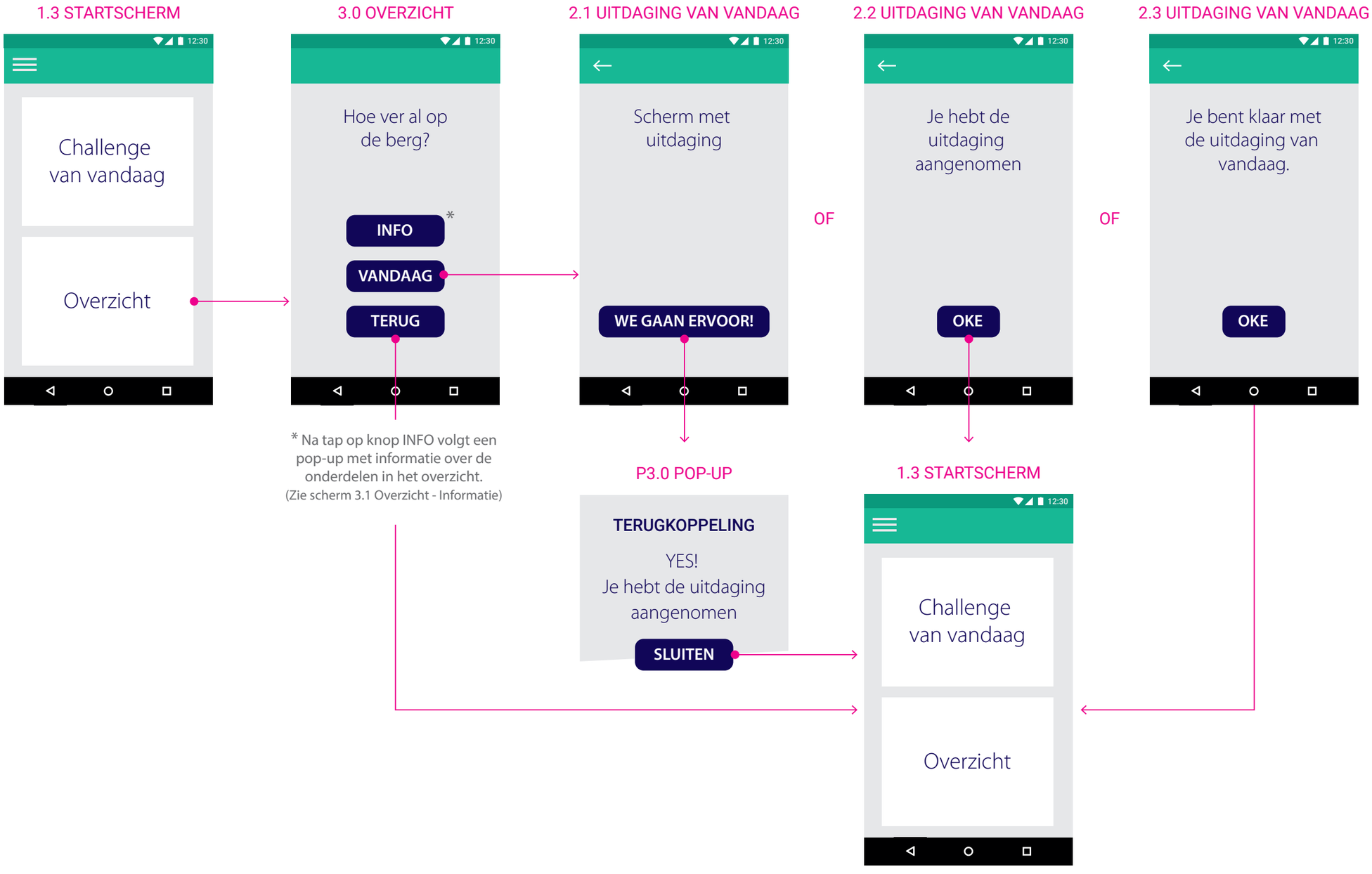
1.0 ONBOARDING



2.0 UITDAGING BEKIJKEN VANAF STARTSCHERM



3.0 OVERZICHT BEKIJKEN VANAF STARTSCHERM

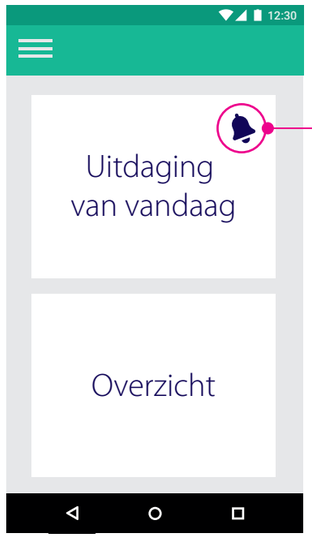


4.0 UITDAGING AANNEMEN

N4 .0 NOTIFICATIE *

Er staat een nieuwe uitdaging klaar!

1.3 STARTSCHERM

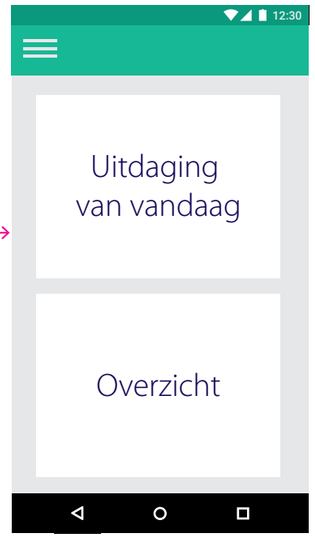


Icoon van bel is zichtbaar.
Er is iets nieuws te zien/doen.

2.1 UITDAGING VAN VANDAAG

P4.0 POP-UP

1.3 STARTSCHERM



7.0 MENU

N4.0 NOTIFICATIE *

De gebruiker krijgt op vaste tijden een notificatie binnen. Het zijn er **4** in totaal.

8:00 Er staat een nieuwe uitdaging klaar!

12:00 Denk je aan je uitdaging?

16:00 Je hebt nog 4 uur voor je uitdaging.

Door een tap op één van deze notificaties komt de gebruiker op het scherm **3.1 UITDAGING VAN VANDAAG** uit of, indien de gebruiker de uitdaging al aan heeft genomen, op scherm **3.2**.

De gebruiker moet de uitdaging de hele dag aan kunnen nemen.

N5.0 NOTIFICATIE

20:00 Hoe ging het?

Door een tap op deze notificatie komt de gebruiker op het scherm **4.1 UITDAGING GELUKT** uit.

Ook wanneer de gebruiker de challenge niet aan heeft genomen, komt zij op dit scherm uit.

5.0 UITDAGING VOLBRENGEN

N5.0 NOTIFICATIE

Hoe ging het?

1.3 STARTSCHERM

12:30

Uitdaging van vandaag

Overzicht

5.1 UITDAGING GEDAAN

12:30

Heb je de uitdaging gedaan?

JA

NEE

5.3 TERUGKOPPELING

12:30

HELAAS

Morgen weer een kans!

OVERZICHT

SLUITEN

3.0 OVERZICHT

12:30

Hoe ver al op de berg?

VANDAAG

SLUITEN

2.3 UITDAGING BEHAALD

12:30

Je bent klaar met de uitdaging van vandaag.

OKE

7.0 MENU

- Waarom zelfcontrole trainen?
- Wat doet deze app?
- Uitdaging van vandaag
- Overzicht
- Behaalde uitdagingen
- Instellingen
- Wie heeft de app gemaakt?

5.2.1 HOE GING HET? *

12:30

Hoe goed is de uitdaging gegaan?

5.2.2 BELONING*

12:30

YES!

Beloning

OVERZICHT

SLUITEN

1.3 STARTSCHERM

12:30

Uitdaging van vandaag

Overzicht

5.2.1 HOE GING HET? *

De gebruiker kan ervoor kiezen om de vragen niet te beantwoorden door 'terug' te gaan.

Wanneer de gebruiker de vragen niet beantwoordt, dan is de dag niet afgerond.

Tot **8:00u de volgende morgen** kan de gebruiker de vraag nog beantwoorden.

Na 8 uur kan dat niet meer. Op dat moment wordt het scherm vervangen voor een nieuwe uitdaging.

Een onafgeronde uitdaging wordt in het overzicht uitgegrijst.

5.2.2 BELONING*

Er zijn 14 beloningsschermen. Op dag **2, 7 en 14** krijgt de deelnemer een beloning+ (ook wel milestone genoemd).
Op deze schermen krijgt de gebruiker een uitnodiging om zijn voortgang te delen met iemand die dicht bij hem staat.

Wanneer de gebruiker in scherm 5.2.1 de vraag niet beantwoord, maar op het pijltje drukt. Is de uitdaging nog niet afgerond.

Om de gebruiker hierop te attenderen, volgt een pop-up.

P5.0 POP-UP

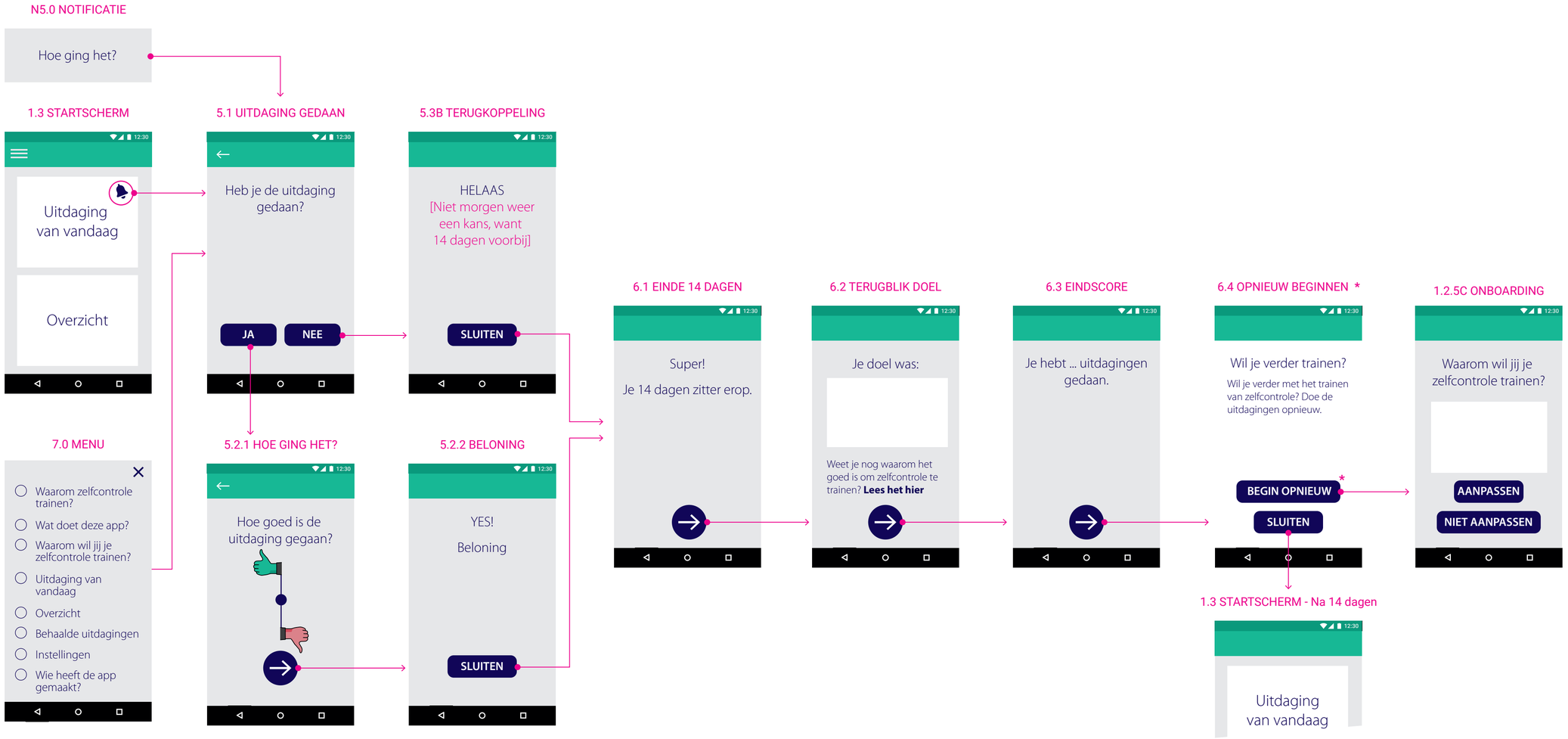
LET OP!

Weet je zeker dat je de vraag niet wil beantwoorden?

JA

NEE

6.0 NA 14 DAGEN



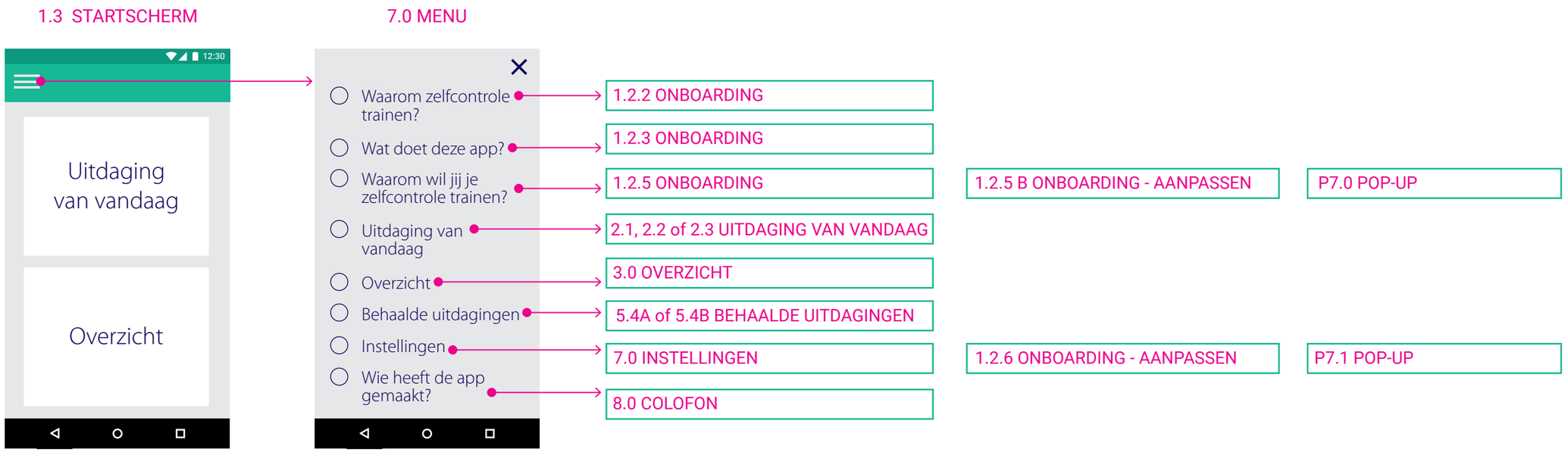
6.4 OPNIEUW BEGINNEN *

Wens is om na 14 dagen opnieuw te beginnen.

Daarbij hoeft de deelnemer niet opnieuw de onboarding door.

De deelnemer moet wel opnieuw haar doel in kunnen vullen (scherm **1.2.5C ONBOARDING**) alvorens op scherm **1.3 STARTSCHERM** te komen.

7.0 MENU


1.3 STARTSCHERM
7.0 MENU
12:30
Uitdaging van vandaag
Overzicht
Waarom zelfcontrole trainen?
Wat doet deze app?
Waarom wil jij je zelfcontrole trainen?
Uitdaging van vandaag
Overzicht
Behaalde uitdagingen
Instellingen
Wie heeft de app gemaakt?
1.2.2 ONBOARDING
1.2.3 ONBOARDING
1.2.5 ONBOARDING
1.2.5 B ONBOARDING - AANPASSEN
P7.0 POP-UP
2.1, 2.2 of 2.3 UITDAGING VAN VANDAAG
3.0 OVERZICHT
5.4A of 5.4B BEHAALDE UITDAGINGEN
7.0 INSTELLINGEN
1.2.6 ONBOARDING - AANPASSEN
P7.1 POP-UP
8.0 COLOFON

People with severe mental illness' perspectives on mHealth self-control training – Protocol of a participatory design study

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Abstract

Improving physical activity (PA) through eHealth can promote health of people with severe mental illness (SMI). Yet, existing interventions are time consuming and are based predominantly on cognitive models. These cognitively underpinned interventions suffer from the behaviour-intention gap and rely on a high level of cognitive skills such as attention, goal setting and writing, which people with SMI often do not fully possess. Therefore, complementary interventions that focus on automatic processes instead, such as self-control training (SCT), may be necessary to promote PA in this vulnerable population.

The goal of this study is to use participatory design to explore the perspectives of people with SMI on self-control training, to ultimately design usable, engaging, and effective digital SCT specifically for people with SMI.

6-8 patients will be enrolled in a series of co-creative design workshops. Each workshop guides patients through creative exercises that explore their perceptions of self-control in daily life (workshop 1), their experiences with eHealth (workshop 2), and their preferences for the design and functionality of a self-control training app (workshop 3). All workshops will be recorded and transcribed, and the resulting data will be analysed according to qualitative content analysis to derive major themes that reflect requirements for a successful SCT app from the patients' perspective.

Background

Improving health behaviour is one of the major challenges of the twentieth century. An especially severe problem is lack of physical activity (PA). While limited PA is detrimental for everyone, it has an especially negative impact of the health and quality of life of people with severe mental illness (SMI) [1]. SMI is characterized by a long duration and major disruptions of daily functioning, due to disorders such as schizophrenia or major depression. Fortunately, even minor improvements in PA can prevent problems with physical health and deterioration of psychiatric symptoms in people with SMI [2].

This makes clear that there is an urgent need to improve PA in this vulnerable population. However, while existing PA interventions for people with SMI show fairly positive results, there is room for improvement in terms of effectiveness and efficiency [3]. Existing PA interventions are often delivered by professionals [3,4], which requires time and effort from already overworked staff. On top of that, most PA interventions are underpinned by cognitive models and rely on a fairly high level of cognitive skills such as attention, goal-setting and writing, which people with SMI often do not fully possess [5]. Finally, they are suboptimal in changing behaviour, partly due to the well-known intention-behaviour gap [6]. This highlights the need for new types of interventions that address these issues.

A very promising focus for these new types of interventions is self-control: the ability to prevent or override unwanted thoughts or behaviours [7,8]. Studies have shown that self-control has a positive impact on a broad range of topics, such as academic success, aggression regulation and physical health [7]. According to the strength model of self-control, it can be seen as a muscle, implying that it can be trained [9]. A large body of research has confirmed this logical and surprisingly straightforward hypothesis: self-control training (SCT) can indeed strengthen self-control [10–12]. In SCT, participants are asked to perform a task that requires self-control for a pre-specified period, often two weeks. An example is using one's non-dominant hand for daily tasks. By adding SCT to existing PA interventions, the intention-behaviour gap can be bridged, resulting in an increased effectiveness of existing interventions that are underpinned by cognitive models. Surprisingly, despite the large body of evidence that shows SCT's potential, it has hardly been applied and studied in clinical practice and for preventive purposes. This shows the potential of developing and evaluating SCT in psychiatric settings to support patients with SMI in improving their PA.

A very promising way to deliver SCT to psychiatric patients with SMI is via a mobile app. Amongst other things, an app can be used by patients individually and in their own time and pace, is scalable, and can increase patient motivation and adherence, making it a suitable instrument to target people with SMI [13]. Such an SCT app can be combined with an existing PA app to bolster its effectiveness by increasing self-control in a relatively cheap, scalable and engaging way. We have previously developed and pilot-tested a functioning prototype of an SCT app, aimed to bolster self-control in students via the non-dominant hand paradigm, mainly to gain insight into whether it would be a feasible solution for forensic psychiatry. A study that used a pre-post design

with only 19 students already showed significant improvements in self-control, indicating the apps potential [14]. However, this app did not contain all necessary functionalities, and was created for English-speaking, highly educated students. While parts of the app such as several tasks and underlying structures can be re-used in the current project, an existing intervention cannot simply be copy-pasted into a technology: engaging design that fits the needs and characteristics of the target group is essential for the success of any eHealth intervention. Fitting design can have a positive influence on matters such as adherence, implementation in practice and effectiveness. To achieve such a fit, participatory design should be used, in which end-users are structurally involved in the development process [15].

Research questions

Consequently, the aim of this project is to apply a participatory design approach to explore the perspectives of people with SMI on self-control (training) through eHealth, so that their perspectives may be used in the design of an appropriate, effective, and engaging app fit to their needs. It is guided by two research questions:

1) How do people with SMI understand self-control in their daily life?
2) What are the preferences of people with SMI concerning a SCT app in terms of functionality and design?

Methods

Participatory Design (PD) is characterized by active involvement of non-designers throughout the design process in a collective creative partnership established through design activities [16–24]. Here, non-designers refer to all individuals with a background in scientific or professional fields other than design, which may include end-users (including patients, friends, and family) and external stakeholders (including caregivers and management) [21]. Active involvement reflects that these people influence the design process and product beyond mere usage, and may range from them taking a role as testers, informants or partners [25]. PD particularly values the latter, which means that PD research is done *with* partners instead of *on* them [17]. In this approach, design activities are used [17,18,22–24], often in the form of focus groups or workshops, which include activities that facilitate collective creativity by allowing all parties to share their experience and knowledge through acts of making (e.g. a foam mock-up), telling (e.g. diary), and/or acting (e.g. role play) [21].

Many benefits of PD have been proposed, ranging from improving effectiveness of interventions to empowering patients [20]. In a pragmatic sense, PD is said to improve the user experience and usability of products and services designed through PD by making them fit more closely to users' needs, as clarified in the PD process [17,20,22,26]. This may be especially important in the context of SMI and the number of social, cognitive, physical, psychological, and sensory impairments people with SMI face [26,27] and the difficulty in truly grasping these concerns using traditional research methods [28]. Interventions are expected to benefit from this improved fit in multiple ways, including increased effectiveness [17], adherence [29,30] and adoption. In addition, PD, some authors claim that involvement in a PD process has direct benefits for partners by providing a method to express their creativity [31] and (re)gaining ownership and

power [17,20] with some studies even claiming therapeutic effects from participation [32]. Again, this may be specifically relevant for patients and people from marginalized communities, including people with SMI.

Participatory design has successfully been used to collaboratively design eHealth services with people with SMI before. Notably examples include the work of Terp and colleagues [33] who worked with young adults with schizophrenia to design a smartphone application supporting early phase schizophrenia care in a participatory design process spanning 10 workshops; the work of Switsers and colleagues [34], who explored self-management needs of people with bipolar disorders to collaboratively design an app over the course of two sessions; and the work of Nakarada-Kordic and colleagues [35] involving teenaged people who had experienced psychosis in the design of an educational website in a series of creative workshops. All studies were considered feasible and successful, and endorse the pragmatic and empowering benefits of participatory design described above: participatory design enabled active engagement of patients and made them feel "lucky, important, and valuable, not as patients, but as experts of their experience" [33], it highlighted the diversity in patients' preferences for mHealth so that fit of the app could be improved [34], and it dispelled misconceptions about people with mental illness ultimately leading more engaging and effective product [35]. These results lead us to believe that participatory design methods may also be appropriate for the forensic psychiatric context, even if it has not been applied there.

Participants

We plan to recruit 3-4 participants from households within two care facilities of the project partners Dimence Groep and GGz Centraal using a convenience sampling strategy in collaboration with the care providers of both facilities. Where possible, we tried to achieve maximum variation in the sample in terms of the type of severe mental illness patients had, whether they were in forensic treatment or not, their level of experience with mobile applications, age, and gender.

To be eligible, participants had to have received a diagnosis for a severe mental illness (bipolar disorder, schizophrenia, major depression, or severe attention-deficit hyperactivity disorder) and either have had treatment for their disorder in the past two years or be undergoing treatment at the time of the study. Participants also had to be at least 18 years old, have sufficient understanding of the Dutch language, and be willing to share information based on their knowledge and experience.

Exclusion criteria included inability to provide written informed consent and a condition that mandated quarantine under the COVID-19 regulations (e.g. an infection, contact with a person with an infection, returning from an at-risk area). Finally, at the time of the workshops, we reconsidered whether participation would not constitute a risk of harm for the patient (for example, in an active manic episode), as evaluated by themselves and their care provider. If doubts existed about the ability of the participant to participate in the workshop, participation was discussed on a case-by-case basis with a care provider not associated with the project.

Procedure

People with several mental illness will participate in three workshops. Workshop 1 will focus on patients' perspectives on self-control in daily life. Workshop 2 will focus on patients' preferences for mHealth. Workshop 3 will combine insights from both sessions to co-creatively design a mHealth app for self-control training in collaboration with patients. Prior to all workshops, the researchers will introduce themselves to the patients and caregivers in a visit to the clinic. During this visit, the study will be explained, and informed consent will be obtained.

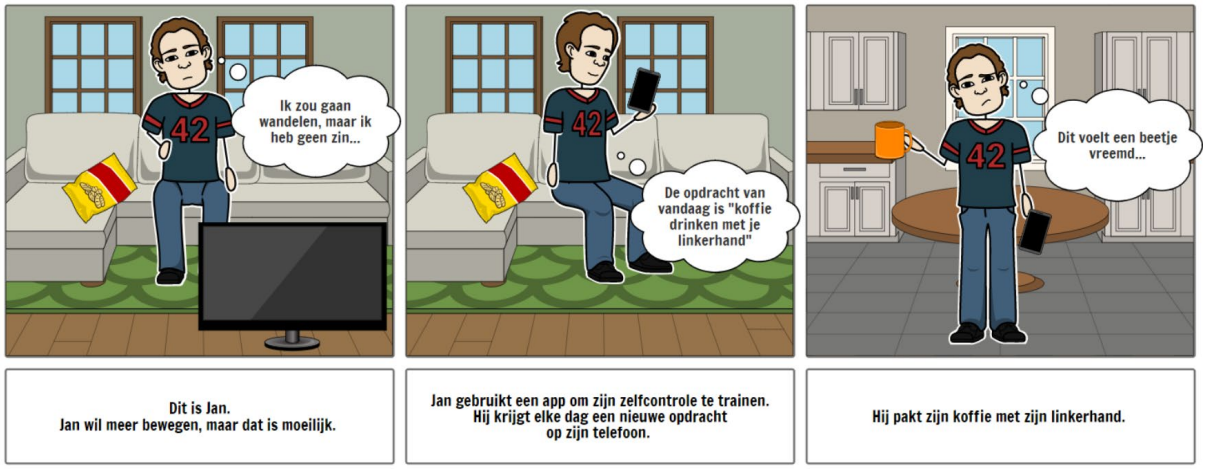
Workshop 1 consists of 2 activities: 2D collaging and a moderated group discussion with a storyboard. Patients will create a collage on self-control using a mix of positive, neutral, and negative magazine clippings, illustrations, words, and abstract shapes. Next, each participant will present their collage to the group, thereby using the created artefact to explain self-control from their perspective. Then, patients will read the storyboard, in which a character experiences low self-control, explains what self-control is, and how he trains self-control using the app. A moderated group discussion will explore participants' experiences with low & high self-control and self-control failure & success, and their attitudes towards self-control training.

Workshop 2 consists of 2 activities, a moderated group discussion of patients' current experiences with mobile applications and creation of a screen of the app. Patients will share the app(s) on their phones they use most often and are asked to estimate when, where, how often, and how long, and they use these apps. Next, participants are asked what they like and dislike about the apps. To facilitate this discussion, patients will pick appropriate labels from a word cloud with post-its with positive and negative valence labels (e.g. "funny" or "boring"). Next, patients will design a screen of the app through a canvas with prompts based on the set of desired qualities discussed earlier.

Workshop 3 consists of 1 activity, codesign of a paper prototype. Based on the insights from workshop 1 & 2, a paper prototype of the app will be developed. Using a think-aloud approach, patients will navigate through the prototype and customize it using a sticker set. The sticker set will include a mix of buttons commonly used in user interfaces of (mHealth) apps as well as abstract shapes that patients can use to represent functions not covered in the sticker set. The session will close with a general group interview, asking patients for their final views regarding the prototype and the extent to which they find it appealing, usable and intuitive.

Finally, all patients are thanked for their participation and receive their reimbursement, including a thank you note, and a postcard stamped with the university as the return address and the request to send the card if they think of new insights they want to share after the formal close of the workshop series.

Example of a storyboard: an accessible method for discussing new technology with patients.



Analysis

Qualitative data will be collected in the form of audio recordings of each workshops, photos of participant artefacts (e.g. the collages developed) and researcher notes. All audio recordings will be transcribed after which audio recordings will be deleted. Each participant will be assigned a study code to allow all data to be anonymized.

Data will be analysed in accordance with the guidelines of qualitative content analysis (Graneheim) to find major themes in the data. Themes will be generated inductively in line with the research questions and may for instance concern patients experiences with self-control in their daily life, their preferences for look and feel of the app, and factors that motivate them to make use of the app.

Additional considerations

The sessions will be conducted in June - July 2021, during which social distancing guidelines of the Covid-19 pandemic are in place. In addition, the sessions involve the vulnerable population of people with a SMI. To ensure that patients can effectively and safely participate under these conditions, we took the following additional ethical considerations.

- *Length:* Typical participatory sessions are 2-4 hours. People with SMI have issues with hyperactivity, inattention, apathy, and motivation which make longer sessions infeasible and difficult to participate in. Therefore, we designed shorter sessions of 90 minutes (including a break).
- *Complexity:* Our previous work showed that people with SMI find it difficult to engage in high-level creative work. To keep sessions accessible to all patients we therefore focused on adapting material (e.g. making existing things one's own) instead of creating something from scratch. At the same time, we brought creative prompts to facilitate creativity on higher levels if patients expressed interest and capability.
- *Group size and composition:* We opted for a flexible approach to group size, meaning that each session was designed to take place in a group but could also be changed to a paired

or individual format at a short notice. In this way, we can also account for existing social relationships of co-habiting inpatients that may inhibit patients' feelings of safety and creative expression (for example, if conflicts had arisen on the day of the session).

- *COVID-19:* Patients will be recruited from the same 'household' (e.g. patients from the same assisted living facility, ward, or location) to accommodate social distancing guidelines. Furthermore, researchers will be tested prior to each workshop.
- *Debriefing and aftercare:* The primary caregiver of each patient (persoonlijk begeleider) will be available during and after the workshops to provide counselling.

Relevance

This project aims to develop an SCT app to improve self-control. While the focus lies on increasing PA, such an app could be used to positively influence a broad range of health behaviours driven by self-control, like quitting smoking, physical persistence or aggression [10,36]. SCT will be a relatively cheap and feasible addition to the existing intervention base and can make a major contribution to the prevention of lifestyle-related disease.

Additionally, involving vulnerable target groups such as people with SMI in research and e-health interventions is very challenging, while these underrepresented groups can often benefit the most from interventions. To date, limited knowledge is available on how to conduct participatory design processes in collaboration with people with SMI effectively. Therefore, this project can also be used to generate insight into best practices for conducting participatory research with vulnerable target groups. To support this secondary goal, an expert-informant study and literature review on this topic will run in parallel.

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210814 REQUEST FOR ETHICAL REVIEW

Request nr: 210814
Researcher: Dekkers, T.
Supervisor: -
Reviewer: Klooster, P.M. ten
Status: Approved by commission
Version: 2

1. START

A. TITLE AND CONTEXT OF THE RESEARCH PROJECT

1. What is the title of the research project? (max. 100 characters)

People with severe mental illness' perspectives on mHealth self-control training

2. In which context will you conduct this research?

Post-doctoral project

3. Date of the application

07-05-2021

5. Is this research project closely connected to a research project previously assessed by the BMS Ethics Committee?

Yes

please provide the ethic request number(s) for the research project(s):

210650 / 210121

B. CONTACT INFORMATION

6. Contact information for the lead researcher

6a. Initials:

T.

6b. Surname:

Dekkers

6c. Education/Department (if applicable):

BMS-PGT

6d. Staff or Student number:

76677020

6e. Email address:

t.dekkers@utwente.nl

6f. Telephone number (during the research project):

+310534899741

6g. If additional researchers (students and/or staff) will be involved in carrying out this research, please name them:

Hanneke Kip [h.kip@utwente.nl]; Stephanie Schouten [s.e.schouten@student.utwente.nl]

6h. Have you completed a PhD degree?

Yes

8. Is one of the ethics committee reviewers involved in your research? Note: not everyone is a reviewer.

No

C. RESEARCH PROJECT DESCRIPTION

9a. Please provide a brief description (150 words max.) of the background and aim(s) of your research project in non-expert language.

Improving physical activity (PA) can prevent a broad range of negative consequences for the physical and mental health of people with severe mental illness (SMI). While existing PA interventions show positive effects in the general population, there is room for improvement when employed for people with SMI. Amongst other things, existing interventions are time consuming and are based predominantly on cognitive models. These cognitively underpinned interventions suffer from the behaviour-intention gap and rely on a fairly high level of cognitive skills such as attention, goal-setting and writing, which people with SMI often do not fully possess. Therefore, novel interventions that are specifically designed with and for people with SMI are necessary to support this vulnerable population in increasing PA. Self-control training (SCT) is an evidence-based intervention that has much potential to address these concerns. In SCT, participants perform everyday tasks that require self-control, hereby training their ability to prevent or override unwanted thoughts or behaviours. SCT can bridge the intention-behaviour gap, and can thus be added to existing, cognitively underpinned interventions to bolster their effectiveness. To design usable, engaging and effective SCT specifically for people with SMI, this study uses participatory design to explore the perspectives of people with SMI on self-control (training) through mHealth. It is guided by two research questions: 1) How do people with SMI understand self-control in their daily life? 2) What are the preferences of people with SMI concerning a digital self-control training app in terms of functionality and design?

9b. Approximate starting date/end date of data collection:

Starting date: 2021-05-20

End date: 2021-08-31

9c. If applicable: indicate which external organization(s) has/have commissioned and/or provided funding for your research.

Commissioning organization(s):

Not applicable

Funding organization(s):

ZonMw

Grant number:

555003023

2. TYPE OF STUDY

Please select the type of study you plan to conduct:

My study will involve both existing and new data.

3. RESEARCH INVOLVING EXISTING DATA OR DOCUMENTS

A. WHICH DATA AND/OR DOCUMENTS WILL BE ACCESSED AND HOW?

10. Please provide a brief description of the data or documents that you plan to use (max. 2000 characters, including spaces).

In project #210650, one-on-one interviews are conducted with people with SMI. The anonymized, written transcripts of this study will be used in addition to the workshop data to answer the first research question. In project #210121, a literature review and survey among experts is conducted to determine best practices in participatory research with vulnerable populations. The anonymized survey data will be used to derive suggestions that can be implemented in the workshops to improve their quality.

11. Please indicate whether the data/documents you will use are:

- Private

11d. Please indicate the purpose for which these data were originally collected (max. 2000 characters, including spaces):

The data from project #210650 was collected in the context of a master thesis. The goal was to comprehend what self-control means to people with severe mental illnesses. The data from project #210121 was collected in the context of the postdoc project and a master thesis. The goal was to describe best practices in participatory design with people with SMI.

11e. How will you obtain access to these private data, and what are the conditions for use?

I have collected this data myself and already have access.

11f. Have the individuals/organizations to whom these data pertain provided consent for additional, later use of the data?

Yes

B. CONFIDENTIALITY AND ANONYMITY

12. Does the dataset contain information (or a combination of information) that can be traced back to specific individuals/organizations?

No

4. RESEARCH INVOLVING THE COLLECTION OF NEW DATA

A: RESEARCH POPULATION

20. Please provide a brief description of the intended research population(s):

We plan to recruit 6-8 participants from households within two care facilities of the project partners Dimence and GGZ Centraal using a purposive sampling strategy in collaboration with the care providers of both facilities. Where possible, we tried to achieve maximum variation in the sample in terms of the type of severe mental illness patients had, whether they were in forensic treatment or not, their level of experience with mobile applications, age, and gender.

21. How many individuals will be involved in your research?

2 teams of participants (3-4 participants each) will participate in every workshop. We aim to have the same patients involved throughout the project, instead of involving new patients for each session to ensure that patients grow comfortable with using design activities over the course of the project. The downside to involving the same patients throughout the workshops is that patients may be discharged or moved to other facilities prior to finishing the project. For this reason, we plan to have workshops in rapid succession (e.g. weekly workshops) and in two parallel tracks (1 in forensic psychiatric care facility and 1 in a regular mental health care facility). Thus, if patients do drop out, we can still collect insights in the other track. However, it may still be necessary to recruit new participants to the workshops if more than 2 patients drop out or arranging consecutive workshop puts too much stress on health care professionals. In that case, we will continue recruitment until each workshop is attended by at least 3 participants again.

22. Which characteristics must participants/sources possess in order to be included in your research?

To be eligible, participants have to have received a diagnosis for a severe mental illness (bipolar disorder, schizophrenia, major depression, or severe attention-deficit hyperactivity disorder) and either have had treatment for their disorder in the past two years or be undergoing treatment at the time of the study. Participants also have to be at least 18 years old, have sufficient understanding of the

Dutch language, and be willing to share information based on their knowledge and experience. Exclusion criteria include inability to provide written informed consent and a condition that mandated quarantine under the COVID-19 regulations (e.g. an infection, contact with a person with an infection, returning from an at-risk area). Finally, at the time of the workshops, we reconsidered whether participation would not constitute a risk of harm for the patient (for example, in a manic episode), as evaluated by themselves and their care provider. If doubts existed about the ability of the participant to participate in the workshop, participation was discussed on a case-by-case basis with a care provider not associated with the project.

23. Does this research specifically target minors (<16 years), people with cognitive impairments, people under institutional care (e.g. hospitals, nursing homes, prisons), specific ethnic groups, people in another country or any other special group that may be more vulnerable than the general population?

Yes

(please explain): The research targets people with severe mental illness. The inclusion of people with SMI in participatory design (PD) research is necessary to ensure that the SCT intervention, which can have a beneficial impact on their health, is designed to meet their specific needs, preferences, and capabilities. PD is said to improve the user experience and usability of products and services by making them fit more closely to users' needs. This may be especially important in the context of SMI and the number of social, cognitive, physical, psychological, and sensory impairments people with SMI face and the difficulty in truly grasping these concerns using traditional research methods. Interventions are expected to benefit from this improved fit in multiple ways, including increased effectiveness, adherence, and adoption. PD also has a moral imperative in empowerment. Involvement in a PD process can have direct benefits for partners by providing a method to express their creativity and (re)gaining ownership and power. Some studies have even observed therapeutic effects after participation. Again, this may be specifically relevant for patients and people from marginalized communities, including people with SMI. To protect the interest of people with SMI all participation will be on a strictly voluntary basis. Consent will not only be asked at the start of the research, but also during the workshops and as the project continues. It will be

emphasized that the decision to participate will not affect the care they receive in any way and that they are free to stop any time they want to. To further prevent dependent relationships, none of the researchers will be involved in the care of participants. Their usual care givers will be present during the workshop to ensure safety of both the researchers (in the closed forensic psychiatric clinic) and the patients (regarding the potential emotional impact of the sessions).

24. Are you planning to recruit participants for your research through the BMS test subject pool, SONA

No

B. METHODS OF DATA COLLECTION

25. What is the best description of your research?

- Research using focus groups and/or stakeholder workshops

26. Please prove a brief yet sufficiently detailed overview of activities, as you would in the Procedure section of your thesis or paper. Among other things, please provide information about the information given to your research population, the manipulations (if applicable), the measures you use (at construct level), etc. in a way that is understandable for a relative lay person.

People with SMI will participate in 3 sessions. Session 1 will focus on patients' perspectives on self-control in daily life. Session 2 will focus on patients' preferences for mHealth. Session 3 will combine insights from both sessions to co-creatively design a mHealth app for self-control training in collaboration with patients. Prior to all workshops, the researchers will introduce themselves to the patients and caregivers in a visit to the clinic. During this visit, the study will be explained, and informed consent will be obtained. Workshop 1 consists of 2 activities: 2D collaging and a moderated group discussion with a storyboard. Patients will create a collage on self-control using a mix of positive, neutral, and negative magazine clippings, illustrations, words, and abstract shapes. Next, each participant will present their collage to the group, thereby using the created artefact to explain self-control from their perspective. Then, patients will read the storyboard, in which a character experiences low self-control, explains what self-control is, and how he trains self-control using the app. A moderated group discussion will explore participants' experiences with low & high self-control and self-control failure & success, and their attitudes towards self-control training. Workshop 2 consists of 2 activities, a moderated group discussion of patients' current experiences with mobile applications and creation of a screen of the app. Patients will share the app(s) on their phones they use most often and are asked to estimate when,

where, how often, and how long, and they use these apps. Next, participants are asked what they like and dislike about the apps. To facilitate this discussion, patients will pick appropriate labels from a word cloud with post-its with positive and negative valence labels (e.g. "funny" or "boring"). Next, patients will design a screen of the app through a canvas with prompts based on the set of desired qualities discussed earlier. Workshop 3 consists of 1 activity, co-design of a paper prototype. Based on the insights from workshop 1 & 2, a paper prototype of the app will be developed. Using a think-aloud approach, patients will navigate through the prototype and customize it using a sticker set. The sticker set will include a mix of buttons commonly used in user interfaces of (mHealth) apps as well as abstract shapes that patients can use to represent functions not covered in the sticker set. The session will close with a general group interview, asking patients for their final views regarding the paper prototype and the extent to which they find it appealing, usable, intuitive, etc. Finally, all patients are thanked for their participation and receive their reimbursement, including a thank you note, and a postcard stamped with the university as the return address and the request to send the card if they think of new insights they want to share after the formal close of the workshop series.

How much time will each participant spend (mention the number of sessions/meetings in which they will participate and the time per session/meeting)?

3 x 3 workshops of 90 minutes (including break)

C: BURDEN AND RISKS OF PARTICIPATION

27. Please provide a brief description of these burdens and/or risks and how you plan to minimize them:

The sessions will be conducted in May - July 2021, during which social distancing guidelines of the Covid-19 pandemic are in place. In addition, the sessions involve the vulnerable population of people with a SMI. To ensure that patients can effectively and safely participate under these conditions, we considered the following aspects in the design of the sessions. Length: Typically participatory sessions are 2-4 hours. People with SMI have issues with hyperactivity, inattention, apathy, and motivation which make longer sessions infeasible and difficult to participate in. Therefore, we designed shorter sessions of 90 minutes (including a break). Creativity: Our previous work showed that people with SMI find it difficult to engage in high-level creative work. To keep sessions accessible to all patients we therefore focused on adapting (e.g. making existing things one’s own instead of creating something from scratch). At the same time, we brought creative prompts to facilitate creativity on higher levels if patients expressed interest and

capability. Group size and composition: We opted for a flexible approach to group size, meaning that each session was designed to take place in a group but could also be changed to a paired or individual format at a short notice. In this way, we can also account for existing social relationships of co-habiting inpatients that may inhibit patients' feelings of safety and creative expression (for example, if conflicts had arisen on the day of the session). COVID-19: Patients will be recruited from the same 'household' (e.g. patients from the same assisted living facility, ward, or location) to accommodate social distancing guidelines. Furthermore, researchers will be tested prior to each workshop. Debriefing and aftercare: The primary caregiver of each patient will be available during and after the workshops to provide counseling.

28. Can the participants benefit from the research and/or their participation in any way?

Yes

Please Explain:

As stated before, participation in design studies can result in feelings of empowerment in patients. Previous studies that have used PD to collaboratively design eHealth services with people with SMI have reported that it made people with SMI feel "lucky, important, and valuable, not as patients, but as experts of their experience" (Terp et al, 2016). Furthermore, design activities are fun, creative and social, and can form a pastime which may be very welcome to (forensic) patients, especially during the COVID-19 pandemic.

29. Will the study expose the researcher to any risks (e.g. when collecting data in potentially dangerous environments or through dangerous activities, when dealing with sensitive or distressing topics, or when working in a setting that may pose 'lone worker' risks)?

No

D. INFORMED CONSENT

30. Will you inform potential research participants (and/or their legal repsentative(s), in case of non-competent participants) about the aims, activities, burdens and risks of the research before they decide whether to take part in the research?

Yes

Briefly clarify how:

Participants will receive a information letter and oral information by the researcher. They will also have the opportunity to ask questions about the research.

32. How will you obtain the voluntary, informed consent of the research participants (or their legal repsentatives in case of non-competent participants)?

Signed

33. Will you clearly inform research participants that they can withdraw from the research at any time

without explanation/justification?

Yes

34. Are the research participants somehow dependent on or in a subordinate position to the researcher(s) (e.g. students or relatives)?

No

35. Will participants receive any rewards, incentives or payments for participating in the research?

- Other, briefly clarify:

  Patients will either receive a voucher of 15 euro for their participation in the project (5 euro per session). If patients have no opportunity to spend the voucher (which may be the case for patients in forensic care) a small gift (chocolates, flowers) will be given as a token of appreciation instead.

36. In the interest of transparency, it is a good practice to inform participants about what will happen after their participation is completed. How will you inform participants about what will happen after their participation is concluded?

- Participants will receive the researcher's contact details, so that they can contact the researcher if they have questions/would like to know more.

E. CONFIDENTIALITY AND ANONYMITY

37. Does the data collected contain personal identifiable information that can be traced back to specific individuals/organizations?

No

39. Will you make use of audio or video recording?

Yes

• What steps have you taken to ensure safe audio/video data storage?

All data will be processed according to the data management plan "Can self-control training (SCT) improve the effectiveness of interventions?" approved 23-09. Audio recordings will be collected using a dedicated device and deleted from the device after they have been transferred to a password protected network drive (p-schijf). Next, the qualitative data will be collected as soon as possible, after which the audio files will be removed from the network drive and deleted. The transcripts will be fully anonymized and stored on the drive. In publications, quotes of participants might be used, but these will be anonymized as well.

• At what point in the research will tapes/digital recordings/files be destroyed?

The audio recordings will be destroyed as soon as transcripts are completed, no more than 6 months after

the workshops have concluded.

5. DATA MANAGEMENT

- I have read the UT Data policy.
- I am aware of my responsibilities for the proper handling of data, regarding working with personal data, storage of data, sharing and presentation/publication of data.

6. OTHER POTENTIAL ETHICAL ISSUES/CONFLICTS OF INTEREST

40. Do you anticipate any other ethical issues/conflicts of interest in your research project that have not been previously noted in this application? Please state any issues and explain how you propose to deal with them. Additionally, if known indicate the purpose your results have (i.e. the results are used for e.g. policy, management, strategic or societal purposes).

All ethical issues have been discussed.

7. ATTACHMENTS

Begrijpelijk-patientinformatieformulier_ontwerponderzoek.pdf, Begrijpelijk-toestemmingsformulier_ontwerponderzoek.pdf

8. COMMENTS

Klooster, P.M. ten (10-05-2021 15:02):

NB: The approval given for your research project is CONDITIONAL. As your study intends to make use of methods requiring social and physical interaction, this poses risks for both participants and researchers, which have to be taken into account. You have to COMPLY with the current RESTRICTIONS ON SOCIAL AND PHYSICAL INTERACTION regarding the COVID19 outbreak. This may imply that you have to find alternative ways to collect data or to delay the start of your study until the restrictions have been adjusted or lifted. If adjustments lead to substantive changes in the design of your study (excluded: digital/online means to get in contact with your participants), send your changes to ethicscommittee-bms@utwente.nl stating your request number.

Please consult the standing guidelines of the UT and national authorities on research and educational activities www.utwente.nl/corona

9. CONCLUSION

Status: Approved by commission

The BMS ethical committee / Domain Humanities & Social Sciences has assessed the ethical aspects of your research project. On the basis of the information you provided, the committee does not have any ethical concerns regarding this research project. It is your responsibility to ensure that the research is carried out in line with the information provided in the application you submitted for ethical review. If you make changes to the proposal that affect the approach to research on humans, you must resubmit the

changed project or grant agreement to the ethical committee with these changes highlighted.

Moreover, novel ethical issues may emerge while carrying out your research. It is important that you re-consider and discuss the ethical aspects and implications of your research regularly, and that you proceed as a responsible scientist.

Finally, your research is subject to regulations such as the EU General Data Protection Regulation (GDPR), the Code of Conduct for the use of personal data in Scientific Research by VSNU (the Association of Universities in the Netherlands), further codes of conduct that are applicable in your field, and the obligation to report a security incident (data breach or otherwise) at the UT.

Attachment: Begrijpelijk-patientinformatieformulier_ontwerponderzoek.pdf

Studie: Meedenken over app voor controle over gezond leven

Beste lezer,

Wij vragen je om mee te denken over een nieuwe app.
Tessa Dekkers en Stephanie Schouten organiseren de studie.
Je beslist zelf of je mee wilt doen.

1. Waarom is deze studie belangrijk?
Veel mensen vinden het moeilijk om gezond te leven.
Daarom maken wij een mobiele app om meer controle te krijgen over gezond leven.
Wij kunnen van jou horen hoe je denkt over gezond leven. En wat je fijn of niet fijn vindt aan andere apps.
Jouw informatie helpt ons om een betere app te maken. Daarom praten we in deze studie met mensen zoals jij.

2. Wat moet je doen als je meedoet?
Als je meedoet, vorm je samen met andere patiënten een groep.
Tessa en Stephanie komen langs en helpen jou en de groep met creatieve oefeningen.
Daarna stellen zij vragen over jouw ervaringen en wensen.

We gaan bijvoorbeeld:

- Plaatjes kiezen die passen bij “controle hebben” en “gezond leven” en het daarover hebben.
- Praten over de apps die je nu gebruikt.
- Een eerste versie van de app aanpassen met stickers.

Dit duurt ongeveer 90 minuten per keer. Er is een pauze met wat lekkers.

Tessa en Stephanie komen 3 keer langs. Je kunt 1 keer mee te doen of vaker.
Dit mag je ook later nog beslissen.

3. Als u niet wilt meedoen of wilt stoppen
Je kiest zelf of je meedoet. Zo niet, verandert er niks voor je. Je kunt ook altijd later stoppen als je niet meer mee wilt doen.

4. Geheim
We nemen graag onze gesprekken op.
Ook willen we foto's maken van de dingen die je maakt.
Zo kunnen we later luisteren of we alles goed begrepen hebben.

Alles wat je aan ons vertelt blijft geheim.
De opname krijgt een nummer. Jouw naam staat niet op de opname.
De opnames worden nooit openbaar gemaakt en kunnen niet voor juridische doeleinden gebruikt worden.
Het is voor deze wetenschappelijke studie en mogelijk voor vervolgstudies.

De opnames en foto's worden bewaard op de Universiteit Twente.

Wij hopen dat u mee wilt doen met deze studie.
Heb je nog vragen? Stel ze aan Tessa en Stephanie of aan je begeleider. Die kan jouw vragen doorgeven aan ons.

Hartelijk bedankt,

Tessa Dekkers & Stephanie Schouten
(werken bij Universiteit Twente)

Attachment: Begrijpelijk-toestemmingsformulier_ontwerponderzoek.pdf

TOESTEMMINGSFORMULIER

Studie: Meedenken over app voor controle over gezond leven

- Ik begrijp dat Tessa Dekkers en Stephanie Schouten aan mij vragen om mee te denken over een nieuwe app over gezond leven. We gaan creatieve oefeningen doen en het hebben over mijn ervaringen en wensen.
- Tijdens het onderzoek worden geluidsopnames en foto's gemaakt. Ik kom niet herkenbaar in beeld.
- Ik begrijp dat **alleen** Tessa Dekkers en Stephanie Schouten mijn naam en verhaal horen.
- Ik heb genoeg tijd gehad om na te denken of ik mee wil doen.
- Ik weet dat ik kan stoppen wanneer ik wil.
- Ik doe mee aan de studie.

Naam: .....

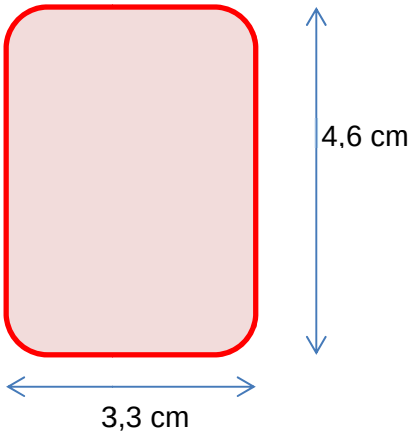
Handtekening: ..... Datum: .....

Ondergetekende, verantwoordelijke onderzoeker, verklaart dat de hierboven genoemde persoon zowel schriftelijk als mondeling over bovenvermelde gebruikerstest is geïnformeerd. Zij verklaart tevens dat een voortijdige beëindiging van de deelname door bovengenoemde persoon, van geen enkele invloed zal zijn op de zorg die hem of haar toekomt.

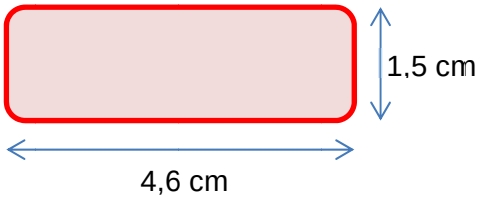
Naam:

Handtekening: ..... Datum: .....

Bijlage 3 – ActiGraph GT3X+



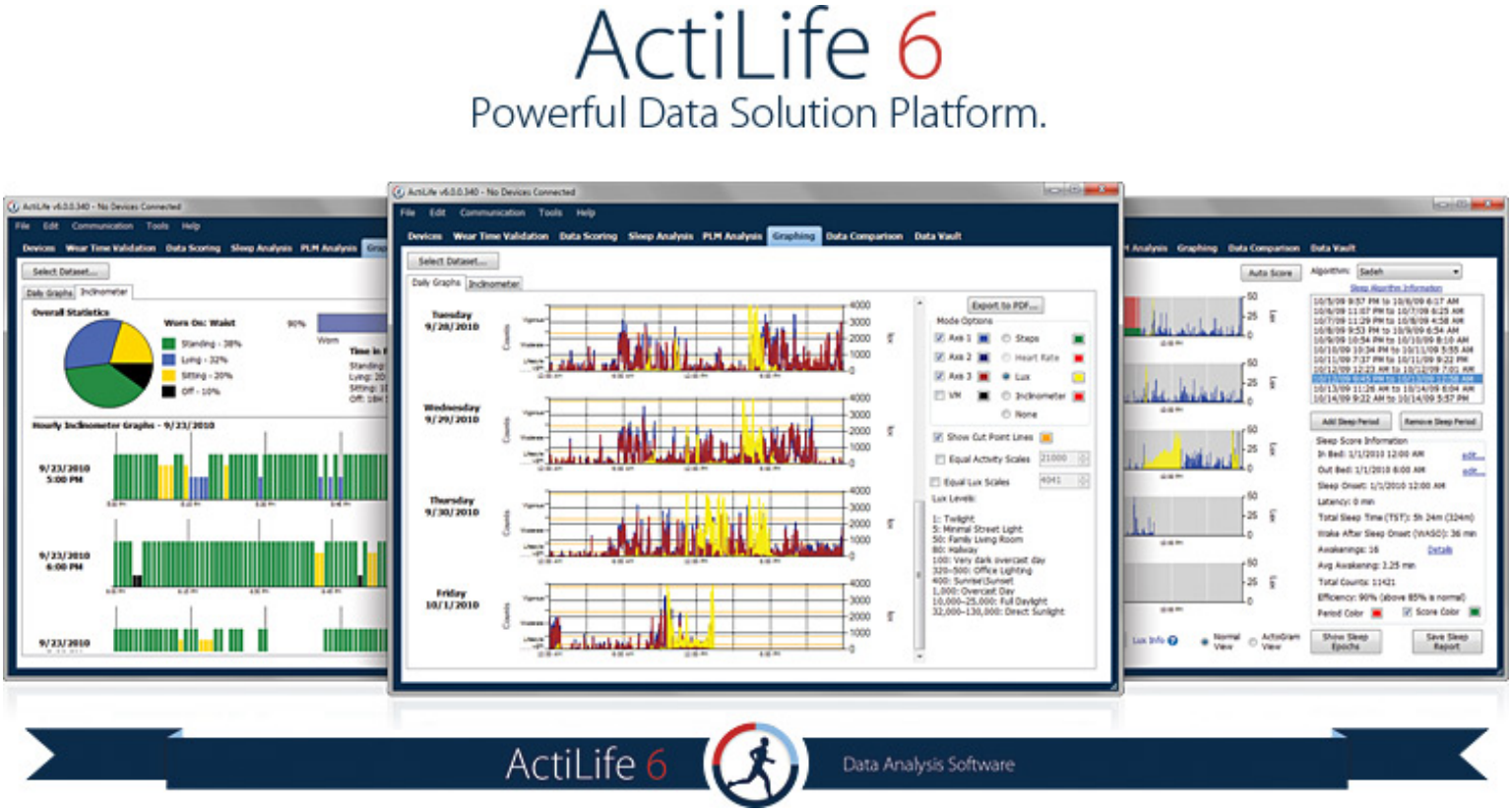
Figuur 1. Bovenaanzicht.



Figuur 2. Zijaanzicht.

Figuur 3. Aanzichten van de GT3X+ met de assen [81].

Figuur 4. Dragen van de ActiGraph GT3X+, zijaanzicht en bovenaanzicht.



Figuur 5. Screenshots ActiLife 6 [82].

De Vector Magnitude

De Vector Magnitude verwijst naar de omvang van de resulterende vector die gevormd wordt door het combineren van de gesampelde versnelling van alle drie de assen op de GT3X+. Onderstaande figuur illustreert de oriëntatie van de assen voor de GT3X+.

Figuur 6. Assen van de GT3X+ [83].

Wanneer we kijken naar de data op epoch-niveau (gefilterde en opgeslagen data), kunnen we de Vector Magnitude (VM) definiëren worden als:

$$\boldsymbol{Vector\ Magnitude} = \boldsymbol{VM} = \sqrt{(\boldsymbol{Axis\ 1})^2 + (\boldsymbol{Axis\ 2})^2 + (\boldsymbol{Axis\ 3})^2}$$