RESEARCH PROTOCOL

"Sticking to your Exercises"

Empowering rehabilitating patients in their exercises with NFC technology accompanied by an app

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LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS

ABR	ABR form, General Assessment and Registration form, is the application form that is required for submission to the accredited Ethics Committee (In Dutch, ABR = Algemene Beoordeling en Registratie)
AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CCMO	Central Committee on Research Involving Human Subjects; in Dutch: Centrale Commissie Mensgebonden Onderzoek
CE	Conformité Européenne
ESES	Exercise Self-Efficacy Scale
EU	European Union
EudraCT	European drug regulatory affairs Clinical Trials
HSP	Hereditary Spastic Paraplegia
IC	Informed Consent
METC	Medical research ethics committee (MREC); in Dutch: medisch ethische toetsing commissie (METC)
NA	Neuralgic Amyotrophy
NFC	Near Field Communication. Technology for wireless data transfer.
OIP	Osseointegration Prosthesis
(S)AE	(Serious) Adverse Event
SP	Socket Prosthesis
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.
SUS	System Usability Scale
SUSAR	Suspected Unexpected Serious Adverse Reaction
UTAUT2	Unified Theory of Acceptance and Use of Technology version 2
WPB	Personal Data Protection Act (in Dutch: Wet Bescherming Persoonsgevens)
WMO	Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen

SUMMARY

Rationale: Approximately half of rehabilitating patients do not fully adhere to their prescribed home exercise program, resulting in dissatisfactory treatment outcomes. One factor involved in several aspects of non-adherence and important for physiotherapy is self-efficacy, or one's belief in his or her ability to engage in specific behaviours that will yield a desired outcome. Empowering patients with location-specific reminders, digital instructions and digital feedback options in home exercise programmes may improve their self-efficacy and benefit therapy adherence.

Objective: To study a potential improvement in self-efficacy when using the so-called sticky reminders as compared to usual care without this intervention and to assess user experiences with the sticky reminder intervention.

Study design: This pilot is a controlled mixed methods feasibility study.

Study population: Rehabilitating adult patients suffering from Neuralgic Amyotrophy and rehabilitating adult wearers of a leg prosthesis following home exercise programmes for physiotherapy.

Intervention (if applicable): Introduction and use of an intervention encompassing reminders and an app that transform written and verbal feedback and instructions into digital feedback and instructions.

Main study parameters/endpoints: Self-efficacy quantified with Exercise Self-Efficacy Scale questionnaire before and after 4 weeks of using the application; User experience (patient and physiotherapist); System usability quantified using the System Usability Scale questionnaire after using the app; Frequency of application use; Feasibility of using this app.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants in the study will be asked to download the application and make use of the reminders and app for four weeks. During these four weeks, the verbal feedback during usual physiotherapy sessions will be filled in briefly, daily and digitally. Before and after the intervention period, they will complete short questionnaires (approximately 10-15 minutes) and frequency of use will be logged. User experiences will be assessed with semi-structured interviews. Participation in the study does not result in any physical or physiological discomfort.

1. INTRODUCTION AND RATIONALE

Improving patient health outcomes and decreasing costs are challenges currently faced by healthcare systems all over the world (Barello *et al*., 2015; Elf *et al*., 2015). Several trends are emerging to address these challenges, such as "patient-centred care" and "participatory healthcare". Both trends represent acknowledged ways of engaging patients in the management of their health (Epstein *et al*., 2010; Gruman *et al*., 2010). Actively and efficiently engaged patients show improved clinical outcome and patient engagement represents a crucial factor for improving quality of care and increasing patient safety (Barello *et al*., 2015; Schwappach, 2010). A concept called eHealth and its sub-concept mHealth (mobile Health) interventions are recognized to have a tremendous potential to promote patient engagement (Barello *et al*., 2015; Hamine *et al*., 2015). Further, eHealth interventions show promise for increasing medication adherence (Linn *et al*., 2011). Possibly, physiotherapy adherence could be enhanced using eHealth interventions as well.

Although figures differ, it is assumed that at least half of rehabilitating patients does not adhere to their prescribed physiotherapy exercises, resulting in dissatisfactory treatment outcomes (S Frances Bassett, 2003; Sandra F. Bassett & Prapavessis, 2011; Engström & Öberg, 2005; Forkan *et al*., 2006; Sluijs, 1991). During and after the transition from short-term (therapy under guidance) to long-term (autonomous) physical therapy, this share is likely to increase (Friedrich *et al*., 1998). Furthermore, physiotherapists frequently interpret poor treatment outcomes as evidence of their treatments being inadequate, which in turn might lead to them making unnecessary treatment changes (S Frances Bassett, 2012). Either of these factors are likely contributing to why physiotherapy does not always result in the optimal outcome (Friedrich *et al*., 1998).

As increasing exercise adherence leads to improved treatment outcome in various rehabilitation programs, this is an interesting field of research (Brewer *et al*., 2000; Groth *et al*., 1994; Lyngcoln *et al*., 2005). However, within physiotherapy, adherence is a multi-dimensional concept not easily assessed and thought to be affected by many factors related to patient, healthcare provider and healthcare organization (S Frances Bassett, 2003; Kolt *et al*., 2007; Miller *et al*., 1997). Due to its broad concept, increasing adherence remains a challenge not likely solved with a single intervention (Martin *et al*., 2005).

Sluijs *et al*. and Jack *et al*. noted three main patient-focussed factors regarding nonadherence: (1) Barriers perceived and encountered ("too little time", "does not fit in daily routine", "forgetfulness" and "pain", among others), (2) lack of positive feedback and (3) degree of helplessness (Jack *et al*., 2010; Sluijs, 1991; Sluijs *et al*., 1993). An aspect involved in these three main factors is self-efficacy, which reflects an individual's belief in his or her ability to engage in specific behaviours that will yield a desired outcome (Bandura, 1997). It is conceivable that the degree of self-efficacy is involved in nonadherence. Self-efficacy correlates with barriers such as pain and greater helplessness correlates with lower self-efficacy (Litt, 1988; Martin *et al*., 2005 Shnek *et al*., 1997). Positive feedback was shown to increase self-efficacy (Bandura, 1991; Campion & Lord, 1982; Ilgen *et al*., 1979; Podsakoff & Farh, 1989). Indeed, previous research found that lower levels of self-efficacy were associated with lower adherence to a rehabilitation program (Chen *et al*., 1999; Flynn *et al*., 1995; Hall *et al*., 2002; Woodgate *et al*., 2005). Adhering to a home exercise program often requires lifestyle changes, such as changing habits and daily routine. Exercise adherence and self-efficacy were linked to lifestyle changes, thus empowering patients in changing their lifestyle might prove beneficial for these parameters (Bandura, 1998; Martin *et al*., 2005; Sluijs *et al*., 1998).

The Radboud REshape & Innovation Center has developed an eHealth intervention for this patient empowerment in collaboration with a company called Touchless Industries. Together, they have designed NFC-equipped (Near Field Communication) stickers accompanied by a smartphone app that provide visual reminders along with instruction videos at appropriate locations for exercises to be performed. With this intervention, we aim to increase physiotherapy self-efficacy in home exercise programs as compared to usual care.

These so-called "sticky reminders" seen above contain certain components and aspects that could help in increasing either adherence or self-efficacy, or to empower patients in changing their habits. The sticky reminders provide visual triggers in appropriate locations. In healthy people and likely in patients, such contextual cues were proven effective in changing habits (Stawarz *et al*., 2015). The reminders engage the lack of positive feedback by enabling milestones and corresponding motivating

feedback in the application, which can be seen by the patients and are thought to improve adherence (Bassett & Petrie, 1999). Further, the application allows for daily feedback provided by patients (e.g. pain scores) that can be seen in a graphic representation by both patient and physiotherapist. This provides an indication of rehabilitation progress and complements the need for verbal feedback, which often proves erroneous (Sluijs *et al*., 1998). Pain, correlated to self-efficacy, could be (partly) prevented via the provision of the daily feedback to the physiotherapist and subsequent adaptations in therapy (Parker *et al*., 1993). Further, self-efficacy is positively affected by personalizing home exercise programs (Akinsola & Awofala, 2009). The sticky reminders will incorporate that by both allowing tailored exercise programs and providing a possibility to show videos of the patient, with spoken feedback from the physiotherapist. Such instructional videos might be effective in empowering patients in physiotherapy since instructional support was shown to enhance self-efficacy for learning (Sewell & St George, 2009).

In this mixed methods pilot study, we will present an eHealth intervention comprised of NFC-equipped stickers and an accompanying app. The intervention will be tested in a distinct target population consisting of patients suffering from Neuralgic Amyotrophy (NA) or lower extremity amputations. For these patients, physiotherapy is important in their rehabilitation for preventing or treating strain and coordination dysfunction (NA) or retaining gait and walking symmetrically with a prosthesis (amputation) (Christensen et al., 1995; Frölke et al., 2017; Leijendekkers et al., 2017; van Alfen & van Engelen, 2007; Van Eijk et al., 2016). With this (primarily) digital intervention, we aim to enhance self-efficacy of these patients during their physiotherapy home exercise programs as compared to usual care, where they receive written and verbal instructions and feedback. Next to self-efficacy assessment, we will gather user experiences and perception about usability, with which we will assess the feasibility of this intervention in physiotherapy.

2. OBJECTIVES

Primary Objective:
To study whether NFC-equipped sticky reminders increase physiotherapy self-efficacy in home exercise programmes as compared to usual care in rehabilitating patients suffering from Neuralgic Amyotrophy or a lower extremity amputation over a period of 4 weeks.

Secondary Objective(s):
To assess the usability of the app and user experiences with NFC-equipped sticky reminders for home exercise programmes in physiotherapy as perceived by rehabilitating patients suffering from Neuralgic Amyotrophy or a lower extremity amputation and how this could be improved.

Other Objective(s)
To determine whether the intervention is used, and thus whether observed effects in intervention group could be caused by the intervention.

3. STUDY DESIGN

This pilot is a controlled mixed methods feasibility trial.
The Radboudumc department REshape & Innovation Center in collaboration with two physiotherapy departments will execute the pilot. The envisioned duration of the project is five months. Patients will be included in April and May 2018, after which we will analyse data and publish results. The product-testing period is 4 weeks per patient. There will be an intervention group and a control group. The control group will only execute point 1 and 5 in the research design described below besides their regular treatment (excluding interview and SUS component). The control group is present to exclude conclusions based on treatment effects instead of intervention effects. The intervention group will go through all five steps. Millen et al. chose a similar study design, where they measured self-efficacy in cardiac rehabilitation (Millen *et al.*, 2009).

In the present course of therapy, supporting their home exercise program, patients suffering from Neuralgic Amyotrophy or a lower extremity amputation (using a socket or an osseointegrated prosthesis) receive a folder with written instructions on performing the exercises which can be consulted when needed. Patients give feedback during every hospital visit regarding their exercises and progression. In these sessions, the physiotherapist asks for information on the whole week schedule, whereas for patients it is hard to remember the exercises of the beginning of the week. To improve this, the osseointegrated prostheses patients keep a daily paper-based diary for pain scale, pain location, prosthesis wearing time and time spent on muscle exercises and standing or walking. Apart from this, patients do not register or monitor their progress in current course of therapy.

The introduction of the sticky reminders in combination with the app alters the method of registration compared to the present course, but the overall process remains the same. *Instead of written or spoken instructions and feedback, this information will be digitally provided and available*.

The patient process is described and depicted below.

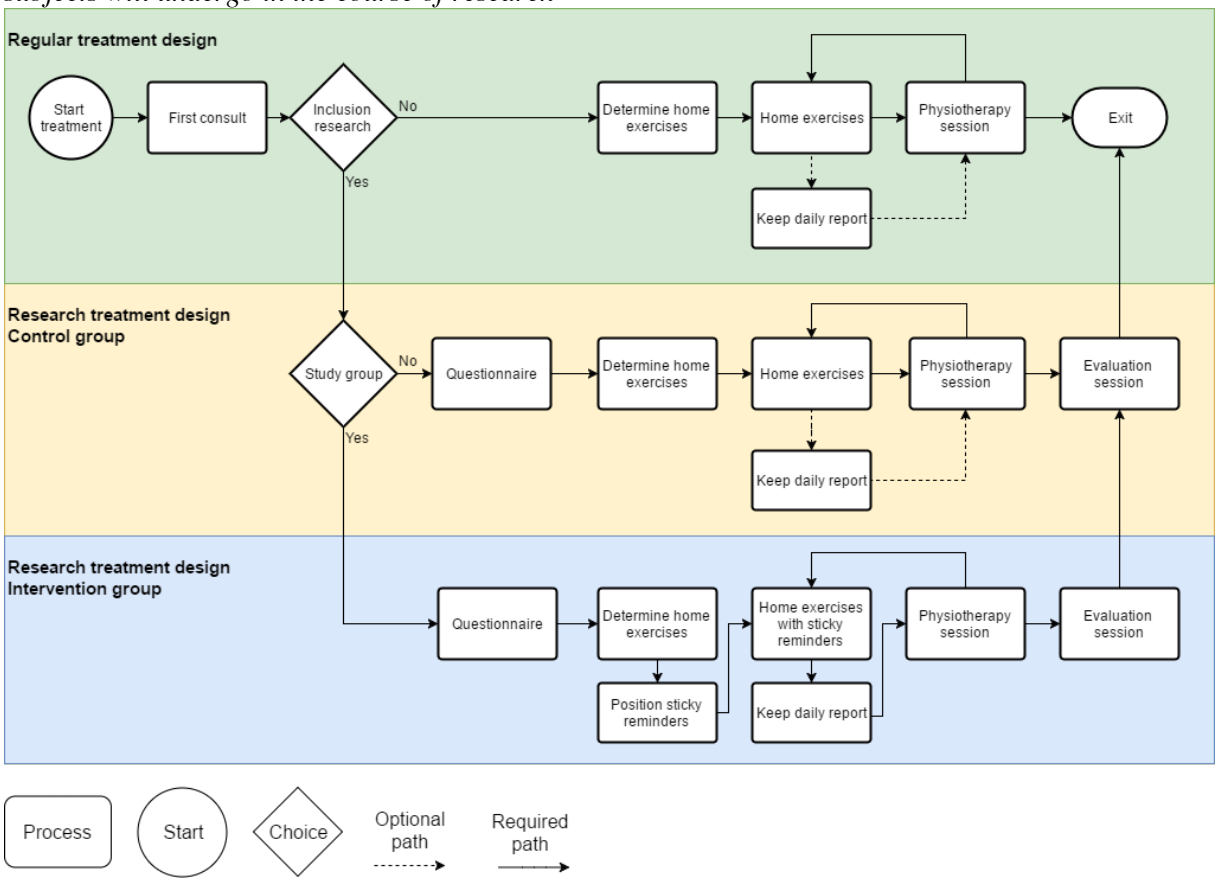
1. **Baseline measurement:** To monitor self-efficacy patients are asked to fill out a validated self-efficacy questionnaire. This outcome is supposed to be the baseline value of the pilot. For extra information regarding the patient, demographic questions will be included in the questionnaire.
2. **Technology introduction:** In the first hospital visit, the patient will get all the necessary or desired information on the new technology. Following this meeting, patients have time to decide whether they want to participate in the pilot. After inclusion, patients receive help for installing the app and will get an introduction on how to use the application.
3. **Home registration:** After the regular physiotherapy appointment in the hospital, patients will receive exercises to execute in the home situation. These exercises are also linked to at least one NFC tag. These NFC tags are illustrated with a location, suitable for the exercises. Patients will discuss their personal appropriate locations for the NFC tags with their physiotherapist. When walking by the NFC tag, the patient can scan the tag with their personal smartphone, showing them a video of the corresponding exercise. All information that was previously provided in the folder is now handed to the patient via the video. The application registers the scanning of the tag on a secure server. If no prescribed exercises are performed within a predefined timeslot, the app will send a one-time push notification to the patient. At the end of the day, a tag will be scanned to show the daily report form. This daily report contains questions matching the regular treatment supplemented with questions on efficacy.
4. **Physiotherapy session:** Back in the hospital setting, the regular treatment is continued and the progress of the rehabilitation will be discussed. The app can support this session by presenting graphic representations of the daily feedback gathered with the daily reports. Step 3 and 4 will be repeated until the NFC tag trial period is over.
5. **Evaluation:** In the end, the questionnaire answered at the start is repeated as an end-measure, supplemented with a system usability scale (SUS) questionnaire. Elaborate opinions will be gathered by interviewing patients and physiotherapists in a semi-structured way. In semi-structured interviewing, a guide is used, with questions and topics that must be covered.

However, in contrast to structured interviews, this conversational style of interviewing allows for gathering elaborate opinions.

The timeline is shown below. The control group and intervention group will undergo a different timeline:

- **Control group**: The control group is present to exclude conclusions based on treatment effects instead of intervention effects. These participants will receive a questionnaire regarding exercise self-efficacy (specifically the Dutch translation of the Exercise Self-Efficacy Scale (ESES), validated in spinal cord injury (Nooijen *et al*., 2013)), before and after the testing period of the intervention group. For extra information regarding the patient, demographic questions will be included in the questionnaires.
- **Intervention group**: They will receive the ESES questionnaire before the testing period. After the testing period, this questionnaire will be handed out as well, supplemented with questions regarding usability (System Usability Scale or SUS (Brooke, 1996)). For extra information regarding the patient, demographic questions will be included in the questionnaires. Further, a semi-structured interview will be conducted with participants from the intervention group. We expect that patients need 15 additional minutes per day using the intervention as compared to usual care. Apart from the interview, no additional hospital visits are required.

A flow chart can be included to give an overview of the study design and the main procedures that subjects will undergo in the course of research



4. STUDY POPULATION

4.1 Population (base)

This study will include patients that, within their rehabilitation program, receive frequent physical therapy exercises to perform at home. These patients will be recruited from their rehabilitation by physiotherapists from within the Radboudumc. We will recruit patients with distinct situations, namely Neuralgic Amyotrophy and a lower extremity amputation who use a socket prosthesis or an osseointegrated prosthesis.

4.2 Inclusion criteria

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

Intervention group:

- Willing to participate and to provide informed consent
- Minimal remaining rehabilitation period of 4 weeks
- Access to NFC-compatible smartphone
- Within their rehabilitation program, included patients have exercises to perform at home.
- Patient is able to speak, read and understand Dutch

Control group:

- Willing to participate and to provide informed consent
- Minimal remaining rehabilitation period of 4 weeks
- Within their rehabilitation program, included patients have exercises to perform at home.
- Patient is able to speak, read and understand Dutch

These inclusion criteria show that patients who are excluded from the intervention group can be included in the control group. Therefore, patients will be asked whether they have a NFC-compatible smartphone at the start of inclusion. At this point, most Android smartphones are NFC-compatible. This makes the study not truly randomized, but seems reasonable as this is a pilot study.

4.3 Exclusion criteria

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

- Patients that are incompetent to make a decision themselves.
- Age <18
- Unstable medical situation due to a disorder not being NA or a leg amputation.

4.4 Sample size calculation

This project primarily aims to provide an insight and preliminary evaluation of utilizing NFC-equipped stickers to increase self-efficacy in home exercise programmes. As this is an exploratory pilot study, no formal power analysis has been conducted. We aim to include 30 patients spread across control and intervention group. This includes patients with a lower extremity amputation and Neuralgic Amyotrophic patients. If the pilot is successful, the data provided can be used to expand the research and calculate a sample size for randomized controlled trials.

5. TREATMENT OF SUBJECTS

5.1 Investigational product/treatment

This pilot aims to provide insight in the feasibility of "smart" (NFC-equipped) stickers accompanied by an app in increasing self-efficacy to physical therapy exercises at home.

In the present course of therapy, supporting their home exercise program, patients suffering from Neuralgic Amyotrophy or a lower extremity amputation (using a socket or an osseointegrated prosthesis) receive a folder with written instructions on performing the exercises which can be consulted when needed. Patients give feedback during every regular hospital visit regarding their exercises and progression. In these sessions, the physiotherapist asks for information on the whole week schedule, whereas for patients it is hard to remember the exercises of the beginning of the week. To improve this, the osseointegrated prostheses patients keep a daily paper-based diary for pain scale, pain location, prosthesis wearing time and time spent on muscle exercises and standing or walking. Apart from this, patients do not register or monitor their progress in current course of therapy.

The introduction of the sticky reminders in combination with the app alters the method of registration compared to the present course, but the overall process remains the same. Instead of written or spoken instructions and feedback, this information will be digitally provided and available. The details of these stickers and app are found in "Paragraph 6.1: Name and description of investigational product(s)".

5.2 Use of co-intervention (if applicable)

Not applicable

5.3 Escape medication (if applicable)

Not applicable

6. INVESTIGATIONAL PRODUCT

6.1 Name and description of investigational product(s)

To address the self-efficacy and to empower patients in performing exercises, Radboud REshape is developing an innovative intervention in close collaboration with a company called Touchless Industries. Together, they came up with a sticker, equipped with the recently developed NFC technology. NFC is a technology that has emerged and is still growing in availability. Estimates by Statista (one of the world's leading statistics portals gathering data from more than 18.000 sources) show a expected number of 1.9 billion NFC-enabled smartphones in 2018 (Statista, 2013). However, this includes Apple iPhones, whose NFC technology is not freely accessible by all apps. IHS Markit (claiming to be the leading source of information, insight and analytics in critical areas that shape today's technology ecosystem) has estimated that by 2018, 844 million, or 75 percent of Android phones will be equipped with accessible NFC technology (IHS, 2014). Furthermore, mobile network providers (such as the Dutch provider KPN) have started to equip their SIM cards with NFC technology, which supersedes the need for NFC technology on the mobile device itself (KPN, n.d.). Thus, although the market is still growing, a wide availability for NFC smartphones shall be present in the near future.

The developed NFC-stickers are called sticky reminders (see above) and should be placed at locations where certain exercises can be performed. Bringing a NFC-compatible smartphone in close proximity to the sticker automatically launches a video or app on the smartphone, in this case showing an instruction for your exercise. The mobile device application is called "Touchless Fysio", which distinguishes between physiotherapist and patient. Using these stickers, the patient is visually reminded and receives exercise instructions at a location where he/she can perform the exercise immediately. The Sticky Reminders in combination with Touchless Fysio is the investigational product. Since this intervention does not give medical advice, it is not regarded as a medical device and thus does not have a Conformité Européenne (CE) mark. The videos are static and are recorded when the subject visits the physiotherapist and are not altered based on registrations in the mobile application. The physiotherapist does not change the treatment approach in between visits. The information that is registered in the application is in current care registered in a journal or provided orally during a visit. Next to that, the application is not an alternative treatment, but it complements regular care.

For NA patients, videos of the individual him/herself will be linked to the stickers, as they are often filmed during (usually biweekly) physiotherapy sessions already. The video's however will not contain personal features like the face of the patient. Only the back of the patient is filmed. These videos can be uploaded using an online portal. Prosthesis wearers, however, will see generic instruction videos due to frequent physiotherapy sessions (2 times a week), time limitations and a wide variety of possible exercises within their rehabilitation.

The stickers will be supported by the patient application which records all activities on the sticky reminder and securely stores this information. All data will be coded and encrypted and stored on an ISO 27001 certified platform. This application will provide the back-end for the content on the stickers and link the videos to the users. This platform also allows feedback between physiotherapist and patient through logins and daily reports. The application is split into two user interfaces, one for the physiotherapist (web-based) and one for the patient (app-based):

Patient: Sees how many exercises are provided to him/her and how much he/she still needs to accomplish on a daily basis. The patient can also provide feedback to the physiotherapist and to themselves via daily reports or log-ins. In addition, the app will show a timeline with desirable targets, which should provide an extra motivation to perform the exercises.

Physiotherapist: Physiotherapists can easily connect the appropriate video and sticker combination at the desired moment in the rehabilitation via a web-interface. The physiotherapist can log in to this interface and see all the appropriate anonymized patients (per disorder). For each patient, the physiotherapist can look into collected data on log-ins and daily reports, and adapt the therapy accordingly if necessary.

6.2 Summary of findings from non-clinical studies

In the past year, Radboudumc organised two sprint days. During these days, patients, physiotherapist, researchers and Touchless Industries discussed the fit of new innovations into the healthcare sector. The aim of the sprint was to determine the need for integration of exercises into daily activities. The needs of all parties were scanned and all ideas were combined into a first prototype. The prototype consisted of NFC stickers, which could be scanned by a NFC-compatible Android phone or tablet presenting interesting content on the mobile device. The prototype was tested the same day, where stickers were placed in a living room like environment.

The first sprint included a patient affected by hereditary spastic paraplegia (HSP) during rehabilitation. In this prototype, the stickers were linked to videos of physiotherapy exercises, which could help them perform their exercises in a better way. The HSP patient on site saw great potential in this application, because it would guide him through his daily exercises. This sprint is the foundation and idea for the project “sticking to your exercises”. Based on the potential seen by all included parties, there is a need for further development and evaluation of this idea, investigated in this pilot study.

The second sprint was focussed on an osseointegrated prosthesis wearer. This session was used to determine the potential of this new technology and to get a first design of the implementation into the regular treatment. Again, patient, physician and developers were enthusiastic about the idea and wanted to further investigate the possibilities of this technology used in clinical practice. After this session, the project team and developers were able to assemble the first design, presented in this pilot study.

6.3 Summary of findings from clinical studies

Not applicable, no clinical studies have been carried out yet.

6.4 Summary of known and potential risks and benefits

Risks

Wrong positioning of the tags.

Exercises are executed on mismatched locations, which may lead to non-optimal performance or worse injuries due to obstacles. This risk will be reduced by designing the NFC-tags with a clear label indicating the appropriate location. In addition, the physiotherapist will be instructed on how to hand out the tags to the participating patients.

Benefits

More insight into the real data of home therapy/Improved communication between patient and physiotherapist.

Because patients monitor their exercises, the application data can be used during physiotherapist meetings to discuss the activities of the patient during his/her home sessions. Using the application the physiotherapist is provided with the real activity data instead of the being dependent on the memory ability of the patients. As data regarding therapy is more accurate, this allows for adequate adaptation of therapy if necessary.

Rehabilitation might be improved by increased therapy adherence and a different instruction method for exercises in home environment.

Due to the video instructions, patients will get visual feedback on their home exercises by comparing their own performance to the example on their phone. Besides improvement on correct performance of the exercise, we also expect an increase on therapy adherence. There are more and smarter (location based) reminders making it likely that the frequency of exercises increases.

6.5 Description and justification of route of administration and dosage

Not applicable

6.6 Dosages, dosage modifications and method of administration

Not applicable

6.7 Preparation and labelling of Investigational Medicinal Product

Not applicable

6.8 Drug accountability

Not applicable

7. NON-INVESTIGATIONAL PRODUCT

Not applicable

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

7.2 Summary of findings from non-clinical studies

7.3 Summary of findings from clinical studies

7.4 Summary of known and potential risks and benefits

7.5 Description and justification of route of administration and dosage

7.6 Dosages, dosage modifications and method of administration

7.7 Preparation and labelling of Non Investigational Medicinal Product

7.8 Drug accountability

8. METHODS

8.1 Study parameters/endpoints

8.1.1 Main study parameter/endpoint

We will assess the self-efficacy during exercising. Self-efficacy reflects an individual's belief in his or her ability to engage in specific behaviours that will yield a desired outcome. Self-efficacy beliefs are important because the belief that one can exercise, even given constraints and impediments such as feeling tired or being busy, is associated with a greater likelihood of doing it (Neupert *et al*., 2009).

8.1.2 Secondary study parameters/endpoints (if applicable)

User's experiences:

- Usability (layout, interface, ease of use, relevance of content, etc.)
- Perceived barriers and facilitators for using the sticky reminders and the app within one's daily routine. It is not being used as part of clinical care
- Perceived positive and negative effects of the sticky reminders and the app

Healthcare Professionals' Perspective

- Usefulness of information from the sticky reminder app.
- Perceived barriers and facilitators for using the information from the sticky reminders plus app within one's daily workload. How does this affect their workload?

Feasibility

- Users' experiences
- Effect on self-efficacy
- Potential as an empowering tool for physiotherapy exercises

8.1.3 Other study parameters (if applicable)

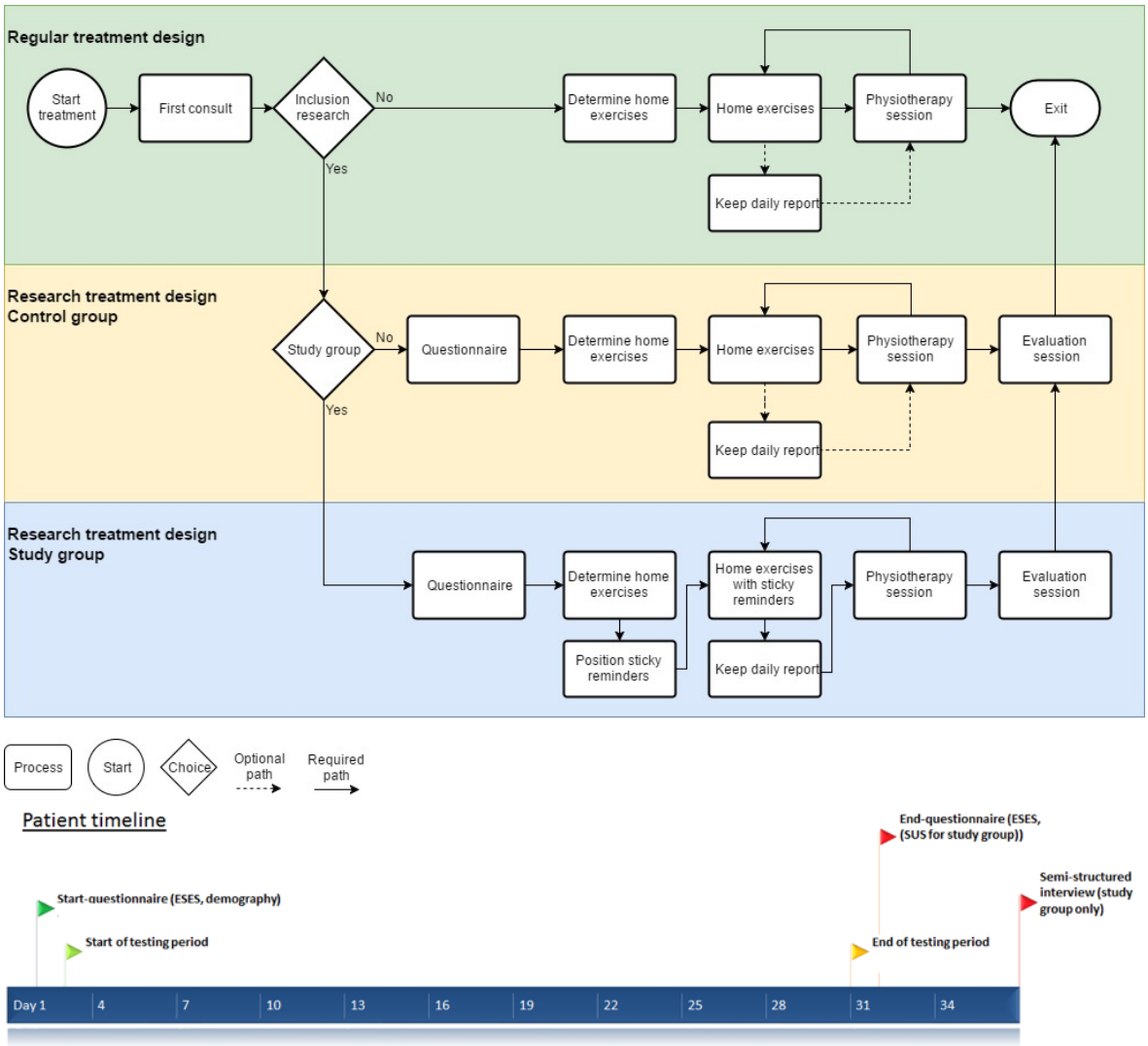
- Frequency of App use. To prove that observed effects could be a result of the intervention, we will determine app usage. We will calculate how often (times per day) the App is used during the research period
- Demography. In the questionnaires, we will ask for age, gender, marital status, medical history (regarding physiotherapy), estimated years affected by symptoms or disorder, employment and highest educational level.

8.2 Randomisation, blinding and treatment allocation

We will randomise the allocation of patients to study groups as much as possible within the patient (and NFC) availability pool. Blinding is not appropriate for this pilot.

8.3 Study procedures

Patient's timeline



The study flow and timeline are depicted above. After inclusion in the study, both the control and the study (intervention) group will fill in a questionnaire. This start-questionnaire will consist of questions regarding self-efficacy (ESES questionnaire) and demographics. Subsequently, they will either follow regular treatment (control) or receive our product and follow rehabilitation aided by the sticky reminders + app. After 4 weeks, the test period is over and patients will take part in evaluation. The evaluation for the control group consists of only one components: a questionnaire. This end-questionnaire is identical to the start-questionnaire and consists of questions regarding self-efficacy (ESES). For the intervention group, the evaluation consists of two components: a questionnaire and a semi-structured interview. This end-questionnaire consists of questions regarding self-efficacy (ESES) and system usability (SUS). The above described is summarized in the table below. The measurements and assessments are described in more detail under the headings "Parameter assessments" and "Measurements" below.

Physiotherapists' assessment

The physiotherapists will fill in a questionnaire (SUS) and will be interviewed in a semi-structured way. The above described summarized in the table below. The measurements and assessments are described in more detail under the headings "Parameter assessments" and "Measurements" below.

Group	**Start evaluation**	**End evalution**
Control	*Questionnaire:* ESES + Demography	*Questionnaire:* ESES
Intervention	*Questionnaire:* ESES + Demography	*Questionnaire:* ESES + SUS *Semi-structured interview*
Physiotherapist	*N/A*	*Questionnaire:* SUS *Semi-structured interview*

Parameter assessments

- Self-efficacy will be determined with the validated Dutch translation of the Exercise Self-Efficacy Scale and analysed with a social-cognitive model of health behaviour change theory. In this theory, self-efficacy is seen as a predictor, mediator or moderator (Burke *et al*., 2008; Schwarzer, 2008) on health behaviour.
- Usability will be determined using the System Usability Scale, developed by J. Brooke, and by interviewing patients and physiotherapist in a semi-structured way based on a healthcare adapted UTAUT2 framework (Slade et al., 2013).
- Scanning the stickers is registered in the application. Using the registrations gathered by the app, the extent to which and how the app is used can be derived and correlated to possible effects on self-efficacy. This way, we can determine whether and how much the app is used, and thus whether we can link observed group effects to intervention use.
- Using the aforementioned gathered data and subsequent analyses, we will assess the feasibility.
- Demography data will be gathered by questions regarding this topic.

Measurements

Exercise Self Efficacy Scale (ESES)

Self-efficacy will be determined with the Dutch translation of the Exercise Self-Efficacy Scale, developed and validated in spinal cord injury by Nooijen *et al*. The ESES consists of 10 items about level of self-confidence with regard to performing regular physical activities and exercise (17). A sample item is: "I am confident that I can overcome barriers and challenges with regard to physical activity and exercise if I try hard enough". Respondents answer using a 4-point scale: not at all true, rarely true, sometimes true, and always true. The minimum score is 10 and the maximum score 40. A higher score indicates higher exercise self-efficacy (Nooijen *et al*., 2013).

System Usability Scale (SUS)

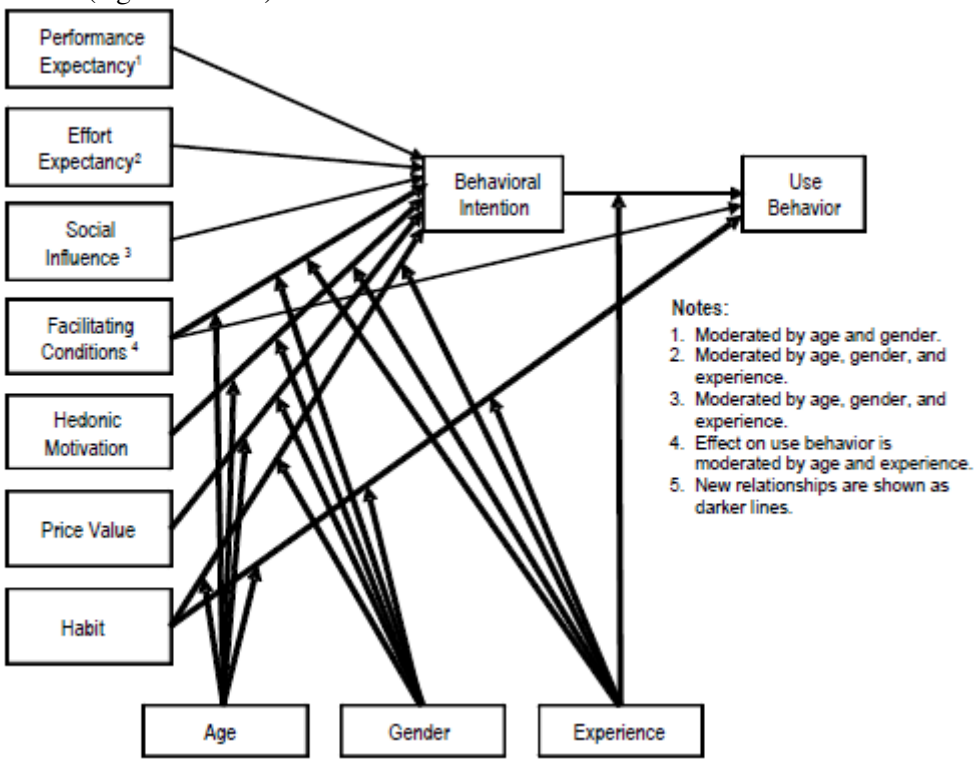
We will assess usability with a Dutch translation of the validated System Usability Scale (SUS) questionnaire. The SUS gives a global view of subjective assessments of usability (Brooke, 1996). This simple questionnaire consists of 10 items with five response options; from 'strongly agree' to 'strongly disagree'. The scores range from 0 to 100, with a score of 68 considered average.

Demographics

A few generic demographic parameters will be asked in the start questionnaire for both the intervention and control group. These include age, gender, medical history (regarding physiotherapy) and highest educational level.

Semi-structured interviews

We will evaluate patients' and physiotherapists' experiences with the sticky reminders + app by means of semi-structured interviews. The interview guides (for patient or physiotherapist) are developed following the UTAUT2 framework, which indicates acceptance of a technological innovation in healthcare and is depicted below (Slade et al., 2013). The interview guide is attached as a separate document in Dutch. We will focus on the topics performance expectancy, effort expectancy, social influence, facilitating conditions, hedonic motivation and habits. During the conversations, we might touch upon price value, but this is not our initial interest. Patients will be interviewed once the intervention phase has ended. Interviews will take approximately 30-60 minutes. In particular, we will focus on advantages and disadvantages of using the sticky reminders in daily practice, and users' expectations for the future. All interviews will be performed face-to-face, recorded and transcribed verbatim. Subsequently, two investigators will systematically analyse all interviews using analysis software (e.g. ATLAS.ti).



Frequency of use

We will use logging data from the app to assess frequency of use.

8.4 Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. They will receive the possibility to have their data deleted, which will then not be used in the study. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

8.4.1 Specific criteria for withdrawal (if applicable)

Not applicable

8.5 Replacement of individual subjects after withdrawal

Given that this is a feasibility trial, dropouts will not be replaced.

8.6 Follow-up of subjects withdrawn from treatment

Subjects withdrawn from the trial or discontinuing, will be asked to complete the after trial measurements. However, if they have addressed the desire to have their data deleted, these after trial measurements will not be asked for.

8.7 Premature termination of the study

Despite being an unexpected scenario, the study will be terminated when an increased amount of injuries linked to the intervention occurs in the intervention group. Physiotherapists will report this scenario to the research group when applicable.

9. SAFETY REPORTING

9.1 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.

9.2 AEs, SAEs and SUSARs

9.2.1 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 use of sticky reminders and/or the prototype user app. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

9.2.2 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.

The investigator will report all SAEs to the sponsor without undue delay after obtaining knowledge of the event. 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.

9.2.3 Suspected unexpected serious adverse reactions (SUSARs)

Not applicable

9.3 Annual safety report

Not applicable

9.4 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.
SAEs need to be reported till end of study within the Netherlands, as defined in the protocol

9.5 [Data Safety Monitoring Board (DSMB) / Safety Committee]

Not applicable as this is a feasibility study with no medicinal investigational product.

10. STATISTICAL ANALYSIS

Analysis and statistics will be performed in the Radboud university medical center using Statistical Package for the Social Sciences (IBM SPSS Statistics version 20.0 or higher, SPSS inc., Chicago, Illinois, USA). P values <0.05 will be regarded as statistically significant. Normally distributed continuous variables will be described using mean and standard deviation (SD). Median and interquartile values will be shown in case variables are not normally distributed. The qualitative or categorical variables, i.e. baseline parameters, will be described using frequencies and percentages.

10.1 Primary study parameter(s)

Depending on whether values are normally distributed, different tests will be executed for self-efficacy values obtained through the ESES questionnaire.

Normally distributed: Self-efficacy values between groups will be compared with paired samples t-test (within and between control or intervention group). These tests will be performed between "before" and "after" self-efficacy values of both control and intervention group.

Not normally distributed: Self-efficacy values between groups will be compared with either a Wilcoxon signed rank test (within and between control or intervention group).

These tests will be performed between "before" and "after" self-efficacy values of both control and intervention group.

As exploratory analyses, self-efficacy values will be correlated with system usability, frequency of use (e.g. using the Pearson or Spearman's rho test, depending on normality of the values) or tested for differences within demographic parameters (independent samples t-tests and/or linear regression).

10.2 Secondary study parameter(s)

Usability data gathered from the SUS will be correlated to self-efficacy (e.g. using the Pearson or Spearman's rho test, depending on normality of the values).

Qualitative data gathered from the interviews will be systematically analyzed using standard systematic research methodology (e.g. Atlas ti). All interviews will be audio-recorded and transcribed verbatim. Next, two researchers will independently perform text analysis, looking for perceived barriers and facilitators that could affect the use of the App, and perceived positive and negative effects of the App. All results will be discussed together, until consensus is reached. The Barriers and Facilitators will be presented following to the framework of Gagnon et al (Gagnon *et al.*, 2012). Positive and negative effects will be presented according to the healthcare-extended UTAUT2 framework (Slade et al., 2013).

10.3 Other study parameters

Frequency of use
Correlation between frequency of use data from the app registrations and self-efficacy will be tested (e.g. with a Pearson or Spearman's rho test, depending on normality of the values).

Demography
Differences between the self-efficacy of groups within demographic categories (age, gender, marital status, employment status, highest educational level, estimated years affected by symptoms or disorder and medical history regarding physiotherapy) will be tested for significance using independent samples t-tests and/or linear regression.

10.4 Interim analysis (if applicable)

Not applicable

11. ETHICAL CONSIDERATIONS

11.1 Regulation statement

Given the minimal difference the described intervention makes within the usual course of rehabilitation, we do not identify this research as subject to the Medical Research Involving Human Subjects Act (WMO). In any case, this research will not be in violation with the principles of the Declaration of Helsinki (version, date, see for the most recent version: www.wma.net) or the WMO.

11.2 Recruitment and consent

First, eligible patients will be invited by their physiotherapists to participate in the pilot study. They will receive an information letter that explains the study in general. After a suitable period of time (1-2 weeks), follow-up telephone contact will explore whether subjects are interested, the purpose of the study and study procedures will be explained and interested patients will receive an extensive information package. The initial information letter and the informed consent form are attached as separate documents.

11.3 Objection by minors or incapacitated subjects (if applicable)

Not applicable

11.4 Benefits and risks assessment, group relatedness

We expect no negative effects for patients. Should a negative effect be perceived, patients are free to quit (as they are always free to quit) participation. Potential risks can include wrong positioning of the stickers and privacy issues. However, positioning will be thoroughly discussed with physiotherapists and privacy will be ensured by encryption and coding.

Although expected, no benefits stated below can be guaranteed.
We expect and hope that empowering patients in performing their exercises will have certain benefits:

- Self efficacy increases;
- Exercises are more often correctly performed;
- Follow-up appointments with physiotherapists are more effective as the therapist should have more veracious information regarding the progression of rehabilitation and the execution of exercises;
- Frequency of exercising is closer to prescribed frequency
- Based on the aforementioned (in the introduction and in this section) information and expected benefits, we expect that the treatment outcome potentially has improved

Group relatedness is not applicable for and thus not relevant to this study.

11.5 Compensation for injury

Due to the expectation of a non-WMO subjective research, a dispensation for insurance obligation was both requested and granted for this study.

11.6 Incentives (if applicable)

Participants of the study will receive travel reimbursement.

12. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

12.1 Handling and storage of data and documents

Data will be handled confidentially and used only in the scope of this study. Patients will be coded with either bird names or mineral names (depending on disorder) in order to create a coded dataset. Only the investigators and physiotherapists (as they need to adapt treatment to each patient) have access to this code and will store the subject identification code list at a separate location from the dataset. All patient data will be encrypted and securely stored on a database in the European Economic Area by Touchless. Data will never leave this area and will be sent securely via https connections. After the study has ended, all patient-related data will be transferred to Radboudumc servers (where they will be kept for 15 years) and subsequently removed from Touchless Industries' server. All in accordance with the Dutch Personal Data Protection Act.

The following table shows who has access to which data during the intervention period. In the table, Radboudumc researchers refers to the three empoyers or Reshape: Barend Heeren, Tom van de Belt and Jolijn van Uden who coordinate the study. Physiotherapists only have access to data of patients in their own patientgroup (NA or prosthesis).

Diary		Amputation	Neuralgic Amyotrophy	Touchless Industries	Survey group	Radboudumc researchers	Physiotherapists
	Medical data						
	Pain score	Yes	Yes	Yes	Yes	Yes	Yes
	Pain location	Yes	No	Yes	Yes	Yes	Yes
	Duration of wearing the prosthesis	Yes	No	Yes	Yes	Yes	Yes
	Number of minutes moved	No	Yes	Yes	Yes	Yes	Yes
	Amount of time practiced	Yes	No	Yes	Yes	Yes	Yes
	Medication	Yes	No	Yes	Yes	Yes	Yes
	Additional data						
	Self confidence during the exercises	Yes	Yes	Yes	Yes	Yes	Yes
	Confidence in making it through the day satisfactorily	Yes	Yes	Yes	Yes	Yes	Yes
	Videos of the patient	No	Yes	Yes	Yes	Yes	Yes

	App use frequency	Yes	Yes	Yes	Yes	Yes	Yes
	Code name	Yes	Yes	Yes	Yes	Yes	Yes
	Password	Yes	Yes	Yes	No	No	No
	Simulated mail address for signing in	Yes	Yes	Yes	Yes	Yes	No
Questionnaires	Self-efficacy	Yes	Yes	No	Yes	Yes	No
	User-friendliness	Yes	Yes	No	Yes	Yes	No
	Age	Yes	Yes	No	Yes	Yes	No
	Gender	Yes	Yes	No	Yes	Yes	No
	Previous experience with physiotherapy	Yes	Yes	No	Yes	Yes	No
	Highest education	Yes	Yes	No	Yes	Yes	No
	Time since diagnosis	Yes	Yes	No	Yes	Yes	No
Interview audio recording	User experiences	Yes	Yes	No	Yes	Yes	No
Other	IP adress telephone	No	No	Yes	No	No	No

Touchless industries has developed the technology that is needed for this research. During the intervention phase they provide the storage of data as well. The relationship between Touchless Industries and the Radboudumc can therefore be best described as the responsible party (Radboudumc) and the editor (Touchless Industries). This is registered in the editors agreement. Touchless Industries describes their security measures in an information security measures document, which is enclosed with the editors agreement. One of the security measures is an IP table that limits the access to the patient videos. This information will be removed from the server after the intervention phase has ended. Locations and telephone numbers will not be accessible for Touchless Industries.

Next to the privacy measure of the encoding of patient names, videos can also not be traced to the identity of the subject. In the study two patient groups are included, patients with a leg prosthesis and patients with Neuralgic Amyotrophy. For the NA patients only the area between their shoulder blades is important in the exercises, so videos are recorded from the back of the patient and therefore do not show the face of the subject. As a consequence, the patients are not (directly) identifiable. For the leg prosthesis group the posture is important which means it is not possible to make a video in which the patient is unrecognizable. As a solution they will not watch videos of themselves, but they will watch videos of an unknown person performing the exercise. Physiotherapist already use these videos in regular care.

The physiotherapists as well as the subjects of the study will use two factor authentication to access the mobile application with the videos. Their telephone is used as the second factor. For access to the videos there will be an IP table and a unique ID for the URL to the videos from the mobile application. The editor will check for attempts to access this application from different IP addresses and reports to Radboudumc at least once a month. Furthermore there have been tests for the right access of a user for

the corresponding videos. Also there is a limited amount of IP address that has access to the server, corresponding to the number of subjects in the study in order to hinder attempts to access the server illicitly.

12.2 Monitoring and Quality Assurance

Not applicable

12.3 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.

12.4 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.

12.5 Temporary halt and (prematurely) end of study report

The investigator/sponsor 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 visit.

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 sponsor 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 investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC.

12.6 Public disclosure and publication policy

All publication rights belong to the principal investigator's department. Data will be published regardless of outcome. Before submission of intended publications, the manuscript will be shared with Touchless Industries, and 30 days will be allowed for review and feedback. However, Touchless Industries cannot block submission / publication. In all cases, the principal investigator decides whether the manuscript will be submitted and published. Subjects will be informed about the results.

13. STRUCTURED RISK ANALYSIS

13.1 Potential issues of concern

a. Level of knowledge about mechanism of action
Not applicable, not an invasive or biological product.

b. Previous exposure of human beings with the test product(s) and/or products with a similar biological mechanism
Not applicable, not an invasive or biological product.

c. Can the primary or secondary mechanism be induced in animals and/or in *ex-vivo* human cell material?
Not applicable, not an invasive or biological product.

d. Selectivity of the mechanism to target tissue in animals and/or human beings
Not applicable, not an invasive or biological product.

e. Analysis of potential effect
Not applicable, not an invasive or biological product.

f. Pharmacokinetic considerations
Not applicable, not an invasive or biological product.

g. Study population
Our population will consist of rehabilitating patients in stable conditions apart from the disorder they receive physical therapy for (either neuralgic amyotrophy or leg amputation and prosthesis). We do not expect any negative (medical) events during the test period since the intervention is non-biological and non-invasive. A (minimal) risk that is present for patients is wrong positioning of the stickers. Further, risks can include privacy issues and unexpected events can always occur (e.g. falling off of stairs when scanning a sticker is located to the stairs). Should such events occur and be attributable to the research in any way, these events will be handled appropriately.

h. Interaction with other products
No interaction with other products is expected, as this product is a non-invasive, non-biological product.

i. Predictability of effect
Not applicable, not an invasive or biological product.

j. Can effects be managed?
Not applicable, not an invasive or biological product.

13.2 Synthesis

This study does not include a product that in any way is expected to affect patients negatively. It is a non-invasive, non-medicinal, non-biological product. Therefore, we do not expect any risks for patients attributable to our product. We have excluded patients with unstable conditions in order to minimize unexpected risks for patients' health. We will design labels that clearly indicate distinct locations for the stickers to minimize incorrect positioning. Further, appropriate locations for stickers will be discussed between physiotherapist and patient (e.g. in the example above, placing sticker below instead of above the staircase). Privacy will be ensured by encryption and coding. Might any unexpected event occur for which patients feel that they want to quit participation, they are free to do so as they are always free to quit, without any consequences to their treatment. Furthermore, might events occur that endanger a patient, the investigator will address this issue and handle it appropriately.

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