Study Protocol - Effectiveness of the SelfBack App in preventing and treating low back pain versus no intervention: a randomized clinical trial

Study Title: Effectiveness of the SelfBack-App in preventing and treating low back pain versus no intervention: a randomized clinical trial

Study Acronym: SelfBack-app

Protocol Version and Date: V3 04-08-2026

Registry Number:

Investigational Product or Medical Device: SelfBack- App

Sponsor: Universitair Ziekenhuis Brussel; Vrije Universiteit Brussel – 101 Laarbeeklaan, B-1090, Brussel, België

Coordinating/Principal Investigator: Prof Dr Marc Schiltz – Dr. Margot Van Cauwenberge

Study Start Date:

Expected Study End Date*:

*In case of extension of study end date a new date must be submitted to the EC via an amendment and the insurance department must be notified regarding the extension.

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PROTOCOL SIGNATURE PAGE

Name	Signature	Date
Sponsor or Legal representative: Universitair Ziekenhuis BRUSSEL **Head of Department:** Prof. Dr. Mark De Ridder, CEO UZ Brussel		
Coordinating Investigator: NA		
Principal Investigator: Prof. Dr. Marc Schiltz Dr. Margot Van Cauwenberge		

I agree:

- to assume responsibility for the proper conduct of this study
- to conduct the study in compliance with this protocol and any future amendments
- not to implement any deviations from or changes to the protocol without prior review and written approval from the Ethics Committee, except where necessary to eliminate an immediate hazard to the subjects, or for administrative aspects of the study (where permitted by all applicable regulatory requirements)
- that I am thoroughly familiar with the appropriate use of the investigational drug/medical device, as described in this protocol
- to ensure that all persons assisting me with the study are adequately informed about the investigational drug/medical device and their study-related duties and functions as described in the protocol
- that I am aware of and will comply with the current good clinical practice (GCP) guidelines and ethical principles outlined in the Declaration of Helsinki
- to conduct the study in accordance with all applicable laws and regulations

Printed name Signature Date

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1 Sponsor/Coordinating Investigator Information

Sponsor: Department of Physical and Rehabilitation Medicine of the Universitair ZIekenhuis BRUSSEL, Brussels, Belgium

Principal Investigator: Prof. Dr. Marc Schiltz
Subinvestigator(s): Margot Van Cauwenberge
Coordinating Investigator: NA
Statistician :
Study Coordinator:
Study site(s) and co-investigator(s) *if applicable*:

2 List of Abbreviations

AE	Adverse Event
AR	Adverse Reaction
ATMP	Advanced Therapy Medicinal Product
AxMP	Auxiliary Medicinal Product
CA	Competent Authority
CRA	Clinical Research Associate
CRF	Case Report Form
CRO	Contract Research Organisation
CT	Clinical Trial
CTA	Clinical Trial Authorisation
CTIS	Clinical Trial Information System
CTR	Clinical Trial Regulation
DSMB	Data Safety Monitoring Board
EC	Ethics Committee
e-CRF	Electronic Case Report Form
EU	European Union
EMA	European Medicines Agency
EQ5D - 5L	The EuroQoL 5-dimension
FABQ	The Fear Avoidance Belief Questionnaire
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
IB	Investigator's Brochure
IC	Informed Consent
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
KCE	Federaal Kenniscentrum voor de Gezondheidszorg
LBP	Low back pain
MS	Member State
NRS	Numerical rating scale
ODI	Oswestry disability index
PSEQ	Pain Self-Efficacy Questionnaire
PI	Principal Investigator
PROM	Patient-Reported Outcome Measures
RSI	Reference Safety Information
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure

SUSAR	Suspected Unexpected Serious Adverse Reaction
UZ	Universitair Ziekenhuis
WAI	Work Ability Index
YLD	Yearls lived with disability

3 Protocol Version History

Version N^{O}	Version Date	Summary of changes
V1	09/07/2025	
V2	16/11//25	
V3	4-8-2026	

4 Trial Registration/Protocol Summary

Information	
Objectives:	Comparison of an intervention consisting of a digital decision support system delivering a weekly plan of suggested activities and educational support via a smartphone app versus no intervention in the prevention of low back pain (LBP) or to self- manage LBP.
Study population:	Currently working as a nurse, assistant nurse or logistical assistance in one of the selected units of the Universitair Ziekenhuis (UZ) Brussel or Valida
In-and exclusion criteria:	Inclusion Criteria: ● Currently working as a nurse, assistant nurse – logistical assistance in one of the selected units of the Universitair Ziekenhuis (UZ) Brussel or Valida ● Presence or not of LBP of any duration ● Age: ≥18 years ● Own and regularly use a smartphone (with at least Android 7.0 or iOS11.0) with internet access (Wi-Fi and/or mobile data) ● Have a working email address and have access to a computer with internet access to complete questionnaires in a web browser. Exclusion Criteria: ● Unable to speak, read or understand the national languages (Dutch/French) ● Presence of red flags as described in the KCE LBP guidelines ● Work leave for medical reasons of more than 3 consecutive days during the last 6 months ● Cognitive impairments or learning disabilities limiting participation ● Mental or physical illness or condition limiting participation ● Inability to take part in exercise or physical activity ● Pregnancy ● Previous back surgery ● Ongoing participation in other research trials for LBP management
Factors of interest / Data to be collected:	- Baseline characteristics ○ Age, gender, BMI ○ Medical history (past back pain, comorbidities…) ○ Lifestyle factors (physical activity, smoking, work …)

	- Treatment & Intervention
	  ○ Group allocation (Usual Care vs. SelfBack App)
	  ○ App usage and adherence
	  ○ Concomitant treatments (e.g., physiotherapy, medication)
	- Patient-Reported Outcome Measures (PROMs – Questionnaires)

Endpoints:	Primary: Roland Morris Disability Questionnaire (3 months) Secondary: Roland Morris Disability Questionnaire (3,6 and 12 months) Oswestry disability index (ODI) (3,6 and 12 months) Promise 29 (3,6 and 12 months) Roland Morris Disability Questionnaire (RMDQ) (3,6 and 12 months) Work Ability Index (WAI) (3,6 and 12 months) EQ5D - 5L (the EuroQoL 5-dimension) (3,6 and 12 months) Pain intensity (3,6 and 12 months) Kinesiophobia (3,6 and 12 months) Diary for socio-economic expenses: Global impression of change Work Status (3,6 and 12 months) The Fear Avoidance Belief Questionnaire (FABQ) (3,6 and 12 months) Pain Self-Efficacy Questionnaire (PSEQ) (3,6 and 12 months) Physical activity (3,6 and 12 months) Exercise volume (3,6 and 12 months) Saltin-Grimby Physical Activity Level Scale (3,6 and 12 months) Tailoring variables (3,6 and 12 months) User ratings (3,6 and 12 months)
Target sample size:	144
Statistical considerations:	Anova, repeated measures

5 Background and Rationale

5.1 Overview of Disease Pathogenesis with Relevant Literature

- Low back pain (LBP) is a major public health issue due to its high prevalence, significant healthcare demand, and substantial societal costs.(1) In Belgium, the 2013 Health Survey revealed that 21% of individuals aged 15 and older experienced low back pain or other chronic back conditions in the past year. (2) It remains one of the most common reasons for seeking medical care. (1)

- Aspecific mechanical lumbar pain refers to low back pain that is not caused by a specific disease, pathology, or structural problem. Low back pain can reduce physical functioning and lead to additional issues such as poor sleep, low mood anxiety…

- Clinical guidelines recommend education, exercise therapy, multidisciplinary treatments, and a combination of physical and psychological interventions for managing low back pain. (3) Self-management programs incorporating these recommended components are suggested as a potential approach for conditions such as nonspecific low back pain.

- Nurses, assistant nurses, and logistical staff are at risk of developing low back pain (4)(5). It is well known that exercise therapy is an effective method for preventing low back pain. The SelfBack system consists of a data-driven decision support system that uses case-based reasoning to capture and reuse participant cases to suggest the most suitable self- management plan for participants (6). The system is an intelligent system delivering self- management plans tailored to individual participant characteristics (6). Information about participant characteristics is collected via a (baseline) questionnaire, weekly self-reports via the app on symptom progression etc., and a wristband that detects the daily number of steps (6).

- The weekly plans are presented in an app to participants. The weekly plan includes three categories of content: information/education, recommended daily number of steps, recommended strength and flexibility exercises.

5.2 Epidemiology

The lifetime prevalence of LBP is estimated to range between 30% and 80%. (7) In 2020, over half a billion people worldwide were affected by low back pain, accounting for 7.7% of all years lived with disability (YLDs) and making it the leading cause of global disability. (8) By 2050, the total number of cases is projected to rise by 36.4%, with the most significant increases expected in Asia and Africa. (8)

5.3 Current Treatments

It is well established that exercise therapy is an effective method for both preventing and treating non-specific low back pain. Systematic review shows us moderate-certainty evidence that exercise therapy is likely effective in treating chronic low back pain when compared to no treatment, usual care, or placebo interventions. (7)(8)

5.4 Study Rationale

The rationale of this study is to improve the self-approach of nonspecific low back pain or to prevent low back pain. The SelfBack intervention consists of the SelfBack system, which provides the participants with an individually tailored weekly plan of suggested activities. These solutions may help improve patient outcomes by supporting adherence to evidence-based care strategies on personal approach. While usual care is commonly provided, it remains unclear whether adding a digital self-management tool further enhances outcomes, although some studies have already shown positive effects. (11)(12)

5.5 Rationale for Study Design

This study has a randomized controlled clinical trial design, where group allocation is determined by the hospital floor on which participants work. Patients are stratified into clusters based on care load, resulting in comparable profile distributions that allow for meaningful comparisons between groups. Group 11 (medium care load): Infectious Diseases, Cardiology, Cardiac and Vascular Surgery, and Diabetology. Group 2 (high care load): Geriatrics, Neurosurgery, Orthopedics, Rehabilitation, and Neurology. Interpreting groups in this manner guarantees a structured and efficient implementation while avoiding the logistical challenges associated with individual randomization. The management is aware of the specific services participating in the investigation. Participants will continue to receive their usual care, standard treatment remains accessible while still enabling an assessment of the app's additional benefits. By mirroring real-world healthcare settings, the study allows patients to follow their standard care while incorporating digital support as an optional treatment.

5.6 Rationale for Dose and Regimen

The frequency and the duration of the exercises are based on the previous study of the selfBACK-app. The standard recommendation is to perform 3 to 5 sessions per week, each lasting 15 minutes (for example, 3 exercises with an estimated duration of 5 minutes per exercise).(12)

6 Study Objectives and Endpoints

6.1 Primary Objectives

To evaluate whether the use of the SelfBack app improves pain-related functional disability over time using the **Roland Morris Disability questionnaire (at 3 months after the begin of the intervention)** .

Due to the high prevalence of low back pain, a systematic review from 2021 found lifetime prevalence of low back in nurses to be 54.8% (Rezai et al. 2021) (13) the Roland-Morris Disability Questionnaire (RMDQ) was chosen as the primary outcome measure to assess functional limitations. The sample size was determined based on the expected change in RMDQ scores to ensure adequate statistical power for detecting clinically meaningful differences. The power analysis was performed exclusively for the primary endpoints, as these were considered most relevant to the study objectives.

6.2 Secundary objectives

- To assess functional disability using the **Oswestry Disability Index (ODI)** and determine whether the intervention enhances back pain
- To investigate the intervention's impact on general health and well-being, including depression, anxiety, physical function, pain interference, fatigue, sleep disturbance, and social participation, using the **PROMIS-29 questionnaire.**
- To examine work ability through the **Work Ability Index (WAI)** and monitor changes in work status.
- To measure quality of life improvements using the **EQ-5D-5L**, assessing mobility, self-care, daily activities, pain/discomfort, and anxiety/depression.
- To analyze changes in pain intensity using the **Visual Analogue Scale** (VAS: 0-10), focusing on overall back and leg pain.
- To explore kinesiophobia (fear of movement) using the **Tampa Scale of Kinesiophobia (TSK)** and assess whether the intervention reduces movement-related fear.
- To assess fear-avoidance beliefs with the **Fear-Avoidance Beliefs Questionnaire (FABQ)**, evaluating patients' perceptions of pain and its impact on daily activities.
- To examine pain self-efficacy, or the confidence to perform daily activities despite pain, using the **Pain Self-Efficacy Questionnaire (PSEQ).**
- To track changes in **physical activity** levels, including weekly step count goals and actual step count data, to assess adherence to recommended activity levels.
- To monitor **exercise volume**, including the number of sets and repetitions of prescribed exercises completed by participants.
- To evaluate physical activity levels using the **Saltin-Grimby Physical Activity Level Scale**, categorizing activity levels from sedentary to vigorous.
- To assess the influence of **tailoring variables**, such as pain intensity, function, fear-avoidance, workability, sleep, stress, depression symptoms, and barriers to self-management, which are monitored weekly in the intervention group.
- To analyze **user ratings**: three rating questions on overall rating, ease of use and recommendation to others scored on a 5-point system

6.3 Endpoints

Primary endpoint:

Roland Morris Disability Questionnaire: The primary outcome is the Roland Morris Disability Questionnaire (RMDQ) assessing pain-related disability. The questionnaire includes 24 items asking participants to indicate if they experience functional impairments. This is tested by answering to a series of descriptions of functional abilities with higher scores indicating higher level of disability. This questionnaire will be held at 3 months after the begin of the intervention.

Secondary endpoint:

Roland Morris Disability Questionnaire: As secondary endpoint it will be held at 6 and 12 months. (14)

Oswestry disability questionnaire: The Oswestry disability index (ODI) is used to measure functional disability because of abnormalities of the spine 1. It contains ten topics whereby each is scored on a scale from 0 (no disability) to 5 (maximum disability possible). Higher values present more disability, low values present less disability. This questionnaire will be held for 3, 6 and 12 months. (15)

Promis 29: The PROMIS 29 is a set of short forms that includes questions from seven different areas: depression, anxiety, physical function, pain interference, fatigue, sleep problems, and social participation. Each area is assessed with four questions, plus an additional question about pain intensity (numeric rating scale) (NRS) (question 29). The PROMIS tools have been tested and validated in large populations, making them suitable for research on various conditions. They are not disease-specific and measure the past seven days, except for Physical Function, which doesn't have a specific timeframe. This questionnaire will be held for 3, 6 and 12 months. (16)

Work Ability Index (WAI): The WAI measures the work ability taking into account physical and mental parts of work as well as different diseases and their impact on work ability. This questionnaire will be held for 3, 6 and 12 months. (17)

EQ5D - 5L: The EuroQoL 5-Dimension questionnaire is used to assess quality of life in five areas: mobility, self-care, daily activities, pain or discomfort, and anxiety or depression. This questionnaire will be held for 3, 6 and 12 months. (17)

Pain intensity: VAS score (VAS: 0-10, with 0 being no pain and 10 being worst pain imaginable) will be used for the assessment of overall pain, defined as a combination of back and leg pain (but not pain from other body parts). The VAS pain score is believed to be reliable, valid and sensitive to change. This questionnaire will be held for 3, 6 and 12 months. (17)

Tampa scale of kinesiophobia (TSK): consists of 17 questions designed to assess the fear of movement (kinesiophobia) in individuals with low back pain. Higher scores suggest a higher fear of movement. The TSK is well-established and demonstrates strong clinical reliability in both acute and chronic low back pain patients. This questionnaire will be hold at 3, 6 and 12 months. (17)

Work Status: The patients will report their current work status, which includes categories such as employed, unemployed, self-employed, on sick leave, on partial sick leave, or undergoing work adaptations. They will also indicate whether they are in gainful employment (yes/no) and describe the nature of their work. This questionnaire will be held for 3, 6 and 12 months.

The Fear Avoidance Belief Questionnaire (FABQ): The FABQ is a 5-item questionnaire, where the participants score their beliefs about their LBP on an ordinal scale ranging from zero [completely disagree] to six [completely agree]. This questionnaire will be held for 3, 6 and 12 months. (17)

Pain Self-Efficacy Questionnaire: The questionnaire assesses the participant's level of confidence in carrying out specific activities despite their pain. The PSEQ is a 10-item questionnaire scored on an ordinal scale ranging from zero to six. This questionnaire will be held for 3, 6 and 12 months. (18)

Physical activity: Weekly recommended step count goal, and the actual achieved step count per day [Timeframe: weekly for 9 months]. This questionnaire will be held for 3, 6 and 12 months.

Exercise volume: The patients report back their completed exercise volume as number of sets and repetitions for their suggested exercises, when they perform them. This questionnaire will be held for 3, 6 and 12 months.

Healthcare service use: Patients will keep a diary to log usage of pain medication as well as physiotherapy and physician visits related to low back pain.

Saltin-Grimby Physical Activity Level Scale: Participants indicate their amount of time per week performing leisure activities with four levels of intensity ranging from sedentary to vigorous physically active. This questionnaire will be held for 3, 6 and 12 months. (19)

Tailoring variables: Participants in the intervention are on a weekly basis asked a set of tailoring questions. These are tracked over the intervention period. The tailoring questions include items on low back pain (NRS for pain intensity), function, fear-avoidance, workability, sleep, pain self- efficacy, stress, symptoms of depression, and barriers for self-management. Note. not all questions are asked on a weekly basis This questionnaire will be held every 9 weeks.

User ratings: Three rating questions are asked, focusing on overall satisfaction, ease of use.. Each question is scored using a 5-point scale. This questionnaire will be held for 3, 6 and 12 months.

7 Research Methods

7.1 Study Design

Primary Purpose: Treatment
Allocation: Randomized
Interventional Model: Parallel Assignment, description: the study design is a multi-center controlled trial with 2 parallel arms
Masking: Single (Investigator)
Masking Description: The analysis of the data will be performed blindly
Experimental: Usual care versus SelfBack-app care

7.2 Study Population

Participant Group/Arm: nurses, assistant nurses, and logistical staff are at risk of developing low back pain. It is well known that education and exercise therapy are effective methods for preventing low back pain. The recruited participants will be assigned to specific groups based on the service they are currently working in. Participants groups are stratified into clusters based on care load, allowing for comparisons between the intervention and control groups. Each study group, based on the floor where the staff (logistic assistants, nurses, assistant nurses) is working will be randomized to either control or intervention and taking into account the stratification.

7.2.1 Inclusion Criteria

Inclusion Criteria:

- Currently working as a nurse, assistant nurse – logistical staff in one of the selected units of the Universitair Ziekenhuis (UZ) Brussel or Valida
- Presence or not of LBP of any duration
- Age: ≥18 years
- Own and regularly use a smartphone (with at least Android 7.0 or iOS11.0) with internet access (Wi-Fi and/or mobile data)
- Have a working email address and have access to a computer with internet access to complete questionnaires in a web browser

7.2.2 Exclusion Criteria

Exclusion Criteria:

- Unable to speak, read or understand the national languages (Dutch/French/German) nor English
- Presence of red flags as described in the KCE LBP guidelines
- Work leave for medical reasons of more than 3 consecutive days during the last 6 months
- Cognitive impairments or learning disabilities limiting participation
- Mental or physical illness or condition limiting participation
- Inability to take part in exercise/physical activity
- Pregnancy
- Previous back surgery

Ongoing participation in other research trials for LBP management

7.2.3 Contraception / Pregnancy Avoidance Measures

Contraception is not mandatory. However, participation in the study cannot continue beyond three months of pregnancy.

7.3 Study Duration for Subjects

The study will last 12 months, with follow-up moments at 3, 6, and 12 months.

7.4 Group Allocation & Blinding *(if applicable)*

UZ Brussel and Valida will not have direct access to which employees participate or not, but access to pseudonomized data. The analysis of the data will be performed blindly. The protocol will follow the intention-to-treat (ITT) principle.

The sample size was calculated using G*Power 3.1, with an effect size of 0.1677, resulting in a minimum of 150 participants (75 per group) to achieve 80% power to detect a 2-point difference in mean RMDQ scores at 3 months. This calculation was based on a standard deviation of 6 points, a correlation of 0.5 between repeated measures within participants, a 2-sided α of 0.05, and an anticipated 30% dropout rate during follow-up. Primary and secondary prevention of low back pain were considered secondary outcome measures and therefore did not influence the power calculation.

8 Study Assessments and Procedures

8.1 Schedule of Activities

First, an introduction to the various services where participants can register will take place. Once this is completed, the screening process will begin. The recruited participants will be assigned to specific groups based on the service they are registered with (intervention group vs. usual care group). Participants groups are stratified into clusters based on care load, allowing for comparisons between groups. Longitudinal follow-up is conducted to assess changes over time. The usual care group will only be required to complete the questionnaires. The intervention group, on the other hand, will be asked to perform exercises as proposed by the SelfBack platform and also complete the questionnaires. These questionnaires will be filled out at 3, 6, and 12 months. The total duration of participation in the study is 12 months. There is no physical contact, only through questionnaires.

Although the study includes several different measurements, the overall workload for participants remains limited, as all assessments are completed via a smartphone application and can be filled out at a time of the participant's choosing. Moreover, the smartphone-based outcome set offers strong potential for consistent follow-up and longitudinal monitoring.

8.1.1 Informed consent

Participants may electronically sign the informed consent form (ICF) when logged into a hospital computer

using their personal identification via the hospital badge reader. This amendment was introduced to simplify the informed consent procedure while maintaining secure participant identification during the electronic signing process.

8.2 Study Assessments/Interventions per Visit

8.2.1 Screening

A standardized presentation about the study and the SelfBack intervention will be provided for each participating unit, including a video explanation. Per unit (intervention vs no intervention) there will be given another video explanation. This will be followed by a Q&A session with one of the investigators. Additionally, an investigator-physician or study staff member will assess whether you are eligible to participate.

At this stage, you are not required to decide whether you wish to participate. You will be given sufficient time to consider your decision. You will receive an information brochure to take home and may contact a study staff member at any time with any questions.

After your visit with the investigator-physician or study staff member, a study staff member will follow up with you to inquire about your interest. If you decide to participate, a study visit will be scheduled. During your first study visit, you will be asked to sign an "informed consent" document before the study officially begins. This confirms that you understand the study information and agree to participate.

8.2.2 Treatment Period

After the initial setup (as described above), there will be 1 study visit at the start of the study (to complete the informed consent) and three follow-up questionnaires at 3, 6, and 12 months after your study enrollment. The target follow-up moment is 3 months to complete the exercises on the app. The exercises are tracked on the app, and you must also indicate which exercises you have done.
Below, you will find a schedule outlining the study-specific assessments that will take place. Table 1 also provides additional explanations about these assessments.

Table 1: Description of Study-Specific Assessments and Procedures

These assessments and procedures are funded by the sponsor.

Procedure/ Assesment	**Description**	**Timing**
Group allocation	You will be assigned to one of two treatment groups 1. Selfback app intervention 2. No intervention This allocation is determined per department. Neither you nor your treating physician (general practitioner or treating specialist) have any influence on this assignment.	Beginning of the study
Questionnaires	You will be asked to complete various questionnaires regarding symptoms, functionality, daily activities, return to work, psychological well-being, and pain medication usage.	3,6,12 months (+/- 40min)

8.2.3 Follow Up Period

The follow-ups with the questionnaires during the study are scheduled at 3, 6, and 12 months. All Patient-Reported Outcome Measures (PROMs), including the study questionnaires, will be collected using REDCap. The SelfBack application will be used exclusively to deliver the intervention, including educational content and personalized exercise recommendations. This amendment clarifies the respective roles of REDCap as the electronic data capture system and the SelfBack application as the platform for delivering the intervention.

8.2.4 End of Study Visit

The end of the study is at 12 months. Physical visits are not required during the study, but if a participant experiences severe pain during treatment, they may schedule an urgent appointment in physical medicine as part of usual care.

9 Interventions/Treatment

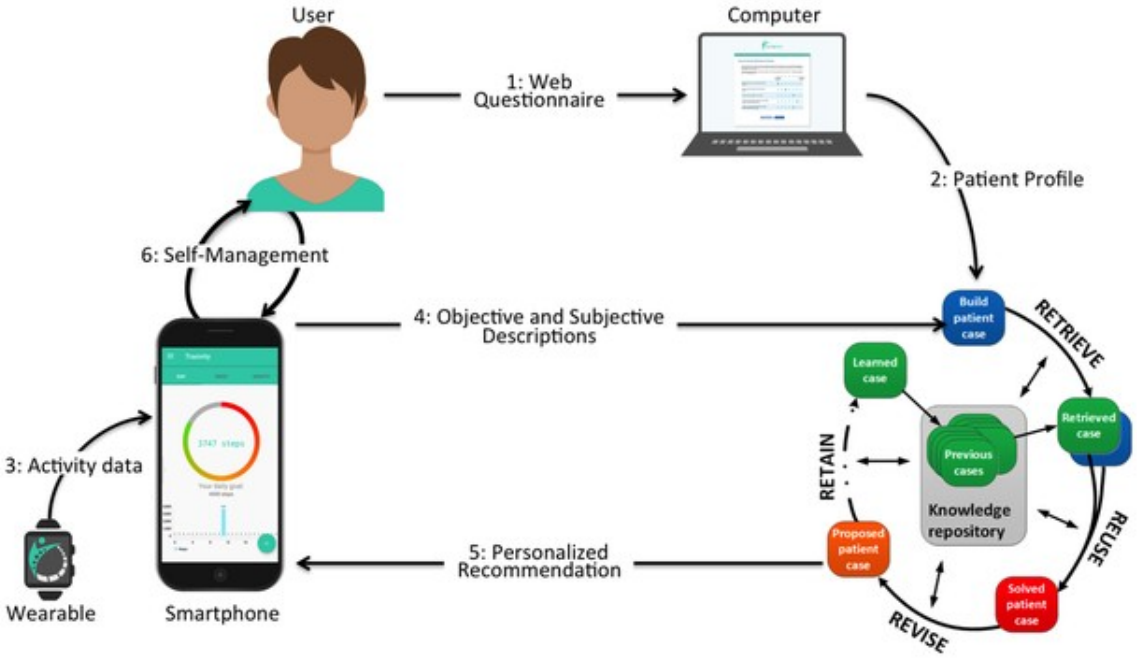
9.1 Treatments Administered

It is a randomized clinical study evaluating the SelfBack app versus no intervention among nurses, assistant nurses, and logistical staff in one of the selected departments of the University Hospital (UZ) Brussels or Valida.

9.2 Product/Device Characteristics

The SelfBack app is a digital decision-support system that provides a weekly plan of recommended activities and educational support via a smartphone app. It serves as an intervention for the prevention or self-management of low back pain (LBP) compared to no intervention.

The SelfBack system is a data-driven decision-support system that uses case-based reasoning to recommend the most suitable self-management plan for participants. It is an intelligent system tailored to the individual characteristics of each participant. Information about the participant's characteristics is collected through a baseline questionnaire, weekly self-reports via the app on symptom progression, and a wristband that detects daily step counts. The weekly plans are presented to participants through the app.



https://www.selfback.eu/

9.3 Storage, Packaging and Labelling

Not applicable.

Treatment Compliance & Accountability

The app asks whether exercises have been performed, but there is no verification of whether they were actually completed.

9.4 Blinding & Unblinding Procedures

It is a randomized controlled clinical trial. Usual care and SelfBack app-based care will be assigned based on the floor where participants are located. UZ or Valida will not have direct access to which employees participate or not, but access to pseudonomized data.

9.5 Concomitant Treatment

During the study, participants may seek advice from primary care providers as they normally would. They are also free to visit a physiotherapist if needed. The aim is to represent usual care as the standard treatment.

9.6 Prohibited Treatment

There are no treatment restrictions. Patients are free to maintain their daily activities and adhere to any therapy prescribed by their primary care provider.

10 Data Collection and Management

10.1 Monitoring

The investigator must make all trial documentation and related records available in case a monitoring visit or audit by the Sponsor is requested. Also in case of regulatory inspections all trial documentation should be made available to the inspector(s). All participant data must be handled and treated confidentially.
The Sponsor's monitoring frequency will be determined prior to the start of the trial. A monitoring plan will be generated detailing the frequency and scope of monitoring for the trial. Throughout the course of the trial the monitoring plan can be adjusted as necessary.

10.1.1 Composition of a Data Monitoring Committee (if applicable)

10.2 Data Collection

"REDCap" (Vanderbilt University, Nashville, USA) will be used as the Electronic Data Capture (EDC) system for the collection and management of all study data. Access to the system will be controlled by a designated sponsor representative. Study data will be entered within a reasonable timeframe following each study assessment, and all modifications will be automatically documented through an audit trail. This amendment clarifies the procedures for electronic data collection and data management throughout the study.

10.3 Database Management and Quality Control

- A full dataset for each user will be provided for each user. This can be done in an agreed interval or at the end of the project.
- All data is stored and processed in Europe Union.
- The "SelfBack" software does not present an unacceptable risk to health or safety. The device is low risk as stated in the "SelfBack" ISO 14971 documentation.
- The manufacturer of "SelfBack" has made a self-assessment and self-declaration as a Medical Device Class I according to and with regards to:
  - MDR Chapter 1, Section 2, Article 19
  - MDR Chapter 5, Section 1, Article 51
  - MDR Chapter 5, Section 2, Article 52
  - MDR Annex IV
  - MDR Annex VIII, Chapter 3, Paragraph, 6.3, Rule 11
  - MDCG 2021-24, Chapter 4, Paragraph 4.2.3, Rule 1

No serious adverse events are expected for this trial. Should a participant contact the research team concerning any worsening of symptoms, the participant will be advised to seek care from their HCP as they normally would. (10)

11 Safety Monitoring and Reporting

11.1 Adverse Events

11.1.1 Definitions

For Medical Device studies: An adverse event is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical investigation, whether or not related to the investigational device.

Note:

a) This definition includes events that are anticipated as well as unanticipated events
b) This definition includes events occurring in the context of a clinical investigation related to the investigational device, the comparator or the procedures involved

11.1.2 Reporting

One possible adverse event in this study is low back pain due to muscular overload related to the exercises. This may occur as a result of repetitive movements, or increased strain on the back muscles.

11.2 Serious Adverse Events

11.2.1 Definitions

For Medical Device studies: Any adverse event that led to any of the following:

a) Death,
b) Serious deterioration in the health of the subject, that resulted in any of the following:
   - Life-threatening illness or injury,
   - Permanent impairment of a body structure or a body function,
   - Hospitalization or prolongation of patient hospitalization,
   - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment of a body structure or a body function,
   - Chronic disease
c) Foetal distress, foetal death or a congenital physical or mental impairment or birth defect.

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.

11.2.2 Immediate Reporting

There are no serious adverse events to be expected in this clinical trial.

11.3 Suspected Unexpected Serious Adverse Reactions (SUSAR)

11.3.1 Definitions

An adverse reaction is any untoward medical occurrence in a patient or clinical investigation subject participating in a clinical trial including any abnormal sign, symptom, or disease temporally associated with the participant's involvement in the research, whether or not considered to be related to the research.

Serious if:

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity,
- Is a congenital anomaly/birth defect

Or

- Other important medical condition (ICH 2EA)

Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in

death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also be considered serious.

Immediate Reporting

There are no suspected unexpected serious adverse reactions in this clinical trial.

11.4 Device Deficiencies

11.4.1 Definitions

Any inadequacy in the identity, quality, durability, reliability, safety or performance of an investigational device, including malfunction, user errors or inadequacy in information supplied by the manufacturer.

11.4.2 Immediate Reporting

If the app is not working due to software issues, a study member may be contacted during working hours.

11.5 Procedures for Handling Special Situations

11.5.1 Pregnancy

Pregnant women are not eligible to participate in the study, but pregnancy during the study is permitted in the first three months.

11.6 Annual Safety Report

Regarding investigational medicinal device, the sponsor shall submit annually through CTIS to all Member States concerned a report on the safety of each investigational medicinal device used in a clinical trial;

12 Ethical Considerations

12.1 Ethical Conduct of the Study

12.1.1 Declaration of Helsinki

The trial will be performed in accordance with the Declaration of Helsinki, the conditions and principles of Good Clinical Practice, the protocol and applicable local regulatory requirements and laws.

12.1.2 Ethics Committee

Before the start of the trial or implementation of any amendment, approval of the trial protocol and amendments, informed consent forms and other relevant documents will be obtained from the applicable ethical committee(s).

12.2 Recruitment and Informed Consent

Each participant shall provide Informed Consent before performance of any study-related activities. The IC form that is approved by reviewing EC and be in a language that the participant can read and understand. The ICF is in accordance with current ICH and GCP guidelines and with applicable local regulations.

12.3 Study Data Protection

The collection and processing of personal data from study participants will be restricted to the information essential for achieving the study's objectives. All data will be gathered and handled with appropriate safeguards

to maintain confidentiality and ensure compliance with relevant data protection laws and regulations.

12.4 Subject Identification

Participant identification will remain confidential and will be documented by the investigator in an identification log. This log will be securely stored at the participating site and will not be duplicated. In all reports and communications between the site and the Sponsor, participants will be referred to by their study number only.

13 Insurance

UZ Brussel/VUB is, as Sponsor of the trial, responsible for ensuring appropriate general/product liability insurance and as required in accordance with applicable laws and regulations, country-specific liability insurance coverage for claims made by a trial subjects for injury arising from the subject's participation in the trial.

Reporting and Dissemination

The data and information collected during this trial will be reported in a clinical trial report and/or a publication in a scientific/medical journal. Reporting of trial results will be performed according to local regulations.

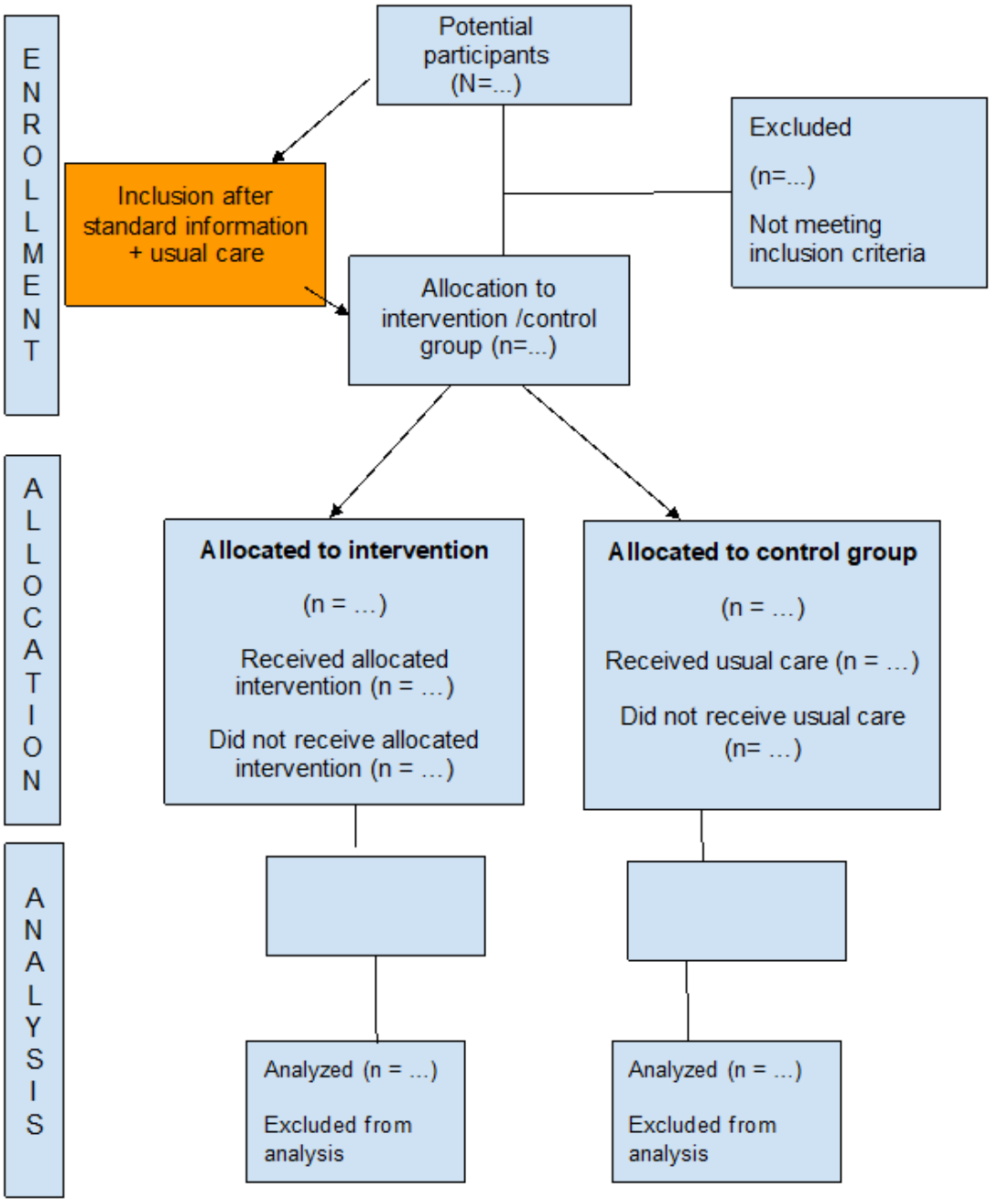
For the correct authorship rules we refer to the International Committee of Medical Journal Editors: https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

Finance and Conflict of Interest Statement

Investigators and study team members will provide the Sponsor with sufficient, accurate financial information in accordance with local regulations to allow the Sponsor to submit complete and accurate financial certification or disclosure statements to the appropriate regulatory authorities/ethics committee. Any update of information on financial interests should be disclosed during the course of the study.

No conflicts of interest to declare

Tables and Figures



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