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Feasibility of an artificial intelligent telerehabilitation platform to treat chronic low back pain: protocol for a clinical trial

Submission date
26/01/2023

Recruitment status
No longer recruiting

Registration date
10/02/2023

Overall study status
Completed

Last Edited
10/02/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aim
Low Back pain (LBP) is the first cause of disability worldwide and an important cause of work absence. Moderate to vigorous physical activity has been shown to improve prognosis in pain, disability, and quality of life in LBP compared to inadequate levels of physical activity. However, coaching and monitoring adherence and performance in self-exercise programs has been a challenge and a barrier to the success of these interventions. Reliable non-invasive monitoring and machine learning applied to telerehabilitation (TR) systems could be a solution if it holds sufficient accuracy in monitoring while providing patient guidance. The authors present a protocol of a randomised controlled trial with the aim of investigating the usability, feasibility, and effects of a self-exercise machine learning-based TR program on the management of chronic LBP in terms of physical and function impact, psychological, economic, and quality of life outcomes.

Who can participate?
Adult patients with chronic unspecific LBP without cognitive issues

What does the study involve?
All participants, including the TR group and control group, will receive the same educational materials (the same exercises indications) but the control group will receive that material in a flyer at baseline and the TR group through the TR platform.

What are the potential benefits and risks of participating?
The benefits for participating patients are that they will learn to manage and prevent their LBP. No real risks are associated with participating in the study.

Where is the study run from?
Outpatient clinics of the central region of Portugal (Portugal)

When is the study starting and how is it expected to run for?
October 2020 to December 2023

Who is funding the study?
European Regional Development Fund (FEDER), through the Regional Operational Program of the Center (CENTRO 2020), of the Portugal 2020 Program (Portugal)

Who is the main contact?
Dr Paula Amorim, paula.amorim.freire@ubi.pt

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
2020-070: ID177

Study information

Scientific Title
Feasibility of a self-exercise machine learning-based telerehabilitation program on the management of chronic low back pain: protocol for a randomised controlled trial

Acronym
TELEREAB LBP

Study objectives
1. A self-exercise machine learning-based telerehabilitation program is a safe, usable and feasible method for the management of chronic unspecific low back pain (LBP)
2. A self-exercise machine learning-based telerehabilitation program is more effective as standard care (home exercises without real-time monitoring and orientated by a TR platform) on the management of chronic unspecific LBP in terms of physical and function impact, psychological, economic and quality of life outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 13/10/2020, Ethics Committee of the University of Beira Interior (Convento de Santo António
6201-001 Covilhã, Portugal; +351275319700; comissaodeetica@ubi.pt), ref: CE-UBI-Pj-2020-070: ID2177

Primary study design
Interventional

Study design
Pilot randomized control trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic unspecific low back pain

Interventions
All potential participants will attend a briefing session prior to the start of the program to receive a description of the research project, conduct eligibility screening and provide informed consent, and will receive the allocation result before the start of the intervention. At the time of recruitment, all subjects will be participating in an outpatient program for chronic low back pain (LBP). After providing informed consent, eligible participants will be randomly assigned in a 2:1 ratio to the intervention group (telerehabilitation [TR] group) or the control group (standard treatment group). All participants, including the TR group and the control group, will receive the same educational material (same exercise instructions), but the control group will receive this material at baseline in the form of a flyer and the TR group will receive it via the platform TR. The allocation sequence (using computer-generated random numbers) is performed by staff not involved in the intervention and outcome assessment. Staff responsible for data collection are not the same as intervention therapists. Allocation results will be communicated to intervention therapists prior to the first intervention. Neither participants nor all staff can be blinded to allocation due to the nature of the intervention. Self-administered questionnaires will be used for all assessment measures and will be submitted by email. Staff answering the questionnaires ensure that no values are missing and that participants' doubts are resolved when answering the questionnaires. These helpers are not the same as the intervention staff. The reviewers who monitor the use of the TR platform are not the same as those who assess the results. The main data analyst should not know which group the participants belong to.

The TR platform is a system consisting of a low-cost mobile tower with a user interface capable of suggesting exercises preconfigured remotely by a physiotherapist and autonomously monitoring and providing real-time feedback on the user's performance. It is a system with innovative features that enables a holistic visual perception of the user's body movements without the use of markers, with the ability to analyze the user's performance using machine learning techniques. In addition to the platform's local analysis capability, it is envisioned that the information obtained for each user in each session will be centralized in the cloud to enable an autonomous temporal analysis of the user's performance across multiple rehabilitation sessions so that alerts can be generated for the therapist when deviations from plan occur.

The platform includes a visual sensor to capture images of the user, a screen for interacting with the user to provide feedback and therapy instructions, and a computer for data processing and implementation of machine learning strategies. These elements are optimally integrated into a mechanical structure that is lightweight and portable so that it can be easily used at home or in a clinic.

Two types of self-exercise are provided by the telerehabilitation platform:
1. Posture adjustment/stretching/range of motion
2. Trunk muscle strengthening

In addition to these exercises, aerobic exercises are also performed - patients are asked to walk for a certain amount of time, which is measured with a pedometer. The exercise program is conducted in three phases, each lasting four weeks (twelve weeks in total). Assessment takes place at the beginning of the study, after 6 weeks, and after 12 weeks

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
TR platform

Primary outcome(s)
1. Usability measured using the following methods: after 6, and after 12 weeks
1.1. The Portuguese version of the System Usability Scale (SUS)
1.2. The Telehealth Usability Questionnaire (TUQ)
2. Adherence and treatment fidelity is measured using the percentage of participants who will adhere to the intervention and the dropout percentage after 6 weeks and after 12 weeks
3. Safety of the telerehabilitation platform assessed by measuring the following variables between the intervention and control group after 6 weeks and after 12 weeks
3.1. Incidence of adverse events measured using a questionnaire.

Key secondary outcome(s)
Timepoint(s): at the beginning of the study, after 6 and after 12 weeks
1. Physical and functionality outcomes
1.1. Pain intensity measured using a numeric rating scale (NRS) and the Brief pain inventory (BPI)
1.2. Functional limitations measured using the Roland-Morris disability questionnaire (RDQ)
2. Economic variables
2.1. Care-seeking associated with low back pain for the last three months, such as any visits to a health practitioner (i.e. doctor, physiotherapist, chiropractor, etc), type of self-management (i.e. heat pack, bed rest, hot shower, etc), and medication intake (type and dose of medication taken) measured using a questionnaire
2.2. Number of days out of work due to low back pain for the last three months measured using a questionnaire
3. Psychological variables
3.1. Fear of movement related to chronic lower back pain measured using the Tampa Scale for Kinesiophobia (TSK)

3.2. Depression, anxiety, and stress measured using the Depression Anxiety Stress Scales (DASS)
4. Quality of life measured using the Portuguese version of the Medical Outcomes Study (MOS) 36-Item Short Form Survey (SF-26)

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Presence of unspecific chronic low back pain, defined as having been recognized in the previous 4 weeks and having persisted beyond 3 months
2. Adults over 18 years of age
3. Provision of informed consent to participate in the study
4. Ability to use a computer

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Specific cause of low back pain (e.g. spinal compression fracture, neurological conditions, cancer or inflammatory diseases affecting the low back spine such as rheumatic arthritis)
2. Cognitive impairment which would impact their ability to comprehend the exercise orientations and answer the questionnaires
3. Insufficient Portuguese reading and writing skills to complete questionnaires and to comprehend and participate in the telerehabilitation exercises
4. Comorbid health conditions that would be contraindications for exercise
5. Recent spinal surgery (within preceding 12 months)

Date of first enrolment
01/05/2023

Date of final enrolment
31/08/2023

Locations

Countries of recruitment

Portugal

Study participating centre
Outpatients rehabilitation clinics of Centre of Portugal
Portugal
Centre region
Portugal
3000

Sponsor information

Organisation
University of Coimbra

ROR
https://ror.org/04z8k9a98

Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund

Alternative Name(s)
Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, ЕФРР, EFRR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
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The type of data that will be shared: the methodology and outcomes.
Dates of availability: The methodology is public as soon as the protocol is published. The outcomes will be shared after the conclusion of the trial.
Whether consent from participants was required and obtained: yes.
Comments on data anonymization: Each record is masked and identified by an identification number and stored in a data centre. Each allocation and analysis dataset will be created at the data centre by masking and replacing identification numbers. The decoding table will be stored at the Institute of Systems and Robotics - University of Coimbra data centre. To preserve participant anonymity, only their allocated trial number will be recorded on trial documentation (except for the consent and contact details). Consent forms will be kept separate from other data in site trial master files at the Institute of Systems and Robotics - University of Coimbra data centre in a locked, secure environment. The conduct of the trial will be supervised by the principal investigator and externally monitored by funders. Personal data collected during the trial will be handled and stored in accordance with the General Data Protection Regulation (GDPR).

IPD sharing plan summary

Available on request