Usability, Reliability and Preliminary Efficacy of a Smartphone App for Patients with Intermittent Claudication

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON46446

Source
ToetsingOnline

Brief title
Claudication App Pilot

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Intermittent Claudication, periheral arterial disease

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Stichting Claudicationet

Intervention

Keyword: Exercise, Intermittent Claudication, Mobile Applications, Telemedicine

Outcome measures

Primary outcome

The primary endpoint is usability and will be assessed through the system usability scale and semi-structured interviews.

Secondary outcome

Secondary endpoints include the effect of the app on symptom severity (treadmill tests, six-minute walk test, vascular quality of life questionnaire 6, walking impairment questionnaire) and daily physical activity. The novel smartphone-based measurements of walking impairment will be assessed by determining their variability and test-retest reliability, agreement with conventional functional tests and patient-reported outcome measures, and response to 12 weeks of SET.

Study description

Background summary

The effectiveness of supervised exercise therapy (SET) for intermittent claudication (IC) regarding reduction of symptoms and improvement of (health-related) quality of life is well established. However, despite its effects on symptomatology, SET programs only moderately stimulate healthy behaviour in daily life. Furthermore, conventional outcome measures in IC provide a poor reflection of walking impairment in daily life.

Study objective

The goal of this pilot study is to assess the usability and preliminary effects on treatment outcomes of an mHealth application supplementary to SET for patients with intermittent claudication. Furthermore, we aim to determine the

reliability, applicability and agreement with the most used functional tests and patient-reported outcome measures of a novel smartphone-based measurement of walking impairment in patients with IC.

Study design

Single-arm pilot study.

Intervention

A patient-centred mHealth smartphone app integrated with SET. The app enables patients to conduct smartphone-guided home-training sessions and set goals and monitor progress regarding walking capacity and daily physical activity.

Study burden and risks

The novel component of the study intervention is a secured online patient-centred smartphone app. This intervention can be beneficial for participants as it aims to improve healthy behaviour. Interacting with the app, e.g. being prompted to start home-training sessions, can possibly burden patients. Risks of the intervention are low; SET is a safe treatment and proper physical and digital security for sensitive data is ensured conform to NEN 7510 standards, which is a Dutch extension of the international ISO 27001. The application does not measure, nor provide feedback regarding, vital parameters.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Diagnosis of intermittent claudication (symptomatic peripheral arterial disease, Rutherford stage 1-3, Fontaine 2a-2b) evidenced by a resting ankle-brachial index of *0.9 in rest and/or a drop of >0.15 after treadmill walking in either leg.
- In possession of a smartphone capable of running the intervention application.
- A signed informed consent form.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Supervised exercise therapy, performed in accordance with the guidelines of the Dutch Society of Physical Therapy, in the 12 months prior to study enrolment.
- The ability to finish the Gardner Skinner treadmill test (i.e. walk for >30 minutes, or >1600 meters).
- Severely limited ambulation due to a cause other than intermittent claudication (e.g. above or below the knee amputation, critical limb ischemia, wheelchair confinement, foot ulcer, significant visual impairment, unstable angina, heart failure NYHA class II or greater, COPD GOLD 3-4) and/or the inability to frequent the physical therapy centre at the expected visit frequency.
- Deemed a poor candidate for inclusion at the discretion of the physical therapist or principal investigator.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Smartphone Application
Registration:	No

Ethics review

Approved WMO

Date:	21-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63118.100.17