Implementation of a personalized prediction model to support decisions during supervised exercise therapy for patients with Intermittent Claudication.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22942

Source
NTR

Brief title
TBA

Health condition

People with Intermittent Claudication

Sponsors and support

Primary sponsor: ClaudicatioNet, Radboudumc (IQ healthcare)
Source(s) of monetary or material Support: National Health Care Institute

Intervention

Outcome measures

Primary outcome

Functional walking distance

Secondary outcome

Maximal walking distance, quality of life, motivation and drop-out rate

Study description

Background summary

The recommended therapy for symptom relief in patients with Intermittent Claudication (IC) is, according to the KNGF and NHG guidelines, supervised exercise therapy (SET). Although SET is known to be effective in increasing walking distance, results can vary substantially between patients. A greater insight into an individual's personal prognosis may support patients and providers in tailoring care to the needs and priorities of the individual, potentially resulting in better outcomes with less variation between individuals. To do so, ClaudicatioNet developed 'KomPas', a prediction tool which is able to visualize the expected outcome of SET for patients with IC, using a neighbors-based prediction approach. After a pilot and test phase of KomPas, ClaudicatioNet intends to implement KomPas among all their affiliated physical therapists (~2100) as part of a quality improvement project.
The primary aim of this study is to evaluate the effectiveness of KomPas as supporting tool to optimize personalized treatment, on the following outcomes: functional and maximal walking distance (assessed with a clinical test) and quality of life (assessed via questionnaire). The secondary aim of this study is to understand what factors (i.e., demand and interaction of therapists and patients with KomPas) mediated this (potential) effect.

Study objective

We hypothesize that the use of KomPas at the start and during the SET will be associated with increased functional walking distance, maximal walking distance and the quality of life of patients with Intermittent Claudication. Moreover, we hypothesize that use of the KomPas will result in increased patient motivation and reducted drop-out rate.

Study design

Baseline, 3 months, 6 months, 9 months and 12 months.

Contacts

Public
Radboud university medical center, Radboud Institute for Health Sciences, IQ healthcare
Thomas Hoogeboom

+31243619529
Scientific
Radboud university medical center, Radboud Institute for Health Sciences, IQ healthcare
Thomas Hoogeboom

+31243619529

Eligibility criteria

Inclusion criteria

Outcome data from each consecutive patient referred to and treated by a ClaudicatioNet physical therapist will be included in this study.

Exclusion criteria

No exclusion criteria are in place.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-08-2020
Enrollment:	10071
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-08-2020
Application type:	First submission

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
NTR-new	NL8838
Other	CMO Regio Arnhem-Nijmegen : 2020-6250

Study results