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

Gepubliceerd: 17-08-2020 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22942

Bron
NTR

Verkorte titel
TBA

Aandoening

People with Intermittent Claudication

Ondersteuning

Primaire sponsor: ClaudicatioNet, Radboudumc (IQ healthcare)
Overige ondersteuning: National Health Care Institute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Functional walking distance

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No exclusion criteria are in place.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	24-08-2020
Aantal proefpersonen:	10071
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8838
Ander register	CMO Regio Arnhem-Nijmegen : 2020-6250

Resultaten