

The effect of therapy podopostural soles on chronic low back pain

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After two months, podopostural therapy has more effect on back and leg pain in people with (radiating) leg pain on the side where the ilium is higher than the other side compared to those with (radiating) leg pain on the side where the ilium is...

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

Samenvatting

ID

NL-OMON24986

Bron

NTR

Verkorte titel

EPOL

Aandoening

Low back pain
Podopostural therapy

Ondersteuning

Primaire sponsor: Podocentrum Alkmaar
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Overige ondersteuning: Stichting LOOP
Podocentrum Alkmaar

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The evaluation of the impact of podopostural therapy in subjects with chronic low back pain by 50 persons to deal with this complaint and following eighteen months.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: For the treatment of low back pain are several methods. A popular and often used method is the manufacturing of specific insoles. The podopostural therapy uses millimeter thin insoles. There is hardly any research conducted into the effectiveness of podopostural therapy on low back pain.

Objective: Primary objective: To evaluate the effect of podopostural therapy in subjects with chronic low back pain.

Secondary Objective: The evaluation of the effects of podopostural therapy in specific subgroups with chronic low back pain.

Study Design: Observational prospective cohort study.

Study population: Fifty people who sign up for treatment in primary care physical therapy practices with chronic low back pain with or without radiation into the leg.

Research: The subjects are treated according to the podopostural therapy and followed for eighteen months. The primary outcome variables are:

1. low back pain (numerical rating scale, 0-10), 2. leg pain (numerical rating scale, 0-10), 3. functionality (Oswestry Disability Index, 0-100) and 4 generally perceived recovery (Likert scale 1-7).

Analysis: Linear mixed model analysis will be used in the evaluation of treatment outcomes for the total cohort. Linear mixed model analyzes will also be used to evaluate possible differences in treatment outcome between specific subgroups.

Risk in participation: There is no risk in participation. The treatment is usual care and does not change if the patient participate in this study.

Doel van het onderzoek

After two months, podopostural therapy has more effect on back and leg pain in people with (radiating) leg pain on the side where the ilium is higher than the other side compared to those with (radiating) leg pain on the side where the ilium is lower than the other side.

Onderzoeksopzet

baseline and after 2, 5, 9 and 18 months

Onderzoeksproduct en/of interventie

soles

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Chronic low back pain (≥ 3 months) with or without radiation in the bone Age 18 years The person accepts the consequences of participation in the study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Neuropathic pain Severe illness (eg. Malignancies) or suspicion on it Rheumatic diseases such as polymyalgia rheumatica, rheumatoid arthritis, lupus erythematosus Severe cardiovascular disease Central and peripheral neurological disorders (stroke, MS, Parkinson's, poly neuropathy, WAD grade 3 etc.) Insulin-dependent diabetes dementia Treatment for a psychiatric disorder Insufficient understanding of the Dutch language Pregnancy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	13-05-2014
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 10-12-2015
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	NL5609
NTR-old	NTR5715
Ander register	METC Noor Holland : M015-035

Resultaten

Samenvatting resultaten

n.v.t.