

Reproducibility and diagnostic accuracy of an internationally-endorsed screening framework for cervical vascular risks following manual therapy and exercise. The Go4Safe trial

Gepubliceerd: 15-03-2020 Laatste bijgewerkt: 13-12-2022

We hypothesize that evaluation of the IFOMPT framework gives insight into the reproducibility and diagnostic accuracy of this screening tool for risk estimation of vascular complications among manual-physiotherapists

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

Samenvatting

ID

NL-OMON21862

Bron

NTR

Verkorte titel

The Go4safe trial

Aandoening

Musculoskeletal neck pain and/ or headache

Ondersteuning

Primaire sponsor: Vrije Universiteit Amsterdam and the MSG Science network
Physiotherapy (<https://msg-sciencenetwerk.nl/>)

Overige ondersteuning: This study was supported by a grant from the Dutch Association for Manual Therapy (Nederlandse Vereniging voor Manuele Therapie) and a crowd funding campaign

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reproducibility:

The overall inter-examiner agreement, specific positive and negative inter-examiner agreement, and inter-examiner reliability (Cohen's Kappa's) will be calculated.

Diagnostic accuracy:

Sensitivity, specificity, and the Area Under the Curve (AUC) will be calculated

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Clinicians are recommended or required to use the screening framework developed by the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) to reduce the risk for vascular complications following cervical manual therapy and exercise. However, the reproducibility and diagnostic accuracy of this screening framework is still unknown.

Aim: This study aimed to determine the inter-examiner agreement and inter-examiner reliability and diagnostic accuracy of the IFOMPT framework among manual therapists in primary care.

Methods: Patients who consulted a manual- physiotherapist for neck pain or headache will be included in the study. Each patient will be tested independently by two manual-physiotherapists for the inter-examiner agreement and inter-examiner reliability part of the study. To determine the diagnostic accuracy, the results of IFOMPT- framework will be compared to a reference standard consisting of an expert panel of two vascular neurologists with access to the results of Magnetic Resonance Angiography (MRA).

Doel van het onderzoek

We hypothesize that evaluation of the IFOMPT framework gives insight into the reproducibility and diagnostic accuracy of this screening tool for risk estimation of vascular complications among manual-physiotherapists

Onderzoeksopzet

Cross-sectional: Time between test and re-test or test and reference test is maximum one

week

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam
Gwendolyne G.M. Scholten-Peeters

020-5988601

Wetenschappelijk

Faculty of Behavioural and Movement Sciences, Vrije Universiteit Amsterdam
Gwendolyne G.M. Scholten-Peeters

020-5988601

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- At least 18 years old
- Consulted a manual physiotherapist for neck pain or headache
- Sufficient knowledge of the Dutch language to participate in the study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Reproducibility: None

Diagnostic accuracy: contraindications for MRA imaging (i.e. claustrophobia, internal pacemaker, metal objects in/or around the neck or face or those who could not lie for 20 minutes)

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-07-2017
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

Not applicable

Ethische beoordeling

Positief advies	
Datum:	15-03-2020
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	NL8459
Ander register	Medical Ethics Review Committee of the Amsterdam University Medical Centre (Location VUmc) : METC- 2017.086

Resultaten

Samenvatting resultaten

Not applicable