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

No registrations found.

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

Summary

ID

NL-OMON21862

Source
NTR

Brief title
The Go4safe trial

Health condition

Musculoskeletal neck pain and/ or headache

Sponsors and support

Primary sponsor: Vrije Universiteit Amsterdam and the MSG Science network Physiotherapy (https://msg-sciencenetwerk.nl/)
Source(s) of monetary or material Support: This study was supported by a grant from the Dutch Association for Manual Therapy (Nederlandse Vereniging voor Manuele Therapie) and a crowd funding campaign

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Not applicable

Study description

Background summary

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).

Study objective

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

Study design

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

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2017
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Not applicable

Ethics review

Positive opinion

Date:	15-03-2020
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	NL8459
Other	Medical Ethics Review Committee of the Amsterdam University Medical Centre (Location VUmc) : METC- 2017.086

Study results

Summary results
Not applicable