Diagnostic Accuracy and Inter Rater Reliability of the Lateral-Flexion-Test and Flexion-Rotation-Test in infants

Published: 01-05-2017
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To determine the diagnostic accuracy and interrater reliability of two tests for upper cervical mobility: the lateral-flexion-test (LFT) and the flexion-rotation-test (FRT), in infants referred with an assumptive UCD.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON45564

Source
ToetsingOnline

Brief title
IRR of diagnostics in infants

Condition

- Joint disorders

Synonym
upper cervical dysfunction; positional preference

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Vereniging voor Manuele Therapie

Intervention

Keyword: diagnostic accuracy, infants, inter rater reliability, manual therapy

Outcome measures

Primary outcome

Outcomes on the LFT and FRT of all manual therapists in terms of upper cervical restriction (yes/no) and indication for treatment (yes/no).

Objectively measured degrees of motion towards the same directions, are measured by a 3D kinematic analysis system and used as golden standard.

Secondary outcome

Parents provide information on characteristics of the infants, the pregnancy and delivery. Posture and movement are being observed by the researcher.

Study description

Background summary

In the Netherlands, every year 7500 infants (younger than 6 months) are treated with manual therapy. These infants are being referred for positional preference of the head. Manual therapists hypothesize that a positional preference is caused by an upper cervical dysfunction (UCD). However, literature on diagnostics on this assumptive UCD is scarce. The diagnostics that are being used in clinical practice showed good reliability in adults, but have never been studied in infants. Nonetheless these diagnostics are frequently used in clinical practice.

Study objective

To determine the diagnostic accuracy and interrater reliability of two tests for upper cervical mobility: the lateral-flexion-test (LFT) and the flexion-rotation-test (FRT), in infants referred with an assumptive UCD.

Study design

Cross sectional observational diagnostic accuracy and interrater reliability

study

Study burden and risks

The execution of the tests will take 20 minutes, which equals the amount of time during an intake or session with a pediatric physiotherapist or manual therapist in the usual care process.
The time investment for parents, and infants, is approximately 1 hour.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

infants of 6 months or younger referred for manual therapy with an assumption of HCFS

Exclusion criteria

previous treatment by manual therapist
assumptive underlying pathology (red flags)
neurologic complaints
other treatment at disfunctional level, such as chiropractic, osteopathy and cranio-sacral therapy

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2017
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	01-05-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	04-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL58488.091.16