Effectiveness of treatment for chronic tension headache by the general practitioner or manual therapist: pilot study for a randomized clinical trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON30066

Source
ToetsingOnline

Brief title
Manual therapy for tension headache

Condition

- Muscle disorders
- Headaches

Synonym
chonic tension headache, tension headache

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: general practice, headache, manual therapy, randomized controlled trial

Outcome measures

Primary outcome

The baseline assessment includes a questionnaire regarding general health, headache, and medication use, limitations in daily functioning, and an assessment of the mobility of the cervical spine (using a Cervical Range Of Movement goniometer). Furthermore, an algometer will be used to measure tender points of the m trapezius descendens.

Outcomes are assessed after treatment (8 weeks) en after 26 weeks. Primary outcome measures are 1) frequency of headache (headache diary) and 2) medication use (diary).

Secondary outcome

Secundary outcome measures are: perceived recovery, limitations in daily activities, mobiilty of the cervical spine, and tender points of the m. trapezius descendens.

Study description

Background summary

This study is aimed at the treatment of chronic tension headache (CSSH). This

type of headache is characterised by pain on both sides of the head, mild to moderate intensity, the pain feels like tension or pressure, and does not increase on physical activity (such as climbing stairs). The symptoms have been present on at least 15 days of each month, during a period of at least 3 months. CSSH is associated with limitations in emotional and social functioning, work disability and frequent use of over-the-counter medication. In primary care CSSH is treated by the general practitioner or physiotherapist/manual therapist. About 15% percent of all physiotherapy referrals by the general practitioner concern neck pain/headache.

There is some evidence for the effectiveness of manual therapy for CSSH, but there are few high quality randomised trials. There is strong need for a pragmatic trial in which the effects of manual therapy are compared to those of usual GP care.

Study objective

The objective of this pilot study is to test the feasiblity of all procedures of the RCT. The aim of the final study is to investigate the short term and long term effects of manual therapy on the frequency of headache and the use of pain medication compared with usual care by the general practitioner.

Study design

The pilot study is designed as a pragmatic randomised clinical trial in two primary care centres.

Intervention

After selection and baseline assessment a total of 20 participants with CSSH will be randomly allocated to manual therapy (n=10) or usual GP care (n=10). The treatment protocol for manual therapy consists of elements that are commonly used for CSSH. No more than 9 sessions will be given, consisting of passive mobilisations of the cervical spine using low and high velocity thrust technieques, stablising exercises and advice regarding better posture. Usual care by the GP will be carried out according to the national headache guidelines issued by the Dutch College of General Practitioners. The total duration of both interventions is 8 weeks.

Study burden and risks

The participants are asked to take part in a baseline assessment carried out by a research assistant. This assessment consists of a patient history, written questionnaire, algometry, and measurement of mobility of the cervical spine. The entire baseline assessment will take approximately 45 minutes. All participnats are asked to keep a diary during the intervention period of 8

weeks, and during 4 weeks preceding the assessment after 26 weeks. Completing the diary will take about 3 minutes each day. The assessment after 8 and 26 weeks are similar to the baseline assessment (45 minutes).

Both interventions are commonly used treatments for CSSH in primary care. Half of all participants are treated by the GP. They receive usual care for headache according to the national GP guidelines. With approximately 3 consultations time investment will be about 30 minutes. The other 10 participants receive manual therapy (no more than 9 sessions of 30 minutes).

The costs of treatment by the GP and maual therapist will be covered by health insurance.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Chronic tension headache according to the classification of the International Headache Society (IHS), age 18-65 year, able to complete written questionnaires in Dutch; informed consent.

Exclusion criteria

Reumatic diseases, fever, pregnancy, possibility of malignancy, manual therapy for chronic tension headache in preceding 2 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2006
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL12139.029.06