Manual therapy for chronic tension-type headache.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28215

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Chronic tension-type headache
(chronische spierspanningshoofdpijn).

Sponsors and support

Primary sponsor: EMGO Institute, VU University medical centre, Amsterdam, The Netherlands
Source(s) of monetary or material Support: Fund = initiator.

Intervention

Outcome measures

Primary outcome

Outcome measures are assessed after 8 and 26 weeks after randomisation:

1. the frequency of days with headache;

2. use of pain medication (no. of pills NSAIDs or simple analgesics) over a period of 2 weeks, both scored by the patient in a headache diary.

Secondary outcome

1. Headache pain intensity measured on a 0-10 point numerical rating scale;

2. impact of headache on daily life using the Headache Disability Inventory (HDI) and the Headache Impact Test-6(Hit-6);

3. active range of movement in flexion, extension, right and left rotation, and right and left lateroflexion of the cervical spine measured with a CROM-device;

4. algometry on the trapezius descendens and the suboccipital muscle with a Wagner FDK algometer;

5. endurance of neck flexor muscles scored as the number of seconds the patient can raise his head from the table when lying on his back;

6. craniocervical angle (digital photography);

7. use of additional medical resources.

Study description

Background summary

Background: Patients with Chronic Type Tension Headache (CTTH) hav functional and emotional impairments (loss of workdays, sleep disturbances, emotional well-being) and are at risk for overuse of medication. We present the design of a randomised clinical trial (RCT) evaluating the effectiveness of manual therapy (MT) compared to usual care by the general practitioner (GP) for CTTH.

Adults with CTTH according to the classification of the International Headache Society who present in general practice with >15 days headache per month (>3 months), are eligible for participation. Participants are randomised to either usual GP care according to the Dutch general practice guidelines for Headache, or manual therapy, consisting of mobilisations, exercise therapy and posture correction. The primary outcome measures are number of headache days and use of medication. Follow-up assessments are conducted after 8 and 26 weeks.

This is a pragmatic trial in which interventions are offered as they are carried out in everyday practice. This increases generalisability of results, but blinding of patients, GPs and therapists is not possible.

The results of this trial will contribute to rational decision making of the GP regarding referral to manual therapy in patients with chronic tension headache.

Study objective

We hypothesise that improvement of cranio-cervical musculoskeletal function by posture correction, mobilisation of the cervical spine and training of cervical muscles, will reduce the number of days with headache and use pf pain medication, compared to usual care by the general practitioner.

An important factor to modify central or peripheral pain mechanism in CTTH.

Intervention

Manual therapy treatment includes a combination of mobilisation of the cervical and thoracic spine, exercises and posture correction Spinal mobilisations consist of low and/or high-velocity cervical and thoracic joint mobilization techniques. Therapeutic exercises consist of low-load craniocervical muscle endurance exercises
and correction of sitting and standing posture. The MT intervention is restricted to a maximum of 9 treatments (each 30 minutes) in 8 weeks after randomisation.

Patients will be treated by the GP according to national general practice guidelines for the management of headache. According to this guideline the GP will give information, reassurance, advice and discuss the benefits of changing lifestyle. If necessary they prescribe analgetics or NSAID or change current pain medication.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 18 and 65 years;

2. Chronic tension type headache according to the classification of the International Headache Society 2004 2nd edition: headache occurring on at least 15 days on average per month for a period of more than 3 months (>180 days a year), headache lasts for hours or may be continuous.

The headache has at least one of the following characteristics:

1. bilateral location;

2. pressing/tightening (non pulsating) quality;

3. mild or moderate intensity, not aggravated by normal physical activities such as walking or climbing stairs. Both of the following: 1. no more than one of photofobia, phonophobia or mild nausea, and 2. neither moderate or severe nausea nor vomiting.

3. able to read and write Dutch;

4. informed consent.

Exclusion criteria

1. Reumatoid artritis;

2. Suspicion of malignity;

3. Pregnancy;

4. Intake of either triptans, ergotamines or opioids on ¡Ý10 days/month or simple analgesics

on ¡Ý15 days/month on a regular basis for ¡Ý3 months;

5. Manual therapy treatment in the 2 months before inclusion.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-09-2007
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	NL1041
NTR-old	NTR1074
Other	METC VU mc : protocol 06/078
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A