Manual therapy for migraine

Published: 07-02-2019
Last updated: 10-02-2025

We hypothesize that, in patients with frequent migraine combined with neck pain, manual therapy can reduce the frequency of migraine days, compared to usual care by the general practitioner for the prophylactic treatment of migraine.

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

Summary

ID

NL-OMON24113

Source
NTR

Brief title
MTmigraine

Health condition

Migraine

Sponsors and support

Primary sponsor: Amsterdam University Medical Center, location VU medical center
Source(s) of monetary or material Support: Healthcare Centre Haarlemmermeer

Intervention

Outcome measures

Primary outcome

The primary outcome of the study is the number of migraine days, administrated by the participant in a headache diary during the four weeks prior to the follow-up assessments at 12, 26 and 52 weeks.

Secondary outcome

The secondary outcome measures are: 1. Number of migraine attacks per four weeks, administrated in a headache diary during the four weeks before follow-up measurements. 2. Pain intensity of migraine, assessed on an 11 point numerical rating scale (0 = no pain, 10 = most severe pain). 3. Medication use in number of doses per 4 weeks of simple analgesics (e.g., paracetamol), NSAIDs, acute migraine medication (triptans and ergotamines) or prophylactic medication. 4. Responder rate will be measured by the number of migraine days before vs. after treatment, dichotomized into ≥50% reduction or not. 5. Disability, assessed by the HIT-6 questionnaire. 6. The endurance of the neck flexor muscles will be scored as the number of seconds the participant can raise his head from the table when lying in supine position as described by Harris et al. (2005). 7. Cutaneous allodynia (CA) will be evaluated with the 12 item allodynia symptom checklist (ASC-12). 8. Pressure pain thresholds (PPT) with a Wagner FDK algometer at the upper trapezius muscle, the suboccipital muscles and the anterior tibial muscle. 9. Global perceived effect on a 7 point rating scale (0 = much worse to 6 = much better). 10. Disability due to attacks assessed on a 5 point rating scale (0 = no disability and no medication to 4 = fully disabled even with medication).

Study description

Background summary

Background: People with migraine experience high disability with consequences for social life and work productivity. The effectiveness of pharmacological prophylactic management of migraine is limited, leading to a demand for alternative non-pharmacological treatment options. We started a pragmatic, randomized controlled trial on the effectiveness of a multimodal manual therapy (MT) treatment compared to usual care by the general practitioner (GP) for the prophylactic treatment of migraine. Methods: Eligible participants will be recruited in primary care using the International Classification of Headache Disorders III criteria for migraine of the International Headache Society. Participants will be randomized to either multimodal manual therapy treatment or usual care provided by the GP. GPs will be asked to treat the usual care group according to the Dutch GP guideline for headache. The multimodal MT intervention will include manual pressure techniques, neck muscle-strength exercises, and mobilization of the cervical spine. The trial will consist of a 12 weeks treatment period and follow-up measurements at 12, 26 and 52 weeks. The primary outcome measure is the number of migraine days, per four weeks, assessed with a headache diary. Secondary outcome measures are the number of migraine attacks, medication use, disability due to headache, headache intensity, number of participants reporting a 50% migraine reduction, measurement of cervical pressure pain thresholds, presence of allodynia, endurance of cervical flexor muscles, days of absence of work and global perceived effect. Parallel to the RCT we will conduct a prospective cohort study with migraine patients with a strong preference for MT treatment who do not want to be randomized. They will be treated with MT; treatment and measurements will be identical to the treatment procedure and measurements used in the RCT. A pilot study showed that the treatment protocols and

measurements are feasible. Discussion: The results of the trial will provide evidence for the effectiveness of an MT intervention as a non-pharmacological treatment option for people with migraine.

Study objective

We hypothesize that, in patients with frequent migraine combined with neck pain, manual therapy can reduce the frequency of migraine days, compared to usual care by the general practitioner for the prophylactic treatment of migraine.

Study design

Baseline, follow-up at 3, 6 and 12 months

Intervention

Intervention Manual therapy treatment A multimodal manual therapy treatment aiming to restore cervical function will be applied. The treatment will include applying manual pressure techniques on myofascial trigger points of the trapezius muscle and upper cervical/suboccipital musculature to decrease neck pain intensity and cervical muscle tenderness. Neck muscle strength will be trained by giving low load craniocervical muscle exercises and correcting sitting and standing posture. The spinal mobilizations that will be applied are low and high-velocity techniques of the cervical and thoracic spine. No high-velocity techniques will be applied to the upper cervical region (C0-3) because of the small risk of serious adverse events. The treatment protocol provides recommendations for techniques that can be used; the treating manual therapist decides which techniques will be applied, depending on the characteristics of the participant. The MT intervention will consist of a maximum of 9 sessions of 30 minutes during the 12 weeks treatment period. Control group (usual care): Participants assigned to the usual care group will be treated by their GP. The GP will treat participants based on the recommendations of the practice guideline for headache of the Dutch College of General Practitioners (care as usual). Apart from lifestyle advice and reassurance, the GP will prescribe acute medication and may prescibe or alter prophylactic medication. The practice guideline recommends the GP to evaluate the treatment in consecutive appointments discussing medication use and the effect the medication has on the migraine.

Contacts

Public
Amsterdam UMC location VUmc
Andreas Amons

0641504519
Scientific

Amsterdam UMC location VUmc
Andreas Amons

0641504519

Eligibility criteria

Inclusion criteria

Eligible participants are between 18-65 years of age and have had migraine attacks for more than one year, according to the diagnostic criteria of the International Classification of Headache Disorders (ICHD) III. A GP or neurologist should have established the diagnosis migraine and the frequency of attacks should be two times a month or more. Co-occurrence of tension-type headache is allowed if the participant can clearly distinguish this headache from migraine. Participants will only be included if they have concomitant neck pain between migraine attacks or during an attack. The use of prophylactic medication is allowed if migraine is stable and medication use has not changed in the last three months. Furthermore, participants have to be able to read and write Dutch.

Exclusion criteria

Exclusion criteria are suspected malignancy, pregnancy, cerebrovascular disease, degenerative central nervous system diseases, medication-overuse headache, a current diagnosis of depression or other severe psychiatric disease, rheumatoid arthritis, serious or systemic infection, fever, or change in medication for migraine within three months before the study, and having received manual therapy treatment for migraine up to three months prior to the start of the study.

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):	04-03-2019
Enrollment:	196
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	07-02-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49763
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7504
CCMO	NL66480.029.18
OMON	NL-OMON49763

Study results

Summary results
N/A