Manual therapy as a prophylactic treatment for migraine. A pragmatic RCT

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The objective of our randomized controlled trial (RCT) is to assess the effectiveness of a multimodal manual therapy treatment compared to usual care for the prophylactic treatment of migraine.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Headaches
Study type	Interventional

Summary

ID

NL-OMON49763

Source
ToetsingOnline

Brief title
MTmigraine research

Condition

- Headaches

Synonym
headache, migraine

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Gezondheidscentra Haarlemmermeer

Intervention

Keyword: general practitioner, manual therapy, migraine, propfylactic treatment

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 (Tfelt-Hansen 2012). A migraine day is defined as a day with migraine characteristics according to the IHS classification ICDH III for longer than four hours, or a headache that resolves with the intake of triptans or ergotamine within two hours of intake.

Secondary outcome

All of the secondary outcome measures will be assessed at 12, 26 and 52 weeks follow-up assessments.

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 (Tfelt-Hansen 2012). Migraine attacks will be considered as separate attacks if 48 hours without headache is reported in the headache diary between migraine days.

2. Pain intensity of migraine, assessed on an 11 point numerical rating scale (0 = no pain, 10 = most severe pain) (Williamson 2005).

3. Neck pain intensity, assessed on an 11 point numerical rating scale (0 = no pain, 10 = most severe pain).

4. 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. Change of medication will be administrated and reported.

5. Responder rate will be measured by the number of migraine days before vs. after treatment, dichotomized into *50% reduction or not (Tfelt-Hansen 2012).

6. Disability, assessed by the HIT-6 questionnaire. The HIT-6 consists of 6 questions measuring pain intensity, social functioning, role functioning, vitality, cognitive functioning and psychological distress on a 5 point ordinal rating scale (never, to always). Internal consistency is considered high (Cronbach's alpha 0.82 to 0.90), and test-retest reliability is fair (ICC 0.77) (Yang 2011). The Dutch version of the HIT-6 questionnaire has shown to be a valid and reliable tool to measure the impact of migraine (Martin 2004).

7. 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).

8. Cutaneous allodynia (CA) will be evaluated with the 12 item allodynia symptom checklist (ASC-12). This questionnaire consists of 12 questions about cutaneous hypersensitivity in the cervical cephalic region. The participant can score yes, no, or not applicable (Jakubowski 2005). Allodynia symptoms and score on CA severity are defined in the following categories: none (0-2), mild (3-5), moderate (6-8) and severe (9 or higher) (Lipton 2008).

9. We will perform algometry, by measuring pressure pain thresholds (PPT) with a Wagner FDK algometer at the upper trapezius muscle (at the midpoint between C7 spinosus and the acromion), the suboccipital muscles and the anterior tibial

muscle. The PPT measurement will be repeated three times at each point, and a mean score will be calculated.

10. Participants will be asked to report global perceived effect on a 7 point rating scale (0 = much worse to 6 = much better). Disability due to attacks will be assessed on a 5 point rating scale (0 = no disability and no medication to 4 = fully disabled even with medication). Also, use of healthcare resources and absence of work will be reported.

11. Adverse events will be administrated for both treatments.

Study description

Background summary

Migraine is one of the most common neurological disorders worldwide, with an annual prevalence of 15%. The individual patient experiences the impact of migraine due to psychosocial problems and during work (Steiner 2014). In the Netherlands, the direct medical costs of migraine and the indirect costs due to absence from work and loss of productivity are estimated at more than 4 billion euros per year (Linde 2012).
The prophylactic management of migraine generally consists of pharmacological treatment (Diener 2015). In Dutch primary care, people with migraine are diagnosed and treated according to the guideline for headache of the Dutch College of General Practitioners (Dekker 2014). The general practitioner (GP) provides lifestyle advice and, if necessary, medication. Depending on the frequency of attacks, the recommended treatment consists of acute medication for a single attack or prophylactic medication when the migraine attacks occur two times a month or more.
Prophylactic medication (e.g., propranolol, topiramate or amitriptyline) reduces migraine attacks by 50% in 50% of the patients (Mulleners 2010). However, taking this medication has some disadvantages. Daily intake of prophylactic medication can cause side effects, such as fatigue and dizziness, which induce some patients to refuse this medication (Dekker 2013). This has led to a growing demand for non-pharmacological prophylactic treatments to reduce the frequency of migraine (Coppola 2016).
One of these alternatives is manual therapy (MT). MT is a specialization within physiotherapy that focuses mainly on spine-related complaints.
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spine-related complaints. In migraine, MT aims to achieve central inhibition of nociception at the level of the caudal nucleus of the trigeminal nerve by using cervical mobilization and pain-reducing techniques of the cervical structures. That manual therapeutic treatment can be effective for patients with migraine has been described in previous studies. However, these studies show several methodological shortcomings such as too small sample sizes, lack of blinding and unclear randomisation procedure (Tuchin 2000, Posadzky 2011). Therefore, a methodologically well-designed research is necessary to evaluate the effectiveness of this intervention.

Study objective

The objective of our randomized controlled trial (RCT) is to assess the effectiveness of a multimodal manual therapy treatment compared to usual care for the prophylactic treatment of migraine.

Study design

This study is a single blinded, multicentre, pragmatic clinical trial, with two parallel groups assessing the potential superiority of a multimodal MT treatment over usual care by the GP. We will include a four weeks run-in period to provide accurate migraine frequency data prior to enrolment. The treatment will last 12 weeks with follow-up measurements at 12, 26 and 52 weeks (Figure 1). The study adheres to the guidelines of the International Headache Society (IHS) for controlled trials in migraine regarding inclusion criteria, outcome measurements and statistical analysis (Tfelt-Hansen 2012).
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.
We assessed the feasibility of the study by performing a pilot study between October 2014 to March 2016.
The design and protocol of the pilot study have been approved by the medical ethics committee of VUmc Amsterdam (approved June 22, 2015, registration number 2015.177 NL52933.029.15). The RCT will be registered in the Dutch Trial Register.

Participants will be recruited by the 40 participating general practitioners (GPs) working in an urban area of Hoofddorp, The Netherlands. Participants will be given usual care by their own GP.
All measurements will take place at health care center Floriande. Manual therapy will be provided at health care center Floriande or Overbos.

Intervention

Intervention

The total treatment duration in both groups is 12 weeks.

The manual therapy consists of a maximum of 9 treatments (30 minutes) during a period of 12 weeks with pain-reducing techniques for the high cervical musculature (stretching), muscle strengthening exercises for the deep neck flexor muscles and mobilization of the cervical and thoracic spine.
The GP will treat participants as usual, based on the recommendations of the practice guideline for headache of the Dutch College of General Practitioners [8]. Apart from lifestyle advice and reassurance, the GP will provide or change acute medication and may provide or alter prophylactic medication. The GP will evaluate the treatment in consecutive appointments.

Study burden and risks

Both interventions (manual therapy, usual care by the GP) are regularly applied treatments. The manual therapist uses conventional techniques (mobilisations, pain-reducing techniques, muscle training, posture instructions) of which only minor short-term adverse reactions in the literature have been described such as stiffness and increase of neck pain immediately after treatment.
For the usual care, the GP acts according to the guideline for headache of the Dutch College of General Practitioners. Medication for migraine is widely used. The possible side effects are described in the product information of the given medication.

Because the treatments in this study are part of daily routine treatment of the MT and GP, our opinion is that there is no extra risk for the participants involved.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Migraine according to the IHS classification ICHD III (2013): repeated attacks of moderate to intense headache, usually unilateral, throbbing headache with nausea and/or vomiting, duration of the headache attack between 4 and 72 hours, two or more attacks per month. Increasing with physical activity such as climbing stairs. Photofobia or phonofobia.
Tensiontype headache (TTH) ICHD III (2013) that can be distinguished by the participant.
Migraine with aura symptoms such as neck pain and additional presence of vision changes , tingling or
numbness in lips, face, or hand (onesided), one-sided muscle weakness, or impaired speech.
Migraine more than 1 year present and participants who are stable on prophylactic medication.
Age: between 18 years 65 years
Participant is able to fill in questionnaires (understand Dutch language)

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 MT 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2019
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2020
Application type:	Amendment
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

ID: 24113
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL66480.029.18
OMON	NL-OMON24113