Effectiveness of manual therapy compared to usual care by the general practitioner for migraine: a pilot study

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

Summary

ID

NL-OMON42697

Source
ToetsingOnline

Brief title
Effectiveness of MT compared to usual care by the GP for migraine

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, pilot study

Outcome measures

Primary outcome

The primary outcome measure of the pilot study is whether the trial is feasible

Secondary outcome

Secondary outcome measures that are evaluated are:

the frequency of migraine (headache diary), number of days headache (headache diary), medication use (headache diary), general perceived effect (7-point scale), limitations in daily functioning (HIT-6), pressure pain on suboccipital muscles, trapezius descendens and the tibialis anterior, isometric muscle strength of the short neck flexors and allodynia.

In addition, the frequency and severity of side effects of medication and manual therapy by means of a questionnaire are measured.

Study description

Background summary

The reason for research into the effectiveness of a manual therapy (MT) treatment of migraine is that there is evidence that manual therapy treatment might be effective for patients with migraine. The conducted studies into the effectiveness of MT in migraine show a positive effect. Allthough there are several limitations to these studies: the number of studies is small, the sample sizes are small and the inclusion criteria are not according to the IHS classification. A well-designed pragmatic RCT is needed in order to evaluate the effectiveness of this intervention.
The present research protocol involves a pilot study: a study to explore the feasibility of a trial on the effectiveness of MT treatment in migraine. An important reason for the implementation of this pilot study is that the rate of inflow of intended participants into the trial is uncertain.

First of all this is related to the inclusion criteria: in the protocol are new and already well-known participants with migraine included if they have at least 2 migraine attacks and suffer from their migraine at least 3 days per month. The annual prevalence of migraine is estimated to be 10-12%, that of chronic migraines (> 15 days per month) is estimated at 2%. However, it is not known what is the prevalence of migraine patients who meet the inclusion criteria as applied in our protocol. We estimate that 100-120 participants per average general practice will be located. If we include 5 general practitioners, we would be able to recruit 10 participants in 2 months time. This expectation is based in part on a previous performed feasibility study on the treatment of chronic tension-type headache with a one-year prevalence of 2-5%. In this study 20 participants were succesfully randomized in 5 months time.
Another reason is that in the aforementioned feasibility study participants with chronic tension-type headaches showed a strong preference for the MT intervention. Therefore, they could not be randomized . A pilot study can provide insight if this preference also applies to participants with migraine.
In addition, it is possible to evaluate the procedures concerning measurements and interventions. This will increase the chance to complete the full trial successfully. In the pilot study we evaluate the logistics of the research, the recruitment of potential participants and the feasibility of the research and treatment protocols

Study objective

Objective of the pilot study is to examine whether a pragmatic randomised trial on the effectiveness of manual therapy compared to general practice care in migraine is feasible.
For this purpose we use the following questions.
* Is it possible to include 10 participants in 2 months time in 5 general practices?
* How many participants have a strong preference for one of the interventions: manual therapy or usual care GP?
* Are the baseline and follow up measurements by the research assistant feasible?
* Is the implementation of the treatment protocol for the manual therapist, doctor and participant feasible

Study design

Design study
Feasibility- study

Study burden and risks

Both interventions (manual therapy, general practice care) are regular applied

treatments. The manual therapist uses common techniques (mobilizations, pain relieving techniques, muscle training, posture corrections) which may cause mild side effects of short duration. In the literature these side effects are described as stiffness and increase of neck pain immediately after the treatment. The GP follows the NHG standard "headache" in their treatment. Side effects of prescribed medication may occur. Because the treatments in our pilot study are part of daily routine treatment of the MT and general practitioner, we are of the opinion that there is no extra risk for the participants involved.

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

Migraine with or without aura according to the I-H-S classification ICHD III (2013):

headache attacks lasting 4 and 72 hours (untreated or unsuccessfully treated) and at least two of the following four characteristics,
- unilateral localisation
- pulsating quality
- moderate or severe pain intensity
- aggravating by or causing avoidance of routine physical activity (e.g. walking or climbing stairs).
During the headache at least one of the following
-nausea and/or vomiting
- photo- and phonophobia.
Migraine with aura symptoms with one or more of the following fully reversible aura symptoms:
-visual, sensory, speech and/or language, motor, brainstem, retinal
with at least two of the following four characteristics:
-. at least one aura symptom spreads gradually over -5 minutes, and/or two or more symptoms
occur in succession
- each individual aura symptom lasts 5-60 minutes
- at least one aura symptom is unilateral
- the aura is accompanied, or followed within 60 minutes, by headache
Migraine in combination with tension-type headache (TTH) ICHD III (2013) that can be clearly distinguished from migraine by the participant.
Presence of neck pain
A frequency of migraine attacks of two or more attacks per month
Migraine is more than 1 year present
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: rheumatic diseases, fever, pregnancy, suspicion on malignancy and MT treatment or usual care by the general practitionere of headache complaints in the 2 months prior to the study.

Study design

Design

Study type:	Observational non invasive
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):	08-10-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	22-06-2015
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	NL52933.029.15