The efficacy of internet training for migraine self-management

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Primary ObjectivesThe primary objectives of this study are to establish:1. The efficacy of internet-delivered SMT for chronic migraine - compared to waitlist control- regarding the post-training improvement of migraine attacks and headache days per...

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

Summary

ID

NL-OMON34096

Source
ToetsingOnline

Brief title
Efficacy of internet training for migraine self-management

Condition

- Headaches

Synonym
headache, migraine headache

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: attack prevention, effect, migraine, self-management

Outcome measures

Primary outcome

Migraine improvement

The primary study parameter is reduction in migraine headaches, calculated as the number of migraine attacks according to the HIS criteria as well as the number of headache days per month. This will be measured by the electronic headache diary and migraine monitor, the content of which is equivalent to the paper diary employed in the former SMT trial (Mérelle, (2008) conform the guidelines for, respectively, clinical trials in prophylactic treatment (Tfelt-Hansen et al., 2000) and behavioural trials (Penzien et al., 2005) in headache research.

The headache diary also yields accounts of medication use for headache, which can be separately assessed regarding abortive, analgesic and prophylactic.

Empowerment

Empowerment is divided in to measurements: perceived control en self-efficacy.

Perceived control over migraine will be assessed with a Dutch translation of the Headache-Specific Locus of Control scale (HSLC; Martin, Holroyd, & Penzien, 1990). The HSLC is a 33-item scale that has responses ranging from 1 (strongly disagree) to 5 (strongly agree). It consists of one Internal Locus of Control subscale and two subscales for External Locus of Control: Health Care

Professionals and Chance. An example of an internal locus of control item is: *If I remember to relax, I can avoid some of my headaches*. An example of a health care professionals locus of control item is: *Only my doctor can give me ways to prevent me headaches*. An example of a change locus of control question is: *When I have a headache, there is nothing I can do to affect its course*.
The sum score for internal control reflects the degree of perceived control over migraine (range 11-55), while the sum score for external control indicates the degree to which migraine is perceived as being due to chance (range 11-55).

Self-confidence in attack prevention (self-efficacy) will be assessed with a Dutch translation of the Headache Management Self-Efficacy questionnaire (HMSE; French, Holroyd, Pinell, Malinoski, O*Donell, & Hill, 2000) of which the sum score reflects the patients* self-confidence to take action that might prevent migraine attacks. The scale consists of 25 items, which are scored on a 7-point scale, ranging from 1= Absolutely disagree to 7= Absolutely agree. Nine questions are negative (for example: **I cannot control the tension that causes my headaches**) and 16 positive (for example *I can do things to cope with my headaches**). The negative items have to be reverse scored. A higher sum score indicates a larger confidence in own capacity (range 25-175).

Secondary outcome

Intensity and duration of the migraine attacks

These two factors will be derived from the 4-week electronic headache diary and migraine monitor. An average score will be calculated per attack.The effect of abortive medication will be taken into account.

Migraine-specific quality of life

Migraine-specific quality of life is measured by the Dutch version of the Migraine Specific Quality of Life Questionnaire (MSQOL; Passchier, Mourik, McKenna, Van den Berg, Erdman, 2001). The questionnaire consists of 20 items, which are scored on a 4-point scale, ranging form 1 (very much) to 4 (not at all). An example of a question is: *I feel powerless when a migraine attack starts*. A higher score on this instrument reflects a better quality of life between attacks (range 20-80).

Migraine disability

Migraine disability is assessed with a Dutch translation of the Migraine Disability Assessment Scale (MIDAS; Stewart, Lipton, Dowson, Sawyer, 2001). It consists of five questions concerning the number of days lost to migraine in the past 3 months. The sum score reflects the number of productive days in the workplace and at home. The sum score is divided in 4 groups: a score ranging from 1-5 means little nuisance, 6-10 indicates mild nuisance, 11-20 moderate nuisance and an above score of 21 indicates severe nuisance.

Cost-effectiveness

We seek to make an economic evaluation of internet-delivered SMT compared to waitlist in chronic migraine. We will base our procedure on a recent approach, outlined for internet intervention for depression Warmerdam, et al, 2010). This study includes estimates of costs induced by, respectively, healthcare uptake (we will explicitly and separately consider medication use), loss of

productivity in terms of work loss days and work cutback days, out of pocket expenses for the patient and his/her family, and the intervention. In the present study a sound preliminary indication of these four points can be retrieved from the questionnaires and the headache diary. In addition to this we wish to use the TiC-P (Hakkaart-van Roijen, 2007) employed by Warmerdam et al. (2010). The questionnaire consists of three sections: healthcare uptake in the last three months (part 1, 15 questions), indirect costs as a consequence of somatic disorders in the last month (part 2, 11 questions) and general data (part 3, 3 questions). The scoring of part 1 entails multiplying the number of contacts by their cost price. The scoring of part 2 is based on the absence due to the illness (in days), the production loss caused by this absence and the production loss without absence (in hours). The amount of loss is defined by the aftertax earnings. Part 2 also produces a *nuisance score*; a sum score which represents the degree to which the health issues cause nuisance in the work environment. Furthermore, it gives insight in the required help in unpaid work (such as domestic chores) by paid or unpaid help.

The first part of the questionnaire was originally designed for a psychiatric population. Nonetheless, we find this questionnaire suitable for our population, as it covers the healthcare options that are available for migraine patients. Because participants in this study do not suffer form severe psychiatric disorders, question 9, 12 and 13 (concerning intensive psychiatric care) have been left out. This is in agreement with the manual. Furthermore, the first two questions form part 3 have been left out, because of overlap with our own demographic questionnaire.

Inclusion of the TiC-P would add approximately 30 minutes per patient to the required time investment (10 min. at T1, T2 and T3). In the manual the authors point out that they find it important to use an adequate sample size and effect size, dependent on the expected differences in healthcare uptake and production losses between the experimental group and the control group. In the present study no differences between groups in healthcare uptake and production losses are expected at baseline. Effort has been made to calculate an adequate sample based on the design and expected drop-out (for more information, see section 4.4 on page 20 and 21).

Study description

Background summary

Migraine - a chronic disease

Migraine is a common, chronic, incapacitating brain disorder, characterized by attacks of severe and pounding headache, often unilateral, which lasts 4 to 72 hours. The headache is accompanied by nausea or vomiting and/or intolerance of light and sound, but also of smell, or movement. About 15% of patients suffer from migraine with aura, which means that the attack is directly preceded by focal neurological symptoms in the visual field (scotoma), which last about 20 minutes. Migraine affects roughly 12% of the western population (Goadsby, et al., 2002; Lipton, et al., 2007, CBS, 2008) with a male-female ratio of about 1:3, which is mostly due to the hormonal changes of the menstrual cycle (Goadsby, et al., 2002; Lipton, et al., 2007). Despite considerable disability migraine remains largely underreported and undertreated (Lipton et al., 2000; 2007). About 50% of sufferers seek medical help; in a recent German study this was 42% (Ratke & Neuhauser, 2008).
Attacks are not confined to the disabling headache but include a prodromal phase of hours up to days, in which premonitory non-headache symptoms occur such as tiredness, poor concentration, neck stiffness or irritability (Giffin et al., 2003; Kelman, 2004) and the patient is susceptible to so-called migraine triggers, such as stress, female hormones, not eating, weather conditions or sleep disturbance (Kelman, 2007). Migraine has a strong genetic background (Russel, 2008), which means that the disease must be managed and

cannot be easily cured. The focus in unravelling its pathophysiology involves cortical spreading depression in patients with aura and the trigeminovascular system and central sensitization in explaining the pain, but now extends to the brainstem and the view that a broad, centrally facilitated dysfunction in sensory processing is at stake, which also explains the accompanying symptoms and expands to the prodromal stage (Sprenger & Goadsby, 2009). There remains controversy regarding the driver(s) of migraine pathogenesis, but abnormal brainstem function seems to push the pathophysiology of the migraine attack (Dodick, 2007).

Preventive behavioral treatment - acceptance and required outreach

The treatment of migraine is primarily pharmacological (Sprenger & Goadsby, 2009), with a recent focus on attack prevention (Lipton, et al., 2007; Goadsby & Sprenger 2010). It is in this area of secondary prevention that behavioural treatment (BT) comes into play. Its clinical utility was proven in numerous studies showing that BT can reduce attack frequency - significantly superior to placebo - with 30-55% (Rains, et al., 2005; Campbell et al, 2000). By now the preventive usefulness of BT has been internationally acknowledged in neurological treatment guidelines (for The Netherlands see Nederlandse Vereniging voor Neurologie, 2007), based on effect sizes of 0.55 and 0.54 (Cohen*s d) of relaxation training and cognitive-behavioral training, the two most prevailing BT elements. BT aims at the reduction of attack frequency (and medication use), but also at the improvement of internal control over migraine and the decrease of impairments due to migraine (Holroyd, et al., 2001). Very promising for outreach as well as cost-effectiveness was the finding that home-based BT was as efficacious as clinic-based CBT (Haddock, et al., 1997). In line with this is the rise of self-management programmes in chronic disease (Bodenheimer, et al., 2002; Farrel, et al., 2004) and evidence that lay trainers with a chronic condition can deliver this type of intervention (Foster, et al., 2007). The present focus on self-management in chronic disease, and on self-efficacy (Farrel, et al., 2004) or empowerment of patients (Samoocha, et al., 2010), is driven by the societal urgency to solve the growing gap - induced by an escalation in chronic disease - between care supply and care demands (Irsel van, 2006). Thus, effective self-management is at stake too in chronic migraine, as is its outreach and cost-effectiveness.

Self-management for attack prevention and training offered by lay trainers

We therefore developed a self-management training (SMT) rooted in evidence-based protocols for BT in migraine (McGrath, Holroyd, & Sorbi, 2000; Sorbi, & Swaen, 2000a/b; 2004). SMT includes patient education, detailed self-monitoring, a relaxation training protocol and a limited dose of cognitive-behavioral training. SMT has two main focal points: (1) identification and modification of prodromal features of the attack (premonitory symptoms and migraine triggers), and (2) direct employment of voluntary body relaxation and cognitive-behavioral self-regulation skills to

counteract the dysregulation and prevent attack occurrence in the prodromal stage (Mérelle, 2008a-c). Both steps are not easily achieved given the habitual responses of many migraine patients. One is to focus on the hell of the attack while ignoring the prodromal features that are comparatively inconspicuous; the other is to increase effort and exertion when facing an imminent headache, which promises to get things done before the pain strikes but in fact is vastly counterproductive (Sorbi, 2010).
If brainstem dysfunction drives attack occurrence, then it is plausible that stabilization of arousal and buffering the susceptibility to sensory and other stimulation makes sense and potentially supports attack prevention. This is what SMT intends through the early detection of warning signals and direct employment of behavioural self-regulation. This self regulation is crucial when attacks are close, but also seems relevant in between attacks, given that evoked and event-related potential studies in migraine revealed an interictal lack of habituation of the sensory cortices (Schoenen, et al., 2006). Last, these skills help to regulate the proposed sympathetic hyper-function in migraine (Ludwig, et al., 2006).
SMT was extended from the clinic to the open population, and from education to training of prevention skills, while involving trained lay trainers as positive role models to provide SMT at home to small groups of new patients with chronic migraine (Mérelle, 2008). It was offered to who suffered from one to six attacks but less than 15 migraine days per month (Bigal, et al., 2008), and did not present with medication overuse, evident psychopathology or complex comorbidity (Mérelle, 2008a-c).

Outreach, efficacy and acceptance of migraine self-management training

SMT was tested in a large randomized controlled trial with 13 patient trainers and 30 groups of new patients with an extended follow-up of six months (N=95). Participants were recruited through the patient organisation (11%), multimedia in the open population (87%) and headache specialists (1%). The outreach was good given the large response (N=607). Of 264 patients who provided informed consent 48% could be included on the basis of diagnostic questionnaires and a four-week headache diary. After inclusion the drop-out rate was very reasonable: 15% of participants did not complete the training, 10% did not provide the follow-up measurements six months after SMT (Mérelle, 2008b,c). The efficacy of the present SMT application in reducing attack frequency was modest (-23%, effect size: 0.6)
compared to clinic-based BT, but was comparable to that of training by lay trainers for other chronic diseases (Foster, et al., 2007). Migraine-specific quality of life significantly increased over time and SMT strongly improved perceived control and self-confidence in attack prevention that remained stable during six months follow-up (Mérelle, 2008a-c). The acceptance of SMT and of the patient trainers who provided it was very good (Mérelle, 2008a-c).
Therefore the Dutch Society of Headache Patients urged to extend the provision of SMT by offering it through the internet, which would also enhance SMT accessibility by making it independent of time and place or travel distance.

This plea of the patient organisation was reinforced by our introduction during the study of an online method to support SMT directly and in real life (Mérelle, 2008; Kleiboer et al., 2009).

Use of mobile SMT support

Online Digital Assistance (ODA) employs mobile monitoring and coaching with smartphones and wireless internet. Mobile monitoring consists of random prompting the keeping of an electronic diary to record migraine, prodromal features and self-management. This method is scientifically sound and generates valid real time assessments unbiased by retrospection (Bolger, et al., 2003). Mobile coaching consists of direct personal feedback in three parts on the smartphone screen concerning (1) actual state of prodromal features and attack risk displayed by a traffic light with brief arguments from the present diary, (2) advice and tips for preventive action, and (3) positive reinforcement of self-management supported by an emoticon.
ODA runs on advanced and protected clinical software and was employed in 44 patients to reinforce self-management during the last part of SMT. ODA was feasible and its acceptance when offered in training was high. ODA was found useful and supportive while the burden was low, and according to the participants sustained attack prevention (Sorbi, et al., 2007; Kleiboer, et al., 2009). However, SMT with ODA did not yield better improvements, compared to SMT only (Kleiboer, et al., 2009). In this respect it was considered that surplus effects up and above the effects of training that served the same purpose require larger groups for statistical power. In addition, two alternatives were taken into account to render ODA more profitable than when applied during training. First, since SMT is intensive and its effect consolidates over time, ODA could be employed several months after completion of SMT to reinforce the maintenance of self-management. Second ODA may be prolific as a method in its own right to promote self-management or as a means to prepare subjects for SMT (Mérelle, 2008; Kleiboer, et al., 2009).

Preparation of the present study: development of SMT through the internet with independent options for mobile monitoring and coaching

Development of an internet SMT for migraine was in perfect alignment with the current general trend in internet intervention, which evolves rapidly and successfully (Barak, et al., 2008; Cuijpers et al., 2008, Webb, et al., 2010). Supported by a national grant we developed the technology (content management system, CMS) for the advanced and protected delivery of screening, training and effect measurement through the internet, and we translated the materials to suit the internet medium in eight SMT lessons. The internet training *MyMigraine* was completed in 2009 after its feasibility and acceptance was successfully tested in 10 new patients and evaluated by 6 patient trainers who participated as SMT experts (Sorbi, 2009; Sorbi & van der Vaart, 2010). The patient ratings consistently confirmed the clarity, instructiveness, importance and easy execution of all lessons, and after training the patients were

positive about user-friendliness and clarity, training content and benefits, and their general satisfaction with the internet-provided SMT. The expert patients considered MyMigraine instructive, captivating and fun to work with and were highly positive regarding the web application, digital support and web adaptation of the protocol (Sorbi & van der Vaart, 2010). One point of consideration is growing evidence that minimal support, contact and coaching during internet intervention is essential to induce benefit and prevent substantial drop-out (Andersson, 2009; Donker et al., 2009). Therefore MyMigraine will be supported by weekly e-mail contact according to current empirical standard (Wammerdam, et al., 2008; Carlbring et al., 2007), which takes 20 minutes per participant per week.
After MyMigraine was finalized the ODA application was integrated into the CMS and evaluated regarding feasibility, compliance and acceptance in five migraine patients (Sorbi, et al., 2010). ODA as part of the CMS can be employed on call, that is, when the researcher decides to do so either before, during or after completion of the SMT.

The present study: is SMT through the internet efficacious in chronic migraine and does mobile monitoring and coaching contribute to maintain benefits or to prepare for training?

The primary focus of the present study is on the efficacy - post training and after six months follow-up - of SMT for chronic migraine when SMT is provided through the internet. This is a challenge because, if established, SMT could be made widely available in Dutch health care. In addition, it is conceivable that the present SMT with its surrounding technology could also serve as an interface between the patient organisation and the Society of Dutch Headache Centres and function as a preventive aid in the public health arena, involving professional input (and costs) on indication only. This would be in line with the present web-driven shift in health care, now coined as *health 2.0*, which substantially extends the impact of patients and their control over care (RVZ, 2010). And last, next studies could focus on translating the SMT and making it available to other (European) countries.
Other aims of the present study concern three issues: the evaluation of change induced by mobile monitoring and coaching employed either after or to prepare for SMT; the comparison of SMT provided through the internet with former home-based SMT offered by patient trainers, and first steps in the economic evaluation of internet-delivered SMT compared to a waitlist for adults with chronic migraine (Warmerdam, et al, accepted; Edwards, et al., 2010).

Study objective

Primary Objectives

The primary objectives of this study are to establish:
1. The efficacy of internet-delivered SMT for chronic migraine - compared to waitlist control- regarding the post-training improvement of migraine attacks

and headache days per month, as well as two measures reflecting empowerment, e.g. self-efficacy (the confidence that one can take action to prevent attacks) and internal control (the belief that migraine occurrence and relief are within one*s own power);
2. The maintenance of internet-delivered SMT benefits six months after training regarding all measures outlined above;
3. The utility of mobile monitoring and coaching in (a) supporting the maintenance of internet-delivered SMT benefits and in (b) preparing for this type of training.

Secondary Objectives
4. Secondary measures of efficacy are the intensity and duration of the attacks, migraine-specific disability and quality of life;
5. The economic evaluation of internet-delivered SMT compared to waitlist.

Study design

We conduct a parallel-group randomised controlled trial with a delayed intervention design, conform the study that established the efficacy of home-based SMT delivered by patient trainers (Mérelle, 2008a-c). Measures are taken at baseline (T1: pre-test), after training (T2: post-test) and six months following the post-test (T3: 6-mths follow-up). Inclusion criteria are conform the former study and established with an headache diagnostic indicator (ID-Migraine), four weeks of headache monitoring according to the criteria of the International Headache Society (IHS, 2004) and medical consultation in case of doubt, and an extended questionnaire to establish psychopathology and psychological comorbidity (SCL-90R). A training group (TG) and waitlist control group (WL) will enter the study in three cohorts.
The decision to use a waitlist control group - rather than a psychological placebo condition - is based on the difficulties previous studies had in realizing a sound placebo procedure (Rains, & Penzien, 2005; Blanchard et al., 1990). In contrast to the former study, however, we will extend the control period to T3 to cover the 6-months follow up.
The assessments of the primary and secondary measures are in line with the study of Mérelle (2008). A headache diary according to the IHS (2004) is employed for four weeks at T1, T2 and T3 (and is kept during training as well), which allows to assess the primary outcome measure migraine attacks, and which yields accounts of headache days as well as the use of abortive, analgesic and prophylactic medications for headache. In the former study a paper diary was employed, which is presently replaced by an electronic headache diary measuring the same variables. Its feasibility and acceptance was successfully established in 29 migraine patients who kept it for 80 days at average (van Silfhout et al., 2010). A large advantage is that migraine attacks according to the IHS (2004) are identified by the software and are graphically represented over time in the so-called migraine monitor. This improves the view on progress for participants and investigators; it also excludes potential errors due to the calculation by hand required with the former paper diary.

The Dutch versions of four international and migraine-specific questionnaires are employed at T1, T2 and T3 to assess the primary measures for empowerment (self-efficacy and perceived control) and the secondary measures for migraine disability, quality of life, (see section 5.2 in the research protocol). In addition, participants fill in SMT evaluative questionnaires at T2 and T3, as well as an ODA evaluative questionnaire after conclusion of the three weeks of online monitoring and coaching, which are derived from the former study. Mobile monitoring and coaching will be offered halfway in the 6-months follow-up period to 50% of the participants in both groups (ODA+; N=60). In this way a 4x4 delivery matrix is realized in which ODA+ and ODA-, as well as ODA pre-training (WL) and ODA post-training (TG), is systematically varied with 30 participants per sub-condition. This enables the analysis of whether ODA supports the preparation for - and/or the effect maintenance of - internet delivered SMT (3rd objective of the study).
The data acquisition will be completed after 30 months and publications will be finalized in the six months that follow.

Intervention

The internet training *MyMigraine* is grafted on an evidence-based SMT protocol, tailored to the format of an Internet-delivered intervention. Potential participants can enrol via the website www.mymigraine.nl. Subsequently they are asked to fill in the Symptom Checklist 90R (SCL-90R), the ID-migraine (diagnostic scale), and a 4-week headache diary. When decided that the training is suited for the participants they receive authorization and can commence with the training. The training consists of BT strategies that are central to attack prevention in migraine: 1) identification and modification of triggers and affective, cognitive and behavioural premonitory symptoms; 2) use of physiological and cognitive-behavioural self-regulation skills. The main BT techniques for migraine are relaxation training (mean ES = 5.5) and cognitive-behavioural training (mean ES = 5.4) (Nederlandse Vereniging van Neurologen, 2007) and the SMT includes a complete autogenic relaxation training, supplemented with cognitive behavioural strategies such as goal setting, self-reinforcement and positive thinking.
The online SMT consists of 8 lessons that are spread over 8-12 weeks. The lessons will take the participant approximately 1 hour to complete and preferably take place once every 7 to 10 days. The average time investment is approximately 30 minutes per day for two daily relaxation exercises (30 minutes in the first half and 10 minutes in the latter part of training) and cognitive-behavioural homework. Headache self-monitoring requires a few minutes per entry.
The first lesson acquaints the participants with the principles of the training and provides health education on the subject of behavioural attack prevention. Lessons 2-4 focus on 1) detection of premonitory features of the attack (migraine triggers and premonitory warning symptoms) by daily monitoring, and 2) acquisition of relaxation skills by stepped practice of autogenic and breathing exercises twice per day at home. Sessions 5-8 focus on

1) application of relaxation skills and other proactive strategies under the condition that premonitory symptoms or triggers prevail, while continuing the daily exercises at home, and 2) the formulation of personalized prescriptions for migraine and health with a focus on individualized target conditions of attack risks and specific actions or lifestyle changes to prevent attack occurrence. Evaluation takes place in lesson 8, which includes the specification of individual goals and actions to maintain the self-management skills.
Participants in the waiting-list condition (WL) continue with their current treatment, i.e. care as usual, while keeping the electronic headache diary. The WL-group receives the training after the waitlist period.
To keep participants informed they will receive an annual (online) newsletter concerning the research project.
After completion of the training in the TG condition and before the start of training in de WL condition, half of the participants are offered 3 weeks of mobile monitoring and coaching with a smartphone that connects through wireless internet to the content management system of the internet training. The smartphone contains a digital diary, of which selected ratings are the target of direct and personalized online feedback provided by a staff member of the project or by trained master students under supervision. The diary keeping takes several minutes to fill in questions about 1) migraine and medication use; 2) prodromal features of attacks; 3) voluntary relaxation and other self-regulation strategies for attack prevention. Four beeps are randomly programmed within 2.5 hour blocks separated by 0.5 hour each day to signal that the diary should be filled in. In addition to the beep diary participants fill in shorter diaries upon waking up and before going to sleep.
Mobile coaching is provided by direct feedback to the digital diary within a template on the smartphone screen (see figure 1in the research protocol) that consists of three parts: 1) current attack risk with markers from the diary, accompanied by a traffic light, 2) tips and advice for self-management derived from the training and 3) positive reinforcement with brief encouragements underscored by an emoticon (smiley). In case of moderate or severe headache the device automatically provides the option to stop the diary.

Study burden and risks

The benefits of self-management training for migraine, and of mobile monitoring and coaching to support it, have been outlined (see the section on the background of the study). There are no foreseeable risks for the participants in this study. This was confirmed by the absence of adverse events in the former study of home-based SMT provided by patient trainers (Mérelle, 2008; reviewed by the METC of the Erasmus MC in Rotterdam, code P03.1227L). The time participants have to invest in the training program was and is substantial , but this did not translate into a large percentage of drop-out. Participation is voluntary and participants are fully informed from the start about the nature of the training. Strong efforts were made to make the internet

application user-friendly and captivating, which was confirmed by six expert patients involved in the feasibility pilot study (Sorbi & van der Vaart, 2010). The burden of travel time and expense is relieved by offering the intervention through the Internet, which has the additional advantage that it can be followed at a time and place of the participants own choosing.

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

Participants are included according to the scientific guidelines of the International Headache Society (IHS) subcommittee on clinical trials. Participants have to be between 18 and 65 years old, fulfil the IHS criteria for migraine with (G43.1) or without (G43.0) aura, and have an attack frequency of 2-6 per month.

Exclusion criteria

Participants are excluded in case of a migraine duration of less than one year, a migraine onset at an age above 50 years referring to underlying organic disease, headache occurring on 15 or more days per month, medication overuse (identified by four weeks of headache monitoring), and an above score (>178) on the Symptom Checklist 90R (SCL-90R); an extended questionnaire to establish psychopathology and psychological comorbidity. Patients that have participated in the group version of the SMT in the Mérelle study (2008), are also excluded. Furthermore, pregnant women or women who expect to get pregnant during the study are excluded, because of the hormonal influence on migraine.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	30-11-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32736.041.10