Transcendental Meditation or Hypnotherapy in children with primary headache.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28446

Source
Nationaal Trial Register

Brief title
THIKHO

Health condition

Primary headache, Migraine, Tension-type headache, Primaire hoofdpijn, spierspanningshoofdpijn

Sponsors and support

Primary sponsor: Louis Bolk Institute, Hoofdstraat 24
3972 LA Driebergen, The Netherlands
Source(s) of monetary or material Support: Derde geldstroom; Ekhagastiftelsen (Stockholm), Fonds NutsOhra, BIAL foundation (Portugal), TM foundation (Nederland), Gaymans foundation (Nederland)

Intervention

Outcome measures

Primary outcome

1. Mean frequency of primary headache attacks: will be noted in a headache diary (4 weeks);

2. Percentage of children with a > 50% reduction in mean frequency of headache attacks after the 3-month intervention and 9 month follow-up.

Secondary outcome

1. Mean headache severity and headache duration, associated symptoms and used pain medication;

2. Quality of life using the 50-item CHQ-PF50 (parent form);

3. Anxiety and depression scores using the Revised Children's Anxiety and Depression Scale-short version (RCADS-25);

4. Coping with pain using the 37-item Dutch Pain Coping Questionnaire (PCQ);

5. Somatisation scores using the Children Somatisation Inventory (CSI);

6. Sense of Coherence using the 13-item Dutch Sense of Coherence questionnaire for children (SOC-K);

7. Compliance and satisfaction TM/HT/SMT;

8. Adverse events.

Study description

Background summary

N/A

Study objective

Although some symptomatic and prophylactic drugs have shown to be effective in children with primary headaches there is a clear need to evaluate the effectiveness of non-pharmacological treatment options for this condition with minimal or no side effects. HT has shown to be beneficial in the treatment of headache in adults. Furthermore, TM has shown to decrease stress and anxiety in adults. Recently, we have demonstrated that HT is a highly effective and safe treatment option for children with chronic abdominal pain. Taking into consideration the positive clinical results of HT and TM in adults, the proven efficacy of HT in the treatment of children with abdominal pain and the lack of adverse events with HT and TM in children, the possible benefits of HT and TM in the treatment of children with primary headaches clearly outweigh any possible risk.

We expect additive treatment with TM or HT to reduce headache attacks and headache related factors without adverse events.

Study design

Visit 1 (intake: at least 4 weeks before intervention):

1. Screening;

2. Information for patient and both parents, provided by paediatrician or paediatric neurologist;

3. Medical history;

4. Demographic and anthropometric data;

5. Pre-study medication (pain/ psychiatric);

6. Headache diary 4 weeks prior to the intervention (baseline).

Visit 2/ T=0 (Before the start of the intervention):

1. Diagnosis and classification headache;

2. Informed consent;

3. Inclusion and randomisation;

4. According to randomisation: Instruction by the paediatrician about the specific randomised intervention and corresponding timelines;

5. Child Health Questionnaire (CHQ-PF50);

6. Revised Children's Anxiety and Depression Scale-short version (RCADS-25);

7. Pain Coping Questionnaire (PCQ);

8. Children Somatisation Inventory (CSI);

9. Sense of Coherence questionnaire (SOC-K).

Intervention during 3 months:

(TM, HT or SMT according to randomisation).

Visit 3, T=1 (end of intervention, 3 months after start intervention):

1. Headache diary (4 last weeks of intervention);

2. CHQ-PF50;

3. RCADS-25;

4. PCQ;

5. CSI;

6. SOC-K;

7. Telephone interview concerning compliance and satisfaction with treatment TM/HT/SMT and averse events.

T=2 (end of study, 9 months after start intervention):

1. Headache diary (4 weeks);

2. CHQ-PF50;

3. RCADS-25;

4. PCQ;

5. CSI;

6. SOC-K;

7. Telephone interview concerning still practising TM/HT/SMT and adverse events.

Intervention

Transcendental Meditation:

The technique of TM will be taught to the children in a 6-step course program, including personal and group sessions. Subsequently, children will exercise TM at home two times a day for 10 minutes over a period of 3 months.

Hypnotherapy:

Children will receive 6 sessions of HT over a 3 month period given by certified hypnotherapists. It is encouraged to do hypnosis exercises at home once a day.

Standard Medical Treatment:

Standard medical treatment is provided according to the hospital guidelines. This is an individual mixture of symptomatic (pain, antiemetic) and prophylactic medication. It includes attention for daily regimen: sleep hygiene, diet, caffeine and stress reduction. Regularly children will be referred to a physiotherapist or psychologist for relaxation exercises. In line with the TM and hypnotherapy groups, children in the control group will be offered relaxation exercise sessions with a maximum of 6 times within the three-month intervention period. Referral and amount of relaxation exercise sessions, as a part of the SMT will be carefully documented.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children attending a paediatrician/ paediatric neurologist;

2. Written informed consent by patients and parents;

3. Children age 9-18 years;

4. Suffering from primary headache (according to ICHD-2 criteria);

5. Headache attack frequency: >2 times per month;

6. Ability to understand and speak the Dutch language;

7. Accessible by phone and internet.

Exclusion criteria

1. Start of prophylactic medication for headache during the trial;

2. Epilepsy or other serious neurological disease;

3. Previous treatment with hypnotherapy or meditation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	141
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL2814
NTR-old	NTR2955
Other	ABR : 37155
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A