Transcendental Meditation or Hypnotherapy in children with primary headache.

Gepubliceerd: 28-06-2011 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28446

Bron
NTR

Verkorte titel
THIKHO

Aandoening

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

Ondersteuning

Primaire sponsor: Louis Bolk Institute, Hoofdstraat 24
3972 LA Driebergen, The Netherlands
Overige ondersteuning: Derde geldstroom; Ekhagastiftelsen (Stockholm), Fonds NutsOhra, BIAL foundation (Portugal), TM foundation (Nederland), Gaymans foundation (Nederland)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Louis Bolk Institute
Hoofdstraat 24
M. Jong
Driebergen 3972 LA
The Netherlands
+31 (0)343 523860

Wetenschappelijk

Louis Bolk Institute
Hoofdstraat 24
M. Jong
Driebergen 3972 LA
The Netherlands
+31 (0)343 523860

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Epilepsy or other serious neurological disease;

3. Previous treatment with hypnotherapy or meditation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	141
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2814
NTR-old	NTR2955
Ander register	ABR : 37155
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A