Multicentre, Randomised, Controlled Trial of Gut-directed Hypnotherapy or Standard Medical Therapy in Children with Functional Nausea or Functional Dyspepsia

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The aim of this study is to compare gut-directed hypnotherapy with standard medical treatment in children and adolescents with chronic idiopathic nausea or nausea due to functional dyspepsia. We will examine the effect of these treatments on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON46845

Source
ToetsingOnline

Brief title
Hyena (HYpnotherapy & NAusea)

Condition

- Gastrointestinal motility and defaecation conditions
- Anxiety disorders and symptoms

Synonym
chronic nausea, functional nausea

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Christine Bader Fonds;Stichting Emma Kinderziekenhuis

Intervention

Keyword: children, chronic nausea, functional dyspepsia, hypnotherapy

Outcome measures

Primary outcome

The primary outcome is the proportion of patients with at least 50% reduction in their nausea at 12 months follow-up. Based on our pilot study and the success percentages in studies in adults with functional dyspepsia, using hypnosis in paediatric cancer patients, we expect this percentage in hypnotherapy group to be around 80%. In the standard medical treatment group, we anticipate this percentage to be much lower, around 50%
A two group continuity corrected *2 test with a 0,050 two-sided significance level will have 80% power to detect the difference between a Group 1 proportion, *1, of 0,80 and a Group 2 proportion, *2, of 0,500 (odds ratio of 0,250) when the sample size in each group is 45. With an estimated drop out of 10% we will include a total of 100 children.

Secondary outcome

Secundary outcomes are:

1. Quality of life scores (measured by KIDSCREEN-52 questionnaire), assessed at baseline, after treatment and at 6 and 12 months follow-up. Questionnaires needs to be filled out by the patients.

2. Health Utility Index (suited for valuation of health states of children > 6

years), assessed at baseline, after treatment and at 6 and 12 months. This questionnaire needs to be filled out by the parents.

3. Depression and anxiety scores (RCADS-25), measured at baseline, end of treatment, 6 and 12 months. Questionnaires needs to be filled out by the patients.

4. School absence (child), absence from work (parents) during the first year after treatment. Also use of medication, doctor visits and costs of treatment will be monitored during the first year after treatment. This questionnaire needs to be filled out by the parents.

5. The proportion of patients with at least 50% reduction in their nausea after treatment and at 6 months follow-up.

Study description

Background summary

Chronic idiopathic nausea (CIN) and functional dyspepsia (FD) are common disorders in children. They are associated with substantial physical and psychosocial distress as well as school absences and decreased social functioning. The treatment of nausea in CIN and FD in pediatric patients is mostly symptomatic with patients using prokinetics and/ or anti-emetics for years. In adults gut-directed hypnotherapy has been shown to be a promising treatment option. In children with chronic nausea its efficacy has not been studied yet.

Study objective

The aim of this study is to compare gut-directed hypnotherapy with standard medical treatment in children and adolescents with chronic idiopathic nausea or nausea due to functional dyspepsia.
We will examine the effect of these treatments on reduction of severity and frequency of nausea, vomiting, quality of life, anxiety and depression, school

absence, parental work absence and use of health care sources. Costs and effectiveness will be compared in order to answer the question which therapy should become the treatment of choice for children with CIN or FD.

Study design

Multicentre radomized controlled trial comparing gut-directed hypnotherapy with standard medical treatment + 6 sessions supportive therapy to correct for the aspecific effect of patient-therapist time.

Intervention

Patients will be randomly allocated using a computerized random-number generator for concealment to gut-directed hypnotherapy given by a therapist (group A) or standard medical treatment + supportive therapy (group B). Hypnotherapy will be carried out by one of six participating experienced hypnotherapists and will consist of 6 sessions of 50 minutes over a 3-month period. A variant of our gut-directed hypnotherapy protocol will be applied. This protocol has been used in our pilot study and contains exercises aiming for normalization of the gastric motility, stress reduction and ego strengthening exercises.

Children assigned to group B will visit their treating physician 6 times over a 3-month period. They will follow the standard AMC treatment protocol for children with functional nausea/ functional dyspepsia. This AMC protocol consists of education and reassurance, prokinetic agents, protonpump inhibitors, and/ or anti-emetic medication if considered necessary. Moreover they will receive 6 half hour sessions of supportive therapy, given by a their treating physician or physician assistant, depending on the local hospital. In these sessions symptoms of the previous weeks will be discussed with an exploration of possible contributory triggers like dietary products, emotional problems and stressful events. This supportive therapy is added to correct for aspecific treatment effects and patient-therapist time.

Study burden and risks

Burden, risks and benefits :
1. Control group: During the study children in the control group will visit the hospital 6 times, which is more often than in usual care for CIN and FD. Besides the obvious disadvantage of these visits (time spent by parents and patient), there is also an advantage. It is known from other studies that extra time invested by health care professionals results in better outcome. The children in the control group will receive standard medication for functional dyspepsia and nausea and therefore we expect no extra risks in the control group.

2. Hypnotherapy group: The children in the hypnotherapy group will visit the hypnotherapist 6 times. Moreover, they will be asked to practice self-hypnosis everyday for 10 to 15 minutes. So they will invest more time than the children in the control group. Previous studies with hypnotherapy in children have not resulted in adverse events, besides some dizziness during or after the exercises in a few children. This dizziness was self-limiting and usually occurred only during the first session. The benefit of the participants in this group, is that studies in adults have shown that hypnotherapy may result in long term disappearance of symptoms without the need for medication use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Children aged 8 to 18 years who are diagnosed with functional nausea for at least 2 months due to chronic idiopathic nausea or functional dyspepsia will be included. . To exclude underlying organic diseases, all children will undergo routine laboratory testing before inclusion: complete blood cell count, C-reactive protein, liverfunctions, creatinine, total bilirubin, amylase, celiac screening (anti-transglutaminase antibodies and IgA), urinalysis, stool parasite analysis, H pylori antigens in stool. Gastric emptying tests will be performed to verify the functional nature of the nausea. The need for further diagnostic testing, such as a upper endoscopy to rule out eosinophilic esophagitis or 24h pH measuring will be left to the discretion of the treating paediatrician or paediatric gastroenterologist.

Exclusion criteria

Exclusion criteria will be a concomitant organic gastrointestinal disease, treatment by another health care professional for the nausea, mental retardation and insufficient knowledge of the Dutch language.

Study design

Design

Study phase:	3
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):	11-08-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	21-12-2015
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-07-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-09-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-05-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-07-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	

Date:	14-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-03-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 25887
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51167.100.15
OMON	NL-OMON25887