Hypnotherapy for chronic idiopathic nausea and functional dyspepsia in children.

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Gut-directed hypnotherapy compared to standard medical treatment leads to a substantial reduction in symptoms of nausea in children clinically diagnosed with chronically idiopathic nausea and/or functional dyspepsia

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25887

Bron
Nationaal Trial Register

Verkorte titel
Hyena trial

Aandoening

Functional nausea, chronic idiopathic nausea, functional dyspepsia

Ondersteuning

Primaire sponsor: St. Antonius hospital, Nieuwegein, the Netherlands
Overige ondersteuning: Christine Bader Fonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the number of patients with > 50% reduction of their nausea

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND

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 often using prokinetics and/ or anti-emetics for years. In adults gut-directed hypnotherapy has been shown to be a promising treatment option.

AIM:

To investigate the effectiveness of gut-directed hypnotherapy (HT) for reduction of complaints of nausea in children with CIN or FD.

METHODS:

The study population consists of 100 children between 8 and 18 years clinically diagnosed with functional nausea by a paediatrician, either due to chronic idiopathic nausea or functional dyspepsia according to the Rome IV criteria.
Children will receive either 6 sessions of gut-directed HT during 3 months or SMT consisting of antiemetics and prokinetics + 6 sessions of supportive therapy during 3 months. The main outcome parameter is the number of patients with > 50% reduction of their nausea after one year follow-up. Severity and incidence of functional nausea is scored using 7-day diary cards and validated paediatric facial analogue scales for measuring nausea. The secondary outcomes include: quality of life, health utility index, depression, anxiety and somatisation, absence of school, use of health care resources and additional costs, use of medication.

Doel van het onderzoek

Gut-directed hypnotherapy compared to standard medical treatment leads to a substantial reduction in symptoms of nausea in children clinically diagnosed with chronically idiopathic nausea and/or functional dyspepsia

Onderzoeksopzet

Primary outcome: At 12 months follow-up.

Onderzoeksproduct en/of interventie

Patients will be randomly allocated to either 6 sessions of gut-directed hypnotherapy (HT) during 3 months or standard medical treatment (SMT) consisting of antiemetics and prokinetics + 6 sessions of supportive therapy during 3 months.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children between 8 and 18 years clinically diagnosed with functional nausea by a paediatrician, either due to chronic idiopathic nausea or functional dyspepsia according to the Rome IV criteria.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	30-06-2016
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-06-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46845
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5492
NTR-old	NTR5814
CCMO	NL51167.100.15
OMON	NL-OMON46845

Resultaten

Samenvatting resultaten
N/A