

Hypnotherapy self-exercises in primary care

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

Samenvatting

ID

NL-OMON21692

Bron

Nationaal Trial Register

Verkorte titel

ZelfHy study

Aandoening

Functional abdominal pain (FAP) and irritable bowel syndrome (IBS)

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of children with adequate relief of abdominal pain/discomfort (yes/no) at 12 months follow-up

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Functional abdominal pain (FAP) and irritable bowel syndrome (IBS) are the two major functional abdominal pain disorders in children in which symptoms cannot be explained by an organic condition. These functional disorders are associated with a substantial reduced quality of life, school absence, sleep disturbances, and anxiety and depression. Most children with FAP or IBS are managed in primary care. Management of FAP or IBS in primary care is challenging, however in specialist care hypnotherapy by self-exercises is an evidence-based treatment. Evidence from applying these hypnotherapy self-exercises in primary care is absent, but this approach may be effective, reduce costs and minimize time investments for children, parents, physicians and therapists.

Objective:

To determine the (cost)-effectiveness of home-based hypnotherapy by self-exercises added to usual care (UC) of general practitioners (GPs) compared with UC of GPs alone in children with FAP or IBS.

Study design:

Randomised controlled trial with a total follow-up of 12 months.

Study population:

Children, 7 to 18 years, with FAP or IBS according to the ROME IV criteria presenting in primary care in the Netherlands.

Intervention (if applicable):

Home-based hypnotherapy through self-exercises 5 times a week for approximately 15-20 minutes per day during 3 months in addition to UC of the GP. This will be compared with a control group receiving UC, which is defined as care according to the Dutch Society of GPs' (NHG) guideline for abdominal pain in children.

Main study parameters/endpoints:

Primary outcome is the proportion of children with adequate relief of abdominal pain and discomfort at 12 months. Secondary outcomes are frequency and intensity of abdominal pain/discomfort, school absence, impact on daily functioning, depression and anxiety, pain beliefs, sleep disturbances, use of healthcare services and cost-effectiveness at 3, 6, and 12 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Risks of participation are considered negligible. The risks for the intervention group are minimal as adverse effects are rare and not observed from previous studies on hypnotherapy by self-exercises. The exercises may be comparable with day-dreaming or relaxation. Furthermore, all children receive care as usual according to national treatment guidelines.

The burden of the home-based hypnotherapy intervention has been based upon results from a previous study and thereby limited to approximately 15-20 minutes per day, five days per week during 3 months. This may ultimately prevent the child from a long course of abdominal symptoms, impairments, referrals to specialists and extensive diagnostic testing. The burden of administering questionnaires is expected to be approximately 30 minutes per measurement moment. The study investigates FAP and IBS in minors, therefore involving parents too.

Doel van het onderzoek

We hypothesize that home-based hypnotherapy by self-exercises is more effective in obtaining adequate relief of abdominal pain and discomfort than care as usual of General Practitioners (GPs). We expect that by using the hypnotherapy self-exercises in primary care, functional abdominal pain (FAP) and irritable bowel syndrome (IBS) will be treated earlier, more adequately and in the home environment. This will shorten the duration of the children's symptoms, impairments and reduce the use of healthcare services, time investments of parents and costs. We believe that home-based hypnotherapy by self-exercises could reduce costs for health care visits, hospital admissions and medication prescription (healthcare perspective). We calculated an average costs reduction of €288 per child per year with FAP or IBS, meaning that it could save €15,977,390 in the Netherlands each year.

Onderzoeksopzet

Baseline

3 Months

6 Months

12 Months

Onderzoeksproduct en/of interventie

The intervention includes existing home-based hypnotherapy self-exercises in MP3 format for a period of three months. These exercises will be made available at a separate and responsive online website/platform. It consists of a public part with study information and background details, as well as a closed portal for the study participants in the intervention group. After logging in to the portal, the participants in the intervention group will have full online access to the package of audio exercises, instructions and supporting movies.

The home-based hypnotherapy self-exercises have been scientifically validated in comparison to regular hypnotherapy by a therapist in a previous trial in secondary care. The package will contain five standard hypnosis exercises, that have also been used in that trial. The package consists of one breathing exercise, the progressive relaxation exercise according to Jacobson, and four visualisation exercises. Two separate sets adjusted to the child's developmental age will be used: one for children younger than 12 years and one for children of 12 years and older. The children will be asked to listen to the exercises at least 5 times per week, for approximately 15-20 minutes a day, during a period of 3 months. The

closed portal of the website will provide children and/or parents with the instructions and planning of the exercises. The children will receive a reminder via the website/portal, if they do not use the exercises adequately, and to stimulate treatment adherence and progress.

The intervention group of children with FAP or IBS in primary care receives the home-based hypnotherapy self exercises in addition to care as usual by their GP according to the guideline commissioned by the Dutch Society of GPs (Nederlands Huisartsen Genootschap, NHG).

The control group of children with FAP or IBS in primary care will receive only care as usual by their GP. The current NHG-guideline 'abdominal pain in children' recommends as usual care good communication, psycho-education and reassurance as treatment of children with FAP or IBS. Communication comprises information about pain and anxiety, pain triggers, and positive educational strategies. GPs monitor the child's abdominal pain and plan at least one follow-up visit after four weeks. If symptoms persist, the child is asked to keep up a diary to evaluate what factors may trigger the abdominal pain. The guideline recommends referring a child to general paediatric care when symptoms are severe and have a high impact on daily functioning. Dietary advice (extra fibres or probiotics) or medical treatment (spasmolytic or antidepressants) are not advised in primary care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Aged 7 to 18 years
- General Practitioner (GP) consultation concerning chronic gastrointestinal symptoms
- Functional abdominal pain (FAP) OR irritable bowel syndrome (IBS) according to the GP

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- A concomitant organic gastrointestinal disease
- Treatment by a pediatrician for abdominal symptoms
- Mental retardation
- A history of a psychotic disorder
- Previous hypnotherapy treatment in the last year
- Insufficient knowledge of the Dutch language by the child or parents

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	200

Type:

Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

Restricted access. Data will be shared upon request. Details are described in Data Management Plan on DMPonline.

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
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NTR-new	NL8500
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Ander register ZonMw / METC Groningen : ZonMw 852002035 / NL 73562.042.20

Resultaten