# Hypnotherapy through self-exercises in children with functional abdominal pain in primary care

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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.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Gastrointestinal signs and symptoms |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON52720

**Source**
ToetsingOnline

**Brief title**
ZelfHy study

### Condition

- Gastrointestinal signs and symptoms

**Synonym**
"Functional Abdominal Pain" OR "Irritable Bowel Syndrome"

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen
**Source(s) of monetary or material Support:** Ministerie van OC&W,ZonMw

## Intervention

**Keyword:** Children, Functional abdominal pain, Hypnotherapy, Primary care

## Outcome measures

### Primary outcome

The proportion of children with adequate relief of abdominal pain and discomfort at 12 months.

### Secondary outcome

The frequency and intensity of the 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.

# Study description

### Background summary

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.

### Study 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.

### Intervention

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* guideline for abdominal pain in children.

### Study burden and risks

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 a 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.

## 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

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

- aged 7 to 18 years
- GP visit concerning chronic gastrointestinal symptoms
- FAP OR IBS according to their GP

## Exclusion criteria

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 paediatrician for abdominal symptoms
- mental retardation
- a history of a psychotic disorder
- hypnotherapy treatment in the past year
- insufficient knowledge of the Dutch language by the child or parents

# Study design

## Design

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 05-03-2021 |
| Enrollment: | 200 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 20-10-2020 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 17-11-2021 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 29-06-2022 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |
| Approved WMO Date: | 29-09-2022 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Groningen (Groningen) |

# 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 |
|---|---|
| CCMO | NL73562.042.20 |
| Other | NL8500 (NTR register) |