

No registrations found.

Ethical review	Positive opinion
Status	Completed
Health condition type	-
Study type	Interventional

Summary

Source

NTR

Brief title

BOKi

Health condition

child, constipation, physiotherapy, kinderen, obstipatie, fysiotherapie

Sponsors and support

Primary sponsor :	University Medical Center Groningen (UMCG), department of general practice
Source(s) of monetary or material Support :	ZON-MW, The Netherlands Organization for Health Research and Development

Intervention

Outcome measures

Primary outcome

Treatment success at 8 months follow-up.

Treatment success is defined as the absence of constipation according the QPGS ROME III questionnaire without the use of laxatives.

Secondary outcome

Secondary outcome measures are treatment success at 4 months, the absence of constipation according to the ROME III criteria in the past 4 weeks irrespective of the use of laxatives at 4 and 8 months, quality of life, costs.

Study description

Background summary

Rationale: Education, dietary advice, toilet training and laxative treatment is currently recommended as the first choice therapy for children with functional constipation in primary care (conventional treatment). Paediatric pelvic physiotherapists claim to obtain good results with their treatment and they already treat many children with functional constipation. However because a lack of randomised controlled trials, paediatric pelvic physiotherapy is not yet evidence-based.

Objective: The primary objective is to study the effect of paediatric pelvic physiotherapy in addition to conventional therapy on the number of patients with treatment success in children aged 4-17 years in primary care with functional constipation in comparison to conventional treatment alone.

Study design: Randomised controlled trial with a follow-up of 8 months.

Study population: Children aged 4-17 years with functional constipation in primary care.

Intervention: The therapy will consist of education about defecation, toilet training, breathing exercises, training of the pelvic floor muscles, and training of the abdominal muscles. This will be added to the conventional treatment of functional constipation.

Main study parameters/endpoints: Primary outcome measure is treatment success at 8 months follow-up. Treatment success is defined as the absence of constipation according the ROME III criteria for functional constipation; without using laxative treatment in the past 4 weeks. Secondary outcome measures are treatment success at 4 months, absence of constipation irrespective of laxative use at 4 and 8 months, quality of life and costs.

Study objective

We expect paediatric pelvic physiotherapy in addition to conventional treatment to be more (cost)- effective than conventional treatment alone, after 8 months follow-up.

Study design

Follow up visits will be at 4 and 8 months.

Intervention

Paediatric pelvic physiotherapy will be given by a certified paediatric physiotherapist with additional education in pelvic physiotherapy, according to the standards of the Dutch Pelvic Physiotherapists Organization (NVFB). Treatment will start within one week after randomisation. The therapy will consist of assessment of motor development, extensive physiotherapy training, breath control, pelvic floor training, core stability training and abdominal massage. It includes isometric training of the abdominal muscles, defecation stimulating exercises on the toilet, and relaxation and diaphragmatic breathing exercises. The paediatric physiotherapist will decide on treatment frequency and duration (usually 3-6 sessions). We will not use a standard protocol for the physiotherapeutic intervention but chose a more flexible, pragmatic approach in which the participating pediatric physiotherapists tailor their treatment to the need of each child, as would be the case in normal practice.

To gain insight in the treatment techniques and treatment duration in our study population pediatric physiotherapists register their treatment and the number of visits for each patient on a structured form.

Contacts

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Eligibility criteria

Inclusion criteria

- Children aged 4 to 17 years
- Diagnosis of functional constipation by GP or Paediatrician
- Informed consent of both parents and the child (if aged ≥ 12 years)

Exclusion criteria

- Physiotherapy or urotherapy for constipation in the past 3 years
- Psychopathology disabling protocol adherence
- Severe/terminal illness

Study design

Design

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

Recruitment

NL	
Recruitment status :	Completed
Start date (anticipated) :	01-09-2014

Enrollment : 180
Type : Actual

IPD sharing statement

Plan to share IPD : Undecided

Ethics review

Positive opinion
Date : 08-09-2014
Application type : First submission

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
NTR-new	NL4654
NTR-old	NTR4797
Other	ZonMW : 80-83700-98-41027

Study results