

A multicenter randomized controlled trial of the effectiveness of pelvic physical therapy for children 5-17 years with functional constipation as SURPLUS to paediatric usual care

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The purpose of this study is to investigate the effectiveness of pelvic physical therapy as a SURPLUS to the paediatric usual care in children (5-17 years) with functional constipation. Other research questions are: Does pelvic physiotherapy...

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

Summary

ID

NL-OMON39172

Source

ToetsingOnline

Brief title

Pelvis physiotherapy in children with functional constipation

Condition

- Gastrointestinal motility and defaecation conditions

Synonym

blocked, constipation

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, constipation, physiotherapy, RCT

Outcome measures

Primary outcome

The primary outcome measure in this study: The Rome III criteria for functional obstipatie in conjunction with the use of macrogol 3350 or 4000.

Secondary outcome

Secondary outcome measurements in this study: The results of the measuring instruments which, in different ways, measure quality of life and the perceived impact of treatment

Study description

Background summary

Constipation in children is common. The prevalence of constipation in children aged 0-18 years in the Netherlands, depending on the criteria is 0.3% -8%. Functional constipation can be caused by the dysfunction of the various systems, colon and rectum, pelvic floor muscles and sphincter complex. Defecation disorders including constipation, often have a major impact on the psychosocial functioning of a child and can be stressful for the whole family, and in particular for the development of the child. Wrongly is assumed that the signs or symptoms of constipation naturally pass, while recent longitudinal Dutch study found that about one third remain constipated. In 20% of the respondents, the quality of life in adulthood is negatively affected by constipation. In addition constipation in adults appears as a major influence on damage to the pelvic floor as obstetric trauma, resulting in urinary and fecal incontinence. To date, there is little scientific evidence for both the medical and psychological effective treatment of this complaint. No studies were found on physiotherapists treatment, while in the Netherlands more and

more children are referred to the physiotherapist specialized in these problems, the pelvic physiotherapist. Scientific studies in paediatric pelvic physical therapy for the pelvic floor parameters in conjunction with functional use of the pelvic floor muscles are not done.

Study objective

The purpose of this study is to investigate the effectiveness of pelvic physical therapy as a SURPLUS to the paediatric usual care in children (5-17 years) with functional constipation.

Other research questions are:

Does pelvic physiotherapy treatment has an effect on the quality of life of the child

Is it possible to develop a standard of pelvic floor function in children.

Study design

A multicentre RCT is developed in which 367 children (5 to 17 years) with functional constipation according to Rome III criteria are randomized into two research groups. In this controlled, pragmatic research the control group receives only the paediatric usual care and the experimental group the pediatric usual care supplemented with pelvic physiotherapy. Paediatricians from seven hospitals and 11 (pelvic) physiotherapists spread over the Netherlands take part in this study. An electronic patient document (EPD) was developed. The EPD consists all measuring instruments used in the study, including questionnaires and urinary and defecation diaries. Doctors and pelvis physiotherapists can keep up their files in the EPD. The parents and children can keep up the diaries and the questionnaires at home. Immediately after the consultation with the pelvic physiotherapist blinded randomization takes place to control or experimental group for the total cohort in the ratio 1:1.

Blinding of therapist and child in the study is not possible. By using the EPD, all data provided anonymously what allows blinding the investigator.

Intervention

The treatment process of a child with constipation in this study starts and stops at the paediatrician and takes in total not more than seven months. The treatment at the paediatrician will consist the prescription of laxantia, information about the complaint, eating, drinking and exercising and of toilet training. For additional urinary complaints the doctor follows his own treatment policy.

The treatment at the pelvic physiotherapist will consist the use of laxantia, information about the complaint, eating, drinking, exercising, toilet training and of locomotor therapy. The locomotor therapy (teaching changes in posture, muscle tone, muscle coordination and movement, both general and specific to the abdominal and pelvic floor muscles) shall be supplemented , when needed, with

myofeedback and / or rectal balloon training.

Study burden and risks

not applicable

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

- * There is functional constipation according to the Rome III criteria.
- * The children are being treated for this complaint by a pediatrician or (children)-gastroenterologist

- * The children are referred by a pediatrician or (child)- gastroenterologist
- * The child (at least 5 years and up to 17 years) at baseline measurement.
- * The parents sign an informed consent.
- ** Children 12 years and older sign an informed consent

Exclusion criteria

- * Severe motor retardation, making it impossible to independently go to the toilet and / or the clothes off and / or sit without help.
- * Endocrine and metabolic disorders, such as hypothyroidism, diabetes mellitus and diabetes insipidus.
- * Neurological and psychiatric disorders such as autism and PDD-NOS. spina bifida, cerebral palsy, anorexia nervosa.
- * Psychiatric disorders such as autism and PDD-NOS.
- * SDQ at baseline is above 14
- * Down syndrome
- * M. Hirschsprung

Study design

Design

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):	21-12-2010
Enrollment:	367
Type:	Actual

Ethics review

Approved WMO

Date: 26-04-2010

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 20-12-2010

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 01-04-2011

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 09-06-2011

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 21-06-2011

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 18-07-2011

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 25-04-2012

Application type: Amendment

Review commission: MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Approved WMO

Date:	29-06-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO	
Date:	01-08-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO	
Date:	20-06-2013
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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	NL30551.068.09