

# Peppermint Oil for the treatment of Irritable Bowel Syndrome or Functional Abdominal Pain in Children: the MINT study

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Gastrointestinal motility and defaecation conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON52287

### Source

ToetsingOnline

### Brief title

MINT-study

### Condition

- Gastrointestinal motility and defaecation conditions

### Synonym

Functional abdominal pain, Irritable Bowel Syndrome

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis

**Source(s) of monetary or material Support:** Prins Bernhard Cultuurfonds

## Intervention

**Keyword:** Childeren, Functional abdominal pain, Irritable bowel syndrome, Peppermint oil

## Outcome measures

### Primary outcome

The primary outcome measure is the percentage of children with >30% reduction in abdominal pain intensity after 8 weeks of treatment from baseline. Abdominal pain intensity is measured daily for 7 consecutive days using an abdominal pain app.

### Secondary outcome

Secondary outcome measures are other recently internationally defined outcome measures for trials in children with chronic abdominal pain: degree of reduction in pain frequency and pain intensity, percentage of patients with an adequate improvement in complaints, school absenteeism hours, quality of life, feelings of anxiety & depression, defecation pattern, taste, ease of use and side effects of the treatment. In addition, genetic polymorphisms associated with susceptibility to placebos are investigated and related to both primary and secondary outcome measures.

## Study description

### Background summary

Irritable bowel syndrome (IBS) and functional abdominal pain (FAP) are common conditions in children. Every year, approximately 13,000 children in the Netherlands visit the pediatrician with this complaint. IBS and FAP are associated with a reduced quality of life and an increased risk of psychiatric

disorders. Therapeutic options include an explanation of the condition, painkillers, often in combination with dietary modifications, or psychological therapies such as hypnotherapy or cognitive behavioral therapy. Currently, there is no proven effective pharmacological treatment for children with IBS or FAP.

Peppermint oil is a very interesting therapeutic option to investigate further: it relaxes smooth muscle tissue in vitro and modulates visceral nociception. Two small studies of low quality in children suggest a positive effect on abdominal pain. A systematic review from 2020 in adults with IBS and a subsequently published Dutch study in adult IBS patients concluded that peppermint oil capsules lead to a reduction of complaints. Peppermint oil is therefore recommended in the recently published American treatment guideline for adults with IBS.

Pediatricians therefore regularly recommend peppermint oil capsules to children with FB or IBS, even though there is no convincing evidence of an effect in children. For a long time, peppermint oil capsules were not registered for children < 10 years and in that case, regular peppermints were often prescribed, with positive reported effects. As mentioned, the effectiveness of peppermint oil capsules in children has not been sufficiently studied and the effect of peppermints on abdominal pain has not been studied at all. In the first phase of formulating and planning this study, several (parents of) children with abdominal pain were consulted about the study design. They advised comparing peppermint oil capsules with both placebo capsules and peppermints because both research questions are important in their view.

## **Study objective**

The aim of the Mint study is to investigate the effectiveness of peppermint oil capsules compared to placebo capsules in reducing abdominal pain intensity in these children. In addition, we investigate the effect of peppermint oil capsules compared to placebo capsules on other disease-related outcome measures such as anxiety & depression, quality of life, absenteeism from school, and healthcare costs. The second aim is to explore the effectiveness of regular mints in reducing abdominal pain intensity compared to peppermint oil capsules and placebo capsules and the effect of mints on secondary outcome parameters.

## **Study design**

Multicenter, partially blinded, placebo-controlled study consisting of 3 groups (blinded peppermint oil capsules or placebo capsules and an open-label group with regular mints) with a treatment duration of 8 weeks and a follow-up period of 4 weeks.

## **Intervention**

Peppermint oil capsules 182 mg 2 d.d.1 capsules (8-11 years) or 3 d.d. 1 capsule (12-18 years) versus placebo capsules versus regular mints 2-3 times 1 day for 8 weeks

## Study burden and risks

The subjects have to visit the pediatric department twice in 12 weeks. Moreover, the subjects and their parents, separately, have to fill out questionnaires and a pain diary on an app four times: (I) at the start of the baseline period, (II) in the fourth week of the study (III) in the eight week of the study (end of treatment), and (IV) four weeks after the end of treatment. Patients will be randomly allocated to peppermint oil capsules, placebo capsules, or peppermints. Also, a saliva swab will be taken for DNA studies. Side-effects of peppermint oil capsules are generally mild and transient of nature.

## Contacts

### Public

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### Scientific

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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

Children aged between 8 and 18 years  
Diagnosos of IBS or FAP-NOS according to the Rome IV-criteria.  
Patients are required to have an average daily pain rate of  $\geq 2$  on the Wong-Baker Faces Pain Scale

## Exclusion criteria

Current treatment by another health care professional for abdominal symptoms  
Previous use of peppermint oil for abdominal complaints  
Known hypersensitivity to mints or peppermint oil  
Gastrointestinal blood loss  
Recurrent or unexplained fevers  
Decreased growth velocity  
History of previous abdominal surgeries in the past 3 months  
Significant chronic health condition requiring specialty care (e.g., lithiasis, ureteropelvic junction obstruction, sickle cell, cerebral palsy, hepatic, hematopoietic, renal, endocrine, or metabolic diseases) that could potentially impact the child\*s ability to participate or confound the results of the study  
Known concomitant organic gastrointestinal disease  
Current use of drugs which influence gastrointestinal motility, such as erythromycin, azithromycin, butyl scopolamine, domperidone, mebeverine and Iberogast. If laxatives are being used (in patients with IBS-C) they can continue using them during the study.  
Current use of proton-pump inhibitors  
Insufficient knowledge of the Dutch language  
Pregnancy or current lactation. Women with childbearing potential must have a negative urine pregnancy test within 7 days prior to first dose of study treatment

## Study design

### Design

Study phase: 3  
Study type: Interventional

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	06-05-2022
Enrollment:	240
Type:	Actual

## Medical products/devices used

Product type:	Medicine
Brand name:	Tempocol
Generic name:	Peppermint Oil
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Wilhelmina Peppermints
Generic name:	Peppermint

## Ethics review

Approved WMO	
Date:	21-09-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	10-11-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 07-03-2022  
Application type: Amendment  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO  
Date: 10-03-2022  
Application type: Amendment  
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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
EudraCT	EUCTR2021-003690-65-NL
CCMO	NL78304.100.21