# A cognitive behavioural treatment programme for children with chronic abdominal pain

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
15/09/2009		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
03/11/2009		[X] Results		
Last Edited	Condition category	[] Individual participant data		
29/12/2020	Digestive System			

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Contact details

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#### Additional identifiers

**Protocol serial number** N/A

# Study information

#### Scientific Title

Evaluation of a cognitive behavioural treatment programme for children with chronic abdominal pain: a ranomised controlled trial

#### Acronym

#### **STOPCAP**

#### **Study objectives**

The main goal of the study is to investigate if the cognitive behavioural treatment ('Stop the Pain') is able to decrease the frequency and intensity of pain symptoms as well as to increase the quality of life as compared to 'wait-list-controls' (control group [CG]). The main hypothesis is that the treatment group (EG) will experience an improvement in pain-related coping skills and pain-related cognitions in comparison to the CG.

Publication on the pilot study (in German): Warschburger, P. & Gross, M. (2008). "Stopp den Schmerz" ein kognitiv-behaviorales Behandlungsprogramm für Kinder mit Bauchschmerzen. Erste Ergebnisse einer Pilotstudie. Verhaltenstherapie, 18, 162-167.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Ethics Committee of the University of Potsdam, 11/06/2008

#### Study design

Randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Chronic abdominal pain

#### **Interventions**

The developed and pilot-tested cognitive-behavioural treatment programme includes the following:

#### For children:

- 1. Guided relaxation
- 2. Information on CAP
- 3. Coping strategies
- 4. Altering negative cognitions

Children attend at least 6 weekly sessions (90 minutes each). The courses will be taught by psychologists.

#### For adults:

- 1. Information on the etiology and maintenance of CAP
- 2. How to support their child in pain-related coping

Adults attend one 2-hour training session. The course will be taught by psychologists and nutritionists.

The control group will receive only usual care during the interventions. They will have the opportunity to receive the same interventions once the trial has been completed.

#### Intervention Type

Other

#### Phase

Not Applicable

#### Primary outcome(s)

- 1. Abdominal pain (frequency and intensity). Intensity of pain is measured using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain).
- 2. Qualitty of life:
- 2.1. Quality of Life Inventory™ (PedsQL™)
- 2.2. Generic children's health-related quality of life (KINDL-R)

All primary and secondary outcomes will be measured at baseline, post-interventions and 3-month follow-up.

#### Key secondary outcome(s))

- 1. Coping with pain, assessed by PedsQL™ Pediatric Pain Coping Inventory (PedsQL™-PPCI)
- 2. Stress vulnerability (scale of SSKJ 3-8, Fragebogen zur Erhebung von Stress und Stressbewältigung im Kindes- und Jugendalter)

All primary and secondary outcomes will be measured at baseline, post-interventions and 3-month follow-up.

#### Completion date

31/12/2009

## Eligibility

#### Key inclusion criteria

- 1. Age: 8-12 years, either sex
- 2. Informed consent (parent and children) to participate in the study
- 3. Children must have suffered from abdominal pain for at least three months
- 4. Pain occurs frequently (once a week), episodes of pain are severe enough to affect the child's activities

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

8 years

#### Upper age limit

12 years

#### Sex

All

#### Total final enrolment

29

#### Key exclusion criteria

- 1. Previous participation in a similar intervention for chronic abdominal pain (CAP)
- 2. CAP as a consequence of psychiatric disorders (e.g. depression, anxiety disorder)

#### Date of first enrolment

01/08/2008

#### Date of final enrolment

31/12/2009

### Locations

#### Countries of recruitment

Germany

# Study participating centre Karl-Liebknecht-Str. 24-25

Potsdam Germany 14476

# Sponsor information

#### Organisation

University of Potsdam (Germany)

#### ROR

https://ror.org/03bnmw459

# Funder(s)

#### Funder type

Government

#### Funder Name

Department of Science, Research and Culture of the State of Brandenburg (Germany) - scholarship

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013	29/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes