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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 15/09/2009 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/11/2009 | Completed | [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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
01/08/2008

### 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

### Age group
Child

### Lower age limit
8 Years

### Upper age limit
12 Years

### Sex
Both

### Target number of participants
28

### 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**
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# Sponsor information

**Organisation**
University of Potsdam (Germany)

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**Sponsor type**
Government

**Website**
http://www.uni-potsdam.de/

**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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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 |