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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

Contact name
Ms Martina Gross

Contact details
Karl-Liebknecht-Str. 24-25
Potsdam
Germany
14476
+49 (0)331 977 2892
martina.gross@uni-potsdam.de

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
Potsdam
Germany
14476

Sponsor information

Organisation
University of Potsdam (Germany)

Sponsor details
Potsdam Graduate School
Am Neuen Palais 10
Haus 2
Potsdam
Germany
14469
+49 331 977 1855
pogs@uni-potsdam.de

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