Trial Description

Title

“Stop the pain – A multicenter, randomized-controlled study of a cognitive-behavioral intervention for children with functional abdominal pain“

Trial Acronym

Stop-FAP

URL of the trial

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Brief Summary in Lay Language

This trial aims to compare two training programs for children suffering functional abdominal pain. These two programs are comaprable in number of sessions and group sizes, but show differences in content (very focused on pain management vs. more general information and support).
Focus of the trial ist the evaluation of "Stop the pain", which has shown high effectivenes in one first trial. This time, five clinics, experienced in diagnosis and treatment of childhood chronic abdominal pain, will take part. Children aged 7-12 years are eligible. The programs imply six weekly group session for the children and 2 parent evenings. The study group assumes that participation in "Stop the pain" will reduce pain experience and will improve the childrens' quality of life and coping strategies - up to 12 months after training.

Brief Summary in Scientific Language

The trial aims to assess the efficacy of a cognitive- behavioral self-manegement program (intervention group, IG) compared to an equally extensive information-only control group (CG). The interventions contain 6 weekly group sessions and 2 parent meetings according to the cognitive-behavioral, manualized program "Stop the pain with Happy Pingu". Follow up per patient: 3- and 12 months.
Children aged 7-12 years suffering functional abdominal pain (according to Rome III criteria H2a, H2b, H2d, H2d1) are eligible. Our primary hypothesis is that for participants in the IG the frequency and intensity of pain will be reduced more successfully and more sutainably than for children in the CG. Secondary hypotheses state that the IG will experience a higher increase in quality of life and psychosocial well-being compared to the active CG.

Organizational Data

- DRKS-ID: **DRKS00005038**
- Date of Registration in DRKS: **2013/07/25**
- Date of Registration in Partner Registry or other Primary Registry: **2014/01/07**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

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- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **19/2013 , Ethikkommission der Universität Potsdam**

Secondary IDs

- Primary Registry-ID: **NCT02030392 (ClincialTrials.gov)**

Health condition or Problem studied

- Free text: **pain related functional gastrointestinal disorders ("functional abdominal pain", Rome-III criteria H2a, H2b, H2d, H2d1; F 45.4 resp. F54))**
- ICD10: **F45.4 - Persistent somatoform pain disorder**

Interventions/Observational Groups

- Arm 1: **Intervention group: participation in the cognitive-behavioral program "Stop the pain with Happy Pingu". The program comprises six weekly sessions for the children in small groups (90 min each) and 2 sessions for the parents (50 min each).**
- Arm 2: **active control group: participation in an information and education control group (physical well-being, health and gastrintestinal tract). The program of the control group comprises six weekly sessions for the children in small groups (90 min each) and 2 sessions for the parents (50 min each).**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **patient/subject, assessor, data analyst**

Control: **Active control (effective treament of control group)**

Purpose: **Treatment**

Assignment: **Parallel**

- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary efficacy endpoint is the frequency and intensity of pain (composite score) over the course of treatment and follow-up (pre, post, 3 and 12 months follow up). This primary outcome will be assessed by pain diary in childrens self-report (over 2 weeks).

Secondary Outcome

Secondary efficacy endpoints are health-related quality of life and pain-related coping and cognitions.
The secondary outcome variables will be assessed by self -report questionnare (each assessed at pre, post, 3- and 12 months follow-up). Following questionnaires are included: PedsQL, PPCI, KINDL-R. Parents report on childs quality of life (PedsQL proxy report).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Abteilung pädiatrische Gastroenterologie, Düsseldorf**
- University Medical Center **Abteilung Pädiatrische Gastroenterologie, Ulm**
- University Medical Center **Klinik für Pädiatrie m.S. Endokronologie, Gastroenterologie und Stoffwechselmedizin. Abteilung Pädiatrische Gastroenterologie, Berlin**
- Medical Center **Abteilung Pädiatrische Gastroenterologie, Hamburg**

- Medical Center **Abteilung Pädiatrische Gastroenterologie, Darmstadt**
- Medical Center **St. Vincenz Krankenhaus, Klinik für Kinder- und Jugendmedizin, Pädiatrische Gastroenterologie, Paderborn**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/04/01**
- Target Sample Size: **112**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **7 Years**
- Maximum Age: **12 Years**

Additional Inclusion Criteria

Inclusion criteria for medical screening:

-abdominal pain for at least 2 months

-abdominal pain at least once per week

-aged 7-12 years

Exclusion criteria

exclusion criteria for medical screening:
very limited german language skills; mental retardation; concomitant psychological treatment; at point of screening constant physician-prescribed treatment (psychological, medical) of gastrointestinal complaints; at point of screening participation in a training program for gastroinestinal complaints during the last 6 months; at point of screening participation in a clinical trial which might have effects on abdominal pain in the last 4 weeks; presentation of sibling aged 7-12 years with abdominal pain.

Exclusion Criteria for study participation:

Addresses

- **Primary Sponsor**

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  Department Psychologie
  Beratungspsychologie
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  URL: **[---]***

- **Contact for Scientific Queries**

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  URL: **www.psych.uni-potsdam.de/counseling/index-d.html**

- **Contact for Public Queries**

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  URL: **http://www.psych.uni-potsdam.de/counseling/index-d.html**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and**

Research (BMBF), etc.)

Deutsche Forschungsgemeinschaft
Kennedyallee 40
53175 Bonn
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2017/07/07**

Trial Publications, Results and other documents

- Paper **Studienprotokoll**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*