Attentional Bias to Activity in the Abdomen in Children with Functional Abdominal Pain (FAP).

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Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal conditions NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34682

Source
ToetsingOnline

Brief title
Attentional Bias in FAP

Condition

- Gastrointestinal conditions NEC

Synonym
functional abdominal pain, physically unexplained abdominal pain

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Attentional Bias, Children/adolescents, Functional Abdominal Pain (FAP), Recurrent Abdominal Pain (RAP)

Outcome measures

Primary outcome

Reaction times of children with and without FAP

Secondary outcome

Not applicable

Study description

Background summary

RAP affects about 0.3 to 19% of children in Western countries (Chitkara, Rawat, & Talley, 2005). For most children, no organic abnormalities can be found to explain the pain. In those cases, the pain is considered to be functional (FAP). Children with FAP may experience significant school absenteeism, family disruption and withdrawal from social activities (Youssef, Murphy, Langseder & Rosh, 2006). FAP has been associated with a high comorbidity of anxiety (about 80%) and depression (about 40%). Many children with FAP go through potentially risky and possibly unnecessary hospitalizations, tests and procedures, thus placing a heavy burden on the medical community (Dufton et al., 2009). To treat these children effectively and prevent further (psycho)pathology, it is very important to learn more about the etiology of FAP.
A promising explanatory theory for FAP is that of attention bias. According to the symptom perception hypothesis and empirical findings (Watson & Pennebaker, 1989; Whitehead, & Palsson, 1998), children with many somatic complaints might selectively direct their attention to ambiguous physical sensations and interpret them more readily as signs of disease. Children who focus their attention on pain may not only perceive more pain, but also have fewer attentional resources available to engage in adaptive coping strategies to deal with their pain (Compas & Boyer, 2001). One previous study focused on the presence of a selective attention bias in children with RAP (Boyer et al., 2006). However, this study has two major limitations. First, it does not include a control group, which makes it impossible to draw any conclusions on the specificity of this attention bias for children with RAP. Second, this study used words as stimuli to measure an attentional bias, whereas it is questionable whether an attentional bias for words draws on the same processing

mechanisms in the brain as an attentional bias for physical sensations. Therefore, the current study will follow the research design of Boyer and colleagues, while correcting for these two major limitations.

Study objective

The objective of this study is to determine if children with FAP demonstrate subliminal and supraliminal attentional biases to assumed activity of the abdomen compared to healthy children and if children with FAP interpret the assumed activity as pain.

Study design

Approximately 30 children with FAP and 30 healthy children will be included. The study has a between subject design including two conditions: children with FAP and healthy children that match the age, gender and ethnicity of children with FAP. The duration of the study will be approximately 12 months. Children will perform a dot probe task to measure selective attention for physical stimuli.

Dot probe:
In a visual dot probe task, participants are shown a pair of stimuli for a short time at two different spatial locations on a screen. One of the stimuli is threatening, the other stimulus is neutral. After the offset of these stimuli, a dot probe emerges at the location of the threatening stimulus (congruent presentation) or at the location of the neutral stimulus (incongruent presentation). The allocation of attention is measured by the time needed to respond to the dot probe (Koster et al., 2004).
In this study the threatening stimuli are assumed activity in parts of the body (abdomen and heart). The neutral stimulus is assumed activity of the computer on which the task is done. Another neutral but personally relevant stimulus is activity in the legs. Stickers that are attached to the computer will be put on the breast and stomach of the children. Straps will be put on the legs. The participants will be told that the stickers and the straps measure the activity in their heart (heartbeats), abdomen (bowel movements) and legs (blood circulation). Every activity is translated in a schematic meter. The meter of the neutral stimulus will measure the *activity* in the computer.
The participant will see a pair of stimuli, a threat related stimulus and a neutral one (on the left and right of the computer screen) on subliminal level for 20 ms. This will be followed by a scrambled picture (mask) for 1230 ms, to ensure the stimuli are processed subliminally. On supraliminal level a pair of stimuli will be seen for 1250 ms.

Participants complete questionnaires concerning abdominal pain, pain vigilance, anxiety, depression, somatic complaints before and/or after the dot probe task. Also, the children will answer a few questions concerning the influence of the

task on bodily sensations. After performing the dot probe and filling out the questionnaires, the children will be debriefed about

Study burden and risks

There is no record of dot probe tasks being unsafe. They do not constitute a heavy burden for participants and our experience is that children enjoy these tasks. It is imperative that the study will be performed in children, as the information processing systems of the brain might be very different in adults due to maturation processes. Also, it is very important to include a healthy control group, as without a comparison group, we cannot make any inferences about whether the attention bias is specific for children with FAP. This control group cannot constitute of adults but should be children, because of the differences in information processing between children and adults as stated above.

Contacts

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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

The inclusion criteria for children with FAP are in line with those used in the RCT mentioned above:
* Age 8-18.
* Main complaint is abdominal pain.
* Abdominal pain has lasted at least 8 weeks in last 12 months.
* No abnormalities in general physical examination.
* No abnormalities in abdominal examination.
* AP is present at least 3 times a week during at least 15 minutes a day, and of considerable severity (score of 5 on a scale of 1-9)
* Laboratory tests in blood, urine and feces and an echo do not show any physical causes for the AP
* No physical disease present (e.g. Crohn*s disease) that might explain the pain
* Patient has not endured any significant surgeries that might explain the pain ;NB:
1. Helicobacter pylori, Entamoeba fragilis, Blastocystis hominis are organic causes of the AP if the complaints disappear after treatment. Patients experiencing enduring pain after adequate treatment can be included.
2. Patients that suffer from both AP and constipation should be treated for their constipation first. If the pain persists after adequate treatment, the patient can be included. ;Inclusion criteria for children without FAP:
* Age 8-18.
* No enduring AP in past year
* No current or past physical disease.

Exclusion criteria

Exclusion criteria for children with FAP:
* Red flag signals
* Organic cause abdominal pain
* Major surgery
* Previous major medical illness;Exclusion criteria for children without FAP:
* Enduring AP in past year
* Current or past physical disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2010
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL30949.018.09