A parent-focused intervention for anxiety in inhibited children

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To examine whether this promising parent intervention can reduce behavioral inhibition and anxiety symptoms in Dutch behavioral inhibited children, and whether parental factors influence the treatment outcomes.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON37831

Source
ToetsingOnline

Brief title
A parent-focused intervention for anxiety in inhibited children

Condition

- Anxiety disorders and symptoms

Synonym
anxiety, fear

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Universiteit Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: anxiety, children, intervention

Outcome measures

Primary outcome

Main study parameters are children*s levels of behavioral inhibition and anxiety symptoms. These parameters are measured by several parent and teacher questionnaires at pre-intervention, post-intervention, and 6 months follow-up.

Secondary outcome

Secondary study parameters are parent overprotection and parent anxiety. These parameters are measured by two parent questionnaires at pre-intervention, post-intervention, and 6 months follow-up.

Study description

Background summary

Anxiety disorders are among the most common forms of childhood psychopathology, with prevalence estimates in preadolescent children ranging from 2.6% to 41.2% (Cartwright-Hatton, McNicol, & Doubleday, 2005; Costello, Mustillo, Erkanli, Keeler, & Angold, 2003; Ford, Goodman, & Meltzer, 2003). Anxiety disorders significantly impair children*s quality of life and functioning, particularly their family and emotional functioning (Bastiaansen, Koot, Ferdinand, & Verhulst, 2004; Ezpeleta, Keeler, Erkanli, Costello, & Angold, 2001). In addition, childhood anxiety shows developmental continuity both among anxiety disorders and in relation to other psychiatric disorders (Bittner et al., 2007; Costello et al., 2003). The high prevalence, adverse outcomes, and continuity of childhood anxiety disorders emphasize the importance of early, effective treatment programs.
One construct that seems particularly valuable for the early detection of anxiety-prone and anxious children is behavioral inhibition. Behavioral inhibition refers to the consistent tendency of some children to react with anxiety and withdrawal in the presence of unfamiliar people, objects, or situations (e.g., Garcia-Coll, Kagan, & Reznick, 1984). Research has shown that about 10 to 20% of all children display this tendency. When faced with new or

unfamiliar stimuli, they become quiet, stop the activities they were engaged in, and seek the proximity of their caregivers. These children are described by their parents as watchful and shy and are called inhibited (Garcia-Coll et al., 1984; Kagan, Reznick, Clarke, Snidman, & Garcia-Coll, 1984; Kagan, Reznick, & Gibbons, 1989; Kagan, Reznick, & Snidman, 1988). During the past two decades, research has consistently shown behavioral inhibition to be related to the development of anxiety disorders in childhood and adolescence (e.g., Biederman et al., 1993; Hirshfeld-Becker et al., 2007; Muris, Van Brakel, Arntz, & Schouten, 2011; Schwartz, Snidman, & Kagan, 1999). Most importantly, research has indicated that behavioral inhibition can be detected at a fairly young age, before an anxiety disorder has developed. This underlines that behavioral inhibition is a highly relevant construct that could be useful for detecting vulnerable, anxiety-prone children at an early point during their development. The past few years there has been a progress in cognitive-behavioral therapies for older children and adolescents (see for a review: Barett et al., 2001), however, an effective intervention for young children would be highly relevant, especially from a prevention perspective. This intervention would have to target the way in which parents handle their anxiety-prone children. Parents of these children are often anxious themselves, and model their anxious behavior to their children. Further, parents tend to be overprotective to their anxiety-prone or anxious children (often augmented by the parents* own anxiety), by taking over tasks of their child or restrict its exposure to a broad range of situations. This enhances the child*s behavioral inhibition across development, ultimately increasing the risk for developing an anxiety disorder (Rubin, Burgess, Kennedy, & Stewart, 2003).
Rapee, Kennedy, Ingram, Edwards, and Sweeney (2005) developed an early intervention program for anxiety-prone preschoolers. This brief intervention program focuses on educating the parents about the nature of anxiety and reducing anxious modeling by the parents overprotective parenting. The first studies evaluating this program in Australian preschoolers yielded positive results (Rapee et al., 2005; 2010). As indicated by the Inventgroep (2005), in the Netherlands there is a need for an intervention for young children with anxiety problems, therefore, it would be highly interesting to evaluate this program also in our country, and to extend previous findings by evaluating the role of parental factors, namely overprotective parenting and parental anxiety.

Study objective

To examine whether this promising parent intervention can reduce behavioral inhibition and anxiety symptoms in Dutch behavioral inhibited children, and whether parental factors influence the treatment outcomes.

Study design

The study uses a randomized controlled trial: parents of anxiety-prone children will be randomly allocated to either a parent-education intervention condition

or a monitoring-only condition.

Intervention

The intervention condition consists of a six-session parent-education program, which is a translation of the program of Rapee et al. (2005; 2010). The sessions will be conducted in groups of approximately six sets of parents and teach parents to reduce inhibited and anxious behaviors in their children. More specifically, the program focuses on psychoeducation about behavioral inhibition and anxiety (session 1), parent management strategies (session 2), and cognitive restructuring and exposure techniques (sessions 3 to 6). The first four sessions are held weekly, with the fifth session two weeks later, and the final session after one month. Each session lasts approximately 90 minutes.
Participants in the monitoring condition will be asked to complete all assessments, but will not receive any intervention yet.

Study burden and risks

The burden for participants consists of the time needed for completing the questionnaires and attending the intervention (six sessions of approximately 90 minutes). There are no risks associated with participation in the study. The value of the study is that it can advance theory about risk factors and prevention of anxiety disorders in young children, and it contributes to the development and evaluation of a new early intervention program.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Parents will be included in the study if the following inclusion criteria are met:
- Their child scores above 43 on the BIQ-SF, a screenings instrument measuring anxiety-proneness in young children. This cut-off score is based on a large sample of normal children between the ages of 4 to 6 years and represents the top 20% inhibited children (Vreeke et al., submitted).
- Their child attended school for at least one month. Based on the suggestion that an inhibited temperament can be influenced by environmental factors, we hypothesize that preschool children will experience more naturalistic exposure to novel situations when they first attend primary school and may consequently show a greater reduction of inhibition in this period. Hence, selecting slightly older, school-age children may lead to more stable measures of inhibition, which may in turn make intervention effects more apparent.
- Written informed consent is given.

Exclusion criteria

Children who are currently being treated for anxiety disorders are excluded from the study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2012
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL39656.078.12