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Anxiety Symptoms Prevention Investigation (ASPI): Transmission of anxiety from parent to child investigating cognitive-behavioural processes, developing and piloting a brief preventative intervention

Submission date	Recruitment status
30/07/2012	No longer recruiting
Registration date	**Overall study status**
30/07/2012	Completed
Last Edited	**Condition category**
21/01/2019	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
We have recently begun to understand how the risk for anxiety disorders is transmitted from parent to child. Part of the transmission is genetic, but a large proportion is environmentally mediated. This project will explore some key pathways through which anxiety is transmitted from anxious parent to child. These pathways are cognitive-behavioural pathways, meaning that they focus on thoughts and behaviours of parents. Although we now understand some of the pathways, we have no interventions/treatments that aim to reduce the increased risk of anxiety that such children run. One approach might be to prioritise treatment of anxiety in adults who have children. However, treatment is not always available or wanted, and there is no guarantee of success. For these reasons, a preventive/early intervention for children of anxious parents, which does not depend on the parents recovery, will be developed.
This study has two stages. In the first stage, we will be inviting parents and children into the lab to test how confidence and anxiety gets transmitted from parents to children, and seeing whether we can alter this. In the second stage, we will be inviting parents who suffer from anxiety to come to a one-day workshop. At this workshop we will give parents tips and advice to help them raise confident children. We will then be testing out whether this has any impact on the children.

Who can participate?
For the first stage of the project, this study aims to recruit 64 non-anxious parents and 64 parents who have a diagnosed anxiety disorder. Parents must have a child aged 5-9, who will also take part in the study. For the second stage of the study, 100 parents with an anxiety disorder will be recruited. For stage two, parents must have a child aged 3-9.

What does the study involve?
This study has two stages. In the first stage, we will be inviting parents and children into the lab

to test how confidence and anxiety gets transmitted from parents to children, and seeing whether we can alter this. In the second stage, we will be inviting parents who suffer from anxiety to come to a one-day workshop. At this workshop we will give parents tips and advice to help them raise confident children. We will then be testing out whether this has any impact on the children.

What are the possible benefits and risks of participating?
We dont think that there will be any direct benefit for the families that take part in stage one. Parents assigned to the experimental group in stage two may benefit from taking part in the group workshop. Parents will be reimbursed for their time, and children will receive a t-shirt. We dont think that there are any risks in taking part. Some of the tasks might involve the parents and children feeling mildly scared. However, it is emphasised that parents and children do not have to take part in any tasks that they dont want to.

Where is the study run from?
Stage one is run at the Child Anxiety Theory and Treatment (CATT) Lab, University of Sussex. The workshops in stage two will be run in NHS seminar facilities.

When is study starting and how long is it expected to run for?
Families started taking part in January 2012 and the study will run until 2015.

Who is funding the study?
The research is being funded by the National Institute of Health Research.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
9414

Study information

Scientific Title
Transmission of anxiety from parent to child investigating cognitive-behavioural processes, developing and piloting a brief randomised preventative intervention

Acronym
ASPI

Study objectives
This research is based on the observation that children of parents who have anxiety disorders are at substantially increased risk of developing anxiety disorders themselves. Part of this risk is genetic, but a large part is due to environmental factors. In particular, we know that many anxious parents behave in ways that might help to transmit their anxiety to their children. The research comprises two studies that will explore the processes that transmit anxiety from parent to child and will develop a brief, pragmatic intervention to reduce this risk.

Stage 1 is a laboratory-based study, and will examine cognitive-behavioural processes that are hypothesised to be involved in the transmission of anxiety from parent to child. It will recruit both families where a parent has an anxiety disorder and families where they do not.
1. Self reported parenting of clinically anxious and non-anxious parents will differ
2. Observed parenting, in a fear-evoking situation, will differ between clinically anxious and non-anxious parents
3. Clinically anxious parents will exhibit greater attentional bias to child threat words than non-anxious parents
4. Clinically anxious parents will show a different pattern of errors in detecting emotion in children’s faces and voices compared to non-anxious parents

Stage 1 will also explore techniques that might be employed in a preventative intervention. Parents and children will complete a number of tasks exploring parents ability to: disguise their fear; change their patterns of reinforcement and verbal fear-information giving; and rapidly learn to devise fear-exposure programmes.
1. Non-anxious parents will be more successful at disguising their fear than clinically anxious parents
2. A brief (ten minute), educational intervention will improve parenting of both groups of parents when in a fear-evoking situation
3. A brief (ten minute) educational intervention will enable clinically anxious and non-anxious parents to devise acceptable fear hierarchies for managing fear in children

Stage 2 will develop and pilot an intensive, one-day, group parenting-based intervention for anxious parents. An intervention manual will be developed, taking account of existing knowledge, clinical experience, new results from the PI's other research, and by running

exploratory workshops. It is hypothesised that anxiety at 12 months will be lower in the children of the parents who were randomised to receive the intervention, when compared to those in the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The NRES Committee London East approved the project on 18/8/2011, ref: 11/LO/0759. An amendment was approved on 1/12/2011. A second amendment was approved on 12/7/2012.

Study design
Interventional and Observational; Design type: Prevention, Cross-sectional study, stage 2: randomised study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Topic: Mental Health Research Network; Subtopic: Anxiety; Disease: Anxiety

Interventions
In stage 1, participants with an anxiety disorder or without an anxiety disorder take part in some lab-based tasks.

In stage 2, a different group of participants are randomised to the parenting intervention or no parenting intervention.

Parenting workshop, Intensive, one-day, group parenting-based intervention for anxious parents with two follow-up telephone calls.

Follow-up length: 12 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Stage 1:
The Fear Survey Schedule for Children – Revised
The Revised Children's Anxiety and Depression Scale

Stage 2:
Anxiety Disorders Interview Schedule for Children; Timepoint(s): 12-month follow-up

Secondary outcome measures
1. Fear Survey Schedule Parent version
2. Fear Survey Schedule revised Child version
3. Spence Child Anxiety Scale – Parent Version
4. Spence Child Anxiety Scale
5. Semi-structured interview examining parental behaviour management style

Overall study start date
13/01/2012

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Parents with children aged 3 to 9 years
2. For the intervention component, the parent must have an anxiety disorder

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Stage 1: Planned sample size: 128; UK sample size: 128. Stage 2: Planned sample size: 100; UK sample size 100

Key exclusion criteria
Stage 1
1. Parent or child has moderate to severe learning disability
2. Parent or child does not have moderately strong English

Stage 2
1. Parent or child has moderate to severe learning disability
2. Parent or child does not have moderately strong English
3. Parent has a disorder that would make participation in a group intervention problematic (e.g. severe personality disorder, uncontrolled psychosis), as determined by the referring clinician

Date of first enrolment
13/01/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
Brighton
United Kingdom
BN1 9QG

Sponsor information

Organisation
Brighton and Sussex Medical School

Sponsor details
Medical Research Building
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Sponsor type
University/education

ROR
https://ror.org/01qz7fr76

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) Grant Codes: NIHR-CDF-2010-03-036

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/09/2018	21/01/2019	Yes	No