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 No longer recruiting	Prospectively registered		
30/07/2012		Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/07/2012	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
21/01/2019	Mental and Behavioural Disorders			

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

Contact name

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Contact details

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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 Biology Road Falmer Brighton England United Kingdom BN1 9PS

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