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Treatment of child anxiety disorder in the context of maternal anxiety

Submission date	Recruitment status	[ ] Prospectively registered
06/06/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/01/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/02/2016	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G0601020

Study information

Scientific Title
Treatment of child anxiety disorder in the context of maternal anxiety: a randomised controlled trial

Acronym
MaCh

Study objectives
In an RCT for child anxiety occurring in the context of maternal anxiety:
1. Is the impact of Child Cognitive Behaviour Therapy (CCBT) enhanced by first providing CBT to the mother for her own anxiety?
2. Is the impact of CCBT enhanced by the addition of therapeutic measures designed to improve the quality of the mother-child relationship?

Secondary questions:
3. Is sustained improvement in child anxiety significantly associated with a reduction in maternal anxiety?
4. Is sustained improvement in child anxiety significantly associated with improvements in maternal modelling, encouragement, over-controlling/over-protective behaviour, and associated cognitions?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Local Research Ethics Committee, 13/11/2007, ref: 07/H0505/156

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Mental and behavioural disorders

Interventions

Current interventions as of 24/04/2012
Arm 1: CCBT + MCBT + MCI control
Arm 2: CCBT + MCBT control + MCI
Arm 3: CCBT + MCBT control + MCI control

MCBT: CBT for maternal anxiety disorder
This will consist of an eight-session (one hour each) intervention for mothers delivered by a clinical psychologist (or equivalent) over eight weeks. Sessions will take place in the participants' local Child and Adolescent Mental Health Service (CAMHS), within their home, or at the University of Reading. The programme will follow a manualised transdiagnostic treatment for adult anxiety disorders.

MCBT control: Supportive Counselling
This will consist of either two or eight sessions (one hour each) of supportive counselling, delivered by a clinical psychologist (or equivalent) over eight weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading. The supportive counselling programme will follow a manualised treatment.

CCBT: CBT for child anxiety disorder
All participating children will receive an eight-session (one hour each) intervention based on the Cool Kids programme, delivered by a clinical psychologist (or equivalent) over eight weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading.

MCI : Treatment of mother-child interaction
This intervention consists of 10 sessions; eight with the mother alone and two
with the mother and child together. This is a novel intervention which specifically targets anxiogenic features of the mother-child relationship. Specifically it aims to enhance maternal cognitions associated with child competence, reduce maternal overcontrol/overprotection, and enhance maternal warmth and encouragement. This is achieved through a combination of specific materials from existing family interventions for childhood anxiety and video-feedback techniques developed and piloted by the trial investigators. This intervention is provided by a clinical psychologist (or equivalent) in parallel with the CCBT sessions. Sessions will generally take place in the participants' local CAMHS, within their home, or at the University of Reading. The two mother and child sessions will be conducted within the laboratory at the University of Reading, as these involve the mother and child completing structured tasks which are video-recorded for feedback purposes.

MCI control: Family Lifestyle Management
This will consist of four sessions, two with the mother alone and two with the mother and child together. These sessions will focus on promoting a healthy lifestyle with a focus on family diet and exercise, based on existing packages applied within school settings. This intervention is provided by a clinical psychologist (or equivalent) in parallel with the CCBT sessions. Sessions will generally
take place in the participants' local CAMHS, within their home, or at the University of Reading.

For all treatment conditions, therapists will routinely rate the extent to which participants adhere to the intervention (e.g. completion of in-session and homework exercises, session attendance).

Previous interventions
Arm 1: CCBT + MCBT (CBT for maternal anxiety disorder) + MCI control (Treatment of mother-child interaction)
Arm 2: CCBT + MCBT control + MCI
Arm 3: CCBT + MCBT control + MCI control

MCBT control:
This will consist of an eight-session (one hour each) intervention for mothers delivered by a clinical psychologist (or equivalent) over eight weeks. Sessions will take place in the participants' local Child and Adolescent Mental Health Service (CAMHS), within their home, or at the University of Reading. The programme will follow a manualised transdiagnostic treatment for adult anxiety disorders.

MCBT control:
Supportive Counselling. This will consist of either two or eight sessions (one hour each) of supportive counselling, delivered by a clinical psychologist (or equivalent) over eight weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading. The supportive counselling programme will follow a manualised treatment.

CCBT:
All participating children will receive an eight-session (one hour each) intervention based on the Cool Kids programme, delivered by a clinical psychologist (or equivalent) over eight weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading.

MCI:
This intervention consists of 10 sessions; eight with the mother alone and two
with the mother and child together. This is a novel intervention which specifically targets anxiogenic features of the mother-child relationship. Specifically it aims to enhance maternal cognitions associated with child competence, reduce maternal overcontrol/overprotection, and enhance maternal warmth and encouragement. This is achieved through a combination of specific materials from existing family interventions for childhood anxiety and video-feedback techniques developed and piloted by the trial investigators. This intervention is provided by a clinical psychologist (or equivalent) in parallel with the CCBT sessions. Sessions will generally take place in the participants' local CAMHS, within their home, or at the University of Reading. The two mother and child sessions will be conducted within the laboratory at the University of Reading, as these involve the mother and child completing structured tasks which are video-recorded for feedback purposes.

MCI control: Family Lifestyle Management
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take place in the participants' local CAMHS, within their home, or at the University of Reading.

For all treatment conditions, therapists will routinely rate the extent to which participants adhere to the intervention (e.g. completion of in-session and homework exercises, session attendance).

Intervention Type

Behavioural

Primary outcome measure
The primary outcome is child anxiety (assessed both categorically [i.e. diagnosis] and continuously
[i.e. symptoms]). Diagnostic status will be assessed by the Anxiety Disorders Interview Schedule (ADIS) for DSM-IV: C/P administered to both the mother and child. Assessors will be blind to treatment condition. Assessors' beliefs about treatment condition will be formally assessed. Child anxiety symptoms will be assessed using questionnaires (Spence Children's Anxiety Scale [SCAS]) administered to the child, the mother and the child's teacher. These measures will be administered post-treatment, and at 6 and 12 month follow-up assessments.

Secondary outcome measures
1. Maternal anxiety, assessed categorically using the ADIS (DSM-IV) post-treatment, and at 6- and 12-month follow-up assessments
2. Maternal anxiety, assessed continuously using the following questionnaires post-treatment, and at 6- and 12-month follow-up assessments:
2.1. Depression Anxiety and Stress Scales (DASS)
2.2. Penn State Worry Questionnaire (PSWQ)
2.3. Social Interaction Anxiety Scale (SIAS)
2.4. Social Phobia Scale (SPS)
3. Maternal interactive behaviours will be assessed by filming the mother assisting the child perform an anxiety provoking task and applying standardised ratings of anxiogenic behaviours (i. e. modelling, lack of encouragement, overcontrol/overprotection). Interactive behaviours will be coded by independent, trained, reliable raters. Coders will be blind to the purpose and conditions of the trial. Maternal cognitions will be assessed by a standardised interview. These measures will be conducted at the post-treatment assessment.

Overall study start date
01/01/2008

Completion date
01/12/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 21/03/2012
Child:
1. Aged 7 to 12 years
2. Primary diagnosis of DSM-IV generalised anxiety disorder, social phobia, separation anxiety disorder , panic disorder/agoraphobia or specific phobia, co-morbid with one of the previous disorders
3. Absence of significant physical or intellectual impairment (including autistic spectrum disorders)

Mother:
1. Primary carer
2. Current maternal DSM-IV anxiety disorder
3. Absence of severe comorbid disorder (e.g. severe major depressive disorder, psychosis, substance/alcohol dependence)

For both the mother and child:
Absence of psychotropic medication (or, if psychotropic medication is prescribed, it should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study)

Previous inclusion criteria
Child:
1. Aged 7 to 12 years
2. Primary diagnosis of Diagnostic and Statistical Manual of Mental Disorders - fourth edition (DSM-IV) generalised anxiety disorder, social phobia, or separation anxiety disorder
3. Absence of significant physical or intellectual impairment (including autistic spectrum disorders)

Mother:
1. Primary carer
2. Current maternal DSM-IV anxiety disorder
3. Absence of severe comorbid disorder (e.g. severe major depressive disorder, psychosis, substance/alcohol dependence)

For both the mother and child:
Absence of psychotropic medication (or, if psychotropic medication is prescribed, it should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
210

Key exclusion criteria
Child:
1. Aged less than 7 or over 12 years
2. No primary diagnosis of DSM-IV generalised anxiety disorder, social phobia, or separation anxiety disorder
3. Presence of significant physical or intellectual impairment (including autistic spectrum disorders)

Mother:
1. Is not primary carer
2. Absence of current maternal DSM-IV anxiety disorder
3. Presence of severe comorbid disorder (e.g. severe major depressive disorder, psychosis, substance/alcohol dependence)

For both the mother and child:
Presence of psychotropic medication at a stable dose for less than one month

Date of first enrolment
01/01/2008

Date of final enrolment
01/05/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Reading
Reading
United Kingdom
RG6 6AL

Sponsor information

Organisation
University of Reading (UK)

Sponsor details
Research & Enterprise Services
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Sponsor type
University/education

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Berkshire Healthcare NHS Trust (UK)

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	01/05/2015		Yes	No