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A pilot randomised controlled trial of an internet-based cognitive behavioral therapy (CBT) treatment for adolescent anxiety

Submission date
11/06/2012

Recruitment status
No longer recruiting

Registration date
11/06/2012

Overall study status
Completed

Last Edited
04/07/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to evaluate the effectiveness of an internet-based cognitive behavioral therapy (CBT) treatment for adolescents with an anxiety disorder. We want to find out whether anxious adolescents who receive the internet-based CBT treatment experience an improvement in their symptoms of anxiety immediately following treatment and whether these treatment gains are maintained 6 months and 1 year later. We also want to find out whether parental over-protection and over-control reduces the impact of treatment.

Who can participate?
Adolescents (aged 13 to 18) who meet the diagnostic criteria for a primary anxiety disorder, and the parent who is their primary caregiver.

What does the study involve?
Participants are randomly allocated to receive either internet-based CBT, the same internet-based CBT with additional sessions for their parent, or to be put on a waiting list to be randomly allocated to receive one of the treatments at a later date. Assessments are conducted before and after treatment and at 6-month and one-year follow-up.

What are the possible benefits and risks of participating?
The benefit of taking part is receiving treatment for an anxiety disorder. There are no anticipated adverse effects of the treatment. Thirty participants will wait 10 weeks for treatment to begin. However, local clinical services typically have a wait of 10 weeks or more for treatment and participants are given contact details for the clinic and asked to get in contact if they have any concerns or if there is a deterioration in the adolescent's symptoms in that time. Successful treatment of anxiety may involve some distress. However, this will be managed and contained by the therapists, who will receive regular supervision from an experienced Clinical Psychologist.

Where is the study run from?
University of Reading (UK)

When is the study starting and how long is it expected to run for?
June 2012 to May 2013

Who is funding the study?
Medical Research Council (MRC) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
12109

Study information

Scientific Title
A pilot randomised controlled trial of an internet-based cognitive behavioral therapy (CBT) treatment for adolescent anxiety

Study objectives
The study is a randomised controlled trial to evaluate the efficacy of an internet-based cognitive behavioral therapy (CBT) treatment for adolescents with an anxiety disorder. The purpose of this research is to evaluate the treatment and conduct a preliminary investigation of whether any family processes associated with adolescent anxiety are associated with treatment outcome.

The study hypotheses are:
1. Anxious adolescents who receive an internet-based cognitive-behavioural treatment will be

less likely to meet criteria for their primary anxiety diagnosis and be more likely to experience improvement in their symptoms of anxiety immediately post-treatment than a waitlist control group; and these treatment gains will be maintained at 6-month and one-year follow-up assessment.
2. Parental over-protection and over-control will moderate the impact of treatment that is, the more these parental characteristics are present, the less well the adolescents will fare in treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES London - Brent, 30/01/2012, ref: 12/LO/0119MHRNB

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Anxiety; Disease: Anxiety

Interventions
Adolescents will be randomised to receive either internet-based CBT (n=20), the same internet-based CBT with additional parental sessions (n=20), or waitlist control (n=20)

1. CBT for adolescent anxiety: 10 sessions of internet-based CBT for adolescent anxiety.
2. CBT adolescent anxiety + parents: 10 sessions of internet-based CBT for adolescent anxiety and 5 sessions of internet-based sessions for parents.
3. Once the waitlist period is completed, the waitlist group will be randomly allocated to receive one of the two treatments. Systematic assessments will also be conducted for the waitlist group once they have received treatment (to give total treated sample of n=60).

Assessments will be conducted pre- and post-treatment and at 6-month and one-year follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Clinical diagnoses; Timepoint(s): post-treatment and at 6-month and one-year follow-up

Key secondary outcome(s)
Added 12/04/2016:
1. Anxiety severity, measured by the ADIS-C/P
2. Self-report measure of anxiety symptoms (SCAS-C/P)
3. Impact of anxiety on the adolescent's life (CAIS-C/P)
Timepoint(s): post-treatment and at 6-month and one-year follow-up

Completion date
01/05/2013

Eligibility

Key inclusion criteria
1. Current primary anxiety disorder identified as primary problem
2. Any psychoactive medication at a stable dose for at least two months before the initial assessment, with agreement to maintain that dose until after the laboratory assessment
3. Able to understand and speak English at an age-appropriate level
4. Parent who is primary caregiver and the person that the adolescent lives with (for the majority of the time) agrees to participate in the study
5. Target Gender: Male & Female; Upper Age Limit 18 years; Lower Age Limit 13 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
1. Presence of psychotic symptoms, substance dependence, a risk of deliberate self-harm, attention deficit hyperactivity disorder (ADHD), conduct disorder, an autistic spectrum disorder or learning problems that would interfere with their understanding and participation in the trial (based on school/clinic/parent information)
2. Currently receiving therapy for their anxiety disorder
3. Parent has a significant intellectual impairment (as evidenced by them receiving a service from the local learning disabilities service)

Non-anxious adolescents:
Parent has a significant intellectual impairment (as evidenced by them receiving a service from the local learning disabilities service)

Date of first enrolment
01/06/2012

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
University of Reading (UK)

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) Grant Codes: G1002011

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository