ISRCTN86123204 https://doi.org/10.1186/ISRCTN86123204

Treatment of anxiety disorders in adolescents

Submission date
10/10/2017

Recruitment status
No longer recruiting

Registration date
23/11/2017

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Anxiety disorders affect a quarter of people during their lifetime and the majority will first be affected in childhood or adolescence, often carrying on into adulthood and creating a risk for other mental health problems, such as depression and substance abuse, as well as having a negative impact on educational and occupational prospects. Although Cognitive Behaviour Therapy (CBT), the gold standard psychological therapy for treating anxiety disorders, has been developed for adolescents, it is expensive and time consuming to deliver, resulting in lengthy waiting lists and limited access to treatment. There is a clear need for brief, low intensity treatments for anxiety disorders to be available within Child and Adolescent Mental Health Services (CAMHS). The aim of this study is to assess the feasibility of a full study to compare a new, brief treatment to an existing group therapy for adolescents with anxiety.

Who can participate?
Young people between 11 and 17.5 years old who are referred to the University of Reading Anxiety and Depression in Young People (AnDY) Research Clinic with an anxiety disorder

What does the study involve?
Participants are invited to join the study after their initial assessment at the clinic. Participants are randomly allocated to receive one of two treatments. One treatment is the new Adolescent Cognitive Treatment for Anxiety (ACTA), which involves six 1-hour sessions. The other treatment is an existing group therapy which involves eight 2-hour group sessions, and also two separate 2-hour parent sessions. Both treatments also have a 3-month booster session. Participants' involvement in the study lasts about 6 months. Participants and their parent/guardians are asked to complete some questionnaires, in addition to those used routinely in treatment, before and at the end of their treatment sessions and also at the 3-month booster session. Patient outcomes, expectations and experiences, as well as health economic factors, are assessed.

What are the possible benefits and risks of participating?
Participants will not benefit directly from taking part as those declining to participate will still receive routine treatment at the clinic. However, the additional time spent on assessments will increase the likelihood that the treatment works well for them. A wider benefit if the study is successful will be progression to a full study, which would potentially lead to the adoption of the ACTA treatment across clinical services in the UK to fulfill the need for a low-intensity treatment for adolescent anxiety. Participation in the study will involve completing more questionnaires

than would be usual in typical treatments. Information sheets will provide clear information regarding this and participants will be informed that they are free to withdraw from the study at any time should they wish. The assessments are similar to those used in routine clinical practice, and any distress of discomfort caused by these will be monitored and dealt with according to clinic procedures.

Where is the study run from?
The Anxiety and Depression in Young People (AnDY) Research Clinic at the University of Reading (UK)

When is the study starting and how long is it expected to run for?
July 2017 to August 2018

Who is funding the study?
University of Reading (UK)

Who is the main contact?
Lucy Taylor, Trial Coordinator
l.a.taylor@reading.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Lucy Taylor

Contact details
Anxiety and Depression in Young People (AnDY) Research Clinic
School of Psychology and Clinical Language Sciences
University of Reading
Earley Gate
Reading
United Kingdom
RG6 6AL
+44 (0)118 378 6435
l.a.taylor@reading.ac.uk

Additional identifiers

Protocol serial number
TAD-A 1.0

Study information

Scientific Title
Treatment of anxiety disorders in adolescents - a feasibility study for a brief cognitive therapy for adolescent anxiety disorders

Acronym
TAd-A

Study objectives
Is it feasible to run a randomised controlled trial to compare a novel, brief psychological treatment for anxiety disorders to an existing group psychological treatment?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS South Central Berkshire B Research Ethics Committee, 07/09/2017, REC ref: 17/SC/0412

Study design
Single-centre interventional feasibility study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adolescent anxiety disorders

Interventions
Participants are invited to join the study after their initial assessment at the clinic. 48 adolescents whose primary presenting problem is an anxiety disorder will be randomised to receive either this new treatment or an existing group therapy. Randomisation will be conducted using computer generated random numbers (using online randomisation software) with the allocations in numbered sealed envelopes so that they are concealed until the assignment of treatment group. Families will be assigned to treatment condition within the clinic follow-up assessment which is organised by clinic staff who have not been involved in the generation of the random allocation sequence.

1. New treatment: Adolescent Cognitive Treatment for Anxiety (ACTA) - 6 individual 1-hour sessions with a trained therapist.
2. Control treatment: Established group therapy of 8 2 hour group sessions with a trained therapist followed by a 3-month booster session. Parents also attend 2 separate group sessions.

Both treatments also have a 3-month booster session. Participants' involvement in the study lasts approximately six months. Participants and their parent/guardians are asked to complete some questionnaires, in addition to those used routinely in treatment, before and at the end of their treatment sessions and also at the 3 month booster session.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of a definitive RCT on the basis of acceptability of the treatments and trial procedures measured at the end of treatment and after the 3 month follow-up session.

Treatment and trial acceptability is assessed through examination of recruitment rates, rate of treatment drop out, and retention to research assessments post treatment and at 3 month follow up (and also a self-report measure, the Commission for Health Improvement Experience of Service Questionnaire (ESQ) completed by parent and young person post treatment and at 3-month follow up).

Feasibility will also be informed by evidence that ACTA can be delivered so that it is clearly distinct from the Chilled Group Therapy, with high levels of fidelity by practitioners and credibility with patients in both arms. This will be measured using a treatment integrity scale to compare video tapes of a sample of the sessions, and also on a session by session basis using therapy content checklists completed by clinicians and Session Rating Scales (SRS) completed by the young person.

Key secondary outcome(s))
1. Anxiety symptoms, measured using Revised Children Anxiety and Depression Scales (RCADs, child and parent report), administered at baseline, prior to each treatment session, at the end of treatment and at the 3 month follow up session
2. The extent to which anxiety interferes in the adolescent's life, measured using the Child Anxiety and Impact Scale (CAIS, child and parent report) at baseline, post treatment and after 3 months and supplemented by Adolescent Sleep Questionnaire (child report) administered at these time points to probe participants' sleep patterns
3. Diagnostic status, measured using a full diagnostic assessment which will take place prior to treatment and after the 3-month follow up. Each of these will comprise two diagnostic interviews (one with the parent/carer, one with the young person) where presence of an anxiety disorder will be determined by administering the Anxiety section of the Anxiety Disorders Interview Schedule (ADIS) and presence of a mood disorder will be determined by administering the Kiddie Schedule for Affective Disorders and Schizophrenia (K-SADS)
4. Overall functioning assessed using the Children's Global Assessment Scale (CGAS), and changes to this will be measured using the Clinical Global Impression Scale – Improvement (CGI-I)
5. Health-related quality of life, measured using the EuroQol (Quality of Life) (EQ-5D, parent and child report) and the paediatric measure Child Health Utility (Paediatric Quality of Life) (CHU-9D, parent and child report) at baseline, post treatment and at 3-month follow up
6. Healthcare resource usage, measured by parent/care completion of a Client Services Receipt Inventory (CSRI) at baseline, post treatment and at 3 month follow up using patient-health diaries to facilitate recall. Also, economic logs will be completed by Clinicians and Supervisors to measure time and resources spent on all aspects of the treatment
7. Negative impacts of the treatments and the trial procedure to participants and their parents as identified through qualitative interviews after the 3-month follow-up session

Completion date
04/06/2019

Eligibility

Key inclusion criteria
1. Young people (aged 11-17.5 years at intake) whose primary presenting disorder is a DSM-5 diagnosis of an anxiety disorder
2. If young people have been prescribed psychotropic medication the dosage must have been stable for two months

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 years

Upper age limit
17 years

Sex
All

Key exclusion criteria
1. Young people with co-morbid conditions that are likely to interfere with treatment delivery, to include an established autistic spectrum disorder or learning disabilities, suicidal intent or recurrent or potentially life-limiting self-harm (i.e., current frequency of at least once per week or self-harm that requires medical attention)
2. Young people with a primary presenting disorder other than an anxiety disorder (including a DSM-V diagnosis of major depressive disorder (MDD))
3. Young people identified by social services as currently 'at risk' due to child protection concerns

Date of first enrolment
02/10/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Anxiety and Depression in young People (AnDY) Research Clinic
School of Psychology and Clinical Language Sciences
University of Reading
Earley Gate
Reading
United Kingdom
RG6 6AL

Sponsor information

Organisation
University of Reading

ROR
https://ror.org/05v62cm79

Funder(s)

Funder type
University/education

Funder Name
University of Reading

Alternative Name(s)
The University of Reading, UoR

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Quantitative data will be stored in anonymised form as SPSS files. The datasets generated during and/or analysed during the current study will be stored in a publically available repository, the University of Reading Research Data Archive (http://researchdata.reading.ac.uk), to be made available one year after the completion of the study.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/04/2019	29/04/2019	Yes	No

HRA research summary	28/06/2023	No	No