

# Treatment of anxiety disorders in adolescents

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| <b>Submission date</b><br>10/10/2017   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>23/11/2017 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>29/11/2022       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> Record updated in last year |

## Plain English Summary

### 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 or 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](mailto:l.a.taylor@reading.ac.uk)

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 hypothesis

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

## Condition

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 measure**

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.

## **Secondary outcome measures**

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

**Overall study start date**

03/07/2017

**Overall study end date**

04/06/2019

## **Eligibility**

**Participant 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

**Age group**

Child

**Lower age limit**

11 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

48

**Participant 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

**Recruitment start date**

02/10/2017

**Recruitment end date**

31/12/2018

# Locations

## Countries of recruitment

England

United Kingdom

## 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

## Sponsor details

University of Reading

Whiteknights Campus

Reading

England

United Kingdom

RG6 6AK

## Sponsor type

University/education

## ROR

<https://ror.org/05v62cm79>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Reading

## Alternative Name(s)

UoR

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

The study protocol is being prepared for submission for publication to Trials, an open access peer-reviewed journal. Planned publication of the results in a high-impact peer reviewed journal.

## Intention to publish date

04/06/2020

## 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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>     | protocol | 25/04/2019   | 29/04/2019 | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |