

The AnDY (Anxiety and Depression in Young People) Research Clinics – Oxford and Reading

RESEARCH ACTIVITY APPROVAL PROCESS

Background

The National Institute for Health Research (NIHR) Oxford Health Biomedical Research Centre (BRC) was set up to create an effective interface between translational research and clinical care. One of the BRC themes is 'Mental Health in Development', which has an overall aim of developing targeted, effective, and accessible mental health interventions that meet the needs of diverse Children and Young People 0 - 18 years. A key objective for the BRC has been to establish an integrated research and clinical assessment and treatment centre for children and adolescents with anxiety disorders and depression, known as the Anxiety and Depression in Young People (AnDY) Research Clinic – Oxford, in collaboration with Oxford Health NHS Foundation Trust Child and Adolescent Mental Health Services (CAMHS). This partners the successful AnDY Research Clinic at the University of Reading, a collaboration between the University of Reading and Berkshire Healthcare NHS Foundation Trust. Both AnDY Research Clinics provide high quality assessments and treatment for patients, who have improved access to research opportunities. This in turn enables the development of better assessment and treatment approaches that can be rapidly implemented to provide better care for patients.

The AnDY Research Clinics (Oxford and Reading)

The AnDY Research Clinics provide assessments and brief/low-intensity psychological interventions to children and young people who meet diagnostic criteria for an anxiety disorder, depression or OCD. They occupy the gap between services that offer intervention for emerging mental health difficulties such as worry and low mood (e.g., psychoeducation, non-directive counselling, and sleep hygiene) and specialist NHS CAMHS teams that offer high-intensity treatments for severe and complex difficulties (e.g., high-intensity CBT). They are guided by the CYP IAPT programme principles of service user participation, collaborative care, clinically relevant routine outcome monitoring and timely access to evidence-based interventions. Because of this, it is not possible to deliver treatment studies that involve a 'waitlist' control.

Once a child or young person has been referred to the clinic, they (and their parent/carer) are invited to attend an initial diagnostic assessment and to complete baseline self-report measures. The diagnostic assessment is conducted to determine eligibility to the service and guide decision-making around which intervention the young person receives. It uses sections from two validated semi-structured interview schedules to determine whether the young person met diagnostic criteria for an anxiety or related disorder and/or depression; the Anxiety Disorders Interview Schedule (ADIS-IV-C/P; Silverman et al., 1996) (adapted for DSM-5) and the Kiddie Schedule for Affective Disorders and Schizophrenia Present and Lifetime (K-SAD-S-PL; Kaufman et al., 1997).

The assessment always includes a comprehensive assessment of risk to identify any past or current risks to self (e.g., self-harm and suicidality), to others (e.g., physical violence), and from others (e.g., abuse and neglect). The diagnostic assessment typically involves the young person and parent/carer being interviewed separately. All assessments are carried out by trained assessors (under the supervision of an experienced clinician who oversees the assessment) or clinicians working within the service. Assessors are trained to high levels of reliability and receive supervision for every assessment from a clinical psychologist (or equivalent) with extensive experience of delivering and supervising diagnostic assessments and proven reliability.

Following assessment, the young person and their parents/carers attend an intervention planning appointment to discuss the outcome of the assessment, reach a mutual understanding of the young person's main problem/s and

goals, and make shared decisions about next steps. This is also the point at which they are offered the opportunity to take part in research. If the young person is not eligible for the service, they receive signposting or are referred elsewhere as appropriate.

Most interventions are delivered by qualified or trainee CWP (or the equivalent role in adult IAPT services, Psychological Wellbeing Practitioners (PWP)), who have had subsequent training to work with children and young people). Patients (parents/carers if parent-led CBT) complete routine outcome measures prior to every session to guide therapy and track progress.

Please note, due to resource limitations, diagnostic assessments are only conducted pre-treatment but can be included post-treatment if the project is able to fully resource this (please see later 'Costs' section). At the end of treatment, the young person's progress is reviewed and if they require further input they are referred on as appropriate and discharged from the service.

Service criteria

- The young person is school-aged (between 4 and 17 years)
- The young person is entitled to mental health support from Oxford Health NHS Trust or Berkshire Healthcare NHS Foundation Trust
- The young person's main difficulty is anxiety, obsessive compulsive disorder (OCD) or depression, which causes distress and/or interferes with day-to-day functioning
- The level of risk is not at a level that would require constant monitoring and management (i.e., at a level that would make engaging in a psychological therapy difficult)
- If the young person is taking psychotropic medication, that this is part of a coordinated package of care with clear lines of responsibility and accountability
- The young person (and/or parent/carer where applicable) is willing to engage in a psychological therapy (and willing to prioritise and adhere to an agreed therapy contract)

Measures routinely used in the clinic

- The Revised Child Anxiety and Depression Scale (RCADS; Chorpita et al., 2000) is used to measure symptoms of anxiety disorders and depression at every session.
- The Child Anxiety Impact Scale (CAIS; Langley et al., 2004) is used to determine the extent to which anxiety interferes in the young person's life.
- The Outcome Rating Scale (ORS; Miller et al., 2003) is used to assess functioning across different areas of the young person's life.
- The Goal Based Outcomes tool (GBO; Law & Jacob, 2015) is used to develop and evaluate the young person's progress on their goals.
- The Session Rating Scale (SRS; Duncan et al., 2003; Miller et al., 2000) is used to assess key dimensions of an effective therapeutic relationship and is typically given at the end of each therapy session.
- At the end of treatment, children and young people and their parents/carers rate their satisfaction with the service they have received using the Experience of Service Questionnaire (ESQ; Astride-Stirling, 2002).

Other measures may also be routinely given to some children/young people (e.g., for specific disorders) and parents/carers. We can discuss this further with you. Where possible, we prefer you not to introduce additional measures. If additional measures are included, we would prioritise those that are clinically meaningful. We also require studies to collect data on adverse events and report this data in subsequent outputs.

Patient numbers

When operating at full capacity, each clinic will conduct approximately 250 new assessments per year. Based on our experience from AnDY Research Clinic – Reading, we anticipate that in the Oxford clinic, at least 90% of referrals will be offered treatment and at least 90% will complete a full course of treatment.

Research oversight

The AnDY Research Clinics (Oxford and Reading) Research Steering Committee oversees the development and implementation of the research programmes across the AnDY Research Clinics in Oxford and Reading.

The objectives of the Steering Committee are to:

- Ensure that there are fair and transparent processes for researchers wishing to conduct research in the clinic, and implement changes where necessary.
- Review proposals for research to be undertaken in the clinic.
- Monitor and review ongoing research projects being conducted in the clinic.
- Ensure appropriate liaison with PPI members and key stakeholders including the Department of Experimental Psychology and Department of Psychiatry, University of Oxford, Oxford Health NHS Foundation Trust, University of Reading, and Berkshire Healthcare NHS Foundation Trust.

To support the set-up of the Oxford clinic (which launched in 2024), the committee will evaluate its progress to ensure that it is meeting the objectives and specific milestones set out in the BRC ‘Mental Health in Development’ Theme work package (WP) 3.3 ‘Innovation Through Research-Ready Clinics’. The objectives and milestones are initially (first 1-2 years) to establish governance and operational procedures, establish advisory groups, launch activities for the clinic and recruit the first clinical participants to research. In the medium term, the objective is to recruit clinical participants to multiple research studies.

The Research Steering Committee meets quarterly (and more frequently if needed). It is chaired by one of the Oxford-based co-leads for the BRC Mental Health in Development Work Package ‘Innovation through research-ready clinics’.

Members are:

- Oxford-based co-leads for BRC Mental Health in Development WP3.3: Innovation through research-ready clinics
- Clinic Director of the AnDY Research Clinics - Oxford and Reading (in the case of absence, an appropriate delegate will be assigned for each clinic)
- Representative from Child and Adolescent Mental Health Services (CAMHS), Oxford Health NHS Foundation Trust
- Representative from the University of Reading
- Representative from Berkshire Healthcare NHS Foundation Trust
- Representatives from Oxford University from a range of relevant research areas (e.g., different anxiety disorders and depression; different age ranges; associated difficulties)
- 2 Patient and public involvement (PPI) representatives (including young people and parents/carers)
- An independent researcher

Research priorities in the clinic

The following principles are used to determine what research is undertaken in the clinics:

1. That the proposed research project will enable the BRC overall aims and milestones to be achieved (i.e., recruitment to research studies, prioritising studies that involve the development of targeted, effective, and accessible mental health interventions that meet the needs of diverse children and young people)
2. That the research project is aligned with the priorities of Oxford Health NHS Foundation Trust and/or Berkshire Healthcare NHS Foundation Trust. (depending on the AnDY Research Clinic(s) you wish to recruit through).
3. That the research project has patient and public involvement (PPI) and involvement of other key stakeholders as necessary.
4. That the project reflects principles of equality, diversity and inclusion.
5. Where there are competing research projects, those that are externally funded will take priority, followed by those which have a good chance of underpinning future research funding.
6. That the work in the project plan is sufficiently resourced.
7. That risks have been assessed and appropriate mitigating actions are in place.

Research in the clinic is likely to be wide-ranging and may involve the development/validation of measures, analysis of previously collected data, clinical studies (including single case design, pilot/feasibility, randomised controlled trials) and service evaluation. Research activity must be able to be embedded within existing clinical procedures and therefore researchers will need to work with the clinic to ensure that the study methodology can be fully embedded.

Research involving digital technology

Research involving digital technology (e.g., apps, online interventions) may require additional approvals within Oxford Health and/or Berkshire Healthcare NHS Foundation Trust, e.g., cyber security and clinical safety reviews. These can take a substantial amount of time to complete, even if the technology is already in use elsewhere (including within the NHS Trust associated with the clinic(s) you are applying to recruit through). Please get in touch as early as you can to ensure this does not cause undue delay to your research study.

Applying to conduct research in the clinic

Please see Figure 1 for an overview of the process of applying for your research to be conducted in the AnDY Research Clinics (Oxford and Reading). You will need to complete an application and arrange a meeting to discuss your proposed research with the Clinic Director. If the Clinic Director considers your research to be feasible in principle, then your application will be reviewed by the Steering Committee.

Process of getting approval for research to be conducted in the AnDY Research Clinic- Oxford

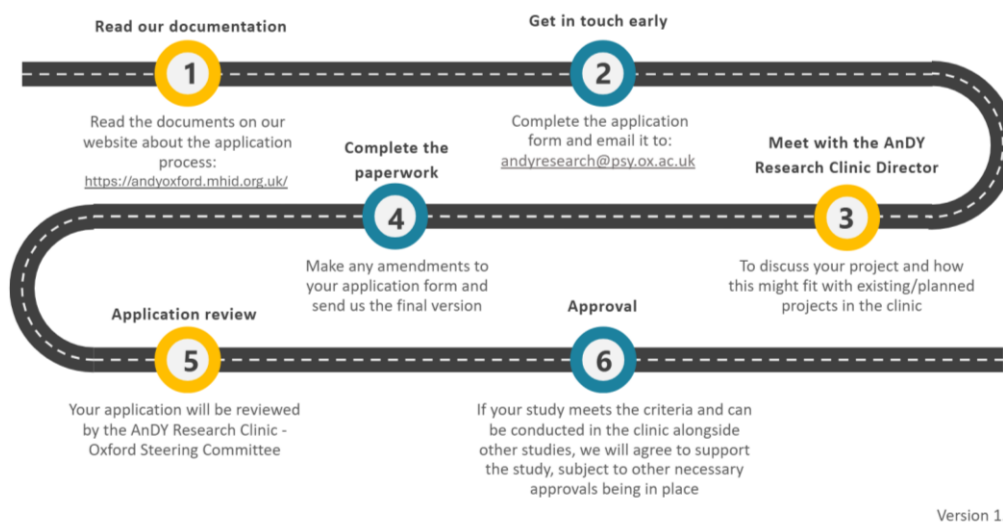


Figure 1. Process of getting approval for research to be conducted in the AnDY Research Clinics (Oxford and Reading).

Costs

Please ensure that you can resource the initial diagnostic assessments and any additional measures that will need to be collected within the clinic(s). This can either be done by costing for a research assistant (including training as well as conducting assessments) or providing funding directly to the clinic(s). We can provide further advice around this.

Recruitment

Although we can give an indication of likely numbers coming through the clinics (e.g., by age and clinical presentation), this can only ever be approximate. This means that you may need to also conduct additional outreach activities (e.g., via local schools and other services) in liaison with the Clinic Director (to ensure any additional patient throughput is manageable). The responsibility for achieving recruitment targets lies with the research project lead.

Project timelines

Approval for projects will be given for the recruitment period provided on the project's application form. The Steering Committee will monitor the progress of research studies through the clinics to ensure that the wider programme of research is on track. If there are problems with recruitment to a study, there may be some flexibility around dates. However, this will depend on other studies being conducted in the clinics.

Once research is approved

Once your research in the clinics has been approved by the Steering Committee, please keep us updated as to progress, e.g., funding application and liaise with us around your protocol development and ethical and local R&D approval. If there are any major changes, especially to recruitment timelines, please let us know immediately, as your approval will only be for the start/end date outlined in your application. We will also need to work with you around the management and transfer of data.

Authorship on research outputs

Contributions from members of the AnDY Research Clinics may warrant authorship on publications and other outputs (for example, where there has been substantial contribution to the design of the study and acquisition of the study data) either as individuals or a multi-author group. Researchers must follow recommendations (e.g., [ICMJE authorship criteria](#)) to ensure that contributors who have made substantive contributions to an output are given credit as authors.

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