

# The feasibility of cognitive behavioural therapy for depression and anxiety adapted for psychosis risk in primary care

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<b>Registration date</b> 29/07/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/07/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many people experience mild or brief sensations that can be hard to make sense of, for example, seeing or hearing things that other people cannot see or hear (hallucinations) and believing things that are not true (delusions). For some people, these experiences pass or are not troubling. For others, these can be extremely disturbing, and for about a third, these can develop into psychosis. Most people who go on to develop psychosis describe these mild or brief symptoms before becoming unwell. Usually, these people first seek help for anxiety or depression and do not mention their unusual experiences. This can delay access to the treatments they need, and people often wait years to access treatment, which results in more severe symptoms and higher healthcare costs.

Talking therapies for anxiety and depression are delivered by NHS 'Improving Access to Psychological Therapies' (IAPT) services. Up to a third of people referred to IAPT have unusual experiences (but may not report them). These individuals usually do not meet the criteria for 'secondary care' services designed for people with severe and enduring mental health problems. IAPT services are designed for people with anxiety and depression, and do not routinely take into account unusual experiences. If people do disclose their unusual experiences, they may be subject to multiple referrals between services, which is unhelpful to the person and costly to the NHS.

Mental health teams expect a significant increase in demand following Covid-19, including from people with unusual experiences. This will place considerable pressure on services. NHS resources need to be used flexibly and effectively. The current study will assess (1) the use of measures to identify and assess individuals who have unusual experiences referred to IAPT, (2) whether they can be offered psychological therapy from a qualified therapist with additional training to take account of unusual experiences, and (3) whether this is beneficial. This study will ask participants to complete outcome measures and tell us about their experience of the adapted therapy. If the study shows that the adapted therapy is acceptable and may be beneficial, a controlled trial will be run to assess the impact in more detail.

### Who can participate?

Adults over 18 years, who meet criteria for NHS IAPT services (i.e. have a primary diagnosis of mild to moderate anxiety or depression)

### What does the study involve?

This longitudinal controlled trial compares best practice CBT for depression and anxiety (CBT-BP) with CBT adapted for psychosis risk (CBT-PR), in patients meeting criteria for UK primary care services and who are also clinically high risk for psychosis.

### What are the possible benefits and risks of participating?

Participants will receive best practice CBT for their depression or anxiety, which will also take into account their unusual experiences. They will be invited to reflect on these experiences, which may cause some discomfort. However, most people find it helpful to talk about these experiences, and they will be doing so with qualified NHS clinicians.

### Where is the study run from?

University of Southampton (UK)

### When is the study starting and how long is it expected to run for?

April 2021 to March 2023

### Who is funding the study?

Economic and Social Research Council (UK)

### Who is the main contact?

Prof Katherine Newman-Taylor, [knt@soton.ac.uk](mailto:knt@soton.ac.uk)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Prof Katherine Newman-Taylor

### ORCID ID

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### Contact details

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## Additional identifiers

### Integrated Research Application System (IRAS)

290648

## Central Portfolio Management System (CPMS)

51024

### Protocol serial number

Grant Code 519251215, protocol number 64425

## Study information

### Scientific Title

Adapting primary care services to meet the needs of people with early signs of psychosis: A feasibility study

### Study objectives

Is CBT-PR feasible and acceptable in primary care mental health settings?

Does CBT-PE signal improvements in clinical and recovery outcomes?

Are socio-demographic, clinical and relational factors associated with therapy engagement and outcomes?

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 21/12/2021, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8384, 02071048061, 0207 104 8077; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 21/NE/0206

### Study design

Longitudinal non-randomized feasibility study

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Psychosis

### Interventions

Design: This feasibility study will use a within-participants, repeated measures design. An initial six-month control period will be implemented in participating services, comprising treatment as usual with just the initial two-item screen that participating services have decided to employ routinely. Following this, participants will be recruited over the following six months, forming a 12-month intervention period (allowing for completion of therapy, which lasts no more than six months).

Measures: Routine clinical measures and additional at-risk mental states (ARMS) and relational measures will be taken regularly over intervention and control periods.

Procedure: Assessing clinicians will introduce the study to patients meeting criteria and seek agreement to pass on their contact details (via secure nhs.net email) to a researcher with the necessary approvals to work within the NHS Trust. The researcher will contact the participant and arrange to meet (in line with current NHS patient contact protocols, e.g., face to face, phone call or videoconferencing). Potential participants will be provided with a written information sheet and allowed to ask any questions. After a minimum of 48 hours to reflect on their decision, the researcher will contact potential participants to answer any further questions about the study and ask if they would like to provide informed consent (written or verbal, depending on mode of contact). This is estimated to take no longer than 15 minutes. The assessing clinician and researcher will confirm that participants will receive full treatment as usual if they decide not to participate.

During the control period, as per routine clinical practice, the assessing clinician will administer standard IAPT service measures: GAD-7, PHQ-9, WSAS, ADSM (anxiety-specific measures used as indicated), and the two-Item ARMS screen.

During the intervention period, the researcher will administer additional ARMS and relational measures (PQ-16; PAM-R; ECR-12) and the DWM-S (Adapted) before the first treatment session and following the last treatment session. An option will be provided for the participant to self-complete the measures via a secure Qualtrics link if preferred.

A routinely implemented patient experience questionnaire will also be completed, once at the end of assessment and once at the end of treatment, to gain feedback on patient experience of assessment and treatment.

Additionally, the researcher will invite patients and therapists to participate in a qualitative post-therapy interview to gain feedback on their experience of the augmented assessment and intervention.

Informed consent for the use of measures collected over the intervention period, augmented CBT+ARMS intervention, and qualitative post-therapy interview will be sought from all participants to meet the research aims. At the end of the research, participants will be fully debriefed and offered a written summary of the research findings when completed.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

The following primary outcome measures are completed pre- and post-therapy:

1. Eligibility rate measured using the number of positive responses on the two-item at-risk mental states (ARMS) screen
2. Problem indicator measured using the frequency of problem descriptors in the routine clinical data captured at assessment
3. Acceptability measured via the rates for consent, therapy completion and completion of measures using the IAPT Minimum Data Set Measures: Generalised Anxiety Disorder Questionnaire (GAD-7), Patient Health Questionnaire (PHQ-9), Work and Social Adjustment Scale (WSAS), Anxiety Disorder Specific Measures (ADSM), and Phobia Scales
4. Data on acceptability will also be sought via qualitative feedback on intervention from clinicians and patients

## **Key secondary outcome(s)**

The following secondary outcome measures are completed pre- and post-therapy:

1. Anxiety-specific measures that differ by presentation: IAPT CORE Minimum Data Set: GAD-7; PHQ-9; WSAS; ADSM; Phobia scales
2. At-risk mental states (ARMS) measures: two-Item screen, 16-Item Prodromal Questionnaire (PQ-16)
3. Relational measures: Psychosis Attachment Measure (PAM)-R 26-item measure of attachment, Experience in Close Relationships Scale (ECR)-12 12-item measure of attachment, and the Dysfunctional Working Models of Self and Others (DWM-S Adapted) 35-item measure of beliefs about self and others

**Completion date**

31/03/2023

## Eligibility

**Key inclusion criteria**

1. Over the age of 18 years
2. Meet criteria for NHS IAPT services (i.e. have a primary diagnosis of mild to moderate anxiety or depression)
3. Meet one or more of the two item ARMS screen
4. Able to engage in IAPT provision of care
5. Capacity to consent as determined by their assessing clinician

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Unsuitable for IAPT services (e.g. due to severity of illness or organic problems)
2. Lack capacity to consent as determined by their assessing clinician
3. Meet EIP/CMHT threshold criteria (e.g. due to severity of illness)
4. At significant risk to themselves or others
5. Participating in any other interventional research

**Date of first enrolment**

01/10/2021

**Date of final enrolment**

31/03/2022

## Locations

## **Countries of recruitment**

United Kingdom

England

## **Study participating centre**

### **Solent NHS Trust**

Solent NHS Trust Headquarters

Highpoint Venue

Bursledon Road

Southampton

United Kingdom

SO19 8BR

## **Study participating centre**

### **Dorset Healthcare University NHS Foundation Trust**

Sentinel House

4-6 Nuffield Road

Nuffield Industrial Estate

Poole

United Kingdom

BH17 0RB

## **Study participating centre**

### **St Marys Hospital**

Parkhurst Road

Newport

United Kingdom

PO30 5TG

## **Sponsor information**

### **Organisation**

University of Southampton

### **ROR**

<https://ror.org/01ryk1543>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Economic and Social Research Council

**Alternative Name(s)**

Social Science Research Council, ESRC, SSRC, UKRI ESRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Katherine Newman-Taylor, [knt@soton.ac.uk](mailto:knt@soton.ac.uk).

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/05/2025	22/07/2025	Yes	No
<a href="#">Participant information sheet</a>	version 1	28/06/2021	22/07/2025	No	Yes