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

Submission date
21/01/2022

Recruitment status
No longer recruiting

Registration date
29/07/2025

Overall study status
Completed

Last Edited
29/07/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Katherine Newman-Taylor

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290648

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51024, 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

Secondary study design
Non randomised study

Study setting(s)
GP practice, Medical and other records

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
07/04/2021

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 64; UK Sample Size: 64

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
England

United Kingdom

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
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PO30 5TG

Sponsor information

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Sponsor type
University/education

Website
https://www.southampton.ac.uk/

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal

Intention to publish date
15/05/2025

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.

IPD sharing plan summary
Available on request

Study outputs

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