

Tailoring evidence-based therapy for people with a common mental disorder (including psychotic experiences)

Submission date 25/06/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 27/08/2020	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 24/03/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Many people who access IAPT services have psychotic experiences in addition to common mental disorder, and are less likely to recover from depression and anxiety than people without psychotic experiences. We want to understand whether providing CBT therapists in IAPT services with additional skills training can help them to work more effectively with these service users, increasing the likelihood of recovery.

Who can participate?

Qualified Step 3 IAPT CBT therapists and adults aged 17+ who access CBT therapy in IAPT services with the presence of psychotic experiences will be eligible to take part.

What does the study involve?

We will aim to recruit 10 teams of 8-10 therapists in the IAPT service (Updated from 8 teams as of 23/03/2023). The teams will deliver usual care to service users with psychotic experiences and common mental disorder; people who have scored above a threshold on the Community Assessment of Psychic Experiences (CAPE) questionnaire, referred to as CAPE+. Following a control period, teams will be randomly selected to receive the additional skills training and supervision package at regular intervals. Non-identifiable data will be collected on service users treated by therapists in both the control and intervention periods of the trial. Additionally, CAPE+ service users will be invited to participate in a health economic questionnaire sub-study, and service user and staff participants will be invited to participate in qualitative interviews as part of a process evaluation.

What are the possible benefits and risks of participating?

Participation in this study is unlikely to provide any direct benefits, but it may help to enhance IAPT services in the future. It may benefit participants if they ever need to use IAPT services again. We do not envisage any harm from taking part in the study.

Where is the study run from?

TYPPEX WP4 is running in Improving Access to Psychological Therapies services in three NHS

mental health Trusts in England: Cambridgeshire and Peterborough NHS Foundation Trust (CPFT), Norfolk and Suffolk NHS Foundation Trust (NSFT) and Sussex Partnership Foundation Trust (SPFT).

When is the study starting and how long is it expected to run for?
December 2019 to January 2025

Who is funding the study?
Programme Grant for Applied Research (PGfAR) National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Polly Ashford, p.ashford@uea.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Polly Ashford

ORCID ID
<https://orcid.org/0000-0002-0865-2439>

Contact details
Norwich Clinical Trials Unit
University of East Anglia
Norwich
United Kingdom
NR4 7TJ
+44 (0)1603 597666
P.Ashford@uea.ac.uk

Type(s)
Scientific

Contact name
Prof Jesus Perez

Contact details
CAMEO South Union House
37 Union Lane
Chesterton
Cambridge
United Kingdom
CB4 1PR
+44 (0)1223 341500
jesus.perez@cpft.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

275169

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 275169, CPMS 44919

Study information

Scientific Title

Addressing common mental disorder and psychotic experiences: a stepped wedge cluster randomised trial with nested economic and process evaluation of a training package for CBT therapists in Improving Access to Psychological Therapies (IAPT) services.

Acronym

TYPPEX WP4

Study objectives

Providing CBT therapists with training to enhance existing CBT skills to allow them to work more effectively with people with common mental disorder and psychotic experiences will improve recovery rates for these patients in IAPT services.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 23/06/2020, South Central Berkshire REC (Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT; +44 (0)207 1048043; berkshire.rec@hra.nhs.uk), ref: 20/SC/0135

Study design

Interventional multi-centre cluster-randomized controlled trial with a stepped-wedge design

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mental health

Interventions

The trial intervention is a training and supervision package for IAPT therapists. The study will receive pseudonymised clinical data for service users on the caseload of a TYPPEX therapist in order to ascertain the impact of the intervention on service user recovery. Therefore most service users will not be consented to take part (with the exception of those taking part in the questionnaire sub-study), and the nature of their treatment and its duration will not be proscribed by the trial.

Step 3 Cognitive Behavioural Therapy (CBT) training for therapists treating people experiencing common mental disorder with psychotic symptoms.

The structured training programme includes:

Module 1: Background to the TYPPEX programme and psychotic experiences in the IAPT population.

Module 2: Assessment and formulation of common mental disorder with psychotic experiences.

Module 3: Interventions

Training is delivered across 3 days and is supported by 6 clinical supervision sessions.

Control type: internal control as part of the stepped-wedge design, whereby each cluster (therapy team) acts as its own control before receiving TYPPEX training, in a sequence determined by randomisation.

All eligible service users will be approached to take part in a questionnaire sub-study centered around the health economics outcomes of the trial. If they agree to take part, service users will receive a pack of questionnaires at the time of consent (baseline) and then again at 3, 6, 9 and 12 months after baseline. Service users will be asked to agree to the linkage of their questionnaire responses with their clinical data provided by the IAPT service.

Interviews will be carried out with service users, therapists, and wider stakeholders including the study team, observations of study team meetings, and analysis of non-confidential study documents. The aim of this qualitative work is to assess the views and priorities of all stakeholders involved in the experience and delivery of TYPPEX and to investigate implementation of TYPPEX as designed, including any influences on uptake, delivery and fidelity. Interviews will commence following CBT training.

Intervention Type

Behavioural

Primary outcome(s)

Proportion of CAPE+ caseload who reach IAPT-defined recovery, as calculated from routinely collected outcome data measured at discharge from the IAPT service:

1. Depression measured using the PHQ-9
2. Anxiety measured using GAD-7
3. Anxiety Disorder Specific Measures (there are several ADSMs, and the relevant one is chosen in each case based on the specific type of anxiety being experienced (e.g. OCD, social anxiety, generalised anxiety, etc).

Key secondary outcome(s)

1. Cost-effectiveness measured using: participant-reported service use at 3, 6, 9 and 12 months post-baseline, IAPT service costs, and service user IAPT-defined recovery at 1-year post-baseline
2. Health-related Quality of Life (HRQoL) measured using EuroQol EQ-5D-5L and EQ-5D-3L at 3, 6, 9, and 12 months post-baseline
3. Qualitative experiences of health care staff and service users measured using interviews after

the first CBT training sessions

4. Therapist adherence measured using a supervision checklist and adherence score completed during the 6 monthly supervision sessions held after CBT training

Completion date

31/01/2025

Eligibility

Key inclusion criteria

1. IAPT therapist - Training inclusion criteria:

1.1 Qualified Step 3 IAPT CBT therapist

1.2 Willing and able to provide informed consent to receive TYPPEX training and supervision

2. IAPT User - pseudonymised clinical data collection inclusion criteria:

2.1 Accepted onto the IAPT caseload for therapy and therefore meets service specific inclusion criteria to access IAPT treatment

2.2 Assessed for psychotic experiences, according to the presence of a scored Community Assessment of Psychic Experiences (CAPE-P15) questionnaire in their clinical record

3. IAPT User - health economic questionnaires inclusion criteria:

3.1 Meets IAPT service user Eligibility Criteria for pseudonymised clinical data collection

3.2 Presence of psychotic symptoms (according to a Community Assessment of Psychic Experiences (CAPE-P15) questionnaire cut-off value of 1.30 or above on both the frequency and distress sub-scales (hereafter referred to as CAPE+)

3.3 In the judgement of the treating therapist has sufficient proficiency in English to complete research questionnaires

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. IAPT therapist - Training exclusion criteria:

1.1 Has not completed Step 3 CBT IAPT training.

1.2 Works across more than one locality IAPT team.

1.3 Participated in the earlier TYPPEX WP3d feasibility study.

2. IAPT User - pseudonymised clinical data collection exclusion criteria:

2.1 Presence of mental disorder based on standard IAPT assessment meriting routine referral to National Institute of Clinical Excellence (NICE) step 4 treatment, i.e. to secondary mental health services.

3. IAPT User - health economic questionnaires exclusion criteria:

3.1 None

Date of first enrolment

30/09/2020

Date of final enrolment

30/04/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Fulbourn Hospital

Cambridgeshire and Peterborough NHS Foundation Trust

Elizabeth House

Cambridge

United Kingdom

CB21 5EF

Study participating centre

Hellesdon Hospital

Norfolk and Suffolk NHS Foundation Trust

Drayton High Road

Norwich

United Kingdom

NR6 5BE

Study participating centre

Sussex Partnership NHS Foundation Trust

Swandean

Arundel Road

Worthing

United Kingdom

BN13 3EP

Sponsor information

Organisation

Cambridgeshire and Peterborough NHS Foundation Trust

ROR

<https://ror.org/040ch0e11>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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 the current study will be available upon request from Prof Jesus Perez (jesus.perez@cpft.nhs.uk) once the trial follow-up and analyses are completed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/06/2022	23/06/2022	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes