

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

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

**Study website**  
<https://typpe.co.uk/>

## Contact information

**Type(s)**  
Public

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Scientific

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

275169

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

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

### **Secondary study design**

Cluster randomised 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.

**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 questionnaires 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 measure**

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)).

### **Secondary outcome measures**

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

### **Overall study start date**

01/12/2019

### **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

### **Age group**

Adult

**Sex**

Both

**Target number of participants**

Therapist recruitment target: 80 Service user recruitment target: 572 Service user health economics sub-study recruitment target: 286

**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**

England

United Kingdom

**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  
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## **Sponsor information**

**Organisation**  
Cambridgeshire and Peterborough NHS Foundation Trust

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CPFT and University of Cambridge Joint Research Office  
Elizabeth House  
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**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.cpft.nhs.uk/>

**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

### Publication and dissemination plan

Current publication and dissemination plan as of 23/03/2023:

Trial protocol in January 2022 and results of the trial in February 2026 in a high-impact peer-reviewed journal.

Previous publication and dissemination plan:

Trial protocol in January 2021 and results of the trial in February 2024 in a high-impact peer-reviewed journal.

### Intention to publish date

01/02/2026

### 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?
<a href="#">Protocol article</a>		22/06/2022	23/06/2022	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No