ISRCTN93895792 https://doi.org/10.1186/ISRCTN93895792

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

Submission date
25/06/2020

Recruitment status
No longer recruiting

Registration date
27/08/2020

Overall study status
Completed

Last Edited
24/03/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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://typpex.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
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United Kingdom
BN13 3EP

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

Sponsor details
CPFT and University of Cambridge Joint Research Office
Elizabeth House
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Cambridge
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United Kingdom
CB21 5EF
+44 (0)1223 746009
R&D@cpft.nhs.uk

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?
Protocol article		22/06/2022	23/06/2022	Yes	No
HRA research summary			28/06/2023	No	No