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Tailoring evidence-based psychological therapy for people with common mental disorder including psychotic experiences work package 3d: a feasibility study

Submission date 06/12/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/03/2019	**Overall study status** Completed	
Last Edited 26/03/2019	**Condition category** Mental and Behavioural Disorders	

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.
We also want to assess the feasibility of collecting additional health economics data from these patients to inform a definitive trial planned for 2020.

Who can participate?
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?
This feasibility study will train 8-10 therapists in each of three teams within the IAPT service (one team per mental health Trust). The training package will support therapists to deliver 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 training, therapists will treat an average of 3 CAPE+ service users each.

What are the possible benefits and risks of participating?
Participation in this study in 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 WP3d 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). CPFT is co-sponsor with University of Cambridge and is the lead site.

When is the study starting and how long is it expected to run for?
It will begin in April 2019 and recruitment will close in October 2019.

Who is funding the study?
It is funded by a Programme Grant for Applied Research (PGfAR) NIHR grant.

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
v1

Study information

Scientific Title

Addressing common mental disorder and psychotic experiences: a feasibility and preliminary effectiveness study of a training package for Step 3 CBT therapists in Improving Access to Psychological Therapies (IAPT) services.

Acronym
TYPPEX WP3d

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 Reliable Recovery rates for these patients in IAPT services

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/03/2019, South Central Berkshire REC (Bristol HRA Centre, Level 3, Block B, Whitefriars, Lewins Mead, Bristol BS1 2NT; nrescommittee.southcentral-berkshire@nhs.net; 0207 1048043), ref: 19/SC/0077

Study design
Single arm non-blinded interventional feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web for,at, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Mental health

Interventions
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 supervision sessions.

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A total of 45 CAPE+ service users will be asked to consent to the collection of health economic data via online questionnaires at baseline (therapy session 2), then at 3 months and 6 months after that. Routine clinical data for all CAPE+ service users will be provided by the Trusts to the Norwich Clinical Trials Unit in an anonymised form.

In this feasibility study, we will assess the viability of recruiting, training and supervising therapists, and their use of TYPPEX strategies. The most feasible and effective methods of collecting health economic data from service users will be assessed. Clinical and health economic data collected in the feasibility study will inform the design of the TYPPEX randomised controlled trial, which will test the hypothesis that care delivered to CAPE+ IAPT users by TYPPEX-trained therapists will be more effective and cost-effective than treatment-as-usual in IAPT services.

Intervention Type
Behavioural

Primary outcome measure
Reliable Recovery proportion rate for people with psychotic experiences (the proportion of service users reaching scores below 10 in PHQ-9 and 8 in GAD-7) measured via scores on the routinely collected PHQ-9 and GAD-7 and additionally at 24 weeks post-therapy commencement.

Secondary outcome measures
1. Feasibility of collecting health economics data via the EQ-5D and Adult Service Use Schedule to inform definitive RCT
2. Recruitment rate of consented CAPE+ IAPT users for health economic data collection
3. Assessment of the most feasible and effective methods of collecting health economic data
4. Feasibility of using an adapted version of the Early Intervention in Psychosis Adult Service Use Schedule (EI-ADSUS) with the IAPT patient population

Overall study start date
01/04/2019

Completion date
31/10/2019

Eligibility

Key inclusion criteria
1. IAPT therapist - Training inclusion criteria:
1.1 Qualified Step 3 IAPT therapist.
1.2 Willing and able to participate in TYPPEX training and supervision.
2. IAPT User - pseudonymised clinical data collection inclusion criteria:
2.1 Accepted onto the IAPT caseload for therapy and therefore meet service specific inclusion

criteria to access IAPT treatment,
2.2 Meet current criteria for IAPT Step 3 treatment,
2.3 Presence of psychotic experiences, according to CAPE-P15 cut-off values of 1.47 on both the frequency and distress sub-scales.
3. IAPT User - Health economic questionnaires inclusion criteria
3.1 Meets IAPT User Eligibility Criteria for pseudonymised clinical data collection
3.2 In the judgement of the treating therapist has sufficient proficiency in English to complete research questionnaires.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
45

Key exclusion criteria
1. IAPT Therapist - Training exclusion criteria:
1.1 Has not completed Step 3 High Intensity IAPT training.
1.2 Works across more than one locality IAPT team.
2. IAPT User - pseudonymised clinical data collection exclusion criteria
2.1 Presence of mental disorder based on standard IAPT assessment meriting routine referral to 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
04/04/2019

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House, Fulbourn Hospital
Cambridge
Cambridgeshire

United Kingdom
CB21 5EF

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

Sponsor details
Elizabeth House
Fulbourn Hospital
Cambridge
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Sponsor type
Hospital/treatment centre

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
We intend to publish the trial protocol in April 2019 and results of the feasibility study in January 2020 in a high-impact peer-reviewed journal.

Intention to publish date
31/01/2023

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No