Evaluating a training workshop for highintensity therapists to improve how well depression and anxiety treatments in Improving Access to Psychological Therapies (IAPT) services are tailored for clients who also experience difficulties managing their emotions, relationships and sense of self

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
06/12/2022		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
03/01/2023		Results		
Last Edited		Individual participant data		
23/10/2023	Mental and Behavioural Disorders	Record updated in last year		

Plain English summary of protocol

Background and study aims

Some people have difficulties managing their relationships, emotions or sense of self, some of whom have lived through adverse early life experiences. These difficulties are sometimes referred to as personality difficulties and sometimes are diagnosed as a personality disorder. People with these problems often experience other common mental health problems such as depression and anxiety and seek help from primary care mental health Improving Access to Psychological Therapy (IAPT) services. Screening tools show that many IAPT clients struggle with these additional difficulties, and research shows these clients have a poorer response to depression and anxiety treatments in IAPT. IAPT therapists are not routinely trained to tailor their treatment for people with these additional needs, and delivering training to improve therapist knowledge, skill and confidence to work with this group may lead to improvements in clinical outcomes.

Who can participate?

IAPT services will be recruited to take part in the research, where all their 'high intensity' 'Cognitive Behavioural' Therapists (CBT) will be offered the opportunity to attend a training workshop focused on understanding and assessing personality difficulties and tailoring depression and anxiety treatments for those who can be safely treated in an IAPT setting.

What does the study involve?

We will measure a range of therapist outcomes before, after and 3 months after the training workshop, including their knowledge skill and confidence to work with this client group, and

levels of well-being, burnout and presentee/absenteeism. We will also measure their feedback on the workshop itself. We will ask a small group of therapists to attend in-depth interviews to discuss their experiences and views on the workshop and any impacts on clinical practice. Services will introduce a brief screening tool for personality difficulties into their routine care during the study, and we will extract clinical outcomes for clients accessing treatment from participating in IAPT services in the 6 months before and after the workshop is delivered. This will enable us to understand if the workshop leads to any changes in clinical outcomes for clients with personality difficulties.

What are the possible benefits and risks of participating?

There are no direct benefits to individual therapists for taking part in the research. Therapists participating in IAPT services will have the opportunity to attend the workshop regardless of whether they take part in the accompanying surveys and interviews.

For staff attending the training intervention, while the training discusses some challenging material and work, we do not anticipate this, nor the linked surveys or interviews will result in any negative mood impact. Of 51 therapists who have already received this training, 48(94%) would recommend it to other therapists and 47 (92%) improved their knowledge, skills, and confidence working with this group. No attendees to date have reported an adverse reaction. The trainers are experienced therapists, have significant experience delivering similar training events to both IAPT staff and other clinicians, and have the necessary skills to manage any unintended negative mood impacts in participants should this arise as a result of the workshop.

A potential impact of the workshop on routine care not linked to direct participants: It is also important to consider if training could lead to unintended iatrogenic outcomes for service users. Evidence to date suggests that this group of service users can and do benefit from IAPT treatments for depression and anxiety. The training focuses on upskilling therapists to make subtle adaptations to their usual practice to accommodate the additional difficulties this group may experience. It is well documented that individuals with additional or different needs may need subtle adaptations to best benefit from psychological treatments, and the IAPT Positive Practice Guide series offers guidance around reasonable adjustments for service users with Learning difficulties, from BAME backgrounds and with long-term health conditions (e.g. ("IAPT Learning Disabilities Positive Practice Guide," 2015)). Given a remote possibility of unintended iatrogenic outcomes for service users, upon the report of, or if evidence of trial- or intervention-related harms emerges through examining the qualitative and service-level outcome data, we will discuss with the trial team and consider stopping further sites (but not the ongoing evaluation of existing sites).

Where is the study run from? Mood Disorder's Centre, University of Exeter (UK)

When is the study starting and how long is it expected to run for? October 2021 to March 2024

Who is funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR) Three Schools Mental Health Fellowship Award, held by Laura Warbrick the Chief Investigator. The study will also receive support from some researchers who are funded by NIHR ARC West.

Who is the main contact?
Laura Warbrick, l.a.warbrick@exeter.ac.uk

Contact information

Type(s)

Principal Investigator

Contact name

Ms Laura Warbrick

ORCID ID

http://orcid.org/0000-0002-9486-8550

Contact details

Sir Henry Wellcome Building for Mood Disorders Research University of Exeter Perry Road Exeter United Kingdom EX4 4QG +44 (0)1392722420 l.a.warbrick@exeter.ac.uk

Type(s)

Scientific

Contact name

Prof Barney Dunn

ORCID ID

http://orcid.org/0000-0002-0299-0920

Contact details

Sir Henry Wellcome Building for Mood Disorders Research University of Exeter Perry Road Exeter United Kingdom EX4 4QG +44 (0)1392722420 b.d.dunn@exeter.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

312857

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 53996, IRAS 312857

Study information

Scientific Title

A multi-site mixed-methods evaluation of brief Improving Access to Psychological Therapies (IAPT) staff training to adapt practice for secondary personality difficulties

Study objectives

This is a pilot and feasibility study, so the main aim of the work is to preliminarily examine the feasibility and acceptability of the workshop and the evaluation process, and we have not laid out a priori hypotheses. However, we have laid out a set of continuation rules to aid decision-making as to whether to proceed to definitive evaluation without modification, this includes establishing proof-of-concept that the workshop leads to improvements in therapist attitudes (perceived knowledge skill and confidence) to work with this client group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 19/10/2022, South Birmingham REC (Equinox House, City Link, Nottingham, NG2 4LA; +44 (0)207 104 8345; southbirmingham.rec@hra.nhs.uk), ref: 22/WM/0218

Study design

Psychological and behavioural complex intervention cohort study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Mental health

Interventions

DESIGN:

This study is a multi-site mixed-methods evaluation and intervention development project of a

new training initiative for IAPT high-intensity therapists focusing on adapting usual practice to accommodate secondary personality difficulties alongside a primary problem of depression and /or an anxiety disorder.

A single-site pilot evaluation, which just captures a subset of outcomes and is not formally a priori powered to detect therapist attitudinal change is being conducted in a non-NHS site with non-NHS therapists to preliminarily explore the acceptability and effectiveness of the current version of the training. Feedback from this will be used to refine the training approach before running the present research described here. This pilot site has already been approved under a separate ethics application (IRAS 303144).

SAMPLE

This evaluation will take place within three diverse Improving Access to Psychological Therapies (IAPT) sites (chosen to differ in terms of geographical area and service-user socio-economic status and ethnicity).

The present study will evaluate the refined training using a pre-post cohort design to examine if training led to changes in therapist attitudes, perceived capability, wellbeing, burnout, or presenteeism/absenteeism and will explore the acceptability and perceived usefulness of training to IAPT therapists. Qualitative analyses will also aim to understand the implementation and usefulness of the training to IAPT therapists using normalization process theory (NPT). Therapist data will be captured within three surveys: pre- and post-training and at 3-months follow-up. The pre-training survey will consist of basic demographic information (Age range, gender, ethnicity, experience level); bespoke Likert scale questions exploring attitudes and beliefs about working with clients with personality difficulties; the Sussex burnout scale, a brief measure of well-being (SWEMWBS); and questions capturing self-reported presenteeism and absenteeism.

The post-training survey will be sent out immediately after the training. This will consist of bespoke Likert scale questions exploring attitudes and beliefs about working with clients with personality difficulties, Likert scale and open-answer questions capturing views on the workshop, and open-answer questions about the impact of training workshops, such as the one they just attended on their wellbeing.

The 3-month follow-up questionnaire will be sent out 3 months after the training intervention. This will include a brief measure of well-being (SWEMWBS); the Sussex burnout scale; questions capturing self-reported presenteeism and absenteeism; and written qualitative questions about the impact of the training on own well-being and own work.

Approximately one month after the workshop, a subset of the therapist participants will be invited to attend qualitative interviews. This initial invitation will be made by email and potential therapist interview participants will be given a participant information sheet about the interviews. Two further email reminders will be sent at approximately 2-weekly intervals following the initial invitation. Potential interview participants will be asked to respond directly to the researcher if they are interested in taking part.

We will also examine preliminary proof-of-concept that training improves service-level outcomes. For this, we will extract and examine routine clinical outcomes and routinely collected Patient Experience Questionnaires (PEQ) relating to individuals accessing care during 6-months pre- and post-training cohorts.

Intervention Type

Behavioural

Primary outcome measure

Primary outcome measures are feasibility and acceptability of training and treatment: Recruitment: 1. Number of IAPT sites recruited, % of eligible therapists attending workshop, % of attending therapists completing pre-and post-surveys, % of attending therapists completing 3-month follow-up surveys

Acceptability:

- 1. Clinical outcomes data completion (% clients receiving routine care during the study with sufficient data for inclusion in secondary analyses) measured using at least two occasions of a measure of depression (PHQ-9) and anxiety (GAD-7) symptoms, and at least one measure of personality difficulties (SAPAS-SR)
- 2. Proof of concept:
- 2.1. Therapist attitudes measured using a bespoke attitudinal questionnaire (5 items on a 5-point Likert scale from strongly disagree to strongly agree) pre-, post- and 3-months after the training workshop
- 2.2. Quantitative workshop feedback measured using a bespoke 4-item questionnaire on a 5-point Likert scale from strongly disagree to strongly agree post-workshop

Secondary outcome measures

- 1. Therapist well-being measured using the adjusted short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS) pre-, post- and 3-months after the training workshop
- 2. Therapist burnout measured using the Sussex Burnout Scale (SBS) measured pre-workshop at 3 months follow-up
- 3. Therapist presentee and absenteeism measured using the Presenteeism and Absenteeism questionnaire 3-item self-report questionnaire capturing the frequency of difficulties over the past month at pre-workshop and 3 months follow-up
- 4. Client clinical outcomes:
- 4.1. Depression symptoms measured using the Patient Health Questionnaire (PHQ-9) at the first and last treatment sessions
- 4.2. Anxiety symptoms measured using the Generalised Anxiety Disorder scale (GAD-7) at the first and last treatment sessions
- 4.3. Work and social functioning measured using the Work and Social Adjustment scale (WSAS) at the first and last treatment sessions
- 4.4. Personality difficulties measured using the Standardised Assessment of Personality Abbreviated scale (self-report version) (SAPAS-SR) at the first treatment session/instance recorded in clinical notes

Overall study start date

01/10/2021

Completion date

31/03/2024

Eligibility

Key inclusion criteria

- 1. UK IAPT services
- 2. Therapists: High intensity Cognitive Behavioural therapists working within a participating IAPT service, who plan to attend the training workshop
- 3. Service level outcomes will be examined based on all clients accessing the service during the

research study (6 months prior to and post-therapist training), and focusing on those with scores indicating personality difficulties (i.e. 9 and above on the PDS-IC-11 and/or 3 and above on the SAPAS*)

Subject to necessary Copywrite permissions. If Permissions cannot be obtained prior to study commencement, services will collect just the PDS-ICD-11.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria

- 1. IAPT services will be excluded if they are unable to implement a measure of personality disturbance as a measure routinely collected at the assessment and treatment end
- 2. Therapists will be excluded if they do not subsequently take part in the training

Date of first enrolment

01/03/2023

Date of final enrolment

31/10/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Homerton University Hospital

Homerton Row London United Kingdom E9 6SR

Study participating centre St Georges Hospital Corporation Street Stafford United Kingdom ST16 3SR

Study participating centre University of Exeter

Department of Psychology Sir Henry Wellcome Building for Mood Disorders Research Exeter United Kingdom EX4 4QQ

Study participating centre Kent and Medway Insight IAPT

2 Esh Plaza Sir Bobby Robson Way Newcastle upon Tyne United Kingdom NE13 9BA

Study participating centre Nottinghamshire Insight IAPT

2 Esh Plaza Sir Bobby Robson Way Newcastle upon Tyne United Kingdom NE13 9BA

Sponsor information

Organisation

University of Exeter

Sponsor details

C/o: Pam Baxter Research Ethics and Governance Office Lafrowda House St Germans Road Exeter England United Kingdom EX4 4PY +44 (0)1392 723588 p.r.baxter2@exeter.ac.uk

Sponsor type

University/education

Website

http://www.exeter.ac.uk/

ROR

https://ror.org/03yghzc09

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care 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

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/03/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Laura Warbrick, l.a.warbrick@exeter.ac.uk. This study will generate two types

of data:

1. Raw therapist data:

Any requests for sharing of the anonymised dataset for future research will be screened by the University of Exeter prior to any sharing and may require a Data Sharing Agreement to be in place. This will include data from only those participants who consented for their data to be shared for use in future research.

2. Secondary, anonymised client routine outcome data:

By default, this data will not be shared with any other parties beyond the immediate research team without first seeking prior approval from both the University sponsor and the NHS/HSC organisations.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
<u>Protocol article</u>		05/10/2023	06/10/2023	Yes	No