# Enhancing the quality of telephone psychological treatments for anxiety and depression: testing an intervention to help services

Submission date	Recruitment status No longer recruiting	Prospectively registered		
28/05/2021		[X] Protocol		
<b>Registration date</b> 01/09/2021	Overall study status Ongoing	Statistical analysis plan		
		Results		
Last Edited	Condition category	Individual participant data		
13/11/2024	Mental and Behavioural Disorders	[X] Record updated in last year		

# Plain English summary of protocol

Background and study aims

Depression and anxiety cause substantial difficulties for people who experience them. The NHS has created a world-leading psychological therapy service, called 'Improving Access to Psychological Therapy (IAPT)', to help people with these conditions.

To help people access IAPT, many thousands of sessions are delivered by telephone. Telephone-delivered treatments are helpful and are recommended by the National Institute for Health and Care Excellence for depression and anxiety.

In this study the researchers want to improve the way that psychological interventions are delivered over the telephone. They have explored IAPT data to understand which groups of people have the greatest difficulties with telephone-delivered treatments. They have worked with patients and professionals to understand their experiences of telephone treatments and the types of challenges they face.

They have developed an intervention to help services improve the quality of telephone treatments. This intervention includes professional training, educational materials to help patients understand telephone-delivered treatments, and best-practice guidelines and workshops for IAPT teams.

This study will compare services that receive the intervention with those that do not. The researchers will test whether the introduction of the intervention means that more patients finish telephone treatment, and whether this has benefits for their health. They will talk to patients and professionals about their experiences of telephone treatments following the intervention. This will address the following questions:

- 1. Does the EQUITy intervention improve treatment engagement and cost-effectiveness of treatment compared to usual IAPT care?
- 2. How acceptable is the EQUITy intervention to patients and professionals?

# Who can participate?

- 1. Any IAPT service (NHS or third sector) that supports patients at Step 2 over the telephone
- 2. Patients aged 18 years and over with depression or anxiety accessing telephone-delivered

#### Step 2 treatment

- 3. IAPT service team members (service managers, service leads, supervisors, practitioners, administrators) will be invited to attend the team workshop
- 4. All practitioners providing psychological treatment by telephone will be invited to attend the telephone training sessions

#### What does the study involve?

IAPT services are randomly allocated to receive the EQUITy intervention or continue with the usual IAPT services. The EQUITy intervention is a service quality improvement intervention that seeks to build on existing services and does not involve the introduction of a new treatment. The intervention is made up of three components:

- 1. Guidelines for services and team workshops
- 2. Practitioner telephone training
- 3. Resources for patients

Patient outcomes (at both intervention and control services) are collected from the routine IAPT data set for sessions attended, and 6 and 12 months by the research team after they enter the study. In the intervention services patients at each service who were referred to telephone treatment will be invited to take part in a telephone interview (up to 60 minutes) to discuss their experience of accessing telephone treatment following implementation of the EQUITy intervention within their service. Service team members will also be invited to participate in a telephone interview or discussion group in relation to their experience of implementing the intervention.

What are the possible benefits and risks of participating?

Although the researchers cannot guarantee (to patients, professionals and services who participate) that the study will have personal value, the information all participants provide may help improve the delivery, quality, engagement and outcomes of telephone treatments in the future.

Where is the study run from? The University of Manchester (UK)

When is the study starting and how long is it expected to run for? May 2021 to August 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Judith Gellatly
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# Study website

https://sites.manchester.ac.uk/equity/

# Contact information

Type(s)

Public

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Scientific

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# Additional identifiers

# **EudraCT/CTIS** number

Nil known

#### IRAS number

298615

# ClinicalTrials.gov number

Nil known

# Secondary identifying numbers

IRAS 298615, CPMS 50002

# Study information

#### Scientific Title

Enhancing the quality of psychological interventions delivered by telephone (EQUITy): a cluster randomised trial of a service quality improvement intervention

#### Acronym

**EQUITy** 

# **Study objectives**

The EQUITy intervention will help services improve the quality of telephone treatments.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Approved 25/08/2021, North West - Preston Research Ethics Committee (Barlow House, 3rd Floor 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8364, +44 (0)207 104 8181; preston.rec@hra.nhs.uk), ref: 21/NW/0218

#### Study design

Multicentre cluster randomized trial

# 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 the contact details to request a participant information sheet

# Health condition(s) or problem(s) studied

Anxiety and/or depression

#### **Interventions**

Current interventions as of 27/11/2023:

This is a cluster randomised trial, so randomisation will take place at the service level. Half (11) of the services will be allocated to the intervention arm and will receive the EQUITy intervention, the other half (11) will be allocated to the control arm and will continue with treatment as usual.

The EQUITy intervention includes workshops for IAPT teams, practitioner telephone training, educational materials to help patients understand telephone-delivered treatments, and service guidelines to enhance practice.

Services will be involved in the trial for 12 months (recruitment of follow-up patient sample by 9 months), with patient follow-ups being conducted by the EQUITy research team up to 12 months.

#### Previous interventions:

This is a cluster randomised trial, so randomisation will take place at the service level. Half (13) of the services will be allocated to the intervention arm and will receive the EQUITy intervention, the other half (13) will be allocated to the control arm and will continue with treatment as usual.

The EQUITy intervention includes workshops for IAPT teams, practitioner telephone training, educational materials to help patients understand telephone-delivered treatments, and service guidelines to enhance practice.

Services will be involved in the trial for 6 months, with patient follow-ups being conducted by the EQUITy research team up to 12 months.

#### Intervention Type

Behavioural

#### Primary outcome measure

- 1. Depression measured using the Patient Health Questionnaire 9 (PHQ-9) at baseline, 6 and 12 months
- 2. Anxiety measured using General Anxiety Disorder-7 (GAD-7) at baseline, 6 and 12 months

# Secondary outcome measures

Current secondary outcome measures as of 14/10/2021:

- 1. Treatment engagement and cost-effectiveness of treatment measured using the EQ-5D-5L and Economic Patient Questionnaire (EPQ) at 6 and 12 months
- 2. Patient-therapist relationships measured using the Agnew Relationship Measure (ARM-5) at 6 months
- 3. Acceptability of the EQUITy intervention to patients and professionals (Psychological Wellbeing Practitioners (PWPs), service leads, managers, supervisors) will be collected via qualitative interviews and discussion groups (professionals only) at weeks 16-24

#### Previous secondary outcome measures:

- 1. Treatment engagement and cost-effectiveness of treatment measured using the EQ-5D-5L and Economic Patient Questionnaire (EPQ) at 6 and 12 months
- 2. Acceptability of the EQUITy intervention to patients and professionals (Psychological Wellbeing Practitioners (PWPs), service leads, managers, supervisors) will be collected via qualitative interviews and discussion groups (professionals only) at weeks 16-24

# Overall study start date

01/05/2021

# Completion date

31/08/2025

# **Eligibility**

#### Key inclusion criteria

Current participant inclusion criteria as of 11/02/2022:

#### Services:

- 1. Any IAPT service (NHS or third sector) that supports patients at Step 2 over the telephone will be eligible
- 2. Services will need to be providing at least 20% of their treatment sessions using the telephone and have enough referrals likely to allow for a sample of 100 patients for the enriched sample
- 3. Multiple IAPT services within the same Trust will be included if they work independently to each other

#### Professionals:

All professionals working within the IAPT teams in services that are recruited will be eligible to take part (Service Leads, Managers, Psychological Wellbeing Practitioners (PWPs), Administrators)

#### Patients:

Patients will be recruited via the services that are recruited into the trial. Patients who meet the following criteria 1-3 below will be eligible.

- 1. Adults aged 18+ years
- 2. Experiencing anxiety and/or depression
- 3. All patients who are allocated to receive telephone therapy

Previous participant inclusion criteria:

#### Services:

- 1. Any IAPT service (NHS or third sector) that supports patients at Step 2 over the telephone will be eligible
- 2. Services will need to be providing at least 20% of their treatment sessions using the telephone and have enough referrals likely to allow for a sample of 100 patients for the enriched sample
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#### Professionals:

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#### Patients:

- 1. Adults aged 18+ years
- 2. Experiencing anxiety and/or depression
- 3. All patients who are allocated to receive telephone therapy

# Participant type(s)

Mixed

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

The cluster randomised trial will include 22 clusters (11 will receive the EQUITy intervention). In both trial arms (intervention and control) 100 patients from each site will be recruited to complete follow-up measures (2600 in total). For the intervention arm IAPT teams will be involved (and consented) in the workshops (number unknown at present). Qualitative post-intervention implementation interviews/discussion groups will also be held in intervention arm sites (approx sample size 30 IAPT team members, 30 patients)

#### Total final enrolment

1423

# Key exclusion criteria

Current exclusion criteria as of 27/11/2023:

Services:

IAPT sites where telephone referral level would feasibly generate a participant sample of 100 over a period of up to 6-9 months.

#### Patients:

Does not meet inclusion criteria

Professionals – workshop and training sample:

No individuals working within the IAPT teams will be excluded from taking part. The decision as to whether to attend will be made by individuals or the sites (who may have to take into account practitioner workloads etc).

Professionals – post-intervention qualitative interviews/discussion groups:

No individuals who attended the workshop or training will be excluded from taking part in an interview, the decision to take part will be for each individual to make.

#### Previous exclusion criteria:

Services:

IAPT sites where telephone referral level would feasibly generate a participant sample of 100 over a period of up to 6 months.

#### Patients:

Does not meet inclusion criteria

Professionals – workshop and training sample:

No individuals working within the IAPT teams will be excluded from taking part. The decision as to whether to attend will be made by individuals or the sites (who may have to take into account practitioner workloads etc).

Professionals – post-intervention qualitative interviews/discussion groups: No individuals who attended the workshop or training will be excluded from taking part in an interview, the decision to take part will be for each individual to make.

# Date of first enrolment

26/07/2021

#### Date of final enrolment

30/06/2024

# Locations

#### Countries of recruitment

England

**United Kingdom** 

# Study participating centre University of Manchester

Oxford Road Manchester United Kingdom M13 9PL

# Sponsor information

#### Organisation

University of Manchester

#### Sponsor details

Faculty of Biology, Medicine and Health Room 5.012 Carys Bannister Building Manchester England United Kingdom M13 9PL +44 (0)161 2755436 fbmhethics@manchester.ac.uk

#### Sponsor type

University/education

#### Website

http://www.manchester.ac.uk/

#### **ROR**

https://ror.org/027m9bs27

# 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

The EQUITy Programme is detailed on the PGfaR website (https://fundingawards.nihr.ac.uk /award/RP-PG-1016-20010) and further information and details of publications provided on the dedicated EQUITy website hosted by The University of Manchester (https://sites.manchester.ac. uk/equity/).

The researchers will work with their patient (LEAP) and professional (Implementation Reference Group) advisory panels to develop an engagement strategy to target patients, PWPs, service managers, commissioners, national IAPT leads, policymakers and third sector networks. They will identify and address potential barriers that make it harder for knowledge to pass between these groups.

The researchers will work closely with the EQUITy Lived Experience Advisory Panel (LEAP) to ensure that their communications are clear and concise and take account of the needs and preferences of our audiences.

The researchers anticipate using a range of media including summary briefings, engagement events, online communications (e.g. webinars) and mainstream and social media. Local, national and international dissemination will occur via patient, professional and research-orientated

conferences and blogs. The selection of specific engagement activities and communication channels will be informed by current evidence on dissemination and knowledge mobilisation. An appropriate NIHR 'house style' will be adopted to build recognition and credibility for all programme outputs.

The researchers will develop a written publication strategy, publishing in high-impact academic, patient-focused and professional journals to ensure that they make an enduring contribution to the evidence base. Their service-user co-applicant and researcher will contribute as lead and co-authors.

No personally identifiable information will be reported in publications. In qualitative publications, patients will be referred to using a numerical identifier or by using a pseudonym. Basic demographic information will be reported in study publications (age, sex) however the researchers will ensure this is not done in a way that would make particular individuals identifiable.

The researchers will send a lay summary of the study to patients who take part in a qualitative interview using the personal details they provide (if they consent to this optional point on the consent form). Study sites and team members involved in the study will also be provided with a summary of study findings to circulate within their teams.

Papers from EQUITy studies that examined the clinical and organisational contexts in which telephone-delivered psychological interventions were being used and the challenges faced in practice that lead to the development of the EQUITy intervention have been published in peer-reviewed journals.

# Intention to publish date

01/05/2026

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.

# IPD sharing plan summary

Stored in publicly available repository

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary	version 11		28/06/2023	No	No
Protocol file		16/10/2023	27/11/2023	No	No