RESEARCH PROTOCOL

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

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Cluster trial and process evaluation

General issues

1) RESEARCH TEAM & KEY CONTACTS

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2) INTRODUCTION

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 the 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.

We want to improve the way that psychological interventions are delivered over the telephone. We have explored IAPT data to understand which groups of people have the greatest difficulties with telephone-delivered treatments. We have worked with patients and professionals (practitioners, service leads, managers and decision-makers) to understand their experiences of telephone treatments and the types of challenges they face.

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

We will compare services that receive our intervention with those that do not. We will test whether the introduction of our intervention means that more patients finish telephone treatment, and whether this has benefits for their health. We will talk to patients and professionals (i.e. PWPs, service leads, managers, supervisors) about their experiences of telephone treatment and involvement on the EQUITy intervention following its implementation.

3) BACKGROUND

Mental health problems affect approximately 110 million people worldwide; they are the main cause of disability and the third leading source of disease burden, after cardiovascular disease and cancer [WHO 2019].

The 'Increasing Access to Psychological Therapies (IAPT)' programme is the first line of response in meeting this mental health need. The rate of referrals to the IAPT service has increased year-on-year from under 9000 in 2012-3 to 1.7 million in 2019-2020 with the majority suffering from anxiety and/or depression [NHS Digital 2019].

The clinical and economic success of IAPT is dependent on its ability to find new cost-effective ways of providing evidence-based interventions to an increasingly high volume of patients, without compromising quality of care.

Telephone delivery is a National Institute for Health and Care Excellence (NICE) recommended mode of treatment for mild to moderate depression and anxiety in routine practice [NICE 2009, NICE 2011]. IAPT offers a stepped care model, in which guided self-help based on cognitive behavioural theory (CBT) principles is delivered by Psychological Wellbeing Practitioners (PWPs). Telephone-delivered psychological therapies offer significant advantages to patients. By removing the need for practitioners and patients to be located together, telephone-delivered interventions improve service flexibility, enhance patient choice and increase access for people unable to travel to appointments [Brenes et al 2011, Mohr et al 2010, Bee et al 2010]. Analysis of routine IAPT data (n=39 227) shows that, when treatment is completed, outcomes of psychological interventions delivered by telephone are comparable to face-to-face treatments, with 36% less service cost (Hammond et al 2012).

Despite the advantages, implementation of telephone delivered interventions in routine care remains a challenge [Faija et al 2020, Rushton et al. 2020, 2019; Irvine et al 2020, Drew et al 2021] Concerns have been expressed about the use of telephone in mental health settings, including difficulties in developing a therapeutic alliance, perceptions of reduced effectiveness, concerns about patient safety, and lack of patient engagement [May et al 2001, Brenes 2011, Bee et al 2016, Stiles Shields et al 2014, Turner et al 2018, Rushton et al 2020; Faija et al, 2020].

National audit data suggest telephone treatments are not used consistently across IAPT, with uptake being variable across services [HSCIC 2014]. The benefits shown by research studies have been difficult to reproduce in real world settings. Our research indicates that where telephone delivered interventions have been introduced, this is with limited training and lack of adequate service support (Faija et al 2020, Rushton et al 2019). We are conducting a programme to better harness the full potential of telephone treatments.

We have completed a number of research studies within the first part of the programme to understand the barriers and facilitators of telephone delivery, and the evidence has led us to the development of a behavioural change complex quality improvement intervention (referred to from this point forward as the EQUITy intervention) (see Box 1). The EQUITy Intervention has been initially tested in a feasibility study (see Box 2).

Box 1 Other EQUITY studies used to develop the EQUITy intervention

Patient and Practitioner perspectives

Qualitative interviews with patients and PWPs to explore barriers and enablers to telephone treatment

Therapeutic conversations by telephone

Audio-recording and conversation analysis of IAPT routine telephone assessments and treatment sessions

Organisational perspectives

Key informant qualitative interviews exploring organisational culture

Routine dataset analysis

Identifying patient, professional and site predictors of telephone -treatment use and outcome

EQUITy Intervention Acceptability and Feasibility

Three meetings with stakeholder groups (patients, PWPs, service leads/clinical managers) to create a first draft of our EQUITy intervention and explore their acceptability and feasibility

Box 2 Equity Feasibility study

3 sites took part in the feasibility study:

Training took place between Nov 2020 and Jan 2021

Covid modifications were made to deliver training online rather than face-to-face.

Each site received two 3-hour training sessions over 2 days.

The EQUITy intervention was -assessed by:

-Qualitative interviews with PWPs, service leads and patients

-Access to routine datasets from each site in progress

4) STUDY OBJECTIVES

4.1 Primary Question/Objective:

Does the EQUITy intervention improve the health outcomes of patients with depression (PHQ-9) and/or anxiety (GAD-7), depending upon diagnosis, compared to usual IAPT care?

4.2 Secondary Question/Objectives:

Does the EQUITy intervention improve treatment engagement and cost-effectiveness of treatment compared to usual IAPT care?

How acceptable is the EQUITy intervention to patients and professionals (PWPs, service leads, managers, supervisors)?

5) STUDY DESIGN & PROTOCOL

5.1 Services: Inclusion Criteria

Informed by our routine dataset analysis (Study 4), and knowledge of IAPT services we set broad, service-level inclusion criteria, identifying and approaching services who currently, or wish to, provide a proportion of their services (minimum 20%) by telephone. Due to the COVID pandemic, and the subsequent significant shift towards telephone/remote delivery modalities, IAPT services continue to offer a significant amount of their sessions by telephone. The number of referrals sites receive will also be evaluated to ensure that an 'enriched sample' of 100 is potentially feasible.

Participants

Adult patients (18+) experiencing anxiety and/or depression accessing telephone-delivered Step 2 treatment in IAPT services

5.2 Study Intervention and Procedures

STUDY DESIGN

The overall design is a cluster randomised trial comparing IAPT services receiving the EQUITy intervention with usual IAPT services. We will include an internal pilot (over 6 months).

A linked process evaluation will be conducted using qualitative methods with patients and professionals (and is described in a separate section for clarity).

Description of intervention

The EQUITy intervention is a service quality improvement intervention which seeks to build on existing services and does not involve the introduction of a new treatment.

The intervention is made up of 3 components (see Box 3):

1. Guidelines for services, team workshop and follow-up meetings
2. Practitioner telephone training
3. Resources for patients

Box 3 Summary of the EQUITy intervention

The intervention consists of three components:

1. **Guidelines for services, team workshop and follow-up meetings**
2. **Practitioner telephone training**
3. **Resources for patients**

Guidelines for services, team workshop and follow-up meetings
Whole team day workshop with afternoon team action planning task.

The service guidelines were developed as a result of previous EQUITy studies (detailed in Box 1). They have been refined following feedback from stakeholders in the feasibility study. The guidelines cover 5 areas: 1) Promoting Telephone Work 2) Key elements of Telephone -Work 3) Working Environment and Resources 4) Boosting Telephone Skills and 5) Promoting Reflection.

Team Workshop (full-day). The workshop will provide information about: 1-The EQUTy research programme, 2-The EQUITy intervention and 3-Policy and Evidence for psychological interventions delivered by telephone; and it will introduce the Service Guidelines Booklet and facilitate its implementation in routine practice.

Follow-up meetings (45-60 minutes, within 6-8 weeks of workshop/training)
6-8 weeks following the team workshop a follow-up session (online or via telephone) will take place. During this session general thoughts and feelings related to the implementation of the EQUITy intervention will be explored, a review of proposed action plans will take place and next steps will be identified and discussed. The named action plan lead within each site will be expected to attend, with other team members who attended the workshop/training also invited.
Subsequent bi-monthly follow-up meetings (online or via telephone) with named action plan leads within each site to review and update agreed action plans will be offered to examine any barriers and facilitators to success and explore alternative ways of achieving agreed action plan targets.

Practitioner telephone training
The telephone training will consist of two 3-hour telephone training sessions held on different days.

The telephone training sessions will include a mix of teaching and activities to maximize understanding and engagement of psychological interventions delivered by telephone. The training will include interactive presentations, audio visual clips, small group exercises, skills practice exercises (including role play) and live demonstrations of good practice.

Team workshops and practitioner training will be delivered remotely (Microsoft Teams/Zoom; should Covid restrictions still be in place) on days identified as convenient for the service.

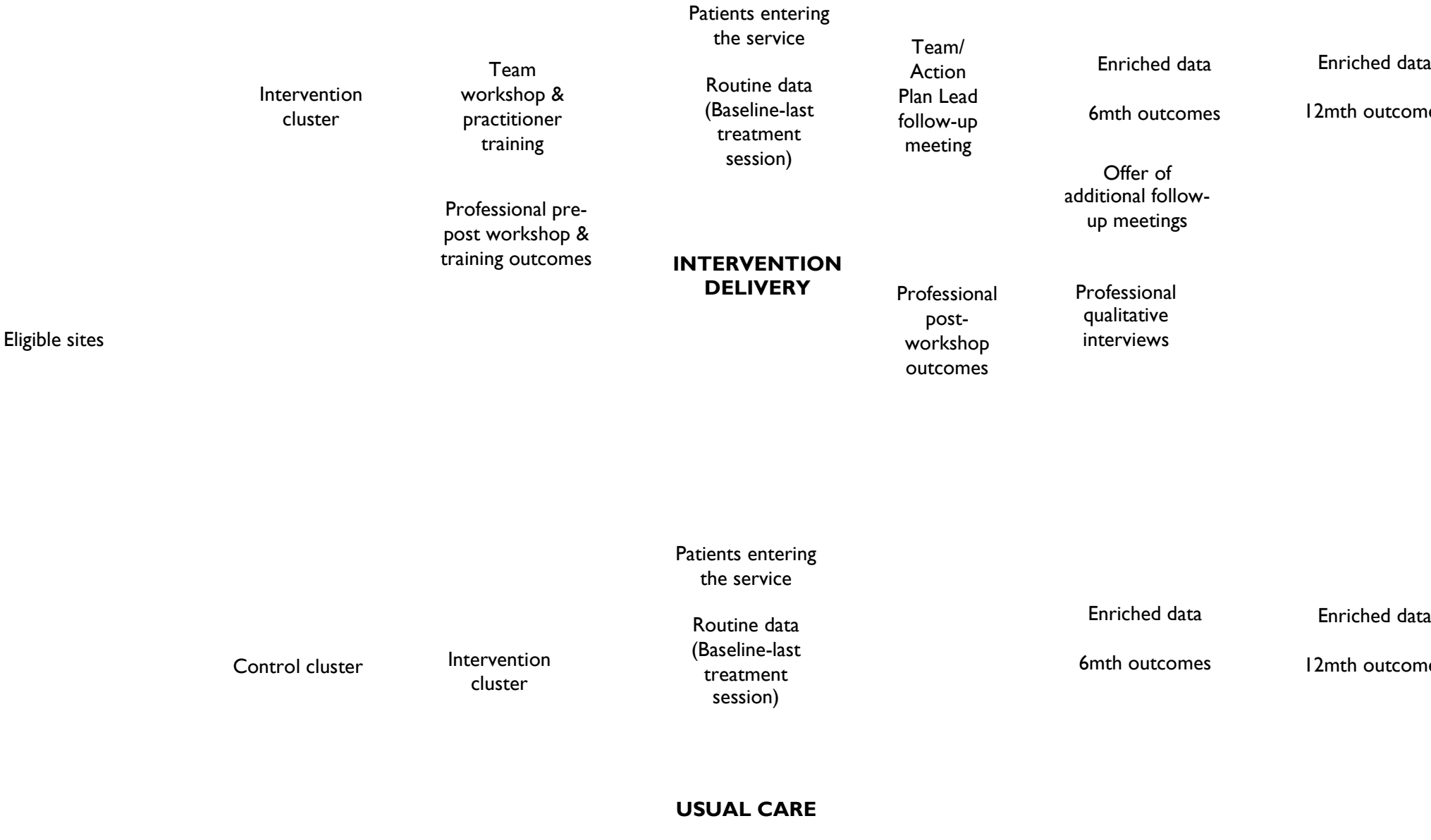
Workshop and training facilitators will consist of an academic researcher with a mental health clinical background (KL), academic researcher with a clinical psychology background (DMc), and the EQUITy service-user/practitioner researcher (CM). Other research team members who have experience as a professional or a patient may also provide training support.

Resources for Patients

Patient resources were co-designed and co-developed with service users who have accessed or had experience with IAPT services and/or received treatment for anxiety and/or depression, alongside the EQUITy Lived Experience Advisory Group (LEAP) They have been designed to address issues around patient knowledge and expectations of treatment identified in Workstream 1 and refined in the Workstream 2 feasibility study (described above). These resources comprise a patient leaflet, an appointment card and poster (paper copy or electronic) which will be send to all patients accessing IAPT services when initially referred to telephone treatment or with their first appointment notification letter.

Figure 1 provides an overview of the trial design

Figure 1 Trial Design



The following table (Table 1) provides an overview of trial activities and timelines for the EQUITy trial, most of which relate to the intervention arm. Further information about the enriched patient sample follows the table.

Table 1

ENTRY INTO TRIAL Week 1	**1-day service guidelines team workshop** (PWPs, service leads, admin staff etc)	
Weeks 2 – 3	**Practitioner telephone training** Two 3-hour training sessions held on separate days	Weeks 2 - 24 **Distribution of patient resources** (electronic and/or hard copies dependent on service preference) Weeks 3 - 24 **Recruitment of an enriched patient sample (intervention and control arms)**
Weeks 6 – 8	**45-60-minute** action plan lead/team **follow-up meeting** online or via telephone	
Weeks 10 - 24	Offer of **additional follow-up meetings** online or via telephone	
Weeks 16 – 24	**Qualitative interviews/discussion groups** with patients and professionals	

Sites will be informed of their allocation approximately 1 month prior to their chosen intervention dates (Trial Entry Date). Regardless of the trial arm they are allocated to, the Trial Start Date for each service will be the date of their chosen workshop (the initial delivered component of the intervention).

EVALUATION

The trial design is embedded in routine IAPT services and takes advantage of data that is available through IAPT operations, supplemented by bespoke research data. IAPT datasets are comprehensive at baseline with consequent high external validity [Gyani et al 2011]. However, they lack long term outcomes, as services do not follow up service users after discharge. Additionally, they do not collect broader service use measures and generic, preference-based health status measures.

In order to effectively and efficiently evaluate the long term and economic impact of the EQUITy intervention, we will combine routine IAPT data with additional data from consenting patients from the intervention and control sites (see Figure 1).

The addition of the EQUITy intervention, compared with usual routine IAPT care, will therefore be evaluated (via patient and professional measures) in a number of different ways.

1. Routine IAPT data
2. Enriched data set
3. Pre-post workshop questionnaires/measures
4. Pre-post telephone training questionnaires/measures
5. Qualitative interviews

Detail about each of these activities/methods are included below, further details of the outcome measures for each is included in Section 6.

1. Routine IAPT data

The 'Routine Data Sample' will include all those patients entering each IAPT service, taking advantage of data that IAPT already collects. This data is comprehensive (as it includes all patients) but limited in scope (as they exist at baseline and end of treatment only and lack measures of certain important issues).

IAPT collects outcome measure data on a session-by-session basis for every patient who receives treatment, delivered via all modalities (i.e. face-to-face, telephone, internet). We will request data from services for 12 months pre and 12 months post implementation of the EQUITy trial. The start date of the intervention at each of the intervention arm sites will be the day of the initial workshop. Box 4 provides detail on the data collected as part of the routine IAPT Data Set (for more detail please see Appendix 1):

Box 4 Routine IAPT data

Descriptive data

patient demographics (including geographical locations, gender, age, employment, ethnicity, language, religion, sexual orientation and disabilities); care pathway referral details, mental health care cluster details; information on presenting complaints (mental and physical) ; sessions attended/unattended; intervention details; clinical, economic and social outcomes; waiting times and practitioner qualifications.

Treatment engagement

treatment attendance and duration data including: Date of referral, Date of Assessment, Date Start of Treatment, Date End of Treatment, Number of Sessions attended/unattended, Reason for Termination.

Outcomes
Patient Health Questionnaire [PHQ-9; Kroenke et al 2001] for depression, Generalised Anxiety Disorder scale [GAD-7; Spitzer et al 2006] for anxiety, IAPT Phobia Scale [IAPT Data Handbook, Appendix D3 2011], and the Work and Social Adjustment Scale [WSAS; Mundt et al 2002] for functioning. Dependent on patients' presenting symptoms a disorder-specific assessment questionnaire(s) may also be collected that include: Social Phobia Inventory [SPIN; Connor et al 2000], Impact of Events Scale – Revised [IES-R; Weiss 2007], Mobility Inventory [MI; Chambless et al 1985], Obsessive-Compulsive Inventory [OCI; Foa et al 1998], Panic Disorder Severity Scale [PDSS; Shear et al 1997], Francis Irritable Bowel Scale (Francis et al 1997) or The Chalder Fatigue Scale [Cella & Chalder 2010]. IAPT Employment Status Questionnaire, Patient Assessment Experience Questionnaire, Patient Treatment Experience Questionnaire.

2. Enriched Data Sample

We will also recruit a 'Enriched Data Sample' of patients from within the wider 'Routine Data Sample'. These patients will be approached for consent at the beginning of their engagement with the service. We will access baseline and end-of-treatment outcomes from the routine IAPT data, and then collect additional outcomes 6 and 12 months after they enter the trial.

The 'Enriched Data Sample' will be a selected group of patients (selected in terms of patient agreement to provide data). However, the selection will likely be the same in both intervention and control clusters and thus will serve as a robust basis for comparison. The main advantage of the 'Enriched Data Sample' is that it will provide more extensive data over the longer-term.

Patients who consent to be included in this sample will complete the following measures at 6 and 12 months:

6 months only

- Agnew Relationship Measure [ARM-5; Agnew-Davies et al 1998, Cahill et al 2012]. Adapted, by permission of the authors, for the EQUITy trial.

6 and 12 months

- Patient Health Questionnaire [PHQ-9; Kroenke et al 2001] for depression

- Generalised Anxiety Disorder scale [GAD-7; Spitzer et al 2006] for anxiety.
- EQ-5D-5L [Herdman et al 2011]
- Economic Patient Questionnaire (EPQ)

Measures will be completed by patients electronically. It is estimated they will take approximately 15-20 minutes to complete. Layout and presentation of the measures was verified by the EQUITy LEAP to confirm ease of understanding and accessibility in terms of layout and presentation, along with language, layout and wording of the EPQ.

NOTE: The enriched sample will be asked to provide date of birth following consent, in order to link each participant to their routine IAPT baseline demographics and outcome data, and end-of-treatment outcome data. Date of birth data will be downloaded and stored separately on a secure password-protected University of Manchester server, separate to patient name and contact details.

3. Pre-post workshop and training questionnaires/measures

Attendees will be sent a link to pre-workshop/training questionnaires at the same time as the joining details by email. Individual emails will be sent to each participant which will include an ID for the purposes of completion of the questionnaires. They will be informed that they can complete the measures prior to the workshop/training session or that time will be made available at the start of the workshop training if they have been unable to do so. Attendees will be asked to complete a demographic questionnaire. They will also be asked to the Capability (C), Opportunity (O), Motivation (M) and Behaviour (B) (COM-B) measure [Keyworth et al 2020] (pre and post-workshop, and pre-post training), the Organizational Readiness for Implementing Change (ORIC) questionnaire [Shea et al 2014] (pre-workshop only) and the Training Acceptability Rating Scale (TARS) [Davis et al 1989; TARS-2: Milne and Noone 1999] (post-training only) – see Table 3. Questionnaires will be available online, prepared by the research team using Qualtrics XM [Qualtrics, June 2021].

4. Qualitative interviews/group discussions with professionals and patients

We will conduct semi-structured interviews or group discussion (professionals only) to explore the impact and implementation of the EQUITy intervention on professional development, patient experience and service performance.

Interview schedules, informed by Normalisation Process Theory [NPT; May et al 2009] and Consolidated Framework for Implementation Research [Damschroder et al 2009] will be developed and piloted with our PPI advisory panel (EQUITy LEAP). They will focus on:

- How the EQUITy intervention is developed and translated into practice

- How the EQUITy intervention becomes/does not become incorporated into the everyday work of professionals and patients
- How the EQUITy intervention is sustained as routine practice

Interviews/group discussion will be conducted by a Research Associate trained and experienced in taking consent and qualitative methods. Consenting patients will be interviewed for up to one hour at a convenient time over the telephone or via video-call (using Zoom or Microsoft Teams) pending on preference. Consenting professionals will have the option of an interview or group discussion. Interviews will take place by telephone or video-call (using Zoom or Microsoft Teams) pending on professional's preference. Group discussions will take place over Zoom or Microsoft Teams. Telephone interviews will be recorded, with consent using an encrypted digital recorder and transcribed verbatim. Video-calls will be recorded with consent and the video will be immediately destroyed and only the audio will be kept and transcribed..

Table 2 provides information regarding the collection of the evaluation data for patients, while Table 3 provides information about the professional measures, further information can be found in Sections 6.1-6.3.

Table 2. Schedule of enrolment and data collection for patients (intervention and control arms).

	Study Period				
	Enrolment	*Baseline*	*End of Treatment*	*6 months follow-up (Enriched Sample)*	*12 months follow-up (Enriched Sample)*
Intervention and Control Arms					
Consent to be contacted (Enriched sample)	X				
Informed Consent (Enriched sample)	X				
Identifiable Data					
Date of birth (Enriched sample)	X				
Primary Outcome Measures					
Patient Health Questionnaire (PHQ-9)		**X**	**X**	X	X
Generalised Anxiety Disorder scale (GAD-7)		**X**	**X**	X	X
Secondary Outcome Measures					
Patient Demographics		**X**			

IAPT Phobia Scale		**X**			
Work and Social Adjustment Scale		**X**			
EQ-5D-5L				X	
Agnew Relationship Measure (ARM-5)				X	X
Economic Patient Questionnaire (EPQ)				X	X
Social Phobia Inventory (SPIN)		**X***			
Impact of Events Scale – Revised (IES-R)		**X***			
Obsessive-Compulsive Inventory (OCI)		**X***			
Panic Disorder Severity Scale (PDSS)		**X***			
Francis Irritable Bowel Scale		**X***			
Chalder Fatigue Scale		**X***			
Additional Information					
IAPT Employment Status questionnaire		**X**			
Patient Assessment Experience Questionnaire		**X**			
Patient Treatment Experience Questionnaire			**X**		
Number of sessions attended			**X**		
Intervention Arm only					
PWP who delivered telephone sessions			**X**		
Additional participation					
Qualitative interview			X		

X = Data collected routinely by services; X = Data collected by the research team; * = Collection of this measure is dependent on the patient's presentation

Practitioners who are involved in the intervention arm sites will be asked to complete before and after workshop and training measures to explore impact and acceptability of the EQUITy intervention. They will also be invited to take part in a qualitative interview. Practitioners who are working in a site allocated to the control arm will not be asked to take part in any data collection or feedback activities.

Table 3. Schedule of enrolment and data collection for professional data (intervention and control arms).

	Study Period	
	Pre-activity	*Post-activity*
Intervention Arm Activity		
Team Workshop		
Demographic questionnaire	X	

COM-B	X	X
ORIC	X	
Telephone Training		
Demographic questionnaire*	X	
COM-B	X	X
TARS		X

* if they have already completed this at the first team workshop, they will not be asked to complete this again.

STUDY PARTICIPANTS

6.1 Inclusion Criteria:

Services

Any IAPT service (NHS or third sector) who supports patients at Step 2 over the telephone will be eligible. 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 (aim to achieve 100 but not a compulsory condition of involvement).

Multiple IAPT services within the same Trust will be included if they work independently to each other.

Patients

Patients – Routine IAPT dataset

We will request pseudonymous IAPT routine data of all patients who access the service, irrespective of which treatment modality they are referred to (12 months of data pre-intervention implementation, 12 months of data post-intervention implementation).

We are interested in exploring the data associated with patients accessing Step 2 treatment, which may include information of if they have been stepped up to receive Step 3 treatment. Some services may not be able to manually extract only the data requested by the research team from the dataset that they submit regularly to NHS England and thus they will be unable to exclude any subsequent Step 3 service data in the dataset they provide. This is due to resource and time issues. They will, however, be able to remove any patient identifiers such as full date of birth and postcode, ensuring that the date set remains pseudonymous. If this occurs the research team will manually remove any irrelevant Step 3 data. The data that they submit to NHS England is made available in the public realm thus no concerns have been identified about the sharing of this data.

Patients – enriched sample

As a pragmatic trial of a model of a service quality improvement intervention, the inclusion criteria are simple to enhance the external validity of the study. All adults (18+) accessing telephone-delivered Step 2 treatment following randomisation (intervention or control arm) will be eligible to participate in the enriched sample.

All patients who enter a service and are referred to telephone treatment will be invited to consent to being part of enriched data sample (although we will restrict the numbers in

that sample in each site). Recruitment will continue for a maximum of 9 months at each site to allow for as close to 100 patients consenting to participate.

Patients – post-intervention implementation qualitative interviews

We will purposively sample across all the services allocated to receive the EQUITy intervention (i.e. 11) to ensure variance in clinical and organisational contexts. A sampling frame will capture patients with different clinical profiles (diagnosis, severity) and levels of intervention engagement (e.g. no sessions attended, first session only, multiple sessions) Maximum variation sampling will ensure patients of different socio-economic background, age, ethnicity and gender are included.

Following the sampling strategy, patients who have accessed telephone treatment following implementation of the EQUITy intervention at the intervention arm sites will be eligible to participate. Invitations to participate will be sent by the sites utilizing a sampling frame to capture patients with different clinical profiles (diagnosis, severity) and levels of intervention engagement (no sessions/first session only/multiple sessions) and to ensure participants of different socio-economic background, age, ethnicity and gender are included.

Patients who are part of the enriched sample, and who have agreed to being contacted about other research projects, may also be contacted directly, by email, by the research team. This method will be used to support intervention sites who are experiencing resource or capacity issues.

We will recruit until data saturation [Miles and Huberman 1994], with an estimated sample size of 25-30 patients.

Professionals

Professionals – team workshop, workshop follow-up and training sample

Team workshop and follow-up workshop - All individuals working at intervention arm sites (Service Leads, Managers, PWPs, Administrators) will be invited to attend the team workshop. If sites take up the offer of bi-monthly update meetings following the workshop follow-up session these will take place on the telephone with the named action plan lead.

All practitioners providing psychological treatment by telephone will be invited to attend the telephone training sessions.

Professionals – post-intervention qualitative interviews/discussion groups

We will purposively sample across all the services allocated to receive the EQUITy intervention (i.e. 11) to ensure variance in clinical and organisational contexts. A sampling frame will capture professionals with different levels of experience in their current role (e.g. less than 6 months, more than 5 years). Maximum variation sampling will ensure professionals of different socio-economic background, age, ethnicity and gender are included.

Following the sampling strategy, individuals who attended either the team workshop and/or the telephone training session will be eligible to take part in a qualitative interview to provide feedback about the EQUITy intervention. We will purposively sample across multiple services to ensure variance in clinical and organisational contexts.

We will recruit until data saturation, with an estimated sample size of 25-30 professionals (Service Leads, Managers, Supervisors, PWPs).

6.2 Exclusion Criteria:

Services

As we aim to obtain a sample of 100 patients at each site (intervention and control arms) for the enriched sample, only sites where telephone referral level would feasibly generate a sample of this number will be included. Data will be collected over the period of a minumim of 6 months, maximum of 9 months.

Although successful recruitment of the required 100 patients per site will not be possible in all sites, we will have routine outcome data for all sites in the trial, due to routine collection of data within IAPT services (as described previously). This data will be comprehensive (on all patients) but of restricted duration (pre-post treatment only, not longer-term follow-up) and scope (clinical data only).

Patients

For the trial, there is no explicit inclusion criteria for any patient sample. Patients aged 18+ who is referred to telephone treatment at Step 2 during the trial period will be eligible to participate in the enriched sample and/or in a qualitative interview (post-EQUITy intervention implementation).

Professionals

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.

6.3 Recruitment:

Services

Information about the trial will be disseminated via Twitter, direct contact with IAPT services and CRN Networks and expressions of interest from services will be collated. Key service members (i.e. service leads, managers, PWPs, administrators) will be introduced to the study via remote meetings to facilitate understanding of what will be involved if they decide to take part.

Following agreement to participate, and the necessary governance approvals being obtained, sites will be randomly allocated to an intervention or control cluster. Services will be made aware that there is a 50% percent chance to be allocated to the intervention cluster and a 50% chance to be allocated to the control arm. The details of the cluster randomisation process are given below.

Intervention clusters

At the intervention clusters, site team members will receive information about the team workshop, telephone training, follow-up meetings, patient resources and service guidelines.

Patients in an 'intervention' cluster site allocated to receive telephone treatment will receive the additional patient resources (leaflet introducing telephone treatment, an appointment card and poster). These resources will be sent by electronic or postal means, dependent on service/patient-preferred means of communication, along with an advisory letter detailing what they are and why they have been sent.

Patients who are allocated telephone treatment at services will be invited to take part in providing data as part of the enriched data sample 6 and 12 months after the date of entry (1 week after the trial start date) into the service. They will be sent an invitation pack from their service including an invitation letter, information sheet and consent to contact form). These will be sent electronically or a hard copy in the post. Packs sent electronically will include a link to the online consent to consent to contact form and

consent form. Patients can make contact with the research team prior to completing the consent form if they wish.

Control Clusters

At the control clusters, staff participation will be minimal. They will be made aware that the service is taking part in a trial and that they will be asked to facilitate sending out invitations to patients who are allocated telephone delivery to identify if they would like to take part in providing data as part of the enriched data sample 6 and 12 months after the date of entry into the service. Patients will be sent an invitation pack from the service including an invitation letter, information sheet and consent to contact form).

Patients

Patients – Routine IAPT dataset

Patients in the intervention cluster will be exposed to telephone treatments which has been influenced by the EQUITy intervention, although decisions made with patients regarding their treatment will not be influenced directly, and no new treatments will be introduced.

Participants taking part in trials usually provide written informed consent for a range of research procedures, including participation and data collection. However, seeking patient consent for all research procedures is not always appropriate. As the the EQUITy intervention will be offered to all PWPs and other staff members working in those services (i.e. service leads, managers, supervisors, administrators), all patients receiving telephone treatment after delivery of the EQUITy intervention have the potential to be 'exposed', and this exposure is not under their control. However, as detailed previously, the intervention is a service quality improvement intervention, not the introduction of a new treatment. Furthermore, data collected by IAPT services currently is shared by services anonymously and used for evaluation and monitoring processes.

Patients - Enriched Data Sample

As noted above, a sub-sample of patients (up to 100 per site) entering the service (intervention and control arms) during the trial will be invited to participate in a more detailed data collection as part of the Enriched Data Sample.

Eligible patients (those offered a Step 2 telephone treatment) will be identified from the computer systems at intervention and control arm IAPT services. All patients who are allocated to receive treatment by telephone will be sent a patient information pack

(electronic or postal, dependent on service/patient-preferred means of communication) containing a patient invitation letter, an information sheet, a consent to contact form and consent form. Packs sent electronically will include a link to the online consent to consent to contact form that can be returned if they wish to contact the research tream prior to consenting. Anyone who is interested in taking part can return the consent to contact form by email to the research team or email/phone the research team directly, prior to providing consent.

Patients may also be informed about the study at the point of referral to telephone therapy by a practitioner/a member of the service who will use a script provided by the research team to introduce the study and indicate that if patients are interested they will be sent an information pack. Interested patients can choose to make contact directly with the research team by returning the consent to contact form or via email/telephone or can inform the practitioner that they are happy for their contact details to be passed to the research team or complete consent with a staff member.

Those who agree to take part will be asked to sign a consent form, as part of this consent process they will also be asked to consent to their follow-up (enriched) 6- and 12-month data being linked to their routine IAPT outcome data.

Patients will be provided with researcher contact details and will have the opportunity to ask the research team any questions they may have.

Patients – post-intervention qualitative interviews

At approximately 16-24 weeks after the EQUITy intervention has been implemented, patients in the intervention cluster that have accessed telephone treatment will be sent an invitation pack (electronically or postal as per the enriched sample) by the IAPT service. The pack will include a patient invitation letter, an information sheet, and a consent to contact form. Anyone who is interested in taking part can return the consent to contact form by email to the research team or email/phone the research team directly.

Patients who are part of the enriched sample, and who have agreed to being about other research projects, may also be contacted directly, by email, by the research team. A PIS and consent form will be attached to the email. This method will be used to support intervention sites who are experiencing resource or capacity issues.

For those who remain interested in taking part in an interview, an interview date will be arranged. The interview will be by telephone or video-call (using Zoom or Microsoft

Teams) pending on patient's preference. The interview will be audio/video-recorded on an encrypted device with the patient's consent. Consent will be obtained online (using Qualtrics XM) prior to the interview taking place or verbally (at the start of the interview on a separate recording). In order so the qualitative sample can be described fully, and to avoid patients having to complete further questionnaires, patients who take part in an interview will be asked to consent to their data from the routine IAPT dataset being identified and shared with the research team.

Patients will be provided researcher contact details and will have the opportunity to ask the research team any questions they may have.

Professionals

Professionals – workshop and training sample

Recruitment of site team members to attend the online team workshops and/or telephone training will take place following allocation to the intervention arm. Potential workshop/training dates will be agreed between sites and the EQUITy team and sites will communicate those among all team members.

Potential attendees of workshops will be provided with a particiant information sheet outlining the purpose of the workshop and will be asked to consent to taking part which will include consenting to the workshop being audio recorded. The telephone training sessions will not be recorded but the process evaluation lead (HB) or the chief investigator (PB) will attend 10% of the training sessions to assess training fidelity.

Lists of those who are attending will be obtained and Zoom/Microsoft Teams calendar invites sent by the EQUITy team.

Professionals – post-intervention qualitative interviews/discussion groups

Following the sampling strategy, individuals at intervention arm sites (Service Leads, Managers, PWPs, Administrators) who attended the team workshop and/or the practitioner telephone training sessions will be invited to take part in a qualitative interview or discussion group to provide feedback with respect to their thoughts about attending the workshop/training and/or reflective sessions and subsequent implementation of the intervention in practice.

All attendees will be sent an information pack that will include an invitation letter, information sheet, and a consent to contact form. Anyone who is interested in taking part can return the consent to contact form by email to the research team or email/phone the research team directly.

For those who would like to take part in an interview or group discussion, a date will be arranged. Interviews will be conducted by telephone or video-call (via Microsoft Teams or Zoom), while discussion groups will be held online (via Microsoft Teams or Zoom). Consent will be obtained online (using Qualtrics XM) prior to the interview/discussion group taking place or verbally (at the start of the interview/discussion group on a separate recording).

For professional discussion groups, ground rules will be set and highlighted at the outset. These will remind participants about the issues surrounding these i.e., not speaking over each other and being respectful, limiting the amount of identifiable information discussed (trying not to list place names and names of people), breaking confidentiality if disclosures are made.

Internal pilot

We have specific stop-go criteria for the trial based on an internal pilot.

Stop/go criteria for our 6-month internal pilot will comprise:

a) the recruitment and allocation of a minimum of 10 participating sites

b) delivery of the EQUITy intervention in 5 of these sites

c) an average of 50 patients recruited per site into the Enriched Data Sample.

Meeting all three criteria will support progression to full trial, whereas a failure on one or more will require discussions with the Steering Group and funder.

6.4 Randomisation:

This is a cluster randomised trial, so randomisation will take place at service level.

Services will be recruited via site meetings prior to allocation. Services will be aware that they could be allocated to the intervention or control arm.

A Principal Investigator or Local Collaborator will be allocated at each site. Allocation of sites (clusters) to the intervention or control arm will be undertaken sequentially and independently by Manchester Clinical Trials Unit (CTU) to maintain concealment of allocation. The Principal Investigator or Local Collaborator will be informed of their allocation by the trial manager.

6.5 Participants who withdraw consent [or lose capacity to consent]:

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. All information sheets will make clear that participants do not need to take part, that consent is voluntary and, if they choose to participate, they are free to withdraw at any time.

Participants will have up to two weeks to withdraw their data if they change their mind about taking part, this will also be detailed in the information sheets. If they take part in an individual interview, the audio recording of the interview and associated transcription (if already transcribed) will be destroyed. If the participant is taking part in a discussion group, we will be unable to remove their data from the transcription. The recording will be destroyed after transcription.

For most of the studies in this research programme, loss of capacity to consent is unlikely to be a significant risk as the interview/group discussion data collection will take place on a single occasion and there will be minimal gap between consent and data collection.

Additionally, patients recruited into the study will be accessing IAPT services. As per NICE guidance for anxiety and depression [National Institute for Health and Clinical Excellence (NICE) 2011; 2009] this sample will include people with mild-to-moderate depression, anxiety or mixed depression-anxiety. However, often people presenting with more severe depression or anxiety symptoms (i.e. moderate – severe) are supported within IAPT services at Step 2. Should capacity have been identified as an issue by the IAPT service, then they would have been referred to a different service.

6) OUTCOME MEASURES

The main aim of the EQUITy programme are to improve patient outcomes, uptake and engagement for psychological treatment delivered by telephone. Evidence of the impact of the EQUITy intervention will be achieved through outcome measures and questionnaires completed by both patients and professionals taking part in the trial. The following sections describe this in detail.

Routine IAPT Data Set

Patient outcome measures are routinely collected by the IAPT service as part of their 'minimum data set'; we will combine data routinely collected within IAPT with data from a cohort of recruited participants to assess outcomes at baseline, end of treatment, 6- and 12-months follow-up. Baseline data (and subsequent end of treatment data) is routinely

collected by IAPT services, 6- and 12-months follow-up data will be collected by the EQUITy team.

Primary Outcomes

The severity of mental health symptoms and recovery rates will be measured by the Patient Health Questionnaire [PHQ-9; Kroenke et al 2001] for depression and the Generalised Anxiety Disorder scale [GAD-7; Spitzer et al 2006] for anxiety. These will be collected at baseline and end of treatment via routine IAPT data, and at 6 and 12 months from a cohort of recruited participants (enriched sample).

PHQ-9

The PHQ-9 is a 9 item measure of the severity of depression. Patients are asked how often they have been bothered by the 9 symptoms of depression on a 4 point scale from 'Not at all' to 'Nearly every day' scoring from 0 to 3. A total raw score ranging from 0 to 27 indicates the overall level of severity of depression. Total scores of 5, 10, 15, and 20 represent cut-points for mild, moderate, moderately severe and severe depression, respectively. The validity and reliability of the PHQ-9 was first established within primary care mental health services by Kroenke, Spitzer, & Williams (2001). The PHQ-9 demonstrated 88% sensitivity and specificity; and showed good reliability (Cronbach's alpha =.89). This measure was suggested to be effective in screening for and monitoring severity symptoms of depression in primary care.

GAD-7

The GAD-7 is a 7 item measure of the severity of anxiety commonly used in primary care and research trials, and is part of IAPT minimum data set. Patients are asked how often have they been bothered by the 7 symptoms of anxiety over the past 2 weeks. Responses are on a 4 point scale from 'not at all' to 'nearly every day' scoring '0' to '3' respectively. The GAD-7 total score ranges from 0 to 21. Total scores of 5, 10 and 15 are taken as cut-off points for mild, moderate and severe anxiety respectively. The validity and reliability of the GAD-7 was first established by Spitzer, Kroenke, Williams, & Löwe (2006) mainly within primary care mental health services. The GAD-7 revealed 89% sensitivity and 82% specificity; and showed good reliability (Cronbach's alpha =.92). This measure was suggested to be effective in screening for and monitoring severity symptoms of generalized anxiety in primary care.

Secondary Outcomes

a) We will also explore data on other IAPT routine measures included in the 'minimum data set' as detailed previously in Box 4:

IAPT Phobia Scale [IAPT Data Handbook, Appendix D3 2011] ,and the Work and Social Adjustment Scale (WSAS; Mundt et al 2002) for functioning.

If relevant, based on patients' presenting symptoms, these may also include:

- Social Phobia Inventory (SPIN; Connor et al 2000), Impact of Events Scale – Revised (IES-R; Weiss 2007), Mobility Inventory (MI; Chambless et al 1985), Obsessive-Compulsive Inventory (OCI; Foa et al 1998), Panic Disorder Severity Scale (PDSS; Shear et al 1997), Francis Irritable Bowel Scale (Francis et al 1997) or The Chalder Fatigue Scale (Cella & Chalder 2010).

b) Patient engagement will be measured by routinely collected treatment attendance and duration data from the IAPT routine data. The number of sessions attended/unattended will be the primary source of data. Other data to corroborate this will include dates referred, assessed, started and ended -treatment and also reason for termination.

c) Service engagement will be measured by numbers attending the team workshop, telephone training, and implementation of the action plan prepared at the first workshop. Organisational readiness for change will be measured by asking workshop attendees to complete the ORIC.
Professional behaviour change will be monitored using the COM-B questionnaire.

Enriched Data Sample (patients)
The enriched data sample will complete additional measures (as detailed below) at 6 and 12 months, following their initial appointment.

Primary outcomes (6- and 12-month follow-up)

The severity of mental health symptoms will be measured using the Patient Health Questionnaire [PHQ-9; Kroenke et al 2001] for depression and the Generalised Anxiety Disorder scale [GAD-7; Spitzer et al 2006] for anxiety. Primary outcome measures will be collected at 6- and 12-months follow-up.

Baseline and end of treatment outcome measure data will be obtained and matched with the 6 and 12-month follow-up data, with patient consent, from the Routine IAPT data set.

***Therapeutic Relationship* (6-month follow-up only)**

The therapeutic relationship has been shown to be associated with psychotherapy outcomes [Horvath and Luborsky 1993] and is considered by many therapists to be negatively impacted when therapy is conducted over the phone. As this is not an IAPT routinely collected measure we will ask the enriched data patient cohort participants to complete the Agnew Relationship Measure [ARM-5; Agnew-Davies et al 1998, Cahill et al 2012]. The ARM-5 consists of 5 questions which assesses the three dimensions of the alliance known to be important for treatment efficacy: Bond; Partnership; and Confidence in therapy. Patients respond to the 5 questions on a 6 point scale from 'Strongly Disagree' to 'Strongly Agree'. A total raw score ranging from 5 to 35 indicates the overall level of therapeutic alliance. In addition, scores are presented as "mean scores", indicating the average responses (from 1 to 7). A percentile rank is presented using the mean and standard deviation from the Cahill et al. (2012) sample, indicating the level of alliance compared to a normative sample.

The wording of the questions included in the ARM-5 have been slightly modified, with approval of the developers, to make them applicable for use at the 6-month follow-up point in the EQUITy trial.

Economic Evaluation (6- and 12-month follow-up)

The economic evaluation will be assessed using two measures, the EQ-5D-5L and the Economic Patient Questionnaire (EPQ). Details of both measures provided below.

EQ-5D-5L

As part of the economic evaluation recruited cohort patients will be asked to complete the EQ-5D-5L which is a self-report standardised measure of health status commonly used for clinical and economic appraisal. It consists of 5 questions regarding Mobility, Self-Care, Usual Activities, Pain/Discomfort and Anxiety/Depression. Each question can be answered using five options of severity which indicate: no problem; slight problems; moderate problems; severe problems; unable to/extreme problems. Overall health status is estimated using the visual analogue scale (EQ-VAS) where patients score their overall health status on a scale from 0-100 where 100 is the best health you can imagine and 0 the worst. The EQ-5D-5L used together with published utility-tariffs (Van Hout et al 2012, Devlin et al 2018) will be used to estimate Quality of Life Years (QALYs) commonly used for economic analysis.

***The Economic Patient Questionnaire* (EPQ)**

Recruited patient cohort participants will also be asked to complete the EPQ, a measure of health and social care service use developed in-house. The EPQ was used in the NIHR funded EQUIP programme [Lovell et al 2019; EQUIP, RP-PG-1210-12007] and has been adapted to collect data about use of IAPT and non- IAPT services (e.g. hospital, CMHT, primary care, social services and third-sector care). Members of the EQUITy Lived Experience Advisory Panel (LEAP) assisted with the adaptations. Questions about non-NHS & social care services paid forby the participant and paid/unpaid employment will be included for sensitivity analysis.

Professional sample data

Professionals who attend the team workshops, and telephone training sessions will be asked to complete some measures. These measures include the COM-B [Keyworth et al 2020], ORIC [Shea et al 2014] and TARS [TARS-1: Davis *et al.* 1989, TARS-2: Milne & Noone 1996]. Please see previous table (Table 1) Schedule of enrolment and data collection for professional data (intervention and control arms) for detailed information.

COM-B

Initials of the COM-B model stand for Capability (C), Opportunity (O), Motivation (M) and Behaviour (B). This model highlights that behaviour change is driven by an interaction involving all these domains. Recently, a generic 6-item self-evaluation questionnaire to assess the impact of interventions on COM was developed by behavioural change experts and it has demonstrated acceptability, reliability and validity for self-evaluating the three domains of the COM-B model (i.e. capabilities, opportunities and motivations) [Keyworth et al 2020]. This 6-item questionnaire has been adapted for the purposes of this research with the permission of the developers.

ORIC

Organizational readiness refers to 'the extent to which organizational members are psychologically and behaviourally prepared to implement organizational change' (Weiner et al 2008). The Organizational Readiness for Implementing Change (ORIC) questionnaire ORIC [Shea et al 2014] is a 12-item self-report questionnaire. The 12 items are divided into two main subscales: (1) five items on change commitment (i.e. do the intended members of the organization want the change?) and (2) seven items on change efficacy (i.e. are the intended members of the organization able to change?). Items are rated on a five-point Likert scale, ranging from 'disagree' (1) to 'agree' (5). Scores across all items are summed. Lower scores represent less organisational readiness for implementing change; higher scores represent a more favourable organisational readiness for implementing

change.

TARS

The Training Acceptability Rating Scale [TARS-1: Davis *et al.* 1989, TARS-2: Milne & Noone 1996] will be used to explore professional acceptability of the EQUITy training course. TARS consists of two sections:

1. TARS-1 is a six-item self-report scale that measures training 'appropriateness' or 'acceptability' (covering general acceptability, perceived effectiveness, negative side effects, appropriateness, consistency and social validity). Items are rated on a six-point Likert scale, ranging from 'strongly disagree' (1) to 'strongly agree' (6). TARS-1 has good test–re-test reliability ($r = 0.83$ $P < 0.01$) and internal consistency (0.99) [Davis *et al.* 1989]. An acceptability score will be calculated by summing responses to all questions (range 6-36).
2. TARS-2 is a nine-item scale that measures overall perceptions of the impact of the training process and its outcomes. Items are rated on a four-point Likert scale from 'not at all' (0) to 'a great deal' (3). The reliability of TARS-2 has not been psychometrically assessed, but it has repeatedly demonstrated good face and concurrent validity [Carpenter *et al.* 2007]. A perceived impact score will be calculated by summing responses to all questions (range 0-27). TARS-2 concludes with three open-ended questions asking about the 'most helpful' part of the training, any 'recommended changes' and 'any other comments'.

An overall TARS score will be calculated by summing the responses to questions to both sections (range 6–63).

Workshop attendees:

Attendees of the Team Workshop (Service Leads, Managers, PWPs, Administrators) will be asked to complete a Demographic form prior to attending the workshop (this will be sent with the workshop joining details email). There will also be the opportunity to complete this throughout the day if they have been unable to complete before. They will also be asked to complete the COM-B measure (pre-post-workshop) and the ORIC (pre-workshop).

Telephone Training attendees:

Practitioners who have attended the telephone training session(s) will be asked to complete a demographic form (if they did not attend the workshop), the COM-B measure (pre and post-training) and the TARS measures (post-training only).

Post-intervention implementation qualitative interviews/discussion groups

Patient interviews

Patients who attend a qualitative interview will be asked to complete a demographic questionnaire prior to their interview (online via Qualtrics platform) or over the telephone/video-call at the start of their interview. The demographic questionnaire will include questions about geographical locations (GP surgery), gender, age, ethnicity and telephone treatment access. This data will be used in the write up and dissemination of the research findings to describe the sample and identify if the sample is comparable to the population accessing IAPT services.

Professional interviews/discussion groups

Professionals (Service Leads, Managers, Supervisors, PWPs, Administrators) invited to take part in a qualitative interview or discussion group would have previously completed a demographic questionnaire (at the workshop/training) and this will be used to purposively approach the sample.

7) DATA COLLECTION, SOURCE DATA AND CONFIDENTIALITY

DATA COLLECTION

Routine IAPT data

The IAPT Programme routinely collects robust and comprehensive data for all patients accessing NHS-funded IAPT Services in England. Data routinely collected by IAPT is detailed at https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/improving-access-to-psychological-therapies-data-set. Service inclusion in the trial will necessitate access permission to pseudonymised routine IAPT service data.

Enriched Data Sample

IAPT datasets are comprehensive at baseline with consequent high external validity [Gyani et al 2011]. However, they lack long term outcomes; services do not follow up service users after discharge. Additionally, they do not collect broader service use measures and generic, preference-based health status measures.

To overcome this, we will seek patient consent at service entry/start of treatment, to collect 6 and 12-month follow-up data for a sub-sample of patients (up to 100 per service), via mail or online, with or without telephone support, for a minimum outcome set: depression and anxiety symptoms (PHQ-9, GAD-7), health status (EQ-5D-5L), a brief measure of health and social care service use (EPQ), and, at 6 months only, the Agnew Relationship Measure (ARM-5) of patient alliance ratings of telephone-treatment sessions.

Clinical Trials Unit Involvement

The main data collection method will be online completion of the measures directly into a Clinical Trials Unit (CTU) database (Manchester CTU, https://www.bmh.manchester.ac.uk/research/manchester-ctu/). Manchester CTU will be responsible for data management of the Enriched data sample using their Electronic Data Capture Database.

Following gathering patient consent (by the research team), which will include obtaining consent to share name, contact details and service location with Manchester CTU, patient details will be passed to the CTU who will register the patient with the trial and allocate an ID.

Participants will be sent an email prepared by the EQUITy research team automatically by the CTU via email to complete the follow-up measures (6 or 12-month) online. If, at the time of consent patients indicated they are adverse to completing measures electronically (online/email), telephone contact will be made by the research team dependent upon the participant's needs. Online follow-ups will be supported by telephone reminders from the research team should deadlines for completion be missed. All losses to follow-up, withdrawal and loss of contact will be fully recorded and reported.

Participants will receive a small thank you (£5 gift voucher at each follow-up time point) to support all methods of follow-up at 6 and 12 months, with circulation of incentives dependent upon method of completion.

Enriched sample data will be stored by the CTU. Data from participants taking part will be made available members of the research team conducting the analysis via secure electronic transfers. If researchers obtain the 6 or 12-month follow-up data via telephone, this data will be entered immediately into the CTU database, no paper documents will be produced.

Professional and Patient Interview data

With participant consent, interviews/group discussions will be audio/video-recorded by study researchers using encrypted devices. Group discussions (professionals only) will be held on Zoom/Microsoft Teams. For the video-calls, only the audio part of the recording will be retained. Professionals taking part in a group discussion can join the meeting and turn off the video if they would prefer not to be video-recorded.

All of the research team have read and understood the University of Manchester SOP for taking recordings of participants for research projects. Data will be transferred from these sources (encrypted digital recorders/Zoom or Microsoft Teams) as soon as possible and

transferred to secure University servers via secure data transfer systems. Recordings will be transcribed verbatim by a University approved company with transfer of audio recordings to the transcribing company via a secure file transfer system.

Team Workshop data

Team workshop will be recorded with all participants consent. Recordings will be transcribed verbatim by a University approved company with transfer of audio recordings to the transcribing company via a secure file transfer system.

Follow-up meetings and any subsequent online/telephone meetings with action plan leads that take place (optional) will not be audio-recorded but minutes of these meetings will be taken instead.

Should all participants not consent detailed digital notes will be taken by researchers and these will be immediately saved to secure University Servers.

STORAGE OF DATA

All data will be subject to the University of Manchester Research Data Management Policy and GDPR.

Data will be stored in two ways:

1. Storage of personal data on University computers and laptops: University encrypted laptops will only be used for temporary storage. The primary repository for study data will be secure University servers, accessible only via password. Names and addresses etc will be removed from electronic records, except where identifiable details are essential (e.g. for purpose of mailing participants).

The majority of data collated will be stored on secure University of Manchester servers. Where data is collected by EQUITy researchers working at Universities other than the University of Manchester, i.e. York, Cambridge or Sheffield Universities (who may assist with data collection), data will be stored on encrypted servers at those locations. At the end of the study data will be transferred to the University of Manchester via secure transfer systems or personally by an EQUITy researcher.

No physical documents will be collected, all electronic documents will only be accessible to study personnel who have obtained the necessary approvals.

Electronic data will be stored in the EQUITy Research Data Storage area hosted by the University of Manchester. The data for this study will be archived in a folder within this area that only the CI (PBe) and Programme Manager (JG) will have access to.

In line with University regulations and good practice, at the end of the project all confidential or important digital data is sent into secure storage for 10 years. Date of birth data collected during the enriched sample study will be permanently deleted at the end of the study. Consent forms will be held for 7 years following the end of the study. Data that will requires long- term storage e.g. consent forms will be stored as per UoM procedures managed by the Information Governance Office (IGO) who use a recognised external storage provider. Retention dates and contact details for the record owner will be added to all data sent off-site.

TRANSFERRING DATA

Data will be stored on the University of Manchester EQUITy Research Data Storage area that is accessible only to members of the research team based at the University of Manchester (CI, Programme Manager, Researchers) who are granted access by the controller (JG or PBe). Where data is collected by an EQUITy researcher working at another educational institution, the data will be transferred to the University of Manchester for storage as soon as is possible in line with collaboration guidance using an approved digital storage option e.g. ZendTo, all data will be encrypted prior to transfer.

Pseudonymous routine IAPT Data sets will be transferred from trial sites using an approved IAPT (NHS or third sector) transfer procedure such as via Egress secure platform.

CONFIDENTIALITY

Personal Information:

For patients involved in the enriched data sample and those who take part in a qualitative interview we will, with their consent, ask the data manager at each service to identify their data within the routine IAPT dataset. This may involve sending the research team the patient's unique IAPT service number (not NHS number). This will be used for linking data purposes but as soon as the data is linked this linking number will be deleted.

Consent-to-contact and consent forms for qualitative interviews will hold participant name, signature and contact details - address, phone number, email (consent-to-contact form only).

This will only be used to arrange interviews with participants or for dissemination of a summary of the findings at the end of the study (if they consented to this) and will only be available to members of the research team who have the correct governance approvals.

Pseudonymised personal data:

All personal information that could potentially identify an individual will be removed from routine IAPT data (i.e. we will request year of birth rather than DOB and part patient postcode or GP postcode rather than full patient postcode) by individuals at the site (i.e. data manager) prior to transfer to University of Manchester researchers. As the data set will contain special category data it will be considered as pseudonymised, despite the possibility of being able to identify an individual person as highly unlikely. Data will be transferred by secure transfer systems approved by the sites (NHS/third sector) e.g. Egress, and the University of Manchester.

Participant (professional and patient) demographics will be collected in the qualitative study but will be pseudonyminised. All participants on entry to the study will be allocated a study ID which will appear on the demographic form. Only researchers involved in the qualitative interview data collection and analysis will have access to the pseudonymisation key.

Audio recordings of interviews and group discussions which may contain personal identifiable information such as patient names, service names etc. which will be removed at the point of transcription.

Transcription of audio recordings will be conducted by an approved University of Manchester supplier and completed transcriptions will be stored within a secure electronic server area for access by the researchers working on the studies only. When transcribed, transcripts will be checked and any personal information will be removed. Pseudonyms will be used for the purposes of transcription and verbatim quotations used within publications. Direct quotation of respondents will be fully anonymised before publication - no data will be published that will make an individual identifiable.

Audio recordings will be destroyed after transcription and checking.

Person identifying information will therefore be anonymised/pseudonymised as soon as possible, with the exception on consent forms which will be held electronically and destroyed when the associated research data is destroyed (7 years following the end of the study).

Study data may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, for monitoring and auditing purposes, and this may well include access to personal information.

8) ANALYSIS CONSIDERATIONS

7.1 Statistical Analysis

The study statistician will prepare a full statistical analysis plan prior to data analysis, which will be agreed with the PSC.

Although the exact details of the analysis will be in that plan, the broad analysis will be as follows. Analysis of the primary outcome will use analysis of covariance to undertake a between-group comparison adjusting for clustering by service and pre-specified covariates to estimate the effect of our intervention on outcomes, for those patients referred to IAPT telephone-treatment.

Robustness check: The focus of our intervention will be on improving patient outcomes and engagement among those offered telephone treatments. However, there is a risk that our intervention will affect the types of patients who are offered telephone treatment in intervention sites, compared to controls. We will conduct a range of robustness checks to assess any potential impact, and these will be fully detailed in the statistical analysis plan. These checks will include: exploring interview data with professionals to understand changes that might have been implemented; comparison of types of patients referred for telephone-treatment before and after the intervention; comparing baseline characteristics of patients in intervention and control groups. If we identify bias related to changes in referral practice, we will undertake sensitivity analyses to test the robustness of the primary analysis. Sensitivity analyses will include adding control for unbalanced covariates into the primary analysis, and re-analysing using patient-level propensity score adjustment or using a difference-in-difference method.

Economic evaluation

The study economist will prepare a full economic analysis plan prior to data analysis, which will be agreed with the PSC.

Although the exact details of the analysis will be in that plan, the broad analysis will be as follows. We will assess the intervention's cost-effectiveness at two levels. The first (within-study analysis) will assess whether the intervention is cost-effective in the services and participants included in the implementation trial. The second (decision analysis) will explore potential cost-effectiveness outside the trial setting. Both analyses will use a cost-effectiveness acceptability approach to generate a cost-effectiveness acceptability curve, estimate the likelihood that the intervention is cost-effective, and calculate the net benefit statistic [Briggs & O'Brien 2001; Fenwick et al 2001; Hoch et al 2002; Pedram Sendi & Briggs 2001].

Within-study analysis: The primary analysis will use the NHS and Personal Social Services Perspective, (recommended by NICE) and time horizon of 6-months from 6-month follow-up to end of scheduled follow up (12-months). Regression analysis with bootstrapping, controlling for key covariates will estimate the net costs and QALYs of the intervention and generate a cost-effectiveness acceptability curve [Briggs and O'Brien 2001; Fenwick et al 2001; Hoch et al 2002; Pedram et al 2001], estimate the likelihood the intervention is cost-effective at a willingness to pay threshold of £15,000, and the net benefit statistic.

We will combine psuedonymised, routine IAPT data with the EQ-5D-5L [Herdman et al 2011] and health and social care service use data collected from participants at 6 and 12-month follow-up. The Economic Patient Questionnaire (EPQ) used in the NIHR funded EQUIP programme will be adapted to collect data about use of non-IAPT services (e.g. hospital, CMHT, primary care, social services and third-sector care). Questions about non-NHS & social care services paid for by the participant and paid/unpaid employment will be included for sensitivity analysis.

Costs will be estimated as service use multiplied by published unit cost, by type of service [PSSRU 2017, Department of Health 2017]. Intervention costs will include the costs of providing the intervention and annual equivalent cost developing intervention components. QALYs will be estimated from EQ-5D-5L responses and published utility-tariffs [van Hout et al 2012; Devlin et al 2018].

The primary analysis will use the utility-tariff recommended by NICE at the time of the analysis. All missing data will be treated as missing at random. Multiple imputation will use predictive mean matching and sequential chained equations. Cost data will be imputed by category so that all available data inform imputed values. Sub-group analyses will be defined prior to primary analysis, based on research team and Steering Committee.

It is anticipated a combined decision-tree and Markov model will be used to represent immediate treatment pathways in the index episode (decision tree) and the longer-term course of depression and anxiety (Markov model). The analysis will take an NHS and social care perspective to explore cost-effectiveness over longer time-frames (5 and 10 years) and to explore potential for the intervention to be cost-effective in IAPT services and patients not included in the trial.

Qualitative Analysis

Analysis will occur blind to trial outcomes to avoid biased interpretation [Oakley et al 2006]. Anonymised transcripts will be analysed independently by two qualitative researchers using thematic analysis, guided by the constructs of NPT and CFIR.

Analysis will be supported by NVivo software [QSR International Pty Ltd 2018]. Individuals will meet regularly to discuss codes, develop a provisional coding framework

and ensure that all emerging codes remain grounded in the original data. Additional members of the research team may assist with this.

7.2 Sample Size:

Enriched Sample

There are approximately 107 IAPT providers in England. We will recruit a minimum of 22 services. With 11 clusters per arm, an ICC of 0.027, a baseline-endpoint correlation of 0.5 and 100 patients/site, we would have 85% power to detect a standardised mean difference of 0.2. This calculation is based on a mean cluster size of 607 (based on the routine data per site) and a co-efficient variation of 1.14 (due to the high variation in siite size). As expected with a relatively small number of clusters, this calculation is sensitive to ICC; we retain 70% power at an ICC of 0.04.

Workshops

Professional attendance at workshops will vary depended on service size and professional availability to attend. We anticipate approximately 10-20 professionals per site (total 130-260 participants).

Telephone training

Professional attendance at the training sessions will vary depending on service size and professional ability to attend. We anticipate approximately 5-20 practitioners per site (total 65-260).

Qualitative Interview Sample

Patients

We will recruit until data saturation [Miles and Huberman 1994] with an estimated sample size of 25-30 patients from intervention arm sites who have accessed telephone treatment following implementation of the EQUITy intervention.

Professionals

We will recruit until data saturation [Miles and Huberman 1994], with an estimated sample size of 25-30 professionals (Service Leads, Managers, Supervisors, PWPs) from intervention arm sites.

The total sample size across all workshop, training sessions and studies will be 3180 (minimum 2845).

9) DATA MONITORING AND QUALITY ASSURANCE

The study will be subject to the audit and monitoring regime of The University of Manchester. Programme Steering Committee (PSC) comprising an independent chair, statistician, key IAPT professionals and PPI expert will convene and meet twice-yearly.

10) SAFETY CONSIDERATIONS AND ADVERSE EVENTS

Given the nature of the study and methodology that will be adopted we anticipate no clear risks inherent in the intervention under evaluation that would make us set a priori stopping criteria.

If any untoward event is observed, any decision about stopping the trial (including in response to data generated outside the trial) will follow regulatory procedures.

11) PEER REVIEW

The study was reviewed extensively by external reviewers and a Panel as part of the NIHR PGfAR application process. The statistical aspects of the research were reviewed by Prof. Richard Emsley, Professor of Medical Statistics & Trials Methodology, Kings College London. In addition, during the NIHR application process it was reviewed anonymously by external reviewers.

12) ETHICAL and REGULATORY CONSIDERATIONS

13.1 Approvals

NHS Research Ethics Committee and HRA approval will be obtained before commencing research.

The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2020.

13.2 Risks

Risk procedures and reporting of adverse events

We will set out and follow standard operating procedures in relation to assessing patient risk and reporting and acting upon serious adverse events.

Treatment delivered over the telephone

There is a perception amongst practitioners that delivering psychological treatment remotely entails greater risk than psychological treatment delivered face to face and is one of the reasons that remote delivery may not have become routine practice (Bee et al 2016). Whilst there is no evidence for this it is deemed important that practitioners feel confident that they can deal with any such difficulties should they arise. For this reason, procedures surrounding risk management are addressed in the telephone training element of the intervention.

Patient cohort participants - completion of outcome measures

The PHQ9 measure completed by participants at baseline and last treatment session, 6 and 12 month contains a question related to suicidal thoughts and self-harm. At the end of this questionnaire a statement will inform patients that they should be aware that their responses will not be seen by a clinical member of staff and that if they are feeling distressed they should contact their GP, The Samaritans, NHS 111 or to go to their local A&E department (dependent on level or risk/need)

Team workshop and telephone training

Attending the training may cause minor inconvenience to professionals as they may have to make changes in their diaries to attend. However, all sites have indicated that they will support their staff to attend and regard it as beneficial. Training will also take place on days that the sites have indicated would be most convenient for them. The feasibility study highlighted that, with notice, taking time out to attend such sessions was possible.

Professional (PWP/Service Lead/Manager/supervisor/admin) interviews/group discussions

We expect participation in an interview or group discussion to cause minor inconvenience to professionals, as it will take up to 90 minutes of their time (maximum time of taking part in a group discussion). Although this is flexible and, if an individual interview, could be considerably less. For individual interviews we anticipate they will take approximately 45-60 minutes. We will ensure participants understand this prior to taking part. During the feasibility study sites were supportive of the opportunity for their team to provide feedback for the training they received and with regards to the implementation of the intervention.

Patient interviews

While interviews are not exploring the experiences of individuals with anxiety and/or depression, focussing on their views of the patient resources and how/if they felt they may

have enhanced their treatment experiences, the main ethical concern relates to the potential vulnerability of the patient population (anxiety and depression). However, patients deemed to be high risk (e.g. of suicide or self-harm) would not be normally receiving telephone treatment within Step 2 IAPT services and thus not be included in the trial. During the interview patients may draw upon their own personal experiences when addressing these questions. Our team is very experienced in working with this population. We will ensure all participants receive clear information about the study (including receipt of a participant information sheet) and have the opportunity to ask questions before giving their consent.

There is a small risk that patients could become distressed. A distress protocol will be followed by all researchers involved in conducting interviews. This protocol means that researchers will seek further advice from team clinicians if concerns are raised. Patients will be informed before the interview commences that the interview is confidential and that we will only disclose the content of the interview to a clinician should something they say make us concerned for their, or others, welfare and that we will inform them that we are doing this. During the feasibility study and no such incidences occurred.

Although some of the patients we interview will already be regularly in contact with mental health support (through IAPT), our participant information sheet also provides links to additional sources of support that can be contacted if required.

13) STATEMENT OF INDEMNITY

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

14) FUNDING and RESOURCES

The EQUITy Programme is funded by the National Institute for Health Research (NIHR), Programme Grants for Applied Research (PGfAR, RP-PG-1016-20010).

15) PUBLICATION POLICY

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/.

We will work with our 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. We will identify and address potential barriers that make it harder for knowledge to pass between these groups.

We will work closely with the LEAP to ensure that our communications are clear and concise and take account of the needs and preferences of our audiences.

We 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.

We will develop a written publication strategy, publishing in high-impact academic, patient-focused and professional journals to ensure that we make an enduring contribution to the evidence base. Our 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 we will ensure this is not done in a way which would make particular individuals identifiable.

We 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 which examined the clinical and organisational contexts in which telephone-delivered psychological interventions were being used and the challenges faces in practice that lead to the development of the EQUITy intervention , have been published in peer reviewed journals:

- Rushton K et al. 'I didn't know what to expect': Exploring patient perspectives to identify targets for change to improve telephone-delivered psychological interventions. BMC psychiatry. 2020 Dec;20:1-3.

- Faija CL et al. What influences practitioners' readiness to deliver psychological interventions by telephone? A qualitative study of behaviour change using the Theoretical Domains Framework. BMC psychiatry. 2020 Dec;20(1):1-6.
- Rushton et al. A case of misalignment: the perspectives of local and national decision-makers on the implementation of psychological treatment by telephone in the Improving Access to Psychological Therapy Service BMC health services research. 2019 Dec;19(1):1-2.
- Irvine et al. 'So just to go through the options…': Patient choice in the telephone delivery of the NHS Improving Access to Psychological Therapies services. Sociology of Health and Illness. 2020, 43(1):3-19.
- Drew et al. Telephone delivery of psychological interventions: Balancing protocol with patient-centred care. Social Science and Medicine, 2021, 277; 113818.

16) REFERENCES

Agnew-Davies R, Stiles WB, Hardy GE, Barkham M, Shapiro DA. (1998). Alliance structure assessed by the Agnew Relationship Measure (ARM). *British Journal of Clinical Psychology, 37*(2), 155-72.

Bee PE, Lovell K, Lidbetter N, Easton K, Gask L. (2010). You can't get anything perfect: "User perspectives on the delivery of cognitive behavioural therapy by telephone". *Social Science & Medicine*, *71*(7), 1308-15.

Bee P, Lovell K, Airnes Z, Pruszynska A. (2016). Embedding telephone therapy in statutory mental health services: a qualitative, theory-driven analysis. *BMC Psychiatry*, *16*, 56. doi: 10.1186/s12888-016-0761-5

Brenes GA, Ingram CW, Danhauer SC. (2011). Benefits and challenges of conducting psychotherapy by telephone. *Professional Psychology: Research and Practice*, *42*(6), 543.

Briggs AH, O'Brien BJ. (2001). The death of cost-minimization analysis? *Health economics*, *10*(2), 179-84.

Cahill J, Stiles WB, Barkham M, Hardy GE, Stone G, Agnew-Davies R, Unsworth G. (2012). Two short forms of the Agnew Relationship Measure: the ARM-5 and ARM-12. *Psychotherapy Research*, *22*(3), 241-55.

Carpenter J., Milne D., Lambardo C., et al. (2007). Process and outcomes of training in psychosocial interventions in mental health: a stepwise approach to evaluation. *Journal of Mental Health, 16*, 505–520.

Cella M, Chalder T. (2010). Measuring fatigue in clinical and community settings. *Journal of Psychosomatic Research, 69*, 17-22.

Chambless DL, Caputo GC, Jasin SE, Gracely EJ, Williams C. (1985). The Mobility Inventory for Agoraphobia. *Behavior Research and Therapy*, *23*, 35-4.

Connor KM, Davidson JRT, Churchill LE, Sherwood A, Foa EB, Weisler RH. (2000). Psychometric properties of the Social Phobia Inventory (SPIN): a new self-rating scale. *British Journal of Psychiatry*, *176*, 379–386.

Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. (2009). Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implementation Science*, *4*, 50. doi: 10.1186/1748-5908-4-50

Davis J.R., Rawana E.P. & Capponi D.R. (1989). Acceptability of behavioural staff management techniques. *Behavioral Residential Treatment, 4*, 23–44.

Department of Health. NHS reference costs. Available at: https://www.gov.uk/government/collections/nhs-reference-costs (Accessed 02/06/2021).

Devlin NJ, Shah KK, Feng Y, Mulhern B, van Hout B. (2018). Valuing health-related quality of life: An EQ-5D-5L value set for England. *Health economics*, *27*(1), 7-22.

Drew et al. Telephone delivery of psychological interventions: Balancing protocol with patient-centred care. (2021). *Social Science and Medicine*, *277*, 113818. doi: 10.1016/j.socscimed.2021.113818

Faija CL, Connell J, Welsh C, Ardern K, Hopkin E, Gellatly J, Rushton K, Fraser C, Irvine A, Armitage CJ, Wilson P. (2020). What influences practitioners' readiness to deliver psychological interventions by telephone? A qualitative study of behaviour change using the Theoretical Domains Framework. *BMC psychiatry*, *20*(1), 1-6.

Fenwick E, Claxton K, Sculpher M. (2001). Representing uncertainty: the role of costeffectiveness acceptability curves. *Health economics, 10*(8), 779-87.

Foa EB, Kozak MJ, Salkovskis PM, Coles ME, Amir N. (1998). The validation of a new obsessive-compulsive disorder scale: The Obsessive-Compulsive Inventory. *Psychological Assessment*, *10*, 206-214

Francis CY, Morris J, Whorwell PJ. (1997). The irritable bowel severity scoring system: a simple method of monitoring irritable bowel syndrome and its progress. *Alimentary Pharmacology and Therapeutics*, *11*, 395-402

Gyani A, Shafran R, Layard R, Clark DM. (2011). Enhancing recovery rates in IAPT services: Lessons from analysis of the year one data. Available at: www.iapt.nhs.uk

Hammond GC, Croudace TJ, Radhakrishnan M, Lafortune L, Watson A, McMillan-Shields F, Jones PB. (2012). Comparative effectiveness of cognitive therapies delivered face-to-face or over the telephone: an observational study using propensity methods. *PLoS One*, *7*(9), e42916. doi: 10.1371/journal.pone.0042916

Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research, 20*(10), 1727-36.

Hoch JS, Briggs AH, Willan AR. (2002). Something old, something new, something borrowed, something blue: a framework for the marriage of health econometrics and cost-effectiveness analysis. *Health economics, 11*(5), 415-30.

Horvath AO, Luborsky L. (1993). The role of the therapeutic alliance in psychotherapy. *Journal of consulting and clinical psychology*, *61*(4):561-73.

Improving Access to Psychological Therapies (IAPT) Data Handbook Appendices v2.0.1 (2011) , Appendix D3 IAPT Phobia Scale. Available at: https://vdocuments.net/iapt-data-handbook-appendicies-v2.html

Irvine A, Drew P, Bower P, Ardern K, Armitage CJ, Barkham M, Brooks H, Connell J, Faija CL, Gellatly J, Rushton K, Welsh C, & Bee P. (2020). 'So just to go through the options…': Patient choice in the telephone delivery of the NHS Improving Access to Psychological Therapies services. *Sociology of Health and Illness*, *43*(1), 3-19.

Keyworth C, Epton T, Goldthorpe J, Calam R, Armitage CJ. (2020). Acceptability, reliability, and validity of a brief measure of capabilities, opportunities, and motivations ("COM-B"). *British Journal of Health Psychology, 25*(3), 474-501.

Kroenke K, Spitzer RL, Williams JB. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, *16*, 606-13.

Lovell K, Bee P, Bower P, Brooks H, Cahoon P, Callaghan P, *et al.* (2019). Training to enhance user and carer involvement in mental health-care planning: the EQUIP research programme including a cluster RCT. *Programme Grants for Applied Research.* Southampton (UK): NIHR Journals Library. doi: 10.3310/pgfar07090

May C, Gask L, Atkinson T, Ellis N, Mair F, Esmail A. (2001). Resisting and promoting new technologies in clinical practice: the case of telepsychiatry. *Social science & medicine*, *52*(12), 1889-901.

May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, Rapley T, Ballini L, Ong BN, Rogers A, Murray E. (2009). Development of a theory of implementation and integration: Normalization Process Theory. *Implementation Science*, *4*(1), 1-9.

Miles MB, Huberman AM. (1994). *Qualitative Data Analysis* (2nd edition). Thousand Oaks, CA: Sage Publications.

Milne D. & Noone S. (1996) *Teaching and Training for Non-Teachers*. The British Psychological Society, Leicester.

Mohr DC, Ho J, Duffecy J, Baron KG, Lehman KA, Jin L, Reifler D. (2010). Perceived barriers to psychological treatments and their relationship to depression. *Journal of clinical psychology, 66*(4), 394-409.

Mundt JC, Marks IM, Shear MK, Greist JM. (2002). The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *The British Journal of Psychiatry, 180*, 461-64.

NHS Digital 2019. Psychological Therapies: Annual Report on the use of IAPT services England, 2019/20. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/psychological-therapies-annual-reports-on-the-use-of-iapt-services

National Institute for Health and Clinical Excellence. (2011). Clinical Guideline 113 Generalised anxiety disorder and panic disorder in adults: management. Department of Health, London.

National Institute for Health and Clinical Excellence (2009). Clinical Guideline 90 Depression in adults: recognition and management. Department of Health, London.

Oakley A, Strange V, Bonell C, Allen E, Stephenson J. (2006). Process evaluation in randomised controlled trials of complex interventions. *British Medical Journal, 332*, 413. doi: 10.1136/bmj.332.7538.413

Pedram Sendi P, Briggs AH. (2001). Affordability and cost-effectiveness: decision-making on the cost-effectiveness plane. *Health economics*, *10*(7), 675-80.

QSR International Pty Ltd (2018). NVivo qualitative data analysis Software: Version 12 [computer program].

Qualtrics, Provo, UT, USA. https://www.qualtrics.com

Rushton K, Ardern K, Hopkin E, Welsh C, Gellatly J, Faija C, Armitge CJ, Lidbetter N, Lovell K, Bower P, & Bee P. (2020). 'I didn't know what to expect': Exploring patient perspectives to identify targets for change to improve telephone-delivered psychological interventions. *BMC psychiatry*, *20*, 156. doi: 10.1186/s12888-020-02564-6

Rushton K, Fraser C, Gellatly J, Brooks H, Bower P, Armitage CJ, Faija C, Welsh C, & Bee P. (2019). A case of misalignment: the perspectives of local and national decision-makers on the implementation of psychological treatment by telephone in the

Improving Access to Psychological Therapy Service. *BMC health services research, 19*(1), 997. doi: 10.1186/s12913-019-4824-4

Shea, C.M., Jacobs, S.R., Esserman, D.A. et al. (2014). Organizational readiness for implementing change: a psychometric assessment of a new measure. *Implementation Science, 9*, 7. doi: 10.1186/1748-5908-9-7

Shear MK, Brown TA, Barlow DH, et al. (1997). Multicenter collaborative Panic Disorder Severity Scale. *American Journal of Psychiatry*, *154*(11), 1571–1575.

Spitzer RL, Kroenke K, Williams JB, Löwe B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. *Archives of Internal Medicine*, *166*(10), 1092-7. doi: 10.1001/archinte.166.10.1092

Stiles-Shields C, Kwasny MJ, Cai X, Mohr DC. (2014). Therapeutic Alliance in face-to-face and telephone-administered cognitive behavioral therapy. *Journal of Consulting and Clinical Psychology*, *82*(2), 349–54.

Turner J, Brown JC, Carpenter DT. (2018). Telephone-based CBT and the therapeutic relationship: the views and experiences of IAPT practitioners in a low-intensity service. *Journal of Psychiatric and Mental Health Nursing*, 25(5–6), 285–96.

UK Policy Framework for Health and Social Care Research. (2020). Available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Personal Social Services Research Unit. Unit costs of health and social care Available at: http://www.pssru.ac.uk/project-pages/unit-costs/ (Accessed 27th May 2021).

Van Hout B, Janssen MF, Feng Y, Kohlmann T, Busschbach J, Golicki D. (2012). Interim scoring for the EQ-5D-5L: mapping the EQ-5D-5L to EQ-5D-3L value sets. *Value Health*, *15*(5), 708-15.

Weiss DS. (2007). The Impact of Event Scale-Revised. In Wilson JP and Keane TM, eds. *Assessing Psychological Trauma and PTSD: A Practitioner's Handbook* (pp. 168-89). New York: Guilford Press.

World Health Organization [WHO]. 2019. Available from: http://www.euro.who.int/__data/assets/pdf_file/0004/404851/MNH_FactSheet_ENG.pdf?ua=1

Appendix I

Routine IAPT data collection detailed information

IAPT Data Requested (as listed in Box 4)	**Further detail (examples of codes)**
Patient Demographics	
Local ID	
Geographical location	GP postcode or part patient postcode
Gender	
Age	year of birth (rather than DOB)
Language	LanguageCodePreferred
Employment	Employment status
Ethnicity	EthnicCategoryGroup
Disabilities	Disability code
Care Pathway Referral Details	Referral source Onward referral reason Referral team Referral care professional staff group
Information on presenting complaints (mental/physical)	Present complaint Diagnosis Referred problem Primary reason for referral Long term condition
Sessions attended/unattended	Attendance Case status End of care reason Appointment outome Reason for Termination
Intervention details	Appointment Type Patient therapy mode Consultation medium/ mechanism Intreventions Tier of service Type of activity undertaken for contact Step intensity
Economic/Social	Accommodation Benefit receipt indicator Educational establishment type Employment support suitability indicator Employment and support allowance receipt indicator Interpreter present Job seekers allowance receipt indicator Marital status Other benefits receipt indicator Planned care contact indicator

	Personal independence receipt indicator Psychotrophic medication usage Self imployed indicator Short notice indicator/cancellation Sickness absence indicator Statutory sick pay receipt indicator Universal credit receipt indicator Weekly hours worked Care Contact patient therapy mode Case status episode completed Appointment the last Employment Support appointment? EQ-VAS Integrated IAPT LTC service indicator Contact result of planned appointment Sign post
Practitioner qualifications	Care professional
Treatment Engagement *Dates of all contacts with patients*	
Date of referral	
Date of assessment	
Dates of sessions	
Start date of treatment	
End date of treatment	
Number of sessions attended/unattended	
Outcomes *All item by item (if available) or total score for each session/contact*	
PHQ-9	
GAD-7	
WSAS	
IAPT Employment Status Questionnaire	
Patient Assessment Experience Questionnaire	
Patient Treatment Experience Questionnaire	
The following measures may or may not be collected, depending on presenting problem	
Social Phobia Inventory (SPIN)	
Impact of Events scale (IES-R)	
Mobility Inventory (MI)	
Obsessive-Compulsive Inventory (OCI)	
Panic Disorder Severity Scale (PDSS)	
Francis Irritable Bowel Scale	
Chandler Fatigue Scale	