# Patient-led appointment scheduling in NHS Talking Therapies

Submission date	Recruitment status	[X] Prospectively registered
08/04/2025	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
10/04/2025	Ongoing	☐ Results
Last Edited	Condition category	Individual participant data
15/07/2025	Mental and Behavioural Disorders	[X] Record updated in last year

# Plain English summary of protocol

Background and study aims

Depression and anxiety are common mental health problems that can reduce people's quality of life and increase their risk of suicide. NHS Talking Therapies deliver evidence-based psychological interventions using a stepped care model. Some people find it difficult to access support from these services. This includes people from ethnic minority groups, disabled people, and older people. Inflexible approaches to delivering psychological interventions appear to be one significant barrier to people accessing support from NHS Talking Therapies. Patient-led appointment scheduling (PLAS) is an approach that gives patients more control over factors such as the frequency and number of therapy sessions booked. The team believes that therapy delivered using PLAS could be as helpful as therapy delivered using the usual methods of arranging appointments in NHS Talking Therapies. However, they think that therapy delivered using PLAS might be more cost-effective, more accessible, and could improve patient satisfaction. Ultimately, they would like to conduct a study that compares the effectiveness of PLAS to usual methods of appointment scheduling. First, however, they are conducting this smaller study to ensure it is feasible to run a larger effectiveness study. This study aims to ensure it is possible to get enough people to take part in the study and to follow their progress. The team wants to see if they can collect information from people about their mental health and their use of NHS services. They also want to find out how many people would be needed for a larger study and hear from patients about whether they find PLAS helpful.

# Who can participate?

Adults who have been referred to NHS Talking Therapies for psychological interventions (also known as 'talking therapy') and have also been assessed as suitable for one-to-one guided self-help interventions with support from a Psychological Wellbeing Practitioner (also known as 'Step 2').

What does the study involve?

Providing consent

If someone is interested in being involved in the study, a member of the research team will contact them to discuss this and confirm their eligibility to take part. This will give them the opportunity to find out more about what participation would involve. They will have at least 24 hours to decide whether to take part in the study after receiving the information sheet. If they

decide to be involved, they will be asked to either sign a consent form or have a member of the research team audio record their consent.

## Completing questionnaires

Participants will be asked to complete several questionnaires that inquire about the kinds of problems they are experiencing and their satisfaction with the support received. They will also be asked for some personal information, including age, gender, ethnicity, any physical or mental health conditions, the kinds of support received, and details about their personal circumstances. Participants can choose to skip any questions they prefer not to answer.

#### Randomisation

Participants will be randomly assigned to one of two groups if they choose to take part in the study. The research team does not have any control over which group participants are assigned to. Participants will be contacted to inform them of their group assignment.

#### The two groups are:

Usual Appointment Scheduling (UAS): Participants will continue to receive the usual support from NHS Talking Therapies, meaning they will be offered psychological therapy appointments in the usual way.

Patient-Led Appointment Scheduling (PLAS): Participants will be offered psychological interventions using patient-led appointment scheduling, allowing them to choose how many sessions of therapy they book and how often they attend sessions. They will be able to book appointments for up to six months. More details on booking appointments will be provided if assigned to this group. Two-thirds of participants will be allocated to the PLAS arm of the study.

Follow-up Participants will be asked to complete the same questionnaires they completed at the start of the study six months later and again nine months later.

#### Interviews

Participants might also be invited to take part in an interview. However, they can choose not to participate in an interview and still take part in the rest of the study. If they decide to take part in an interview, they will be asked about the support received and their experience of participating in the study. Interviews will last no more than 60 minutes and will be audio recorded. Quotes from interviews might be used in articles, conference presentations, and a short film, but it will not be possible to identify participants from these quotes. Participants can choose not to take part in an interview and still participate in the rest of the study.

What are the possible benefits and risks of participating?

What are the possible benefits of taking part?

Many people report that taking part in research of this kind is a helpful experience. Others say that it is rewarding to take part in research that helps to improve mental health services for other people. Participants might find it helpful to talk about their difficulties or their experiences of working with NHS Talking Therapies.

What are the possible disadvantages and risks of taking part?

Topics may be discussed when completing questionnaires or during interviews, or focus groups that some people might find distressing. It is unlikely, however, that participants will experience any long-term distress from taking part in this study. Participants can choose to skip any questions that cause discomfort or distress. Participants can also end their participation in the study at any time without giving a reason.

#### **Payments**

To acknowledge participants' time, they will be paid £20 on each of the three occasions they complete questionnaires during the study. Participants who also choose to take part in interviews will be paid an additional £25 for their time.

Where is the study run from?

This study is led by a research team from the University of Manchester, UK

When is the study starting and how long is it expected to run for? December 2024 to May 2027

Who is funding the study?

The National Institute for Health and Care Research (NIHR) Health and Social Care Delivery Research programme.

Who is the main contact? Dr Robert Griffiths, robert.griffiths-2@manchester.ac.uk

# Contact information

# Type(s)

Public, Scientific

#### Contact name

Dr Robert Griffiths

#### **ORCID ID**

https://orcid.org/0000-0002-5960-914X

#### Contact details

Lecturer in Mental Health, Room 6.310, Jean McFarlane Building, Division of Nursing, Midwifery & Social Work, School of Health Sciences, Faculty of Biology, Medicine &Health, University of Manchester, Oxford Road Manchester United Kingdom M13 9PL

Robert.griffiths-2@manchester.ac.uk

# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

340071

ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

CPMS 60830; NIHR160668

# Study information

#### Scientific Title

Using patient-led appointment scheduling to improve cost-effectiveness, access, and patient satisfaction in NHS Talking Therapies services: A feasibility study.

### Acronym

**PLANS** 

# Study objectives

These are the aims of our feasibility trial as they appear in our protocol. They are not stated as hypotheses because this study aims to address some key feasibility issues prior to progressing to a larger trial.

"Ultimately, the aim is to conduct a larger evaluation trial that will answer the following question:

Do low-intensity psychological interventions delivered according to the principles of PLAS by PWPs at Step 2 of NHS Talking Therapies services lead to:

- improvements in cost-effectiveness, patient satisfaction, and access compared to current appointment scheduling approaches; and
- at least as good clinical outcomes for patients (depression/anxiety)?

Because PLAS represents a significant change in practice, however, the first aim is to answer some key feasibility and acceptability questions that will enable us to refine the study design, optimise the intervention for testing in a larger trial, and ensure the approach is ready for implementation.

Primary objectives:

- 1. Develop a suitable PLAS pathway, evaluate its acceptability amongst key stakeholders, and refine the approach prior to further testing and implementation.
- 2. Determine the feasibility of recruiting and retaining participants to inform a larger trial. Secondary objectives:
- 1. Determine the feasibility of collecting clinical, health economic, and patient satisfaction data.
- 2. Generate further evidence regarding PLAS's potential and estimate key parameters to inform a sample size calculation for an evaluation trial."

# Ethics approval required

Ethics approval required

# Ethics approval(s)

approved 28/04/2025, South Central - Oxford B Research Ethics Committee (Health Research Authority, 2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8197; oxfordb. rec@hra.nhs.uk), ref: 25/SC/0112

# Study design

Randomized controlled trial

# Primary study design

Interventional

# Study type(s)

Treatment

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

Specialty: Mental Health, Primary sub-specialty: Service evaluations - service users; Health

Category: Mental health

#### **Interventions**

This project will use a mixed-methods design comprising four work packages (WPs).

WP1: Stakeholder workshops

Our initial stakeholder work and key NHS policy documents (NHS England, 2019; NHS England & NHS Improvement, 2019) suggest that making PLAS accessible to people from a variety of backgrounds should be a priority. We aim to draw on the expertise of relevant stakeholders to co-adapt the PLAS pathway to ensure it is ready for testing in WP2. To achieve this, we will conduct a series of workshops.

#### **Participants**

Workshop participants will be patients with lived experience of seeking support from NHS Talking Therapies, staff working in a variety of roles within these services, (clinical, administrative, and managerial), and senior NHS Talking Therapies leaders.

#### Recruitment

We are seeking to recruit participants who have experience of accessing support from Step 2 services, or who are working within these organisations. We are specifically seeking to recruit people from currently underserved groups (e.g., people from minority ethnic backgrounds and those with disabilities). In addition to promoting workshops in NHS Talking Therapies services and via our social media accounts (e.g., Twitter/X, Facebook, Bluesky), we will reach out to third /voluntary sector providers, grassroots community organisations, and lived-experience networks. Members of our Lived Experience Advisory Panel (LEAP) will also be invited to attend these workshops.

#### Methods

We are aiming to conduct a series of 4-6 workshops each attended by 6-12 participants. Workshops will be attended by a mixture of participants from different stakeholder groups. These will be facilitated by two members of our study team (VH and SJ). Participants will be invited to attend two paired workshops occurring on the same day: the first will focus on identifying potential problems with the PLAS pathway within Step 2 services; and the second will seek to generate solutions to the problems identified. Workshops will be structured to provide an overview of the project's aims, seek attendees' views on factors that might impact the implementation and evaluation of the PLAS pathway, and seek to establish group consensus on solutions to identified problems. In addition to seeking more general feedback on PLAS, we will specifically ask participants to consider topics such as whether a maximum number of therapy sessions per patient should be specified in the PLAS manual, the appropriateness of the proposed 6-month treatment window, issues relating to risk management and patient safety, how to manage situations where demand for sessions exceeds available capacity, and how to respond in situations where patients do not engage with the PLAS pathway. Workshops will use the Nominal Group Technique (Delbecg & Van de Ven, 1971), an effective method for gaining group consensus regarding problem identification and the development of solutions (Harvey & Holmes, 2012).

Participants will be made aware that they are able to invite supporters to attend the workshop with them. The venues for workshops will be in locations that are accessible to public transport.

We will provide taxis for patient participants if this is required. The use of remote or hybrid workshops will be considered if this addresses potential barriers to attendance for some participants.

With participants' consent, we will audio record workshops as a means of capturing key learning points. If audio recording appears to be a barrier to participation, we will opt for making detailed notes during the workshops.

After each pair of workshops, we will refine the PLAS pathway ready for discussion at the next round of workshops.

Feedback and recommendations generated in workshops will be taken forward by the research team. This will ensure that PLAS pathway is ready for testing in WP2.

WP2: Feasibility randomised controlled trial (RCT)

#### Trial setting

A feasibility trial will be conducted in two NHS Talking Therapies services in the North of England.

#### Recruitment

We will work with NHS Talking Therapies services and our LEAP to develop our recruitment strategy. Leaflets, posters, presentations to staff, and social media will be used to promote the research at study sites and to help identify potential participants. All participant-facing material will be developed in collaboration with our LEAP to ensure they are accessible to prospective participants from a wide range of backgrounds. We will also work with the LEAP to develop a short film or animation that can be shared with potential participants to support inclusivity and the recruitment of a diverse and representative sample. Participant recruitment will take place after patients have first been referred to Step 2 services and have attended an initial assessment appointment to determine their suitability for support provided at Step 2. Once assessed as suitable for individual psychological interventions delivered at Step 2 by a Psychological Wellbeing Practitioner, clinicians will be asked to give potential participants information about the study and seek verbal consent for the research team to contact them to discuss this further. Accessible study information and recruitment packs will be developed and made available to support clinicians' initial discussions with patients about study participation. We will develop a short animated film to support recruitment. NHS Talking Therapies staff will be given them detailed information about the study, participant eligibility criteria, and recruitment processes. Those patients who provide verbal consent at this stage will be contacted by the research team to complete an eligibility check. Those patients who meet the eligibility criteria will be given detailed verbal and written information about the study, and be invited to provide their consent to participate.

#### Trial treatments

This a randomised controlled trial with two arms:

1) Usual Appointment Scheduling (UAS):

Participants allocated to UAS will receive whatever support they would usually receive from their NHS Talking Therapies service. This will be individual low-intensity cognitive behavioural interventions delivered by Psychological Wellbeing Practitioners (PWPs) using guided self-help materials. Typically, this consists of weekly sessions for 6 weeks.

2) Patient-Led Appointment Scheduling (PLAS):

Participants allocated to the PLAS arm of the trial will also receive individual low-intensity psychological interventions delivered by a PWP. Interventions, however, will be delivered using PLAS. Participants will be able to choose the number and frequency of appointments they attend within a six-month timeframe.

#### Measures and data collection

Clinical measures that are validated and routinely used in NHS Talking Therapies, along with health economic and patient satisfaction measures, will be completed at baseline, 6 months (close of PLAS treatment window), and 9 months (3 months after close of PLAS treatment window). In addition, we will also collect clinical and demographic data from participants to further understand the characteristics of the study sample. This will include:

- Age
- Gender
- Ethnicity
- Any physical or mental health diagnoses
- Medications
- Previous access to psychological therapies
- Accommodation status
- Employment details

Assessments will be conducted by trained and experienced research assistants with participants either in-person or remotely, depending on participant preference. Research assistants who are collecting study data will not know which arm of the trial participants have been allocated to (i. e., they will be masked to group allocation). Participants will also have the option to choose to self-complete online or paper-based measures.

Participants who opt to self-complete measures online will be provided with a unique link to enter their response into REDCap, a secure web application for building and managing online surveys and databases. Research assistants will enter data into REDCap on behalf of participants who either choose to self-complete paper measures or complete measures with the support of a research assistant. Research assistants will contact participants up to two weeks prior to planned follow-up time points (6 and 9 months) to request that participants complete outcome measures.

This study aims to take an inclusive approach to participant recruitment. Participants who meet the study's inclusion criteria who either do not speak English or have other difficulties that might impact their ability to share their data will be supported to participate in the study. In the case of standard outcome measures for non-English speakers, for example, we will use the translated versions of measures that are routinely used in NHS Talking Therapies services (where these are available). Where translated versions of measures or other study documents (e.g., Participant Information Sheets) are not available, we will either request translated versions of these (if appropriate) and/or work with translators to communicate effectively with prospective or recruited participants.

We will also collect routine appointment booking and clinical data from participants' clinical records. This will include data collected with routine outcome measures that are used by NHS Talking Therapies, and the number of appointments booked and the outcome of booked appointments (attended, cancelled, or not attended). These data will be collected at 6 months (close of treatment window) by members of the research team.

# Changes in participation

Where a participant expresses a wish to stop taking part in some or all aspects of the PLANS study, we will follow a protocol that is informed by the PERSEVERE Checklist. The protocol (1) seeks to establish what change the participant wants to make with their level of participation, (2) establishes their preferences for further contact (3) if the participant is willing, explores the reasons for stopping some or all of their participation, (4) ensures the participant has the necessary information about their change in participation, (5), ensures there is a clear record of the changes in the participant's level of participation, and (6) makes sure that all relevant parties have been notified of the change. We will monitor and report changes in participants' levels of participation.

# Statistics and data analysis

Analysis and reporting will be consistent with the CONSORT extension for pilot and feasibility studies (Eldridge et al, 2016). A full Statistical Analysis Plan (SAP) will be produced, reviewed, and approved by our Project Steering Committee prior to commencement of any betweengroup analysis of clinical outcome data.

We will report participant flow through the study, including both recruitment rate and proportion (% recruited out of those approached, as an ancillary measure of acceptability), and retention (%).

Therapy session usage will be presented in terms of descriptive statistics. To indicate the representativeness of our sample, we will compare the demographic characteristics of our study sample to routinely collected demographic data for patients accessing care from the NHS Talking Therapies services that are acting as study sites (where these data are available).

Analyses of clinical outcomes at 6 and 9 months to explore the effect of PLAS (ie, whether they offer a signal that progression to a larger trial is warranted) and to estimate parameters to inform a sample size calculation for a future evaluation trial will involve descriptive statistics (mean (standard deviation), median [inter-quartile range), number [%]. as appropriate) and the use of linear mixed-effects longitudinal models to compare groups (adjusted for the baseline value of the respective key outcome, service, and any other baseline covariates believed a priori to be predictive of outcome), as randomised. No testing of effects will be performed, but 75% -95% confidence interval estimates will be presented, in line with recommended practice (Lee et al, 2014).

#### Health economic evaluation

The feasibility of carrying out a within-trial cost-effectiveness analysis will be determined. We will compare the difference in total cost and health outcomes for PLAS versus UAS over the 9-month follow-up period. A health economics analysis plan (HEAP) will be developed prior to the analysis. Healthcare resource use per participant for the previous 6 months will be measured at baseline, and at months 6 and 9, using routine data collection and a purposely designed healthcare services utilisation form based on existing adaptations of the Client Service Resource Inventory (CSRI) (Beecham & Knapp, 2001). Costs will comprise primary care (e.g., GP practice visits and phone contacts with the GP practice personnel); secondary care (eg, days spent on wards, accident and emergency departments, outpatient visits); community and social care costs. Using the CSRI, we will also collect data on costs incurred by patients (patient health-related costs and expenses (eg, travel to healthcare appointments and private medical expenses)).

## WP3: Qualitative study

Design

A qualitative study, nested within the RCT, will explore the acceptability of PLAS amongst key stakeholders (including patients and clinical, administrative, and managerial staff). This work package will also identify potential barriers to the subsequent implementation of PLAS and participants' experiences of trial participation. We will seek to understand participants' perceptions of factors such as the burden (ie, perceived amount of effort required to participate in the intervention), coherence (ie, extent to which participants understand the intervention and how it works), and perceived effectiveness (ie, the extent to which the intervention is perceived as likely to achieve its purpose) of PLAS. Findings will be used to further refine the PLAS pathway and study procedures.

#### Participants and recruitment

Patient participants (n = 20) will be a sub-sample of participants of the trial conducted in WP2. All trial participants from WP2 will be eligible to participate in WP3. These will primarily be participants who were allocated to the PLAS arm of the trial, but we will also seek to recruit a smaller number of participants from the UAS arm to understand their experiences of the trial. To understand people's reasons for not participating in the trial, and whether this was related to PLAS, we will give patients who declined to participate in the trial the option to take part in WP3. We will specifically aim to recruit patient participants from ethnic minority and other underrepresented groups to understand more about their experience of the PLAS pathway. We will also recruit NHS Talking Therapies staff (n=15-24) working in a variety of roles (clinicians, administrators, and managers) as well as senior NHS leaders (n = 5) involved in the planning and delivery of the NHS Talking Therapies programme.

#### Data collection

We will conduct semi-structured interviews, informed by a topic guide, with patient participants. Topic guides will cover the following topics relating to PLAS:

- How participants feel about the PLAS pathway:
- How much effort is required to engage with PLAS:
- To what extent PLAS is perceived to fit with participants' values and preferences:
- The extent to which participants understand the PLAS pathway and how it is designed to work
- Any perceived disadvantages to using the PLAS pathway:
- Whether the 6-month treatment window for PLAS was considered to be appropriate and sufficient
- The extent to which PLAS is perceived to be likely to achieve its intended purposes of improving patient satisfaction, access, and cost-effectiveness; and
- Participants' level of confidence that they can use PLAS.

The above topics will be discussed in relation to prospective (prior to intervention), concurrent (during intervention). and retrospective (after the intervention) acceptability. We will also ask participants assigned to UAS about their experience of therapy delivered using usual appointment scheduling systems. We will ask participants in both arms of the trial about their experience of trial participation more generally, such as the process of randomisation and the acceptability and number of outcome measures to be completed.

We will also conduct three focus groups with NHS Talking Therapies staff (n = 5-8 participants per group: n = 15-24 participants in total) working in a variety of roles to understand their perceptions of PLAS. Interviews and focus groups will be conducted in-person or remotely, depending on participant preference. In addition, research assistants and PWPs will keep diaries to document their reflections on the implementation of the PLAS pathway and other study procedures.

#### Data analysis

Data will be analysed using the six-stage process of reflexive thematic analysis (Braun & Clarke, 2019), an accessible and theoretically flexible method of qualitative analysis (Byme, 2022). It is a useful method for understanding patients' experiences of healthcare interventions and can be used in situations where a team of researchers are involved in the analysis (Braun & Clarke, 2022). Data collection and analysis will occur concurrently and in an iterative fashion to allow the ongoing identification of themes and topic guide refinement based on participants' responses. Audio recordings of interviews and focus groups will be transcribed verbatim. Transcripts will be entered into qualitative data analysis software (NVivo). Other sources of qualitative data (eg, reflective diaries of the research team) will be used to contextualise data collected from interviews and focus groups.

Themes generated during this work package will be used to further refine the PLAS manual, to ensure that it is informed by the perspectives of key stakeholders and is ready to be presented

in WP4. Findings from this work package will also be used to refine the trial design and address issues relating to implementation in advance of a potential evaluation trial.

# WP4: Reflection and problem-solving workshops

We will conduct two reflection and problem-solving workshops using the World Café (Brown, 2005) method with the aim of integrating and synthesising the findings of WP2 and WP3, to evaluate findings in relation to our overall study aims, and to resolve any problems that might impede the future testing and implementation of PLAS

#### Participants and recruitment

Participants (n = 40) will be people with lived experience of accessing support from NHS Talking Therapies, staff who work in a variety of roles (clinical, administrative, and managerial) within these services, and NHS Talking Therapies senior leaders. Participants who participated in WP1 will also be invited to participate in WP4. We will aim for at least 50% of participants across the two workshops (n = 20) to be people with lived experience of using NHS Talking Therapies.

#### Methods

We will conduct two World Café (Brown, 2005) events with 20 participants attending each event. Participants will be invited to attend one event only. World Café is a well-defined and structured approach to facilitating discussions amongst relatively large groups of people (Banfield et al., 2022; Brown, 2005). The aim is to create a relaxed and informal environment where the larger workshop group (n=20) breaks into small-group discussions (n = 4-5). Experts on the topics of interest will facilitate the small-group discussions. Clinical, academic, and expert-by-experience members of the research team will take on the role of experts and facilitate these small-group discussions. Small-group discussions are periodically fed back to the larger World Café group. Participants are then shuffled to other groups and the process is repeated several times with the aim of generating insights into the topic of interest from multiple perspectives.

Participants will be presented with the findings of WP2-3 and asked to discuss the following questions:

- What do the findings of WP2 and WP3 tell us about the feasibility and acceptability of PLAS in NHS Talking Therapies?
- What do the results suggest about PLAS's suitability for further testing in a larger trial and (if it proves effective) how should it be implemented?
- What barriers might exist to further testing and subsequent implementation, and how can these barriers be addressed?

Detailed notes and graphic recording will be used to capture feedback from small group discussions. Graphic recording is the recommended approach for capturing World Café discussions (Brown, 2005).

# Use of findings

Findings from World Café events will be used to interpret and integrate the results of the feasibility trial and qualitative study, refine the PLAS manual, and (if our success criteria are met) inform a funding application to conduct a larger evaluation trial. Results will also be used to inform the write-up and dissemination of findings from the overall project.

#### Study duration

The overall project commenced on 1st December 2024 and is due to complete on 31st May 2027. WP1 (stakeholder workshops) is due to run from March to June 2025. Recruitment for WP2 (clinical trial) will start in July 2025 with participant data collection ending in September 2026. Data collection for WP3 (qualitative study) will start in January 2026, with participant data

collection due to end in September 2026. WP4 (World Café events) will take place between November 2026 and March 2027.

Public and Patient Involvement and Stakeholder Engagement

This project benefits from significant Public and Patient Involvement (PPI). This study has two PPI co-applicants who have been involved in the design and delivery of the study from the outset. Salima Jones has experience of using NHS Talking Therapies and Tanya Mackay is Head of Research and Involvement for The McPin Foundation, an organisation that aims to promote lived experience in research. In addition, we will form a Lived Experience Advisory Panel (LEAP) that will play an active role in the delivery of the study. The LEAP will meet four times a year for the duration of the study.

In preparing our funding application, we conducted a number of stakeholder engagement sessions with patients (n = 4), clinical staff (n=5), and those in leadership roles in NHS Talking Therapies services (n=2). Patients described how current systems of appointment scheduling create a sense of disempowerment and fail to accommodate changes in their mental health that happen during treatment. The pressure to complete treatment within a constrained and predetermined timeframe was also judged to be unhelpful. Patients described discontinuing treatment as a result (and later requiring a re-referral to the same service). Clinical staff agreed that the inflexible nature of the current system makes it difficult for some patients to benefit from the support offered by NHS Talking Therapies. They also described how a large amount of their time was spent contacting patients to encourage them to attend sessions of therapy about which they were ambivalent. Clinicians described how encouraging patients to attend therapy at times when they were not motivated to do so often resulted in missed appointments.

#### Intervention Type

Other

#### Phase

**Not Specified** 

# Primary outcome(s)

- 1. Depression severity is measured using the Patient Health Questionnaire-9 [PHQ-9] at baseline, 6 months, and 9 months.
- 2. Generalised anxiety disorder severity is measured using the Generalised Anxiety Disorder-7 [GAD-7] at baseline, 6 months, and 9 months.
- 3. The impact of mental health difficulties on different dimensions of social functioning is measured using the Work and Social Adjustment Scale [WSAS] at baseline, 6 months, and 9 months.
- 4. Patient experience and satisfaction with service provision are measured with the Patient Experience Questionnaire [PEQ] at 6 months
- 5. Health outcomes are measured using the EuroQoL Five Dimension Five Level Version [EQ-5D-5L] at baseline, 6 months, and 9 months.
- 6. Data on participants' use of healthcare resources in the preceding six months will be collected using a bespoke Resource Use Questionnaire (RUQ) at baseline, 6 months, and 9 months.

# Key secondary outcome(s))

There are no secondary outcome measures

# Completion date

31/05/2027

# **Eligibility**

# Key inclusion criteria

- 1. Referred to NHS Talking Therapies for low-intensity psychological interventions
- 2. Attended an initial appointment and assessed as requiring one-to-one psychological interventions with a Psychological Wellbeing Practitioner delivered at Step 2 of NHS Talking Therapies
- 3. Aged > = 18 years or older
- 4. Has capacity to provide informed consent

# Participant type(s)

Patient

## Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

#### Sex

All

# Key exclusion criteria

Participants not meeting the participant inclusion criteria

#### Date of first enrolment

09/07/2025

#### Date of final enrolment

09/01/2026

# Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre

# **Prestwich Hospital**

Bury New Road Prestwich Manchester United Kingdom M25 3BL

# Study participating centre Pennine Care NHS Foundation Trust

225 Old Street Ashton-under-lyne United Kingdom OL6 7SR

# Sponsor information

# Organisation

Greater Manchester Mental Health NHS Foundation Trust

#### **ROR**

https://ror.org/05sb89p83

# Funder(s)

# Funder type

Government

#### **Funder Name**

National Institute for Health and Care Research

# Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

#### Location

United Kingdom

# **Results and Publications**

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

# IPD sharing plan summary

Data sharing statement to be made available at a later date

# **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes