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# Creative psychotherapy for depression, Arts for the Blues

**Submission date**
31/03/2026

**Recruitment status**
Not yet recruiting

**Registration date**
14/04/2026

**Overall study status**
Ongoing

**Last Edited**
14/04/2026

**Condition category**
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

## Plain English summary of protocol

Background and study aims
Depression is one of the most common mental health problems in the world. In the UK, around 21% of people suffer from depression, which costs the UK economy about £27 billion per year. There are several therapies for depression available within the NHS Talking Therapies and the main therapy provided is cognitive behavioural therapy (CBT). In these therapies, people are encouraged to talk to understand and manage their problems. However, about half of the people who use these therapies do not complete all the sessions. Prior research found that some people find CBT difficult as it focuses on identifying problematic thoughts and does not address underlying issues. Given that a lot of people struggle with depression, a greater variety of therapies must be available within the NHS.

Research shows that arts psychotherapies might be a good option for people who find it difficult to talk about their thoughts, as they use drawing, songs or movement to express difficulties. Research undertaken with service users and a Patient and Public Involvement group (PPI) indicates that they would like to see arts psychotherapies offered in the NHS.
To address this need, a new creative psychotherapy has been developed for depression, combining arts and talking psychotherapies called Arts-for-the-Blues. A small evaluation followed, involving seven service users in the charity MIND, who found this psychotherapy was helpful. To find out whether the intervention reduces people's depression, it needs to be tested through a larger study. This project aims to check if the design for a larger study will work by testing it in a smaller study.

Who can participate?
Adults aged 18 years and over who have/had depression or symptoms of depression (assessed by PHQ9 >5) and who are service users and registered with a GP in Greater Manchester (GMMH services covering: Bolton, Manchester, Salford, Trafford, and Wigan) or a partner organization, such as Six Degrees in Salford or 1 Point in Bolton

What does the study involve?
Adults who agree to take part will be put into two groups by chance (randomisation) to receive either treatment-as-usual (TAU) for depression or twelve sessions of Arts-for-the-Blues. To inform the larger study design, information will be recorded about how people are recruited, if

they attend until the end of the study and what is the TAU they receive. All participants will be asked to complete questionnaires in relation to their symptoms of depression at the start of therapy, after the end of therapy, and then 6 months later. The study team will also interview participants and therapists about their experiences of the study. All this information will feed into the design of the larger study comparing Arts for the Blues and TAU.

What are the possible benefits and risks of participating?
Benefits:
While there is existing evidence that creative psychotherapies can be helpful, the effectiveness of Arts for the Blues is yet to be established, as it is a new approach. Participants of the previous Arts for the Blues groups said they found it helpful, and it is anticipated that they may also benefit from the sessions. By taking part in this research, participants will be helping to improve mental health services for other people.

Disadvantages and risks:
Taking part in Arts for the Blues allows participants to explore their mental health difficulties. They may find that exploring some of these difficulties can be potentially upsetting, which is not uncommon in therapy, as difficult feelings can be stirred up during the sessions. Additionally, completing the research processes may become distressing and the therapists and researchers will be able to support individuals in distress if required. Participants will not need to do or answer anything that they don't want to do. If further support is needed, the therapist or members from the research team will discuss any further referral with them that they may need.

Where is the study run from?
The study will be run from GMMH Talking Therapies services in Manchester, Salford, Trafford, Bolton and Wigan, and third sector organisations such as Six Degrees and 1 Point, UK.

When is the study starting and how long is it expected to run for?
May 2026 to May 2028.

Who is funding the study?
The National Institute of Health and Care Research (NIHR), UK.

Who is the main contact?
Dr Joanna Omylinska-Thurston, Principal Investigator, joanna.omylinskathurston@gmmh.nhs.uk, j.omylinska-thurston1@salford.ac.uk

# Contact information

### Type(s)
Public, Scientific, Principal investigator


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# Additional identifiers

### Central Portfolio Management System (CPMS)
56270

### National Institute for Health and Care Research (NIHR)
304099

### Integrated Research Application System (IRAS)
328898

# Study information

### Scientific Title
A feasibility Randomised Controlled Trial (RCT) of an evidence-based creative group psychotherapy for adults with symptoms of depression (Arts for the Blues) in National Health Service (NHS) Talking Therapies compared to treatment as usual

### Acronym
Arts for the Blues

### Study objectives
To address the following uncertainties via feasibility RCT:
· Is it possible to recruit participants to the study?
· Are participants willing to be randomised?
· Do service users who engage in A4B receive a minimum therapeutic dose of 4 sessions?
· How acceptable and sensitive are the outcome measures used?
· What constitutes Treatment as Usual (TAU)?
· How acceptable is the intervention for participants and therapists?
· Is the training provided for the therapists sufficient to deliver the intervention?
· Can the therapists follow the intervention protocol?
· Is it possible to collect reliable cost and resource-use data?

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 17/03/2026, North West – Greater Manchester (GM) Central (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 0207 104 8388; gmcentral.rec@hra.nhs.uk), ref: 26/NW/0059

### Primary study design

Interventional

## Allocation
Randomized controlled trial

## Masking
Blinded (masking used)

## Control
Active

## Assignment
Parallel

## Purpose
Treatment

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Depression; Health Category: Mental health; Disease/Condition: Mood [affective] disorders

## Interventions
Trial design
The study will involve a randomised controlled feasibility trial with two parallel groups. Sixty participants will be randomised at a ratio of 1:1 to either 12 sessions A4B (active arm) or Treatment as Usual (TAU) (control arm). Potential participants will be assessed for suitability for A4B using inclusion/ exclusion criteria. Outcomes will be collected at clinical assessment/ baseline, 12 weeks and 24 weeks post baseline. The researcher undertaking randomisation will not be blinded to treatment allocation. Therapists will be blinded to treatment allocation at the assessment stage but not at the treatment stage. Participants will be randomly allocated to either A4B or TAU using an independent web-based randomised procedure (www.sealedenvelope.com) after baseline assessment. The trial framework is exploratory, assessing whether a future definitive trial is possible and how it should be designed.

Trial settings
Participants will be recruited via stepped-care primary care mental health services in the Greater Manchester Mental Health NHS Foundation Trust (GMMH), including NHS services such as Talking Therapies (Step 3 and Step 3 plus) and community partner agencies such as Six Degrees in Salford, 1 Point in Bolton (Step 2 and Step 3). Clinical assessments will be in person, on the phone or online on Microsoft Teams in line with the Trust's policies for remote consultations.

Recruitment
The study will be based in Greater Manchester Mental Health NHS Foundation Trust (GMMH) and partner organisations covering Greater Manchester, including the boroughs of Manchester, Trafford, Salford, Bolton and Wigan. People will be able to access the study in the borough where they are registered with a GP.

The research will be advertised externally on social media (e.g. Facebook, LinkedIn, WhatsApp groups etc) and websites (e.g. GMMH or University of Salford website etc). People who are interested in the study will be able to self-refer via the usual self-referral links to GMMH/ Partner organisations. Following self-referral, people will be offered an initial assessment to the service in accordance with the service policy. During the initial assessment, interested service users will be screened for inclusion and exclusion criteria.

Additionally, GMMH Taking Therapies/ Partners practitioners will be invited to ask potentially eligible service users they already work with at the point of clinical assessment or at the end of therapy if they would like to be referred to the study.

Moreover, eligible service users who are on the waiting lists for treatments will also be contacted, asking if they would like to participate in the study.

Interested and potentially eligible service users will be contacted by phone or video call by a researcher/ therapist to discuss the study in more detail. People who wish to take part in the study will be given a date for the Clinical Assessment meeting. Participant Information Sheet (PIS) and Consent Form will be sent to them for information.

The Clinical Assessment meeting will be either in person or remote, depending on service users' preferences. The meeting will consist of two parts. During the first part, service users will be able to discuss any issues and questions related to the study and informed consent will be taken. Consent will be taken using a signed form or audio-recorded consent. The latter process involves a recording of the researcher/ therapist reading the consent statements while the participants respond with their agreement to each statement. During the process of taking consent, participants will also be asked if they would like to take part in the qualitative component of the study (e.g. interview). This aspect of the study will have been explained in writing in the Participant Information Sheet, and also verbally by the researcher/therapist. Participants who decline to take part in the interviews will still be able to participate in the remaining components of the study. All participants will have at least 24 hours to decide whether they would like to take part in the study.

Following the signing of the consent, the researcher/ therapist will conduct the second part of the meeting involving a clinical assessment. At the clinical assessment, demographic data, including data on diversity and membership of minority groups, will be collected. Socioeconomic deprivation will be measured (via IMD). Mental Health difficulties will be assessed using MINI and ZAN-BPD assessment tools, which will confirm eligibility. The following baseline outcome measures will be collected: PHQ9, GAD7, WSAS, WEMWBS and WHO5. The whole meeting will take about 60 min.

Intervention and comparator

Intervention - Arts for the Blues
A4B is a creative group psychotherapy and it is outlined in using the TiDierR checklist for intervention description and replication. Theoretically speaking, it is a pluralistic model with humanistic philosophical underpinnings, including the focus on the therapeutic relationships and tailoring relevant approaches to clients' goals. A4B is based on the phases of the group therapy process, including introduction, building strengths, addressing challenges and closure. Eight key ingredients found in the systematic literature review of helpful factors/ mechanisms of change in depression provide a structure and a guide in relation to the use of different creative activities in the sessions. The key ingredients include encouraging active engagement, learning skills, developing relationships, expressing emotions, processing at a deeper level, experimenting with

different ways of being and integrating useful material. Creative activities in the sessions may include drawing, movement, creative writing and music making, depending on clients' preferences and goals and therapists' training.

A4B is offered as 12 sessions, 90 min each, delivered weekly. The therapists delivering A4B will complete an adherence form in relation to the delivery, which will be discussed in clinical supervision. Clinical supervision will be provided (app 4 x 60 min per group) by an experienced supervisor (external to GMMH Talking Therapies service) trained in A4B. Intervention sessions can be conducted in person or remotely via secure videoconferencing software (e.g. Microsoft Teams).

The therapists will be trained in A4B before the start of the intervention. The training will last two days and will be focused on the A4B model and the groupwork aspect of the work. The training will include didactic and experiential components focused on the key ingredients of the model and the phases of the groupwork, respectively.

Comparator - Treatment as Usual (TAU)
TAU provision within the Greater Manchester Mental Health, where the study will take place, is typical of the provision for depression and anxiety available in the UK, which is based on treatments as recommended by the NICE guidelines.

Currently, TAU may include:
1. Individual Talking Therapies such as CBT, counselling or EMDR.
2. Group interventions such as psycho-educational groups, mindfulness groups, or compassionate focused groups for parents.
3. Medication as prescribed by the client's clinician (e.g. GP or Psychiatrist) (e.g. antidepressants).
4. Individuals may not be accessing any formal intervention at the time of therapy (e.g. on a waiting list for the above interventions), but they will still be able to access prescribed medication, crisis services and 3rd sector input.

Each TAU will be recorded (using information on the service's records system, PCMIS) to see which TAU options are most commonly offered.

Recruitment and training of therapists for the Arts for the Blues intervention
Psychological therapists delivering the Arts for the Blues intervention in the study will be recruited from within GMMH, partner organisations or externally. They will be eligible to take part in the project if they have a psychological therapy qualification and a formal arts therapy training or experience of using creativity and the arts in a mental health context. Interested eligible talking therapy practitioners without formal arts therapy training or experience of the arts in mental health contexts will also be considered, but they may be required to complete additional introductory training. All interested therapists will undertake the Arts for the Blues Practitioner training. The training will be provided by an experienced Arts for the Blues trainer.

New psychological therapists' roles will be created within GMMH using existing Agenda for Change job descriptions. The roles will be open to part-time hours and secondment will be a possible option.

A range of employment options will be used, which may include the following:
Eligible therapists currently working in GMMH Talking Therapies may be appointed through internal secondments (subject to agreement with relevant services) or offered short-term contracts.

Arts therapists within GMMH Psychological Services may be recruited via external secondments (with approval from relevant services) or through short-term contracts.

External arts therapists may also be employed on short-term contracts.

Trainees in arts therapies or other eligible training programmes will also be considered for placements.

These roles will be advertised both internally and externally via the Trust's communication channels and social media platforms.

The therapists recruited to the project will be trained in A4B prior to the start of the intervention. The training will include:
1) Introduction to working with creativity and the arts in psychological therapy (two days) (for those without formal training in arts therapies or experience in using arts and creativity in mental health contexts)

The Introduction to working with creativity and the arts will be offered to talking therapists (e.g. counsellors and CBT Therapists) who don't have a prior formal training and experience in working with creativity and the arts. This training will equip talking therapists with basic skills in working safely and effectively with creativity and the arts within the context of psychological therapy. The training will use elements of evidence-based arts psychotherapies and introduce participants to working with a range of arts modalities such as visual art, music, drama, dance and movement.

2) Arts for the Blues Practitioner training (two days) (all therapists)

The Arts for the Blues Practitioner training will be focused on the A4B model and the groupwork aspect of the intervention. The practitioners will learn about the development of the model, its evidence base and the key ingredients the model is based on. The training will also focus on working creatively with groups and basic skills needed for effective group facilitation. This training will be open to arts therapists and talking therapists who have prior experience of using the arts in mental health contexts and/or who have undertaken the Introduction to working with creativity and the arts training.

Both the Introduction and the Practitioner training will include didactic and experiential components where practitioners will be working using their own psychological material while practising clinical skills. No artistic skills will be required, but the therapists will be asked to take care of their own well-being, as psychological material is likely to be stirred up while using the arts during the training.

Outcomes
Acceptability and Feasibility Data
Acceptability and feasibility data will be collected in relation to recruitment strategies, referrals received and screened, number of participants consented. Reasons for non-eligibility or withdrawal of interest and any issues related to randomisation will be documented.

Additionally, the following data will be recorded:
Monthly recruitment rate and participants' position on the timeline (13. Participants timeline) will be recorded

Completed outcome measures and missing data for each assessment point
Therapy sessions attendance (number of sessions attended, cancelled/ missed)
Date of treatment completion

Qualitative interviews with participants and referrers/ stakeholders (see below in the Qualitative evaluation section), as well as retention/ attrition and adherence rates, will inform the evaluation of the acceptability of the intervention and trial procedure. Quantitative data and levels of missing data will guide decisions about the most appropriate primary outcome for the efficacy trial.

Safety
Safety will be evaluated throughout the study via routine monitoring and recording of adverse events and self-report assessments of adverse experiences arising from therapy captures with the Adverse Effects in Psychotherapy (AEP) measure.

Resource costs
The cost of the intervention will be estimated by recording staff time (including supervision and training) and any resources (e.g. arts materials) needed to deliver the intervention. These will help with estimating the costs per participant.

Service use will be measured using a questionnaire based on the Client Service Receipt Inventory (CSRI). The participants will be asked to report their utilisation of health and social care services (beyond the intervention received) at the baseline and then 12 weeks and 24 weeks after baseline assessment. Questions about psychological and pharmacological therapies are included on CSRI.

The EQ-5D-5L (EuroQol Research Foundation, 2019) will be used to inform economic evaluation of healthcare interventions. It is a self-reporting measure in relation to health status and comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/ depression. Service users can rate these dimensions using 5 levels (coded 1-5): no problems, sight problems, moderate problems, severe problems and extreme problems. The digits for the five dimensions are combined into a 5-digit number that describes the patient's health state, which has a specific value set. The EQ-5D-5L will be used at baseline, 12 weeks and 24 weeks following baseline assessment.

Demographic data
Demographic data will be collected at baseline and will include data in relation to work, education, gender and ethnic diversity as well as physical health and neurodiversity. Information about socioeconomic status will be collected at baseline using the Index of Multiple Deprivation (IMD) (Department for Communities and Local Government, 2015) based on the participants' postcodes (https://deprivation.communities.gov.uk). This information will be important for monitoring whether the recruitment strategy is inclusive of participants from deprived areas, especially in relation to priority groups as outlined in Core20PLUS5 (NHS England, 2023).

Mental health status
The mental health presentation will be assessed to confirm eligibility for the study at the study's clinical assessment by the Mini International Neuropsychiatric Interview (MINI). MINI is a structured interview that assesses mental health difficulties, including modules in relation to suicidality, alcohol and substance misuse, psychosis and personality disorders. The therapists administering MINI will be trained in the delivery via online training accessed on https://harmresearch.org/training-and-workshops. Additionally, mental health status and eligibility for the study will be confirmed by existing diagnoses in service users' records.

As MINI can only assess antisocial personality disorder, the Zanarini Rating Scale for Borderline Personality Disorder (ZAN-BPD) will be used to assess for Borderline Personality Disorder (BPD), as this condition is commonly encountered in primary care. ZAN-BPD is a standardized, diagnostic rating scale designed to measure the severity of BPD. It assesses each of the nine criteria for BPD, with the evaluation period spanning the previous week. Each criterion is rated on a five-point Likert scale from 0 (no symptoms) to 4 (severe symptoms). The sum of scores from each criterion yields the ZAN-BPD total score, which measures BPD symptom severity. This total score can range from 0, indicating no symptoms, to 36, indicating severe symptoms in all categories. The questions focus on difficulties in relationships, hurting self, impulsivity, changes in mood, acting in an angry manner, difficulties in trusting others, feeling unreal, feeling empty, not knowing who one is and avoiding feeling abandoned.

Intervention fidelity
As part of the fidelity check, the therapists will be completing an adherence form designed to self-reflect on phases and key ingredients of the delivery of the intervention. The therapists will then use these to reflect in supervision in relation to adherence to the intervention protocol.

Additionally, if all clients provide consent, the sessions will be video recorded. The recording will be only used for the fidelity check and will not be used as research data. The recordings will be checked by an independent researcher trained in Arts for the Blues.

Clinical outcomes data
The following outcome measures will be collected:
a) Candidate Primary Outcome - depression - Patient Health Questionnaire (PHQ-9)
b) Candidate Secondary Outcomes-anxiety, wellbeing and quality of life - Generalized Anxiety Disorder 7 (GAD-7); Work and Social Adjustment Scale (WSAS); World Health Organisation-Five Well-Being Index (WHO-5); Warwick-Edinburgh Mental Health Wellbeing (WEMWBS) scale; Goal-Based Outcome measure (GBO)
c) Candidate therapy process measures - Group Session Rating Scale (GSRS); Types of Positive Affect Scale (TPAS); Session Evaluation Form

The researcher will collect clinical outcomes face-to-face or remotely. For the A4B arm - PHQ9, GAD7, WSAS, WEMWBS and WHO5 will be collected at clinical assessment/ baseline, 12 weeks and 24 weeks post baseline. GBO and GSRS will be collected at sessions 1st, 6th and 12th. TPAS and Session Evaluation Form will be collected at each session. For the TAU group - PHQ9, GAD7, WSAS, WEMWBS and WHO5 will be collected at clinical assessment/ baseline, 12 weeks and 24 weeks post baseline assessment. The length of follow-up will allow for assessment of short to medium-term outcomes.

Qualitative data
Qualitative evaluation will be gathered via semi-structured interviews with participants, therapists and referrers/stakeholders 12 weeks after baseline assessments.

The interviews will be conducted with clients who completed or withdrew from the study, including participants from the A4B arm (n= 8-10) and TAU arm (n= 3-5) to gather views about the acceptability of A4B and TAU. Participants will be asked during the study's clinical assessment if they would like to be involved in the interviews. Potential participants will be given Participants Information Sheet (PIS) where the interview will be explained. During the process of taking consent (during clinical assessment), participants will be asked if they would like to take part in the interview, but participation will be optional. They will have at least 24 hours to decide whether they would like to take part in the interview. Participants who decline

to take part in the interviews will still be able to participate in the remaining components of the study. The interviews will take about one hour and will be conducted by the researcher either in person or online via NHS approved platform (e.g. Microsoft Teams). Interviews will be recorded (e.g. on Microsoft Teams). Although the sample in the study is small, maximum variation sampling will be adopted for the interviews to include factors such as gender, ethnicity and sexual minority status to gather a range of views from as diverse a group as possible. The interviews will be guided by the schedule (developed in consultation with people with lived experience). For participants in the A4B arm, the interview focus will be on acceptability of the intervention, perceived helpfulness or unhelpfulness, challenges to engagement, adverse experiences and any contextual factors affecting the engagement and impact of the intervention. For participants in the TAU arm, interviews will focus on acceptability of study procedures, including assessment, randomisation, outcome measures and contact with the research team.

Therapists who delivered A4B (n=2-4) will be interviewed in terms of the suitability of the training for delivery. Managers of services where A4B is delivered, and referrers who referred for A4B (n=2-4) will be interviewed in relation to the recruitment process and engagement. The consent taking and the interview process will be as described above.

Sample size
60 participants (n=60) will be recruited to the study (30 per trial arm). This number will be sufficient to estimate key parameters to inform a future definitive trial (e.g. the standard deviation of key outcomes, the attrition rate) to an adequate degree of precision.

Randomisation: Sequence generation, allocation concealment mechanism and implementation
Following clinical assessment, sixty participants will be randomised (1:1 ratio) to receive TAU or A4B. A researcher will use a randomised block design (with random blocks of 4 or 6) to randomise via www.sealedenvelope.com.

The researcher allocating participants will not be aware of the next trial group allocation as a computer programme (www.sealedenvelope.com) will perform randomisation.

The researcher will access the random allocation sequence and will allocate participants to the intervention. The researcher will speak to all randomised participants to inform them of their treatment allocation.

Blinding
The researcher performing randomisation will not be blinded to treatment allocation. Blinding of the participants and therapists delivering the intervention is not possible, as it will be obvious which study arm they are allocated to. In terms of reducing outcome detection bias, the researcher collecting outcome data and undertaking analysis will not be involved in delivery.

All breaking of the blind will be monitored and recorded on a structured form. The researcher /TSC will review blind breaks to establish and implement learning and reduce further blind breaks. Deliberate unblinding during the trial is unlikely but will be considered by the researcher/ TSC and could occur in cases of risk or safeguarding.

Participant retention will be supported by email/telephone "check-ins" with participants involved in the trial, particularly when participants cancel or do not attend, and also between follow-up data collection time-points to remind the participant of upcoming data collection and to give them the opportunity to ask questions.

Qualitative evaluation will be gathered via semi-structured interviews with participants, therapists and referrers/stakeholders 12 weeks after baseline assessments.

Data management
During the trial, data will be processed and stored on the GMMH secure system (the study's host). After the end of the study, the data will be transferred to the University of Salford's secure system (study's sponsor), where it will be stored for 10 years.

The study's file and database for study data will be set up on GMMH's secure network drives (e. g. Sharepoint). Data will include quantitative data sets, evaluation forms, written interview transcripts and audio recordings. Data will be collected on paper or online via secure GMMH's systems (e.g. Microsoft Forms). Photographs of creative work may also be collected during the study, which will not include any identifying details.

Anonymized data for analysis will be shared with the statistician (or other relevant members of the research team) via a secure shared drive, secure file transfer, or an encrypted device. All study data will be stored separately from personal identifiable data, and the only way of linking these will be via a Participant Identification Number (PIN) held by the researcher. Each participant will be assigned a PIN allocated at entry to the study, for use on trial documents and all information stored on the electronic database.

A separate confidential record will be made of the participant's name, date of birth, contact details, and PIN to permit identification of all participants enrolled in the study. This record will be securely stored (password-protected) on the GMMH's secure network drive, separate from research data. All other information will be anonymised and stored separately from information containing personal details. Personal data will not be shared outside of the GMMH-based research team except for safeguarding or auditing purposes.

All paper copies, including Consent Forms, will be scanned and saved on the GMMH secure network drive, following which the paper copies will be shredded through the GMMH confidential waste system. Identifiable data on portable devices (e.g. audio recorders, etc.) will be encrypted and deleted after being uploaded to the GMMH network drive.

After the study is completed, all research data will be transferred to the University of Salford's secure network. Anonymised copies of the dataset will be made available on request (as per NIHR good practice guidelines) and will be held at the University of Salford for a minimum of 10 years after completion of the study. All personal data would be destroyed upon completion of the study, with the exception of documents required by the study protocol, such as consent forms (or consent recordings) or adverse event reports, which need to be held for 10 years in line with the University of Salford policy. At the end of the retention period, electronic data will be deleted.

The anticipated length of the project is 24 months, allowing six months after the final follow-up assessment for data cleaning, analysis and write-up. At this point, HRA and the sponsor will be notified of the end of the study and will initiate close-out activities, including archiving.

## Intervention Type
Behavioural

## Primary outcome(s)
1. Acceptability and feasibility data, assessed via recruitment strategies, referrals received and screened and the number of consenting participants, reasons for non-eligibility or withdrawal of

interest and any issues related to randomisation measured using study records at at the end of the study

2. Monthly recruitment rate and participants' position on the timeline; completed outcome measures and missing data for each assessment point; therapy sessions attendance (number of sessions attended, cancelled/ missed); and, the date of treatment completion measured using study records at at the end of the study

3. Candidate Primary Outcome - depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 12 and 24 weeks

### Key secondary outcome(s))
1. Candidate Secondary Outcomes – Anxiety measured using the Generalized Anxiety Disorder 7 (GAD-7) at baseline, 12 and 24 weeks

2. Candidate Secondary Outcomes – Functioning measured using the Work and Social Adjustment Scale (WSAS) at baseline, 12 and 24 weeks

3. Candidate Secondary Outcomes – Wellbeing measured using the World Health Organisation-Five Well-Being Index (WHO-5) and the Warwick-Edinburgh Mental Health Wellbeing (WEMWBS) scale at baseline, 12 and 24 weeks

### Completion date
31/05/2028

## Eligibility

### Key inclusion criteria
1. Must be registered with a GP in Greater Manchester
2. Must be 18 years old or older
3. Must have/had depression or symptoms of depression (assessed by PHQ9 > 5)
4. Is interested in taking part in group work
5. Is interested in taking part in the creative interventions.
6. Must be able to communicate in English
7. Willing to be randomised to A4B or TAU

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
110 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Receiving concurrent active psychological therapy, including structured psychological therapies such as CBT, EMDR or counselling. Other forms of support, such as support groups, skills groups, seeing a clinician for informal support or medication advice, or engaging in self-help materials, will not be an exclusion criterion
2. Participating in another current clinical trial involving psychological therapy
3. Currently at high (imminent or immediate) risk of harming self and others (determined by the presence of suicidal intent and/or plan and marked as 'current' and 'high' in related sections of MINI neuropsychiatric interview (Sheehan, 1998))
4. Current alcohol or substance use disorder (determined by a 'severe' score in related sections of the MINI neuropsychiatric interview (Sheehan, 1998))
5. Those who are psychologically or physically too unwell to attend the group or/ and are presenting with any condition which would make participation in the group difficult, such as current, active episode of psychosis or mania or have symptoms associated with personality disorder (determined by related sections of MINI neuropsychiatric interview (Sheehan, 1998), Zanarini BPD Scale (Zanarini, 2003) and/or existing diagnosis). History of the above difficulties will not be an exclusion criterion, if clients don't have current symptoms

### Date of first enrolment
01/05/2026

### Date of final enrolment
31/05/2028

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Greater Manchester Mental Health NHS Foundation Trust**
Prestwich Hospital
Bury New Road
Prestwich
Manchester
England
M25 3BL

### Study participating centre
**Six Degrees Social Enterprise**
8th Floor, 2, City Approach, Albert Street
Eccles, Greater Manchester

England
M30 0BL

**Study participating centre**
**1 Point (North West)**
Silver House, 1 Silver Lane
Bolton, Lancashire
England
BL1 1QN

# Sponsor information

**Organisation**
University of Salford

**ROR**
https://ror.org/01tmqtf75

# 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 datasets generated and/or analysed during the current study will be published as a supplement to the results publication (consent will be sought for this from the participants and all data will be anonymised).

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other files | version 6 | 16/03/2026 | 07/04/2026 | No | No |
| Participant information sheet | version 6 | 16/03/2026 | 07/04/2026 | No | Yes |