

Participant Information Sheet

Study 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

Researcher Team

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FIGURE 1: A GROUP OF SIX PEOPLE USING MOVEMENT TOGETHER



FIGURE 2: TWO PEOPLE SITTING AT A TABLE PAINTING

Summary of Research / Invitation

We would like to invite you to take part in a research study. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. You are welcome to discuss this project with others before you make your decision. Please read the following information carefully before deciding to take part. If you find anything unclear or would like additional information, please let us know.

In this research study we will use information from you. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study we will save some of the data in case we need to check if and for future research. We will make sure no one can work out who you are from the reports we write. This Participants' Information Sheet tells you more about this.

What is Arts for the Blues?

Arts for the Blues is a 12-week creative group psychotherapy which is a psychological therapy that includes creative methods such as, drawing, writing and movement as well as talking. Artistic abilities are not required as the psychotherapy is based on individual expression and creativity. This psychotherapy is for everyone, whether or not you see yourself as creative — it's about expressing yourself in ways that feel right for you. Arts for the Blues has been developed as there is evidence that creative therapies may be helpful in improving mental health and wellbeing, however access to these therapies are limited within the NHS.

Arts for the Blues was developed in collaboration between University of Salford and Edge Hill University which involved academics, psychological therapists and artists. People with lived experience have also been involved in developing the study.

What is the purpose of this study?

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We wish to carry out a large piece of research (a clinical trial) to see if Arts for the Blues is helpful for adults receiving treatment in the NHS Talking Therapies service. Firstly, however, we need to undertake a smaller, preliminary piece of research (called a feasibility study) to test if the plans for the larger study will work, and this is the purpose of this study.

Greater Manchester Mental Health NHS Talking Therapies (GMMH) is the host of the study, the University of Salford is the sponsor organisation, and Edge Hill University, the University of Manchester are research partners. National Institute for Health and Care Research (NIHR) is a funder of the study.

Why have I been invited?

You have been invited to take part in the study as you are a service user in GMMH or partner organization such as Six Degrees in Salford or 1 Point in Bolton experiencing depression and someone who would like to address their mental health issues using creative approaches working with others in a group. The eligibility criteria for taking part in the study are as follows:

You must:

- be registered with a GP in Greater Manchester (GMMH services covering: Bolton, Manchester, Salford, Trafford, and Wigan)
- be 18 years old or older
- have/had depression or symptoms of depression (assessed by PHQ9 >5)
- be interested to take part in group work
- be interested to take part in the creative interventions.
- be able to communicate in English
- be willing to be randomised to Arts for the Blues or Treatment as Usual

You cannot take part if you are:

- receiving concurrent psychological therapies such as CBT, EMDR or counselling.
- participating in another current research involving psychological therapy
- currently at high risk of harming self and others
- currently have severe alcohol or substance use disorder
- 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.

Do I have to take part?

No. Your participation is voluntary and you do not have to agree to take part. You are free to withdraw at any time, without giving any reason and without your medical care and/or legal rights being affected. Even if you decide to participate you are still free to

withdraw.

You can withdraw from the study at any point but you will be able to withdraw your data only up to 7 days after the data collection (at which point the raw data has become a part of the study's data set).

Whether or not you choose to take part will not affect your ability to access other services offered by the NHS and the study will not affect any treatments you are currently receiving.

To withdraw from the project, please contact your therapist or Joanna Omylinska-Thurston, Primary Investigator listed at the top of this information sheet. We can then discuss whether you require any further support from community or NHS services.

If for any reason you lose the capacity to consent during the study your wellbeing and welfare will be prioritised including contacting appropriate services as required. You will be withdrawn from the study and any data collected where consent was given will be kept in the study.

How will we use information about you?

We will need to collect information from you for this research project. This information will include your:

- Name
- Date of Birth
- Gender
- Name / Address of GP
- Responses to questionnaires
- Video recordings of the sessions
- Photographs of artwork and, if relevant,
- Opinions about participating in the study.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

University of Salford is the sponsor and Greater Manchester Mental Health NHS Foundation Trust (GMMH) is the host for this research.

University of Salford as a sponsor is responsible for looking after your information and your information related to this research project will be shared between

- GMMH and
- University of Salford.

University of Salford and GMMH will keep all information about you safe and secure by:

- Data will be stored on password protected University of Salford/ GMMH secure network
- Data will be accessed only by research team members who have been granted permission.
- Research data will be anonymised and will not contain personal data.
- Files containing personal data (consent forms, referral forms etc) will be stored separately to any research data.

International transfers

Your data will not be shared outside the UK.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We will keep your study data for a maximum of 10 years. The study data will then be destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting data from you. If you do not want this to happen, tell us and we will stop.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this

Where can you find out more about how your information is used?

You can find out more about how we use your information by

- contacting Data Protection Officer at the University of Salford (foi@salford.ac.uk)
- asking one of the research team (email addresses above)
- checking the sponsor website <https://www.salford.ac.uk/privacy>

- checking the host website www.hra.nhs.uk/patientdataandresearch

What will I be asked to do?

1. Referral and initial contact:

You can refer to the study yourself or you can be referred to the study by your therapist or other clinician within the service you are with.

Your referral will be based on the eligibility criteria listed above, but if you or the therapist decide that Arts for the Blues is not the right option for you or you do not meet the eligibility criteria, you can be signposted to more appropriate services within NHS or community.

If you are currently on a waiting list for another type of therapy within Talking Therapies, your place on the waiting list will be preserved but you will not be able to start this therapy until the study is finished. However, you can withdraw from the study at any point in order to access this therapy if you wish to.

If you are interested and eligible to take part in the study, the researcher will ask for your permission to get in touch. They will then send you this Participant Information Sheet and Consent Form, and help arrange a time for your clinical assessment.

2. Clinical assessment:

Following the initial contact, you will be invited for a clinical assessment meeting with one of the researchers to discuss the study and you will have the opportunity to ask any questions you may have. The meeting will be arranged to suit you and can be conducted face-to-face, online or by telephone and will take about 60 minutes.

If you are interested in taking part in the group, you will be asked to sign a Consent Form, which includes a series of statements to check you are happy to take part and understand what is involved. During the process of taking consent, you will also be asked if you would like to take part in the interview following the intervention to explore the helpful and unhelpful aspects of the intervention. Taking part in the interview is optional and you can still participate in the study if you decide not to take part in the interview.

After you have signed the Consent Form, your eligibility to participate in the study will be confirmed using structured assessment tools and you will be supported to complete six short questionnaires asking about symptoms of depression, anxiety, wellbeing and quality of life. These are mainly multiple choice, and extra support to complete these will be available if needed. During the meeting, you will be also asked about yourself and your interest and experience with using creative methods and working in a group

with others. We may also access your clinical records to confirm your eligibility for the study.

Following the clinical assessment, if you and the researcher agree to proceed with the study, the researcher will use a website to allocate you at random to one of the two groups:

- a) Arts for the Blues
- b) Treatment as Usual

The researcher will inform you of your group allocation. There is an equal (50/50) chance of being assigned to either the Arts for the Blues group or the Treatment as Usual group.

3. Arts for the Blues or Treatment as Usual

Arts for the Blues

If you are allocated to Arts for the Blues group, you will be asked to participate in the Arts for the Blues group sessions, lasting 90 minutes each which could be either online or face to face (which will be decided collaboratively, based on preference and service availability). There will be approximately 4 to 8 participants in the group, including yourself. The group will meet at the same time and place for 12 consecutive weeks and will be facilitated by two research therapists trained in Arts for the Blues.

The sessions will include working in the group, in pairs and independently. We will use a range of creative methods such as drawing, simple movement or writing words. You do not have to do anything that you do not feel comfortable with during the group and no artistic abilities are necessary.

Arts for the Blues is intended to be positive and beneficial, but like in any psychological therapy, there is a potential that you may become distressed while working on personal issues. In the unlikely event that you feel distressed, the research therapists will be trained psychotherapists, psychologists and counsellors and they will be able to offer you support, a follow up session or discuss referral to an appropriate service if needed.

Treatment as Usual

If you are allocated to Treatment as Usual group, you will receive a treatment that is usually provided within the Talking Therapies service (e.g. counselling, CBT or waiting list) and you will take part in data collection described below. After the final data collection point (24 weeks after clinical assessment), you will have an option of accessing Arts for the Blues if you wish so.

4. Questionnaires

We will ask you to complete online or paper based questionnaires which measure

symptoms of depression, anxiety, wellbeing and quality of life during clinical assessment, at the time when the intervention ends and three months following the end of the intervention. The questionnaires will take about 10 minutes to complete. Additionally, Arts for the Blues group will be asked about personal goals and experience of working in the group during the group sessions.

5. Interviews

If you agreed to take part in the optional interview when you gave consent during, you may be invited to be interviewed about a week after the intervention is completed. During the interview you will be asked about your experience of participating in intervention, including what was helpful and unhelpful about the sessions and your views on the clinical assessment and research processes. You will not need to answer anything that you don't want to discuss.

The interview will last about 60 min, be conducted by a researcher and it might be in - person or online. The interview will be recorded on an encrypted digital voice recorder/ Microsoft Teams. The researcher will transcribe and anonymise the recording. The recording will be stored on the University of Salford One Drive which is a secure online system. The transcription will be analysed to identify any common themes across the interviews. If quotes from the interviews are used in publications, they will not contain any identifiable details. Following this process the recording will be deleted.

6. 3-Month Follow up

Three months after the sessions have ended, we will ask you to complete the same questionnaires you completed earlier in the study.

How long will I be involved in the study?

The total duration of your involvement in the study from screening to the end of the study will be a maximum of 7 months.

What are the possible benefits or disadvantages of taking part?

The 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 we anticipate that you may also benefit from the sessions. By taking part in this research you will be helping to improve mental health services for other people.

The Disadvantages and Risks:

Taking part in Arts for the Blues will give you the opportunity to explore your mental health difficulties. You may find that exploring some of these difficulties can be potentially upsetting, which is not uncommon in therapy as difficult feelings can be stirred 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. You will not need to do or answer anything that you don't want to do.

If further support is needed, your therapist or members from the research team (listed above) will discuss with you any further referral you may need.

Will my General Practitioner be informed of my participation?

Your GP will be informed about your participation in the study.

Will my participation be confidential?

Your participation will remain as confidential, however, it is important to be aware that taking part in a group setting means you cannot remain totally anonymous as group members will get to know you. However, as part of the group introduction all group members will be asked to keep what said in the group confidential and not repeat anything about the group to people outside the group.

Confidentiality will only be broken to relevant services if we are concerned about a risk of harm to yourself or others which will be discussed with you.

We will ask for your consent to video record group psychotherapy sessions. This allows an independent researcher to check that the therapy is being delivered in line with the therapy manual. The recordings will focus on the therapists and filming of participants will be kept to a minimum. You do not have to agree to being video recorded to take part in the study. If you choose not to be recorded, you can still attend the therapy sessions and take part in the research but the sessions will not be recorded. All clients participating in Arts for the Blues sessions need to provide consent before the sessions are video recorded. The recording will not be used as data in the research.

As the study will take place at GMMH, a study research file will be set up on GMMH secure network. Personal data (names, contact details, identifying videos or voice recordings) will be kept separately from research data (questionnaires or interviews) to preserve anonymity. To protect your privacy, any information in the research data that could identify you will be either removed or replaced with a pseudonym or a code, so that you cannot be identified in the data. Any paper-based data will be scanned and physical copies destroyed. We may want to photograph some of your creative work from the sessions, and you will have the opportunity to remove any creative work you do not want included in the research. Once the project is completed, personal data will be destroyed as per University of Salford policy. All research data will be transferred and stored securely as digital files on the University's secure network for

10 years in accordance with University's policy.

Clinical notes in relation to your participation in study will be added to your clinical records as per GMMH policy.

Will I be reimbursed for taking part?

For in-person sessions, travel expenses to attend clinical assessments, the 12 Arts for the Blues sessions and the interviews will be reimbursed at a flat rate.

What will happen to the results of the research study?

The results will be analysed and written up to be published in scientific journals. If you would like a summary of the findings, please indicate so on the Consent Form. Anonymity will be preserved in publications. The data will remain on the University of Salford secure network drive for a minimum of 10 years.

Who has reviewed the study?

All research is looked at by an independent group of people called a Research Ethics Committee to protect your interests. The project has been reviewed by Ethics Committee at the University of Salford and by PRS Sub-Committee of North West - Greater Manchester Central Research Ethics Committee.

Is there someone independent I can talk to about the research or if there is a problem?

In the first instance If you would like to ask any other questions regarding the research, or what is expected from you please email Joanna Omylinska-Thurston at j.omylinska-thurston1@salford.ac.uk or joanna.omylinskathurston@gmmh.nhs.uk

If you would like to talk to someone independent of the study, please email Heather Iles-Smith at h.m.iles-smith@salford.ac.uk.

What should I do if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please email the Chief Investigator email Joanna Omylinska-Thurston at j.omylinska-thurston1@salford.ac.uk or joanna.omylinskathurston@gmmh.nhs.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers, please contact the University of Salford Ethics Chair Dr Graeme Sherriff (g.sherriff@salford.ac.uk)

If you are not happy with the way your data has been handled, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What should I do if I need additional support?

If you require additional support please speak to your therapist or research team listed above who may be able to respond to needs or questions about the intervention. If you have any further mental health needs they may be able to help with appropriate referrals.

If you are in crisis or emergency please use the following advice:

- Go to the nearest Accident & Emergency hospital department
- Call 999 and ask for an ambulance
- Use helpline numbers (see below)
- Contact your GP
- Dial 111 – NHS Direct (Mental Health option)

If it is not an emergency but you require urgent advice, call 101 for non-emergency access to the police.

You may also contact the following helplines:

- Samaritans: **0161 236 8000** (local call charges apply) or **116 123** (free to call). Open 24 hours a day 7 days a week. They offer confidential emotional support.
- Saneline: **0300 304 7000**. Open 4.30pm – 10.30pm every day. They provide emotional support and information.

