

Participant Information Sheet

Study Title

Feasibility study of implementation of an evidence-based creative group psychotherapy for depression (Arts for the Blues) into primary care mental health services.

Researcher Team

Principal Investigator:

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FIGURE 2: TWO PEOPLE
SITTING AT A TABLE
PAINTING



FIGURE 1: A GROUP OF SIX
PEOPLE USING MOVEMENT
TOGETHER

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.

What is Arts for the Blues?

Arts for the Blues is a 12-week creative psychotherapy 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. Arts for the Blues has been developed as there is evidence that creative therapies can be effective in improving mental health and wellbeing, however access to these therapies are limited within the NHS.

Arts for the Blues is a collaborative research project between Edge Hill University, University of Salford and Greater Manchester Mental Health NHS Foundation Trust and includes academics, psychological therapists and artists. People with lived experience have also been involved in developing the study.

What is the purpose of this study?

The aim of this study is to explore whether it is viable to use Arts for the Blues in mental health services. This will include trying to measure if it works for people.

Why have I been invited?

You have been invited to take part as you are a service user from Greater Manchester Mental Health NHS Talking Therapies, Six Degrees Salford or 1Point Bolton who might benefit from Arts for the Blues.

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.

If you decide to withdraw from the study, any research data collected will be destroyed. You will have seven days after the focus groups (please see page 6 for more details about focus groups) to tell us if you don't want your information to be used. After this time, it will not be possible to withdraw your data as the analysis will begin but all identifiable data will be anonymised. Please note that it will not be possible to withdraw personal data from the study but it will be kept on a password protected file in Greater Manchester Mental Health NHS Trust's secure network drive. Your personal data will be stored separately from any research data.

Taking part and/ or withdrawal from this study will not affect your ability to access other services offered by Greater Manchester Mental Health NHS Trust, Six Degrees Salford or 1Point Bolton and the study will not affect any treatments you are currently receiving. However, it will not be possible to take part in Arts for the Blues and another therapy at the same time as per service policy.

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

What are my choices about how my information is used?

After reading this information sheet it is up to you to decide if you would like to take part in the study. There is no obligation but if you do decide to take part, we will ask you to sign a Consent Form. Once completed, the Consent Form will be scanned (if completed on paper) and stored securely in password protected files on the Greater Manchester Mental Health Trust secure network drive, original paper copies will be destroyed.

We are committed to ensuring compliance with current data protection legislation and ensure that all data collected is used fairly, stored safely, and not disclosed to any other person unlawfully.

What will I be asked to do?

Section	Time in Minutes
1. Screening	20 minutes
2. Arts for the Blues Meeting	45 – 60 minutes
3. Arts for the Blues Therapy	90 minutes per session for 12 sessions
4. Questionnaires	3 - 5 minutes per session for 12 sessions
5. Focus Group	60 minutes
6. 3 - Month Follow up	5 minutes

1. Screening:

Once you have been referred, you will be invited to a screening appointment with the first contact team who will assess your eligibility to participate in the study. Your eligibility to take part will be based on the following:

You must:

- Be aged 18 or older
- Have depression or symptoms of depression
- Be interested and willing to take part in group work
- Be interested and willing to take part in creative therapies
- Be able to communicate in English at a basic level without the need for an interpreter.

You cannot take part if you are:

- Too physically unwell to attend the intervention (e.g. acute pain/ fatigue, contagious illness, recovering from a major operation which could make participation in the sessions very difficult)
- Currently at risk of harming yourself and / or others
- Regularly misusing alcohol or other illegal substances which would make engaging in the intervention difficult.
- Experiencing psychotic episodes which would make participating in the intervention difficult.
- Severely psychologically distressed and/or who currently has a condition that would make engaging in the intervention difficult, such as, significant dissociation, severe social anxiety, paranoia, difficulties in comprehension, difficulties in emotional regulation, severe personality disorder, severe depression.
- Currently participating in other research

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 that Greater Manchester Mental Health NHS Trust , Six Degrees Salford or 1Point Bolton offer.

If you are interested and eligible to take part in the study, you will be given this Participant Information Sheet to keep alongside a Consent Form. We will ask your permission for an Arts for the Blues therapist to contact you, which should take around a week.

2. Arts for the Blues Meeting:

Following the screening, you will be invited for an Arts for the Blues meeting with one of the group facilitators to discuss the sessions 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 45 – 60 minutes.

During the meeting, you will be asked about yourself and your interest and experience with using creative methods and working in a group with others. You will be able to experience an example of a therapeutic activity used in the Arts for the Blues sessions. 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 explaining what data is being collected, what will happen with the results of the study, withdrawal from the study etc.

After you have signed the Consent Form, your eligibility to participate in the study will be confirmed using medical records where necessary and you will be supported to complete five short questionnaires asking about symptoms of depression, anxiety, wellbeing, quality of life and goals you may have for therapy.

If you and the therapist agree, you will be invited to join the Arts for the Blues group and information about dates and times of the sessions will be given. The group will take place at least one week following the meeting.

3. Arts for the Blues Psychotherapy

Following the Arts for the Blues meeting, you will be asked to take part in the Arts for the Blues group sessions, lasting 90 minutes each. There will be approximately 8 – 10 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 psychological 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 expressive creative methods such as drawing, simple movement, writing words or phrases. 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 there is a potential that you may become distressed while working on personal issues. In the unlikely event that you feel distressed, the group facilitators 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.

4. Questionnaires

Throughout the study we will ask you to complete questionnaires which measure symptoms of depression, anxiety, wellbeing, quality of life and your experience of working in the group. The questionnaires will take approximately 3 – 5 minutes to complete.

The questionnaires we will ask you to complete are:

Name	Description	When
Patient Health Questionnaire (PHQ9)	9 questions which measure depression symptoms.	<ul style="list-style-type: none"> • Arts for the Blues meeting • Before each session (12) • Three month follow up
General Anxiety Disorder Scale (GAD7)	7 questions which measure anxiety symptoms.	<ul style="list-style-type: none"> • Arts for the Blues meeting, • Before each session (12) • Three month follow up
Work and Social Adjustment Scale (WSAS)	5 questions which measure quality of life	<ul style="list-style-type: none"> • Arts for the Blues meeting • Before each session (12) • Three month follow up
The World-Health Organisation – Five Well-Being Index (WHO-5)	5 questions which measure current sense of wellbeing.	<ul style="list-style-type: none"> • Arts for the Blues meeting • Before the 6th Arts for the Blues session • Before the last Arts for the Blues session • Three month follow up
Goal Based Outcomes (GBO)	A tool to track progress in relation to personal goals throughout the psychotherapy.	<ul style="list-style-type: none"> • Arts for the Blues meeting • Before the 6th Arts for the Blues session • Before the last Arts for the Blues session
Group Session Rating Scale (GSRS)	4 questions to measure individual experience in the group.	<ul style="list-style-type: none"> • After each Arts for the Blues session (12)

5. Focus Group

All participants of Arts for the Blues will be invited to attend a focus group the week after the end of the sessions. You will be invited to discuss your experience of participating in Arts for the Blues, including what was helpful and unhelpful about the sessions in order to improve the service in the future. The focus group may be in-person or online. The focus group will be with someone from the research team and should take around 60 minutes. There will be approximately 8 – 10 participants in the focus group including yourself and you will be with the same people who took part in your group.

The focus group will be recorded, and the recording will be transcribed and anonymised. The transcription will be analysed to identify what was helpful and unhelpful during the Arts for the Blues sessions. 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. Once the study has been completed, depending on your needs, you will be referred to other services or discharged back to GP's care. If you would like to be seen again by NHS Talking Therapies, you can ask your GP to refer you or you can self-refer by calling 0161 226 3871.

What are the possible benefits or disadvantages of taking part?

The Benefits:

While there is existing evidence supporting the effectiveness of arts psychotherapies, 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.

During Arts for the Blues, you will have an opportunity to focus on your wellbeing and work on your personal goals in a supportive and safe group environment with other like-minded individuals. Following the Arts for the Blues sessions, you will be invited to a focus group to discuss helpful and unhelpful aspects of Arts for the Blues which may help in shaping a new treatment pathway for depression and potentially improve mental health services in general.

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. The group facilitators will be able to support individuals in distress if required.

If further support is needed, your therapist or members from the research team (listed above) will discuss with you any referral you may need from Greater Manchester Mental Health NHS Talking Therapies, Six Degrees Salford, 1Point Bolton or other the NHS or community settings.

Will my General Practitioner be informed of my participation?

If you are a client of Greater Manchester Mental Health NHS Talking Therapies or Six Degrees, your GP will be informed about your participation the Arts for the Blues and they will be kept informed about the outcomes of the sessions.

Will my participation be confidential?

Your participation will remain 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 if you share, or the facilitator uncovers, information that suggests an intention to harm yourself or others. Any safeguarding concerns will be discussed with the safeguarding lead (named research team at the top of this sheet) at the relevant participating organisation and we will discuss any action to be taken with you. Safeguarding referrals will follow the participating organisation's safeguarding policies and protocols.

Clinical data (e.g. brief clinical notes and outcomes from questionnaires) will be stored confidentially by the relevant participating organisation as per services policies.

Research data (e.g. number of participants, attendance records, numerical data from questionnaires, evaluation forms, focus groups data, photographs) will not have any identifiable information. All identifiable data (e.g. names, contact details) will be changed and anonymised. All research data will be stored on Greater Manchester Mental Health NHS Trust's secure network drive for at least 10 years.

Any recordings from the focus group will be transcribed and made anonymous by changing names and removing all potentially identifiable details. The recordings will be deleted once transcribing is finished, and the transcripts will be kept on a password protected file on Greater Manchester Mental Health NHS Trust's secure network drive.

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. Any photographs of creative work will be kept as digital files on the Greater Manchester Mental Health NHS Trust secure network drive and any of your identifiable details will be changed or removed to preserve anonymity.

Any identifiable data (e.g. name and contact details) will be removed, changed or coded by using a different name or number, encrypted and stored on a password protected file on the Greater Manchester Mental Health NHS Trust's secure network drive. If these details are paper-based, they will be scanned and uploaded to a password protected file on Greater Manchester Mental Health NHS Trust's secure network drive, and the physical copy will be destroyed.

Personal data will be stored separately from the research data to preserve anonymity. Once the project is completed, personal data (names, contact details, identifying videos or voice recordings) will be destroyed as per Greater Manchester Mental Health NHS Trust's Information Security Policy.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Full name
- Contact details including phone number and email address
- Anonymised responses to questionnaires and evaluation forms
- Transcripts of focus groups
- Photographs of artwork

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 different name or a code number instead. We will keep all information about you safe and secure.

What are my choices about how my 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.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can i find out more about how my information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team listed above
- by sending an email to Greater Manchester Mental Health Trust's Data Protection Officer by email at grace.birch@gmmh.nhs.uk

Will I be reimbursed for taking part?

Travel expenses to attend the screening visit, Arts for the Blues meeting, the 12 Arts for the Blues sessions and the focus group will not be reimbursed.

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. Anonymised direct quotations from the focus groups may be used in reports or publications. Anonymity will be preserved in publications. The data will remain on the Greater Manchester Mental Health NHS Trust's 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 the South East Scotland REC 02 (IRAS ID: 324474)

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 joanna.omylinskathurston@gmmh.nhs.uk or Vicky Karkou at Karkouv@edgehill.ac.uk.

If you would like to talk to someone independent of the study, please email Lisabeth Thomas at lisabeth.thomas@gmmh.nhs.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: Joanna Omylinska-Thurston (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 in the first instance then please contact The Customer Care Team/ PALS, by emailing customercare@gmmh.nhs.uk or by telephoning: 0161 358 0600.

If you want to complain about how researchers have handled your information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The Greater Manchester Mental Health Trust Data Protection Officer is Grace Birch and can be emailed at grace.birch@gmmh.nhs.uk.

If you are not happy with the Data Protection Officer's response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Support

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 or dial 111 – NHS Direct
- Call Greater Manchester Mental Health NHS Trust Crisis Line – **0800 953 0285**

If it is not an emergency but you require urgent advice, call 101 for non-emergency access to the police or NHS 111.

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.