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

Short Title: Implementing creative psychotherapy in primary mental health services

Protocol Version: V5_15.03.24.

Research Reference Numbers:

IRAS Number: 324474

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FUNDER Number: SRF005/23

Lead Researchers:

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Prof Vicky Karkou, Research Centre for Arts and Wellbeing, Health Research Institute, Faculty of Health, Social Care and Medicine, Edge Hill University

Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date: 18/03/2024

....

Name (please print):

Joanna Bryant

Position:

Research Support Service Manager

Chief Investigator:

Date: 15/03/24

Signature:
.....

Name: (please print):

Dr Joanna Omylinska-Thurston

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Key Study Contacts

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Committees	Steering Group, chaired by CI Operational Group, chaired by CI PPI Group, chaired by CI

Study Summary

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
Short Title	Implementing creative psychotherapy in primary mental health services
Study Design	Mixed Methods
Study Participants	Service users with depression
Planned Size of Sample	24 Total – 8 for each setting
Follow up duration	3 months
Planned Study Period	12 months
Research Question/ Aims	Research Questions: • How can the Arts for the Blues model be implemented into primary care mental health services? • How acceptable is the Arts for the Blues model within the services for the participants and therapists? • What is the impact of the Arts for the Blues model for participants on depression scores as well as anxiety, wellbeing, and quality of life? The study aims to evaluate the feasibility of implementing the Arts for the Blues into primary care mental health services.

Funding and Support in Kind

Funder	**Financial and Non Financial Support Given**
Greater Manchester Mental Health NHS Foundation Trust	Strategic Research Funding

Role of Study Sponsor and Funder:

The responsibility of study design, conduct, data analysis and interpretation, and dissemination of results lies with the Chief Investigator and Co-Investigators. GMMH will have oversight of monitoring and audit as the project sponsor with support from the research team

Roles and Responsibilities of Study Management Committees/ Groups & Individuals:

Steering Group

The Steering Group will meet 12 times a year, with the following members invited: Chief Investigator (CI), Research Assistant, Clinical Lead for 1Point Bolton, Clinical Lead for Six Degrees Salford and co-applicants.

Operational Group

The Operational Group, consisting of the CI and Research Assistant will meet weekly. The operational group will be responsible for the administration of the project.

Patient and Public Involvement Group

PPI group consulted at design stage

Protocol Contributors:

Dr Joanna Omylinska-Thurston (NHS Talking Therapies)

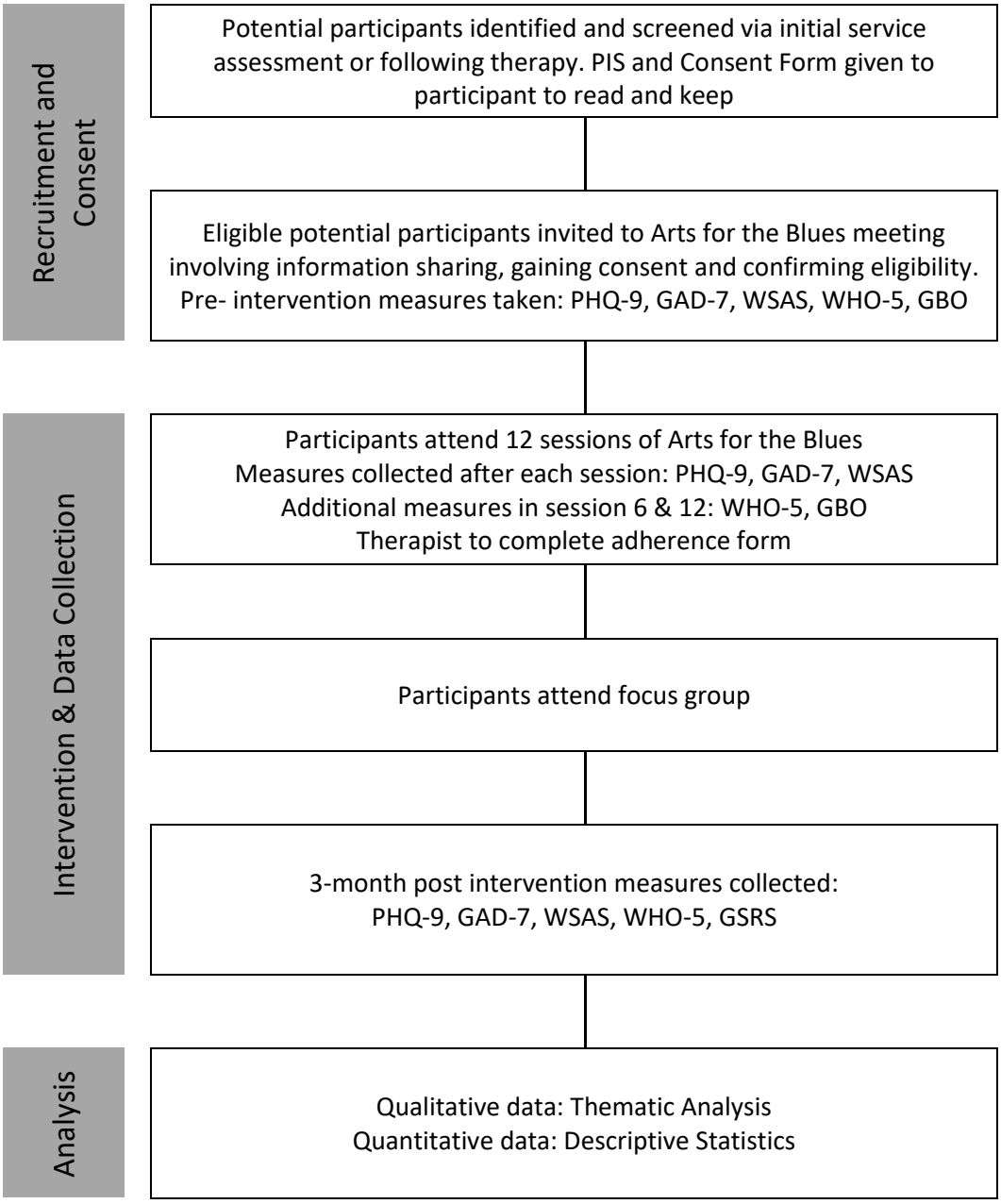
Prof Vicky Karkou (Edge Hill University)

Rebecca Clark (University of Salford)

Pascale Barrett (Edge Hill University)

Keywords: Arts for the Blues; NHS Talking Therapies; Creative Psychotherapies; Depression; Feasibility study.

Study Flow Chart:



Study Protocol.

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

1. Background:

According to the World Health Organisation (2021), depression is a condition affecting over 280 million people worldwide and in the UK, depression and anxiety are the most common mental health problems affecting 7.8% of the population (Mental Health Foundation, 2016). Given that depression often remains undiagnosed, it is possible that the size of the problem is much larger than these statistics show.

Currently, National Health Service (NHS) talking therapies (formally Improving Access to Psychological Therapies [IAPT]) is the main provider of evidence-based psychological therapies for adults within the NHS. Whilst Cognitive Behavioural Therapy (CBT) is the main modality offered, other approaches such as 'counselling for depression' are offered in a limited capacity. Even less common is the provision of any arts psychotherapies, i.e. music, drama, art or dance movement psychotherapy. Recent findings identified that about 48% of clients drop out of IAPT (NHS Digital, 2022) indicating that therapies offered in IAPT may not always meet the clients' needs (Martin et al., 2021).

A recent survey by Millard et al. (2021) reported that over 60% of service users and the general public would like to see creative forms of psychological therapies as an option when they contact services. There is evidence for the effectiveness of arts psychotherapies for depression. The Cochrane review by Meekums et al. (2015) and the recent meta-analysis by Karkou et al. (2019), which focused on specific studies in dance movement psychotherapy for depression, along with a similar review in music therapy (Maratos et al., 2011) and art psychotherapy (Uttley et al., 2015) indicate that, despite the limited number of good quality randomised controlled trials, the evidence suggests positive effects for these arts interventions. Similarly, systematic review of arts psychotherapies for older adults (Dunphy et al., 2018) suggests that these positive outcomes can be relevant for all forms of arts psychotherapies across age groups.

More recently and following recommendations from the Medical Research Council (Skivington et al., 2021) on the development and evaluation of complex interventions, we have developed a manualised treatment called **Arts for the Blues** that capitalizes on best practice from CBT, counselling for depression and psychodynamic psychotherapy as well as best practice in arts psychotherapies. Following a synthesis of the evidence (Parsons et al., 2020), we invited public input (Haslam et al., 2019) and contributions from IAPT staff and service users (Karkou et al., 2022) integrating creative ideas (Thurston et al., 2022). We have also delivered the full model in schools (Moula et al., 2020) and at the charity Mind (Omylinska-Thurston et al., in preparation).

2. Rationale:

The model described at Omylinska-Thurston et al. (2020) offers the promise of a useful intervention but further evaluation is needed in adult services since the one group offered at

the charity Mind involved only seven participants and was delivered online due to Covid-19 restrictions.

The evidence for Arts for the Blues for adults for depression has been established in the context of the charity MIND but the study had a small sample size. In this study we aim to translate the findings from MIND to the NHS context in order to build our evidence base and also to see whether this intervention could be implemented in the NHS setting in the future.

3. Theoretical Framework:

Arts for the Blues is a manualised group psychotherapy which utilises best practices from Cognitive Behavioural Therapy (CBT), counselling for depression, psychodynamic psychotherapy and arts psychotherapies. The model offers a structured, evidence-based, group, short-term psychotherapy (Haslan et al., 2019). It follows a pluralistic approach to psychotherapy using creative methods and holds the therapeutic relationship at the heart of the work. There are eight key ingredients which are core components of the intervention model and are regarded as responsible for therapeutic change (Omylinska-Thurston et al., 2020). The model is offered over twelve 90-minute sessions and is comprised of eight key ingredients which are delivered through diverse forms of creative engagement such as visual arts, music, dance and movement, drama and creative writing. The eight key ingredients are as follows:

- Encouraging active engagement
- Learning skills
- Developing relationships
- Expressing emotions
- Processing at a deeper level
- Gaining understanding
- Experimenting with different ways of being
- Integrating useful material

The Intervention will be facilitated by psychotherapists trained in the Arts for the Blues model. It is expected that creative methods will support engagement, enable non-verbal opportunities for recovery and contribute towards the attractiveness, acceptability and value of the Intervention. Ongoing research suggests Arts for the Blues is a useful group intervention, however further evaluation of the model is needed in adult services

4. Research Question / Aims:

This study aims to evaluate the feasibility of implementing the Arts for the Blues into primary care mental health services.

Research Questions:

(i) How can the Arts for the Blues model be implemented into primary care mental health services?
(ii) How acceptable is the Arts for the Blues model within the services for the participants and therapists?
(iii) What is the impact of the Arts for the Blues model for participants on depression scores as well as anxiety, wellbeing, and quality of life?

4.1 Objectives:

1. To prepare for the delivery of a creative group psychotherapy Arts for the Blues within primary care mental health services (NHS Talking Therapies, 1Point Bolton and Six Degrees Salford)
2. To deliver the Arts for the Blues psychotherapy group (One group per primary care mental health service)
3. To evaluate the impact of the Arts for the Blues groups using:
   a. Qualitative methods (understanding participant and therapist views on helpful and unhelpful aspects of the Arts for the Blues model)
   b. Quantitative measures (Depression, anxiety and wellbeing scores)

4.2 Outcome:

Our intention is to integrate Arts for the Blues into primary care mental health services and to provide an alternative treatment option for adults with depression in Greater Manchester. The study will help towards building the evidence base for this approach, preparing for a Randomised Clinical Trial (RCT) in the future. The overall aim is to propose changes on a policy level for inclusion of creative approaches into national provision of therapies for depression.

5. Study Design and Methods of Data Collection and Data Analysis:

We will adopt an overall case study design (Yin, 2017) that will include pre- and post-measures in a mixed methods approach (Creswell, 2014). The mixed methods design will collect both quantitative and qualitative data.

<u>Quantitative</u>

Quantitative data will be collected pre and post intervention, weekly, in week 6 of the intervention and 3 months post intervention. All quantitative data will be analysed and presented using descriptive statistics. Quantitative data will be collected using:

- Patient Health Questionnaire (PHQ-9) (Kroenke et al., 2001) - (collected pre and post intervention, weekly and 3 months post intervention).
- Generalised Anxiety Disorder assessment (GAD-7) (Spitzer et al., 2006) - (collected pre and post intervention, weekly and 3 months post intervention).
- Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002) - (collected pre and post intervention, weekly and three months post intervention).
- WHO's Five Well-Being Index (WHO-5) (Topp et al., 2013) – (collected pre and post intervention and 3 months post intervention).
- Goal Based Outcomes (GBO) (Law & Jacob, 2013) – (collected pre and post intervention, midway (in week 6 of the intervention) and 3 months post intervention).
- Group Session Rating Scale (GSRS) (Quirk et al., 2013) – (Collected weekly).

PHQ-9 and GAD-7 are relevant measures for adults with depression and anxiety and are standardised measures used within NHS Talking Therapies services. These measures are extensively used in the NHS, allowing for findings to become comparable with routine psychological provision and outcomes.

WSAS is used routinely in NHS settings and assess the impact of an individual's mental health on their ability to function across various settings (e.g. work, home, social)

WHO-5 is a brief measure that is quick to complete and relevant for the intervention. Whilst PHQ-9 and GAD-7 will measure reduction of difficulties, WHO-5 will capture strengths.

The GBO measure will be used to personalise the intervention and identify any goal-orientated changes over time. A weekly GSRS (Quirk et al., 2013) will be completed to identify participants' experience of group therapy and therapeutic progression.

The Arts for the Blues research team will only have access to anonymised data which will be used for analysis.

Qualitative

Qualitative data will be collected post-intervention and will be subjected to thematic analysis (Clarke & Braun, 2013). Qualitative data will be collected using:

- Evaluation forms completed by participants
- Adherence forms completed by therapists
- Focus groups – Online or in-person. Facilitated by a member of the research team or therapist and will be audibly recorded

Focus groups will be transcribed and analysed by a research assistant using a password protected computer. Once the transcriptions have been completed, the recordings will be deleted. Any paper-based data will be uploaded to the GMMH secure network drive and the hard copy will be destroyed.

Adherence Forms will be completed by the Arts for the Blues therapist which comprise of quantitative and quantitative data. The Adherence Form requires the therapist to evaluate the Arts for the Blues model each week using numerical scales with space for additional comments on the Arts for the Blues model.

6. Study Setting:

This study is a multicentre study. The following centres will be participating in the study:

NHS Talking Therapies
Greater Manchester Mental Health NHS Foundation Trust
Prestwich Hospital
Bury New Road
Prestwich
Manchester
M25 3BL

1Point Bolton
Silverwell House
1 Silverwell Lane
Bolton
BL1 1QN

Six Degrees Salford
8th Floor
2 City Approach
Albert Street
Eccles
M30 0BL

The study will take place either in-person or online. If in-person, the sessions will take place at the above locations where the participant has been recruited from. In-person groups from GMMH will take place at the Booth Centre:

Edward Holt House
Pimblett St,
Cheetham Hill,
Manchester
M3 1FU

Risk assessments will be completed for in-person locations. If online, the sessions will take place on MS Teams, with the link being sent directly to participants via email.

7. Sample and Recruitment:

7.1 Eligibility Criteria:

Participants will be screened against eligibility criteria during the screening and their eligibility will be confirmed at the Arts for the Blues meeting.

7.1.1 Inclusion Criteria:

- aged 18 years or over.
- must have depression or symptoms of depression (assessed by PHQ9 >5).
- is interested and willing to take part in group work.
- is interested and willing to take part in the creative interventions.
- is able to communicate in English at a basic level without the need for an interpreter.

7.1.2 Exclusion Criteria:

- too physically unwell to attend the intervention.
- currently at risk of harming self and/or others.
- regularly misusing alcohol or other illegal substances which would make engaging in the group difficult.
- experiencing psychotic episodes which would make engaging in the group difficult.
- is severely psychologically distressed and/or who is presenting any condition which could interfere with regular attendance, such as significant dissociation, severe social anxiety, paranoia, difficulties in comprehension, difficulties in emotional regulation, severe personality disorder, severe depression.
- Is currently participating in other research

7.2 Sampling

7.2.1 Size of Sample

The data collection in qualitative research is usually carried out with a relatively small sample of participants (Clark & Braun, 2023). Furthermore, the research has limited funding, therefore it was decided that approximately 8 participants will be recruited for each primary care mental health service, resulting in approximately 24 participants in total.

7.2.2 Sampling Technique

Purposive sampling will be used: participants will have to meet pre-identified inclusion and exclusion criteria (Outlined in sections 7.1.1 & 7.1.2)

7.3 Recruitment

Recruitment will be initiated from NHS Talking Therapies (GMMH) and through 2 social enterprises (Six Degrees Salford and 1Point Bolton).

Potential participants will be identified by a trained staff member at each primary care mental health service at initial screening / following therapy. Service user eligibility for the Arts for the Blues intervention will be screened using inclusion / exclusion criteria. Electronic records may be checked as per service policy. If needed, eligibility will be discussed with the person acting as the 'checkpoint' (Dr Joanna Omylinska-Thurston, Ann Grant, Jody Comiskey) who will facilitate contact with the relevant practitioners if required. For potentially eligible service users, permission will be sought to refer to the Arts for the Blues Therapist, and a Referral Form will be completed to confirm eligibility and sent to the Arts for the Blues Therapist within the primary care mental health service. Potentially eligible service users will be provided with a PIS and Consent Form to read and keep.

Potentially eligible and agreeable service users are invited to an Arts for the Blues meeting, either online, in-person or by telephone. Further details of the intervention will be provided and the service user's ability to attend will be discussed. Service users will be given opportunities to ask questions. The Arts for the Blues Therapist will check the service user's understanding and experience of creative interventions and their ability to take part in creative group work. Consent will be sought to take part in the intervention.

The participants' eligibility will be confirmed and they will be asked if there are any emotional or physical difficulties that might affect participants in the sessions so the therapist can take these into account.

Pre-intervention outcome measures will be taken (PHQ-9, GAD-7, WSAS & WHO-5).

There will be no pressure on participants to take part in the research and they will be free to withdraw at any point of the research process without it affecting any other contact with the services they receive.

If the service user declines or is not eligible for the study, they will be supported and signposted to more appropriate services within the primary care mental health service and the study will not be mentioned again.

7.3.1 Sample Identification

The recruitment process will be initiated from within the participating primary car mental health services. Staff conducting the initial screening / previous therapy will have knowledge of the study.

7.3.2 Consent

Written consent will be sought from all participants in order to take part in the study, including the intervention, questionnaires and focus groups. Participants will not be pressured into joining the study and will be given opportunities to ask questions and will be given time to consider whether they want to participate in the study.

Potentially eligible service users will be given the relevant PIS which outlines the purpose of the study, benefits to participants, the intervention and the focus groups. They will also be given a blank consent form to look over that addresses consent for data storage, withdrawal processes and confidentiality of personal data.

Service users will then be invited to an Arts for the Blues meeting with the Arts for the Blues Therapist within the primary care mental health service, where full details of the intervention will be given and service user's eligibility will be assessed. Service users will have the opportunity to ask any questions they may have regarding the intervention and study. Consent forms are collected and pre-intervention measures are taken.

Service users will then be invited to the intervention sessions.

Ongoing consent will be incorporated into the Arts for the Blues sessions, checking key issues such as confidentiality with the participants.

8. Ethical and Regulatory Considerations

8.1 Assessment and Management of Risk

Due to the nature of the study, it is possible that some amount of distress may be experienced by participants. Psychological therapies, while shown to offer relief of symptoms, can sometimes cause distress for participants as it is a reflective process.

The therapists are registered and have extensive clinical experience and are trained to recognise symptoms of distress and respond accordingly. If participants become distressed, they will be able to discuss follow-up care options and a referral to an appropriate NHS or community service will be considered. Participants will be reminded that they reserve the right to withdraw from the study at any time.

Alongside distress to participants, there are ethical issues around safeguarding, confidentiality and informed consent. The nature of the intervention means that opportunities may arise in which participants make disclosures that require a safeguarding referral, this will be addressed with the relevant service's safeguarding lead. Safeguarding referrals will follow the relevant service's safeguarding protocols.

Confidentiality will be maintained as per UKCP (United Kingdom Council for Psychotherapy), BACP (British Association for Counselling and Psychotherapy) and BPS (British Psychological Society) codes of Ethics. This includes protecting sensitive and personally identifiable data pre, during and post intervention and that policy on breaches

of confidentiality is made clear in advance to the participants. Confidentiality must only be breached in any of the following three events:

1. Disclosure that requires a safeguarding referral
2. Disclosure that highlights risk of harm to the participant (s) or others
3. Disclosure of serious criminal activity

Confidentiality will only be breached in specific circumstances and in specific ways. In the event of safeguarding concerns, advice will be sought from the relevant primary care mental health service's safeguarding lead and a referral may follow. Any disclosures of risk of harm to participants or others will be referred to the relevant agency. Disclosure of criminal activity will be referred to the police. Participants will be assured that their participation remains confidential, and that confidentiality will only be breached in any of these three events.

Confidentiality of data used for research purposed (data analysis, dissemination and publication) will be reached by anonymizing the data using encryption and following the data management plan for storage.

All data will be securely stored online on the GMMH secure network drive in accordance with GDPR regulations and following the data management plan.

Other key ethical issues include the risks and burdens to participants. Due to the creative nature of the research, participants may engage in light physical activity which can increase the likelihood of injury. Participants will be aware through the participant information sheet and the consent form of their overall commitment to the project. Risk assessments from the participating primary care mental health services will be reviewed every 3 months and amended where necessary. Participants will be fully informed of their commitment at every step of the project which will reduce the potential burden experienced by the participants.

Participants have one week following the focus groups to request full withdrawal of data. After the one-week withdrawal period has passed, participants will not be able to withdraw their data as it will become part of a larger data set used for analysis. Participants are informed of the above on the PIS and consent form. Any photographs of creative group artwork will not be able to be withdrawn as it will also contain other participant's data and individual participants will not be able to be identified.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Regulatory Review & Compliance
A favourable opinion will be sought from the Health Research Authority Ethics Committee before commencing the study.
The CI will notify the REC of the end of the study which is defined as occurring once the three-month follow up questionnaires have been collected from participants.

For any amendment to the study, the CI or designee, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. The CI or designee will work with sites so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments
In the event of substantial amendments to the REC application or supporting documents, the Research Assistant, in co-ordination with the research team, will submit a valid notice of amendment to the REC for consideration. NHS R&I at GMMH will be notified of all amendments, both non-substantial and substantial. Amendment history information is available at the bottom of this document (section 11.3)

8.3 Patient & Public Involvement

People with lived experience (PLE) have been key to the development of this proposal. Our current PLE group consists of six members, four of whom took part in our first Arts for the Blues therapy group in MIND in 2020, and who have attended four formal consultations. Three sessions involved two-hour online events including creative activity and formal discussion taking place in 2022 and 2023.

8.4 Protocol Compliance

Whilst accidental protocol deviations can happen at any time, they must be adequately documents on the relevant forms and reported to the Chief Investigator (Dr Joanna Omylinska-Thurston) and Sponsor immediately.

Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.5 Data Protection and Patient Confidentiality

Of the research team, only the CI will have access to participant's personal data and key to pseudonyms, this will be stored separately from the research data to preserve anonymity. The relevant primary care mental health services will have access to personal data as is routine practice. Only anonymised data will be shared with the research team.

The research team who will transcribe the focus groups and assist with data analysis will sign confidentiality agreements and research passports prior to accessing any participant data. They will adhere to these arrangements with particular regard to confidentiality and safeguarding of any personal data, including being mindful of Data Protection Act (2018) and GDPR (2018) requirements, as well as possible Freedom of Information (2000) requests and procedures.

Confidentiality will be maintained as per UKCP (United Kingdom Council for Psychotherapy), BACP (British Association for Counselling and Psychotherapy) and BPS (British Psychological Society) codes of Ethics. This includes protecting sensitive and personally identifiable data pre, during and post intervention and that policy on breaches of confidentiality is made clear in advance to the participants. There may be occasions when confidentiality may have to be breached to the appropriate authorities due to risks of harm to self or others, these instances are:

- 1. Disclosure that requires safeguarding referral,
- 2. Disclosure that highlights risk of harm to the participant(s) or others,
- 3. Disclosure of serious criminal activity.

The above instances are outlined in the PIS and consent form. All concerns will follow a staged process of consultation and reporting and will be addressed according to the relevant mental health service's safeguarding policies and protocols which will be addressed by the designated safeguarding lead in each of the settings.

Recordings of focus groups will be stored on the GMMH secure network drive and will only be used for transcription purposes, they will be transcribed and anonymised as soon as possible, participants will be given pseudonyms and all potentially identifiable data (e.g. significant events/ dates / diagnoses) will be removed. Once transcription is complete, recordings will be deleted, and the remaining transcripts will be stored on the GMMH secure network drive. Transcripts may be shared electronically between researchers using password protected secure emails: nhs.uk, nhs.net, edgehill.ac.uk and Salford.ac.uk.

In addition to anonymised transcripts, numerical and arts-based data may be shared between the research team via secure password protected email: nhs.uk, nhs.net, edgehill.ac.uk and salford.ac.uk. Only anonymised email will be shared via email and no files containing identifying patient details will be transferred electronically. Although direct quotations from respondents and non-identifiable arts-based data may be published, any identifying material will be excluded and pseudonyms will be used.

Consent will be sought for regulatory authorities to access anonymised data for audit purposes; that anonymised transcriptions and photographs of art work generated during the intervention will be held on a password protects file on the GMMH secure network drive for up to 5 years; and Referral Forms and Consent Forms will be kept digitally in password protected files on the GMMH secure network drive for 5 years. All files will be confidentially destroyed after this period.

8.6 Indemnity

NHS indemnity scheme will apply.

8.7 Access to the Final Study Dataset

Access to the final dataset will be restricted to Dr Joanna Omylinska-Thurston, Prof Vicky Karkou and the Research Assistant.

9. Dissemination Policy

9.1 Dissemination Policy

Excerpts of transcripts may be used in analysis reporting, all identifiable information will be removed prior to publication and pseudonyms will be assigned to protect anonymity.

Findings of this work may be published online through NHS channels, present at one event minimum and the results will be published in at least one peer-reviewed journal.

10. End of study

The total duration of the client's involvement in the study from screening to the end of the study (including 12 weeks intervention and three months follow up) will be a maximum of 7 months. Once the study has been completed, depending on the client's needs, they will be referred to other services (e.g. CMHT, Psychotherapy Service etc) or discharged back to GP's care. If the client would like to be seen again by NHS Talking Therapies, they can ask for GP re-referral or can self-refer by calling 0161 226 3871.

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12. Appendices

12.1 Appendix 1 – Required Documentation

1. Recruitment Pathway
2. Arts for the Blues Referral Form
3. GMMH Participant Information Sheet
4. 1Point Bolton Participant Information Sheet
5. Six Degrees Salford Participant Sheet
6. Consent Form
7. Arts for the Blues Adherence Form
8. Evaluation Form
9. Focus Group Question Schedule
10. Data Management Plan
11. 1Point Bolton Risk Assessment
12. Six Degrees Risk Assessment
13. 1Point Bolton Organisation Information Document
14. Six Degrees Organisation Information Document
15. GMMH Schedule of Events
16. 1Point Bolton Schedule of Events
17. Six Degrees Schedule of Events
18. CV for Dr Joanna Omylinska-Thurston
19. CV for Prof Vicky Karkou

Appendix 2 – Schedule of Procedures

	Screening	Baseline	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14
Initial Assessment / Screening	X															
Arts for the Blues meeting		X														
Consent Process		X	X													
Intervention			X	X	X	X	X	X	X	X	X	X	X	X		
Questionnaires		X	X	X	X	X	X	X	X	X	X	X	X	X		X
Evaluation forms														X		
Focus Groups															X	

12.2 Appendix 3 – Amendment History

Amendment No.	Protocol Version No.	Date Issued	Author of Changes	Details of Changes Made
1	V3_25.10.23	25.10.23	R.Clark	Formatting to HRA template
2	V3.1_13.11.23	13.11.23	R.Clark	Removed HRA protocol compliance declaration. Added withdrawal period to section 8.1, clarification re eligibility confirmation in section 7.1, updated PIS and Consent to latest versions (dated 13.11.23)
3	V3.2_14.11.23	14.11.23	R.Clark	Updated PIS and consent form to latest versions (dated 14.11.23)
4	V3.3_27.11.23	27.11.23	R.Clark	Changed storage of data from 'CI's GMMH OneDrive' to 'GMMH secure network drive' Updated DMP to include above wording.
5	V3.4_29.11.23	29.11.23	R.Clark	Removal of study documents and added as list in Appendix 1
6	V3.5_07.12.23	07.12.23	R.Clark	Added Booth Centre as location for in person at GMMH and consent collection moved to Arts for the Blues meeting
7	V3.6_12.12.23	12.12.23	J. Omylinska-Thurston	Consent process refined
8	V3.7_18.12.23	18.12.23	R.Clark	Eligibility moved to after consent
9	V3.8_21.12.23	21.12.23	R.Clark	Removed ethical approval sought from University of Salford. Added to rationale. And clarified 'midway'
10	V4_26.02.24	26.02.24	R.Clark	Removal of 'had symptoms of depression' from inclusion criteria

11	V5_15.03.24	15.03.24	J. Omylinska-Thurston	Point 10 in relation to the end of study has been added

For further details on the model, publications and training opportunities, see: www.artsfortheblues.com

For creative group ideas and resources, see: https://artsfortheblues practice.co.uk