East London NHS Foundation Trust

EFFECTIVENESS OF GROUP ARTS THERAPY COMPARED TO GROUP COUNSELLING FOR DIAGNOSTICALLY HETEROGENEOUS PSYCHIATRIC COMMUNITY PATIENTS: RANDOMISED CONTROLLED TRIAL IN MENTAL HEALTH SERVICES

Short title: Effectiveness of group arts therapy: Randomised controlled trial

Acronym: ERA

- **This protocol has regard for the HRA guidance and order of content.**

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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

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 clinical investigation without the prior written consent of the Sponsor

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

For and on behalf of the Trial Sponsor:

Signature: DocuSigned by: Angela Williams

Date: 29/Nov/2022

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Position: Head of R&D

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Date: ...../...../.....

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Committees	Trial Management Group (all co-applicants and researchers employed on the study) Lived Experience Advisory Panel Trial Steering Committee comprising an independent chair, a clinician, statistician and patient representative. Data Monitoring and Ethics Committee

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ii. LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CSO	Clinical Studies Officer
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
LEAP	Lived Experience Advisory Panel
NHS R&D	National Health Service Research & Development
NIHR	National Institute for Health Research
PCTU	Pragmatic Clinical Trials Unit
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RA	Research Assistant
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

iii. TRIAL SUMMARY

Trial Title	Effectiveness of group arts therapy compared to group counselling for diagnostically heterogeneous psychiatric community patients: Randomised controlled trial in mental health services	
Internal ref. no. (or short title)	Effectiveness of group arts therapy for diagnostically heterogeneous patients (ERA)	
Clinical Phase	Phase III (non-medicinal product, complex intervention)	
Trial Design	Pragmatic, 2-arm randomised controlled single-blind trial comparing group arts therapy (art, dance movement or music) to active group counselling control with internal pilot and nested process evaluation.	
Trial Participants Process evaluation- staff qualitative interviews:	Adults aged 18 or above, living in the community, ICD-10[1] F2 (schizophrenia and related psychotic disorders), F3 (mood disorders), F4 (anxiety and other non-psychotic disorders); at least moderate symptom level on BSI[2] Capacity to give informed consent Arts therapists providing the trial intervention Arts therapy co-facilitators providing the trial intervention	
Planned Sample Size	N=420 (Internal pilot: 180, Full trial: 240) *Process evaluation- qualitative interviews:* N=8-12 (arts therapists); N=45-55 participants from above sample	
Treatment duration	20 weeks of group arts therapy or group counselling, 2 times per week (40 sessions)	
Follow up duration	12 months post intervention period	
Planned Trial Period	September 2018 – November 2023	
	Objectives	Outcome Measures
Primary: To test whether group arts therapies are effective for diagnostically heterogeneous patient groups receiving care in community secondary mental health services to inform commissioning and development of NHS mental health services.	1. Test the effectiveness of manualised diagnostically heterogeneous group arts therapy on reducing psychological symptoms (primary outcome) in patients receiving treatment in community mental health services as compared to an active group counselling control (both conditions in addition to treatment as usual)	Global Severity Index, Brief Symptom Inventory- End of intervention.

Secondary	2. Conduct an internal pilot to ensure recruitment and adherence to the intervention are sufficient to proceed to a full trial	Recruitment rate Attendance rates Therapist adherence rates
	3. Test the effectiveness of group arts therapy on observer rated symptoms, quality of life and objective social situation.	Brief Symptom Inventory Brief Psychiatric Rating Scale Manchester Short Assessment of Quality of Life Objective Social Outcomes Index
	4. Test whether effects on primary and secondary outcomes hold true at six and 12 month follow-up periods post-intervention.	
	5. Explore the impact of adherence, diagnosis and type of arts therapy upon outcomes in sub-group analyses.	Group attendance Socio-demographic data
	6. Explore processes in above sub-groups in a nested process evaluation	Group attendance Outcome Rating Scale Personal Health Questionnaire Ferrara Group Experiences Scale Qualitative End of therapy Interviews with patients and therapists Observer and therapist-rated adherence to manual Group therapy use
	7. Assess the cost-impact and cost-effectiveness of group arts therapy.	Client Services Receipt Inventory Health service use EQ-5D-5L ReQoL-20
Intervention Control Both arms:	Group arts therapy (art, dance movement or music) provided by an HCPC registered arts therapist and co-facilitator. Group counselling with no use of arts provided by an accredited counsellor and co-facilitator. Group size: 10 service users Setting: Community venue	
Duration	Up to 90 minutes, twice per week for 20 weeks	

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIALSUPPORT GIVEN
National Institute for Health Research	Funding as part of Health Technology Assessment Programme - ERA
East London NHS Foundation Trust (supported by Noclor)	Study sponsorship
East London NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users.
Avon & Wiltshire Partnership NHS Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users.
Central and North West London NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users.
Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and service users.
Queen Mary University of London	Substantive employer of CI, Co-CI, Statistician and Health Economist; Pragmatic Clinical Trials Unit support.
Imperial College London	Substantive employer of co-applicant.
Edge Hill University	Substantive employer of co-applicant.
Brunel University	Substantive employer of co-applicant.
British Association of Art Therapists	Substantive employer of co-applicant.
Service User and Carer Group Advising on Research (SUGAR)	Advice on patient and public involvement throughout the study.

v. ROLE OF TRIAL SPONSOR AND FUNDER

East London NHS Foundation Trust is the study sponsor. Noclor Research Support Service is acting on behalf of East London NHS Foundation Trust to assume overall responsibility for the initiation and management of the study.

This study/project is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme (project reference 17/29/01). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Trial Management Committees

The trial will have four management committees: the Independent Trial Steering Committee, the Data Monitoring and Ethics Committee, the Trial Management Group and the Lived Experience Advisory Panel. All membership to the different committees has been confirmed and agreed by the funder. The main roles and responsibilities of each committee are outlined below:

Trial Steering Committee:

The independent Trial Steering Committee (TSC) has been set up in accordance with the funder (NIHR) requirements and regulations. The TSC includes the following independent members: An independent chair (Professor of Psychiatry), a clinician (experienced music therapist working in mental health settings), a statistician and a patient representative. The TSC will meet jointly with the Data Monitoring and Ethics Committee (DMEC) at the beginning of the study and then immediately following the expected delivery of major milestones i.e. month 9 (after recruitment of first groups and 4 weeks of intervention delivery), month 15 (after recruitment to full trial), month 22 (after completion of all treatment groups) and month 36 (after preliminary analysis of all trial data). Further meetings will be arranged as and when required. During meetings the TSC will be joined by a maximum of two members of the research team- usually the CI and co-CI. The agenda for the meetings will be agreed by the chair, circulated to all members and kept in the Trial Master File (TMF). During the meetings, the TSC will monitor study progress and send reports to the sponsor.

Data Monitoring and Ethics Committee:

The Data Monitoring and Ethics Committee (DMEC) will include committee members who are completely uninvolved in the running of the trial and who cannot be unfairly influenced (either directly or indirectly) by people or institutions involved in the trial. The DMEC will include one trial methodologist, a statistician and a patient representative. They will meet once together with the TSC and then immediately prior to TSC meetings (and more regularly if required).

Trial Management Group:

The Trial Management Group (TMG) includes the CI, co-CI and 9 co-applicants, the main researchers and patient representatives from the Lived Experience Advisory Panel. The TMG will meet regularly to ensure all practical details of the trial are progressing and working well, and to ensure everyone within the trial understands them. The TMG will meet every two to three months initially, and at least three times per year throughout the trial. Project timelines and milestones will be reviewed at each meeting. More regular and individual meetings between the PIs, site leads and different parts of the research team will be arranged, including teleconferencing as appropriate.

In addition to the TMG, a smaller focused group made up of members of the TMG will manage the day-to-day running of the trial. This will primarily involve the CI, co-CI and all researchers on the project, with input from different co-applicants, such as the statistician, depending on the need of the project.

Lived Experience Advisory Panel

The Lived Experience Advisory Panel (LEAP) will consist of up to 8 patient and carer members with experience of secondary mental health care services or caring for someone accessing such services. The LEAP will be chaired by the lived experience co-applicant, who has experience of using arts

therapies groups. The panel will be recruited from an existing service user and carer group (Service User Group Advising on Research (SUGAR)) and from East London NHS Foundation Trust mental health services. The LEAP will meet at least twice per year to advise on study materials, progress and findings. Meeting will be arranged flexibly with members given the option of either a full or half day meeting. Their role will be specified and the terms of reference agreed during the first meeting. The focus of LEAP meetings will be firstly, to advise on website content and development, recruitment strategy, all patient-facing information. Later meetings will involve advice on issues as they occur, and contribution towards analysis and interpretations of findings, including suggestions as to how to present these to wider members of the public and develop plain English summaries.

vii. Protocol contributors

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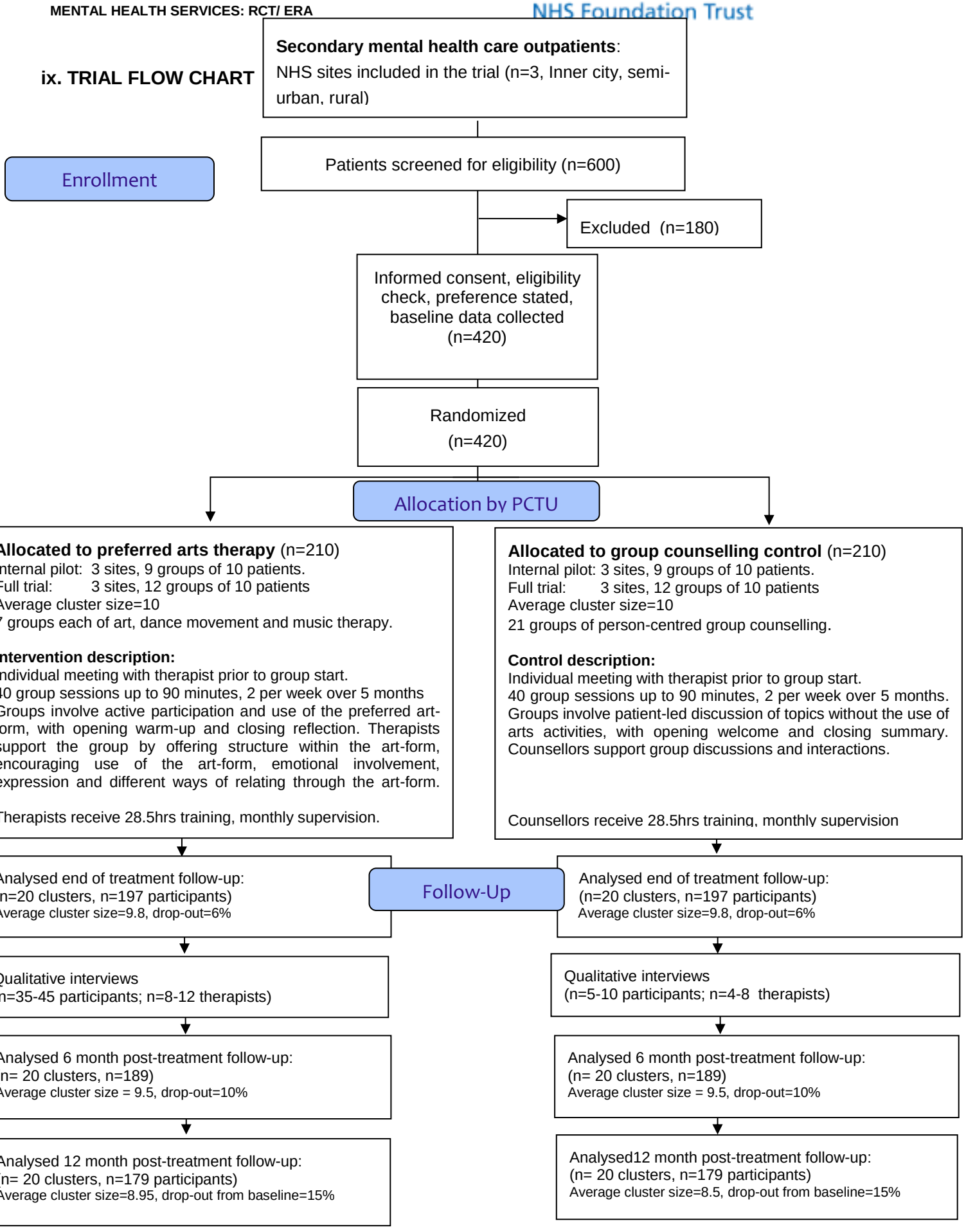
Professor Stefan Priebe

Stephen Sandford

Dr Richard Hooper

viii. KEY WORDS: Group arts therapies, randomised controlled trial, process evaluation, mental health, mixed diagnoses

ix. TRIAL FLOW CHART



1 BACKGROUND

Arts therapies are widely, but inconsistently provided across NHS Trusts. Art, music and dance-movement therapies can enable patients to identify difficulties and strengths through use of the art-form in varying group interactions, facilitate emotional expression in creative activities, allow experiences and learning in non-verbal and verbal communication, strengthen self-esteem in art production (e.g. painting, song, dance), and help exploration of new emotional and cognitive approaches with the support of the group and the therapist (Karkou & Sanderson, 2005). A core principle in group therapies is the composition of group members to ensure heterogeneity of problems and experiences (American Group Psychotherapy Association, 2007; Yalom & Leszcz, 2005). A mix of different perspectives and experiences therefore allows greater opportunities for new behaviours and learning between group members.

This study is based on the concept that therapeutically effective processes are common to all arts therapies modalities (Orfanos, Banks & Priebe, 2015; Orfanos & Priebe, 2017; Crawford & Patterson, 2007; Karkou & Sanderson, 2005; Havsteen-Franklin, Maratos, Usiskin & Heagney, 2016; Havsteen-Franklin, Jovanovic, Reed, Charles & Lucas, 2017; Heynan, Roest, Willemars & van Hooran, 2017). Accordingly, NICE combines the evidence for them in one analysis (National Collaborating Centre for Mental Health, 2014). However, for any arts therapy to have an effect, patients need to engage with the group and the art form used. The appeal of art forms and patient preferences vary. A poor match of preference and the offered art form is likely to lead to poorer attendance and – even in attending patients – poorer outcomes, as suggested by both MATISSE and NESS (Crawford, Killaspy, Barnes et al, 2012; Priebe, Saville, Wykes et al, 2016). A similar picture is seen in wider psychological treatment, where lack of preference matching has been associated with lower perceived benefit from treatment (Howard & Thornicroft, 2006; Preference Collaborative Review Group, 2008; Crawford & Dunlea, 2010; Williams, Farquharson, Palmer et al, 2016). Also it does not really reflect the clinical reality as patients, if they have a choice, rarely accept a form of arts therapy that does not strongly appeal to them.

To date, effectiveness trials of group arts therapies have mostly focused upon patients with a single psychiatric disorder with mixed results (Ren & Xia, 2013; Meekums, Karkou & Nelson, 2015; Ruddy & Milnes, 20015; Aalbers, Fusar-Poli, Freeman et al, 2017; Mössler, Chen, Heldal & Gold, 2011; Crawford, Killaspy, Barnes et al, 2012; Priebe, Saville, Wykes et al., 2016; Röhricht, Papadopoulos & Priebe, 2013; Erkkilä, Punkanen, Fachner et al., 2011). The focus on a single disorder limits the extent findings can be generalised to how arts therapies are routinely provided. For example, the MATISSE and NESS trials, whilst pragmatic in nature, both focused on narrowly defined populations (patients only with schizophrenia) rarely encountered in usual clinical practice. In contrast, a study of individual music therapy for patients with low therapy motivation (Gold, Mössler, Grocke et al., 2013) is one of the few trials to have included a diagnostically heterogeneous population but did not examine this within a group context. One further study for psychiatric outpatients with severe mental illness (Grocke, Bloch, Castle et al, 2013) utilised group music therapy only with a songwriting focus and found significant effects on quality of life.

We will test whether arts therapies provided in groups are effective for diagnostically heterogeneous patients in mental health services. Patients will choose which of the three forms of arts therapy they want to participate in, be randomised to either their preferred form of arts therapy or an active group counselling control, and be offered 40 sessions over a five month period. Outcomes will be assessed at

baseline, at the end of treatment, and after 6 and 12 month post-intervention follow-up periods. Overall, the study will provide pragmatic evidence for the effectiveness and cost-effectiveness of group arts therapies as they are most commonly provided within NHS community mental health services.

Evidence explaining why this research is needed now:

The 5-year forward view for mental health emphasises the central importance of choice and personalisation in recovery (Mental Health Taskforce, 2016; NHS England, 2014). The importance of the arts in maintaining health and wellbeing is also gaining increased recognition, and a recent All Party Parliamentary Group report highlights that such initiatives – including arts therapies- are often under-funded, short-term and poorly understood (APPG, 2017). Whilst provided across many NHS services, the evidence base for arts therapies is relatively limited, with few high quality studies of effectiveness and which provide, mixed results.

In response to the HTA call brief, we will test the effectiveness of three forms of arts therapies: art, music, and dance-movement therapy, which have a focus on different senses (eye, ear, body). We did not include drama therapy, because of its more heterogeneous methods and lack of research evidence (NICE (2014) did not consider drama therapy for this reason), and body psychotherapy given its overlap with dance-movement therapy.

We will recruit patients from secondary mental health services who are motivated to attend group arts therapy over five months and, after being informed with video clips about what the three forms entail, express a preference for one of them. We will include out-patients aged 18 years and above with a primary diagnosis of either schizophrenia and related disorders (ICD F2), mood disorders (F3) and anxiety disorders (F4) (World Health Organisation, 2010). This diagnostic mix includes the main categories in mental health services, reflecting practice and ensures a sufficient pool of patients to deliver groups even in small services. Yet, we will exclude primary diagnoses of substance misuse and personality disorders, as arts therapies for these specific groups are often provided in different formats (e.g. over much longer periods for personality disorders). Beyond this, we aim to be inclusive with few exclusion criteria (e.g. physical condition preventing participation). People whose first language is not English will be included as long as they have sufficient command for basic communication with patients and therapists and are able to complete the baseline assessment.

Recruited patients will be asked for their informed preference and randomised to either their chosen therapy or control condition, so that preferences are randomly distributed between the two arms. As recommended by NICE (2014), we will use an active control – person-centred counselling in groups - which has been used in a body psychotherapy trial before (Röhricht & Priebe, 2006). This controls for offering regular group sessions with a therapist, verbal interactions and group support, without the specific appeal and potential of using a form of art (Hill, 2011). The counselling groups will be run by person-centred counsellors with experience in secondary mental health care.

Theoretical framing:

The diagnosis and course of mental illness can be complex, with many individuals holding multiple diagnoses which can change over time (Nesse & Stein, 2012; Phillips, Frances, Cerullo et al, 2012a; 2012b). This complexity suggests that specific diagnostic treatments are limited in their validity and

generalisability in the wider healthcare system. For example, a single diagnostic sub-group may be too limited to justify a specific treatment. On the other hand, many treatments have been shown to be effective across different classes of disorders, suggesting there are shared features across mental disorders (Cuthbert & Insel, 2013). Specifically for group therapies, diagnostically heterogeneous groups may provide a wider range of behaviours and experiences that patients can share and learn from. Our hypothesised model is based on three features, not yet considered in group arts therapies trials: the matching of patients with their preferred art-form, the role of the art-form in instigating non-specific group processes and a diagnostically heterogeneous patient mix.

Whilst no single model of mental illness exists, current theory suggests that across all psychiatric diagnoses, concepts of negative valence (e.g. acute threat/fear, loss), positive valence (e.g. motivation and reward), cognition, social processes, arousal and regulation are of relevance to understanding shared features of mental illness (Cuthbert & Insel, 2013). Within secondary mental health care, these concepts are seen in challenges faced by patients in terms of managing and regulating mood and anxiety, maintaining motivation in daily life and becoming stuck in patterns of thinking, feeling or relating, leading to emotional and relational distress. Relationships are further affected through difficulties communicating effectively making developing and sustaining relationships with others difficult. Through social isolation and associated stigmatisation, many lack confidence to socialise and be with others with wider effects of disempowerment, loss of identity, role and self-esteem.

Theoretical starting point: Contextual model of psychotherapy and common factors:

Whilst there are many forms of psychological and psychotherapeutic approaches, evidence suggests that features that are shared by all forms of therapy are most important in effecting change. The contextual model (Wampold, 2001) suggests that patient expectancy (what patients expect to happen in therapy), patient and therapist belief in the therapy (commitment and conviction in the therapeutic model) and establishment of a therapeutic relationship play a greater part in determining outcomes than the unique and specific features of an individual model. In line with the contextual model, a meta-analysis completed within our group showed that, across group therapies, common shared factors account for the greatest amount of change in therapy, rather than unique factors (Orfanos, Banks & Priebe, 2015). These factors, as suggested by Yalom & Leszcz (2005), include acceptance and cohesion, altruism, installation of hope, guidance, modelling, self-understanding, learning from interpersonal action, self-disclosure, imparting of information and development of social skills.

More recent research in our group (Orfanos & Priebe, 2017) suggests that within closed community therapy groups, the first few sessions of the group are the most important in determining outcomes. Sessions where group members showed high cohesion in the first sessions predicted future engagement and greatest therapeutic gains. Reporting similar findings for different types of group psychotherapy, Tchuschke and Dies (1994) proposed that such early group integration promotes capacity for self-disclosure, which increases interpersonal feedback thus increasing opportunities for positive feedback from the group. The above suggests that important factors within group therapy are patient understanding and clear expectations of what will happen in therapy, patient and therapist shared commitment to working in a particular way and time to develop and establish a good working alliance and therapeutic relationship. Within groups this highlights the importance of patient preference, clear information on what to expect, fostering group cohesion in the initial phases and promoting active engagement quickly and early on in the therapeutic process.

Contribution of the arts in therapy:

The arts therapies are a form of psychotherapy that utilise active participation in an art-form to facilitate the therapeutic process. These include art, dance movement, music and dramatherapy. Whilst available in some secondary mental health services, NHS provision varies between geographical areas.

Inclusion of an active and creative arts-based process provides opportunities for self-expression, creativity and a nonverbal means of relating with other people. The art-form brings a third object-concrete (such as a recording or piece of art work), or experienced (such as movement or heard sound)-into the matrix of relations within the group (Karkou & Sanderson, 2005). Each person brings their own unique creative and cultural identity. This can be explored as part of the therapy with the potential to link this and expand their personal relationship and use of the art-form as a 'helping resource' in their day-to-day lives (Ansdell & Meehan, 2010). Arts therapies are therefore well placed to help patients identify difficulties and strengths through the use of the art-form in the varying interactions in the group. Use of the art-form can facilitate expression of emotions and discovery of personal meaning in creative activities, allowing experiences and learning through non-verbal and verbal communication. Through creativity, imagination and play, patients are helped to explore new or different emotional and cognitive experiences with support of both the group and the therapist. The production of a piece of art is often cited as a means of strengthening self-esteem by clients (Grocke, Bloch, Castle et al, 2013; Taylor Buck & Havsteen-Franklin, 2013) and can provide access to personal and interpersonal resources which may be continued into wider daily and creative life in the community (Ansdell & Meehan, 2010).

Historically, arts therapists have looked to wider theories within psychotherapy as a means of understanding the underlying processes. A recent survey, circulated by the British Association of Art Therapy to all arts therapies professions identified that therapists drew upon a range of models, with expressive, psychodynamic, person-centred, attachment and group-interactive models most commonly cited. Principles from each of these have informed understanding of arts therapies interventions, along with wider principles of resource orientation (Mössler, Fuchs, Heldal et al, 2011; Priebe, Omer, Giacco & Slade, 2014) and recovery (McCaffrey, 2014; McCaffrey & Edwards, 2016; McCaffrey, Edwards & Fannon, 2011; Rolvsjord, 2004). The principles of person-centred therapy (Rogers, 1967) are especially relevant to how the therapist models and interacts with members of the group involving a non-directive, empathic stance. The psychodynamic model (Montgomery, 2002) provides a means of understanding patterns of relating and emotional responses across unconscious and conscious levels, which is particularly suited to understanding nonverbal and implicit levels of communication. Huet and Springham (2018) suggest art-work in art therapy may be considered a second order representation within psychological processes (representing alternative 'as if' scenarios, rather than reality). This provides a means of trying out different ways of relating to oneself and others in an imaginative and safe way. Resource and recovery-oriented approaches (Ansdell & Meehan, 2010; Taylor Buck & Havsteen-Franklin, 2013; Rolvsjord, 2004; McCaffrey, Carr, Solli & Hense, 2018) are informed by a move towards a contextual and health-promotion focus rather than a deficit or treatment-based one. Principles include a shared, equal, collaborative process; focus on patients' strengths and potentials; acknowledging the patients' creative identity; being emotionally involved in the creative process and fostering positive emotions (McCaffrey et al, 2018).

Implications for the different modalities:

Whilst we hypothesise that it is the shared, or common factors of therapy that are associated with eventual change of health outcomes, each arts modality has particular multi-sensory and aesthetic properties which can provide different and unique opportunities and experiences within a group context (Malchiodi, 2005). Whilst in simple terms a single sensory modality is implied (art, the eye; music, the ear; dance movement, the body), a range of senses are activated, offering a range of different sensory modes of expression (McNiff, 1981). Stern (2010), and Malloch and Trevarthen's (2010) studies of human communication show how timing, shape and intensity ("vitality affects") are used to communicate intention and regulate interaction from birth onwards. The multi-sensory and multi-modal features of arts-based work can therefore facilitate basic physical and behavioural experiences, such as facilitating a relaxation response, self-soothing, and building of healthy attachments (Huet & Springham, 2018).

On the basis of the above, the arts therapies co-applicants have developed core principles and proscribed ways of working in these groups. Principles specific to arts therapies include encouragement to quickly engage with, explore and use the art-form, employing structure in the art-form and only letting this become free where there is space and safety to do so, emotional involvement in the creative process and use of the art-form to support self-regulation through containment and transformation of expression.

In our model (Figure 1), the importance of the art form is the appeal to the patient, the facilitating of active participation and emotional engagement, the introduction of creativity, and the support of exchange and interactions. The final therapeutically effective processes however are non-specific to the art form and will rather benefit from the diagnostic heterogeneity of the group. This model is distinct from the ones used in the three large trials on arts therapies that have been conducted in the UK (or with a site in the UK). MATISSE (art therapy; Crawford et al., 2012), NESS (body psychotherapy which overlaps with dance movement therapy; Priebe et al, 2016), and TIME-A (individual music therapy; Bieleninik, Geretsegger, Mössler et al, 2013) all focused on one diagnostic group and hypothesised therapeutic processes that were specific to the given diagnostic group and the given art form. Although at least two of these trials were methodologically rigorous and well implemented, no clinically significant effects were detected and none elicited patient preference for the art-form. Whilst some had methodological problems, a further reason may be the theory and model behind the intervention. The homogeneous samples limit both the generalisability of such studies and the option for richer interactions and group processes. We believe that our model and approach are more likely to utilise the different art forms effectively to engage patients early on and support therapeutically beneficial interactional processes in the groups.

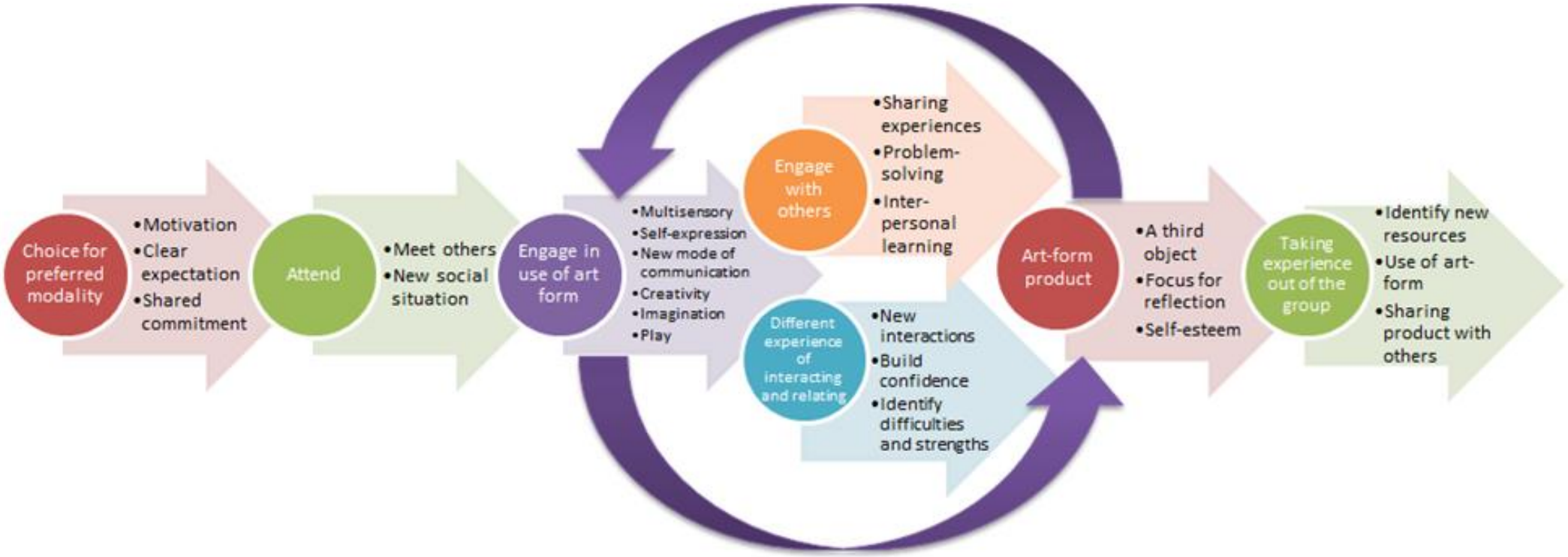


Figure 1: Proposed model of processes over time in arts therapies groups

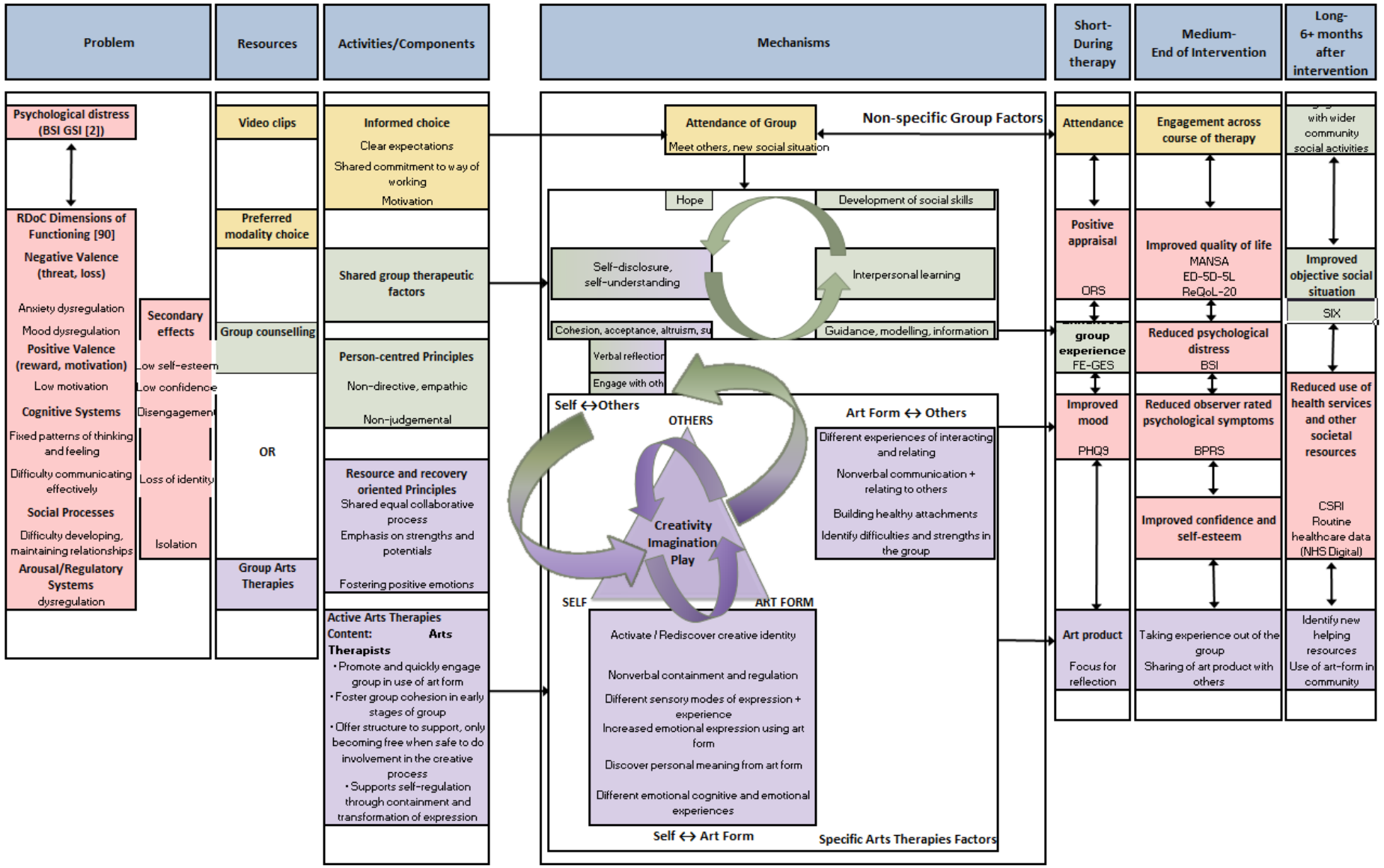


Figure 2: Logic model and outcome measurement

2 RATIONALE

Treatment of mental illness in secondary mental health care usually comprises a mixture of psychopharmacological medication, regular consultations with a health care professional and access to psychological therapies. Whilst medication can assist in the alleviation and maintenance of symptoms, a range of side effects can also be experienced and these medications do not address relational and social challenges that many diagnoses bring. In terms of psychological therapies, most formats involve either cognitive behavioural, psychodynamic or targeted 'third wave' approaches, such as mentalisation based therapy or acceptance and commitment therapy. The aim across all these approaches is to provide a safe space within the context of a therapeutic relationship, where issues, behaviours, cognitions and relationships can be explored in discussion with a therapist directly, or within a group setting. Whilst helpful for many, talking therapies can become problematic if the person is unable to put their experiences into words. This is particularly evident in diagnoses where alexithemia or poverty of speech is present (for example depression, psychosis) or in cases of psychological trauma (for example post-traumatic stress disorder).

There is a long history of provision of arts therapies in mental health care. Using the arts as a means of relating and communicating can be helpful when patients find it difficult to engage, or to talk about their problems and provide an alternative means of communicating and relating when in distress. They are often appealing to patients in the sense that there is the opportunity for creativity, self-exploration and a means of expressing experiences and emotions that may be difficult to put into words. Patients who have taken part in our previous studies of music therapy and body psychotherapy told us that it was important they could access the art-form they preferred and that research should include more than one art form. Our consultation with the Service User and Carer Group Advising on Research (SUGAR) led them to recommend us using video clips to explain what arts therapies are to patients and referring clinicians.

The format of arts therapies sessions can be individual, but more often, arts therapies are provided in groups. Group provision offers a number of advantages in that a greater number of patients can access the therapy and utilises therapeutic factors associated with groups (such as recognising shared issues, support and the relationships developed). In practice, these groups often include people with a range of diagnoses (diagnostically heterogeneous). This is often due to pragmatic reasons, as it can be difficult to arrange groups for one single diagnosis. However, the diagnostic mix also provides a range of different experiences and behavioural styles which can facilitate interaction and engagement between members.

Arts therapies practice is diverse and influenced by a range of psychotherapeutic models (Crawford & Patterson, 2007; Karkou & Sanderson, 2005; Röhricht et al, 2011) . Cochrane reviews suggest promising evidence for music therapy and dance movement therapy in schizophrenia and depression (Aalbers et al, 2017; Meekums, Karkou & Nelson, 2015; Mössler et al, 2011; Ren & Xia, 2013). Despite this, the most recent trials in the UK (MATISSE, NESS) were negative. However, these trials followed diagnostic and modality-specific models which do not reflect the way arts therapies groups are provided in practice (Karkou & Sanderson, 2005; Havsteen-Franklin et al, 2016;2017). Our model differs in that there is a focus on group processes, comparing the additional effect of arts to a counselling group (Orfanos et al, 2015;2017;Montgomery, 2002; Solovieva, 2015;Johanssen & Werbart, 2009 Caruso et al, 2013;Wampold, 2001; Heynan et al, 2017).

This study will test whether arts therapies provided in groups are effective in reducing psychological distress for diagnostically heterogeneous patients in mental health services. Our hypothesis is that for those patients with a strong preference for an arts modality, the addition of arts as a means of expressing and relating to others in therapeutic groups will reduce symptom distress to a greater degree

than wider non-specific group effects (as seen in talking therapies such as group counselling) alone. The null hypothesis is that there is no difference between arts therapy groups and talking groups without using any art form. Should we fail to find a difference, this will suggest that there is no beneficial effect to the addition of arts in therapeutic groups. Thus, while non-specific groups – as provided in the control group- may or may not be effective, there would be no evidence that using art forms improves the effect, even where patients have expressed a preference for the art form used in their group.

We have chosen psychological distress (as measured on the Brief Symptom Inventory Global Severity Index) as this is a clinically relevant outcome to all patients in secondary mental health care irrespective of diagnosis. The Brief Symptom Inventory (Derogatis & Melisaratos, 1983) is a widely used self-reported measure of symptom distress with established norms in psychiatric community patients (Ryan, 2007). Attendance of arts therapies may contribute to wider long-term recovery (such as re-connecting patients to the community and creative activity). However, we would expect these to follow from experiencing relief from the distress of symptoms.

Trials of art (Richardson et al, 2007), dance movement (Brauninger et al. 2012) and music therapy (Grocke et al., 2014) demonstrate modest improvements pre- and post- therapy after 10-12 sessions on this measure. It is notable that baseline scores for all of these studies were lower than the threshold set for the current study.

Justification of frequency and timing of groups:

A recent survey of 199 arts therapists suggests that therapists tend to see patients for more than 20 sessions with around 20% seeing patients for >40 sessions. The format of a maximum of 40 group sessions over a five month period and core components has been agreed with experts of the three forms of arts therapies. In order to account for the group frequency and effect, we will offer the same frequency, timing and duration of our control condition- group counselling.

Each of the three forms of arts therapies (and the control condition) will be provided in groups of 10 patients. Patients will be offered 40 sessions over a five months period, i.e. two per week (allowing for short breaks for organisational reasons eg. over Christmas). Systematic reviews in the area suggest a minimum of 20 sessions delivered from twice to three times per week (Orfanos et al, 2015; Meekums et al, 2015; Mössler et al, 2011 Gold et al, 2009). A meta-analysis of music therapy suggests a large effect may be expected after about 40 sessions, whilst a medium effect will still occur after about 20 sessions (Gold et al, 2009). Thus we will provide enough sessions for a large effect in well attending patients. Yet, even if attendance is much lower (eg. In the NESS trial on body psychotherapy it was only 56% on average (Priebe et al, 2016)) patients will still attend more than 20 sessions so that we should expect a medium effect.

2.1 Assessment and management of risk

Art, dance movement and music therapy are currently part of standard NHS community mental health care. At present, it is provided to groups of mixed diagnoses both as inpatients and in the wider community. Within the literature, very few risks have been described for the arts therapies in secondary mental health care. The risks reported in studies are assessed to be no greater than risks in normal standard practice.

Risk of death, suicide and self-harm

Three studies report the death of participants at various points of the recruitment, assessment and intervention stages of their study design (Crawford, Killaspy, Barnes et al., 2012; Richardson, Jones, Evans, Stevens and Rowe, 2007; Grocke, Bloch, Castle, Thompson, Newton, Stewart and Gold, 2014). One art therapy study of 417 participants with schizophrenia specifies that 'of the seven deaths, four were from suicide or probable suicide' (Crawford, Killaspy, Barnes et al., 2012). In the same study "three additional serious adverse events were reported, one a near fatal episode of deliberate self-harm and two involving harm to others." None were assessed to be related to the study intervention.

Risk of suicide was specifically monitored alongside other outcome measures in a study of individual art therapy by Blomdahl, Guregard, Rusner and Wijk (2018) through the Scale for Suicidal Ideation (SSI) working with people diagnosed with moderate to severe depression. A high risk of suicide was detected in 3 cases out of 79 but the authors report no suicide attempts being made during the course of the study.

Worsening of condition

Only one study (Erkkila, Punkanen, Fachner, Ala-Ruona, Pontio, Tervaniemi, Vanhala and Gold, 2011) reported specific worsening of condition studied during the course of the intervention leading to withdrawal of two participants (one in each arm of the trial) from the study. Grocke, Bloch, Castle, Thompson, Newton, Stewart and Gold (2014) working with community patients with severe mental illness reported that "music provoked painful memories in one client". The intervention in this case focused on singing familiar songs and composing and recording original songs.

Disappointment at treatment allocation

There is also a possibility that some participants may become upset at not being allocated to the experimental group. The researcher will mitigate this by explaining clearly the randomisation process and emphasising that all participants will receive the support of a group therapy whichever treatment arm they are assigned to. At the end of the trial the research team will also be able to signpost participants to other available services if required.

Management of risk

The intervention will be provided by accredited arts therapists and group counsellors with experience in provision of groups in community mental health services. The therapists will liaise closely with the clinician in charge of care (eg. Psychiatrists, care coordinators and GPs) to ensure full risk management and will be fully trained in and familiar with NHS risk management and safety policies. A full risk management assessment schedule is in Appendix 1.

This trial is categorised as: • Type A = No higher than the risk of standard medical care

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

The overall aim is to test whether group arts therapies are effective for diagnostically heterogeneous patient groups receiving care in community secondary mental health services, to inform commissioning and development of NHS mental health services.

3.1 Primary objective

The primary objective is to test the effectiveness of manualised diagnostically heterogeneous group arts therapy on reducing psychological symptoms in patients receiving treatment in community mental health services as compared to an active control of group counselling (both intervention groups will be in addition to treatment as usual).

Our hypothesis is that for those patients with a strong preference for an arts modality, the addition of arts (art, music or dance) as a means of expressing and relating to others in therapeutic groups will reduce symptom distress to a greater degree than wider non-specific group effects of group counselling alone.

3.2 Secondary objectives

1. To conduct an internal pilot to ensure recruitment and therapist adherence to the intervention are sufficient to proceed to a full trial.
2. To test the effectiveness of group arts therapy on observer rated symptoms, quality of life and objective social situation (secondary outcomes)
3. To test whether effects on primary and secondary outcomes hold true at six and 12 month follow-up periods post-intervention.
4. To explore the impact of adherence (completers vs non-completers, adherence of therapists to the manual), diagnosis and type of arts therapy upon outcomes in sub-group analyses.
5. To explore processes in above sub-groups in a nested process evaluation utilising treatment fidelity analysis, attendance data, measures of patient appraisal and experiences in the groups and qualitative interviews exploring subjective experiences and attributions for change from the perspective of patients and therapists.
6. To assess the cost-impact and cost-effectiveness of group arts therapy.

3.3 Primary endpoint/outcome

Psychological distress as measured by the *Brief Symptom Inventory, Global Severity Index* at the end of 20 weeks treatment.

3.4 Secondary endpoints/outcomes

Secondary outcomes will be measured post-intervention, 6 months and 12 months post-intervention and comprise:

Brief Symptom Inventory (BSI) Global Severity Index and subscales: Somatisation, Obsessive-compulsive, Interpersonal sensitivity, Depression, Anxiety, Hostility, Phobic Anxiety, Paranoid Ideation, Psychoticisim and Positive Symptom Distress Index.

Observer-rated symptoms on the Brief Psychiatric Rating Scale (BPRS)

Quality of Life on the Manchester Short Assessment of Quality of Life Scale (MANSA)

Objective Social Situation (SIX)

3.5 Economic evaluation:

Economic evaluation will include the following measures at baseline, post-intervention, 6 months and 12 months post-intervention.

Generic health-related quality of life: (5-level EQ-5D-5L) and Recovering Quality of Life (ReQoL)-20

Use of health services: Data on the secondary healthcare use of study participants will be requested via linkages with Hospital Episode Statistics (HES) and Office of National Statistics (ONS) datasets and the Mental Health Services Data Set (NHS Digital) medical records

Use of health and social care on the Client Services Receipt Inventory (CSRI)

The cost estimation of study group therapy interventions (arts and counselling) using further study-specific inventory forms designed by the Health Economist.

3.6 Exploratory endpoints/outcomes

A process evaluation will consider the following data:

Attendance of therapy sessions and reasons for non-attendance over the 20 week intervention period

*Patient reported appraisal of the sessions i*n weeks 2,7,12 and 17 of the intervention period on the Outcome Rating Scale (ORS)

Self-reported depression in weeks 2, 7, 12 and 17 of the intervention period on the Personal Health Questionnaire (PHQ-9)

Group experiences in weeks 2, 7, 12 and 17 of the intervention period on the Ferrara Group Experiences Scale (FGES).

Qualitative end of therapy interviews with a purposive selection of 13% of participants and therapists using the Client Change Interview.

Therapist self-rated adherence to the manual on an adherence form designed for the purposes of this study.

Observer ratings of treatment fidelity of 10% of therapy sessions, selected at random and rated on the adherence form designed for the purposes of this study.

3.7 Table of endpoints/outcomes

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)- see Appendix 2 SPIRIT diagram**
Primary Objective To test the effectiveness of manualised diagnostically heterogeneous group arts therapy on reducing psychological symptoms (primary outcome) in patients receiving treatment in community mental health services as compared to an active group counselling control (both conditions in addition to treatment as usual).	Brief Symptom Inventory, Global Severity Index	T1, T3 (End of intervention)
Secondary Objectives To conduct an internal pilot to ensure recruitment and	Recruitment rates	-24w to T0

adherence to the intervention are sufficient to proceed to a full trial.	Attendance rates Observer rated adherence on adherence rating form	+4w +2w and +3w
To test the effectiveness of group arts therapy on observer rated symptoms, quality of life and objective social situation (secondary outcomes).	Brief Psychiatric Rating Scale Manchester Short Quality of Life Objective Social Outcomes Index	T3 (End of intervention)
To test whether effects on primary and secondary outcomes hold true at six and 12 month follow-up periods post-intervention.	Brief Symptom Inventory Brief Psychiatric Rating Scale Manchester Short Quality of Life Objective Social Outcomes Index	T4 (+44w), T5 (+68w)
Tertiary Objectives To explore the impact of adherence (completers vs. non-completers), diagnosis and type of arts therapy upon outcomes in sub-group analyses. To explore processes in above sub-groups in a nested process evaluation utilising treatment fidelity analysis, attendance data, measures of patient appraisal and experiences in groups and qualitative interviews exploring subjective experiences and attributions for change from the perspective of patients and therapists. To assess the cost-impact and cost-effectiveness of group arts therapy.	Attendance rates BSI, BPRS, MANSA, SIX Therapist self-rated adherence on adherence rating form Observer rated adherence from videos on adherence rating form Attendance rates Outcome Rating Scale Ferrara Group Experiences Scale Client Change Interview Use of secondary healthcare services (via linkage with NHS Digital datasets) Client Services Receipt Inventory EQ-5D-5L Re-QoL-20 Intervention cost inventory forms	T5 (+68w) Every session (0w to +20w) Random sample of 10% of therapy session videos T1 (0w) to T3(+20w) T2 (+2w, +7w, +12w, +17w) T2 (+2w, +7w, +12w, +17w) T3 (+20w) Data extract from NHS Digital for 6 months prior to intervention to 12 months post end of intervention; longer term follow-up enabled T1-T5 (0w, +20w, +44w, +68w) T1-T5 (0w, +20w, +44w, +68w) T1-T5 (0w, +20w, +44w, +68w) T1 (0w), T3 (+20w), T4 (+44w),T5 (+68w)

4 TRIAL DESIGN

A pragmatic, two-arm randomised controlled trial comparing group arts therapy (art, dance movement, music) to an active group counselling control, with internal pilot, economic evaluation and nested process evaluation.

The study will begin with an internal pilot, which aims to recruit 180 participants (60 at each site). In week 4 of the intervention phase, the following stop-go criteria will be discussed by the TMG, TSC and funder to decide whether or not to proceed to a full trial:

Criterion	**Green** Progress to full trial	**Amber** Discussion with TSC and funder about progression	**Red** Trial is stopped
Recruitment within 6 months	≥90% of recruitment target at each site	66-89% of recruitment target at each site	<66% of recruitment target at each site
Attendance of at least one group session in the first 4 weeks of intervention	≥90% of sample attend at least 1 session	66-89% of sample attend at least 1 session	<66% of sample attend at least 1 session
Attendance rates in the first 4 weeks of the intervention	≥90% attendance rate	66-89% attendance rate	<66% attendance rate
Therapist adherence to manual using observer-rated videos from sessions taken from week 2 and week 3 of the intervention.	≥90% agreement with manual criteria	66-89% agreement with manual criteria	<66% agreement with manual criteria

Recruitment will continue throughout this time period, with the aim of commencing the next round of groups as soon as possible after receiving this decision, and with the aim of recruiting a further 240 participants (120 inner city, 60 semi-urban, 60 rural) over a six month period. Should the decision be made to stop the trial, all participants signed up to this point will be offered their choice of group arts therapy within usual clinical services or referred to existing psychological therapies.

5 TRIAL SETTING

The study is a multicentre trial, hosted by East London NHS Foundation Trust. Recruitment and data collection will take place within Secondary Mental Health Care NHS Trust community services at urban, semi-urban and rural sites. Services include Community Mental Health Teams (CMHTs), Recovery teams, Assertive Outreach Teams (AOT), Early Intervention Services (EIS) and Extended Primary Care Liaison teams within secondary care. The intervention will be provided by arts therapists and psychologists working within these services.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

Patient participants:

- Outpatient in secondary mental health care
- Motivation to attend group arts therapy for 5 months and expression of preference for one of three forms
- 18 years of age and above
- Primary diagnosis of ICD-10:
    - F2 (schizophrenia and related psychotic disorders)
    - F3 (mood disorders)
    - F4 (anxiety and other non-psychotic disorders)
- Duration of current mental disorder of 6 months or longer
- At least moderate symptom level on BSI (score of 1.65 or above on Global Severity Index)
- Capacity to provide informed consent

Therapist interviews (nested process evaluation):

- Therapist providing arts therapy or group counselling as part of the trial
- Capacity to provide informed consent

6.2 Exclusion criteria

Patient participants:

- Primary diagnosis of organic mental disorder (F0), substance misuse (F1), personality disorder (F6)
- Duration of current mental disorder <6 months (i.e. patients with short-term crises)
- Physical condition that prevents attendance of group arts therapies
- Insufficient command of English for communication with other group members and therapists.

7 TRIAL PROCEDURES

A SPIRIT diagram outlining trial procedures can be found in Appendix 2.

7.1 Recruitment

Recruitment will commence six months before the first scheduled intervention groups and is planned to run for up to 24 weeks in total. Clinical Studies Officers (CSO) will assist the Trial Manager and Research Assistants with identification, approaching, informing and recruiting patients into the study. The research team will provide regular updates to the participant in the time between recruitment and the start of the groups.

Recruitment will take place across Secondary Care Community Mental Health Teams and Service-User and Carer groups within participating NHS Trusts.

7.1.1 Participant identification

Clinicians and CSOs will screen the caseload of clinical teams to identify potentially eligible participants via medical records from secondary care services. The CSO/Research Assistant will record pseudonymised information for CONSORT reporting regarding the team's caseload. Information will be kept to the minimum required to ascertain eligibility:

- Age 18 or above (Yes or No)
- Diagnosis
- Duration of illness

The CSO/Research Assistant will review this pseudonymised information against the eligibility criteria

Potentially eligible patients will then be contacted by a member of the clinical team either a) during attendance of routine appointments where they can be provided with a handout for potential participants or b) via telephone or letter contact. The clinician will provide them with information about the study, and obtain assent to be contacted by the researcher, including their preferred method (telephone, email or letter). A record of this assent will be kept at site. Those who assent will have their information passed on to researchers/CSOs either face to face (if during a clinic); directly from the patient via a returned form addressed to the research team in the post (if via letter) or telephone call (if via the handout for potential participants) to the research team; or from the clinician via NHS to NHS encrypted email. The researcher will then make contact using the patient's preferred contact method.

The researcher will go through the information sheet and answer any questions or concerns raised. The researcher will explain the assessment process (visits at consent/baseline, post-intervention, 6 and 12 months later) as well as explaining that individuals may be invited to an individual qualitative interview at the end of treatment to share their experiences. They will explain that it is possible that they will be found ineligible at baseline and the procedures to support them, should they no longer be eligible for the study. The researcher will explain randomisation (to either their preferred form of art therapy or group counselling) and that there is a 50/50 chance of getting either intervention. If the patient is interested in participating, the researcher will then confirm contact details and arrange to meet to obtain informed consent, complete the eligibility screening, and complete the baseline measures.

Patients linked into service-user and carer involvement groups across the Trust will also be made aware of the study, through attendance of a researcher at their local meetings who will provide information as outlined above. Any patients interested in the study, will be provided with an information sheet or handout for potential participants by the researcher which contains contact details for the researchers and CSOs. If interested patients are ineligible, the researcher will thank them for their interest and advise them to contact their healthcare professional for further signposting to arts therapies and group therapies within the Trust.

7.1.2 Meeting to take informed consent, eligibility check and complete baseline measures

Timepoint	Purpose	Assessments
Informed consent, eligibility check and baseline	Obtain written informed consent Show video on arts therapies Confirm preference for one arts modality Confirm psychiatric diagnoses Confirm symptom distress >1.65 on Global Severity Index Complete baseline measures	Consent Form Arts therapies modality preference form Medical records BSI Baseline clinical and socio-demographic form CSRI BPRS MANSA SIX EuroQuoL EQ-5D-5L ReQoL-20

All patients who express interest in the study will be contacted and invited by phone or letter to attend a face-to-face meeting with a researcher. Researchers will go through the information sheet and take time to answer any further questions or concerns.

All participants will be asked to provide written informed consent by initialing, signing and dating an informed consent form prior to any data collection commencing. Three copies of the written consent form will be signed by the participant and a member of the research team. One copy will be kept by the participant, one will be stored with the participant's medical notes and the other will be kept by the research team in a locked filing cabinet on NHS premises. Mental capacity will be assessed throughout.

Once written informed consent is given, patients will be invited to complete the Brief Symptom Inventory (GSI score >1.65) to screen for current symptom severity. If the patient scores 1.65 or higher, video clips of arts therapies will be shown and the service user will be asked to state their preference for one single modality. Should the patient meet inclusion criteria, the baseline assessments will be completed. Should the patient not meet the inclusion criteria, this will be explained and they will be thanked for their time and interest, with recommendations to speak with their healthcare professional, should they wish to access arts therapies or other group therapies within their service. Should a patient not meet eligibility criteria, and have potential for this criterion to change, they will be eligible for rescreening up to the point of randomisation.

7.1.3 Payment

Patients who attend the informed consent and eligibility check will be offered £10 to acknowledge travel and time taken in addition to their normal care visits. Those who consent and attend baseline and follow-up assessments (post-intervention, qualitative interview, 6 months and 12 months) will be offered £20 to acknowledge the time taken to travel and complete each of the assessments.

7.2 Consent procedures

Those with delegated roles for informed consent are the Trial Manager, Research Assistants and Clinical Studies Officers. The Chief Investigator retains overall responsibility for the informed consent of participants and will ensure that all those with delegated responsibility are authorised, trained and competent to participate according to the HRA approved protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki (World Medical Association, 2013).

Informed consent will be taken after a minimum of 24 hours after first discussing the study with the researcher. Participants will be free to withdraw at any time without giving reasons and without prejudicing any further treatment. Further information about the trial and who to contact for further discussion is provided on the information sheet.

Mental capacity

Mental capacity will be assessed at every assessment and attendance of the intervention and discussed with patients' clinicians if necessary. Should a person be assessed as lacking capacity prior to informed consent, they will be informed they cannot participate in the study at this time. Should the participant wish to continue, a further meeting will be arranged to re-assess capacity at a later point. Assessment will involve ensuring the person:

- understands the purpose and nature of the research
- understands what the research involves, its benefits (or lack of benefits), risks and burdens
- understands the alternatives to taking part
- is able to retain the information long enough to make an effective decision.
- is able to make a free choice
- is capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)
- where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected

Should a person lose capacity whilst attending the intervention, the therapists will liaise with the clinical team to assess current risks and whether they should continue receipt of the intervention at this time. If the team decides it is in the best interests of the participant to cease the intervention, this will be documented. Capacity for the purposes of assessment will continue to be assumed and re-assessed on the day data collection is arranged. If a participant is assessed to have lost capacity to consent when attending a research assessment, the participant will be withdrawn from the study and all data collected up to that point will be retained. This is outlined in the PIS and consent form. Should the participant wish to continue with the study, we will gain permission to contact them at the next scheduled research assessment period. If capacity is regained at this point, and the participant wishes to resume participation, the participant will be re-consented into the study and the assessment of regained capacity documented.

Contingency Consent Procedures due to Covid-19

Due to the outbreak of COVID-19, face to face appointments are minimised to mitigate risks to participants and to allow for the continuation of the study in case of local restrictions. Participants identified as potentially eligible for the trial, will be contacted over the phone by the research team to introduce themselves and inform them that they will receive the Patient Information Sheet and blank consent form either by a) the post or b) email. If the participant agrees, the research team will post or email the relevant documents. The research team will contact the participants 3 working days after posting/emailing the documents. The research team will confirm if the participants have received the documents and will fully inform the participant about the study. If the participant agrees to enrol in the study, the researcher will take verbal consent by filing in a copy of the consent form, which includes a) a note that the consent is taken verbally and b) the participant can contact the research team if they wish to withdraw at any point. The researcher will clearly sign, date and note that the consent was taken verbally. The researcher will post a copy of the signed consent form to the participant and file a copy. In the instance that participants have access to email/electronic device, the consent will take place over a video-based teleconference system. The participant will initial and sign the form electronically. The signed form will be emailed to the researcher. The researcher will email a copy of the completed consent to the participant.

7.2.1 Additional consent provisions for collection and use of participant data in ancillary studies

Participants will be given the option to have their data used in future ancillary studies and for consent to being contacted about future studies. Participants will be assured that they do not have to consent to this and participation in the current trial and their existing care will not be affected. This will be explained as part of the informed consent process and is outlined in the participant information sheet and a separate section marked optional in the consent form to make this clear.

7.3 Baseline assessment

The baseline assessment will take place once informed consent has been taken and eligibility confirmed

The following baseline data will be collected on the case report form, using the following measures:

Socio-demographic and clinical: Date of birth, sex, country of birth, first language, highest level of education, employment status, diagnosis, year of first contact with mental health services, ethnicity.	Baseline clinical and socio-demographic form from interview/medical records in CRF
Use of arts and psychological therapies history: Arts education level Previous receipt of arts therapies Previous receipt of psychological therapies (type, number of sessions, inpatient or community)	Baseline clinical and socio-demographic form from interview in CRF
Use of health and social care	Client Services Receipt Inventory (CSRI) in CRF

Psychological distress	Brief Symptom Inventory (BSI) in CRF
Observer rated psychiatric symptoms	Brief Psychiatric Rating Scale (BPRS) in CRF
Quality of life	Manchester Short Assessment of Quality of Life (MANSA) in CRF
Objective social situation	Objective Social Outcomes Index (SIX) in CRF
Generic self-reported health-related quality of life to estimate QALYS	EuroQuoL EQ-5D-5L and ReQoL-20 in CRF

The following data (from 6 months prior to the start of intervention) will be collected from NHS routine medical records for health economic evaluation:

Economic evaluation Use of secondary healthcare services	Linkage with NHS Digital Hospital Episodes Statistics, ONS Mortality and Mental Health Services Data Sets

7.4 The randomisation scheme

Randomisation will be on a site-by-site basis (three sites in the internal pilot stage, and four sites in the full trial stage), and will be further stratified at each site by preferred modality. To minimise the time between enrolment and commencing the intervention, we will aim to conduct randomisation as soon as a batch of 20 people with the same modality preference have been enrolled at a site and have completed baseline measures. Participants in each batch of 20 will be randomised in a 1:1 ratio to two therapy groups, one receiving the preferred modality, and one receiving group counselling (the control), using constrained randomisation to balance the distribution of primary diagnosis, age and gender in each therapy group. An independent PCTU statistician will randomise participants, passing the allocations to the Trial manager and to therapists and PIs at each site.

If 15-19 participants with a preferred modality are still to be randomised at the end of the recruitment window they will be randomised 1:1 to two therapy groups, possibly enlarging groups with non-study patients. In the case where there are fewer than 15 participants with a preferred modality at the end of the recruitment window they will be randomised (where feasible) in a 2:1 ratio to intervention and control, with the option of enlarging groups with non-study patients or of combining control groups from different modality preference strata.

Each new participant's details will be entered on to a database, and when a batch of recruitment for preferred modality at a site is complete an independent PCTU statistician will then randomise participants, passing the allocations to the Trial manager and to therapists and PIs at each site.

Repetition of Baseline Measurements and Re-randomisation due research activities being paused, as a result of the Covid-19 Pandemic

In March 2020, all research activity was paused due to the impact of lockdown restrictions and management of the Covid-19 pandemic. At the time of pausing, there were participants who were enrolled and randomised but had not started therapy. Because therapy groups will now commence more than a year after the baseline date for these participants were collected, baseline data and eligibility will be re-assessed for these participants, and if still eligible they will be re-randomised immediately prior to accessing treatment. Neither the participants nor the therapists will be aware of the participants' original randomised allocations.

Management of low preference quotas at the end of recruitment

At the end of study recruitment, there is a chance that the number of participants with a preferred modality is below that of the number required to feasibly run a group. Taking into account drop-out and non-attendance, we estimate that we require a minimum of 8 participants for a group to be viable. This equates to a minimum of 12 participants per preference cohort if randomising 2:1. In order to minimise loss of consented participants, we will ask participants to provide a second modality choice, and also to indicate whether or not they would be willing to receive this in case numbers for their original preferred modality cannot be met.

For modality preferences with fewer than 12 participants, we will offer their second modality choice. If a participant is unwilling to receive a second choice, we will withdraw them from the study and signpost them to local services.

7.5 Blinding

All research assistants completing follow-up assessments, one Chief Investigator (Priebe), the trial health economist and the trial statistician will be blinded to the treatment allocation until all follow-up assessment data is collected and the statistical and health economics analysis plans are signed off. Prior to each meeting with research assistants, participants will be reminded by an unblinded member of the research team not to disclose any details of the intervention in which they took part. In the event of unblinding, this will be recorded, specifying whether or not this occurred before or after the primary outcome measure (BSI) was completed. Should the research assistant be unblinded, future assessments will be allocated to a different blinded research assistant where possible.

Given the nature of this trial, it is not possible to blind the participants, arts therapists or group counsellors to the arm of the trial they are in as there will be obvious differences due to the presence or absence of arts activity in sessions. One Chief Investigator (Carr), the Trial Manager, Principle Investigators for each site and members of the treating health care team will not be blinded. One Clinical Studies Officer per site will be unblinded to record process measures during the intervention phase.

7.6 Unblinding

Patients, therapists providing the intervention, PIs for each site, one CI (Carr) and members of the health care team are not blinded to the intervention. Should a patient need to be withdrawn from the study due to clinical concerns, this will be logged by the therapists, and the Trial Manager informed. Follow-up assessments will continue to be conducted by a blinded researcher if the participant is happy for this to continue and continues to have capacity to consent. Study code will only be broken if there is a severe adverse event (SAE) where it is necessary for the second Chief Investigator to know which intervention the service user is receiving.

- The CI documents the breaking of the code and the reasons for doing so on the CRF/data collection tool, in the site file and medical notes. It will also be documented at the end of the study in any final study report and/or statistical report
- The CI/Investigating team will notify the Sponsor in writing as soon as possible following the code break detailing the necessity of the code break
- The CI will also notify the relevant authorities.

- The written information will be disseminated to the Data Safety Monitoring Committee for review in accordance with the DMC Charter. The responsibility for providing this will be held by the unblinded CI and provision documented.

7.7 Trial assessments during the intervention period

The following assessments will be taken by therapists and an unblinded CSO after the scheduled therapy groups:

Timepoint	Purpose	Assessments
During intervention period Weeks 1-4, pilot phase only	**Internal pilot only:** Group attendance rates Therapist self-rated adherence Video rated therapist adherence	 Group attendance form Adherence rating form Adherence rating form
Every session 10% of sessions Week 2, 7, 12 and 17	**All groups:** Attendance Therapist self-rated adherence Video rated therapist adherence Patient appraisal of sessions Depression Group experiences	Group attendance form Adherence rating form Adherence rating form ORS PHQ9 FE-GES

7.8 Long term follow-up assessments

Follow-up visits will be arranged by Research Assistants to happen in the first month after the intervention ends (weeks 20-24), 6 months post-intervention (weeks 44-48) and 12 months post-intervention (weeks 68-72). Optional qualitative interviews will take place within 6 months of the intervention ending (week 20-48, see section 7.9 below). The overall duration of the follow-up period is 12 months. The follow-up will be in addition to standard care appointments.

To maximise retention, we will offer payment to contribute towards travel and time taken of £20 per research assessment.

Where possible, dates for assessments will be agreed in the meeting prior (for example, 6 month follow-up date to be agreed in post-intervention follow-up meeting). Research Assistants will make telephone contact and send a reminder of the assessments two weeks prior to the subsequent interview date. As far as possible, the same research assistant will conduct all interviews with a patient so that a positive relationship can be established. Assessments will be arranged to allow for flexibility in accommodating patients' wishes for meetings at specific times and venues and may take place on a clinical site or within patients' homes (applicable lone worker policies will be adhered to).

The following assessments will be taken by blinded research assistants:

Post-intervention follow-up, week 20-24 **6 months post-intervention follow-up, week 44-48** **12 months post-intervention follow-up, week 68-72**	Psychological distress Psychiatric symptoms Quality of life Objective social situation Use of health and social care Generic health-related quality of life	BSI in CRF BPRS in CRF MANSA in CRF SIX in CRF CSRI in CRF EQ-5D-5L in CRF ReQoL-20 in CRF

Patients will be identified as lost to follow-up if:

- There have been at least 3 failed attempts by the researcher to make contact via 2 different methods (eg. Phone and letter)
- The participant chooses to withdraw and does not wish to participate in follow up data collection
- Death or significant incapacity making follow up data collection impossible.

If a scheduled visit or data collection time point is missed, the researcher will:

- Attempt to reschedule the appointment at the earliest possible convenient time
- Where information may be collected from medical records (eg. Service use) this will be accessed by the researcher having obtained informed consent to do this through the informed consent process at the beginning of the trial.
- If it is not possible to reschedule the appointment within 3 weeks of the due date, the time-point will be entered as missing data.

Linkage to data on secondary healthcare use and health-related outcomes of study participants, held by NHS Digital datasets (Hospital Episode Statistics (HES), ONS mortality data and Mental Health Services Dataset) will be processed and data extracted for the period of 6 months prior to intervention to 12 months post intervention to inform health economic analysis of the study. Longer-term follow-up of study participants in national routine data will be enabled.

7.9 Qualitative assessments and nested process evaluation

We plan to conduct a process evaluation in line with recommendations by the Medical Research Council (Moore et al., 2015). The logic model of our intervention provides a theory of the intervention describing assumptions and contextual factors that might shape implementation and outcomes, hypothesised processes and mechanisms of impact and our intended outcomes. The aim is to better understand the processes of group arts therapy in comparison to group counselling controls in practice and possible implications. In particular:

1. To understand exactly how the intervention was delivered in practice (treatment fidelity analysis)
2. Describe processes of attendance and hypothesised process factors of self-reported depression, group experiences and session appraisal over the course of the trial
3. Understand subjective experiences and attributions for change of the intervention from the perspective of patients and arts therapists
4. Compare reported quantitative and qualitative processes against the proposed logic model and to revise accordingly.

Method:

The process evaluation will employ an embedded mixed methods design and will consist of data collection of video data of the intervention itself (through treatment fidelity analysis), client self-reported measures (weeks 2, 7, 12, 17- PHQ9, FE-GES, ORS) and qualitative end interviews scheduled within 6 months of the end of the intervention with participants and arts therapists. The interview is optional for participants but we aim to conduct a minimum of 45 interviews.

Quantitative analysis will provide a descriptive analysis of the course of process measures. We will descriptively explore whether there are any differences between compliant and non-compliant attenders, responders and non-responders and whether any socio-demographic and clinical characteristics are associated with outcomes.

End of therapy qualitative interviews

Qualitative evaluation will comprise of one-off end of study interviews with participants from all 3 arts therapies modalities and control groups within 6 months of the intervention ending (weeks 20-48). Participants will be purposively sampled so that we have a range of characteristics based on: treatment completers (attended >75% of sessions) and partial-attendance (attended 35-75% of sessions); representation of each of the diagnostic groups (F2, F3, F4), representation of a range of ages, each mode of therapy and sites. We aim to conduct interviews with up to 3 patients per arts therapies group and up to 10 control group participants, with an anticipated sample size of around 55 participants. Interviews will last up to one hour and will be conducted by an unblinded member of the research team.

We will use an amended version of the Client Change Interview (Elliott, 1999), which explores experience of therapy, changes over a given time period and attributions for this. The amended version, used in existing music therapy studies also explores participants' experiences of the research process and involvement in the study as a whole. This information will provide understanding not only of the interventions but of how best to involve this patient group in trials in the future. Following advice from SUGAR, we will also interview the arts therapists providing the intervention as a means of triangulating patients' experiences of change and relating identified changes to observations within the sessions. These interviews will also last for one hour and will happen within 6 months of the therapy group ending.

Given the relatively large qualitative sample size due to nesting of participants within groups and diagnoses, we will initially analyse the material using the framework approach outlined by Ritchie et al. (2013) whereby after familiarisation with transcripts, a thematic framework is constructed- informed by the theoretical model for this study and interview content- and then use charting within thematic matrices to examine similarities and differences on core characteristics outlined above across and within themes. We will relate this to the hypothesised theory of the intervention (see figures 1 and 2) and highlight where our data supports or conflicts with this hypothesis.

7.10 Withdrawal criteria

During the consent process, researchers will ensure that participants are aware of their right to decline participation at any stage of the research and that withdrawing participation will not affect their treatment or rights in any way.

Participants will be withdrawn from the intervention if the participant becomes too unwell to continue group participation either through:

- Loss of capacity to consent to group attendance
- Level of risk assessed by the clinical team to require hospitalisation
- Arts therapists/ group counsellors and clinical team assess that the current mental state, behaviour or risk to self or others requires discontinuation of group attendance

It is always within the remit of the physician responsible for a patient to withdraw a patient from a trial for appropriate medical reasons, be they individual adverse events or new information gained about a treatment.

If a participant chooses to withdraw from the intervention they will be asked if they wish to continue to participate in the study and provide follow-up assessments or to withdraw from the study as a whole.

Reasons for, and date of withdrawal from the intervention or study as a whole will be recorded in the case report form. If a participant withdraws we will not replace them within this study, but based on group timing and regular attendance, may open the group space to a non-trial participant to ensure a critical mass of group members is maintained.

Should a participant recover or wish to recommence group therapy whilst the group is ongoing, the therapist will liaise with the clinician responsible for the participant's care to ensure the person is ready and able to recommence. The date the intervention is recommenced will be recorded in the case report form.

If a participant is assessed to have lost capacity when attending a research assessment, we will withdraw them from the study and retain all data collected up to that point. Should they regain capacity and wish to continue in the study, we will re-consent them into the study as per procedures for obtaining informed consent.

7.12 End of trial

The end of trial will be when the last follow-up assessment has been conducted. The REC will be informed that the study has been completed. The sponsor, REC and local R&D departments will be informed of end of study and site closure and archiving procedures initiated.

8 INTERVENTIONS

8.1 Group Arts Therapy

Group arts therapy for the purposes of this trial comprise of group art therapy, dance movement therapy and music therapy. All modalities are commonly provided within NHS mental health care. We have taken components of the arts therapies techniques and through consultation with service users and arts therapists, described the practice of the intervention in diagnostically heterogeneous community mental health groups.

Regulation of arts therapies

The titles 'Art therapist', 'Art Psychotherapist' and 'Music Therapist' are protected in the UK with requirements that an approved course is undertaken and that the person is registered with the Health and Care Professions Council (HCPC). Art and music therapists must meet the ongoing CPD and

regulatory requirements and are audited on a bi-annual basis. The art and music therapists in this study will be registered with the HCPC and adhere to their requirements at all times.

Dance movement therapists do not yet have statutory regulation. The professional Association for Dance Movement Therapy is an organisational member of the Humanistic Integrative Psychotherapy College (HIPC) which is compliant with the United Kingdom Council for Psychotherapy (UKCP) standards and regulations for practice. UKCP as an umbrella organisation is compliant with the Professional Standards Authority (PSA). ADMP also maintains HCPC standards with the aim to finalise the registration process with this regulatory body.

Summary of Intervention

The intervention and an accompanying logic model of processes is described in the accompanying manual for this study. All groups will consist of an opening check-in and warm-up before proceeding to use of the arts materials, with spaces to reflect upon the experience. At the end of the session, space will be given to reflect on group themes and discussions and will end with a closing activity.

8.2 Group counselling

Person-centred group counselling will be used as the control condition. As we hypothesise that the main effect of specific arts forms in the arts therapy groups is to increase the appeal and facilitate engagement when a group is offered, the counselling groups are intended to be an active control for those effects that are outside our model i.e. the provision of groups, the attention from professional staff and fellow patients, and the possibility of group interactions and exchange of experiences without using arts forms.

Regulation of group counsellors

Group counsellors do not yet have statutory regulation. The British Association for Counselling and Psychotherapy (BACP) and UKCP both maintain standards and regulations for practice and are compliant with the Professional Standards Authority (PSA). Group counsellors will be recruited for the purposes of this study and will be required to have post-graduate person-centred counselling qualification, registration with BACP or UKCP alongside experience of providing group counselling in NHS secondary mental health services.

Summary of the intervention

Counselling groups will consist of a) opening welcome and introductions, b) informal discussions on topics raised by group members, c) closing activity to summarise discussions and say goodbye. The venue for these groups will be similar to those used in the arts therapy groups and where possible, will make use of the same space. Group counselling sessions will specifically **not** make use of arts activities during the sessions. A brief manual for the counselling groups is provided for the purposes of this study.

8.3 Therapy schedule

Both group arts therapy and group counselling will be provided twice per week, for 20 weeks and a maximum of 40 available sessions. Participants will be invited to meet individually with the therapists in the group space in the 2 weeks prior to the group commencing to discuss any concerns regarding the groups or answer any questions they may have. Each session will last 60-90 minutes comprising a 60 minute focused treatment group with up to 15 minutes either side to afford social activity between group members arriving and leaving.

Participants will be encouraged to attend but are free to choose not to. Should a participant miss a scheduled session, the therapists will contact the participant to ascertain the reason for missing the session, check on their mental state and refer on to the clinician responsible if concerns are raised.

After the final therapy group, participants will be offered an individual end of therapy meeting with the therapists to enable signposting and referral onto further services if needed.

8.4 Maintenance of group membership

To ensure a critical mass of group membership for the trial duration, if group attendance falls below 4 for 2 sessions, therapists will inform the Trial Manager and work with local services to refer additional non-trial participants into the group.

New referrals must meet the inclusion criteria as defined for this study, this will be confirmed through the completion of screening measures.

Additional referrals into the group will be accepted until week 10 of the intervention, after which point, the group will be closed to new referrals.

Patients joining the group for this purpose, will be provided with an information sheet about the study and written informed consent will be obtained for the purposes of audio-visual recording.

8.5 Concomitant medication

Participants will continue with concomitant medication and any other therapies as usual. If concerns are raised regarding the burden or interaction effects of attending both trial intervention and a talking therapy, the participant will be advised to speak with their clinician to ascertain whether or not to continue in the study.

8.6 Assessment of compliance

Compliance with the intervention:

Compliance with the intervention will be assessed by the therapists providing the group therapy recording attendance and reasons for non-attendance on the attendance log. Late arrivals and early departures will be noted with the time and any reason for this.

Should a participant miss a session, the therapists will contact them (as outlined above). Persistent non-compliance will not lead to withdrawal from the study unless requested by the participant. Based on a meta-analysis of music therapy for mental illness and Cochrane review of dance movement therapy for depression, we would expect a medium effect after 20 sessions and a large effect after 40 sessions. We will take attendance of 20 sessions (50% of all available sessions) as a minimum for compliance.

Improving compliance:

Measures to improve compliance will consist of:

- Meeting the therapist individually at the group location in the week prior to the intervention to set expectations and explain the intervention
- Written reminder of the group schedule and telephone call the day prior to the group to remind the group is commencing
- Telephone call reminders offered to participants for the duration of the study
- Telephone call follow-up by the therapist when a session is missed
- Buddy system of travel where participants support each other to travel to sessions together

9 ASSESSMENT AND MANAGEMENT OF RISK

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product.
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

9.2 Operational definitions for (S)AEs

Adverse Events (AEs)

An AE is any untoward medical occurrence in a subject to whom an intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with study activities. As this is a non-CTIMP trial, no medicinal products are being administered as part of this trial. All trial interventions are as per the standard care provided within the NHS for mental health.

If an Adverse Event (AE) either occurs or is identified during the intervention, it is the responsibility of the therapist to first contact the research team. If the event is related to the trial, is severe or results in the intervention being interrupted then they are to notify the Trial Manager once the session has ended by telephone. The research team will then follow up the AE with the patient to record the event on the AE log and to establish whether the AE has been resolved or is continuing. If the AE either occurs or is identified during the assessment, then it is the responsibility of the researcher to follow the same procedure. The AE will be assessed to establish whether it should be classified as a serious adverse event using the guidance as specified below.

AEs for the purposes of this study are defined as:

a) A participant exhibiting aggression (nonverbal or verbal behaviour)
b) A participant causing harm to another person
c) Disclosure of thoughts or plans which may place the individual or others at risk of harm.

If the AE is not defined as serious, the AE will be recorded in the AE log which will be collected at the end of the intervention and stored in a locked filing cabinet with a copy added to the CRF which will omit any information which could lead to unblinding. Dependent on the nature of the AE, an assessment will be made by the CI liaising with the Trial Manager and participant's therapist and/or clinician to establish whether it is safe for the participant to continue with the intervention.

Serious Adverse Events (SAEs):

A serious adverse event (SAE) is defined as an untoward occurrence that:

a) Results in death
b) Is life-threatening
c) Requires hospitalisation or prolongation of existing hospitalisation
d) Results in persistent or significant disability or incapacity
e) Consists of a congenital anomaly or birth defect or
f) Is otherwise considered medically significant by the investigator.

A SAE occurring to a research participant should be reported to the Sponsor and REC where in the opinion of the CI the event was:

- Related- that is, resulted from administration of any of the research procedures and
- Unexpected- that is, the type of event is not listed in the protocol as an expected occurrence.

With reference to the above criteria, SAEs for the purposes of this study may include:

a) A participant making a suicide attempt
b) A participant causing life threatening injury to another
c) An event occurring during the course of the study which results in hospitalisation or prolongation of existing hospitalisation related to their mental health.

Hospitalisation will not be reported if it is for routine treatment, treatment which was elective or pre-planned, hospitalisation for general care where there was no deterioration in condition, or treatment on an emergency outpatient basis for an event **not** fulfilling any of the definitions of serious as given above, and not resulting in hospital admission.

9.3 Recording and reporting of SAEs and SUSARs

All AEs and SAEs occurring from the time of written informed consent until 7 days post-cessation of trial treatment must be recorded on the Serious Incident Form of the NHS Trust and faxed to the Sponsor within 24 hours of the research staff becoming aware of the event. Once all resulting queries have been resolved, the Sponsor will request the original form should also be posted to the Sponsor and a copy to be retained on site.

The active monitoring period for AEs/SAEs will commence from the point of first attendance to group therapy. The monitoring period for AEs/SAEs will end one week after the intervention finishes. Any AEs/SAEs that occur after this period will continue to be reported.

In all cases, SAEs should be reported to the Sponsor.

For each **SAE** the following information will be collected:

- Full details in medical terms and case description

- Event duration (start and end dates, if applicable)

- Action taken

- Outcome

- Seriousness criteria

- Causality (i.e. relatedness to trial intervention), in the opinion of the investigator

- Whether the event would be considered expected or unexpected.

Any change of condition or other follow-up information should be faxed to the Sponsor as soon as it is available or at least within 24 hours of the information becoming available. Events will be followed up until the event has resolved or a final outcome has been reached.

All SAEs assigned by the CI or delegate (or following central review) as both suspected to be related to the intervention and unexpected will be classified as SUSARs and will be subject to expedited reporting to the Sponsor. The Sponsor will inform the REC of SUSARs within the required expedited reporting timescales.

9.4 Responsibilities

Trial Manager:

1. Preparing a line listing all life threatening or SAEs resulting in death within 1 week of their occurrence.
2. Preparing a line listing all other SAEs on a monthly basis.
3. Preparing all safety information for review by the DMC on a 3 monthly basis
4. Preparing total numbers of SAEs per month to be sent to the DMC Chair

Principal Investigator (PI):

Checking for AEs when participants attend for treatment/follow-up.

1. Using clinical judgement in assigning seriousness, causality and expectedness
2. Ensuring that all SAEs are recorded and reported to the Sponsor within 24 hours of becoming aware of the event and provide further follow-up information as soon as available. Ensuring that SAEs are chased with Sponsor if a record of receipt is not received within 2 working days of initial reporting.
3. Ensuring that AEs are recorded and reported to the Sponsor in line with the requirements of the protocol.

Chief Investigator (CI):

1. Clinical oversight of the safety of patients participating in the trial, including an ongoing review of the risk/benefit.
2. Using clinical judgement in assigning seriousness, causality and expectedness of SAEs where it has not been possible to obtain local medical assessment.
3. Immediate review of all SUSARs.
4. Review of specific SAEs in accordance with the trial risk assessment and protocol.
5. Reporting safety information to the independent oversight committees identified for the trial (Data Monitoring Committee (DMC) and / or Trial Steering Committee (TSC)) according to the Trial Monitoring Plan.
6. Expedited reporting of SUSARs to the REC within required timelines.
7. Notifying Investigators of SUSARs that occur within the trial.

8. Central data collection and verification of AEs, SAEs and SUSARs according to the trial protocol onto a database.

Trial Steering Committee (TSC):

In accordance with the Trial Terms of Reference for the TSC, periodically reviewing safety data and liaising with the DMC regarding safety issues.

Data Monitoring Committee (DMC):

In accordance with the Trial Terms of Reference for the DMC, periodically reviewing overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis.

9.5 Notification of deaths

All deaths will be reported to the sponsor irrespective of whether the death is related to disease progression, the intervention, or an unrelated event within 24 hours of the death becoming known by the research team.

9.6 Reporting urgent safety measures

If any urgent safety measures are taken the CI/Sponsor shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the REC of the measures taken and the circumstances giving rise to those measures.

9.7 The type and duration of the follow-up of participants after adverse events.

Should an AE occur during the study, this will be reported immediately to the clinician responsible for the care of the participant. The research team will follow-up the participant's progress on a weekly basis to determine whether or not they should continue participation in the intervention. Follow-ups will continue until participation is resumed, it is deemed the participant should withdraw or until the end of the 20 weeks of intervention.

Any SUSAR related to the intervention will need to be reported to the Sponsor irrespective of how long after attendance of the intervention the reaction occurred.

10 STATISTICS AND DATA ANALYSIS

10.1 Sample size calculation

We have designed the trial to detect a treatment effect of 0.5 standard deviations on the primary health outcome, i.e. the level of psychological distress, as measured by the Brief Symptom Inventory Global Severity Index. In a sample of 378 patients from a UK psychiatric outpatient population, the mean GSI was 1.65 with a standard deviation of 0.81 (Ryan, 2007). An effect of 0.5 standard deviations would therefore represent a difference of 0.4 on the GSI.

We assume clustering of outcomes of patients treated in the same therapy group. In the NESS trial on group body psychotherapy (Priebe et al, 2016), the ICC for therapy groups of 10 patients varied for different outcomes, but did not exceed 0.01 (which applied to the primary outcome). We assumed, conservatively, an ICC of 0.1. We assume a drop out rate of 15% by the end of the study, so that if we allocate 10 patients on average to each therapy group we will end up with clusters with 8.5 patients on average. Assuming a coefficient of variation of cluster size of 0.5, we will need 200 patients before drop out in 20 clusters in each

arm to achieve 90% power at the 5% significance level. Allowing, conservatively, for the additional loss of one full cluster in each arm, we plan to recruit a total of 2 x 210 patients.

The estimated loss takes into account drop outs at each of the different phases of the study ie. between consent and beginning treatment, during treatment, during the six month follow-up period and during the 12 month follow-up period. Some patients will have to wait up to 5.5 months between giving consent and beginning of treatment. Within this period they may drop out due to changing their mind, being offered alternative treatment or experiencing a reduction in symptoms. Base on previous studies (Crawford et al, 2012; Priebe et al, 2016) we expect this drop out rate to be less than 10% and we will be able to compensate for most of that loss through recruiting additional patients closely before the time of the baseline assessment.

During the treatment phase we may have drop-outs from both groups. An intention-to-treat approach to analysis does not mean that all outcome data must have been collected, but it does mean that every effort should be made to minimise the amount of missing data. We expect a low drop out rate from research during treatment but envisage a drop out rate of 10% by the 6 month follow-up (in NESS it was 7.3% after 6 months), and 15% by the 12 month follow-up.

To ensure an adequate follow-up rate we will:

- Maintain regular contact with patients after giving informed consent (every 6-8 weeks)
- Ensure contact occurs in the 4 weeks prior to the groups starting, to ensure greater levels of contact between consent and the intervention starting
- After randomisation, patients will be given the opportunity to meet the therapists and ask questions prior to the group starting
- Patients will be reimbursed for their expenses and time for each research interview (£10 for screening, £20 for each subsequent interview).
- Research assistants will arrange the date for the next interview during the previous assessment and use a telephone and written reminder two weeks prior to the subsequent interview date.
- As far as possible, the same research assistant will conduct all interviews with a patient so that a positive relationship can be established.
- We will accommodate patients' preferences for meeting times and locations, including patients' homes.

Missing data may occur in the study at a number of levels and stages in the study. In addition to procedures to maximise follow-up:

Where an assessment appointment is missed:

- The research assistant will follow-up non-attendees via telephone call to ascertain the reason for non-attendance and whether any assistance from the study team can help in this matter.
- The research assistant will check if the participant is still willing to continue with the study and record the participant's response in the CRF.

To prevent missing data:

- Research Assistants completing assessments will ensure completeness of recording data throughout the research assessment.

- Should missing data be discovered after the assessment, the research assistant follows up with a telephone call to the participant as soon as possible.

Clear signifiers for reasons for missingness will be agreed and specified following the PCTU SOP for data management.

If too few patients choose one form of arts therapy to form a group at one of the sites, or if too many study participants show poor attendance or drop out completely during treatment we will aim to refer additional patients from outside the trial so that a critical mass of 4 or more patients is maintained in each group.

10.2 Planned recruitment rate

We plan to recruit from Secondary Mental Health care services including Community Mental Health Teams, Recovery teams, and Secondary Care service user and carer involvement forums within the participating Trusts.

For the internal pilot, based on a participation rate of 25%, we plan to approach 240 patients at each site, with the aim of recruiting 10 patients per month per site over 6 months.

In the full trial, we plan to double the number of groups in London by including an additional site. For this, based on a participation rate of 25%, we plan to approach 240 patients at each London, with the aim of recruiting 10 patients per month over 6 months.

10.3 Statistical analysis plan

A detailed statistical analysis plan will be agreed by the Trial Steering Committee prior to the analysis of unblinded data.

10.3.1 Baseline data

We will report descriptive statistics for sociodemographic and clinical characteristics by intervention arm along with baseline scores for each assessment.

10.3.2 Primary outcome analysis

The primary outcome will be psychological distress at end of treatment (20 weeks), measured using the BSI global severity index. The primary analysis will be a longitudinal mixed regression analysis that includes end of treatment, 6 months post-treatment and 12-months post-treatment assessments of psychological distress, using all non-missing data on these outcomes. Performing a longitudinal analysis of all time-points using all non-missing data should allow for greater precision in the estimation of treatment effect at end of treatment than an analysis of this time-point alone. The analysis will include a random effect to allow for clustering within each therapy group and individuals. The primary hypothesis of a beneficial effect of arts therapy will be investigated by testing for a fixed effect of intervention vs. control, adjusting for fixed effects of site, patients' preference for the form of arts therapy (art, music or dance), primary diagnosis, age, sex and baseline psychological distress.

The primary analysis will be by intention to treat. Secondary analyses will investigate the treatment effect in compliers.

10.3.3 Secondary outcome analysis

Secondary outcomes, which are all on continuous scales, will be analysed in the same way as the primary outcome.

10.4 Subgroup analyses

Subgroup analyses will repeat the analyses within diagnostic subgroups, and will investigate whether different forms of arts therapy have different effects by including an interaction between patient preference group and intervention vs. control.

10.5 Interim analysis and criteria for the premature termination of the trial

We will conduct an interim analysis of recruitment, attendance and therapist adherence in week 4 of the first cohort to decide whether or not to proceed to a full trial. This will be prepared by the Trial Manager, who is unblinded. The data will be seen by the TMG, LEAP, TSC and DMEC. As the reported data will not include details of specific participants or outcome measures, full blinding will be maintained.

No interim analyses of primary or secondary outcomes are planned. The DMEC will review data on outcomes and adverse events as they accrue, summarised by trial arm, arts therapy modality, study site and diagnosis. Should significant safety concerns arise during the intervention phase, the CI in liaison with the sponsor, TSC and DMEC has ultimate authority to halt the study or withdraw individual participants should concerns arise during the study.

10.6 Procedure(s) to account for missing or spurious data

A longitudinal regression analysis of all non-missing data will give a valid estimate of treatment effect under an assumption that outcomes are “missing at random” (that is, missingness is influenced only by variable that are included in the analysis). If the primary outcome is missing for more than 5% of participants we will conduct further analyses to investigate the sensitivity of our conclusions to departures from the missing at random assumption.

10.7 Other statistical considerations.

Should any deviations from the original statistical plan be necessary, this will first be discussed with the TSC and the decision reported to the sponsor including justification for such changes.

10.10 Economic evaluation

Economic evaluation using recommended methods (NICE, 2013) will be undertaken from an NHS/Personal Social Services perspective to examine the cost-effectiveness of group arts therapy for people with mental health disorders. The evaluation will include within trial analyses over the intervention period and the 12 month post-intervention follow-up period. We will estimate the cost of delivering group arts therapy (art, music and dance) and the cost of the control intervention (counselling). These costs will cover: salaries, room rental, equipment and materials, therapists’ travel expenses, training and administration costs. Resource use associated with delivery of the interventions will be documented by the study team over the five-month treatment period using inventory forms developed by a health economist. Intervention costs will be calculated as cost per group and cost per patient. Sensitivity analyses will be conducted to address uncertainty associated with delivering interventions (eg. number of groups, number of participants in the group, therapists’ wages, including and excluding therapists’ training costs).

In addition to the costs of delivery the interventions, data on the use of health and social care services will be collected at baseline, at the end of the five-month treatment and after 6 and 12 month follow-up periods by the researchers using the Client Services Receipt Inventory (CSRI). Further data on the use of secondary healthcare services will be requested from the Secondary Uses Service (NHS Digital, 2017; PSSRU, 2016). Unit cost estimates from national sources (Department of Health, 2016) will be applied to resource use to estimate individual-level costs. Generic health-related quality of life data will be collected

using the EuroQol EQ-5D-5L (EuroQol Group, 2015) and ReQoL-20 questionnaires at baseline, the end of treatment and the 6 and 12 month post-intervention follow-up periods. Cost-effectiveness analysis will be carried out using the EQ-5D-5L, Recovering Quality of Life (ReQoL-20) and the Brief Symptom Inventory (Derogatis & Melisaratos, 1983) as health outcomes. Treatment costs will be calculated by combining resource use of delivering the interventions with respective costs. The cost-effectiveness analyses will compare:

1. The whole arts therapy arm with counselling
2. Different arts therapies (art, music and dance) with each other and with counselling to identify the most cost-effective treatment(s).

Cost-effectiveness planes will be constructed to illustrate the relation between costs and outcomes for different treatment groups. Probabilistic sensitivity analysis will be conducted using non-parametric bootstrap methods to estimate confidence intervals for incremental cost-effectiveness ratios (Glick et al, 2014). Analyses will be conducted for the intention-to-treat and per-protocol populations to reflect participants' engagement with an intervention. Scenario analyses will be undertaken assuming that the arts therapies could be delivered in an NHS or community setting. Should issues associated with an incomplete dataset arise, the impact of missing data on the cost-effectiveness outcome will be addressed using multiple imputation procedures (Dziura et al, 2013). Longer-term modelling (eg. Lifetime costs and benefits) beyond the trial is not planned given the lack of long-term data with which to extrapolate and the considerable uncertainty and resources such modelling would incur. Whilst our plan is to run a within-trial economic evaluation only, we will gain consent from patients for longer-term follow-up beyond the end of the trial, which will provide an option for longer term modelling if results warrant this.

11 DATA MANAGEMENT

11.1 Data collection tools and source document identification

Data collected for the study will comprise:

Data type	Source	Where stored
Personally identifiable contact information: Name, Rio number, address, telephone, named responsible clinician, healthcare team	Medical records / Interview	Password protected screening and enrolment excel file on access limited folder on NHS computers.
Signed informed consent form	Informed consent interview	Paper copy stored in locked filing cabinet on NHS premises at each study site. Copy sent to health care professional to be stored in patient's medical records. One copy provided to patient for their records.
Screening assessments: BSI, Arts therapy preference	Screening/ baseline interview	CRF locked in filing cabinet on NHS premises at each study site.
Socio-demographic and clinical information	Interview / Medical Records	CRF locked in filing cabinet on NHS premises at each study site.
Audio-visual recordings of therapy	Therapy sessions	Encrypted, password protected hard drive or access limited folder on NHS computers
Process assessment scales: ORS, FGES, PHQ9	Interview	CRF locked in filing cabinet on NHS premises at each study site.
Intervention adherence: Group attendance form Therapist self-rated adherence form	Therapy sessions (recorded by therapists)	Therapist site file locked in filing cabinet on NHS premises at each study site.
Observer rated adherence form	Audio-visual data	Therapist site file locked in filing cabinet on NHS premises at each study site.
Outcome assessment scales: BSI, BPRS, MANSA, SIX, CSRI, EQ-5D-5L, ReQoL-20	Interview	CRF, locked in filing cabinet on NHS premises at each study site.

Economic evaluation data: Secondary care and mental health service data CSRI Cost of providing intervention (including therapists' training)	Centrally held NHS Digital datasets Interview Therapists' and research staff reports	NHS Digital CRF, locked in filing cabinet on NHS premises at each study site. Therapist site file locked in filing cabinet on NHS premises at each study site.
Qualitative interviews: Audio recording of interview Interview transcript, identifiable details removed. Therapist professional details	Digital audio file of interview Digital audio file of interview Therapist self-report	Encrypted, password protected hard drive or access limited folder on NHS computers. To be deleted after transcription Password protected, pseudonymised electronic file saved in access limited folder on NHS computers. Locked filing cabinet on NHS premises at each study site.

Validated assessment scales:

Proposed assessment scales have been validated as follows:

Brief Symptom Inventory (BSI): The Brief Symptom Inventory (Derogatis & Melisaratos, 1983) has good internal consistency (Cronbach's alpha: 0.84), sensitivity of 82%, specificity of 75% and provides information regarding symptom distress on a range of psychological symptoms.

Brief Psychiatric Rating Scale (BPRS): The Brief Psychiatric Rating Scale (Overall & Gorham, 1962) internal consistency varies betwee .75 and .79 (Thomas, Donnell & Young, 2004) and test retest reliability of .78 (Crippa, Sanches, Hallak, Oureiro & Zuardi, 2001). Scores of 31 approximately correspond to Clinical Global Impression (CGI) ratings of 'mildly ill', 41 as 'moderately ill' and 53 as 'markedly ill' (Leucht, Kane, Kissling & Hamann, 2005). As recommended by UCLA BPRS fidelity gold standard (Ventura et al., 1993), consensus rating must be reached by each interviewer on a minimum of six interviews before research assistants could independently conduct BPRS interviews.

Manchester Short Assessment of Quality of Life (MANSA): has good internal consistency for satisfaction ratings of 0.74 and correlations of 0.83 and higher with the longer Lancashire Quality of Life Profile (Priebe, Huxley, Knight & Evans, 1999).

Objective Social Situation (SIX): This assessment was developed as a ranking scale to record social outcomes of work/employment, accommodation/housing and social situation (living situation and social contact in the last week). The scale score ranges from 0-6. The scale has good sensitivity to change and no floor or ceiling effects (Priebe, Watzke, Hansson et al., 2008).

Client Services Receipt Inventory (CSRI): (Beecham & Knapp, 1992) is a widely used and well established format for calculating social care use in clinical populations.

Outcome Rating Scale (ORS): (Duncan & Miller, 2000) has high internal consistency (α=.93) and is moderately correlated with the longer Outcome Questionnaire 45.2 (Lambert, Hanson et al., 1996). Designed for a clinically usable alternative to the OQ45.2, it provides a brief measure of overall, individual, interpersonal and social functioning.

Ferrara Group Experiences Scale (FGES): (Caruso et al, 2014) has good internal consistency (α=.85) and measures the types of group experiences most prominent within a group session (both positive and negative).

Personal Health Questionnaire (PHQ9): (Kroenke et al, 2001) is a widely used, brief self-report measure of depression, with excellent internal consistency (0.86-0.89).

EQ-5D-5L: (EuroQol Group, 2015) is an internationally widely used generic Patient Reported Outcomes questionnaire.

ReQoL-20: (Keetharuth, 2018) is a brief outcome measure focusing on the process of recovery for users of mental health services.

11.2 Data handling and record keeping

Data handling and record keeping are specified in the data management plan agreed with the PCTU, following Standard Operating Procedures.

Data collection and storage:

All data for participants will be collected by the Trial Manager or research assistants and entered onto a CRF designed for the study using a pseudonymisation system set up a-priori allocating each participant to an unrelated code number. Pseudonymised paper forms of the CRF data will be stored in a locked filing cabinet at each participating site, kept separate from the pseudonymisation code sheet identifying participants. Signed consent forms and demographic details will be kept and locked securely and separately from pseudonymised data with the pseudonymisation code kept at the Unit for Social and Community Psychiatry. Data will be backed up digitally through manual data input of pseudonymised CRFs and source documents on password secured NHS computers and saved on password-protected and encrypted hard disks securely stored in a locked cabinet at the Unit.

Data entry and quality assurance:

Data will be entered from hard pseudonymised copies and entered on-site onto an online database by research assistants at each NHS Trust. The blank dataset will be prepared by QMUL PCTU's Data Management team. The data will be viewable online by the central trial team.

The final datasets will be stored as Csv. files and utilised to conduct analyses by the Statistical Packages for Social Sciences and STATA software, as appropriate. The Trial Manager will be responsible for an on-going check of data quality.

The research assistants and Trial Manager will double check data entry from pseudonymised CRFs to digital data entered on a weekly basis. Sites will send copies of 10% randomly selected data files and completed questionnaires to the central research team who will carry out:

a) Review: These data will be entered again by the trial manager and subsequently compared with the data in the files received from the research assistants at the participating Trusts. In case of major differences, the proportion of the reviewed data will be increased.
b) Query: In case of significant mismatch (more than 10%), the Trial Manager will discuss with the research assistants at participating sites in order to further investigate data problems.

Data quality assurance will be discussed in weekly teleconferences with the research assistants at participating sites.

Qualitative interview data:

Data from qualitative interviews will be transcribed verbatim by an NHS approved transcription service. The Trial Manager (or delegated to Research Assistant) will check to ensure the accuracy of the transcription, and removal of any potentially identifiable information prior to deleting the audio file. Transcribed data will be stored in password protected files on NHS computers with restricted access only to the research team.

Data security:

Digital data is backed up securely every night and stored on NHS servers. The Unit/PCTU complies with the Data Protection Act 2018 and all staff involved in the study receive mandatory training on this on an annual basis. The Trial Manager, Chief Investigators and PCTU statistician and health economist are responsible for data analysis once data collection is complete.

Any personally identifiable information (such as consent forms and audio visual recordings) will be stored separately from the pseudonymised data in a locked filing cabinet on NHS premises to which only the study team will have access.

Audio visual files will be stored on password protected and encrypted hard drives in a locked filing cabinet as above. We will seek permission from participants to use non-personally identifiable data (eg. Music making, visual images of art-work, movement without full picture of face or body, re-recorded examples of group discussions with actors) from therapy sessions for the purposes of illustration of findings and presentation. This is outlined in the PIS and consent form. All original audio-visual recordings of therapy sessions will be destroyed one year after the end of the study. All audio files of interviews will be destroyed immediately after transcription.

11.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits and inspections- in line with participant consent.

11.4 Record retention and archiving

Data will be retained and archived in accordance with the UK Policy Framework for Health and Social Care Research and East London NHS Foundation Trust Record Management and IM&T Information and security policies. All essential documents will be archived for 20 years after completion of trial and stored in the Trust Modern Records Centre. The Chief Investigators will be the custodian of the data.

Participants' contact details will be retained (with their permission via the consent form) if they want to be updated about study progress. These will then be destroyed one year after the study end.

12 MONITORING, AUDIT & INSPECTION

The study will be monitored and audited by the sponsor of the study, East London NHS Foundation Trust in accordance with SOPs approved by Noclor.

As the study is a PCTU supported study, a senior trial manager and a trial monitor will be employed within the PCTU to oversee the monitoring and audit processes.

A trial monitoring plan will be developed and agreed by the TMG, PCTU and TSC based on the trial risk assessment which may include on-site monitoring.

A trial set-up meeting between the CIs and PCTU members will occur prior to commencement of data collection. The PCTU will conduct a risk assessment for the project which will determine the level of risk and therefore the frequency and type of monitoring required. A trial monitoring plan will be developed which will specify the frequency of monitoring visits to be conducted by the trial monitor who is an independent member of the PCTU. The monitoring plan will be agreed by the CI, PCTU and Sponsor. Monitoring visits and procedures will be recorded in the TMF and will adhere to the SOPs of both Noclor and the PCTU.

13 ETHICAL AND REGULATORY CONSIDERATIONS

13.1 Research Ethics Committee (REC) review & reports

The CI (Carr) and co-CI (Priebe) will ensure that the study is carried out in accordance with the ethical principles in the Research Governance Framework for Health and Social Care, Second Edition, 2005 and its subsequent amendments as applicable.

As this study involves NHS patients and is being conducted in England, before the study starts it will require approval from the Health Research Authority (HRA) and a favourable opinion from the REC for the study protocol, informed consent forms and other relevant documents.

Substantial amendments that require review by the REC will not be implemented until the REC grants a favourable opinion for the study and approved by the relevant NHS R&D departments and HRA.

The CI will ensure that an annual progress report is submitted to the REC within 30 days of the anniversary date on which the favourable opinion was granted. The annual report will be submitted each year until the study is declared ended.

The CI will notify the REC, HRA and study sponsor of the end of the study. If the study is ended prematurely, the CI will immediately notify the REC, HRA and study sponsor including the reasons for premature termination.

Within one year after the end of the study, the CI will submit a final report with the results including any publications/abstracts to the REC.

13.2 Peer review

The study has been presented to service user and carer groups (SUGAR) and reviewed internally by the CIs' employer (Queen Mary University of London) and independent external scientific advisors as part of the NIHR review process. Ongoing review will occur through attendance at the SUGAR advisory group, Trial Steering Committee and Data Monitoring and Ethics Committee.

13.3 Public and Patient Involvement

The research design was underpinned by patient and public involvement through advice from our previous arts therapies research, presentation to Trust patient and carer groups and the Service User and Carer Group advising on Research (SUGAR), City University, London.

Patients in our previous studies underscored the importance of being able to choose their preferred modality and the importance of better information to understand what each modality might entail. To do this, we have prepared standardised information in a video for patients and clinicians (which will also be used outside of this study) which has been produced in collaboration with East London NHS Foundation Trust's People Participation groups. SUGAR also advised on the importance of enjoyment of the arts therapies and support from other patients. We have included these measures using the ORS and GFES scales as process measures. Finally, they advised that we include clinicians' views of change as this might not be immediately obvious to patients themselves. We have therefore ensured therapists running the groups are also involved in qualitative interviews.

The Lived Experience Advisory Panel (LEAP) will advise on the ongoing running and materials for the study and will advise on dissemination routes and patient and public workshops as part of the study dissemination. We plan for the LEAP to meet 2-3 times per year over the course of the trial. Their role will be specified and terms of reference agreed during the first meeting. The focus of the LEAP will be to advise on study materials, progress, assist in producing lay summaries of findings and advise on routes for dissemination including end of study workshops.

Patient and public involvement and awareness of the research will be maintained through news items published at the start and completion of the study in local NHS Trust R&D newsletters, updates provided on the study specific website and presentation at local NHS Trust meetings and seminars.

The LEAP meetings will be chaired by up to two LEAP members who have lived experience and have been involved in other arts therapies projects in this capacity. The chair(s) will have a lead role in coordinating PPI activities. LEAP members will not be obliged to take part in all pieces of work and participation will be flexible. We will provide training and support for members, with the opportunity to become involved in the data collection and qualitative analysis of interviews, should members wish.

A service user representative will be included on the TMG and TSC and will provide feedback to and from LEAP meetings. All patients involved in the project will be reimbursed in accordance with NHS policies and INVOLVE guidelines.

13.4 Regulatory Compliance

All staff employed on the study receive annual mandatory training from their local NHS Trusts on information governance, safeguarding, health and safety, manual handling and infection control, and work within national and international legislation in these areas. The study team will be trained in all aspects of GCP and informed consent processes via the study sponsor (Noclor).

Before enrolment of patients into the trial, the CI will apply for confirmation of capacity and capability from each site's Research and Development (R&D) department. Should any amendment potentially affect a site's NHS permission, the CI or designee will confirm with that site's R&D department that NHS permission is ongoing. In liaison with the sponsor, the CI or designee will check to ascertain whether substantial amendments or amendments considered to be non-substantial for the purposes of REC need to be notified to NHS R&D.

13.5 Protocol compliance

Protocol compliance will be managed through regular meetings by the TMG, with oversight by the TSC and DMEC. The Trial Manager will be responsible for adequately documenting protocol deviations and reporting deviations on the relevant forms and reporting to the CI and sponsor immediately. Deviations from the protocol which are found to frequently recur will receive immediate action and their significance will be assessed by the TMG, TSC and sponsor to determine whether they should be classified as a serious breach.

13.6 Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to effect to a significant degree –

(a) the safety or physical or mental integrity of the participants of the trial; or
(b) the scientific value of the trial

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase.

13.7 Data protection and patient confidentiality

The trial will be compliant with the requirements of the Data Protection Act, 2018, with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles, throughout the study.

Personal information

All data will be pseudonymised to maintain patient confidentiality. All participants will be assigned participant ID number used for all data processing purposes and the list linking these data with the participant ID number will be stored on NHS computers on a secure drive, within password-protected folders, which will only be accessible to the research team.

All hard copies of data, including signed consent forms socio-demographic details and patient receipts will be kept and locked securely and separately from pseudonymised data and only accessible by the research team.

Where participants provide their consent, participant's names and contact details will be retained to enable the research team to re-approach them to take part in related studies and to share research findings.

Pseudonymised data

Pseudonymised CRF data will be stored in a locked filing cabinet at each site, kept separate from the anonymization code sheet identifying participants. Data will be entered onto a web-based database developed by the PCTU Data Management team. All data stored on the database will be pseudonymised by using the participant ID as the identifier. The database will be accessed by researchers working on the study.

Audio visual recordings

Audio-visual recordings of all therapy sessions (arts therapies and group counselling) and individual interviews will be taken with explicit permission (as indicated on the consent form) from participants. Recordings will be stored on password-protected folders on NHS Trust computers on a secure drive which

will only be accessible by the research team. Audio recordings of interviews will be destroyed immediately after transcription and the transcriptions will not contain any identifiable information. Audio-visual recordings will be destroyed 1 year after the trial as finished, with only excerpts of sessions kept for presentation purposes. These excerpts will not contain any identifiable images or sounds of participants and will be used only with the explicit consent of participants (as outlined in the information sheet and consent form).

Access to data

Access to pseudonymised data will be limited to the following personnel who may all be involved in handling or analysing data during the study: The trial manager, CIs, service user lead, research assistants, clinical studies officers and PCTU staff.

No identifying data will be sent to the sponsor or TSC/DMEC members. The only occasion where information on patients may need to be transmitted via NHS email or telephone would be in the case of a serious adverse event, where a therapist may need to contact the CI. In this case, Trust guidelines will apply ie. minimally identifying data will be used on the emails, NHS to NHS email only will be used and NHS guidelines for checking caller identities for phone calls will be followed.

13.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

The only potential conflict of interest foreseeable in this study is that the study is investigating the effectiveness of group arts therapies using a team comprising music therapists (including one CI), art therapists and dance movement therapists. Two study coapplicants are both dance movement therapists and group counsellors.

Any future study personnel will be asked to provide any potential conflicts of interests, which will then be discussed in conjunction with the sponsor and TSC.

13.9 Indemnity

The study will have indemnity through a standard NHS insurance scheme. NHS indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. They are able to consider an ex-gratia payment in the case of a claim.

13.10 Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of the submission to the REC.
The amendment history will be tracked via version and date control of protocols, with changes to the protocol highlighted in Appendix 4.

13.11 Post trial care

This trial will adhere to the Declaration of Helsinki 2013 with respect to provisions for post-trial access for all participants who still need an intervention identified as beneficial in this trial.

Clinical need and signposting to existing services has been incorporated into the treatment manuals for this trial. Participants will be offered the opportunity to meet with therapists once after the group has finished to discuss remaining needs and services which they may wish to be referred into. Referrals will be made in conjunction with the participants' existing care team.

Any participants wishing to continue group arts therapy will be referred to existing groups within NHS community teams or offered within local charitable organisations (eg. MIND). The study team is well integrated within the local NHS Trust care systems and will liaise on an ongoing basis with participants' care teams in relation to any important information required by or important to care staff.

13.12 Access to the final trial dataset

Members of the research team and PCTU staff will have access to the final data set. Site investigators may be given access upon request. Full details are specified in the Data Management Plan.

14 DISSEMINATION POLICY

14.1 Dissemination policy

Dissemination activities will run throughout the course of the trial with results disseminated to key stakeholders. The LEAP will take an active role in advising on and assisting with dissemination to ensure findings are accessible and meaningful to patients, carers and the general public. Dissemination will target different stakeholders including mental health service commissioners, clinicians, patients, carers and academics.

The trial protocol will be made publicly available via the ISRCTN and publication in an open access journal prior to completion of the first stage of recruitment.

A project specific website will be developed and regularly updated. The website will contain information about the study, video-clips used in the study, lay summaries and access to further resources. We will use social media (including twitter and blogs) to communicate research progress, milestones and upcoming dissemination events. There will be section of resources for arts therapists including references to key literature and a summary sheet of the study that can be shared with colleagues. A further section will provide wider materials for patients and the public on arts therapies and the trial. We will also report progress through NHS Trust newsletters and user publications.

On completion of the trial, the final data will be analysed, tabulated and a final study report prepared for publication in the open access NIHR HTA journal. Further publications will be submitted to peer-reviewed journals. Lay summaries of findings will be made available via the study website and disseminated to local patient and public groups.

We will run workshops with arts therapies professionals and NHS professionals at the end of the study in conjunction with our LEAP. Workshop materials will be made available on the study website.

We will present the study protocol and findings at national and international conferences including NHS specific meetings within each of the participating Trusts and wider professional meetings of arts therapists.

The funding body (National Institute for Health Research) must be acknowledged in all publications and presentations, with a requirement that they are notified of such dissemination activities at least 28 days prior to publication. Requirements for acknowledgement of funding and disclaimer are outlined in the funding contract and NIHR website.

Co-investigators will have the right to publish parts of the trial if agreed in advance by the overall TMG. Participants will be informed of the results of the study via an end of study summary. Participants may request specific results relating to their participation from the CIs or Trial Manager once the study results have been published and members of the TMG are unblinded.

14.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will be determined by contribution to the study design, data collection, data analysis and writing up of the study. No professional writers will be used for the final study report.

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16. APPENDICES

16.1 Appendix 1-Risk

Risks associated with trial interventions

☒ A ≡ Comparable to the risk of standard medical care

☐ B ≡ Somewhat higher than the risk of standard medical care

☐ C ≡ Markedly higher than the risk of standard medical care

Justification: Group arts therapy and group counselling are part of standard community mental health care in the NHS. At present it is provided to groups of mixed diagnoses both as inpatients and in the wider community. Within the literature, very few risks have been described for group arts therapy and counselling. The risks reported within studies are assessed to be no greater than risks in normal standard practice.

What are the key risks related to therapeutic interventions you plan to monitor in this trial?		How will these risks be minimised?		
IMP/Intervention	Body system/Hazard	Activity	Frequency	Comments
Group arts therapy and group counselling	Worsening of symptoms	Ongoing monitoring by therapists and researchers	Every group session/assessment	Any observed reported worsening of symptoms will be reported immediately to the participant's care team.
Group arts therapy and group counselling	May provoke upset or elicit painful or upsetting memories	Check in with participants by therapists if any upset/discomfort observed or reported	Every group session	Therapists offer time for individual support, option to take time out from the group and to speak with clinical staff. Therapists use clinical judgement to decide in collaboration with participant and care team whether to continue intervention or withdraw.

Ongoing safety monitoring and reporting will occur throughout as outlined in section 9 of the protocol.

16.2 Appendix 2 – Schedule of Procedures (SPIRIT diagram)

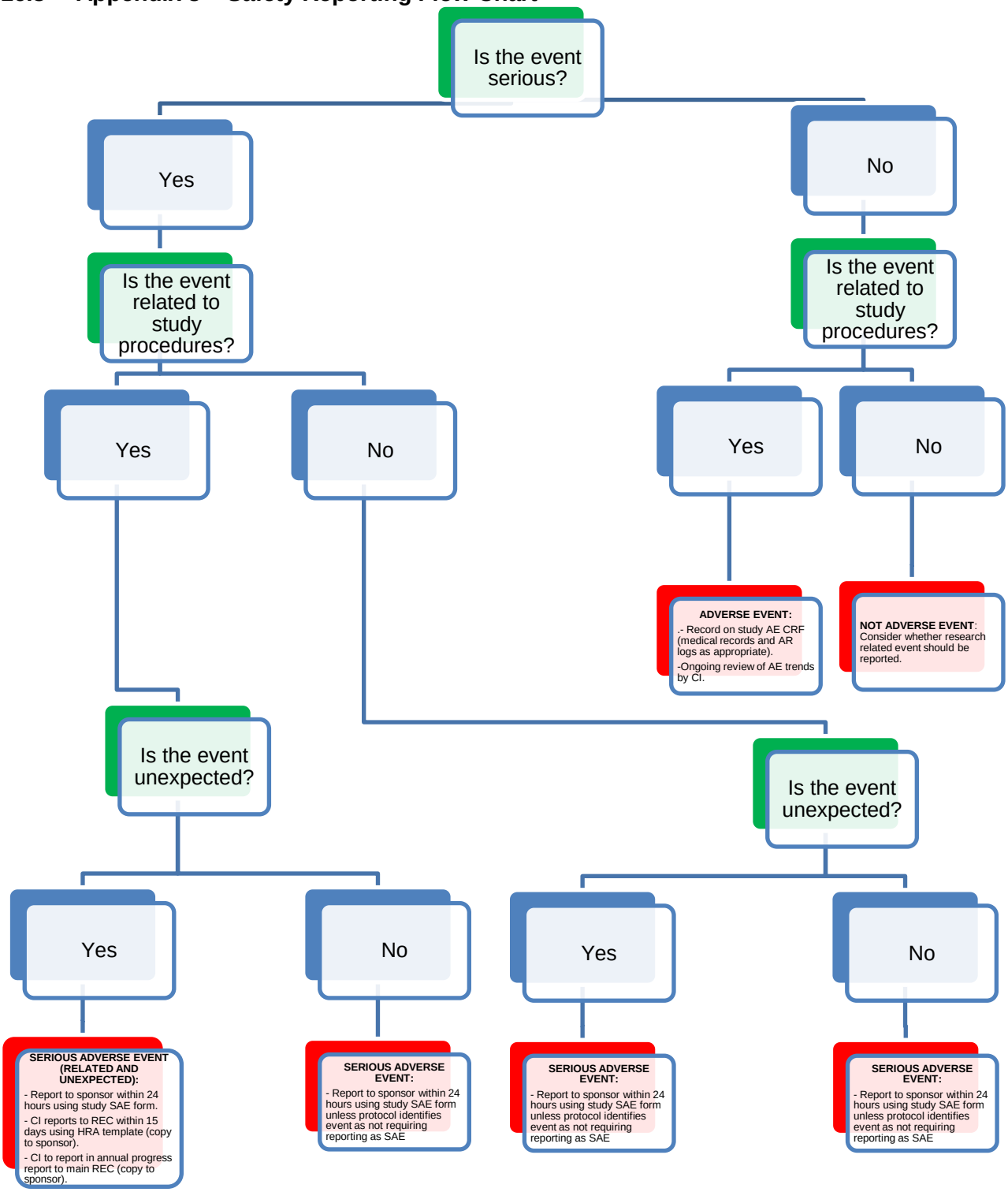
		STUDY PERIOD (weeks)					
	Enrolment + Baseline	Allocation	Intervention period			Post-intervention	
	-24w	-2w	0w	+2, 7, 12,17w	+20w	+44w	+68w
TIMEPOINT	***-t1***	**t0**	***t1***	***t2***	***t3***	***t4***	***t5***
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Baseline measures	X						
Allocation		X					
INTERVENTIONS:							
Group arts therapy			◆	———	◆		
Group counselling			◆	———	◆		
ASSESSMENTS:							
Measures: observer							
BPRS	X				X	X	X
Measures: self-report							
Arts modality preference	X						
BSI	X				X	X	X
MANSA	X				X	X	X
SIX	X				X	X	X
Measures: health economic							
Healthcare service use (via NHS digital)							X
CSRI	X				X	X	X
EQ-5D-5L	X				X	X	X
Cost of study interventions form	X				X	X	X
ReQoL-20	X				X	X	X
Process measures: Group attendance				X	X	X	X
ORS				X			
FGES				X			
PHQ9				X			
End interviews					X		
Fidelity: Therapist adherence[b]			X	X			
Video rated adherence[c]			X	X			
Progression criteria (Internal pilot only):							
Recruitment in 6 months			X				
N attending 1 session[a]				X			
Attendance rates[a]				X			

[a]Measured in the first 4 weeks of the intervention period

[b]Therapist self-rated adherence measured every session

[c]Video rated adherence from one session in weeks 2 and 3 per therapy group will be used for the internal pilot; 10% of sessions will be randomly selected for the process evaluation.

16.3 Appendix 3 – Safety Reporting Flow Chart



16.4 Appendix 4 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	3.0	07.05.19	HT, CC	Addition of one page study summary to give out to potential participants as an overview to those who may be interested.
2	4.0	08.10.19	HT, CC, RH	Revisions to reflect: a) Baseline assessments to now happen at informed consent stage. b) Immediate randomisation when a preference quota is filled c) Continuation of recruitment whilst awaiting decision whether to proceed to full trial d) Correction and clarification of minor typographical errors
3	4.0	08.10.19	HT, CC	Amendments to clarify additional London site (submitted at same timepoint as amendment 3).
4	5.0	26.02.20	CC, RH	Amendment to clarify randomisation procedure in cases of fewer than 15 participants within a preferred modality at the end of the recruitment window.
5	6.0	09.03.21	LK	Amendment to allow for remote consent procedure as a result of Covid-19 pandemic.
6	7.0	06.04.21	LK	Amendment to clarify procedure for repeated baseline measures and re-randomisation due to study pause during Covid-19 pandemic.
7	8.0	30.10.22	CC	a) Amendment to clarify procedure for modality preferences of fewer than 12 at recruitment end. b) Trial manager and NIHR manager personnel updated c) Additional study site (CNTW) included

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee or MHRA.