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FEASIBILITY OF INTENSIVE GROUP MUSIC THERAPY FOR ACUTE ADULT PSYCHIATRIC INPATIENTS: AN EXPLORATORY PILOT TO ASSESS FEASIBILITY OF A RANDOMISED CONTROLLED TRIAL (F-IGMT WP4)

Short Title/Acronym	Feasibility of Intensive Group Music Therapy F-IGMT WP4
Sponsor	Queen Mary, University of London Contact person: Dr Sally Burtles Director of Research Services & Business Development Joint Research Management Office 5 Walden Street London E1 2EF Phone: 020 7882 7260 Email: sponsorsrep@bartshealth.nhs.uk
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Lead NHS site	East London NHS Foundation Trust • Tower Hamlets Centre for Mental Health
Funding	HEE/NIHR Clinical Lectureship

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Recruiting site and Principal Investigator

- East London NHS Foundation Trust [Carr]

Co-Applicants role in study

- Professor Stefan Priebe, research mentor to Carr, Queen Mary University of London
- Mr Stephen Sandford, clinical mentor to Carr, Strategic Lead for Arts Therapies, East London NHS Foundation Trust

Music therapists providing intervention:

- Cornelia Bent, Music Therapist, East London NHS Foundation Trust
- Donald Wetherick, Music Therapist, East London NHS Foundation Trust

Central facilities

- Unit for Social and Community Psychiatry, WHO Collaborative Centre for Mental Health Services Development, Barts and the London School of Medicine, Queen Mary University of London (QMUL).

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1. GLOSSARY of Terms and Abbreviations

AE	Adverse Event
AR	Adverse Reaction
ASR	Annual Safety Report
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
DMC	Data Monitoring Committee
EC	European Commission
GAfREC	Governance Arrangements for NHS Research Ethics Committees
IAP	Independent Advisory Panel
ICF	Informed Consent Form
JRMO	Joint Research Management Office
NHS REC	National Health Service Research Ethics Committee
NHS R&D	National Health Service Research & Development
Participant	An individual who takes part in a clinical trial
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
USCP	Unit for Social and Community Psychiatry

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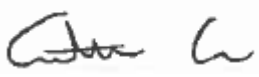
2. SIGNATURE PAGE

Chief Investigator Agreement

The clinical study as detailed within this research protocol **(Version 5, dated 03.03.2017)**, or any subsequent amendments will be conducted in accordance with the Research Governance Framework for Health & Social Care (2005), the World Medical Association Declaration of Helsinki (1996) and the current applicable regulatory requirements and any subsequent amendments of the appropriate regulations.

Chief Investigator Name: Dr Catherine Carr

Chief Investigator Site: East London NHS Foundation Trust

Signature and Date:  **03.03.2017**

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3. SUMMARY/SYNOPSIS

Short Title	**Feasibility study of intensive group music therapy**
Methodology	Randomised controlled single-blind exploratory pilot to assess feasibility comparing ward based and off-ward group music therapy to treatment as usual, supplemented by process evaluation including semi-structured qualitative interviews and observation of key processes.
Research Sites	East London Foundation NHS Trust
Objectives/Aims	To pilot intensive group music therapy in an acute adult psychiatric inpatient setting and examine feasibility of running a full-scale randomised controlled trial. In particular, to assess: 1. Acceptability of two different methodologies to professionals and patients 2. Feasibility of recruitment processes and assessment of recruitment bias 3. Identify the number of eligible participants, participant rates and retention rates 4. Researcher time and costs per participant 5. Obtain initial estimates of parameters of proposed outcome measures including an estimate of group clustering. 6. The intervention in terms of testing components, measuring adherence and estimating the likely intervention effect
Number of Patients	**Off-ward:** 30 (20 group music therapy, 10 treatment as usual) **On ward:** 18 (9 group music therapy, 9 treatment as usual) **Total: 48** *Semi-structured interviews:* Patients: 10 (optional) Music therapists: 2 Ward staff: 10 **Total including staff interviews: 60**
Main Inclusion Criteria	Intervention: • Adults aged 18 or above, any gender, admitted to and receiving treatment on an acute psychiatric ward • Willing to receive group music therapy or treatment as usual • Willing to be randomised to group music therapy or treatment as usual (stage 1, off-ward arm only) • Capacity to give informed consent • Sufficient English language ability to complete measures or access to assistance from an interpreter. *Semi-structured interviews: Music therapists and ward staff* • Music therapists: Providers of music therapy intervention • Ward staff: Working on the ward at the time of study intervention • Capacity to give informed consent

Statistical Methodology and Analysis (if applicable)	Descriptive analysis will show participation rate, intervention usage and retention rate for participants completing the intervention, the distribution of various outcome measures, in both intervention and control groups, characteristics of non-participants. Qualitative methodology will be used to analyse the data from semi-structured interviews and recorded sessions – we will use thematic analysis according to the framework described by Braun and Clarke (2006) which involves six stages of analysis – familiarisation, initial coding, discovery of themes, reviewing themes, formalising and naming final themes and reporting.
Proposed Start Date	10.04.2017
Proposed End Date	31.01.2018
Study Duration	9 months 22 days

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4. INTRODUCTION

4.1 Background

Burden of condition

Acute psychiatric inpatient care has been subject to many criticisms and reforms in the last few years (CQC,2012; MIND, 2011; SCMH,2006). Lengths of stay are reducing rapidly and concerns have been raised regarding the quality and access to therapeutic activities (MIND, 2011; NHS Benchmarking Network, 2013). In the year 2014-15 1.8 million people used mental health services, with 103,840 being admitted to hospital. The costs of inpatient adult acute care are high with a median cost of around £11,500 per admission (CAAPC, 2016). There are large inequalities in those who are admitted. Black or Black British groups had the highest proportion of time in hospital which is more than double white ethnic group figures and are more likely to be detained with 56.9 detentions per 100 inpatients. Women are more likely to be detained than men – for every 100 female inpatients, there were 41.9 detentions, compared to 38.5 among male inpatients. (HSCIC, 2016).

In recent years, there has been a decline in bed numbers, leading to increased occupancy on wards and difficulties discharging patients. This has led to many services raising their threshold for admission, which in turn has led to a higher level of symptom severity and level of risk encountered in those patients who are admitted (CAAPC,2016).

Music therapy in acute inpatient care

Acute inpatient services have undergone rapid changes in the last decade (CQC, 2012; MIND, 2011; SCMH,2006). Current policies seek to offer patients alternatives to hospitalisation, a range of treatment options and to place patients at the centre of their care (HM Government, 2011). Acute inpatient care has been criticised for a lack of therapeutic engagement and emphasis on medical treatment and lengths of stay have reduced (MIND, 2011; NHS Benchmarking Network, 2013). Whilst alternatives to hospitalisation increase, it is widely acknowledged that hospitalisation will still be required for some patients. Music therapy has a history of provision within inpatient care and an increasing evidence base (Carr, Odell-Miller & Priebe, 2013). Despite this, practice can vary and within the UK, sessions are usually offered only once per week, limiting access. Research from the United States suggests that it is possible to provide music therapy up to five times per week for inpatients (Silverman, 2009; Silverman & Leonard, 2013), but intervention methods differ substantially to methods employed within the UK and have not been rigorously evaluated over the duration of inpatient stay.

There is evidence that music therapy is effective in engaging patients with low therapy motivation, and treating negative symptoms and depression (Erkilla et al., 2012; Gold et al., 2013; Mossler et al., 2012). However, a minimum number of sessions are required to achieve clinical benefit and there is little evidence underpinning the practice of music therapy in acute environments (Carr et al., 2013; Gold et al., 2009). A doctoral study ascertained that increasing the frequency of

music therapy was accepted by inpatients and by offering sessions three times per week, patients attended three times as many sessions whilst in hospital (Carr, 2014). The study provided an objective description of practice and identified specific interventions associated with positive appraisals by patients.

Overall rationale for the feasibility study

Within the Medical Research Council framework (MRC, 2008) for the development of complex interventions, the first steps of identifying the evidence base, theories and modelling of processes and outcomes have now been completed. However, if the intervention is to be tested in a randomised controlled trial, further steps are now needed to formalise the intervention and to ascertain how to best implement this methodology in acute inpatient context. A feasibility study will enable an assessment of how best to design a larger trial and will provide information on how to best implement this to ensure methodological rigour (Bird et al., 2014; Lancaster et al., 2004).

The aim of this study is to conduct an exploratory pilot to assess the feasibility and gain experiences of implementing a randomised controlled trial methodology to assess intensive group music therapy on acute adult psychiatric inpatient wards.

The research has potential benefits for both patients and the NHS. The study will lead to improved practice of music therapy in acute settings and improved quality of inpatient care. This research will provide information on the feasibility and variability of outcomes to inform future randomised controlled trials. If demonstrated to be feasible, a protocol for a full randomised controlled trial will be produced as a study deliverable. Such information may inform future music therapy and wider NHS research in acute inpatient contexts.

Preclinical Data

This study is the final piece of work within an ongoing NIHR Clinical Lectureship. Earlier Work Packages have helped to define the intervention and potential change processes. This includes modelling of processes and outcomes of intensive group music therapy (Carr, 2014), microanalysis of processes within music therapy groups, development of a manual and assessment of its acceptability via focus groups with patients, music therapists and ward clinicians.

Rationale and risks/benefits

Music therapy is a complex intervention in that it utilises a range of components to promote health. Such components include a therapeutic relationship, a range of active and receptive musical activities and verbal reflection. These are provided flexibly in response to the individual or group and are often led by the patient.

There is evidence for music therapy being effective for a range of mental health problems including depression (Erkilla et al., 2011), schizophrenia (Mossler et al., 2012, Talwar et al., 2006) and negative symptoms in particular (Gold et al., 2013; Gold et al., 2009). A meta-analysis has identified a dose-effect response, whereby

symptom improvement is associated with the number of sessions received (Gold et al., 2009). Music therapists commonly provide groups to patients with mixed diagnoses and there is evidence for the potential to engage patients with low therapy motivation (Gold et al., 2013). Whilst the evidence base is improving, few studies have examined group music therapy with acute inpatients, where the setting and needs of patients differ dramatically.

Guidance for the development of complex interventions (MRC, 2008) outlines a number of phases. In the development phase, systematic searching of the literature is done to identify evidence for any potential effect. Theories are identified and developed and then applied to modelling of processes and outcomes. Once the intervention is understood in terms of its theory, potential processes and outcomes the feasibility of conducting an experimental study is then ascertained. This provides information as to whether it is possible to conduct a larger scale trial using this methodology, what changes might be required and whether the intervention requires further development for it to work in practice.

A recent doctoral study looked at how group music therapy is delivered in acute psychiatric inpatient settings. A systematic review identified current theories, methods of practice and evidence from outcome studies (Carr, Odell-Miller & Priebe, 2013). It concluded that there is currently no agreed model of music therapy for acute psychiatric inpatients, offering group music therapy intensively may increase access to sessions and active methods may be of particular importance in obtaining positive clinical outcomes.

An observational study (Carr, 2014) then looked at whether providing music therapy intensively (ie. more than once a week) was acceptable to inpatients and built a model of music therapy processes and outcomes. The study identified that intensive delivery is acceptable to inpatients, that patients attending groups offered 3 times per week accessed 3 times more sessions than those offered once or twice per week, and identified aspects of music therapy practice specific to and viewed positively by inpatients. Features included sharing of known songs within an improvised musical structure, following patient preferences for the type of musical activity and providing greater direction and structure when the group loses cohesion. The principles ascertained from this study were then incorporated into a manual for intensive group music therapy, which will be implemented in this feasibility study.

Whilst there is now small but increasing evidence that music therapy is effective in reducing a range of mental health symptoms, studies vary dramatically in the provision of music therapy as an intervention and none have evaluated intensive group delivery within an acute inpatient context (Carr et al., 2013). Conducting research within an acute inpatient setting has a number of challenges. On admission, patients may not be in a mental state where they are able to reflect on whether or not to participate in research. Symptom severity, emotional and behavioural states may fluctuate, and the short lengths of stay mean that there is a rapid turnover of patients. Before evaluating the effectiveness of the intervention developed in

previous work packages, it will be important to assess whether a randomised controlled trial methodology is feasible in this setting. Such an evaluation will provide important information regarding anticipated rates of recruitment, whether such a methodology is acceptable, whether the intervention is adhered to and data regarding the variability of outcomes to aid planning of a larger trial.

In order to test the effectiveness of intensive group music therapy for acute adult psychiatric inpatients, further development is necessary prior to conducting a full scale trial. By running a feasibility study, it will be possible to test the integrity of the study protocol and randomisation procedures, the acceptability of the procedures and questionnaires to patients and provide data on variability of outcomes to enable selection of a primary outcome and sample size calculation (Bird et al., 2014; Lancaster et al., 2004). Such piloting will provide a firmer methodological basis and experience for conducting a future trial. The aim of the present study is to ascertain the feasibility of using a randomised controlled trial methodology piloting two different methodologies: individual randomisation to an off-ward music therapy group and piloting of a cluster randomised design, involving two wards, one with music therapy offered on the ward, and one without music therapy input.

The feasibility study will provide evidence as to whether a randomised controlled trial methodology is feasible to test the effectiveness of this intervention and data to inform decisions as to which methodology (individual randomisation or cluster randomisation) will be most appropriate. The data will also provide information for future studies within acute inpatient settings including data to further refine the intervention manual, and the appropriateness and variability of outcome criteria.

Risks

The risks of participation are considered to be low. Music therapy is currently part of standard acute inpatient care within East London NHS Foundation Trust. To date, the method of delivery has been determined by therapists' training background and service setup. This study will be the first to formally describe the intervention's specific application within an acute inpatient setting. Within the literature, very few risks have been described for group music therapy in these environments and these are assessed to be no greater than risks in normal standard practice (Carr et al., 2013).

Whilst a number of trials have been conducted of music therapy within inpatient settings, few have examined group delivery or adverse events within their design. Of the two that have assessed adverse events, only one risk relating to study design was identified. A trial of individual music therapy for clients with severe mental illness and low therapy motivation assessed no adverse events (Gold et al., 2012). Another study of individual music therapy (Morgan et al., 2011), conducted in Australia found participants learned of each other's allocation, which caused agitation in some patients and led the researchers to change to a quasi-randomised design. Participants were recruited in the first 24 hours of admission and the researcher was also the music therapist providing treatment. In order to address this, we will recruit

only at a point where the participant is assessed to have capacity to consent. We will ensure that the randomisation process is explained carefully to potential participants and ensure that the criterion of willingness to be randomised is met as part of the inclusion criteria. Music therapy will be provided by clinicians separate to the researchers conducting assessments. Patients who wish to receive music therapy immediately will be not be prevented from doing so. They will be advised that they will not be able to participate in the study and will be referred to another music therapist in the service.

For those randomised to treatment as usual (N=10), potentially beneficial treatment will be withheld from the point of consent to 6 months later. Despite the measures outlined above, this still has the potential to cause some distress to some participants. Wider arts therapies services exist within the service where the research will take place which patients will still be able to access. Participants will not be prevented from accessing these (art, dance movement or drama therapy) as inpatients and will be offered the option of referral to a music therapy group in the community should they wish to access this at their 6 month assessment. Should a participant be allocated to the control group and wish to access music therapy sooner, they will be withdrawn from the study and offered individual music therapy over the course of their admission. As this is a feasibility study to assess the acceptability and feasibility of the research procedures, all cases will be recorded and taken into account within the final study analyses.

We will take into account any distress caused by the randomisation process as part of the study safety reporting and will halt the study if the levels of adverse events related to this become frequent or are assessed as severe and related to the study.

The questionnaires contain a number of personal questions but none outside of the scope of usual clinical assessment within acute psychiatric hospitals. The researchers will remind participants that they do not have to answer a question if they feel uncomfortable and are trained to ask questions in a manner sensitive to the current state of the patient.

The intervention will be provided by two HCPC registered music therapists with extensive experience in provision of group music therapy in both acute and community mental health. The music therapists will liaise closely with the clinical teams to ensure full risk management and are fully trained and familiar with Trust risk management and safety policies.

Benefits

Potential benefits of participation are that patients will receive a higher standard of monitored care as a consequence of the research protocol and a potentially beneficial treatment which may possibly help the participant to manage arousal and relationships, shorten the length of inpatient stay and improve the patient's experience of this. Whilst there is some research evidence to indicate this potential, we have as yet no evidence to conclusively guarantee such benefits in the current

study. This is explained explicitly in the Patient Information Sheet. Patients may benefit in the knowledge that their experiences and views are contributing to wider development of care within inpatient services.

5. TRIAL OBJECTIVES

5.1 Feasibility objectives

To assess the feasibility of implementing a randomised controlled trial of intensive group music therapy in acute adult psychiatric inpatient settings, with 2 weeks, 4 weeks, 3 and 6 month follow-up. Including:

1. The acceptability of two different methodologies to professionals and patients
2. Feasibility of recruitment processes
3. Identify the number of eligible participants, participation rates and retention rates
4. Researcher time and costs per participant
5. Appropriateness of outcome measures, data regarding variability of outcome for sample size calculation, and an estimate of control mean to ensure change is feasible
6. The intervention in terms of testing components, measuring adherence and estimating the likely intervention effect.

5.2 Proposed primary clinical outcome

- Psychiatric symptoms as measured by the Brief Psychiatric Rating Scale (BPRS).

5.3 Proposed secondary clinical outcomes

- Social functioning, as measured by the Life Skills Profile (LSP, Rosen et al., 1989).
- Self-esteem, as measured with the Rosenberg self-esteem scale (RSES, Rosenberg, 1989).
- Self-efficacy, as measured with the General Perceived Self-efficacy Scale (GPSES, Schwarzer & Jerusalem, 1995).
- Satisfaction with inpatient stay, as measured with the Client Assessment of Treatment (CAT, Priebe & Gruyters, 1995).
- Challenging behaviour, as measured by number of recorded incidents on ward.
- Hospitalisation, as measured by length of inpatient stay, number of readmissions, numbers discharged or ready for discharge.

5.4 Outcome measures/endpoints

As this is an exploratory pilot we are primarily interested in metrics such as effect sizes and descriptive statistics (mean, mode, standard deviation etc). To cover the range of areas of change we are interested in this context, we will collect data at baseline, weekly process measures during treatment and at 2 weeks, 4 weeks, 3 and 6 month follow up.

- *Primary Clinical Endpoint*

4 weeks after the intervention – as measured by clinical symptomatology, social functioning, self-esteem, self-efficacy, satisfaction with inpatient stay, number of incidents on the ward and hospitalisation.

- *Secondary Clinical Endpoints*

2 weeks, 3 months and 6 months after the intervention - as measured by clinical symptomatology, social functioning, self-esteem, self-efficacy, satisfaction with inpatient stay, number of incidents on the ward and hospitalisation.

5.5 Process measures

Music therapy attendance, mood (Dispositional Mood Scale (Huelsman, Nemanick & Munz, 1998)) and ward relationships (Relationship Satisfaction Scale (Burns, 1983)) will be measured weekly. Questionnaires will be distributed by the music therapists or Clinical Studies Officer and self-completed by the participants.

Objectives	**Outcome Measures**	**Time point(s) of evaluation of outcome**
Assess acceptability of two different methodologies to professionals and patients.	Recruitment rates assessed by number of eligible participants, participation rates and retention rates.	T0, 2 weeks, 4 weeks, 3 and 6 months
Feasibility of recruitment processes.	Compliance with intervention. Semi-structured interviews.	End of intervention 1 month follow-up
Identify N eligible participants, participant rates and retention rates.	Screening log Case report form Researcher diary	6 months
Assess researcher time and costs per participant.	Screening log Case report form Researcher diary	6 months
Appropriateness of outcome measures: variability of outcome for sample size calculation; estimate of control mean to ensure change is feasible.	Variability of outcome and estimate of control mean: BPRS, RSES, GPSES, CAT, ward incidents and hospitalisation data.	T0, 2 weeks, 4 weeks, 3 and 6 months
Intervention components, adherence and estimate of likely intervention effect.	Attendance of music therapy Therapist self-rated adherence Video rated 25%	End of intervention

6. METHODOLOGY

6.1 Inclusion Criteria

- Adults aged 18 or above, any gender, admitted to and receiving treatment on an acute psychiatric ward
- Willingness to receive group music therapy or treatment as usual
- Willingness to be randomised to group music therapy or treatment as usual (stage 1, off-ward recruitment only)
- Capacity to give informed consent
- Sufficient English language comprehension to complete measures, or access to assistance from an interpreter

6.2 Exclusion Criteria

- Presence of an organic mental disorder
- Insufficient language comprehension and no available interpreter
- No capacity to give informed consent (monitoring of capacity will occur throughout)

6.3 Study Design / Plan – Study Visits

This study is a single centre exploratory pilot to assess the feasibility of conducting a randomised controlled trial of ward based and off-ward intensive group music therapy, with a nested process evaluation. Recruitment will take place in two stages.

In stage 1, participants will be randomised to receive the intervention off the ward or treatment as usual. As this is an exploratory study, we will employ an unbalanced allocation with 20 participants allocated to the intervention and 10 to treatment as usual control.

In stage 2, to simulate a cluster randomised design, music therapy will be provided on one single ward, with a second ward, not receiving music therapy input as a comparison. Patients on both wards will be invited to join the study to complete measures. We plan to recruit 18 participants over a 4 week time period.

Data will be collected before randomisation, weekly process measures, 2 weeks, 4 weeks, 3 month and 6 month follow ups. The trial cannot be fully blinded as clinicians and patients cannot be masked from the allocation of patients to experimental or control group. In stage 1, statistical analysis cannot be blinded due to the unequal allocation of patients. However, the researcher conducting outcome assessments will be masked to the allocation of patients and eligibility and baseline assessments will occur pre-randomisation. Some outcome data will also be obtained from medical records and is not influenced by whether or not the researcher is blinded.

A process evaluation will be conducted with the aims of:

1. Understanding exactly how the intervention was delivered in practice (treatment fidelity analysis).
2. Describing processes of attendance and hypothesised process factors of self-reported mood and group relationships from week to week.
3. Understanding subjective experiences and attributions for change of the intervention from the perspective of patients, music therapists and referring staff.
4. To compare reported quantitative and qualitative processes against the proposed logic model and revise accordingly.

The process evaluation will employ an embedded mixed methods design and will consist of data collection of video data of the off-ward intervention itself, client self-reported measures and qualitative end semi-structured individual interviews. Semi-structured interviews will be conducted with a minimum of 10 participants by a researcher with lived experience of mental health services use, who will receive training and support from the Chief Investigator and Unit for Social and Community Psychiatry. These semi-structured interviews are optional for patient participants. Further semi-structured interviews will be conducted with the two music therapists delivering the intervention and a minimum of 10 ward staff.

6.3.1 Setting

The study will take place at a single hospital (Tower Hamlets Centre for Mental Health) within East London NHS Foundation Trust. Assessments and semi-structured interviews will take place on Trust premises, or within participants' homes if discharged at follow up. The intervention will be run by two HCPC registered music therapists (Bent, Wetherick) who are employees of East London NHS Foundation Trust.

6.3.2 Recruitment

- Visit 0: Pre-screening eligibility assessment

The researcher and allocated Clinical Studies Officer (research team) will liaise with ward staff to identify new admissions who fulfil the inclusion criteria and are at a point where they are well enough to understand what the study involves. The ward member of staff will gain assent from this person for the researcher to go through the study using the participant information sheet (PIS).

The researcher will be based at the hospital and will be able to talk to the participants about the study quickly after this first contact. Participants will have the opportunity to ask any questions during this time. They will then have an opportunity to discuss the study with the researcher and their ward team before they decide whether or not to participate. They will have a minimum of 24 hours to think about whether or not they would like to participate in the study. If participants wish to take more time to decide the research team will organise to re-contact them a few days later to discuss their participation.

The study screening number will be allocated as follows:
Study Code **S**01
Ward Code – 3 letter code for each ward
Participant Code – 3 digit code given consecutively and attributed at each ward

For example, the first participant screened on Brick Lane ward would be assigned the code S01-BLA-001. If they were then recruited to the study, they retain the same number with the S removed, upon consent, becoming 01-BLA-001 on the enrolment log.

- *Visit 1: Consent and baseline assessments*
Members of the research team will return after a minimum of 24 hours to ascertain whether the person is willing to take part. Mental capacity will be re-assessed.

Those who are still interested will be talked through the consent form with opportunities for further questions and if they are happy, obtain written informed consent. The researcher will ascertain if the participant is able to continue with the baseline assessment. If it is not possible to do so immediately after taking consent, the researcher will arrange to visit within the next 5 working days in order to complete this.

<u>Screening/Confirmation of eligibility</u>

- Date of admission and absence of organic disorder confirmed by clinical team
- Willingness to receive music therapy
- Willingness to be randomised to music therapy or treatment as usual (off-ward group only)

<u>Baseline assessments</u>

- Demographic and clinical information
- Baseline assessments (BPRS, IIM, CAT, LSP, GPSES, RSES, DMS, RSS)
- Case report form completed by researcher

Randomisation for the off-ward group will be completed at the end of visit 1 (see section 7.3) and the participant will be informed as soon as possible of their allocation.

6.3.3 Intervention
<u>Stage 1: Off-ward group, individual randomisation</u>
The study intervention will be provided for up to 12 weeks. Patients on four wards, not currently receiving group music therapy input will be randomised to receive either group music therapy or treatment as usual. Patients randomised to receive group music therapy will attend group music therapy off the ward, four times per week for the duration of their inpatient stay up to a maximum of 4 weeks, whichever is sooner. The average length of hospital stay is 28 days, so it is expected that

patients will have access to approximately 12-16 sessions of music therapy whilst in hospital.

Stage 2: On-ward group, simulation of cluster randomisation

To simulate a cluster randomised trial design, the study intervention will be provided on one ward, three times per week for up to 4 weeks. Patients on this ward will be free to choose to attend the intervention regardless of study participation.

Patients from two wards (one with music therapy intervention provision, one without music therapy provision) will be invited to join the study to complete assessments over the 4 weeks that the intervention is provided.

Both stages:

Sessions will be run by 2 music therapists, consist of active music making and verbal reflection and will last for 1 hour. Treatment as usual will consist of access to usual treatments provided within the acute inpatient setting including other arts therapies modalities. Process measures of mood (DMS) and ward relationships (RSS) will be taken weekly.

6.3.4 Visits 3-5: Follow up outcome assessments

A full standardised outcome framework and qualitative dataset will be recorded at baseline, 2 weeks, 4 weeks, 3 and 6 months from enrolment into the study. Follow up visits will be conducted face to face on the site of the hospital wherever possible. If participants are unwilling to return to the hospital, they will be offered a space within the study offices, based at Newham Centre for Mental Health, face to face meeting in their home, or via telephone contact.

At least 3 attempts via two different methods (phone and letter) will be made by research staff to contact and collect follow up data, after which the participant will be considered lost to follow up (see criteria for withdrawal).

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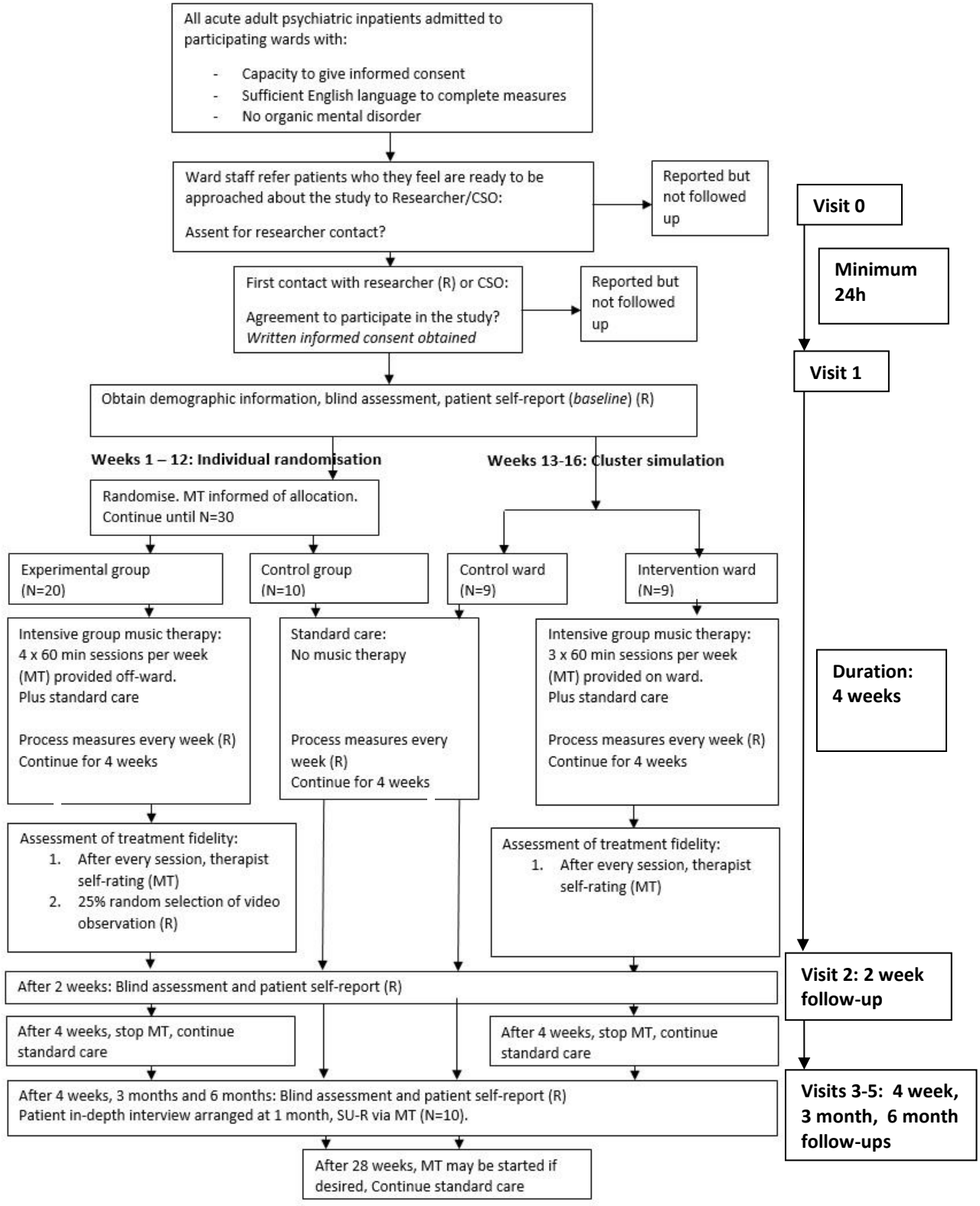
6.4 Study Scheme Diagram

A summary flow chart of the study design, stages of data collection and roles is attached below.



Study design flow chart: R- Researcher; CSO- Clinical Studies Officer; MT- Music Therapists, SU-R- Service-user researcher

7. STUDY PROCEDURES

7.1 Informed Consent Procedures

Those with delegated roles for informed consent are the Chief Investigator, Research Assistant and Clinical Studies Officers (research team). 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 protocol, principles of Good Clinical Practice (GCP) and Declaration of Helsinki (World Medical Association, 2013).

Patients will be recruited from acute adult wards within Tower Hamlets Centre for Mental Health. The researcher and allocated Clinical Studies Officers will liaise with ward staff to identify new admissions who fulfil the inclusion criteria and are at a point where they are well enough to understand what the study involves. The ward member of staff will gain assent from the person to refer them to the researcher to go through the study using the participant information sheet (PIS). Visual aids will be used to explain the study if needed (see flow-chart on final page of PIS; and submitted visual aid documentation).

The researcher will be based at the hospital and will be able to talk to the participants about the study quickly after this first contact. Participants will have the opportunity to ask any questions during this time. They will then have an opportunity to discuss the study with the research team before they decide whether or not to participate. They will have a minimum of 24 hours to think about whether or not they would like to participant in the study. If participants wish to take more time to decide the research team will organise to re-contact them a few days later to discuss their participation. Members of the research team will talk through the consent form with participants and obtain written informed consent.

During informed consent, we will request consent from participants to inform their Health Care team of their participation in the study.

Participants will be free to withdraw and any time without giving reasons and without prejudicing 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 utilising guidance developed by the British Psychological Society (Dobson, 2008). Should a person be assessed as lacking capacity prior to informed consent, they will be informed that 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
- be able to retain the information long enough to make an effective decision
- be able to make a free choice
- be 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 participant lose capacity whilst attending the intervention, the music therapists will liaise with the clinical team to assess current risk and whether they should continue receipt of the intervention. If the team decides it is in the best interests of the participants to continue or cease the intervention, this will be documented. In both cases, no further research data will be collected from this point. The participant will be withdrawn from the study and the reasons documented for the purposes of feasibility assessment.

If a participant is assessed to have lost capacity to consent when attending a research assessment, the participant will be withdrawn from the study. For withdrawn participants, all data collected up to the point of withdrawal will be retained. Participants also have the right to request withdrawal of data at any point. This is outlined in the PIS and consent form.

Payments to participants:
Participants who provide informed consent will be offered £10 at 3 and 6 month follow up. It is anticipated that at the 3 and 6 month follow up, participants will have been discharged from hospital and will be taking time and travelling to attend the 3 and 6 month follow up. We propose a payment of £10 in the form of a shopping voucher, which is in line with Trust policy for reimbursement. This will provide a means of reimbursing time given to the study and may counter possible attrition at these later stages of the study.

For music therapists and ward staff semi-structured interviews, we will offer up to £10 to reimburse travel expenses incurred in attending meetings with the researcher if outside of their usual workplace.

7.2 Screening, Enrollment
A brief screening questionnaire will be used to determine whether patients meet inclusion and exclusion criteria. Eligible participants will be recruited into the first stage of the trial over a 10 week period, starting in April 2017 and into the second stage over a 4 week period, starting in July 2017. Research staff will identify whether each identified potential patient meets eligibility criteria and document the process. Eligible patients will be approached by a member of the ward staff from their team and asked if they are interested in the study and willing to be approached by researchers. If they agree, then the researcher will approach the potential

participants in liaison with clinical staff. Potential participants will be given a detailed explanation of the study and a written Participant Information Sheet (PIS). If they agree to participate, they will be asked to sign a consent form and complete the baseline assessment with the researcher. Baseline data collection will be taken as soon as possible after informed consent and prior to randomisation.

7.3 Randomisation Procedures (stage 1 only)

Randomisation will be conducted via an online randomisation service (randomizer.org) for this study at the individual level. This service is free to use and does not require a contract. In order to obtain sufficient data regarding the intervention, randomisation will be unbalanced so that 2/3 receive the intervention and 1/3 receive treatment as usual. As this is a small scale exploratory study, we will not be using a clinical trials unit.

Randomisation will be made immediately after baseline assessment by a researcher (Dr Giacco or Dr Bird), independent from the study team at the Unit for Social and Community Psychiatry. The randomising person will inform the Chief Investigator and music therapists of participants' allocation via NHS email, who will then inform the participant and give further support and advice if necessary, in liaison with the clinical care team.

7.4 Blinding

Given the nature of the trial, it is not possible to blind the participants to their intervention as there will be obvious differences in the intervention they are involved in. Members of the treating healthcare team will not be blinded.

One Clinical Studies Officer will be unblinded to assist with recording process measures. The researcher and second clinical studies officer conducting the assessments and data entry however will be blind to the allocation, and it is their responsibility to maintain this blinding as much as realistically possible. Blinded outcome assessors will remind participants at every contact not to reveal whether they have received music therapy or not. Unblinding of the study team will happen once the data set has been completed and locked, and preliminary analysis conducted.

Should a participant need to be withdrawn from the study, this will be logged by the music therapists. Study code will only be broken if there is a severe adverse event (SAE) where it is necessary for the investigator to know whether the patient is receiving music therapy.

- The code breaks are held at the Unit for Social and Community Psychiatry (USCP) and are the responsibility of the CI
- In the event a code is required to be unblinded, a formal request for unblinding will be made by the investigator or treating health care professional
- If the person requiring unblinding is a member of the investigating team then a request to the holder of the code break list, or their delegate will be made and the unblinded information obtained
- If the person requiring the unblinding is not the investigator then that health care professional will notify the investigating team that an unblinding is

required for a trial subject and an assessment to unblind should be made in consultation with the clinical and research teams

- On receipt of the treatment allocation details, the CI or treating health care professional will continue to deal with the participant's medical emergency as appropriate
- 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 advisory panel for further safety monitoring.
- As the CI is responsible for the medical care of the individual trial subject (Declaration of Helsinki 2013 and ICH 4.3) the coding system in blinded trials should include a mechanism that permits rapid unblinding (ICH GCP 5.13.4). The investigator cannot be required to discuss unblinding if he or she feels that emergent unblinding is necessary.

7.5 Study intervention

7.5.1 Intensive group music therapy

Stage 1: Individual randomization to off-ward group

Intensive group music therapy will be provided for up to 12 weeks, beginning 2 weeks after recruitment begins, and ending 4 weeks after recruitment ends. Group music therapy will be provided in a room, off the ward for 4 times per week by trained HCPC registered music therapists with experience of providing group music therapy in acute adult psychiatric inpatient settings. Participants allocated to receive the intervention will attend until discharged or up to a maximum of 4 weeks. The intervention will end prior to the 12 weeks, should all 30 participants be recruited into and receive 4 weeks of music therapy before this time.

Stage 2: Cluster simulation with one on-ward group and one ward not receiving music therapy input

Intensive group music therapy will be provided for up to 4 weeks, beginning no more than 1 week after recruitment begins and ending 1 week after recruitment ends. Group music therapy will be provided in a room on the ward for 3 times per week by trained HCPC registered music therapists with experience of providing group music therapy in acute adult psychiatric inpatient settings. All patients on the ward will be invited to attend the group, regardless of whether they have consented to participate in research. The intervention will end after 4 weeks at which point existing weekly music therapy input will resume.

Both stages:

The intervention will be provided in accordance with the manual. Sessions will last for 1 hour, run by 2 music therapists and consist of active music making and verbal reflection. Participants will be encouraged to attend but are free to choose not to.

Should a participant miss a scheduled session, the music therapists will contact the participant to ascertain the reason for missing the session, check on their mental state and liaise with the ward clinicians if concerns are raised.

7.5.2 Music therapist management

Music therapists will be asked to attend a training session across two days to build familiarity with the manual and research procedures. The training will explain in detail the purpose of the intervention and the role of the music therapists. It will also cover common issues encountered in acute inpatient ward environments. The music therapists will already have experience of providing group music therapy in acute adult psychiatric inpatient environments and will have up to date training in safeguarding, prevention and management of violence and aggression, break-away and local policies and procedures.

Music therapists will receive weekly clinical supervision for the duration of the study and meet weekly with the Chief Investigator to discuss any concerns regarding the management and conduct of the study.

7.6 Concomitant medications

Participants will continue with concomitant medication and all other therapies as usual. If concerns are raised regarding the burden of attending music therapy, the service user will be advised to speak with the music therapists and ward team to ascertain whether or not to adjust the frequency of attendance and whether or not to continue in the study.

7.7 Procedure for Collecting Data including Case Report Forms (CRFs) and storage

Data will be a mixture of routinely collected data, patient reported outcome data, collected directly to the CRF and qualitative semi-structured interview data.

All researchers will be trained with the battery of assessments (BPRS, IIM, CAT, LSP, GPSES, RSES, RSS, DMS) and inter-rater reliability established. The assessing researcher will not be informed about the allocation of the patient. The assessment will begin with the primary outcome measure. The researcher will record what they think the allocation of the patient is at the conclusion of the intervention and whether blinding was broken or maintained. Researchers will also collect follow-up longitudinal routine data from medical records including number of recorded incidents during inpatient stay, length of hospitalisation, number of readmissions, numbers ready for discharge, numbers discharged and other psychological, arts therapies or arts based interventions received.

Qualitative semi-structured interviews will be conducted by a researcher with lived experience of mental health problems with support as necessary by the Chief Investigator, at the time of the one month follow up. Participation in these semi-structured interviews is optional. The aim of the semi-structured interview will be to explore the experience of participating in the trial, their experience of group music therapy and the impact the intervention had on their recovery more generally. Semi-structured interviews will also be held with the music therapists and ward staff from participating wards to explore their experience of taking part in the study and what

impact has the intervention may have had. These will be audio-recorded, transcribed and subjected to thematic analysis.
Adherence to the intervention will also be assessed by the proportion of sessions attended during the inpatient stay relative to the number of sessions available.

7.8 Measures

Feasibility measures:

1. Rates of recruitment: Number of eligible participants, participant rates and retention rates
2. Researcher time: calculated based on the number of patient contacts needed to complete assessments
3. Appropriateness of outcome measures: assessed by examining the variability of outcome and estimate of control mean to ensure change is feasible
4. Intervention: assessed by measuring adherence and estimating the possible intervention effect. Treatment fidelity will be assessed from video recordings. Content analysis of 25% of sessions will be performed guided by a rating schedule developed from the manual, assessing presence of required and proscribed features.
5. Acceptability of research methodology: Assessed via rates of recruitment, compliance and end semi-structured interviews with therapists, ward staff and participants.

Proposed primary outcome measure

Psychiatric symptoms as measured by the Brief Psychiatric Rating Scale.

Proposed secondary outcome measures

1. Social functioning (Life Skills Profile (LSP, Rosen et al., 1989); Ward relationships measured with the Relationship satisfaction scale (RSS, Burns, 1994))
2. Patient self-esteem (Rosenberg self-esteem scale (RSES, Rosenberg, 1989); General perceived self-efficacy scale (GPSES, Schwarzer & Jerusalem, 1995),
3. Satisfaction with inpatient stay (Client assessment of treatment (CAT, Priebe & Gruyters, 1995))
4. Challenging behaviour (number of recorded incidents on ward)
5. Hospitalisation: Length of inpatient stay, number of readmissions, numbers discharged or ready for discharge

Weekly process measures

1. Self-reported mood pre- and post session (DMS)
2. Ward relationships (RSS, Burns, 1994)

7.9 Data sources, collection requirements and transfer of data

The following baseline data will be collected:

Socio-demographic and clinical: Date of birth, sex, country of birth, first language, primary diagnosis, secondary diagnoses, length of illness, N previous admissions, medication prescribed, drug type and dose, group and psychological interventions received	Clinical and socio-demographic form: 1. Sociodemographic/clinical information 4. Medication 5. Group and psychological interventions
Musical history: Interest in music Music education level, number of instruments played and type, Previous receipt of music therapy	 Interest in Music Scale (IIM) 1. Clinical and socio-demographic form: 2. Musical history
Hospitalisation: Number of previous hospital admissions. Date of admission to ward. Date ready for discharge, date discharged. Length of hospitalisation (days). Type of admission Voluntary or involuntary Recorded incidents on ward this admission (date, type, victim or perpetrator)	 1. Clinical and socio-demographic form: 3. Hospitalisation. 4. Recorded incidents on ward Data to be taken from medical records.
Psychiatric symptoms	Brief Psychiatric Rating Scale (BPRS)
Social Functioning	Life Skills Profile (LSP)
Self- esteem	Rosenberg Self-esteem scale (RSES)
Self-efficacy	General Perceived Self-efficacy Scale (GPSES)
Satisfaction with inpatient stay	Client Assessment of Treatment (CAT)
Ward relationships Staff and patients	Relationship Satisfaction Scale (RSS)
Current mood	Dimensional Mood Scale (DMS)

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Trial Assessments:

Timepoint	Purpose	Assessments
Process measures: Part 1: Weeks 1-12 Part 2: Weeks 13-18	**Process measurement:** Acceptability/participation rates: Mood pre and post session: Ward relationships: Intervention adherence:	Attendance/reason for non-attendance (MT/CSO) DMS (weekly pre- and post session) (SU) RSS (weekly pre- and post session)(SU) Therapist adherence form (MT)
2 week follow-up	**Outcome measurement:** Psychiatric symptoms Social functioning Self-esteem Self-efficacy Satisfaction with inpatient stay Challenging behaviour Hospitalisation	 BPRS (R) LSP (R) RSES (SU) GPSES (SU) CAT (SU) Medical records (R) Medical records (R)
4 week follow-up	**Outcome measurement:** Psychiatric symptoms Social functioning Self-esteem Self-efficacy Satisfaction with inpatient stay Challenging behaviour Hospitalisation	 BPRS (R) LSP (R) RSES (SU) GPSES (SU) CAT (SU) Medical records (R) Medical records (R)
3 month follow-up	**Outcome measurement:** Psychiatric symptoms Social functioning Self-esteem Self-efficacy Satisfaction with inpatient stay Challenging behaviour Hospitalisation	 BPRS (R) LSP (R) RSES (SU) GPSES (SU) CAT (SU) Medical records (R) Medical records (R)

6 month follow-up	**Outcome measurement:**	
	Psychiatric symptoms	BPRS (R)
	Social functioning	LSP (R)
	Self-esteem	RSES (SU)
	Self-efficacy	GPSES (SU)
	Satisfaction with inpatient stay	CAT (SU)
	Challenging behaviour	Medical records (R)
	Hospitalisation	Medical records (R)

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Methods and timing for assessing, recording and analysing outcome parameters:

Outcome	Method	Success criteria				Timing
		Stop	**Continue, modify protocol**	**Continue with modification but monitor closely**	**Continue without modifications**	
Acceptability of methodology	Recruitment & retention rates as below Compliance Semi-structured interviews	As below Mean attendance <3 sessions Unfavourable views, serious concerns	As below Mean attendance<10 sessions Unfavourable views, suggestions for modification	As below Mean attendance 10 sessions Favourable views, suggestions for modification	As below Mean attendance 10+ sessions Favourable views, no concerns	End of recruitment End of intervention 4 week follow up
Feasibility of recruitment processes	Screening rates	Stage 1: Identify<50 eligible subjects Stage 2: Identify <30 eligible subjects	Stage 1: Identify<65 eligible subjects Stage 2: Identify <35 eligible subjects	Stage 1: Identify 65-70 potentially eligible subjects Stage 2: Identify 35-40 potentially eligible subjects	Stage 1: Identify > 70 potentially eligible subjects Stage 2: Identify > 40 potentially eligible subjects	End of recruitment
	Recruitment rates	Stage 1: Recruit <50% of sample size Stage 2: Recruit <50% of sample size	Stage 1: N<24 in 10wks, <5% per week Stage 2: N<14 in 4 wks, <15% per week	Stage 1: N=25-30 in 10wks, <10% per week Stage 2: N=15-18 in 4 wks, <25% per week	Stage 1: N=30 in 10wks, 10% per week or greater Stage 2: N=18 in 4 wks, 25% per week or greater	End of recruitment
	Participation rates	Participation rate < 5%	Participation rate 5-15%	Participation rate 15-25%	Participation rate 25% or greater	6 month follow up
	Retention rates	Attrition > 75%	Attrition 50-75%	Attrition 30-50%	Attrition<30%	6 month follow up
	Semi-structured interviews	N/A	Major suggestions to improve recruitment processes	Minor suggestions to improve recruitment processes	No suggestions to improve expressed	4 week follow up
Identify N eligible participants, participation rates and retention rates	N identified by ward staff	Stage 1: Identify<50 eligible subjects Stage 2: Identify <30 eligible subjects	Stage 1: Identify<65 eligible subjects Stage 2: Identify <35 eligible subjects	Stage 1: Identify 65-70 eligible subjects Stage 2: Identify 35-40 eligible subjects	Stage 1: Identify > 70 eligible subjects Stage 2: Identify > 40 eligible subjects	End of recruitment
	N expressing interest	Stage 1: <30 express interest Stage 2: <20 express interest	Stage 1: 30-40 express interest Stage 2: 20-25 express interest	Stage 1: 40-60 express interest Stage 2: 25-30 express interest	Stage 1: >60 express interest Stage 2: >30 express interest	End of recruitment

	N providing consent N lost to follow-up	Stage 1: <15 provide consent Stage 2: <10 provide consent Attrition>75%	Stage 1: 15-25 provide consent Stage 2: 10-14 provide consent Attrition 50-75%	Stage 1: 25-30 provide consent Stage 2: 15-18 provide consent Attrition 30-50%	Stage 1: 30 provide consent Stage 2: 18 provide consent Attrition <30%	End of recruitment 1 month follow up
Researcher time and costs per participant	Researcher diary	N/A	Researcher time exceeds allocated time requiring additional study support	Researcher time and cost only just covers time required	Researcher time and cost fully covers time required	6 month follow up
Appropriate outcome measures	Variability of outcome Estimate of control mean and SD of change	No difference or clinically important difference favouring control detected based on confidence limits	Difference cannot be detected based on confidence limits but data suggests improvement favouring intervention	Difference can be detected based on confidence limits	Clinically important difference can be detected based on confidence limits	End of intervention
Intervention components	Therapist adherence Semi-structured interviews	Adherence <50% Serious concerns expressed regarding intervention	Adherence <50% Major suggestions to adapt intervention	Adherence 50-75% Minor suggestions to adapt intervention	Adherence >75% No concerns or suggestions to adapt intervention	End of intervention
Intervention adherence	Therapist self-rated adherence Video rated adherence	Adherence <25%	Adherence 25-50%	Adherence 50-75%	Adherence > 75%	End of intervention

7.9 Follow-up procedures

The study duration allows for follow up to a maximum of 6 months with data collection at 2 weeks, 4 weeks, 3 and 6 months post enrolment into the study. After this point, participants will leave the study and return to 'routine clinical care' as determined within their local NHS institution. The follow-up will be in addition to standard care appointments.

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. hospitalisation) this will be accessed by the researcher having obtained consent to do this through informed consent 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. Deviations from the exact time points for assessments will be noted as a measure of the feasibility of the study methodology.

7.10 Qualitative assessments- nested studies

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 the group music therapy intervention 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, mood and group relationships from week to week
3. Understand subjective experiences and attributions for change of the intervention from the perspective of patients, music therapists and referring staff
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 off-ward intervention itself (through the treatment fidelity analysis), client self-reported measures (weekly quantitative process measures of mood pre- and post- session (DMS), group relationships pre- and post session (RSS)) and qualitative individual end semi-structured interviews at 4 week follow-up with a minimum of 10 participants, 10 referring staff and the two music therapists who provided the intervention. The semi-structured interview is optional for service users but we aim to conduct a minimum of 10 interviews.

Quantitative analysis will provide a descriptive analysis of the course of weekly 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.

Qualitative evaluation will comprise of end of study semi-structured interviews with a minimum of 10 participants, 10 of their referring staff and the two music therapists providing the intervention. Whilst semi-structured interviews will have a component to focus upon experiences of the research and views on the design, a second part will ask for views on the experience of the group music therapy itself. These questions will be based upon a pre-existing semi-structured interview (Client Change Interview, Elliott, 1999) to elicit clients' views of and attributions for change. We have adapted this interview for music therapists and referring clinicians to also reflect upon possible observed changes in the participants that they have worked with and their views of the intervention.

Participant recruitment for semi-structured interviews:
Patients:
Patients will be asked to indicate whether they are willing to participate in an optional semi-structured interview, when providing informed consent for participation in the study as a whole. Those who have indicated they are happy to do so will be reminded at their 4 week assessment. The researcher will go through relevant sections of the information sheet and provide an opportunity for questions. If they are still happy to take part, a convenient time and location will be arranged for the semi-structured interview to take place.

Music therapists:
Inclusion criteria:

- Providing music therapy intervention as part of the study
- Capacity to consent

Approach: The therapists will be invited to participate at the end of intervention provision. They will be provided with an information sheet and the opportunity to ask further questions. The researcher will assure them that they are free to choose whether or not to participate. If still interested, the researcher will arrange a second meeting to take informed consent and conduct the interview.
Informed consent: This will be taken a minimum of 24 hours after approach. The researcher will provide a further opportunity to ask questions before taking full written informed consent. The interview will then be conducted.

Ward staff:

Inclusion criteria:

- Working on the ward at the time of the study
- Capacity to consent

Approach: Ward staff will be invited to participate at the end of intervention provision. A researcher will attend the ward team meeting to inform staff of the semi-structured interviews. Those expressing interest will be provided with an information sheet and the opportunity to ask further questions. The researcher will assure them that they are free to choose whether or not to participate. If still interested, the researcher will arrange a second meeting to take informed consent and conduct the interview.

Informed consent: This will be taken a minimum of 24 hours after approach. The researcher will provide a further opportunity to ask questions before taking full written informed consent. The interview will then be conducted.

Semi-structured interview analysis:

Semi-structured interviews will be transcribed and imported into NVivo qualitative analysis software and read a number of times by members of the research team. Members will individually code 25% of the interviews and then meet to decide upon a preliminary thematic frame. As interviews will be asking about individual experiences, coding will take a phenomenological perspective and seek to retain the essence of individual's narratives. The team will continue to code and meet regularly to discuss the adequacy of the frame in reflecting individual experiences. Once a final thematic frame is agreed, we will then explore relationships between the themes identified in the data and quantitative findings.

Quantitative and qualitative data will be compared against the logic model. We will then refine and revise the logic model based upon these findings.

7.11 Assessment of compliance

As this is a feasibility study, compliance and the acceptability of research methods and intervention will be main outcomes of the study.

Compliance with the intervention:

Service users: Compliance will be assessed by the music therapists recording attendance and reasons for non-attendance on an attendance log. Late arrivals and early departures will be noted with the time and any reasons for this.

Should a service user miss a session, the music therapists will make contact with them (as explained 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 (Gold et al., 2009) we would expect a small effect on general functioning after 3 sessions and general symptoms after 10 sessions so will take 10 sessions (or attendance of 62% of available sessions if discharged before 4 weeks) as a minimum for compliance. As this is a feasibility study we will use this data within our assessment of the feasibility and acceptability of the intervention.

Music therapists: Music therapists will self-rate their compliance to the manual after every session. Should compliance drop below 50%, the music therapists will meet with the research team to discuss barriers to complying with the manual as a whole. Videos of 25% of the off-ward sessions will be rated by the research team as a comparison. End semi-structured interviews will discuss barriers and facilitators to complying with the manual and identify whether any refinements or changes need to be made.

Improving compliance: Measures to improve compliance to the intervention include:

- Meeting the music therapist prior to the intervention to set expectations and explain the intervention
- Music therapists reminding participants prior to the group and following up with participants afterwards if they did not attend

7.12 Procedure for unblinding

Patients and therapists are not blinded to the intervention. Should a patient need to be withdrawn from the study intervention due to clinical concerns, this will be logged by the music therapists. Follow-up assessments will continue to be conducted by a blinded researcher if the participant is happy for this to continue and assessed to continue to have capacity to do so.

7.13 Subject withdrawal (including data collection / retention for withdrawn participants)

Participants will be able to drop out at any time either from the intervention or the study. Should a patient withdraw from the study we will use their data up until the point of the end of their participation, unless the participant specifically withdraws consent for their data to be used. If participants wish to discontinue the intervention but are willing to be followed up with the rest of the cohort we will deliver the assessments as specified by this protocol provided they are assessed to continue to have the capacity to do so.

Withdrawal from treatment criteria:

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

- Level of risk assessed by clinical team to require confinement to the ward or transfer to Psychiatric Intensive Care Unit (PICU)
- Music therapists and clinical team assessing current mental state, behaviour or risk to require discontinuation of music therapy

Withdrawal from study criteria:

Participants will be withdrawn from the study if:

- The participant is assessed to have lost capacity to consent
- Researchers, music therapists and clinical team assess current mental state, behaviour or risk to require discontinuation of study participation
- The participant requests to withdraw

Loss to follow up (no further intervention or follow up data collected):

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

- The participant becomes lost to follow up (LTF) after at least 3 failed attempts by the researcher to make contact via 2 different methods (phone and letter).
- 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

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7.14 Schedule of Researcher Visits and Assessments (in Diagrammatic Format)

Visit	Screening	Informed consent	Baseline	Random-isation (stage 1 only)	Process measures (1 per week)	2 week Follow up	4 week Follow up	Optional In depth Inter-view	3 month Follow up	6 month Follow up
Participant visits										
Consent to researcher contact	x									
Meeting to explain study and go through PIS	x									
Meeting to take informed consent		x								
Participant informed of allocation (stage 1 only)				x						
4 week Intervention period:	Stage 1: 4 x per week off-ward group music therapy Stage 2: 3 x per week on-ward group music therapy Control: Treatment as usual				x	x	x			
Participant assessments										
Demographic and clinical information form			x							
Interest in Music (IIM)			x							
Previous musical experiences			x							
Brief Psychiatric Rating Scale (BPRS)			x			x	x		x	x
Patient mood (DMS)			x		x	x	x		x	x
Ward relationships (RSS)			x		x	x	x		x	x
Social functioning (LSP)			x			x	x		x	x
Self- esteem (RSES)			x			x	x		x	x
Self-efficacy (GPSES)			x			x	x		x	x
Satisfaction with inpatient stay (CAT)			x			x	x		x	x
Semi-structured interviews (optional)								x		

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Assessment	Screening	Informed consent	Baseline	Random-isation (study 1 only)	Process measures (1 per week)	2 week Follow up	4 week Follow up	Optional in-depth interview	3 month Follow up	6 month Follow up
Data collected from medical records										
Prescribed medication			x			x	x		x	x
Interventions received			x			x	x		x	x
N recorded incidents on ward			x			x	x		x	x
Length of inpatient stay										x
N readmissions			x			x	x		x	x
Date ready for discharge										x
Date of discharge										x
Researcher feasibility measures										
Screening log	x									
Patient diary (attempted contacts, appointment outcomes, reason for non-compliance with appointment, difficulties during appointment, patient admission status)	x	x	x	x	x	x	x	x	x	x
Researcher diary (researcher tasks and time taken)	x	x	x	x	x	x	x	x	x	x

Assessment	Screening	Informed consent	Baseline	Random-isation (study 1 only	Process measures (1 per week)	2 week Follow up	4 week Follow up	Optional in-depth interview	3 month Follow up	6 month Follow up
Adherence measures										
Attendance of music therapy					**x**					
Therapist self-rated treatment fidelity					**x**					
Video rating of 25% of off ward sessions for treatment fidelity					**x**					

7.15 End of Study Definition

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

7.16 Criteria for Discontinuation

The intervention is well-established in current clinical practice, although is not always offered at the intensity of 4 times per week. If the IAP, HRA or sponsor determine it is within the best interests of participants or trial to terminate the study, written notification will be given to the CI. This may be due to, but not limited to: safety concerns, serious and persistent non-compliance/serious breaches. If the study is terminated, participants will be returned to the NHS normal service of follow up and routine care.

8. STATISTICAL CONSIDERATIONS

8.1 Sample Size

Sample size calculation

The main aim of this study is to assess the feasibility of recruitment processes including the number of eligible patients and participation/retention rates. The average length of hospital stay is 28 days, so it is expected that patients will have access to approximately 12-16 sessions of music therapy whilst in hospital.

Papers considering sample size for feasibility and pilot studies suggest inclusion of between 24-50 participants (Lancaster et al, 2004; Sim & Lewis, 2012; Julious, 2005). The first stage of the present study aims to recruit 30 patients to participate in either music therapy (N=20) or treatment as usual (N=10). Randomisation will be unbalanced in order to obtain sufficient data regarding the intervention.

A previous study of music therapy, conducted at the same site as this study had a participation rate of 45%. With a sample size of 30, we will be able to estimate a participation rate of 45% to within a 95% confidence interval of +/-18%.

Planned recruitment rate

We plan to recruit from 4 wards (2 more than the previous music therapy study) at Tower Hamlets Centre for Mental Health. Current rates of admission are approximately 90 per month, with 250 admitted over a 3 month period. Assuming a participation rate of 45%, we plan to approach 70 patients in the first stage of the study with the aim of recruiting 2 to 3 patients per week over 8 weeks to a total of 30 patients. We then plan to approach 40 patients in the second stage of the study, with the aim of recruiting 4-5 patients per week over 4 weeks to a total of 18 patients.

Music therapist and staff interviews

We plan to recruit the 2 music therapists providing the intervention plus up to 10 referring ward staff to participate in semi-structured interviews to explore their views on the research design acceptability and intervention. This provides the opportunity to recruit a spread of staff from across the 4 wards covered by the study and was decided pragmatically based upon the study time-period.

8.2 Method of Analysis:

8.2.1 Summary of baseline data and flow of participants

Baseline variable	Form	Reporting
Age	Continuous	Mean (yrs), sd, range
Gender	Categorical	Number and proportion
First language	Categorical	Number and proportion
Primary diagnosis	Categorical	Number and proportion
Secondary diagnosis	Categorical	Number and proportion
Length of illness	Continuous	Mean (yrs), sd, range
Hospitalisation in last 12 months	Continuous	Mean, sd, range
Medication	Categorical	Number and proportion
Music education level	Categorical	Number and proportion
Previous receipt of music therapy	Binary	Number and proportion
Number of previous hospital admissions	Continuous	Mean, sd, range
Psychiatric symptoms (BPRS)	Continuous	Mean, sd, range (total and for individual measures)
Interest in music (IIM)	Continuous	Mean, sd, range (total and for individual measures)
Satisfaction with treatment (CAT)	Continuous	Mean, sd, range (total and for individual measures)
Social functioning (LSP)	Continuous	Mean, sd, range (total and for individual measures)
Self-esteem (RSES)	Continuous	Mean, sd, range (total and for individual measures)
Self-efficacy (GPSES)	Continuous	Mean, sd, range (total and for individual measures)

A consort flow diagram will be produced to show flow of participants through the study and reasons for non-participation at each stage.

8.2.2 Feasibility analysis

As this is an exploratory pilot, the main statistical reporting will be descriptive (mean, mode, standard deviation etc.) and calculation of effect sizes (Cohens d and Pearson r).

In terms of feasibility, we are interested in factors which may inform and generate hypotheses for a larger trial in the future, should this study be found feasible. Consequently, we will assess:

- Acceptability of both methodologies to professionals and patients via recruitment rates, compliance and semi-structured interviews
- Feasibility of recruitment processes
- Deviation around specific 2 week, 4 week, 3 and 6 month follow up assessment dates for actual data collection
- Number of eligible participants, participation rates and retention rates
- Researcher time and costs per participant
- Appropriateness of outcome measures

Descriptive analyses will establish recruitment and drop-out rates as well as the distribution of baseline characteristics and all outcomes at 2 weeks, 4 weeks, 3 and 6 months. The research team will reflect upon the representativeness of the demographics in terms of the general population of patients that could potentially be useful in assessing the intervention.

Recruitment and drop-out will be monitored on a weekly basis allowing for examination and reporting of patterns and whether there are any obvious trends. This may inform the choice of the primary outcome for a full scale trial allowing for drop-outs in a sample size calculation.

8.2.3 Clinical outcome analysis

The primary outcome is clinical symptomatology at 4 weeks. All outcomes will be assessed after 2 weeks, 4 weeks, 3 and 6 months. We will first calculate a mean value of the outcome for each measure and present them with confidence intervals. Outcomes will be compared between intervention and control groups using linear regression models, adjusting for baseline score of the given outcome. The confidence limits of each treatment effect and knowledge of the clinically important difference (where this is available) will be used to determine whether clinically important differences are ruled out by these confidence limits.

8.2.4 Subgroup analyses

We will descriptively explore whether there are any differences between compliant and non-compliant attenders, responders and non-responders, individually randomised and cluster simulated participants and whether any sociodemographic and clinical characteristics are associated with outcomes.

8.3 Interim analyses and criteria for the premature termination of the trial

Given the small and exploratory nature of the trial, no interim analysis is planned. As the nature of the intervention does not pose a significant risk to participants, a data monitoring committee is not considered necessary.

The CI in liaison with the sponsor and Independent Advisory Panel (IAP) has ultimate authority to halt the study or withdraw individual participants should concerns arise during the study. Aside from concerns regarding distress to patients, criteria for stopping the study comprise: Closure of the USCP, withdrawal of funding from the NIHR or notification from other Trusts or international equivalent care providers of unforeseen risks to participants in the study.

8.4 Subject population

This study will employ an 'intention to treat' analysis. Data from all subjects will be included in the analysis as randomised. Adverse events will be reported by sub-groups of those who were currently receiving the intervention and those who were not.

8.5 Procedures to account for missing or spurious data

Missing data may occur at a number of levels and stages in the study. As this is a feasibility study we will examine the extent of missing data at each time point and record where possible, the reasons for this.

A numeric code [9999] will be used as a signifier of missing data when inputting into SPSS. For each CRF where missing data exists, there will be a text box to enter reasons for this to enable monitoring of any trends and full reporting at the end of data collection.

8.6 Other statistical considerations

Should any deviations from the original statistical plan be made they will be reported to the sponsor including the justification for such changes.

8.7 Qualitative data analysis

Semi-structured interviews will be digitally audio recorded, anonymised and transcribed verbatim. Transcripts will be imported into NVivo qualitative analysis software for data management. We will use thematic analysis according to the framework described by Braun and Clarke (2006) which involves six stages of analysis – familiarisation, initial coding, discovery of themes, reviewing themes, formalising and naming final themes and preparation of a report. Analysis will be conducted by the CI and lived experience researcher.

9. ETHICS

9.1 General

The Principal Investigator 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 and applicable legal and regulatory requirements. This study will receive full ethical review through the Health Research Authority.

9.2 Ethical considerations

The main issues that may occur for participants are:

- Deterioration in mental health and potential loss of capacity during the study
- Ending the intervention
- Control group design

These are described in more detail below.

1. Deterioration in mental health and potential loss of capacity during the study: This will be monitored by the researcher, music therapists and ward clinical teams at every study assessment/meeting. If a participant's mental health deteriorates, this will be logged and safety reporting procedures followed (see section below). Given this clinical population, it is likely that capacity will fluctuate. Should a participant lose capacity to consent to any of the research or intervention procedures at any point in the study, they will be withdrawn with the reason documented. All data collected up to that point will be retained. The participant has the right to request that data is withdrawn.

2. Ending the intervention: The end of the intervention is likely to come concurrently with participants' discharge. This is a particularly anxiety provoking time for patients. Participants in the intervention will continue to have support from their clinical teams upon discharge and ongoing assessments up to 6 months later. Participants will be reminded that they can access music therapy and wider psychological interventions in the community and any expressions of wishes for this will be referred with the participant's permission to the clinical team. Should a participant wish to access music therapy before the 6 month follow up is completed, they will be withdrawn from the study and the clinical team informed to make the referral.

3. Control group design: The control condition will not receive music therapy input for the length of the trial. We do not have the resources to run a second round of music therapy to enable us to use a wait-list control model, however we will inform control group participants about music therapy services available in the community and assist a referral to this if they wish.

Should they wish to access music therapy whilst in hospital they will be withdrawn from the study and a referral made to a music therapist not involved in the study.

9.3 Financial and other competing interests for the chief investigator and committee members for the overall trial management

The only potential conflict of interest is that the study is investigating the feasibility of music therapy using a team comprising of five music therapists (namely the CI (Carr) advisory members (Sandford) and two clinicians (Bent, Wetherick)). However, one co-applicant (Priebe) and research assistants/clinical studies officers taking assessments are not. The Independent Advisory Panel will be responsible for assessing whether any professional issues might affect the transparent running of the study. Should personnel change, any potential conflicts of interest will be discussed with the sponsor and the IAP.

10. SAFETY CONSIDERATIONS:

Music therapists will be experienced clinicians who have experience of working within acute adult psychiatric inpatient services. They will be fully trained in Trust policies and procedures including de-escalation, break-away and safeguarding. Patient participants will be assured that if anything happens that they are uncomfortable with they can talk to a member of their own ward care team or with the Chief Investigator.

The Chief Investigator is a trained music therapist with over 10 years' experience of working in acute adult psychiatric inpatient environments and currently provides music therapy within a different service of the Trust. The CI and assisting researchers are fully trained in the above policies and procedures and familiar with working within an acute inpatient environment.

There is a small but potential possibility that the music therapists or researchers may be physically or verbally attacked. All patients will be risk assessed by the referring clinician to minimise the possibility of patients with current risk of physical violence being included in the study. The researchers will follow the clinical team's instructions and advice at every visit to the ward. In the unlikely event that a member of the team is attacked we will end participation in the study and ensure appropriate counselling services are available to them following the incident.

Researchers conducting data collection will be working within inpatient settings and may visit participants in their homes during follow up. They will follow all Trust policies and procedures including ward-based procedures and lone working policies. The Chief Investigator will have regular supervisory meetings with the Unit director (Prof. Priebe) to address any difficulties.

11. DATA HANDLING AND RECORD KEEPING:

11.1 Confidentiality

Information related to participants will be kept confidential and managed in accordance with the Data Protection Act, NHS Caldecott Principles, The Research Governance Framework for Health and Social Care, and the conditions of HRA Approval. All data collected during the course of the study will be kept confidential and will only be discussed among the research team for the purpose of data analysis, and theory and program development.

Identifiable information to be collected from participants:

Full name, date of birth, hospital number and contact details will be collected. This information will be used to contact participants but will not leave the study site. All case report forms will be pseudonymised with an allocated participant identification number. Personally identifiable information will be stored separately from the anonymised data in a locked filing cabinet on NHS premises to which only the study team have access.

Audio recordings will be made for semi-structured interviews and video recordings of the off-ward music therapy intervention. Recordings will be transferred immediately after recording onto a password protected and encrypted hard drive, stored on the clinical site.

Semi-structured interviews will be monitored for any identifiable information. Any such information will be removed from the audio recording and then transcribed by an NHS approved transcription service. The audio recording will be destroyed once the resulting transcription has been made and the transcription imported into NVivo software for analysis.

Video recordings will continue to be stored on the encrypted and password protected hard drive. The drive will be stored in a locked filing cabinet, on NHS premises, to which only the study team will have access. The videos will be destroyed one year after the end of the study.

The trial data will be made available to suitably qualified members of the research team, study monitors and auditors, the sponsor, the REC and regulatory authorities as far as required by law. Participants will not be identifiable with regards to any future publications relating to this study.

11.2 Data Storage

At the study site at least 2 separate lockable cabinets will be used; one allocated to contain all non-patient identifiable data (the Case Report Forms), and one allocated to contain all patient-identifiable data. Only researchers who have been authorised as indicated by the CI will have access to these cabinets.

The lockable cabinet(s) which will store patient identifiable data will include one file for participant consent forms, one file which will include the socio-demographic data from each patient obtained in the initial patient assessment (given such information could potentially identify patients), the audio and video recordings of the semi-structured interviews and treatment groups, and one file which will include the recruitment log. The recruitment log will be used to keep a record of every first contact between the researcher and the potential participant. The log will contain the participant Trial ID, their initials, and the data in which that first meeting took place.

The cabinet assigned to store all non-patient identifiable data will contain one cardboard folder for each trial participant, identifiable only by the participant ID number labelled clearly on the spine. Once a patient assessment has been completed, the CRF should be placed in an individual sleeve and stored in the appropriate participant folder.

All electronic patient-identifiable data will be stored in a database separate from the main study databases, on a secure NHS network in a password-protected file. Researchers authorised to access this database will be named in the data management log. The database will contain the participants' assigned Trial ID number, with which all participants will be identified thereafter, along with the patients' contact details, their care coordinator contact details and all socio-demographic data collected for the study. The contact information database will be constructed by the CI.

11.3 Record Retention and Archiving

An agreement is in place between the sponsor (Queen Mary University of London) and the NHS Trust (ELFT) where the study is based. A letter of confirmation is attached as a supplementary document. East London NHS Foundation Trust will take responsibility for archiving research material related to the study. Research data will be archived in NHS archives and destroyed after 20 years in accordance with East London NHS Foundation Trust policies and procedures and usual research practice within the Unit.

Participant contact details will be retained (with their permission) if they want to be updated about study progress for up to one year after the study end. For this,

contact details will be stored in a lockable cupboard on NHS premises. Only the study researchers will have access to this cupboard.

Audio recordings will be destroyed immediately after transcription. The transcripts (without identifiable details) will be stored on NHS computers on a password protected and encrypted drive accessible only by the research team. Audio-visual recordings will be destroyed one year after the study end. This will enable the study team to ensure there is time to complete the final video analyses of adherence. These will be stored on password protected and encrypted hard drives, stored in a locked filing cabinet within the Unit for Social and Community Psychiatry.

Any physical paper files, including consent forms, will be stored in a lockable cupboard on NHS premises which is only accessible by the study researchers and administrative staff for up to one year after the study end. Digital files will be stored on NHS Trust computers in password protected files, or on encrypted password protected external hard drives.

12. SAFETY REPORTING

12.1 Adverse Events (AE)

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 acute psychiatric inpatients.

Notification and reporting Adverse Events or Reactions

If an Adverse Event (AE) either occurs or is identified during the intervention, it is the responsibility of the music 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 Chief Investigator once the session has ended by telephone. The research team will then follow up the AE with the patient and their clinical team 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 in the flow chart below.

AEs for the purposes of this study are defined as:

a) A participant causing harm to another person
b) 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 locked filing cabinet at the study site, with a copy added to the CRF which will omit any information which could lead to the unblinding. Dependent upon the nature of the AE, an assessment will be made by the Chief Investigator liaising with the participant's music therapist and /or clinician to establish whether it is safe for the participant to continue participation.

12.2 Serious Adverse Event (SAE)

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.

An 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, it 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, expected 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 relating 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 as serious as given above and not resulting in a hospital admission.

12.3 Notification and Reporting of Serious Adverse Events

Serious Adverse Event (SAEs) that are considered to be 'related' and 'unexpected' are to be reported to the sponsor within 24 hours of learning of the event and to the Main REC within 15 days in line with the required timeframe. They will also be reported to the IAP and to the sponsor. For further guidance on this matter, please refer to HRA website and JRMO SOPs.

12.4 Urgent Safety Measures

The CI may take urgent safety measures to ensure the safety and protection of the clinical trial subjects from any immediate hazard to their health and safety. The measures should be taken immediately. In this instance, the approval of the REC prior to implementing these safety measures is not required. However, it is the responsibility of the CI to inform the sponsor and Main Research Ethics Committee (via telephone) of this event immediately.

The CI has an obligation to inform both the Main REC in writing within 3 days, in the form of a substantial amendment. The sponsor (Joint Research Management Office [JRMO]) must be sent a copy of the correspondence with regards to this matter. For further guidance on this matter, please refer to NRES website and JRMO SOPs.

12.5 Annual Safety Reporting

The CI will send the Annual Progress Report to the main REC using the HRA template (the anniversary date is the date on the HRA approval letter from the HRA) and to the sponsor. Please see NRES website and JRMO SOP for further information

12.6 Overview of the Safety Reporting responsibilities

The CI has the overall pharmacovigilance and safety oversight responsibility. The CI has a duty to ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

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Communication organogram for reporting SAEs

ICH E6 1.2 (Adverse Event Definition)
An untoward medical occurrence in a participant which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with their use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Is the AE Serious (SAE)?
A SAE is defined as any untoward medical occurrence or effect that results in either death, is life-threatening, requires hospitalisation or prolongation of hospitalisation, results in persistent or significant disability or incapacity or is a congenital anomaly or birth defect. Please note that all 'near misses' should also be reported via the Trust Incident form.

Yes

No → 1. Record AE.
2. Follow up AE until resolved (if applicable).

1. Record SAE and include in the CRF.
2. Inform the trial sponsor within the time line stated in the protocol (Unless agreed in the protocol that EXPECTED events do not need REPORTING). If BLT/ QMUL is the sponsor, scan and email the signed SAE form or fax it to the R&D Office on 020 7882 7276.
3. A template BLT/QMUL SAE form is provided for BLT/QM sponsored trials.
4. Follow up AE until resolved (if applicable).
5. SAEs in non CTIMPs that are related to the project and unexpected should be reported to the main ethics committee within 15 days of CI becoming aware of the event. "NRES report of serious adverse event form".

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13. MONITORING & AUDITING

The organisation applied to for sponsorship, Queen Mary University of London, may monitor activities and documents associated with the proposed research project to determine whether the research activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

The study may also be subject to audit if:

1. A project may be identified via the risk assessment process.
2. An individual investigator or department may request an audit.
3. A project may be identified via an allegation of research misconduct or fraud or a suspected breach of regulations.
4. Projects may be selected at random. The Department of Health states that Trusts should be auditing a minimum of 10% of all research projects.
5. Projects may be randomly selected for audit by an external organisation.

Internal audits may be conducted by a sponsor's or funder representative.

14. TRIAL COMMITTEES AND PROJECT MANAGEMENT

There are two committees who will oversee the conduct both of the work conducted under this protocol and the wider research program to which the work described here contributes.

The Independent Advisory Panel (IAP) is comprised of individuals, independent from the study team, who have expertise in social psychiatry, in working with NHS mental health services and lived experience of receiving care from such services. The IAP will meet 4 times to discuss research progress according to defined milestones, emerging difficulties and dissemination of results. Additional meetings and telephone conferences will be arranged if required.

The responsibilities of the IAP will include:

- Ensuring views of users and carers are taken into account
- Advising on the trial protocol
- Advising on changes to the protocol based on considerations of feasibility and practicability
- Assist in resolving problems brought to it by the research group

- Monitor the progress of the trial and adherence to protocol and milestones
- Consider new information of relevance from other sources
- Consider and act on the recommendations of the sponsor and/or REC
- Review trial reports and papers for publication

The IAP will meet to review the protocol before the start of the study and then soon after the first participants are recruited. They will meet a further two times: once at the end of intervention provision (September 2017) and once to review initial findings (January 2018).

IAP membership includes:

- CI and study lead (Carr)
- Statistician (Greenberg)
- Fellowship mentor (Priebe)
- External independent members: Psychiatrist and service user representative (to be appointed)

A Study Management Group (SMG) will meet monthly. The SMG will be responsible for day to day project delivery and will report to the IAP. It will include study team members:

- Study CI (Carr)
- Co-applicants (Sandford, Priebe)
- Lived experience researcher (to be appointed)
- Research Assistant (Dilgil)
- Clinical Studies Officers (Fung, Worswick)
- Music therapists (Bent, Wetherick)
- Arts Therapies Managers of the service (French, Hutcheson)

We also have a User Reference Group containing up to 3 service users which will regularly meet to provide advice and feedback on all conceptual and practical issues, inform the methodology and implementation of the work packages, and help to interpret the findings. The group will be chaired by the SMG lived experience researcher who will be formally trained in chairing such groups.

15.1 Project management

A Gantt chart is included in the Appendix. Projected recruitment rates are:

Stage 1: Off-ward group, individual randomisation

10.04.17 First participant (stage 1)
17.04.17 3 participants
24.04.17 6 participants
01.05.17 9 participants
08.05.17 12 participants
15.05.17 15 participants
22.05.17 18 participants
29.05.17 21 participants
05.06.17 24 participants
12.06.17 27 participants
19.06.17 Last (30th) participant

Stage 2: On-ward group with second ward for comparison

10.07.17 First participant (stage 2)
17.07.17 5 participants
24.07.17 9 participants
31.07.17 13 participants
04.08.17 17 participants
07.08.17 Last (18th) participant

Estimated milestones are:

Milestone I: 10.04.17 First participant recruited stage 1
Milestone II: 17.04.17 First participant intervention stage 1
Milestone III: 12.05.17 First participant completes intervention stage 1
Milestone IV: 15.05.17 15 (half) participants recruited stage 1
Milestone V: 19.06.17 Last participant recruited stage 1
Milestone VI: 15.07.17 Last participant finishes intervention stage 1
Milestone VII: 15.01.18 Last assessment recorded at 6 month follow up stage 1

Milestone VIII: 10.07.17 First participant recruited stage 2
Milestone IX: 17.07.17 First participant intervention stage 2
Milestone X: 24.07.17 9 (half) participants recruited stage 2
Milestone XI: 07.08.17 Last participant recruited stage 2
Milestone XII: 11.08.17 Last participant finishes intervention stage 2
Milestone XIII: 07.02.18 Last assessment recorded at 6 month follow up stage 2

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15. FINANCE AND FUNDING

This study is funded through an Health Education England/National Institute for Health Research (NIHR) Clinical Academic Training programme – Clinical Lectureship grant– reference CAT-CL-2014-05-001: £139,802 – Developing and refining intensive group music therapy for acute adult psychiatric inpatients. Additional resources will be provided by the host CLRN. The calculation of all costs and contracting has been performed in conjunction with the sponsor.

16. INDEMNITY

The Sponsor for this project is Queen Mary University of London. They will provide insurance and indemnity for the work undertaken under the remit of this project.

17. PUBLICATION POLICY

The CI will coordinate dissemination of data from this trial. All publications using data from this trial to undertake original analyses will be submitted to the IAP and funder (NIHR) for review before release. To safeguard the scientific integrity of the trial, data will not be presented in public before the main results are published without the prior consent of the IAP. Credit for the results will be given to all who have collaborated and participated in the trial. Acknowledgement will include all local coordinators and collaborators, members of the trial committees, and trial staff. All contributors to the trial will be listed at the end of the report with their contribution to the trial identified. Decisions about authorship will be discussed and agreed by the trial investigators and IAP. A lay summary of the final results will be made available for participants. Participants who wish to receive these by post will be sent the summary. The summary will also be made available on East London NHS Foundation Trust website with a link to the full paper.

18. DISSEMINATION OF RESEARCH FINDINGS

Scientific findings will be subjected to international reporting and peer review (targeting appropriate clinical journals e.g. British journal of Psychiatry, BMC Psychiatry). The assimilation of data from this trial will lead to prototype national guidance for music therapists that will inform delivery within NHS acute inpatient settings. As such we will disseminate information via the British Association for Music Therapy and via NHS networks. Information will be directed towards the following groups:

1. Study participants and carers: Feedback to individual participants, users and carers involved in, or who contributed to the study
2. Charity links and patient groups: Results will be disseminated to groups linked to East London NHS Foundation Trust, Service User Group Advising on Research (SUGAR), Florid and MIND.
3. Local health service providers via specifically convened meetings and written reports
4. The British Association for Music Therapy via their member website and monthly bulletin
5. NIHR collaboration: Results will be disseminated via NIHR newsletters and websites

19. REFERENCES

Bird V.J., Le Boutillier C., Leamy M., Williams J., Bradstreet S., Slade M. (2014) *Evaluating the feasibility of complex interventions in mental health services: standardised measure and reporting guidelines*, British Journal of Psychiatry. DOI:10.1192/bjp.bp.113.128314.

Burns, D.D. (1994). *Ten days to self-esteem.* New york: Harper Collins.

Care Quality Commission (CQC) (2012). *Monitoring the Mental Health Act in 2011/12* London: Care Quality Commission.

Carr, C.E. (2014). *Modelling of Processes and Outcomes of Intensive Group Music Therapy for Acute Adult Psychiatric Inpatients.* Doctoral Thesis. London: Queen Mary University of London.

Carr, C.E., d'Ardenne, P., Sloboda, A., Scott, C., Wang, D. & Priebe, S. (2012). Group music therapy for patients with persistent post-traumatic stress disorder - a pilot randomised controlled trial. *Psychology and Psychotherapy: Research and Practice*. doi: 10.1111/j.2044-8341.2011.02026.x

Carr, C., Odell-Miller, H. & Priebe, S. (2013). A systematic review of music therapy practice and outcomes with acute adult psychiatric inpatients. *PLoS ONE 8,* 8: e70252. Doi:10.1371/journal.pone.0070252

Curran, S.L., Andrykowski, M.A., & Sudts, J.L. (1995). Short form of the Profile of Mood States (POMS-SF): Psychometric information. *Psychological Assessment, 7*, 1, p80-83.

Elliott, R, (1999). *Client Change Interview protocol*. Network for Research on Experiential Psychotherapies website: *http://experiential-researchers.org/instruments/elliott/changei.html*

Erkillä,J., Punkanen,M., Fachner,J., Ala-Ruona, E., Pöntiö, I., Tervaniemi, M., Vanhala, M., & Gold, C. (2011). Individual music therapy for depression: Randomised controlled trial. *British Journal of Psychiatry, 199* pp.132-139.

Fachner, J. & Erkillä, J. (2013). [The Finnish Research Model of Music Therapy for Depression] *Musiktherapeutische Umschau, 34*, 1, pp.37-47.

Gold, C., Erkillä, J. & Crawford, M. (2012). Shifting effects in randomised controlled trials of complex interventions: A new kind of performance bias? *Acta Psychiatrica Scandinavica, 126*, pp.307-314. doi:10.1111/j.1600-0447.2012.01922.x

Gold, C. Grocke, D., Heldal, T.O., Tjemsland, L., Aaarre, T., Aarø, L.E., Rittmannsberger, H., Stige, B., Assmus, J. & Rolvjsord R. (2013). Individual music

therapy for mental health care clients with low therapy motivation: Multicentre randomised controlled trial. *Psychotherapy and psychosomatics, 82*, pp.319-331. Doi: 10.1159/000348452.

Gold, C., Mössler, K., Rolvsjord, R. & Stige, B. (2012). Reliability and validity of a scale to measure interest in music among clients in mental health care. *Psychology of music, 41,* 5, pp.665-682. doi: 10.1177/0305735612441739.

Gold, Solli, Krüger & Lee (2009). Dose-Response relationship in music therapy for people with serious mental disorders: Systematic review and meta-analysis. *Clinical Psychology Review* 29 pp.193-207.

Huelsman, T. J., Nemanick, R. C., Jr., & Munz, D. C. (1998). Scales to measure four dimensions of dispositional mood: Positive energy, tiredness, negative activation, and relaxation. *Educational and Psychological Measurement, 58,* 801-816.

HM Government (2011). *No health without mental health. A cross-government mental health outcomes strategy for people of all ages.* London: Department of Health

Lancaster, G.A., Dodd, S. & Williamson, P.R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice 10,*2, pp.307-312.

McNair, P. M., Lorr, M., & Droppleman, L. F. (1981). *POMS manual* (2nd ed.). San Diego: Educational and Industrial Testing Service.

Medical Research Council (MRC) (2008) *Developing and evaluating complex interventions: New guidance.* London: Medical Research Council.

MIND (2011). *Listening to experience. An independent inquiry into acute and crisis mental healthcare.* London: MIND

Morgan K, Bartrop R, Telfer J, Tennant C (2011) A controlled trial investigating the effect of music therapy during an acute psychotic episode. Acta Psychiatr Scand 124 : 363-71. doi: 10.1111/j.1600-0447.2011.01739.x

Mössler, K., Chen, X., Heldal, T.O. & Gold, C. (2011). Music therapy for schizophrenia and schizophrenia-like disorders. *Cochrane database of Systematic Reviews*, 12. Art. No. CD004025.

NHS Benchmarking Network (2013). *Mental Health Benchmarking 2013.* London: NHS Benchmarking Network.

Overall, J.E. & Gorham, D.R. (1962). The Brief Psychiatric Rating Scale. *Psychological reports, 10,* pp.799-812.

Priebe, S. & Gruyters, T. (1995). [Clients' Scale for the Assessment of Treatment]. Berlin: Freie Universitat Berlin.

Rolvsjord, R., Gold, C. & Stige, B. (2005) Research rigour and therapeutic flexibility: Rationale for a therapy manual developed for a randomised controlled trial. *Nordic Journal of Music Therapy*, 14 pp.15-32.

Rosen, A., Hadzi-Pavlovic, D., Parker, G. (1989). The Life Skills Profile: A measure assessing function and disability in schizophrenia. *Schizophrenia Bulletin, 15,* pp.325-337.

Rosenberg, M. (1989). *Society and the adolescent self-image.* Middletown: Wesleyan University Press.

Sainsbury Centre for Mental Health (SCMH) (2006). *The search for acute solutions: Improving the quality of care in acute psychiatric wards.* London: Sainsbury Centre for Mental Health.

Silverman MJ (2009) Implementing a music therapy program at a new 72-hour acute psychiatric admissions unit: A case study of a patient who was malingering. *Journal of Creativity in Mental Health* 4, pp.17-31. doi: 10.1080/15401380802672518

Silverman, M.J. & Leonard, J. (2012). Effects of active music therapy interventions on attendance in people with severe mental illnesses: Two pilot studies. *The arts in psychotherapy 39,* pp.390-396. Doi:10.1016/j.aip.2012.06.005

Schwarzer, R. & Jerusalem, M. (1995). Generalized Self-efficacy Scale. In J. Weinman, S. Wright & M. Johnston (Eds.) *Measures in health psychology: A user's portfolio. Causal and control beliefs.* Windsor: NFER-NELSON. Pp.35-37.

Talwar N, Crawford MJ, Maratos A, Nur U, McDermott O, Proctor S (2006) Music therapy for in-patients with schizophrenia: Exploratory randomised controlled trial. *British Journal of Psychiatry, 189,* pp. 405-409. doi:10.1192/bjp.bp.105.015073

Ventura, J., Lukoff, D., Nuechterlejn, K.H., Liberman, R.P., Green, M.F. & Shanea, A. (1993). *Brief Psychiatric RatingScale (BPRS) Expanded Version (4.0). Scales, Anchor points and Administration manual.* Los Angeles: UCLA

Waltz, J., Addis, M., Koerner, K. & Jacobson, N. (1993). Testing the integrity of a psychotherapy protocol: Assessment of adherence and competence. *Journal of Consulting and Clinical Psychology, 61* pp.620-30.

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20. APPENDICES

Appendix 1- Study GANTT Chart

		2017																																											
Task/ N assessments	**Pre**	**Feb**				**Mar**				**Apr**				**May**				**Jun**				**Jul**				**Aug**				**Sep**				**Oct**				**Nov**				**Dec**			
Form prep:																																													
PIS	x																																												
Consent	x																																												
Screening log	x																																												
CRF	x																																												
Demographic form	x																																												
Hospital data form	x																																												
MT attendance	x																																												
MT adherence form	x																																												
Researcher diary	x																																												
Database setup	x																																												
Procedural prep:																																													
SOPs	x																																												
Ethics	x																																												
IAP setup	x																																												
MT training		x	x	x	x	x	x	x	x																																				
MHRN CSO training			x	x	x	x	x	x	x																																				
Ward intros			x	x	x	x	x	x	x																																				
Study																																													
Stage 1 recruitment											x	x	x	x	x	x	x	x																											
Randomisation											x	x	x	x	x	x	x	x																											
Off ward MT gp runs											x	x	x	x	x	x	x	x	x	x	x	x																							
Stage 2 recruitment																								x	x	x	x																		
On ward MT gp runs																									x	x	x	x																	
Data collection											x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Data entry											x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	
Analysis																																													
Interview analysis																																												x	x
Recruitment rates																																x	x											x	x
Researcher time																																x	x											x	x
Clinical outcomes																																												x	x
Adherence to manual																																												x	x
Compliance																																													
Study write-up																																													
Meetings																																													
IAP meetings									x													x									x														
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Advice on db setup	x																																												
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Quality Assurance																																													
Risk assessment advi	x																																												
QA procedure advice	x																																												
SOP advice	x																																												
Review of QA procedures													x																																
Review of write up																																													

	2018																															
Task/ N assessments	**Jan**				**Feb**				**Mar**				**Apr**				**May**				**Jun**				**Jul**				**Aug**			
Form prep:																																
PIS																																
Consent																																
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Data collection				x	x	x	x																									
Data entry				x	x	x	x																									
Analysis																																
Interview analysis	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																
Recruitment rates	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																
Researcher time	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																
Clinical outcomes	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																
Adherence to manual	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x																
Compliance									x	x	x	x	x	x	x	x																
Study write-up																	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Meetings																																
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