East London NHS
NHS Foundation Trust

FEASIBILITY TRIAL OF A STRUCTURED INTERVENTION FOR EXPANDING SOCIAL NETWORKS IN PSYCHOSIS

Short study title: SCENE (WP 4)

This protocol has regard for the HRA guidance and order of content;

RESEARCH REFERENCE NUMBERS

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OTHER RESEARCH REFERENCE NUMBERS

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SIGNATURE PAGE

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

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

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

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Date:01/03/2018

Signature: 

Name: (please print): Stefan Priebe

Statistician:

Date:06/03/2018

Signature: 

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Committees	Programme Management Group (co-applicants), Lived Experience Advisory Group, Steering Committee

STUDY SUMMARY

Study Title	Feasibility Trial Of A Structured Intervention For Expanding Social Networks In Psychosis
Internal ref. no. (or short title)	SCENE (WP4)
Study Design	Feasibility trial
Study Participants	Patients with a diagnosis of a psychosis-related condition (ICD10 F20-29); aged 18-65; capacity to provide informed consent; ability to communicate in English; 5 or less score on the quality of life assessment (MANSA) and less than 7 consecutive days with social contacts in the previous week. Mental health professionals: aged 18-65; with experience of providing mental health care; employed by participating NHS Trusts; capacity to provide informed consent; ability to communicate in English
Planned Sample Size	12 clinicians and at least 48 patients at four sites (East London, York, Exeter and Oxford); 32 patients will be randomised to receive the intervention. All patients will be interviewed at baseline to check eligibility. The intervention will be delivered by experienced clinicians who will be trained in it by the research team.
Study duration	9 months
Planned Study Period	01st of June 2018- 28th of February 2019
Study aims and objectives	Aim: Using the developed manual and training as developed in WPs 2 and 3, we will conduct a feasibility trial to prepare the full trial in WP5. The specific objectives are to: 1. Further specify the intervention, intervention manual and training module in preparation for the full randomised controlled trial; 2. Gain further and more systematic practical experience with the intervention in the NHS; 3. Check the feasibility of recruitment and randomisation procedures; 4. Refine the methods for assessing the costs of the intervention including the resources required for the training; 5. Explore further which professional groups should deliver the intervention in the full trial, and 6. Test methods for assessing adherence to the manual.

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this trial)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
National Institute for Health Research	Programme Grant for Applied Research
East London NHS Foundation Trust (supported by Noclor)	Study sponsorship
East London NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and patients
Tees, Esk & Wear Valleys NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and patients
Devon Partnership NHS Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and patients
Oxford Health NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and patients
Queen Mary University of London	Substantive employer of Chief Investigator

ROLE OF STUDY SPONSOR AND FUNDER

East London NHS Foundation Trust the sponsor, Noclor Research Support Service is acting on behalf of East London NHS Foundation Trust to assume overall responsibility for the initiation and management of the study. The National Institute of Health Research has provided funding for the study.

ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Management Committees

The main roles and responsibilities of each committee are outlined below:

- Programme Management Group

  The Programme Management Group (PMG) includes the PI, 10 co-applicants, the main researchers and patient representatives from the Lived Experience Advisory Panel. The PMG will meet regularly to ensure all practical details of the trial are progressing well and working well and everyone within the trial understands them. The PMG will meet every two to three months initially, and at least three times per year throughout. The project timeline and milestones will be scrutinised at each meeting. More regular and individual meetings between the PIs, the co-applicants and the different parts of the research team will be arranged, including Skype video and teleconferencing, as appropriate.

- Programme Steering Committee

  The Programme Steering Committee (PSC) has a membership limited to an independent Chair, three independent members one of whom is a statistician and one of whom represents the interests of patients and the public. The PSC provides expert advice during the conduct of a programme that is independent of the Investigators and supervises the overall programme, on behalf of NIHR and the Sponsor. The PSC will meet regularly, two times/year. The project timeline and milestones will be scrutinised at each meeting.

- Lived Experience Advisory Panel

  The Lived Experience Advisory Panel (LEAP) consists of eight individuals with lived experience of either psychosis-related diagnoses and/or experience of caring for someone with a psychosis-related diagnosis. The LEAP is chaired by the patient co-applicant (Ms Geraldine Allen) whose experience includes working as a Peer Support Worker and trainer as part of ELFT and working as a patient researcher on a project run with East London Trust based on recovery. The panel has been recruited from an existing patient and carer group (Service User Group Advising on Research (SUGAR) and the associated network of users with research interest and experience. The LEAP meets approximately every 4 months for half a day, and meetings are flexibly arranged. The focus of the LEAP meetings is to discuss developing the study material (e.g. topic guides, participants information sheets); the findings; and dissemination, including developing plain English summaries so the results are accessible to individuals within services.

Protocol contributors

Dr Domenico Giacco, Dr Anna Ermakova, Professor Stefan Priebe

KEY WORDS: Social networks, psychosis, schizophrenia, qualitative interviews, exploratory testing, intervention development.

LIST of CONTENTS

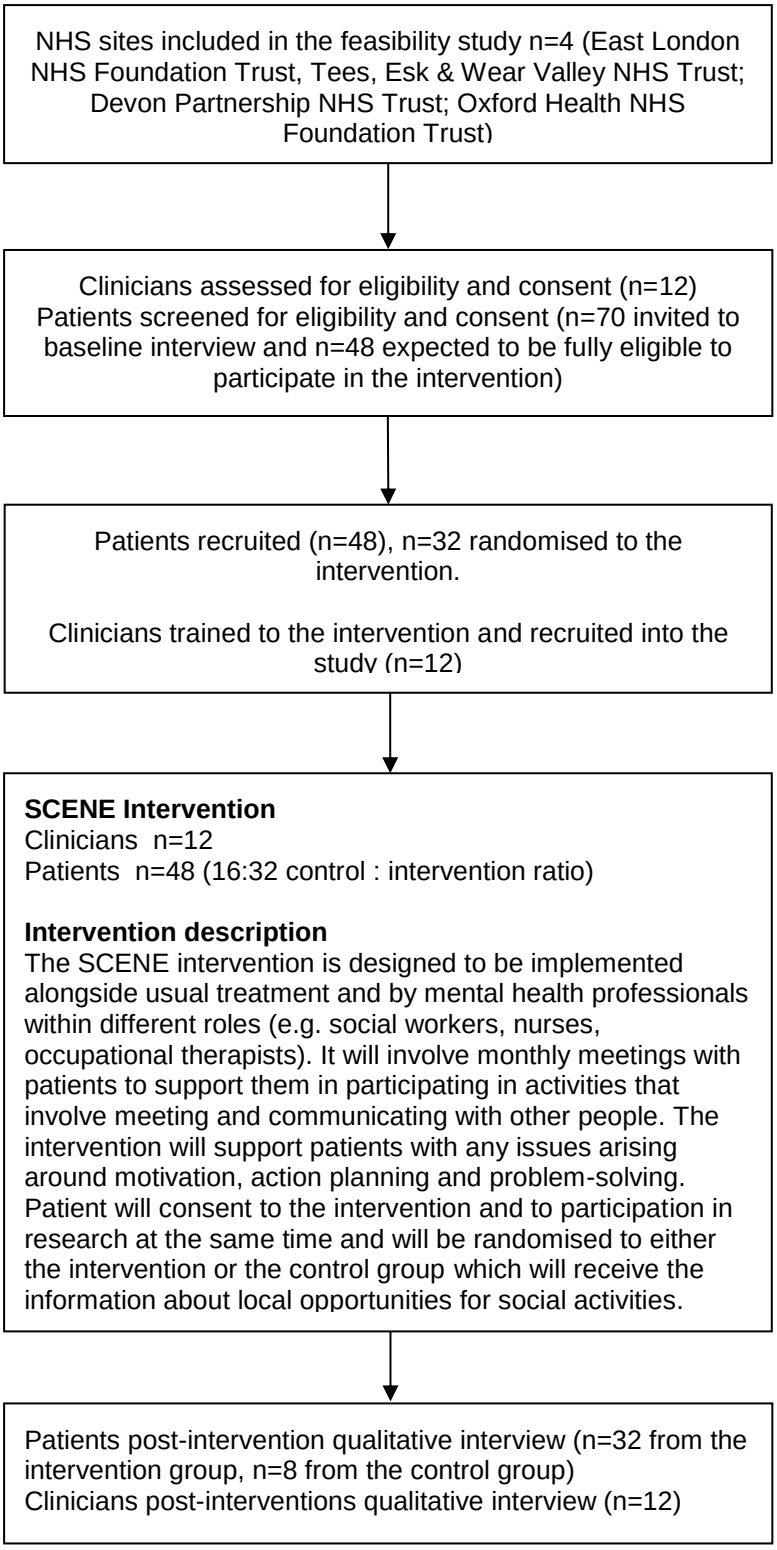
LIST OF ABBREVIATIONS

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

AE	Adverse Event
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
DSUR	Development Safety Update Report
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
IDMC	Independent Data Monitoring Committee
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PMG	Programme Management Group
QP	Qualified Person
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
WP	Work Package

STUDY FLOW CHART

Please see Appendix 1 for schedule of events. Patients will be approached first by their clinicians about the research study, and then researchers will carry out the consent procedure with those who are interested in taking part.



STUDY PROTOCOL

Feasibility trial of a structured intervention for expanding social networks in psychosis

1 BACKGROUND

About 120,000 people with psychosis are being cared for in secondary services in the NHS at any point in time. Reviews show that people with psychosis have much smaller social networks compared with the general population and other groups with long-term mental and physical disorders; and more than 50% of their reduced social networks consist of family members rather than friends and other contacts (Emlet 2006; Palumbo et al. 2015). National Institute for Health and Care Excellence (NICE) (2014) state that one of the symptoms of psychosis is the impairment of the individual's ability to '…maintain relationships; they may become increasingly isolated' (NICE 2014, p.14), therefore isolation for people with psychosis may not always be a choice but a symptom of the illness. Social isolation is cited as one of the factors related to 'recurrent episodes or relapses' (Nice 2014, p.15) and is associated with poorer quality of life and unfavourable health outcomes in patients with psychosis (Cohen et al, 1998; Clinton et al, 1998; Bengsson-Tops and Hansson, 2001; Norman et al., 2005). Studies which have looked into friendships and social contacts of people with psychosis have shown that social isolation may be a problem for most people with psychosis. In an analysis of data of 1396 patients with psychosis from four international multi-centre studies (Giacco et al., 2012), 45% were found not to have met any friend in the previous week. In a recent survey in East London (Giacco et al., 2016), 80% of patients with psychosis felt lonely, and 43% very or extremely lonely. Only 30% had had more than one social contact in the previous week. Previous studies in the UK have focused on urban contexts (Giacco et al., 2016) and there is a need to explore social contacts of people with psychosis living in different areas. There is evidence that social deprivation and inequality are linked to psychosis (Kirkbride et al., 2014; O'Donoghue et al., 2016), however we do not know how these measures of neighbourhood social composition relate to social isolation in people with psychosis.

NICE recommendation for care provision states that one of the initial assessments of those presenting to secondary care with psychosis should be an 'evaluation of their social networks, relationships' (NICE 2014, p.465). However, at the moment, standardised and effective interventions to support patients with psychosis in increasing their social activities and social contacts are not available as part of the NHS care provision.

There is encouraging but preliminary evidence (Anderson et al., 2015) that directly supporting patients with psychosis in meeting new people or engaging in social activities can help them increase their social networks.

A study carried out in Italy has showed that social networks can be expanded with a relatively simple intervention in which mental health professionals help patients to identify their preferences for social activities (Terzian et al., 2013).

The overall aim of this NIHR-funded research programme of which this study is a part of, is to adapt this intervention to the NHS and to test whether it expands social networks and improves patients' quality of life. In this specific study we will carry out a feasibility study, further refining intervention, in order to gain more systematic practical experience of its provision within the NHS. Guidelines for the intervention (which are described in the section 6 of this protocol) were developed in discussions within the expert group, the steering group, lived experience advisory panel (LEAP) and with the

Service User and Carer Group Advising Research (SUGAR) at East London NHS Foundation Trust. They have been further updated in light of the findings from the surveys, focus groups and case series of the previous work packages.

2 RATIONALE

Currently, there are no specific interventions in the UK that focus on expanding social networks for people with psychosis. If NHS services address patients' relationships, they usually focus on established and close relationships, mainly with the patient's partner or family. However, there are good reasons to focus a new intervention on contacts outside families: a) for many patients, particularly for those who live in social isolation, families are not available and/or the potential for contacts with family members are limited; b) when patients are still in contact with families, the relationships are often well-established with little option for further change; c) services usually have already tried family interventions, if possible, at some stage in the patient's history as they are recommended by NICE guidelines for this patient group; d) family relationships can be difficult and rather stressful for some patients; and e) the reduced social networks of patients with psychosis consist mainly of family members and what is missing are other contacts, that can be more flexibly established and shaped, and that patients can also more easily terminate if they wish to.

In consultation with 30 people from various patient groups, 29 strongly endorsed the proposal for developing an intervention to expand social networks. One participant said, "This is very relevant. I witness and experience this isolation… I miss being… part of a group".

The previous work packages of the SCENE research project involved surveys of patients with psychosis, assessing social contacts and social activities of around 500 people across diverse rural and urban areas of England (work package 1); focus groups with 80 patients, mental health professionals and carers to refine the intervention (work package 2); and case series piloting the intervention with small group of patients and clinicians (work package 3). These studies are currently ongoing, so we do not have complete written up results yet, however they have already provided invaluable information for the intervention development. Surveys demonstrate that service users perceive the need for an active support to expand social network and will be interested to take part in the future trial. On the basis of the surveys we have adjusted our original recruitment criteria, as 2 or less social contacts in the previous week turned out to be too conservative and excluded many eligible participants. On the basis of the feedback from focus groups we have included patients from primary care as potential participants and provide more flexible approach with the intervention. Case series were crucial in elucidating practical issues of the intervention delivery which we have taken on board for the feasibility trial.

Interventions with positive evidence from other countries (Anderson et al., 2015; Terzian et al., 2014) require adjusting to the context of the UK and the NHS. For such interventions to be stipulated by guidelines and funded in routine care by commissioners across the NHS, they need to be standardised, well specified and manualised to facilitate replicability, and evidence-based. This study therefore seeks to conduct a feasibility trial of an intervention to expand social networks in patients

with psychosis to test that it is feasible, acceptable, effective and cost-effective in different context across the UK, and scalable into routine practice in the NHS.

During the current study we will test the feasibility of the intervention, recruitment and randomisation procedures through involving clinicians (e.g. assistant psychologists, nurses, trainee psychiatrists etc.) and asking them to deliver the intervention in practice to a small number of patients. To help the refinement we will adopt a mixed method approach. A qualitative approach will enable an in-depth consideration of the views of patients and clinicians in order to specify how the intervention needs to be adapted for delivery in routine mental health services. This will include audio-recording of part of the intervention sessions (we will aim to audio record two sessions per each clinician) in order to identify how the guidelines and training provided to the clinicians will determine the content of the meeting in practice and help further refinement of the training. We will also carry out quantitative assessments in order to be able to describe the characteristics of the sample and explore whether the intervention has a potential for changing outcomes such as number of social contacts and social activities, quality of life and symptoms. We hope that this work package will also help to refine the methods of assessing the costs of the intervention including the resources required for training and gain further and more systematic practical experience with the intervention in the NHS in preparation for a full randomised controlled trial.

2.1 Assessment and management of risk

Risks of the project and measures to prevent them

We do not foresee any significant ethical, legal or management issues arising from this study.

Participation: Patients invited to baseline screening and do not meet our inclusion criteria might be upset because they wanted to do an intervention. Some patients might be upset when they find out that they are randomised to a control group, rather than the intervention. Patients invited to take part in WP4 might also experience anxiety in trying the intervention and meeting new people or be frustrated by failed attempts to increase their social activities and contacts. We will minimise this risk by:

1. Explaining to the participant that if they are not eligible to join this study they will resume care as usual, e.g. with their Community Mental Health Team.
2. Explaining the purpose of the research to patients, as well as the research procedures, at the recruitment stage to manage expectations.
3. Explain early on that participants who enter the study will receive either the intervention or a booklet containing information about local activities. Emphasise this is done because we do not know what is better – information or active support, that's why we are doing this study.
4. Instructing the clinicians delivering the intervention to manage potential feelings of frustration through simple psychotherapeutic techniques (see Section 6).

Research interviews: In case significant distress arises during the research interviews, we will inform patients that the research team is able to contact their clinicians if they would like further support.

Confidentiality: To protect the identification of participants, study IDs will be created and assigned for each individual, and person-identifiable data will be stored separately in a locked filing cabinet at each participating Trust. An electronic file with restricted access (to the core SCENE research team only) will be maintained at each site. Only an ID list (which will not contain any patient identifiable data) will

be transferred to the central study team at East London NHS Foundation Trust. A log will document any formal changes to the ID list document. Only in the cases in which the researcher has concerns regarding the participant's safety or the safety of others, through participant disclosures of thoughts/plans of harming themselves or others, or through criminal disclosures, the researcher will be obliged to break confidentiality and inform the relevant clinical teams, services and/or authorities. This will be made clear to the participant on the information sheet and during the consent process to ensure their understanding.

To further protect confidentiality, we will:

- Ensure that participants understand during the informed consent process where interviews, and intervention sessions might be audio-recorded, the purpose of this, how the audio files will be stored, and who will have access to these files (see section 9.3)
- Remind all participants that they do not have to answer any questions or make any personal disclosures if they do not wish to
- Refrain from using participants' names during audio-recorded interviews.

Use and storage of personal data: All participant data (quantitative and qualitative data) collected will be pseudonymised and handled in line with the Data Protection Act 1998, and other applicable study procedures. All case report forms will be stored in locked cupboards only accessed by the study team. Screening logs and any document linking IDs with names and personal contacts (required for the follow-up) will be stored in electronic forms in password-protected files only accessible to the study teams at different sites. All audio-recorded data will be captured in encrypted and password protected files. Data will be handled and stored in accordance with the conditions set out by the study sponsor (East London NHS Foundation Trust) and in line with PCTU procedures. All database building, data handling and management activities will be carried out by the PCTU in collaboration with the study team according to applicable procedures and other regulatory and information governance requirements. To protect patient confidentiality on the CRF we will only record partial postcode (first half) and Lower-layer Super Output Area codes (LSOA) that each postcode falls within. Although we are collecting participant's full postcodes for administrative purposes, we will convert postcodes to the LSOAs. CRF is pseudo-anonymised and participants will not be identifiable from their partial postcodes or LSOA codes.

Super Output Areas (SOAs) are a set of geographical areas developed following the 2001 census and updated after 2011 census. The Lower Layer Super Output Areas (LSOA) typically contain a population of around 1500 people. The rationale for adding LSOA code is two-fold. First, the data on the rural/urban subdivision and social deprivation index data exist for this metric, rather than for individual postcodes. With LOSA codes we can look into the social deprivation index data and correlate those with levels of social isolation in people with psychosis. Second, LSOA codes are more confidential than full postcodes, given the average population of 1500 people vs. 15 households for each full postcode.

The qualitative interviews with patients and clinicians and some intervention sessions will be audio recorded on an encrypted device and an NHS-approved professional transcription company will be used to transcribe the data. The company will receive the audio files over a secure, encrypted connection and all identifiable data (name of participants or any information that by itself, or in conjunction with other material, may identify participants or other people) will be removed from the

transcripts. Following transcription and completion of data analysis, the audio-recordings will be destroyed.

Benefits of the project

There is a promising emerging evidence base to support the effectiveness of interventions to increase the social networks of people living in the community with psychosis. Moreover, national policies emphasise the involvement of patients in mental health treatment (e.g. Department of Health, 2011, NICE, 2014). For patients involved in testing the intervention in the current study, this might lead to improved social networks, which might lead to other improvements, e.g. improved clinical outcomes and/or quality of life. Clinicians will be providing their personal experiences of the interventions and identify potential barriers for its implementation in the NHS as well as suggestions to further specify the guidelines into a manual. This will help the research team to find solutions and strategies to tailor the intervention to the needs of patients, carers and clinicians within an NHS context; and to develop an intervention that can be scalable into routine NHS practice.

Safety reporting

The study will consist of a baseline interview, followed by trialling an intervention, followed by an individual interview. The intervention is an addition to patients' usual care. Adverse Events and the need for Urgent Safety Measures are not anticipated.

Adverse Events (AE)

Any adverse events will be recorded in the study file and the participant's records, if appropriate. The participants will be followed up by the research team.

Serious Adverse Event (SAE)

SAEs that are "related" and "unexpected" will be reported to sponsor within 24 hours and to the main REC within 15 days of learning of the event.

Urgent Safety Measures

In the case of urgent safety measures being required, the CI will inform the sponsor and the REC of the event immediately via telephone. The CI will then inform the REC and the JRMO in writing within 3 days.

Annual Safety Reporting

If required by the REC, the CI will send the Annual Progress Report to the main REC using the NRES template and to the sponsor.

Overview of the Safety Reporting responsibilities

The CI will ensure that safety monitoring and reporting is conducted in accordance with the sponsor's requirements.

3 STUDY DESIGN

Testing the intervention: feasibility trial of delivering the intervention and mixed method study (individual interviews) of patient experiences and outcomes and clinician experiences. The intervention will be provided in addition to standard care.

4 STUDY SETTING

This multi-centre study is hosted by East London NHS Foundation Trust as the coordinating centre and will take place across the following NHS Trusts and Universities: East London NHS Foundation Trust; Tees, Esk & Wear Valleys NHS Foundation Trust in collaboration with the University of York; Devon Partnership NHS Trust in collaboration with the University of Exeter and Oxford Health NHS Foundation Trust. Participants across all sites will be identified through primary care or secondary care mental health services.

Patient and clinician participants will be recruited, the intervention will be delivered and research data collected in quiet rooms within facilities of all these Trusts or participating Universities, which contain the following sites: East London, Luton, Bedfordshire, North East (York, North Yorkshire, Teeside and Durham), Devon, Oxfordshire, Buckinghamshire, Swindon, Wiltshire, Bath and North East Somerset. If patient participants prefer so, there will be the option to carry out research assessments at their homes or other community locations. Researchers will follow the lone worker policy of their respective participating NHS trusts.

5 ELIGIBILITY CRITERIA

5.1 Inclusion criteria

Patients:

- 18-65 years old
- Diagnosis of psychosis-related condition (ICD-10 F20-29)
- Capacity to provide informed consent
- Ability to communicate in English
- Limited social network size and low quality of life (Score 5 or less on MANSA quality of life assessment and less than 7 consecutive days with social contacts in the previous week)

Clinicians:

- Mental health professional with experience of providing community mental health care (e.g. psychiatrists, clinical psychologists, nurses, occupational therapists)
- Aged 18-65 years old
- Employed by participating NHS Trusts
- Capacity to provide informed consent
- Ability to communicate in English

5.2 Exclusion criteria

Patients:

- Does not meet inclusion criteria
- Primary problem of current drug addiction
- No capacity to provide written informed consent
- An inpatient on a psychiatric ward at the time of recruitment

Clinicians:

- Does not meet inclusion criteria

6 STUDY PROCEDURES

Please see Appendix 1 for schedule of procedures.

This study is part of a larger programme of research to improve social networks and quality of life in people with psychosis. It will test the feasibility of the intervention for use in the NHS; check the feasibility of recruitment and randomisation procedures and test different methods for assessing adherence to the manual, which will be used in the subsequent randomised controlled trial. It will also help to gain further and more systematic practical experience with the intervention in the NHS and refine methods for assessing the costs of the intervention in preparation to a future larger trial.

This specific study will also explore experiences of patients and clinicians who will receive or deliver the intervention in practice and help further refinement and specification of the intervention before the next phase of this programme, a full randomised controlled trial.

Consent

Potentially eligible patients will be identified by members of the clinical team, who will introduce the study and, if interest is shown, request their verbal permission to pass their contact details to a member of the research team. We would also use a data base of the patients that took part in the previous work package, the SCENE survey, and have expressed an interest to participate in the intervention.

The clinician delivering the intervention will not be the treating clinician of a participating patient and this will be clarified when explaining the study and the intervention before taking consent. Informed consent will be sought from all patients to participate in this study, which will include permission to access medical records to retrieve socio-demographic and clinical characteristics. During the baseline interview researchers will ascertain whether patients meet the inclusion criterion of “score 5 or less on the MANSA less than 7 consecutive days with social contacts in the previous week”. If the service user is not eligible to join this study they will be still compensated £15 for their time. They will also be reassured that they will resume care as usual, e.g. with their Community Mental Health Team.

If participants are eligible, they will be invited to take part in the study. Participants will be given the option during the consent process to receive a copy of the findings from the study. This will be a lay summary of results developed with the assistance of the LEAP. Informed consent will be sought from clinicians as well.

The assessment of capacity will be done in two stages: in a first stage (when obtaining permission to be contacted by research team) this will be conducted by mental health clinicians who are trained and experienced in this assessment which is part of their everyday clinical practice. In a second stage

(when obtaining consent), researchers will assess capacity to consent to the participation in the study. The researchers will have experience in mental health studies and will be trained by experienced clinicians (Giacco and Priebe) in assessing capacity to consent to research. At each session of the intervention the capacity to consent to treatment will be ascertained by the delivering clinician according to common clinical practice.

Baseline assessment with the researcher

Demographic and clinical characteristics data collection

Research team member will complete a case report form (CRF) recording patients' responses about demographic and clinical characteristics, such as the diagnoses, duration of illness, number of voluntary and involuntary hospitalisations, current medication, history of psychological and other treatments and record this on a form. Alternatively, participants will be given the option to complete this for themselves. Any information that patients are unable to provide will be collected from patients' medical records with their consent. We would use a shortened version of the Client Service Receipt Inventory (CSRI – 'Generic' UK Mental Health, Beecham and Knapp, 2011) for this. Then the research team member will conduct clinical assessment of the current positive and negative symptoms using two validated measures: Positive And Negative Symptom Scale, (PANSS, Kay, 1991) and Clinical Assessment Interview for Negative symptoms (CAINS, Kring et al., 2013) for a more specific measurement of different aspects of negative symptoms.

Social contacts and activities

The number and quality of social contacts on each day of the previous week will be measured (Giacco et al., 2016), including detailed questions about social activities as developed in the on-going PGfAR VOLUME (on volunteering in mental health) and including questions of the Time Use Survey (Priebe et al., 2016). In addition to the questions from the Time Use Survey we ask about the price of each activity in order to estimate what activities would be reasonable to offer during the intervention.

Quality of life and loneliness assessments

The researchers will collect the information on subjective quality of life (MANSA, Priebe et al., 1999) health-related quality of life (EQ-5D-3L, Rabin et al., 2014), and ICEpop CAPability measure for Adults, which is a measure of capability for the general adult (18+) population for use in economic evaluation (ICECAP-A, Al-Janabi et a., 2013). Unlike most profile measures used in economic evaluations, the ICECAP-A focuses on wellbeing defined in a broader sense, rather than health. We also assess subjective loneliness through UCLA-8 loneliness scale (Hays and DiMatteo, 1987) and Global Rating of Loneliness.

During the baseline interview, researchers will ascertain whether patients meet the inclusion criterion of having "quality of life score 5 or less" using the MANSA (Priebe et al., 1999). If yes, they will be invited to participate in the intervention.

Randomisation procedures

Patients will be randomised to either the intervention or control. The allocation ratio will be 2:1 in favour of the intervention. Randomisation will be stratified by NHS Trust, ensuring balance between

groups in the patient numbers from each NHS Trust. Blocked randomisation with a block size of m=3 will be used within each stratum. A fixed block size of m=3 is appropriate in this trial as the feasibility of intervention and study procedures is of primary interest and not intervention effects. Should blocked randomisation be used in the full trial a variable block size would be utilised.

The randomization will be carried out remotely by the Pragmatic Clinical Trials Unit at Queen Mary, University of London. The PCTU will inform the research team of the results of the allocation by secure email using a password protected file.

Intervention

a. Type and frequency of meetings

Patients will be identified from mental health teams' caseloads and will be offered the intervention if they do not show substantial risk to self or others and this should be monitored as per routine clinical practice. The clinician delivering the intervention will not be the treating clinician of the patient.

Clinicians should meet patients six times over the six-month intervention period; about once per month.

The intervention should start with a sufficiently long first two meetings (about 60 minutes) in the first month to explore preferences, discuss options in detail and agree on the way forward. The following meetings should discuss progress and provide support as required. They should last at least 20 minutes. Further contacts of clinicians with patients, as needed via telephone, text messages, Skype or other electronic means, will be encouraged. Such contacts may also replace face-to-face contacts, but the initial meeting and at least one more meeting will be face-to-face. The location of these meetings can vary and depend on patient preference and local circumstances (including patients' homes, community places and offices of services).

b. Content of meetings

The meetings should focus on the patient's motivation to expand social networks, their preferences for how to do this, local options for doing this and plans for how to achieve it in practice. This may include temporary support through the intervention (e.g. reminders, initial accompanying). The planned activities should be a way to expand social networks, e.g. leisure activities in groups rather than going to the cinema on their own. This will usually mean establishing new contacts, but could also be engaging in new joint activities with previous contacts (outside on-going friends and close family). The intervention will not address potential difficulties in already existing on-going relationships (e.g. with close family).

The meetings should start with a review of progress and should end with an agreement on actions to be taken. This will then be reviewed and possibly revised at further meetings. Normally, the agreement should not specify more than one type of concrete activity at a time. If a patient expresses interest in more than one activity, they should be asked to choose one to prioritise. If there is no substantial progress after three months with one type of activity, an agreement should be made to switch to a different activity. There will be some flexibility about when exactly the switch should be considered and agreed. The switch should be agreed by both patient and clinicians in a face-to-face meeting.

c. Who will deliver the intervention

The intervention will be delivered by employed NHS clinicians who are clinically qualified (e.g. psychiatrists, psychologists, nurses, occupational therapists) and have experience in delivering psycho-social interventions.

d. Training of clinicians

Clinicians will be trained in the intervention in one session of up to three hours, flexibly in either a group format or individual format by a senior member of the core research team. When and if required, depending on the previous experience, additional one-to-one training can be provided.

During the training they will acquire knowledge of the structure and aims of the intervention, i.e. number of sessions, frequency of sessions and procedures to help the patients to reach out to social activities. They will also be taught simple motivational interviewing techniques. Scenarios in which barriers for the patient in engaging in new social contacts may appear and strategies to overcome them will be discussed.

Knowledge about the local context will be helped by a list of possible local options for low cost activities in the local area available to the patient that involve contacts with other people. This list will be provided by the research team. Clinicians will also be expected to and supported in obtaining a good knowledge about the options and encouraged to network in the given community to generate more options for relevant activities. Learning progress will be assessed during the training and in the subsequent supervision, provided by senior members of the research team, which will be organised flexibly in order to identify the ideal frequency. At the end of the case studies, clinicians who have delivered the intervention will receive an in-depth interview and will be encouraged to provide suggestions for further refinement of the intervention, of the training and of the supervision arrangements.

e. Further support of clinicians

Clinicians will receive updates on changes in options for activities from the local research team and from participating clinicians themselves through networking. They will also be supervised through regular phone calls (at least once a month or more if and as required) either locally or centrally from the study team in London.

Recording of the intervention sessions

For each clinician, we will aim to audio-record three interventions sessions (if the patients consent to this). They will be helpful to understand what are the topics and activities discussed during the intervention sessions and to identify ways to help motivation and commitment of patients to social activities in order to help specify training guidelines and obtain examples to be used for a training package.

Control group

Patients in the control group will be provided with comprehensive information about local options for social activities by the researcher. This group is intended to control for the provision of information and non-specific attention through a professional in addition to routine care. Also, the mere provision of information should be regarded as good practice independent of additional targeted interventions, so that patients in the control group should receive it too.

The usual treatment, including care-coordination, medication, and psychological therapies, will not be affected, neither in the intervention nor in the control group.

Follow-up quantitative interviews with a researcher

This applies to both the intervention and control groups. All participants from the intervention group, and half of the control participants, chosen at random, will complete the follow-up. Participants will fill out the same questionnaires as during baseline assessment:

- Sociodemographic information;
- Client Service Receipt Inventory, (CSRI, Beecham and Knapp, 2011);
- Positive And Negative Syndrome Scale (PANSS, Kay, 1991);
- Clinical Assessment Interview For Negative Symptoms (CAINS, Kring et al., 2013);
- Social Contacts Assessment (SCA, Giacco et al., 2016);
- Time Use Survey (TUS, Priebe et al., 2016);
- Manchester Short Assessment of Quality of Life questionnaire (MANSA, Priebe et al., 1999);
- EQ-5D-3L (Rabin et al., 2014);
- ICECAP-A (Al-Janabi et a., 2013);
- Global rating of Loneliness;
- UCLA Loneliness Scale (Hays and DiMatteo, 1987);

Client Satisfaction Questionnaire (Attkinsson and Zwick, 1982) will be added at the follow up assessment in order to evaluate satisfaction with the intervention.

In-depth (qualitative) interviews

Clinician and patient interviews will be conducted to assess their experiences of the intervention. All interviews will be audio-recorded and facilitated by a researcher using a topic guide. Patient interviews will take place at the end of their intervention, and clinician interviews will be conducted when they have completed interventions for all of their patients. Interviews will last between 45-60 minutes and will take place in quiet rooms across NHS sites, quiet rooms at the participating Universities or in patients' homes. We plan to conduct the interviews with 32 patients who took part in the intervention and with 8 out of 16 control participants. We will have sufficient time (9 month allocated to the study) and resources (we can rely on the help from CSOs) to conduct, record and analyse those interviews.

Payment to participants:

Patients taking part in baseline and post-intervention interviews will be offered £15 cash or voucher as a reimbursement for their time for each interview (maximum £30). Clinician participants will not be reimbursed for their time as the intervention sessions will take place during their working hours. The commitment required is not likely to have a significant effect on their working time and the participation of the clinicians will be discussed with their line managers and team leads.

Adherence to manual

Adherence to manual will be assessed through the use adherence checklist, routine documentation (recording document after each session), and audiotapes of patient professional meetings (as far as these can be collected).

Economic evaluation

We will assess costs related to delivery of the intervention based on the professionals involved and the number of sessions offered. We will also collect use of services in the experimental and control group by retrospective participant self-report using a relevantly modified version of the Client Services Receipt Inventory. We will use the EQ-5D-3L and ICECAP-A and evaluate their ease of administration and patterns of missing data in order to choose the final measure to use for cost-effectiveness analysis in the subsequent large trial.

6.1 Recruitment

Patients will be identified through screening community mental health teams' caseloads, primary care caseloads and through the data base of participants of the previous work packages who expressed an interest to take part in the intervention. At this stage, the minimum amount of information will be logged to ascertain eligibility: name, RIO or NHS number, inpatient status (to ascertain eligibility) and diagnosis. We will discuss with treating clinicians if patients are deemed to be socially isolated. Addresses will only be logged for patients eligible to the intervention, so that letters can be sent inviting them to take part.

6.1.1 Patient identification

Mental health professionals with different roles who fit the eligibility criteria will be asked to participate. They will be approached by email, letter, phone or in person.

Patients on community team caseloads will be screened for eligibility by clinical teams. Clinicians will contact patients (by phone or face-to-face) and if patients verbally agree to meet a researcher, they will be invited to the baseline interviews with researchers. The research team will not contact patients unless they have received permission from clinicians or participants from the previous part of the project to do so. Once patients verbally agree to meet a researcher, the clinicians will share permission and patients' contacts with researchers through encrypted email networks, phone or face-to-face meetings. The researchers will then contact patients face to face or via phone, offering to send participant information sheets via post or directly providing them if the meeting is face to face. The

baseline interview could follow during the same session or patients will be allowed one week to think about their participation.

The eligibility will be then confirmed during the baseline interviews by the research team with reference to the criterion of "5 or less score on the MANSA “

If patients meet all the inclusion criteria, they will be invited to participate in the intervention and in the follow-up quantitative and qualitative interviews. The interviews will take place within NHS facilities, quiet rooms at the participating Universities or at patients' home based on patients' preferences.

6.2 Consent

All patients who respond to study information with interest will be contacted and invited to attend a face-to-face meeting. Researchers will go through information sheets with interested individuals and time taken to answer any questions or concerns that are raised.

All participants will be asked to provide informed consent, by initialling, signing and dating an informed consent form before any data collection begins. If patients require some time to think about participation, they will have up to one week to do so, otherwise the baseline interview will be done on the same day. A written consent form will need to be signed by the participant and a member of the research team in order to proceed with study participation The participant will keep one copy and the research team will keep the original which will be scanned and uploaded to the electronic medical records. Participants will also be given the option during the consent process to receive findings from the study, and permission will be sought to access medical records to retrieve clinical characteristics. Patients will also be asked if they consent to some of the sessions being audio-recorded, but this will be an optional criterion and they will still be able to participate if they refuse that their sessions are audio-recorded. Only patients who are fully eligible to the intervention will then be invited to participate in it.

Research team members will ensure each person’s level of understanding during the recruitment and consent process, alongside discussion with patients’ clinicians where necessary. Researchers will discuss the information sheet with patients and answer any questions they might have. If there are any doubts about the person’s capacity to consent, this will need to be resolved before proceeding with study participation. If any doubts about their capacity emerge during the recruitment process, or capacity to consent appears to change during their participation in the study, their capacity to consent will be re-evaluated before continuing with study participation. For each intervention session any change in capacity to consent will be evaluated by experienced clinicians according to standard practice.

If patients decline to participate, or withdraw their participation, this decision will be respected and patients are not required to give a reason for declining or withdrawing their participation. This decision will not have any impact on the patient’s treatment or rights, and this will be made clear to patients on the information sheet and by researchers during the consent process.

6.3 Study assessments

Socio-demographic and clinical characteristics will be collected from all patient participants. A modified form will be used to collect socio-demographic data from clinician participants. Qualitative data only will be collected through individual interviews. There will be baseline and follow up interviews to collect data on patients' social contacts and social activities, quality of life and symptoms.

6.4 Withdrawal criteria

During the consent process, researchers will ensure that participants (both patients and clinicians) are aware of their right to decline participation at any stage of the research and that withdrawing participation will not affect their treatment or rights. Participants will be able to ask that their data is eliminated before the end of February 2019.

For WP4, if patients withdraw from the intervention, then the research team will ask permission to contact them to take part in the post-intervention qualitative interview in order to capture valuable information regarding reasons for withdrawal, which might be associated with the intervention. This will be explained to patients during the consent process and on the information sheet, and patients' decisions to not be contacted for the post-intervention interview will be respected.

If a participant wishes to withdraw from the study, researchers will record date of withdrawal and reason(s) for withdrawal.

Clinicians delivering the intervention will monitor the capacity throughout the intervention duration. If a participant, who has given informed consent, loses capacity to consent during the study. The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study.

6.5 Future Study

If following this feasibility trial there will be no major amendments to the intervention or research procedures, we will propose to the independent Programme Steering Group that: a) we will continue recruitment for a full hypothesis testing randomised controlled trial; b) we will use participant data from the feasibility trial (WP4) in the subsequent full randomised controlled trial (Work Package 5).

If the independent Programme Steering Group will approve our proposals we will submit the protocol for the full randomised controlled trial to the ethics committee as a major amendment.

7 STATISTICS AND DATA ANALYSIS

Objective 1 and 2:

We will gain further experience of how the intervention is delivered in NHS settings and will carry out qualitative interviews with patients and clinicians. We will discuss with the steering group and the LEAP findings from qualitative material from audio-recordings of sessions, open ended sections of the fidelity instrument and clinician and patient interviews with the steering group in order to decide on whether any further modifications to the intervention or the training manual are required.

Objective 3:

In order to assess the feasibility of recruitment and randomisation procedures, the number of screened participants, eligible participants and of those who refused participation or were not approached will be recorded. The number of participants who withdraw from the study will also be recorded. Screening, recruitment and retention will be presented as rates with 95% confidence intervals. Descriptive statistics (mean (sd) for continuous variables and count (%) for nominal) will be reported for socio-demographic data and on social contacts, social activities, quality of life and symptoms scores. Changes in number of social contacts, time spent in social activities, quality of life and symptoms following the intervention will be reported as estimates with 95% confidence intervals. No efficacy related statistical tests will be conducted.

Objective 4:

We will estimate excess treatment costs more in detail through obtaining information from clinical records on the number of sessions offered and whether additional sessions need to be offered because of non-attendance. This will be analysed through descriptive statistics.

We will explore two different methods to calculate cost-effectiveness of the intervention using the EQ-5D-3L and the ICECAP-A. We will explore ease of administration of both instruments through interviews with patients and analyse frequency and type of missing data through descriptive statistics. The final decision on what instrument to be adopted will be made by the programme management group following discussion with the steering group and the lived experience advisory panel.

Objective 5:

We plan to have different professionals delivering the intervention during the feasibility trial (e.g. psychiatrists, nurses, occupational therapists, senior psychologists and psychology graduates). The final decision on which type of professionals will be chosen to deliver the intervention will be made by the programme management group following discussion with the steering group and the lived experience advisory group. The discussion will be based on data from the adherence checklist and from the interviews with patients and clinicians.

Objective 6:

The data collected using the adherence checklist will be triangulated with audio-recordings of sessions to test whether there is accordance and the less expensive method (i.e. adherence checklist) is appropriate to measure fidelity in the trial. The audio-recordings will be rated by independent evaluators in the research team according to the same domains as found in the adherence checklist. We will calculate correlation rates through correlation statistics and report to the steering group. A final decision will then be made on whether to amend the current adherence checklist or use alternative methods to assess fidelity in the trial.

7.1 Qualitative and Quantitative Data Analysis Plan

Quantitative data will be analysed using descriptive statistics. Data on patient statements on reasons for not participating and thoughts about outcome measures will be subjected to content analysis.

Audio recordings of intervention sessions and interviews with clinician and patients will be transcribed verbatim and analysed using content analysis techniques. The steps for inductive content analysis outlined by Elo and Kyngäs (2007) will be followed. After familiarisation, two researchers will independently analyse the data. Open coding will be conducted, making notes and headings in the text in order to describe the content. The process of grouping similar codes under themes will follow. The identified themes and subthemes will be then checked and refined in order to enhance conformability and reduce bias (Elo et al., 2014).

To optimise validity, we will (1) ensure attention is paid to negative cases and (2) conduct respondent validation by checking the analytic interpretation with patients/professionals. Inter-rater reliability in applying second level codes (or categories) will be calculated on 20% of the data. If captured, recordings will be transcribed verbatim and analysed as described above. If possible, data from interviews, recording documents and recorded first sessions will be triangulated as a further validation procedure.

7.2 Sample size calculation

A total of 12 clinicians and 48 patients will be recruited across all sites, with 32 randomised to the intervention (3 patients per clinician). Randomisation services will be provided by the Pragmatic Clinical Trials Unit (PCTU) at QMUL. This number of participants was chosen in order to allow exploratory testing of the intervention in a small number of patients for further refinement and specification before randomised controlled trial in a larger number of patients. Clinicians will be purposively sampled in order to recruit clinicians with different roles and therefore assess feasibility of training and delivering the intervention.

7.3 Subject population

All patient data collected will be subject to data analysis as described in this section. The exception is where participants withdraw individual interviews. In these instances, data will be deleted if this is requested before the end of February 2019. It will otherwise be included in the analysis and only reported in an anonymised form as for the rest of the research data. This will be made clear to all participants during the consent process and on the information sheet.

8 MONITORING, AUDIT & INSPECTION

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

The feasibility trial will be supported by the registered Pragmatic Clinical Trials Unit at QMUL and follow all its Standard Operating Procedures. A Programme set-up meeting with the PCTU Team has been held prior to commencement of data collection. A multidisciplinary risk assessment will be conducted including the PCTU QA manager, CI and other relevant staff members. Based on the risk assessment, an appropriate study monitoring and auditing plan has been produced according to

PCTU SOPs. This monitoring plan will be authorised by the CI/Sponsor before implementation. Any changes to the monitoring plan will be agreed by the CI/Sponsor. Monitoring visits and procedures will be recorded in the TMF and will adhere to the SOPs of both NOCLOR and the PCTU.

9 ETHICAL AND REGULATORY CONSIDERATIONS

9.1 Research Ethics Committee (REC) review& reports

"The Principal Investigator will ensure that the study will be carried out in accordance with the ethical principles in the UK Policy Framework for Health and Social Care Research, with effect from November 2017 and its subsequent amendments as applicable and applicable legal and regulatory requirements".

As this study will be lead from England and involves NHS patients, before the study starts it will require approval from the Health Research Authority (HRA) and REC Favourable Opinion for the study protocol, informed consent forms and other relevant documents, e.g. information sheets. Separate documents for each work package will be submitted where necessary.

Any substantial amendments requiring review by the REC will not be implemented until a favourable opinion has been granted and approved by the relevant NHS R&D departments and HRA.

The Chief Investigator will notify the REC, HRA and study sponsor of the end of the study, and will immediately notify the REC, HRA and study sponsor should the study end prematurely. This will include notification of the reasons for premature termination.

Capacity:

The assessment of capacity will be done in two stages: in a first stage (when obtaining expression of interest and permission to contact individuals), capacity will be assessed by trained and experienced mental health clinicians. In a second stage (when obtaining informed consent), researchers will assess capacity again. The researchers will have experience in mental health studies and will be trained by experienced clinicians (Giacco and Priebe) in assessing capacity to consent to research. They will use a standardised template (Capacity Checklist) for assessing capacity. Clinicians delivering the intervention will assess capacity at each intervention session as per standard clinical practice.

Informed consent:

As detailed in section 6.2, the study researchers will explain to participants what will be expected of them and how long they would be in the study for. The researchers would also ensure they are aware of their right to decline participation at any stage of the research and clarify that declining to participate will not result in any consequences whatsoever on patient treatment. All participants will receive a written information sheet. All participants will be given the option to have the contents of the sheet read aloud to them by the researchers. Researchers will answer all participants' questions about the study before proceeding with the study, and they will have time to decide whether they wish to participate. A written consent form will need to be signed by the participant and a member of the research team in order to proceed with study participation (one copy will be given to the patient). The study team will retain the originals and scan and upload a copy to patent electronic medical records. In the rare case that electronic medical records will not be available or not functioning, we will file a paper copy in paper-based medical records.

Data collection:

Experienced and trained researchers will conduct training in the intervention for clinicians and individual interviews (with patients and clinicians). If a participant shows signs of irritation or dissatisfaction, or any other untoward psychological reaction, the session can be stopped immediately, and researchers will contact the treating clinicians. Participants will be made aware that they are not expected to make personal disclosures and that they do not have to answer any questions that might make them feel uncomfortable or distressed.

Data protection:

Data will be pseudonymised and securely stored. The patients will be identified in datasets and information sheets only by a personal identification number. Patient-identifiable data will be stored securely and accessible only by the research team.

9.2 Public and Patient Involvement

Patient and public involvement has already been sought to further develop initial ideas for this study and the related programme of research through:

- SUGAR (Service Use and Carer Advisory Group on Research) at City University London
- Patient Engagement Group at East London NHS Foundation Trust
- A Community Health Network lay advisors meeting arranged by the McPin Foundation
- A peer review panel at the McPin Foundation

A Lived Experience Advisory Panel (LEAP) has been set up and it will meet every four months throughout the study to advise on the research itself, review material and support the overall public and patient involvement. The LEAP is chaired by a patient who is also a co-applicant on this programme of research, and includes members from SUGAR and the associated network of service users with research interest and experience.

The LEAP has a central role in the preparation of study materials, design of practical procedures, and dissemination. For the development of open questions that form part of the survey in WP1, we have worked with SUGAR to develop this as the LEAP has not yet been formed. The LEAP then helped with the development of topic guides for the focus groups and interviews that form WP2 and 3. LEAP members also provided valuable feedback for facilitating recruitment and finding out about available activities in the community. The LEAP chair is attending regular meetings with the project team and she is directly involved in parts of the research, in particular the interpretation of qualitative material from interviews and focus groups. Findings from all work packages, and ways to further develop the intervention and training will also be discussed with the LEAP. The LEAP's role in dissemination is further described in Section 10.

9.3 Data protection and patient confidentiality

All researchers and study staff must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

Personal information:

All participants will be assigned a participant ID number and this will be used for all data processing purposes. Participants' names and contact details will be retained (with their permission) to share research findings. As the project linked to this is funded for five years, it is envisaged that participants might want to know how their information and suggestions have helped to shape the service on offer.

Directly identifiable patient data (participants' names, contact details, socio-demographic data) and the list linking these data with participant ID number will be password-protected and stored on secure servers at participating research sites', which will only be accessible by the research programme (SCENE) team members on a need-to-know basis. All hard copies of data including socio-demographic forms, consent forms, patient receipts will be kept in lockable filing cabinets on NHS premises of participating sites, and only accessible to the research team members on a need-to-know basis.

Electronic data transfer from the PCTU to ELFT will be carried out securely in accordance with PCTU processes. Lists linking participant names to participant ID numbers will remain with local sites.

Audio recordings

The interviews and some intervention sessions (initial two sessions and at least one follow-up session) will be audio-recorded with participants' permission. Audio recordings will be stored on secure servers in participating Trusts, with access restricted to appropriate members of the research team. Audio recordings from participating sites will be transferred to the host site using encrypted USB sticks or via an encrypted connection and then transcribed using a NHS-approved professional transcription company. The audio recordings will be destroyed immediately after transcription and analysis. We have the resources to conduct this additional follow-up session and analyse further data in a timely manner before the end of the study. Once transcribed, all identifiable information will be omitted or replaced with pseudonymised labels.

Record retention and archiving

In accordance with the UK Policy Framework for Health and Social Care Research and East London NHS Foundation Trust Record Management and IM&T Information and security policies, research data will be archived as per East London NHS Foundation Trust procedures and kept for 20 years in the Trust Modern Records Centre. The Chief Investigator will be data custodian.

9.4 Indemnity

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

9.5 Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of the submission to the REC.

The amendment history will be tracked via version and date control of protocols, with changes to the protocol highlighted in the Appendix 2.

10 DISSEMINATION POLICY

10.1 Dissemination policy

Dissemination activities will be influenced and supported by the LEAP. Throughout all phases of the research, we will disseminate information about the activities of the programme through social media and a project specific website (http://scene.elft.nhs.uk/) in order to reach a wider public audience. The website will provide information for patients, professionals and service commissioners; and will be linked to other websites of local authorities, the participating NHS Trusts, and the academic institutions of the applicants.

When results become available, they will be disseminated through:

- scientific publications in peer-reviewed open access journals;
- presentations at national and international conferences and to professional and non-professional audiences at appropriate events;
- existing networks, in particular
  a) the WHO, utilising the status of the Unit for Social and Community Psychiatry at QMUL as a WHO Collaborating Centre,
  b) the NHS, e.g. the benchmarking network in mental health which is currently co-ordinated by East London NHS Foundation Trust;
  c) the organisation involved in specific Quality Improvement programmes in health care
  d) different professional networks of the applicants;
- workshops and presentations at meetings that are held either as regular events (e.g. East London Mental Health Research Presentation Day, Showcase Conferences of CLRN) or specifically organised at different NHS locations;
- responding to invitations for presentations in different organisations; our experience with developing a new intervention in a PGfAR in the NHS, i.e. the DIALOG+ intervention, has shown that the news of an effective new intervention can spread quickly and lead to many invitations to present; we will arrange that all members of the project team including Research Assistants are in a position to give such presentations and prepare a regularly updated 'road show' for this.

Workshops for NHS Trusts and patient organisations will be delivered in collaboration with the LEAP. The LEAP will also be actively involved in developing lay summaries of the findings.
Study findings for each work package will be sent to participants who gave their permission during the informed consent process. The report will not include any identifiable information. The timeline for the reports will be explained to participants by the researcher during the consent process.

Foreground intellectual property (IP) will be developed during the course of the programme including (but not limited to) a manual for carrying out structured interviews and an associated training programme (and web-based training module, which will be embedded within the project-specific website).
IP protection: All discussions concerning the development of the manual and training programmes will be kept confidential among the research team before the IP is published.

The funders (NIHR) will be contacted at least 30 days prior to any publication arising from the project. Within the publications, the funding body will be acknowledged using the standard text as set out within the research contract.

10.2 Authorship eligibility guidelines and any intended use of professional writers

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

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12 APPENDICES

12.1 Appendix 1– Schedule of Procedures

	2018							2019	
Procedures	**Jun**	**Jul**	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**
Eligibility screening									
Initial meeting to discuss study									
Informed consent									
Socio-demographics									
Clinician training									
Intervention - clinician + patients									
Clinician individual interviews									
Patient individual interviews									

12.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made