East London NHS
NHS Foundation Trust

A RANDOMISED CONTROLLED TRIAL OF A STRUCTURED INTERVENTION FOR EXPANDING SOCIAL NETWORKS IN PSYCHOSIS

Short study title: SCENE (WP 5)

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

RESEARCH REFERENCE NUMBERS

IRAS number: 257667

REC number: 19/LO/0088

PROTOCOL VERSION NUMBER AND DATE Version: 1.0 Date: 04.12.18

OTHER RESEARCH REFERENCE NUMBERS

NIHR reference number: RP-PG-0615-20009

SPONSOR

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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.

Chief Investigator:

Date: 04.12.18

Signature: 

Name: (please print): Domenico Giacco

Statistician:

Date:04.12.18

Signature: 

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

STUDY SUMMARY

Study Title	Randomised Controlled Trial Of A Structured Intervention For Expanding Social Networks In Psychosis
Internal ref. (or short title)	SCENE (WP5)
Study Design	Individually randomised, parallel group, randomised controlled superiority 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; No substantial risk to self or others as per patients' clinical records and treating clinicians' opinions; 5 or lower score on the quality of life assessment (MANSA); three or less social contacts with non-first degree relatives in the previous week. Mental health professionals (minimum NHS band 4): aged 18 or over; with experience of providing mental health care; capacity to provide informed consent; ability to communicate in English. They will be trained to deliver the intervention by a senior member of the research team who has clinical experience.
Planned Sample Size	24 clinicians and 576 patients at seven sites (East London, York, Devon, Cornwall, Leeds, Somerset and Oxford); 288 patients will be randomised to receive the intervention. All patients will be interviewed at baseline to check eligibility. The study includes an internal pilot conducted over 5 months to check the feasibility of patient recruitment rates where 90% of the target (N=140) is needed to proceed with the full trial.
Study duration	40 months
Planned Study Period	01st of November 2018- 28th of February 2022 (or 40 months from start).
Study aims and objectives	Aim: To test the clinical effectiveness and cost-effectiveness of a psychosocial intervention to improve social networks of patients with psychosis as compared to an active control condition, i.e. information on social activities in the local area. The specific objectives are to: 1. Assess whether the intervention improves quality of life of patients with psychosis (primary outcome) relative to the active control. 2. Assess whether the intervention improves secondary outcomes such as social outcomes, mental health symptoms, social situation, feelings of loneliness, time spent in social activities, health-related quality of life and reduces service use; 3. Assess whether changes in social contacts are associated with changes in quality of life 4. Assess costs and cost-effectiveness of the intervention; 5. Evaluate implementation of the intervention and explore the processes which are associated with intervention effects.

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 FINANCIAL SUPPORT 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
Cornwall NHS Partnership Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and patients
Leeds and York Partnership NHS Foundation Trust	NHS treatment and support costs. Permission to conduct study on Trust premises with Trust employees and patients
Somerset Partnership NHS 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 PROGRAMME MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Programme 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 including patient representatives from the Lived Experience Advisory Panel. The PMG has been meeting at least three times per year throughout. The PMG will monitor the trial to check progress and discuss and address any arising issue. The project timeline and milestones will be scrutinised at each meeting. Co-applicants who are site leads meet more regularly on a monthly basis via teleconferences. 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 programme timeline and milestones will be scrutinised at each meeting. PSC meetings are attended by the Chief Investigator, the Programme manager and one senior researcher from the central Programme team at ELFT, the senior statistician on the programme, a sponsor representative and the quality assurance lead.

- 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 representative co-applicant. 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.

- Data Monitoring and Ethics Committee

  A Data Monitoring and Ethics Committee (DMEC) will be set-up prior to the start of the trial and will consist of one independent statistician, one clinician experience in treating people with psychosis and one service user representative. Ideally, at least one of these individuals will have prior experience serving on a DMEC. A DMEC charter, including meeting schedule will be developed with the PCTU and agreed upon at the first meeting. Broadly, their role will be to review the accruing trial data assess, whether there are any ethical or safety issues, whether there is any reason why the trial should stop and to report to the PSC.

Protocol contributors

Dr Domenico Giacco, Miss Agnes Chevalier, Miss Fareha Begum, Dr. Thomas Hamborg, Professor Sandra Eldridge and Professor Stefan Priebe

KEY WORDS: Social networks, psychosis, schizophrenia, quality of life

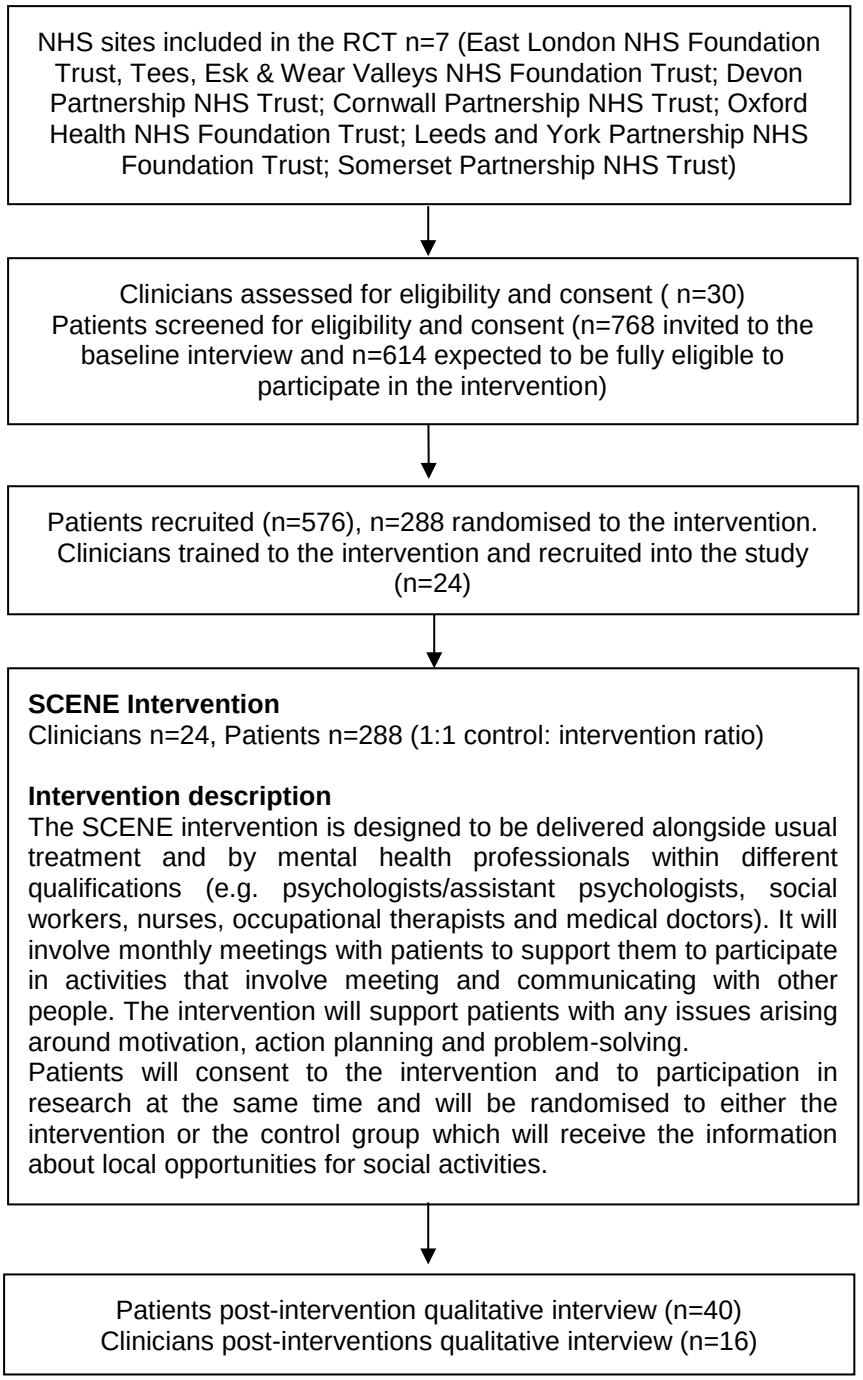
LIST of CONTENTS

LIST OF ABBREVIATIONS

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
NIHR	National Institute for Health Research
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

Randomised controlled 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 to the general population, and compared to other groups with long-term mental and physical health problems. Further, more than 50% of their limited networks consist of family members rather than friends or acquaintances (Emlet 2006; Palumbo et al. 2015). The National Institute for Health and Care Excellence (NICE) (2014) state that because one of the features of psychosis is an impairment in the individual's ability to '…maintain relationships; they may become increasingly isolated' (NICE 2014, p.14). To give an idea of the extent of social isolation among people with psychosis, a pooled analysis of 1396 patients with psychosis drawn from four international multi-centre studies revealed that only 45% of the sample reported to have met a friend in the previous week (Giacco et al., 2012). In a recent survey in London 80% of patients with psychosis felt lonely, and 43% reported feeling very or extremely lonely (Giacco et al., 2016). In line with previous evidence, only 30% had had more than one social contact in the previous week. A high degree of social isolation is one of the factors related to 'recurrent episodes or relapses' in patients with psychosis (Nice 2014, p.15) and is associated with poorer quality of life and unfavourable health outcomes in this group (Cohen et al, 1998; Clinton et al, 1998; Bengsson-Tops and Hansson, 2001; Norman et al., 2005).

The NICE recommendation for care provision states that initial assessments of those presenting to secondary care with psychosis should include an 'evaluation of their social networks, relationships' and consideration of their wider social needs (NICE 2014, p.465). However, as it stands, standardised and effective interventions to support patients with psychosis to increase their social activities and social contacts are not available as part of NHS care provision and little systematic research has been carried out in England or elsewhere. Nevertheless, previous research has provided encouraging preliminary evidence to suggest that directly supporting patients with psychosis to meet new people or to engage in social activities can help them increase their social networks (Anderson et al., 2015). In particular, a study carried out in Italy showed that social networks can be expanded with a relatively simple intervention in which mental health professionals helped patients to identify their preferences for social activities and supervised their progress with follow-up meetings (Terzian et al., 2013).

The present study is part of an NIHR-funded research programme whose overall aim is to; manualise an intervention based on these principles, adapt it to the NHS context, and test whether it is able to expand social networks and improve quality of life for patients with psychosis.

The intervention (which is described in Section 6 of this protocol) was developed through 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. These discussions were based on existing literature and on findings from previous work packages which included a survey, focus groups, a case series and feasibility trial of preliminary versions of the intervention. Following this preparatory work we developed a final version of the intervention with

associated training and supervision schedules, as well as the research procedures described in this protocol.

The proposed study is a randomised controlled trial to test effectiveness and cost-effectiveness of the intervention compared to an active control condition, i.e. information on local options for social activities.

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 close relationships, mainly with the patient's partner or family. However, there are a number of good reasons to focus an intervention on expanding social contacts outside of the family: a) for many patients, particularly those that are socially isolated, families are not available and/or the potential for contacts with the family are limited; b) where patients are still in contact with their families, relationships are often well-established with little option for further change; c) given that they are recommended in the NICE guidelines, services will have usually already tried family interventions at some point in the patient's history; d) family relationships can be difficult and rather stressful for some patients; and e) the limited social networks of patients with psychosis consist mainly of family members and what is missing are other relationships , those that can be more flexibly established and shaped, and those that patients can more easily terminate if they so wish.

In a 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 programme involved: a survey of 550 patients with psychosis from diverse rural and urban areas in England to assess their social contacts and social activities (work package 1); focus groups with 82 patients, mental health professionals and carers to refine the intervention (work package 2); a case series piloting the intervention with a small group of patients (N=27) and clinicians (N=14) (work package 3); a feasibility trial randomising 24 patients to the intervention and 12 patients to the control condition.

Work Package 1 helped define the inclusion criteria, i.e. the maximum number of social contacts conferring eligibility for the intervention (three).

On the basis of the feedback from Work Package 2 we adapted the intervention to include the cheapest or where possible, free options for social activities. We also adopted a more flexible approach to the intervention delivery, allowing for sessions to take place in NHS facilities or at the patient's home and for follow-up sessions to be held via phone or online conferencing tools.

Work Package 3 enabled us to identify the important problem of ensuring that patients understand the nature of and level of commitment required for the intervention as they may mistake it for generic social support (i.e. being allocated a support worker) or occupational therapy. If patients are only

interested in those interventions, they may become unmotivated once they discover that the intervention is different from what they expected. We discussed this with the LEAP and decided that in order to reduce the chance of misunderstandings we will: a) train both researchers and clinicians in explaining the intervention; both what it is and what it is not; b) produce simple, more user friendly descriptions of the intervention in addition to the Participant Information Sheet. These descriptions were developed in collaboration with the LEAP and with local patient representative groups at the different sites.

Work package 4 (feasibility trial) confirmed that the recruitment rate planned for the trial (4 patients per month per site) is feasible. We recruited 36 patients within two months at only three sites (East London, Devon and Tees, Esk and Wear Valleys, i.e. 6 patients per month per site). For the trial, we will keep the conservative rate of four patients per month per site to account for diversity between sites and for the potential need to over-recruit in larger areas or Trusts.

In collaboration with the Programme Steering Group we discussed and agreed three criteria for progression to trial. Following WP3 and WP4 all these criteria were met:

Criterion 1: Rate of patients disengaging from the intervention in work package 3 should be 33% or lower.

- The rate of disengagement from the intervention was 33%.

Criterion 2: Recruitment for WP4 should be completed by the end of September.

- The recruitment of patients for work package 4 was completed in the first week of September with a rate of six patients per month per site, which is much higher than expected. We expected four patients per month per site, which is the conservative rate that we will nevertheless use in the trial to account for site diversity.

Criterion 3: Adherence measure refined or approved.

- We developed an adherence measure that was used during the feasibility trial (WP4). All clinicians involved completed the measure and reported it to be comprehensive and easy to complete.

Hence, we propose that we initiate recruitment for the full trial (Work package 5 of the Programme).
In this full hypothesis-testing randomised controlled trial we will test the effectiveness on clinical outcomes and cost-effectiveness of the new intervention compared to an active control condition, i.e. information on local activities.

2.1 Study aims and objectives

The aim of the study is to test the clinical effectiveness and cost-effectiveness of a psychosocial intervention to improve social networks of patients with psychosis as compared to an active control condition, i.e. information on social activities in the local area.

The specific objectives are to:

1. Assess whether the intervention improves quality of life of patients with psychosis (primary outcome) relative to the active control.
2. Assess whether the intervention improves secondary outcomes such as social outcomes, mental health symptoms, social situation, feelings of loneliness, time spent in social activities, health-related quality of life and reduces service use;
3. Assess whether changes in social contacts are associated with changes in quality of life
4. Assess costs and cost-effectiveness of the intervention;
5. Evaluate implementation of the intervention and explore the processes which are associated with intervention effects.

2.2 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 who do not meet our inclusion criteria might be upset because they wanted to be exposed to 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 may also experience anxiety in trying the intervention and meeting new people or become frustrated by failed attempts to increase their social activities and contacts. We will minimise these risks by:

1. Explaining to the participant that if they are not eligible for the study they will resume care as usual, e.g. with their Community Mental Health Team.
2. Explaining the purpose of the research, as well as the research procedures at the recruitment stage to manage expectations.
3. Explaining early on, that participants who enter the study will receive either the intervention or a booklet containing information about local activities. Emphasise that the study is being done because we do not know what is better – information or active support. We will send thank you cards and letters to participants randomised to the control group informing them that they are still in the study and when they can expect to be contacted for follow-ups.
4. Instructing the clinicians delivering the intervention to manage potential feelings of frustration through simple psychotherapeutic techniques (see Section 6).

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

Confidentiality: Information related to participants will be kept confidential and managed in accordance with the Data Protection Act (2018), NHS Caldecott Principles (UK), UK Policy Framework for Health and Social Care, and the conditions of Research Ethics Committee Approval, or corresponding legislation or approvals for a particular participating site. To protect the identification of participants, study IDs will be created and assigned to 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 which will include contact details, date of birth and NHS number to allow tracing through national records. 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. NHS number and date of birth will be transferred securely and confidentially via the database developed by the PCTU and destroyed once linkage has occurred. Only for 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 in qualitative interviews, we will:

- Ensure that participants understand during the informed consent process that 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.
- As far as possible we will refrain from using participants' names during audio-recorded interviews and where names are used they will not be included in the transcript.

Use and storage of personal data: Participant data (quantitative and qualitative data) collected will be pseudonymised and handled in line with the Data Protection Act (2018), and other applicable study procedures. All case report forms will be stored in locked cupboards at the local research sites only accessed by the researchers on a need to know basis. Screening logs and any document linking IDs with names personal contacts (required for the follow-up), date of birth and NHS number will be stored in electronic forms in password-protected files only accessible to the study teams at the local research sites. The only exception to this is NHS number, date of birth and postcode collected for tracing through national records. These will be transferred to the central study team through a secure database developed by the PCTU and destroyed once linkage has occurred. 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.

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 that social isolation is an important clinical need and a negative prognostic factor, which should be addressed by appropriate interventions (e.g. Department of Health, 2011, NICE, 2014). The benefit of this research is that it will rigorously test a novel intervention which aims to improve social

networks and quality of life of patients with psychosis, and which might lead to other beneficial effects, e.g. better clinical outcomes.

The participating patients may benefit from receiving the intervention or from receiving information on social activities (in the control condition). We will make clear to them that we are not sure whether receiving the intervention is beneficial to their quality of life and this trial is a way of establishing whether the intervention may be helpful for patients.

Safety reporting

The study will consist of a baseline assessment, before patients are randomised to the intervention group or the control group, followed by three follow-up assessments, at six months (end of intervention), 12 months and 18 months. The intervention is an addition to patients' usual care. The DMEC will determine what, if any, safety reporting is needed. The need for Urgent Safety Measures are not anticipated.

Adverse Events (AE)

An adverse event will be defined as any event occurring during the research which results in physical or psychological harm. Any adverse events will be recorded in the study file and the participant's records. Any adverse event will be followed up by the research team.

Serious Adverse Event (SAE)

SAE will be defined as any event occurring to research participants during the research time which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability incapacity. 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. A limited number of SAEs occurred during work package 3 (case studies). None of the SAEs were related to the intervention or to being in the study.

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 study sponsor (NOCLOR team at East London NHS Foundation Trust) in writing within 3 days.

Annual Safety Reporting

The safety record to-date will be documented and reported via the HRA/REC's annual progress report. Unless specified by the DMEC, a separate annual safety report will not be produced.

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

Individually randomised, parallel group controlled clinical trial. 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 and Cornwall NHS Partnership Trust in collaboration with the University of Exeter, Oxford Health NHS Foundation Trust, Somerset Partnership NHS Trust and Leeds and York NHS Foundation Trust. The study will be advertised through the NIHR portfolio system so more sites may request to join the study at a later time. We will evaluate these requests in discussions within the Project Management Group. 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 any of the participating Trusts or Universities and include the following sites: East London, Luton, Bedfordshire, North East (York, North Yorkshire, Teeside and Durham), Devon, Oxfordshire, Buckinghamshire, Leeds, Swindon, Wiltshire, Bath and North East Somerset. If patient participants prefer, they will be given the option to carry out intervention sessions and research assessments at their homes or other community locations. Researchers and clinicians will follow the lone worker policy of their respective participating NHS Trust or University.

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 (three or less social contacts with non-first degree relatives in the previous week)
- Low quality of life (Score 5 or less on MANSA quality of life assessment)

Clinicians:

- Mental health professional with experience of providing mental health care (e.g. psychiatrists, clinical psychologists, nurses, occupational therapists), minimum NHS Band 4
- Aged 18 and over
- 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.

Consent

Potentially eligible patients will be identified by members of their treating clinical team (depending on the local Trust policy this may include clinical studies' officers), 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 will also refer to a database of patients that took part in a previous work package, the SCENE survey (WP1), and contact those who expressed an interest in the intervention and agreed to be contacted.

The clinician delivering the intervention will not be the patient's treating clinician 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 the 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 "a score of 5 or less on the MANSA and three or less social contacts in the previous week". If the service user is not eligible for the study they will still be 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. This will be a lay summary of results developed with the assistance of the LEAP. Informed consent will also be sought from clinicians.

The assessment of capacity will be carried out by researchers who are involved in discussing the study and obtaining informed consent. The researchers will have experience in mental health research and will be trained by experienced clinicians (Giacco and Priebe) in assessing capacity to consent to research. At each intervention session, capacity to consent to treatment will be confirmed by the delivering clinician according to common clinical practice.

Baseline assessment with the researcher

Demographic, clinical characteristics and service use

A member of the research team 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 will use a shortened version of the Client Service Receipt Inventory to record service use (CSRI – 'Generic' UK Mental Health, Beecham and Knapp, 2011).

Social contacts and activities

The number and characteristics of social contacts on each day of the previous week will be measured and recorded with the Social Contact Assessment questionnaire (Giacco et al., 2016). Time spent in social activities and type of social activities that participants have had in the previous week will be recorded with the Time Use Survey (Priebe et al., 2016).

Quality of life and loneliness assessments

The researchers will collect the information on subjective quality of life (MANSA, Priebe et al., 1999) and health-related quality of life (EQ-5D-5L, Herdman et al., 2011). Loneliness will be assessed through the UCLA-8 loneliness scale (Hays and DiMatteo, 1987).

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 study.

Symptoms

The researcher will carry out a standardised assessment of the current symptoms of psychosis using the Positive and Negative Symptom Scale, (PANSS, Kay, 1991).

Randomisation procedures

Patients will be randomised to either the intervention or control. The allocation ratio will be 1:1. Randomisation will be stratified by NHS Trust, ensuring balanced numbers of patients in each group at each NHS Trust. Permuted blocked randomisation with block sizes of m=6, 4 and 2 will be used within each stratum. Patients will be allocated to clinicians based on locality and availability i.e. not randomly.

The randomisation will be carried out remotely by the Pragmatic Clinical Trials Unit at Queen Mary, University of London. One researcher per site will be given a login to the system in order to complete randomisation at that site. Further details will be explained the Data Management plan which will be agreed and signed off between the trial study team and PCTU.

Intervention

In the following pages we provide a brief description of the intervention. The full intervention manual and training schedule are enclosed.

a. *Type and frequency of meetings*

Clinicians (named “social contacts coaches”) should meet patients six times over the six-month intervention period, around once per month.

The intervention will start with two initial meetings, each lasting about 60 minutes, and ideally within the first month. The main aim of these initial meetings is to explore preferences, discuss options for activities and agree a way forward. The subsequent meetings should include discussions around progress and the provision of support as required. The follow-up meetings should last at least 20 minutes each. Where needed further contacts between clinicians and patients, via telephone, text messages, Skype or other electronic means, will be encouraged. Said methods of contact may also replace face-to-face meetings, as long as the initial meeting and at least one other meeting remains face-to-face. The location of these meetings can vary and depend on patient preference and local circumstances (including patients’ homes, community places and NHS facilities).

b. Content of meetings

The meetings should focus on the patient’s motivation to expand their 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 via sms, phone availability at specific times). The planned activities should be a way of expanding 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 include 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 members).

The follow-up 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 will be asked to pick one to prioritise. If there has been little progress with one type of activity after a significant period of time (e.g. three months) a new activity will be discussed and agreed upon. There will be some flexibility around when the switch should be considered and agreed, however it should always be agreed by both the patient and clinician in a face-to-face meeting.

c. Who will deliver the intervention

The intervention will be delivered by clinicians (minimum NHS band 4) from a range of backgrounds, including psychologists/assistant psychologists, social workers, nurses, occupational therapists and medical doctors.

d. Training of clinicians

Clinicians will be trained in the intervention in one session of up to three hours, normally in a group format, although one-to-one sessions may be arranged if it is more practical for some participants (e.g.

inability to attend group training due to other clinician commitments). Training will be provided by a senior member of the core research team.

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 booklet with local options for low cost or free activities available to the patient that involve contacts with other people. These booklets will be produced and updated by the research team for all sites involved in the study.

Learning progress will be assessed during the training and in the subsequent supervision, provided by senior members of the research team.

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 at least two supervision phone calls (or more, if and as required) either locally by SCENE employed researchers or by the members of the central SCENE team in London.

Control group

Patients in the control group will be provided with information about local options for social activities by the researcher. This group is intended to control for the provision of information on social activities in addition to routine care and clinician attention to their social isolation. This control condition should reflect good standard practice, as it includes the assessment of social isolation and the provision of information on local opportunities on social contacts (NICE, 2015).

Usual mental health treatment, including care-coordination, medication, and psychological therapies, will not be affected by participation in this study, neither in the intervention nor in the control group.

Primary Outcome

The primary outcome will be subjective quality of life, measured on the Manchester Short Assessment of Quality of Life (MANSA) at the end of the intervention (6 months after recruitment).

The MANSA has been widely used in research with references in more than 450 research papers and data for comparison from >3000 patients with psychosis (e.g. Priebe et al. 2010). The MANSA is brief with very high completion rates. It has excellent psychometric properties and been shown to be sensitive to change (e.g. Priebe et al. 2015).

Mediator for the primary outcome

Number of social contacts in the previous week (Social Contacts Assessment (SCA, Giacco et al., 2016).

Secondary outcomes

- Psychopathological symptoms Positive And Negative Syndrome Scale (PANSS, Kay, 1991);
- Social situation (SIX, Priebe et al.,2008)
- Feeling of loneliness (UCLA Loneliness Scale, Hays and DiMatteo, 1987);
- Time spent in social activities (Time Use Survey, Priebe et al., 2016);
- Health-related quality of life (EQ-5D-5L, Herdman et al., 2011);
- Service use (Client Service Receipt Inventory, Beecham and Knapp, 2011; NHS Digital datasets, NHS Digital 2017)

Assessment	Screening	Baseline	Study phase (6 months)	Follow up (12 months)	Follow up (18 months)
All Patient Participants					
MANSA	**x**	**x**	**x**	**x**	**x**
Social Contacts Assessment	**x**	**x**	**x**	**x**	**x**
PANSS		**x**	**x**	**x**	**x**
Social situation		**x**	**x**	**x**	**x**
Loneliness		**x**	**x**	**x**	**x**
Time spent in social activities		**x**	**x**	**x**	**x**
EQ-5D-5L		**x**	**x**	**x**	**x**
Client Service Receipt Inventory		**x**	**x**	**x**	**x**
Healthcare source use (NHS Digital)		**x**	**x**	**x**	**x**
Intervention Participants only					
Semi-structured interviews			**x**		
Clinician Participants					
Adherence schedule			**x**		
Semi-Structured Interviews			**x**		

Internal pilot

The trial will have an internal pilot phase at each site. The main aim of the internal pilot is to check the feasibility of recruitment rates. Although the team has recruited to target with similar trials in the past (e.g. Priebe et al., 2015; NESS, Priebe et al., in press), a pilot phase should confirm that recruitment can be achieved and all data collected as defined in the protocol. The recruitment target for the internal pilot is 140, eight months from the start of the study. This is based on the fact that sites are likely to start at different times and represents an average recruitment rate of 4 participants per site per month for 5 months.

We will stop the trial if recruitment is below 50% of the target. If recruitment is above 50% but below 90% of the target, we will notify the funder and assess with the Programme Steering Group whether we can change the recruitment strategy to achieve the sample size required. If recruitment is 90% of the target or above we will proceed with the full trial.

Procedures for follow-up quantitative interviews with a researcher

All participants from the intervention group will be approached to complete the follow-up at 6, 12 and 18 months. Participants will fill out the same questionnaires as during baseline assessment in order to assess primary and secondary outcomes and potential mediators of intervention effect.

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 £60). Patients who will take part in qualitative interview will receive additional £20.

Clinicians will be interviewed as part of their working time so they will not receive any additional compensation for participation in research interviews.

We are applying for excess treatment costs to cover intervention delivery and will in all cases clearly agree the commitment required for the role with their line managers and team leads.

Adherence to manual

Adherence to manual will be assessed through our adherence checklist. Routine documentation and audiotapes of patient professional meetings (for consenting participants) will be compared against the clinician-reported adherence schedule to check reliability.

Economic evaluation

In an economic evaluation alongside the trial, we will measure intervention, health/social care and informal care costs over the follow-up period and combine them with health related quality of life (EQ-5D-5L).

Intervention-related inputs to staff and trial participants will be measured from our adherence forms. Other healthcare resource use information will be extracted from Trust electronic records and via linkages with NHS Digital datasets to cover a retrospective period of 6 months prior to baseline and the three follow-up periods (6,12 and 18 months). Other economic impacts will be collected by retrospective participant self-report using a relevantly modified version of the Client Services Receipt Inventory. This will be administered as an interview during each participant assessment (baseline, 6 months, 12 months and 18 months).

Resource use will then be combined with relevant unit costs, using within-programme estimates related to the intervention, national estimates for other health and social care resources, and both an opportunity cost and replacement cost approach in turn for informal care. Total care costs, with and without informal care, will be computed for each individual over the 18 month follow-up period. Mean cost differences between the two trial arms from these two cost perspectives will be compared using bootstrap methods due to the expected skewness in data distributions.

Cost-effectiveness analyses will combine total costs from the two perspectives with the outcomes specified above. QALY gains will be estimated by attaching relevant general population utility weights to EQ-5D-5L health states at each time point, with appropriate adjustments for the period of time involved and linear interpolation to calculate the area under the QALY curve. The cost-effectiveness analyses will also examine the potential impact on cost-effectiveness from different implementation/costing scenarios related to the intervention to better inform implementation discussions. Other relevant sensitivity analyses will be determined during the study and will be specified in the analysis plan prior to analyses.

For each cost-outcome combination, if one group has both lower costs and better outcomes than the other, then it will be concluded as ‘dominant’ in terms of cost-effectiveness. If costs are higher but outcomes better, then an incremental cost-effectiveness ratio will be calculated to identify the extra costs incurred to produce extra units of the relevant outcome(s). Uncertainty around these estimates will be analysed using cost-effectiveness planes.

6.1 Recruitment

Patients will be identified through screening community mental health teams’ caseloads, primary care caseloads and through the database of participants from previous work packages who expressed an interest in taking part in the intervention. At this stage, the minimum amount of information will be logged to ascertain eligibility: name, electronic patient record number 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 for the study and kept at the local site, so that letters can be sent inviting them to take part. Logs will be kept at local research sites.

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

6.1.1 Patient identification

Patients on community team caseloads will be screened for eligibility by members of clinical teams, clinical studies officers or research team (where applicable based on Trusts' policies). Members of clinical teams or clinical studies' officers 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. Patients who agreed to be contacted for the trial during the WP1 survey will also be contacted by the research team directly. They will be sent a letter or contacted via phone to enquire whether they are still interested in participation.

Once patients verbally agree to meet a researcher, the clinicians and clinical studies' officers 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, email or directly providing them with these documents if the meeting is face to face. The baseline interview could occur during the same session if appropriate. Otherwise, patients will be allowed one week to think about their participation.

In addition to this, leaflet and posters will be created to advertise the study in NHS facilities and online.

The eligibility will be then confirmed during the baseline interviews by the research team with reference to the criterion of " a score of 5 or less on the MANSA" and 3 or less social contacts in the previous week.

If patients meet all the inclusion criteria, they will be invited to participate in the study and in the follow-up quantitative and (if selected) 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 and take time 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. The original signed consent form will then be kept in each individual site file after it is 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.

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 emerges during the recruitment process, or 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. It will be made clear that 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

Study assessments will be carried out at baseline and at three additional time points (6, 12 and 18 months). The measures used to assess different outcomes and mediators are reported on page 22 (Section 6). Socio-demographic characteristics will be collected at baseline, whilst data on outcomes and mediators will be collected at baseline and at the three additional time points. Qualitative interviews will be conducted after the end of the intervention.

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 that withdraw from the intervention will not be withdrawn from the study and will continue to be contacted for follow-up assessments, unless they state otherwise. When a participant expresses a wish to withdraw, a researcher will seek to clarify whether this is from the intervention, from the study or both.

Patients who request to withdraw from their study participation will not be contacted for follow-up assessments and not required to give a reason for declining or withdrawing their participation. It will be made clear that this decision will not have any impact on the patient's treatment or rights, as part of the participant information sheet and of the discussion with researchers during the consent process.

If they also wish their data to be deleted, this will be possible before the end of the study. This is clarified in the PIS.

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. Data already collected with consent would be retained and used in the study.

6.5 Blinding

Due to the nature of the intervention trial participants cannot be masked to treatment allocation. Researchers involved in assessing outcome measures, will be blinded to participants' allocation. To minimise the risk of researchers becoming un-blinded during follow-up assessment, we will instruct the participants to avoid revealing their allocation. To facilitate this there will be one un-blinded researcher per site (in addition to the principal investigator), who will organise assessments and remind participants to conceal their allocation. At the end of the assessments, researchers will record their guesses as to whether participants are in the intervention or in the control group. Either the Chief Investigator or co-lead (Giacco or Priebe) will remain blinded. The statistician analysing the trial will remain masked to patients' allocation until the Statistical Analysis Plan has been signed off and the trial database finalised and locked for analysis.

7 STATISTICS AND DATA ANALYSIS

Quantitative analysis

The primary outcome analysis will be the comparison of means MANSA scores between treatment groups at 6 months follow-up using mixed models to account for clustering occurring in the intervention arm and baseline values of the outcome (MANSA) and *site* as covariates. Any other covariates to be included in the model will be chosen prior to sign off of the formal statistical analysis plan.

Secondary outcomes will be analysed using the same model as for the primary outcome or an equivalent model appropriate for the outcome type where the secondary outcome is not continuous. Differences in outcome measures between groups will be compared for 6 months, 12 months and 18 months follow-up data. Additionally repeated measures models comprising all four time points will be fitted. Baseline characteristics of patients will be tabulated by treatment arms.

The analysis will be on an intention-to-treat basis, and every effort will be made to collect complete data. If any outcome data are missing, available subject data only will be analysed (unbiased analysis under missing-at-random assumption); however, patterns of missing data will be explored, and a strategy for dealing with missing values will be articulated in the formal statistical analysis plan.

Sensitivity analyses will include a complete case analysis and using other covariance structures in the mixed model. A mediator analysis will identify whether the effect on the primary outcome is mediated through expanded social networks (SCA) at six months, as hypothesized. Further mediation analyses will assess the mediation effect of increases in SCA at 6 months on patients' MANSA score at 12 months follow-up.

All analyses will be incorporated into a statistical analysis plan, and allocation codes will not be released to the statistician before the analysis plan is signed off. All researchers involved in developing the analysis plan will remain blinded until the analysis plan is signed off.

Qualitative process evaluation

The statistical analysis will be complemented by a qualitative process evaluation, based on in-depth interviews following the intervention. The final version of the semi-structured interview guide will be developed with input from the LEAP. We will interview 40 purposively selected patients in the experimental group to explore positive and negative experiences of the intervention and descriptions of qualitative changes in their social network. Interviews will be conducted after the end of the six-month outcome assessment, so that the interviews do not interfere with the effects of the intervention in influencing the primary outcome (quality of life at six months). In the purposive sampling, we will include patients with different characteristics, and use gender and age as sampling criteria. We will also sample for patients who have completed the intervention and those who dropped out of the intervention. The invited participants will be identified by an un-blinded researcher, as patients need to be interviewed before the data set is completed. We will also interview 16 randomly selected professionals from different sites who administered the intervention.

Un-blinded researchers will also conduct the interviews and the ongoing management of the qualitative data, to avoid blinding of researchers assessing outcomes from becoming compromised.

7.2 Sample size calculation

It is assumed that the proposed new intervention would be implemented and funded across the NHS only if it achieved at least a medium sized effect. An effect size of 0.35 is equivalent to an improvement of satisfaction ratings in the MANSA of at least one scale point (on a 7 point scale) on 4 out of a total of 12 life domains. An improvement of quality of life in 4 life domains is usually regarded as a meaningful difference to patients' life (Priebe et al., 2015).

For detecting such an effect size with 90% power, assuming a conservative ICC of 0.07 of patients treated by the same professional in the intervention group, 229 patients in the intervention group and 229 in the control group will be required (total sample = 458). This sample size has been calculated using an iterative search algorithm. Initially the required sample size for the pre-specified clinically relevant improvement and power for a range of different pre-specified allocation ratios is calculated and the sample size in the intervention arm then inflated in the experimental arm to account for the clustering due to participants being treated by the same clinician. Then the minimal sample size resulting in equal group sizes is identified. This requires 8 additional patients to be recruited compared to the overall minimum. Assuming a drop-out rate (from the study) at 6 months follow-up of 20% (in line with recent trials of similar interventions with the same patient group) (VOLUME trial, Priebe et al., 2016), we will have to recruit a total sample of 576 patients, 286 in the intervention and 286 in the control group. The sample size calculation is based on 10 patients being treated and followed-up per clinician on average. To account for drop-out 12 patients need to be allocated to each clinician and therefore 24 clinician coaches recruited to participate in the study. Base on recruiting 12 patients per clinician the final total sample size is 576 (288 per arm).

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 specific interviews and request their data to be deleted before the end of February 2022. It will otherwise be included in the analysis and only reported in an anonymised form as with 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 research will be subject by monitoring and auditing by the Sponsor and/or PCTU.

The trial will be supported by the registered Pragmatic Clinical Trials Unit at QMUL and follow all of its applicable Standard Operating Procedures. A Programme set-up meeting with the PCTU Team has been held prior to commencement of data collection for the entire programme. 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 Trial Master File 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.

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 carried out by researchers when obtaining informed consent. 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 confirm 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 SCENE core research team on a need to know basis as described in Section 2.1.

9.2 Public and Patient Involvement

Patient and public involvement has already been sought to 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 meets every four months during the programme to advise on the research itself, review materials 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 worked with SUGAR to develop this as the LEAP had not yet been formed. The LEAP then helped with the development of topic guides for the focus groups and interviews that form WP2, 3 and 4 and to address feasibility issues emerging in WP3 and 4. LEAP members also provided valuable feedback for facilitating recruitment and finding out about available activities in the community. The LEAP chair attends regular meetings with the project team and 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 GDPR (2018) and Data Protection Act (2018) 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 to communicate with them during the study and to share research findings with them. 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, NHS number, 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. Site staff will enter NHS number, date of birth and postcode to a dedicated form in the study database in order for the central research team to link data from NHS digital. This will be clearly explained in the information sheet and only in instances where participants have given their explicit consent to link to this data by endorsing an optional item on the consent form. 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.

At the end of the study, 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, study management, data collection, data analysis and interpretation 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 2 – Amendment History

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