East London NHS
NHS Foundation Trust

EXPLORATORY TESTING OF A STRUCTURED INTERVENTION FOR EXPANDING SOCIAL NETWORKS IN PSYCHOSIS

Short study title: SCENE (WP 3)

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

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.

Chief Investigator:

Date:11/09/2017

Signature: 

Name: (please print): Stefan Priebe

Statistician:

Date:11/09/2017

Signature:

Name: (please print): Sandra Eldridge

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

STUDY SUMMARY

Study Title	Exploratory testing of a structured intervention for expanding social networks in psychosis
Internal ref. no. (or short title)	SCENE (WP3)
Study Design	Exploratory testing through case studies
Study Participants	Patients with a diagnosis of a psychosis-related condition (ICD10 F20-29); aged 18-65; receiving secondary care mental health services; capacity to provide informed consent; ability to communicate in English; two or less social contacts in the previous week outside home, work or mental health services as assessed using the Social Contact Assessment 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 24 patients at three sites (East London, York and Exeter); up to 32 patients will be interviewed at baseline to check eligibility.
Study duration	7.5 months
Planned Study Period	15th of October 2017- 1st June 2018
Study aims and objectives	Aim: To refine an intervention to expand social networks of patients with psychosis. The intervention will be delivered by experienced clinicians who will be trained in it by the research team. The specific objective is to: 1. Further specify the intervention, intervention manual and training module through exploratory testing in preparation for the feasibility trial and full randomised controlled trial.

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
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) will be made up 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 will be 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 will be 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 will meet approximately every 4 months, and meetings will be flexibly arranged, with individuals given the option of either a full or half day meeting. Their role will be specified and the terms of reference agreed during the first meeting. The focus of the LEAP meetings will be to discuss developing the study material (e.g. topic guides for WP3); 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

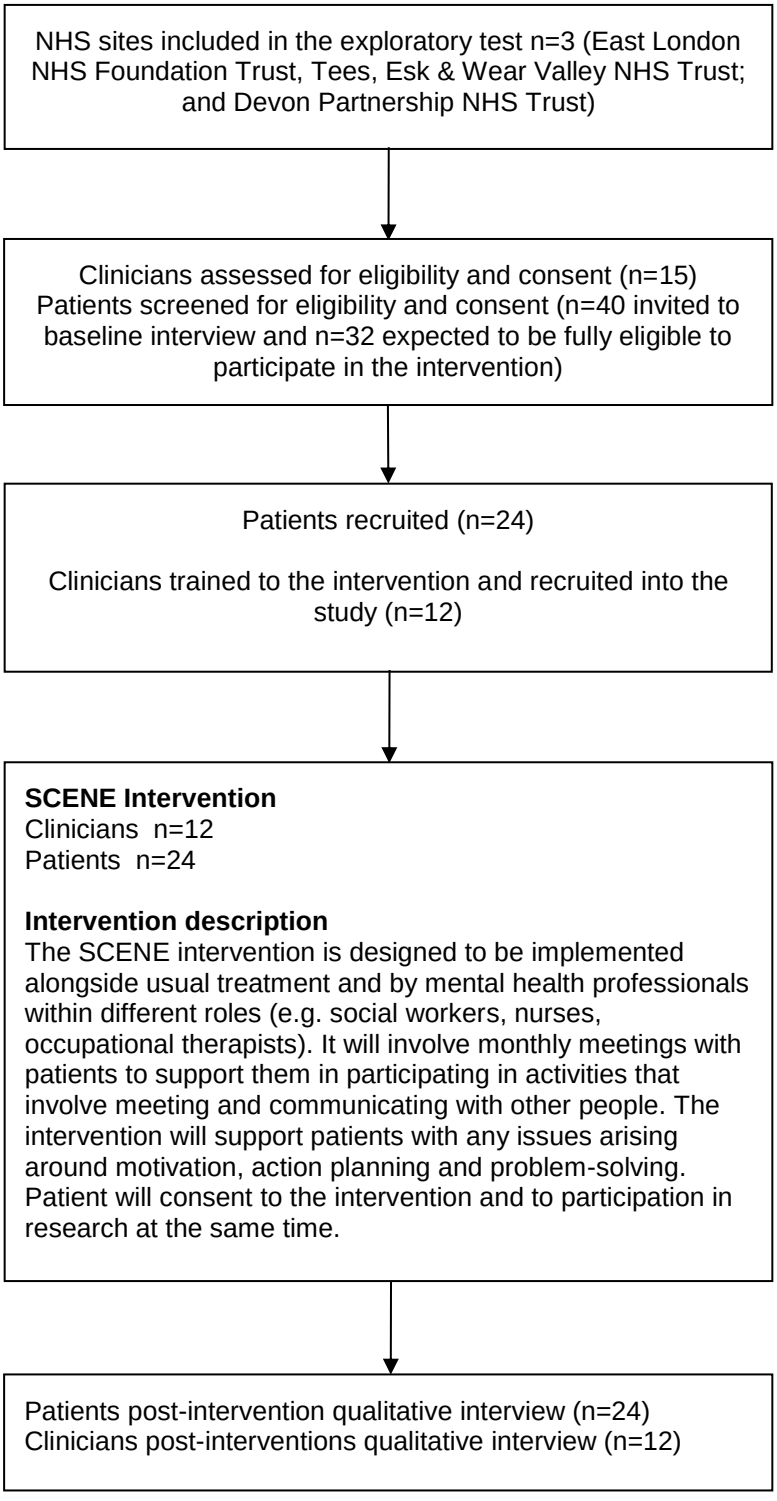
LIST OF ABBREVIATIONS

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. For 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

Exploratory testing 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. 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).

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. 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.

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 series of case studies with a draft intervention, in order to further adapt it to 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 and with the Service User and Carer Group Advising Research (SUGAR) at East London NHS Foundation Trust.

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".

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 refine and test an intervention to expand social networks in patients with psychosis so that it is feasible, acceptable, effective and cost-effective in different context across the UK, and scalable into routine practice in the NHS.

In addition to refining and testing the intervention we aim to develop an intervention manual and training module in preparation for a feasibility study and full randomised controlled trial.

During the current study we will test and refine the intervention through involving experienced clinicians 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.

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 take part in WP3 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 the purpose of the research to patients, at the recruitment stage to manage expectations.
2. 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. 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 form in password-protected folders only accessible to the study teams at different sites. All audio-recorded data will be encrypted and password protected. Data will be handled and stored in accordance with the conditions set out by the study sponsor (East London NHS Foundation Trust). All data handling and management activities will be carried out by the study team according to information governance requirements.

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 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

Exploratory testing: case studies 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 will is hosted by East London NHS Foundation Trust as coordinating centre and will take place across the following NHS Trusts: East London NHS Foundation Trust; Tees, Esk & Wear Valleys NHS Foundation Trust; Devon Partnership NHS Trust. Participants across all sites will be identified through 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, which contain the following sites: East London, Luton, Bedfordshire, North East (York, North Yorkshire, Teeside and Durham) and Devon. If patient participants prefer so, there will be the option to carry out research assessments at their homes. Researchers will follow the lone worker policy of East London NHS Foundation Trust (https://www.elft.nhs.uk/uploads/files/1/Policies%20and%20Procedures/Risk%20Management%20Policies/Lone%20Workers%20Policy%20(V6%200%20June%202016).pdf)

5 ELIGIBILITY CRITERIA

5.1 Inclusion criteria

Patients:

- 18-65 years old
- Diagnosis of psychosis-related condition (ICD-10 F20-29)
- Receiving secondary care mental health services
- Capacity to provide informed consent
- Ability to communicate in English
- Two or less social contacts in the previous week outside home, work or mental health services as assessed using the Social Contact Assessment

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 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 refine an intervention for use in the NHS and develop a preliminary training module, which will be further tested in subsequent work packages. It will also help to develop information for participants to help with recruitment to a future larger trial.

The specific study that we are currently applying for will 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 feasibility 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. 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. During the baseline interview, researchers will discuss informed consent and ascertain whether patients meet the inclusion criterion of “two or less social contacts in the previous week”. If yes, they will be invited to take part in the intervention. Informed consent will be sought from eligible patients and clinicians to participate in this study, which will include permission to access medical records to retrieve socio-demographic and clinical characteristics. 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.

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

Research team member will complete a case report form (CRF) recording patients’ responses. 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) (Priebe et al., 2016), subjective quality of life (Priebe et al., 1999), and symptoms (Brief Psychiatric Rating Scale, Overall and Gorman, 1988). During the

baseline interview, researchers will ascertain whether patients meet the inclusion criterion of having "two or less social contacts outside home, work or mental health services" using the Social Contact Assessment (Giacco et al., 2016). If yes, they will be invited to participate in the intervention. In a previous study, 75% of people with psychosis had less than two social contacts in a week, hence we estimate that we will need to interview 32 patients to invite 24 of them to participate in the intervention.

Demographic and clinical characteristics data collection

The research team member conducting the interview will ask participants about demographic and clinical characteristics 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.

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, clinical 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 intervention sessions

For each clinician, we will aim to audio-record two interventions sessions. 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.

Follow-up quantitative interviews

Participants will fill out the same questionnaires as during baseline assessment: Manchester Short Assessment of Quality of Life questionnaire (MANSA, Priebe et al., 1999), Social Contacts (SCA, Giacco et al., 2016), Time Use Survey (TUS, Priebe et al., 2016) and will be assessed using the Brief Psychiatric Rating Scale (BPRS, Overall and Gorham, 1988).

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 or in patients' homes.

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.

6.1 Recruitment

Patients will be identified through screening community mental health teams' caseloads. 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 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 "two or less social contacts within the previous week".

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 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 be given up to one week, 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 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 May 2018.

For WP3, 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.

7 STATISTICS AND DATA ANALYSIS

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. Descriptive statistics will be reported for socio-demographic data and on social contacts, social activities, quality of life and symptoms scores. We will then use paired t-test to assess any changes in number of social contacts, time spent in social activities, quality of life and symptoms following the intervention.

7.1 Qualitative Data Analysis Plan

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)

At the end of WP 3, the written manual for the intervention will be detailed, and the preliminary training module will have been assessed and specified in greater detail, so that there is a sufficiently detailed training module for the feasibility trial. A policy for the NHS Trusts participating in the research will be written, outlining the procedures of the intervention and addressing governance issues of quality assurance, supervision and professional accountability, as required.

7.2 Sample size calculation

A total of 12 clinicians across all sites will be recruited and up to 3 patients for each clinician (minimum 24 patients). 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 feasibility testing 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 May 2018. 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.

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 Research Governance Framework for Health and Social Care, Second Edition, 2005 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) will be 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 will be chaired by a patient who is also a co-applicant on this programme of research, and who will also recruit members from SUGAR and the associated network of users with research interest and experience.

The LEAP will have a central role in the preparation of study material, design of practical procedures, and dissemination. For the development of open questions that form part of the survey in WP1, we will work with SUGAR to develop this as the LEAP will not yet be formed. The LEAP will then help with the development of topic guides for the focus groups and interviews that form WP2 and 3. The LEAP chair will attend regular meetings with the project team and she will be 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 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 and then transcribed using a NHS-approved professional transcription company. The audio recordings will be destroyed immediately after transcription and analysis. Once transcribed, all identifiable information will be omitted or replaced with pseudonymised labels.

Record retention and archiving

In accordance with the Research Governance Framework 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

	2017			2018					
Procedures	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**
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
1	2	19/10/2017	Anna Ermakova	a) Participants' names and contact details will be retained (with their permission) to re-approach them to take part in related studies and to share research findings" to "Participants' names and contact details will be retained (with their permission) to share research findings" on p.25 of the Protocol. b) Corrected reference for BPRS-18 to Overall and Gorham (1988). Previous reference: Lukoff, D., et al. (1986) refers to BPRS-24 which is a longer version of the same rating scale.