East London NHS
NHS Foundation Trust

ASSESSING SOCIAL CONTACTS AND SOCIAL ACTIVITIES OF PEOPLE WITH PSYCHOSIS

Short study title: SCENE (WORK PACKAGE 1)

DELETE AS APPROPRIATE:

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

RESEARCH REFERENCE NUMBERS

IRAS Number: 228169

TRIAL REGISTRY NUMBER AND DATE

PROTOCOL VERSION NUMBER AND DATE Version: 4.0 Date: 27/11/17

OTHER RESEARCH REFERENCE NUMBERS

SPONSOR

East London NHS Foundation Trust
Contact person: Keji Dalemo
Address: 1st Floor, Bloomsbury Building
St Pancras Hospital
4 St Pancras Way, London NW1 0PE

Phone: 020 3317 3045
Email:sponsor.noclor@nhs.net

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:

Signature: Date: 08/08/17

.....

Name: (please print):

.STEFAN PRIEBE.....

Statistician:

Signature:

Name: (please print): SANDRA ELDRIDGE

Position: Professor of Biostatistics

KEY STUDY CONTACTS

Chief Investigator	Professor Stefan Priebe Unit for Social and Community Psychiatry Newham Centre for Mental Health Glen Road London E13 8SP Tel: 020 7540 4380 Email: s.priebe@qmul.ac.uk
Trial Co-ordinator	Dr Anna Ermakova Unit for Social and Community Psychiatry Newham Centre for Mental Health Glen Road London E13 8SP Tel: 020 7540 4380 Email: anna.ermakova@elft.nhs.uk
Sponsor	East London NHS Foundation Trust Noclor Research Support 1st Floor, Bloomsbury Building St Pancras Hospital 4 St Pancras Way, London NW1 0PE Tel: 020 3317 3045 Email: sponsor.noclor@nhs.net
Funder(s)	National Institute for Health Research Programme Grant for Applied Research Central Commissioning Facility Grange House 15 Church Street Twickenham, TW1 3NL
Clinical Trials Unit	Pragmatic Clinical Trials Unit (PCTU) Centre for Primary Care and Public Health Blizard Institute Yvonne Carter Building 58 Turner Street London E1 2AB Tel: 020 7882 2547
Key Protocol Contributors	Dr Domenico Giacco Catherine Fung Professor Stefan Priebe Unit for Social and Community Psychiatry Newham Centre for Mental Health

	Glen Road London E13 8SP Tel: 020 7540 4380 Emails: d.giacco@qmul.ac.uk; catherine.fung@elft.nhs.uk; s.priebe@qmul.ac.uk
Statistician	Professor Sandra Eldridge Pragmatic Clinical Trials Unit (PCTU) Centre for Primary Care and Public Health Blizard Institute Yvonne Carter Building 58 Turner Street London E1 2AB Tel: 020 7882 2547 Email: s.eldridge@qmul.ac.uk
Committees	Programme Management Group (co-applicants), Lived Experience Advisory Group

STUDY SUMMARY

Study Title	Assessing social contacts and social activities of people with psychosis
Internal ref. no. (or short title)	SCENE (WP1)
Study Design	Mixed methods cross-sectional survey
Study Participants	Patients with a diagnosis of a psychosis-related condition (ICD10 F20-29); aged 18-65; receiving care from outpatient secondary mental health services or in primary care; capacity to provide informed consent; ability to communicate in English
Planned Sample Size	500 patients
Study duration	Month 1-13
Planned Study Period	1st of June 2017-30th of June 2018
Study aims and objectives	Aim: To assess social contacts, activities and wishes to expand social networks of people with psychosis Objectives: 1. Assessing wishes of people with psychosis for expanding their social networks in order to estimate recruitment rates for a future clinical trial. 2. Assessing social contacts and social activities of people with psychosis 3. Identifying patient-level characteristics associated with social contacts and social activities

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 support costs. Permission to conduct study on Trust premises with Trust employees and service users
Tees, Esk & Wear Valleys NHS Foundation Trust	NHS support costs. Permission to conduct study on Trust premises with Trust employees and service users
Devon Partnership NHS Trust	NHS support costs. Permission to conduct study on Trust premises with Trust employees and service users
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 (TMG) 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 study 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.

- 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 service user co-applicant (Ms Geraldine Allen) whose experience includes working as a Peer Support Worker and trainer as part of ELFT and working as a Service User Researcher on a project run with East London Trust based on recovery. The panel will be recruited from an existing service user 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 materials; contribute to the analysis of the findings of this and other work packages; and to help dissemination, including developing plain English summaries so the results are accessible to individuals within services.

Protocol contributors

Dr Domenico Giacco, Ms. Catherine Fung, Prof. Stefan Priebe

KEY WORDS: Social networks, psychosis, schizophrenia, survey.

LIST of CONTENTS

LIST OF ABBREVIATIONS

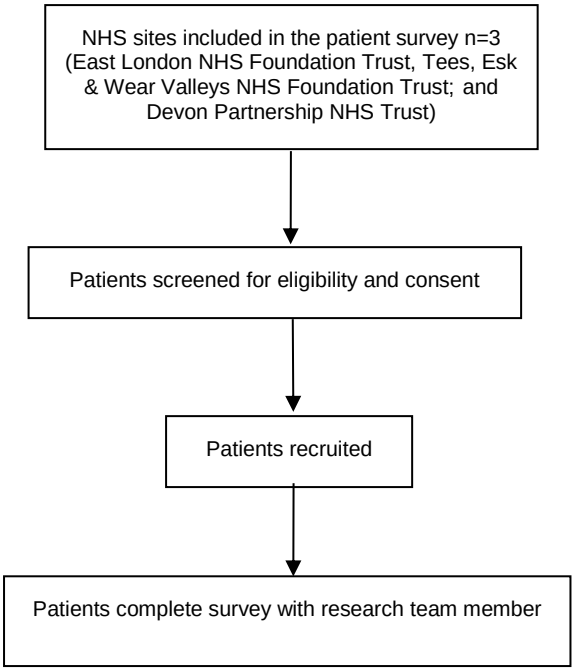
Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

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

STUDY FLOW CHART

Please see Appendix 1 for schedule of events.

Flow chart for Work Package 1 survey:



STUDY PROTOCOL

Assessing social contacts of people with 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 (Emlet 2006); and more than 50% of their reduced social networks consist of family members rather than friends and other contacts (Palumbo et al. 2015).

Social isolation is usually understood as a lack of sufficiently large and supportive social networks, with few friends and limited social contacts. 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. Furthermore, research has shown that smaller networks with loneliness, the absence of reliable social contacts and lower social support predict 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). 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 the NIHR-funded research programme of which this study is part 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 aim to obtain more accurate estimates of social contacts and social activities in people with psychosis in different areas of England and to understand how many of them are willing to engage in an intervention to expand their social networks.

2 RATIONALE

Available research suggests that many patients with psychosis tend to be highly socially isolated (Giacco et al., 2016) and those who are socially isolated have a worse quality of life (Becker et al., 1998; Bengsson-Tops et al., 2001).
Previous studies in the UK have focused on urban contexts (Giacco et al., 2016) and there is a need to explore social contacts of people with psychosis living in different areas. There is evidence that social deprivation and inequality are linked to psychosis (Kirkbride et al., 2014; O'Donoghue et al., 2016), however we do not know how these measures of neighbourhood social composition relate to social isolation in people with psychosis.

Moreover, we also need an indication of how many people with psychosis may be interested and prepared to expand their social networks with the support of mental health staff.

Currently, there are no specific interventions in the UK that focus on expanding social networks for people with psychosis. If NHS services address service users' relationships, they usually focus on

established and close relationships, mainly with the service user's partner or family. However, there are good reasons to focus a new intervention on contacts outside families: a) for many service users, 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 service users 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 service user's history as they are recommended by NICE guidelines for this patient group; d) family relationships can be difficult and rather stressful for some service users; 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 service users can also more easily terminate if they wish to.

We have discussed our plans with 30 people from various service user 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".

2.1 Assessment and management of risk

Risks of the project and measures to prevent them

We have identified potential risks related to participation, confidentiality and use and storage of personal data and devised strategies to avert or minimise them.

Participation: There are unlikely to be adverse effects of taking part in the research. However, as social isolation may be a sensitive topic that might be related to broader personal experiences, some participants may find discussing the subject matter in an interview upsetting.

1. Participants will not be asked to share their own personal experiences (although they are free to do so if they wish).

2. Informing patients that they may leave interviews at any time and that they do not have to answer any questions that might make them feel distressed or uncomfortable.

3. Informing patients that the research team are 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.

Where 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; then the researcher is 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.

We will also remind all participants that they do not have to answer any questions or make any personal disclosures if they do not wish to

Use and storage of personal data: All participant data collected will be pseudonymised and handled in line with the Data Protection Act 1998. 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 delegated to the PCTU will comply with the unit's own procedures and information governance requirements.

Benefits of the project

There are no direct benefits for participants in relation to the study. A potential long-term benefit for all participants taking part in this study is that this survey will help the development of a new intervention to extend the social networks of service users with psychosis in the context of the NHS. Patients who have larger social networks also report higher quality of life compared to those who are socially isolated (Becker et al., 1998; Bengtsson-Tops and Hansson, 2001). Hence, this intervention may improve quality of life of patients with psychosis.

Safety reporting

The study will consist of a survey assessing social contacts. This work package does not involve any treatment or 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

Mixed methods cross-sectional survey

4 STUDY SETTING

This multi-centre study is hosted by East London NHS Foundation Trust as coordinating centre, and Tees, Esk & Wear Valleys NHS Foundation Trust and Devon Partnership NHS Trust are the core centres. Other NHS Trusts within urban and suburban areas within England will participate as research sites. Patient participants will be recruited and data collected at these sites.

Participants across all sites will be identified both through secondary care mental health services and through primary care services in the participating NHS trusts.

5 ELIGIBILITY CRITERIA

5.1 Inclusion criteria

- 18-65 years old
- Diagnosis of psychosis-related condition (ICD-10 F20-29)
- Receiving care from outpatient secondary mental health services or in primary care services
- Capacity to provide informed consent
- Ability to communicate in English

5.2 Exclusion criteria

- Does not meet inclusion criteria
- Primary problem of current substance use disorder
- No capacity to provide informed consent
- Hospitalised in the week before the interview (but these participants can be re-approached at a later time)

6 STUDY PROCEDURES

This study will aim to identify the number of social contacts and social activities in people with psychosis and wishes of patients to expand their social network in order to provide background data for the development of a novel intervention to expand patients' social networks.

Consent

Eligible patients will be identified by members of their wider clinical team (not their main treating clinician) and asked for their verbal expression of interest to speak to a researcher before they do so. Informed consent will be sought from eligible patients to participate in this study, which will include permission to access medical records to retrieve clinical socio-demographic and clinical

characteristics. Participants will be given the option during the consent process to receive a copy of the findings from the survey.

Demographic and clinical characteristics data collection

The research team member conducting the survey will ask participants for consent to obtain demographic and clinical characteristics from medical records and record this data in the Survey CRF. We will record postcodes in order to convert them to the Lower-layer Super Output Area (LSOA) that each postcode falls within. Data will be entered into a database developed by the PCTU, held on a secure server.

Survey

The survey will take place in quiet rooms in community mental health teams or in primary care setting, quiet rooms in the University where researchers are employed or at patients' homes and will be conducted as an interview by a research team member who will complete a case report form (CRF) recording patients' responses. The survey will include questions about the number and quality of social contacts on each day of the previous week (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) and subjective quality of life (Priebe et al., 1999). Participants will also be asked about their wishes to expand their networks; their willingness to do so through a targeted intervention over six months, if such an intervention was offered; and their potential willingness to participate in a randomised controlled trial, if asked to. In further open questions, we will then ask for potential reasons for participating or not participating in a trial. This one-off survey will take between 45 minutes to complete.

Payment to participants

Participants will be offered £15 cash or voucher as a reimbursement of their time after completion of the survey.

6.1 Recruitment

Patients will be identified by clinicians and clinical studies officers (CSOs) using medical records where necessary. At this stage, the minimum amount of information will be logged to ascertain eligibility: name, RIO or NHS number, and diagnosis. Addresses will only be logged for randomly selected and eligible patients, so that letters can be sent inviting them to take part.

6.1.1 Patient identification

Patients will be recruited from the caseloads of primary care services or outpatient secondary care mental health teams. Clinicians or CSOs, who are part of the wider clinical team for the patient will screen and identify eligible patients. Depending on the size of teams, all caseloads or a subset of caseloads will be screened. The eligible patients will be invited to take part in the survey by letter. We will also ask clinicians to provide information about the study to patients (face-to-face or by phone). The research team will not contact patients or speak with them directly unless patients have provided a verbal expression of interest to clinicians or a response from letters to do so. If identified patients cannot be interviewed, we will approach other patients randomly selected from the list.

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 who are independent from clinical teams, will go through information sheets with interested individuals and time taken to answer any questions or concerns that are raised. At this stage, contact details will be confirmed, and availability ascertained for attendance of the survey interview. Participants will be given the option to proceed with the interview immediately or to have up to one week to consider their participation. The option to proceed immediately to interviews is given because of the unlikely harm from the study, consisting in a one-off interview, and weighing the potential burden in terms of time for the patient in case they need to meet the researcher again.

All participants will be asked to provide informed consent, by initialling, signing and dating an informed consent form before any data collection begins. Capacity to consent to research will be ascertained by researchers through a standardised template. Researchers will be trained in assessing capacity by experienced mental health clinicians (Giacco and Priebe). 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 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.

Research team members will assess 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, their capacity to consent will be re-evaluated before continuing with study participation.

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 participants as part of the interview or from medical records. The survey will also include the following questionnaires:

- Social Contacts (SCA) (Giacco et al. 2016)
- Time Use Survey (TUS) (Priebe et al., 2016)
- Manchester Short Assessment of quality of life (Priebe et al., 1999).

Participants will be asked using ad-hoc questions about their wishes to expand their networks; their willingness to do so with the help of professionals or carers or through internet tools; and their potential willingness to participate in a randomised controlled trial, if asked to. In further ad-hoc open questions, we will then ask for potential reasons for participating or not participating in a trial.

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 month 12 from the start of the project. 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 analysis of the data will be discussed with the LEAP, which will have been established at the start of the programme and the LEAP members will help interpretation of the findings.

The number of screened participants, eligible participants and of those who refused participation or were not approached, and reasons for this where available will be recorded. The number and percentages of people who are willing and are not willing to participate in a future trial and of the reasons for this will be calculated. The distribution of the number of contacts in the sample and of the number of social activities reported by participants and the number of those willing to participate in a trial will be presented using descriptive statistics, including mean, median and standard deviation.

We wish to explore which socio-demographic (including social deprivation metrics and urbanicity) and clinical characteristics are associated with the number of social contacts and social activities, in order to identify patient characteristics (and potentially subgroups) which are associated with social isolation. Social deprivation and urbanicity metrics for each participant will be calculated from their LSOA codes bases on the data provided by the Office for National Statistics (English indices of deprivation 2015, Census 2011). We will examine the distributions of all sociodemographic and clinical characteristics and their correlation with each other. For any variables that are highly correlated with each other we will discuss and decide which variables to include in our modelling. We will exclude any binary variables where the prevalence is extreme and any variables with large numbers of missing values since these will not be useful in prediction. We will assess the presence of univariate associations between all remaining socio-demographic and clinical variables (including BPRS scores) and number of social contacts or social activities. Any variables that have a statistically significant relationship with social contacts or social activities univariately at the 10% level will be included in a multivariate model.

7.1 Qualitative Data Analysis Plan

Responses to open questions will be analysed using content analysis to identify trends and patterns in the data by categorising words that share the same meaning (Hsieh and Shannon, 2005; Vaismoradi, Turunen and Bondas, 2013; Cavanagh, 1997). Qualitative content analysis will be conducted on participants' responses to open questions that form part of the survey. An inductive approach will be used to provide new insights and richer understanding of the data without using preconceived

categories (Hsieh and Shannon, 2005; Vaismoradi, Turunen and Bondas, 2013). Inductive content analysis will be conducted following steps as outlined by Elo and Kyngäs (2007). Three members of the research team will familiarise themselves with the steps of analysis and then independently analyse the data using open coding (making notes and headings in the text to describe the content). Similar codes will then be grouped under themes, and the identified themes and subthemes will then checked and refined. This method will aid conformability and allow the resulting themes to accurately represent the voice of participants rather than researchers (Elo et al., 2007).

The analysis will inform the final decision regarding whether primary care services are included in addition to secondary care services within the next phase of the project (not included within this application).

The findings will have a direct impact on all further information material and dissemination.

7.2 Sample size calculation

Patients will be randomly selected for approach by clinicians or CSOs. The overall sample size will be 500 patients, which will give us a sufficiently robust estimate of later recruitment rates. If the rate of patients meeting the inclusion criteria and expressing a willingness to participate in a trial was 50%, we would estimate that with a confidence interval of 40% to 60%, i.e. with a margin of error of 10% which is sufficient for the given purpose.

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 from surveys or individual interviews. In these instances, data will be deleted if this is requested before the end of month 12 from the start of the project. It will otherwise be included in the analysis. 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 will be 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 and 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 service users, before the study starts it will require approval from the Health Research Authority (HRA) and REC Favourable Opinion for the study protocol, informed consent form 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.

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 the survey interviews. 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 service user 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 current study, we have worked with SUGAR as the LEAP is not yet formed. 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. The LEAP's role in dissemination is further described in Section 10.

9.3 Data protection and patient confidentiality

All researchers and study staff will 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.

Identifiable 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 for 12 months for data checking purposes. They may be retained for additional 12 months (with patients' permission to be provided optionally) to re-approach them to share research findings.

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, service user 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.

Data from the survey will be directly entered onto an electronic database by research team members at all participating sites. The data owner will be East London NHS Foundation Trust (ELFT) but the database will be developed and maintained by the Pragmatic Clinical Trial Unit (PCTU), according to a

written collaboration agreement. 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.

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.

Quantitative data that is entered onto the PCTU database will be archived according to Queen Mary University of London procedures.

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 as part of the larger research programme. Throughout all phases of the research, we will disseminate information about the activities of the programme through social media and a project specific website in order to reach a wider public audience. The website will have sections 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 of the different work packages become available, they will be disseminated using the same Channels, as well as 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 service user 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 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.

11 REFERENCES

Becker T, Leese M, Clarkson P, Taylor RE, Turner D, Kleckham J, Thornicroft G (1998). Links between social network and quality of life: an epidemiologically representative study of psychotic patients in south London. Soc Psychiatry Psychiatr Epidemio, 33(7), 229-304.

Bengtsson-Tops, A. & Hansson, L. (2001). Quantitative and qualitative aspects of the social network in schizophrenic patients living in the community. Relationship to sociodemographic characteristics and clinical factors and subjective quality of life. *International Journal of Social Psychiatry, 47*(3), 67-77.

Cavanagh, S. Content analysis: concepts, methods and applications. *Nurse Res 1997, 4*, 5-13.

Clinton. M., Lunney, P., Edwards, H., Weir, D., & Barr, J. (1998). Perceived social support and community adaptation in schizophrenia. *Journal of Advanced Nursing, 27*(5), 955–965.

Cohen, C.I., Talavera, N., & Hartung, R. (1997). Predictors of subjective well-being among older, community-dwelling persons with schizophrenia. *American Journal of Geriatric Psychiatry, 5*(2),145-155.

Elo, S., & Kyngäs, H. (2007). The qualitative content analysis process. *Journal of Advanced Nursing, 62*, 107−15.

Elo, S., Kaariainen, M., Kanste, O., Polkki, T., Utriainen, K., & Kyngas, H. (2014). Qualitative content analysis: a focus on trustworthiness. *SAGE Open, 4*, 1-10.

Giacco, D., McCabe, R., Kallert, T., Hansson, L., Fiorillo, A. & Priebe, S. (2012) Friendship and symptoms in patients with psychosis. *PLOS ONE, 7,* e50119.

Giacco, D., Palumbo, C., Strappelli, N., Catapano, F., & Priebe, S. (2016). Social contacts and loneliness in people with psychotic and mood disorders. *Compr Psychiatry, Apr;66*, 59-66. http://doi.org/10.1016/j.comppsych.2015.12.008

Hsieh, H., & Shannon, S. (2005). Three approaches to qualitative content analysis. *Qual Health Res, 15*, 1277-88.

Kirkbride, J. B., Jones, P. B., Ullrich, S., & Coid, J. W. (2012). Social deprivation, inequality, and the neighborhood-level incidence of psychotic syndromes in East London. Schizophrenia bulletin, 40(1), 169-180.

Norman, R.M., Malla, A.K., Manchanda, R., Harricharan, R., Takhar, J. & Northcott, S. (2005). Social support and three-year symptom and admission outcomes for first episode psychosis. *Schizophrenia Research, 80*(2-3), 227-34.

O'Donoghue, B., Roche, E., & Lane, A. (2016). Neighbourhood level social deprivation and the risk of psychotic disorders: a systematic review. Social psychiatry and psychiatric epidemiology, 51(7), 941-950.

Office for National Statistics, Department for Communities and Local Government, English indices of deprivation (2015), https://www.gov.uk/government/statistics/english-indices-of-deprivation-2015

Office for National Statistics, Census (2011), https://www.ons.gov.uk/census/2011census

Palumbo, C., Volpe, U., Matanov, A., Priebe, S. & Giacco, D. (2015). Social networks of patients with psychosis: a systematic review. *BMC Research Notes 8*:560 http://doi.org/10.1186/s13104-015-1528-7.

Priebe, S., Huxley, P., Knight, S., Evans, S. (1999). Application and results of the Manchester Short Assessment of Quality of Life (MANSA). Int J Soc Psychiatry, 45, 7-12.

Priebe S, Pavlickova H, Eldridge S, Golden E, McCrone P, Ockenden N, Pistrang N, King M. Effectiveness of one-to-one volunteer support for patients with psychosis: protocol of a randomised controlled trial. BMJ Open. 2016;6:e011582.

Terzian, E., Tognoni, G., Braco, R., De Ruggieri, E., Ficociello, R.A., Mezzina, R. et al. (2013). Social Network intervention in patients with schizophrenia and marked social withdrawal: a randomised controlled study. *Canadian Journal of Psychiatry, 58*(11), 622-631.

Vaismoradi, M., Turunen, H. & Bondas, T. (2013). Content analysis and thematic analysis: implications for conducting a qualitative descriptive study. *Nurs Health Sci, 15*, 398−405.

12. APPENDICES

12.1 Appendix 1– Schedule of Procedures

		Month											
	Procedures		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
	Eligibility screening													
	Initial meeting to discuss study													
	Informed consent													
	Socio-demographics													
	SCA													
	TUS													
	BPRS													
WP1	Open questions													

12.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
2	2	10/08/17	Anna Ermakova	• Key Study Contacts, page 4: information on trial co-ordinator has been added; • Study Summary, page 6; and section 7.2: planned sample size increased. • Section 4. Study Setting, page 15: has been changed to reflect the possibility of including more sites in addition to the 3 core ones.
3	3	22/08/17	Anna Ermakova	• Study Summary, page 6; and section 7.2: planned sample size increased.
S1	4		Anna Ermakova	• Study Summary, page 6; and section 7.2, p19: planned sample size increased to 500. • Study Procedures, Survey, page 16: added 'or primary care setting, quiet rooms in the University where researchers are employed' • Study Summary, page 6; Study setting and Inclusion Criteria p 15; 6.1.1Patient Identification, p15: added option to recruit from the primary care teams. • 1. Rationale, page 12; 6.Study procedures, p.16 7. Statistics and data analysis, p.18., References p.24-25. Added explanations on why and how we will collect and use postcodes and LSOA codes.