Feasibility trial of an intervention to increase community connections and reduce loneliness for people with complex anxiety or depression

Community Navigator Study

Study Protocol – Version 2, 09/02/2017.

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Protocol version history

Version Number	Date	Protocol Update Finalised By (insert name of person):	Reasons for Update
1	08/02/16		
1.2	07/07/16	Brynmor Lloyd-Evans	HRA review highlighted a missing exclusion criterion listed in the study IRAS form
2.0	09/02/2017	Brynmor Lloyd-Evans	Amendments to the study documents and procedures, and clarifications to the study intervention following the preliminary testing phase.

Signatures

The Chief Investigator and the JRO have discussed this protocol. The investigator agrees to perform the investigations and to abide by this protocol.

The investigator agrees to conduct the trial in compliance with the approved protocol, the UK Data Protection Act (1998), the Trust Information Governance Policy (or other local equivalent), the current Research Governance Framework, the Sponsor's SOPs, and other regulatory requirements as amended.

Chief investigator

Brynmor Lloyd Evans — 21/02/2017

UCL — Signature — Date

Sponsor

Sponsor representative — 21/02/2017

UCL — Signature — Date

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List of abbreviations

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
ISRCTN	International Standard Randomised Controlled Trial Number
NHS R&D	National Health Service Research & Development
PI	Principal Investigator
PIS	Participant Information Sheet
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
TMG	Trial Management Group
TSC	Trial Steering Committee

1. Trial personnel

See protocol cover page for the Chief Investigators' and sponsor's contact details.

The study base where the CIs work and the Trial Master File is located is the Division of Psychiatry, UCL. The Head of Department for the Division of Psychiatry is:

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2. Summary

Objectives

The aim of this study is to develop and test the feasibility and acceptability of a programme of support for people with significant depression and anxiety who use mental health services. This programme of support will include receiving support from a 'Community Navigator', who will work with the participating service users to increase their social activities and community engagement, with the aim of reducing feelings of loneliness or social isolation.

Type of trial

A randomised, multi-site feasibility trial with qualitative evaluation for people with complex anxiety or depression.

Trial design and methods

Stage 1: Developing the programme of support

This is a 2 year study. Over the first 6 months we developed the programme of support, consulting service users, practitioners, and existing research and programmes which aim to reduce loneliness and social isolation. Community Navigators will meet with service users up to 10 times over a 6 month period to help people review current relationships, activities and interests and make a plan that they think will reduce their feelings of loneliness. Community Navigators will have access to a budget of £100 for each participant to use on agreed goals. Service users will additionally be invited to attend up to three meetings open to all participants, running alongside the intervention, facilitated by the Community Navigators. These meetings will provide opportunities to meet co-

participants, discuss the programme's goals and progress, and share resources and experiences.

Stage 2: Preliminary testing

From months 8-13 we are trying out this intervention with 10 service users. We have aimed to achieve a mixture of gender, age and ethnicity in this sample of service users. Consenting participants met with the study researcher before allocation to a Community Navigator to take part in a research interview. They answered a number of questions about their social networks, feelings of loneliness and general well-being. This research interview will be repeated, subject to participants' consent, after the Community Navigator sessions have been completed.

An additional qualitative interview is taking place following or towards the end of the intervention (after people have had at least five sessions with their Community Navigator). The study peer researcher is seeking feedback from participants and the Community Navigators. This feedback will help us refine the programme of support.

Stage 3: Feasibility trial

From months 14- 24 we will launch a feasibility trial: 30 service users will be randomly allocated the programme of support from a Community Navigator and 10 service users will not receive this support - instead they will be given written information consisting of a list of local resources. We will seek feedback on the programme of support from study participants including: service users who received support from a navigator, any involved family/friends, the Community Navigators themselves and any involved service staff.

Trial duration per participant	6 months
Estimated total trial duration	18 months from enrolment of first participant in the preliminary testing phase to final contact with last participant in the feasibility trial phase (2 year study)
Planned trial sites	Multi-site study (2 planned sites: Camden and Islington NHS Foundation Trust and Barnet Enfield and Haringey Mental Health NHS Trust)

Total number of participants planned	63 (10 participants in preliminary testing; 40 in a feasibility trial; 13 additional stakeholders in qualitative interviews)
Main inclusion/exclusion criteria	Service users will be eligible if they are on the caseload of the Camden and Islington Complex Depression Anxiety and Trauma Team or the Mood and Anxiety Stream of the Barnet Complex Care Team. Service users aged 18 or older, who are receiving care from these multi-disciplinary teams, will be eligible for inclusion in the study regardless of diagnosis or care coordination status. We will, however, prioritise service users currently receiving multi-disciplinary support (e.g. care co-ordination and medical input, and access to psychology support), to help us explore whether community navigation support is a useful addition within these services. People will be excluded from taking part if they: lack capacity to consent; pose such a high risk of harm to others that meetings with a researcher or navigator in their home are not possible; are unable to communicate in English; are currently inpatient in a mental health or general hospital; or do not meet a threshold level for loneliness on a brief screening questionnaire.
Statistical methodology and analysis	Feasibility trial: descriptive presentation of study results only + thematic analysis of qualitative data.

3. Introduction

3.1 Background

Loneliness has been defined as the discrepancy between desired and achieved levels of social relations. It is usually conceptualised as a single concept (Perlman & Peplau 1981), although social and emotional components have been distinguished (de Jong Gierveld & Tilberg 2006). Although related to social isolation, loneliness focuses on subjective experience and may be driven by the quality as well as quantity of social relationships. Loneliness has been demonstrated to predict a range of poor health outcomes in the general population, including shorter life expectancy (Luo et al. 2012) elevated blood pressure (Hawkley et al. 2010), diminished immunity (Pressman et al. 2005), cognitive decline (Tilvis et al. 2004) and progression of dementia (Wilson et al. 2007). Loneliness predicts the onset of anxiety (Flensborg-Madsen et al. 2012) and depression (Cacioppo et al. 2006).

While public policy has focused primarily on initiatives to alleviate loneliness in older adults (ODPM 2006; Campaign to End Loneliness 2015), there is a growing recognition that loneliness may impact people of all ages: a recent national survey (Whitton 2015) found 28% of adults of all ages wished they had more friends. People with mental health problems are particularly vulnerable to loneliness (Windle et al. 2011), and typically have smaller social networks compared to the general population (Goldberg et al. 2003). For people with existing anxiety and depression, loneliness independently predicts poorer symptom outcomes at one-year follow-up (van Beljouw et al. 2010). Interventions which alleviate loneliness for people with anxiety and depression, therefore promise not only improved quality of life, but also reduced mental health problems and reduced risk of a range of poor health outcomes.

Support from "navigators" or "wellbeing coaches" for people to utilise existing networks and access new social contact and activity, may be used in conjunction with "social prescribing", which can provide financial support to access beneficial social activity. These have been identified as promising approaches to alleviating loneliness and reducing social isolation (Jopling 2015, Webber et al. 2015). Wellbeing Enterprises Community Interest Company exemplify this model of intervention: they are one of the largest, most established providers of such services in the UK, with over 10 years' experience. They are currently commissioned by CCGs in Cheshire to support social prescribing for a range of people referred by GPs and to deliver wellbeing reviews and navigation support to service users leaving secondary mental health services. Through this work, Wellbeing Enterprises and others have demonstrated that social navigation approaches can be feasible and engaging in a mental health context, and have a range of developed programmes of support. However, a recent evidence synthesis concluded that, while such social interventions are advocated in policy as a means to provide integrated health and social care and improve health outcomes for people with long term conditions, including mental health problems, and have been reported positively, there is little evidence regarding their effectiveness (CRD 2015). The appropriateness of such interventions, most commonly provided in primary care, for a population of service users using specialist mental health services and with enduring health problems and complex needs, is also unclear from current research. This study aims to develop and test a programme of support designed to reduce loneliness, and thus improve overall outcomes, for people with complex anxiety and depression. This work would comprise modelling, preliminary testing and a feasibility trial of the programme, in accordance with guidance for developing a complex intervention (Craig et al. 2008).

3.2 Risks

A risk assessment form for the study has been completed and was provided to PIs and clinical leads for participating services before the start of participant recruitment and the intervention. The potential risks anticipated from the assessments and study intervention, and plans for how these will be mitigated or managed, is detailed in the table below.

3.3 Assessment and management of risk

Intervention	Potential risk	To whom	Risk management
Study assessments, qualitative interviews	Distress from reflection on upsetting topics (e.g. loneliness)	Participant	What the study involves will be clearly explained to participants in the study information sheet and by researchers, and written informed consent will be taken before participants join the study. The study researcher will check with participants that they are aware their participation is voluntary and they can elect to withdraw from the study, or stop or pause the interview at any point. The outcome measures and interview schedules used have been reviewed after use in the preliminary testing phase of the study. Questionnaires and interview topics deemed unnecessary or which participants repeatedly reported finding difficult or upsetting have been omitted or amended.
	Lone working risks of harm	Researcher	Trial participants will have been screened for risk by clinicians in the relevant service before being contacted about participation in the study: service users who pose a risk of harm to others which precludes them being seen safely at home will be excluded from the study. A lone working policy (attached) for the study will be adhered to at all times. Study researchers will inform colleagues in advance of any home visits to service users and will check in with colleagues afterwards. The study CIs will be contactable by phone by research assistants at all times, if advice or immediate debrief are needed. Research assistants will be given clear information about appropriate NHS clinical

Intervention	Potential risk	To whom	Risk management
			services to contact, and direction to contact emergency services if appropriate, in the event of any immediate concerns about a participant's or others' safety.
Community Navigator intervention	Risk of distress if plans to increase social contact prove too challenging or unsuccessful, or if the intervention otherwise proves unhelpful.	Participant	Risks from the study intervention: Community Navigators will be employed through the NHS Trusts participating in the study, which will be responsible for their training, supervision and management, and ensuring they work in a professional and helpful manner. The study team will take these additional steps to ensure participants' safety: a) Serious adverse events relating to trial participants will be monitored and reviewed, in accordance with the trial protocol and as advised by the study's independent steering committee. b) Study researchers will seek feedback from Community Navigators and their clinical supervisors, in order to check the intervention is being delivered as planned; and feedback will be obtained from trial participants following research interviews. These will be shared with the study Steering Committee, and their advice sought about any requirement to modify the study procedures or the intervention, or pause the study, in the event of concerns. c) Study participants are provided with contact details for the research team, including CIs, and independent complaints bodies, should they wish to voice any concerns about the study or the intervention at the time. Participants will remain under the care of NHS clinical services and receiving standard care throughout the trial intervention, so expert help and support with

Intervention	Potential risk	To whom	Risk management
			any distress or anxiety generated by participation in the study will be readily available.
Community Navigator intervention	Lone working	Navigator	NHS lone working and safety policies will apply; navigators will be provided with regular supervision within participating NHS sites.

4. Objectives

Objectives of the study are:

i) To adapt/develop a social intervention to address the problem of loneliness involving community navigator-support and a personal budget for people with complex depression and anxiety in secondary mental health services; and to refine this programme through preliminary testing with 10 service users

ii) To conduct a feasibility trial of the programme with 40 service users, to test feasibility of participant recruitment and retention and investigate optimal trial procedures.

iii) To explore experience of the programme and develop a theory of change model, based on user-led interviews with service users receiving the intervention, community navigators, service staff and involved others.

5. Trial design

The study comprises: development of a programme to reduce loneliness for people with complex anxiety or depression (months 1-7); preliminary testing of the programme to produce a manualised intervention (months 8-13); and a feasibility randomised controlled trial of the intervention with mixed methods evaluation (months 14-24).

Each participant receiving the study intervention will receive up to ten meetings with a Community Navigator over a 6-month period, who will have access to a budget of £100 per person to help facilitate community participation. Participants receiving the intervention will be invited to attend up to 3meetings open to all participants, running alongside the intervention, facilitated by the Community Navigators. These meetings will provide opportunities to meet co-participants, discuss the programme's goals and progress, and share resources and experiences.

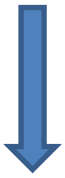
All participants in preliminary testing and the feasibility trial will be asked to complete a research interview at baseline and six months follow up. All participants in preliminary testing, 20 participants from the treatment arm in the feasibility trial, the three Community Navigators and ten other stakeholders will be asked to complete a qualitative interview following the completion of the study intervention.

Community Navigator Study Flowchart

Months 1 – 7 (March – September 2016)

Initial Development

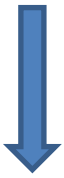
- REC and R&D approvals
- Consultation and intervention development
- Initial manualisation of intervention
- Recruitment and training of Community Navigators



Months 8 – 13 (October 2016 – March 2017)

Preliminary Testing

- Preliminary testing with service users (n=10)
- Qualitative interviews with participants (n=10) and Community Navigators (n=3) and rapid synthesis
- Refinement of intervention manual
- Development of feasibility trial procedures



Months 14 – 24 (April 2017 – February 2018)

Feasibility Trial

- Recruitment of trial participants (n=40)
- Intervention delivered to treatment group (n=30) with 10 controls
- 6-month follow-up data from all participants (n=40)
- Qualitative interviews with treatment group participants (n=20), Community Navigators (n=3), and other stakeholders (n=10)

- Analysis of study data
- Final report to study funder

6. Selection of participants

Setting: We will involve participants from two sites in all stages of the study: the Complex Depression, Anxiety and Trauma (CDAT) Team within Camden and Islington NHS Foundation Trust and the Mood and Anxiety stream of Barnet Complex Care Team (CCT) in Barnet, Enfield and Haringey Mental Health NHS Trust. Both services support about 600 adult service users with enduring moderate or severe depression, anxiety or other affective disorders, offering care coordination, support from a multi-disciplinary team, or psychiatric outpatient appointments with telephone monitoring. Neither service offers navigation support as a standard part of care delivered by the team, although in both areas, service users may access a range of statutory and voluntary sector services which provide some activity, social contact and help with enhancing received social support. Both the inner-London boroughs of Camden and Islington (served by the CDAT team), and the outer-London borough of Barnet (served by the CCT Team), include affluent areas and areas of high deprivation. Both areas include ethnically diverse populations.

Inclusion criteria: Participants will be recruited from both involved services for the preliminary testing (n=10) and the feasibility randomised trial (n=40). Service users will be eligible if they are on the caseload of the CDAT Team or the Mood and Anxiety Stream of the Barnet CCT. Service users aged 18 or older, who are receiving care from these multi-disciplinary teams, will be eligible for inclusion in the study regardless of diagnosis or care coordination status. We will, however, prioritise service users currently receiving support from a number of disciplines (e.g. care co-ordination, psychology and medical review), to help us explore whether community navigation support is a useful addition within these services. To ensure we are working with a population who are experiencing loneliness, we will conduct a brief screening questionnaire with potential participants. We will use the de Jong Gierveld 6-item loneliness questionnaire for this (de Jong Gierveld & Van Tilburg, 2006), for which a score of three has been established as a minimum threshold for loneliness. (Service users who do not meet this loneliness threshold at initial screening will be offered written information about local community resources which may be helpful to develop social connections.)

Exclusion criteria: Participants who do not have capacity to consent to participate; pose such a high risk of harm to others that meetings with a researcher or Community Navigator are not possible; are unable to communicate in English; are currently an inpatient at a mental health or general hospital will not be eligible to participate. Participants who do not score at least 3 on the 6-item de Jong Gierveld loneliness questionnaire at initial screening will also be ineligible.

In preliminary testing, we purposively sampled to achieve diversity in participants' age, gender and ethnicity. For the feasibility trial, all eligible service users will be invited to participate, until recruitment targets are achieved.

Qualitative interviews: These will be conducted at the preliminary testing stage with all participants (n=10) and the Community Navigators (n=3), and at the feasibility RCT stage with participants (n=20), Community Navigators (n=3) and up to 10 significant other people. These could include: the Community navigators' supervisors, other CDAT/CCT practitioners, other social care or voluntary sector staff such as Recovery Centre or peer support workers, or family and friends nominated by participants as important to them in utilising the support. We will purposively sample 20 participants from the feasibility trial for a qualitative interview as far as possible to ensure representation from both services and participants with a range of demographic and clinical characteristics, including those who completed the programme of navigation support and those who discontinued the intervention early.

Recruitment and consent: CDAT/CCT staff will screen current service users for eligibility and contact potential participants about willingness to talk to a researcher. Study researchers from UCL will then contact potential participants and provide written and oral information about the study, and answer any questions. At this point, the researcher will arrange to complete the screening questionnaire with the participant, by phone, email or in person as the potential participant prefers. If a service user does not meet the screening threshold for loneliness, they will not be offered participation in the trial. The researcher will offer to send them written information about local community resources which can help develop social connections. The researcher will then arrange to meet those eligible interested in taking part in the study, at least 48 hours after the researcher's initial contact, to take written informed consent. The researcher will explain that participants are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason. No trial procedures will be conducted prior to the participant giving consent by signing the consent form. A copy of the signed informed consent form will be given to the participant. The original signed form will be retained in the trial file at site and a copy placed in the medical notes. The participant information sheet and consent form will be reviewed and updated if necessary throughout the trial (e.g. where new safety information becomes available) and participants will be re-consented as appropriate.

Participant recruitment at a site will only commence when the trial has:

1. Been confirmed by the Sponsor (or its delegated representative), and
2. Been issued an 'NHS permission letter'.

7. The intervention

Development: The intervention has been developed through a series of informal consultations with CDAT/CCT staff and service users, identified via service user groups or staff within clinical services, in small groups or individually; consultation from and/or site visits to external expert consultants including Wellbeing Enterprises Community Interest

Company http://www.wellbeingenterprises.org.uk/ and Peter Bates from the National Development Team for Inclusion http://www.ndti.org.uk/about-ndti/ndti-people/peter-bates/. A working group of 12 people including service user researchers, practitioners and members of the research team met regularly in the set-up phase to help develop the intervention. This group will continue to meet throughout the project to develop the theory of change, with reference to findings from study process data and qualitative interviews. Service users' contribution to this working group constitutes paid involvement offered on account of their expertise through experience, and is reimbursed in accordance with national guidelines (Involve 2012).

Outline: Participants will be offered 10 meetings with a Community Navigator over a six-month period. Each participant may use a budget of £100 on goals agreed with their Community Navigator to facilitate access to and participation in social activity, and to develop network connections. Participants will also be invited to attend up to 3 meetings open to all participants running alongside the intervention. The content of the intervention draws on existing, tested programmes delivered by consultants to the study. It has been adapted during the initial consultation and planning period and refined as indicated through the experience of and feedback from preliminary testing. The intervention comprises three main components:

a) A thorough review of each participant's existing social network, and the current and potential support it provides; the person's existing strengths and interests; potential areas where new activity, social connection or support would be of interest; and any current barriers to pursuing these. This review has been informed by existing interventions to map social systems and activity including: i) Wellbeing network and asset mapping (Pinfold & Sweet 2015); ii) Wellbeing Reviews: a process developed by Wellbeing Enterprises CIC and reported in the Campaign to End Loneliness "Promising Approaches" bulletin (Jopling 2015); iii) The interpersonal inventory, developed as an initial stage of inter-personal therapy (Frank and Spaner 1995); iv) The Inclusion Web (Hacking & Bates 2008).

b) Support from a Community Navigator to develop and use an action plan to increase connectedness. Support activity will be person centred and include: providing information about available activities and sources of support locally, practical help to access activity including help with phone calls or application forms and access to financial support from a budget provided for each participant; emotional support to overcome barriers to increasing social connectedness (e.g. accompanying someone to a new activity, supportive phone calls), support linking people in to available self-management, skill-building or mental health support, including peer support. Camden, Islington and Barnet offer a wealth of diverse social activities within the boroughs, and access to wider resources within London. Navigators will use their local knowledge to help people develop connections including: new leisure activities (e.g. a choir, a sports group); cultural or social support groups (e.g. a BAME community group, an LGBT group); or wellbeing support (e.g. a Recovery College). The

intervention is designed primarily as 1:1 support from a Community Navigator with linking into available community support and activities. It offers the potential however for Community Navigators to link participants with shared interests in the group sessions.

c) We will also organise at least two group meetings running alongside the 1:1 support facilitated by the Community Navigators – one during the first half or participants' support from their Community Navigator, and one towards the end of the programme. A third session may be added, depending on the enthusiasm for this in the group. . Groups will be run in both C&I and Barnet. Attendance is optional but Community Navigators will encourage and support all participants to join in where possible. The group will provide opportunities to meet co-participants, discuss the programme's aims and progress, and share information about helpful local resources and experiences. Sessions will last about approximately 2 hours, with a break, and will be facilitated by the Community Navigators. The group will follow the principles of the Community Navigator programme with a socially-focused person-centred approach; each meeting will have a loose agenda tailored to the needs of those taking part to achieve maximum impact. Refreshments will be provided during meetings.

Control group: Participants in the control group (n=10), and care coordinators in participating services, will be offered written information about community resources and activities within their area (collected during the development phase of the study). Participants will otherwise receive standard care, unaffected by their participation in the study.

8. Trial procedures

8.1 Pre-intervention assessments

An eligibility screening questionnaire will be used to identify potential participants meeting a minimum threshold for loneliness: the de Jong Gierveld loneliness scale (short form): a 6-item, self-report measure of loneliness, where a score of 3 or more indicates loneliness (de Jong Gierveld & van Tilburg 2006)

Outcomes will be assessed at baseline in a structured interview with participants in preliminary testing and the feasibility trial. The battery of measures has been reviewed and shortened in light of feedback from preliminary testing.

A participant interview will seek information about: participants' socio-demographic characteristics (age, gender, ethnicity, marital status, living arrangements, accommodation, and employment). It will also include the following validated outcome measures, all of which provide data for analysis in continuous form.

Loneliness: The de Jong Gierveld loneliness scale: an 11-item, self-report measure of loneliness, yielding a total score and subscale scores for social and emotional loneliness (de Jong Gierveld & Kamphuis 1985)

Social network: The Lubben Social Network Scale: a 6-item self-report measure assessing quantity and quality of contact with family and friends (Lubben et al. 2007)

Social capital: Resource Generator UK: a 27-item measure of perceived access to social capital (Webber & Huxley 2007)

Activity: Time budget diary: a retrospective self-report measure of activity over the previous week (Jolley et al. 2006)

Wellbeing: The Warwick-Edinburgh Mental Wellbeing Scale: a 14-item self-report scale of mental wellbeing (Tennant et al. 2007)

Depression: The Patient Health Questionnaire: a 9-item self-report measure of depression commonly used in IAPT services (Kroenke et al. 2001)

Anxiety: The Generalized Anxiety Disorder Questionnaire: a 7-item self-report measure of anxiety (Spitzer et al. 2006)

Health-related quality of life: The EQ-5D-5L: a 5-item self-report health outcome measure (EuroQol Group 1990)

Mental health-related quality of life: The Recovering Quality of Life Questionnaire: a 10-item self-report measure of quality of life developed for use across all mental health populations (ReQoL, in submission)

Patient records: We will seek information from Trust IT/Informatics teams regarding participants' current diagnosis, care cluster, attended and missed face-to-face appointments with their clinical team (CDAT or the CCT), use of other community mental health services, admission to acute care, days in inpatient care over previous six months, and use of the Mental Health Act. These records will be sought for the 6 months prior to baseline and at 6 month follow up for the intervention period since baseline.

Social care records: Use of social care services. These records will be sought for the 6 months prior to baseline and at 6 month follow up for the intervention period since baseline.

8.2 Randomisation

In the preliminary testing, all ten participating service users were offered the study intervention and received up to ten sessions from a Community Navigator.

In the feasibility trial, participants will be randomised to a treatment group (n=30) or a control group (n=10). Randomisations will be conducted by an independent statistician in the UCL Division of Psychiatry, who is not connected to the study team. Details of participants allocated to the treatment group will be passed on by the study researcher to the Community Navigators' supervisors at the CDAT/CCT services. Due to limitations in the researcher resources available, participants' allocations will not be concealed from the research team.

8.3 Intervention procedures

Community Navigators are employed through Camden and Islington NHS Foundation Trust and also work in Barnet, Enfield and Haringey Mental Health NHS Trust with an honorary contract, confirmed with a service agreement between the two Trusts. Excellent interpersonal skills, sensitivity to and understanding of mental health difficulties and wide knowledge of local resources are essential requirements for the role. A professional mental health qualification is not required. Lived experience of mental health problems constitutes relevant experience but is not essential. Community Navigators are embedded within the participating services. Five days' initial training was provided by the involved clinical services, study team and external expert consultants. Regular group supervision at both the CDAT and CCT services, facilitated by a clinician from the service, allows Community Navigators to share knowledge of local resources and problem solving strategies and support each other.

Participants in the treatment group will be contacted by a Community Navigator and offered up to 10 meetings over a six month period. Meetings may take place in participants' homes, community spaces or NHS premises, as the participant prefers, within any risk limitations advised by CDAT/CCT staff. Participants receiving the intervention will also be invited to attend up to 3 group meetings, running alongside the intervention, facilitated by the Community Navigators.

8.4 Subsequent assessments and procedures

Qualitative interviews: At or towards the end of their sessions with their Community Navigator (after a minimum of five sessions have been received, or the participant has elected to discontinue meetings with their Community Navigator), the McPin researcher will contact participants for the qualitative part of the study. They will provide verbal explanation and a separate written information sheet for the qualitative interview. They will then take written informed consent and conduct semi-structured interviews, using a topic guide, with those willing to take part. Topic guides for all the qualitative work will be co-produced within a study working group. We will be interested in: experiences of the programme (in various roles) including how it proved helpful; challenges to addressing loneliness; integration of the approach with other services and supports; and suggested improvements to the programme. These interviews will be audio-recorded and transcribed

using a professional transcription company. Transcribed interviews will be checked and the text anonymised where necessary, then uploaded to Nvivo 9 qualitative software for analysis.

Assessments: At six months after study entry, the UCL study researcher will contact participants to arrange a follow-up interview. Written consent from participants will be re-confirmed before the follow-up interview is completed. Study outcome measures assessed at baseline will be reassessed. Data from participants' NHS patient and local council social care records will be sought as at baseline, regarding their use of mental health and social care services over the previous six months.

Upon completion of each of the qualitative and quantitative interviews, participants will be offered a £20 gift in cash to thank them for their time and help with the study.

Process recording: Community Navigators will complete session logs for NHS clinical records following each session with a participant, detailing the location of the meeting, and its content (selecting from a list of planned types of support). These records will be anonymised, removing any personal or sensitive information, and collected by study researchers. These will be used to check intervention content, and cross-checked with participant reports of each session.

Feedback will be sought from participants after 2 of their 10 sessions with their Community Navigator. At which sessions participants are contacted will be randomly selected when participants are randomised to the intervention arm. The UCL study researcher will phone participants and ask them questions from the Study Feedback Form as soon after their Community Navigator sessions as possible. This brief conversation will cover the location of the meeting, and what types of support were provided (using the same menu as in Community navigators' session logs), a one-item rating scale of how they found the session (from very good to very poor), and whether they have any other comments. The aim is to have data spanning all 10 sessions, without having to ask participants for feedback after each session. Data from the Community Navigators and participants will be compared to understand the content of the intervention as delivered in practice, and to explore the level of agreement/shared understanding between intervention providers and recipients about the content of meetings.

Information about all study assessments is provided in the participant information sheets, and confirmation of consent to collect data and contact participants' about follow-up data is included in participant consent forms.

8.5 Withdrawal of participants

If a participant explicitly states they do not wish to contribute further data to the trial, their decision will be respected and recorded in their case record file and study records. If a participant states they wish to withdraw from the study completely, and for data already

collected from them not to be used, this decision will also be respected and recorded. No other criteria for withdrawing a participant from the study are pre-planned. If concerns were raised by involved clinical services or others about whether continued participation in the study is in the participants' best interests, these concerns would be discussed promptly with the study's oversight committees and a decision reached.

8.6 End of trial

The end of the trial is the date of the last 6-month follow-up data collection contact with the last participant. The study runs from March 2016 – February 2018. The end of the trial is scheduled for the end of December 2017.

9. Recording and reporting of adverse events

Procedures for recording adverse events have been reviewed by both the Trial Management Group and the Trial Steering Committee.

9.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or trial participant, which does not necessarily have a causal relationship with the intervention involved.
Serious Adverse Event (SAE)	Any adverse event that: • results in death, • is life-threatening*, • requires hospitalisation or prolongation of existing hospitalisation** results in persistent or significant disability or incapacity.
* A life-threatening event, this refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. ** Hospitalisation is defined as an acute in-patient admission, regardless of length of stay. Hospitalisation for pre-existing, non-mental health conditions, including elective procedures, do not constitute an SAE.	

9.2 Assessment of adverse events

Each adverse event will be assessed for severity, causality, seriousness and expectedness as described below

Severity

Category	Definition
Mild	The adverse event does not interfere with the participant's daily routine, and does not require further intervention; it causes slight discomfort.
Moderate	The adverse event interferes with some aspects of the participant's routine, or requires further intervention, but is not damaging to health; it causes moderate discomfort.
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health.

Causality

The assessment of relationship of adverse events to the intervention is a clinical decision based on all available information at the time of the completion of the case report form. The differentiated causality assessments will be captured in the trial specific AE database and the SAE form. The following categories will be used to define the causality of the adverse event:

Category	Definition
Definitely	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely.
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the trial intervention). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant events).
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial intervention). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatments).
Not related	There is no evidence of any causal relationship.
Not assessable	Unable to assess on information available.

Expectedness

There are no anticipated expected adverse events from the study intervention. However, due to the nature of the participant group – people with severe and enduring anxiety or depression, the following serious adverse events are not considered to be unexpected per se: admission to mental health acute care; attempted suicide; or suicide. Harm to others perpetrated by the participant, or any harm or threat of harm to the participant from the Community Navigator delivering the trial intervention, do constitute unexpected adverse events.

9.3 Recording adverse events

All adverse events will be recorded in the medical records in the first instance.

9.4 Procedures for recording and reporting Serious Adverse Events

All serious adverse events will be recorded in the medical records and the CRF. SAEs will also be recorded in an SAE database throughout the trial, allowing a line-listing of SAEs to be easily extracted for review. The line-listing of SAEs will be reported to the sponsor at least twice per year.

All SAEs (except those specified in section 9.5 as not requiring reporting to the Sponsor) must be recorded on a serious adverse event (SAE) form. The CI will complete the sponsor's SAE form and the form will be emailed to the Sponsor within 5 working days of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised by the sponsor as soon as possible.

Where the event is unexpected and thought to be related to the intervention, this must be reported by the Investigator to the Health Research Authority within 15 days.

Completed SAE forms must be sent within 5 working days of becoming aware of the event to the Sponsor
Email forms to randd@uclh.nhs.uk

Reporting lines for SAEs Community Navigators delivering the trial intervention, their NHS supervisors, and managers of the participating NHS services will be directed to report any adverse events involving trial participants to the relevant site PI without delay. In addition, the study researcher will contact the Community Navigators' supervisor and involved NHS service manager at each site at least monthly, to ask them to screen service and patient records for AEs for trial participants. A report of the circumstances of the AE, and the informant's view on causation and severity will be sought from the PI or study researcher, who will then contact the study CIs without delay. The study co-CI (Sonia Johnson), as the trial's Clinical Reviewer, will complete an SAE form and make final assessments of severity, causality and expectedness, in discussion with the PI where possible. The CI will then send the completed SAE form to the Sponsor and the site PI, and disseminate any necessary safety information to the other site PI.

Following advice from the Trial Steering Committee (TSC), the TSC will also assume the following role in reviewing SAEs.

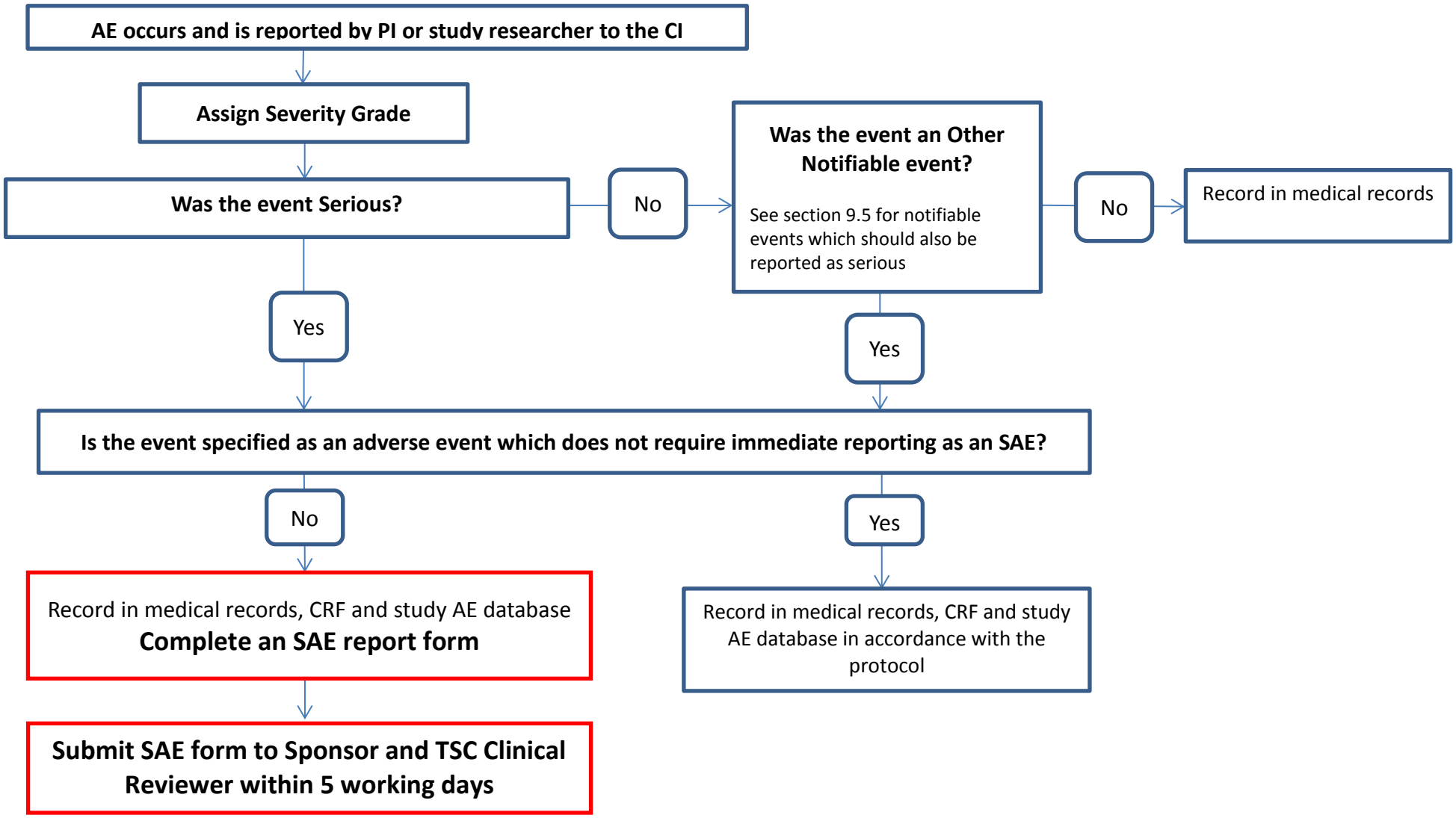
i) SAE report forms will be sent to TSC member Claire Henderson (an academic psychiatrist) who will act as an additional independent Clinical Reviewer and check agreement of assessments of events' severity, causality and expectedness. (Any SAEs assessed as study-

related or unexpected will be sent to the TSC reviewer within 5 days; other SAE reports will be sent at regular intervals for review (at least every two months).

ii) The TSC will review the line list of all study SAEs at TSC meetings.

SAEs will be followed up and screened for each participant until the participant's 6-month follow-up research interview and active involvement in the study are completed. SAEs will be reported to the sponsor until the end of the trial. Follow-up SAE forms (clearly marked as follow-up) will be completed and emailed to the JRO if required as further information becomes available.

Flow Chart for SAE reporting



9.5 Serious Adverse Events that do not require reporting

SAEs involving a psychiatric hospital admission for a participant which occur in the context of a relapse of an existing mental health condition and are assessed as unlikely to be causally related to the trial intervention will not be reported to the Sponsor, unless unusual in frequency or severity. Readmissions to hospital are likely to occur for a number of participants, given the trial participant group – people with complex depression or anxiety. These events will however be recorded in the medical records, CRF and the trial AE database.

No other notifiable events for immediate reporting to the sponsor have been identified for this study.

9.6 Reporting Urgent Safety Measures

If any urgent safety measures are taken the CI shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant REC and Sponsor of the measures taken and the circumstances giving rise to those measures.

9.7. Notification of reportable protocol violations

A reportable protocol violation is a breach which is likely to effect to a significant degree:

(a) the safety or physical or mental integrity of the participants of the trial; or

(b) the scientific value of the trial.

The sponsor will be notified immediately of any case where the above definition applies during the trial conduct phase.

10. Data management

All data will be handled in accordance with the UK Data Protection Act 1998.

Data regarding admissions and service use will be collected by the UCL study researcher or Trust/CRN research support staff from electronic patient records at baseline and follow-up. All participant consent forms and quantitative study data will be stored at UCL. Good Clinical Practice guidelines and UCL data protection requirements will be adhered to at all times. Consent forms identifying participants will be stored separately from Case Report Forms (CRFs), which will not bear the participant's name or other personal identifiable data. The participant's initials, date of birth and trial identification number, will be used for identification and this will be clearly explained to the patient in the participant information sheet. All paper forms will be kept in locked cabinets in secure offices. Quantitative data will be entered into an electronic database using SPSS software. Electronic data will identify

participants by ID number only and will be stored in password protected files on the UCL secure system. Qualitative audio files and transcripts will be kept similarly securely at McPin offices for the duration of the study. After the study, all data will be archived at UCL and audio files will be destroyed.

11. Analysis

Quantitative data: There is no primary outcome for this feasibility trial. Feasibility will be assessed by whether recruitment to target on time was achieved; retention of participants and completeness of outcomes data collection over six months; implementation of the intervention – i.e. for what proportion of participants was engagement with a Community Navigator maintained and the number of sessions of support provided. Quantitative data from the feasibility trial will be reported using descriptive statistics. This trial will be too small to make clear inferences about observed differences between groups.

The study timeline requires the recruitment for the feasibility trial of 20 participants from each participating site over a three month period in 2017, i.e. at least 7 participants per site per month. In both sites, the participating service supports over 500 service users in total, and this recruitment rate was achieved in the preliminary testing phase, so we are confident this rate of recruitment is achievable. Testing recruitment rates is however one of the aims of this feasibility trial. Screening, recruitment and retention of participants into the study's feasibility trial will be recorded in a CONSORT diagram.

Allocation of participants in the feasibility trial (n=40) will be by block randomisation, stratified by NHS site. There will be unequal allocation between treatment arms, with 30 participants in the treatment group and 10 in a control group.

Qualitative data: The qualitative data will be reviewed by researchers based at UCL and McPin. Data from participants in the preliminary testing phase have been rapidly analysed by the study researchers with the main aim of identifying any modifications needed to the programme for the feasibility trial.

With data from the feasibility trial, a collaborative analysis process will use a thematic analysis approach (Braun and Clarke 2006) including the peer researcher from McPin and their supervisor, and members of the study working group and UCL research team. We will hold analysis meetings to review transcripts and develop coding frames. The peer researcher will input all coding using Nvivo, with cross checks by another team member. Further synthesis meetings will be required once coding is complete. The research will thus benefit from explicitly combining research skills and lived experience for both collecting research data and the analysis and synthesis process (Gillard et al 2012). Analysis will include focus on barriers and facilitating factors to the success of the intervention, and mechanisms for how outcomes of the intervention are being achieved.

12. Record keeping and archiving

UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol). The Chief Investigator confirms that he will archive the study master file at UCL for 20 years, in line with all relevant legal and statutory requirements. The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for 20 years and in line with all relevant legal and statutory requirements.

13. Governance and oversight

The study is co-led by Prof Sonia Johnson and Dr Brynmor Lloyd-Evans and will be run day-to-day by a study management group including other study co-applicants: Vanessa Pinfold, Prof Glyn Lewis, and Dr Jo Billings. Co-applicant Glyn Lewis is a member of the Steering Committee for the PRIMENT Clinical Trials Unit and will provide expert advice regarding procedures for the study feasibility trial. The study management group will meet approximately six times per year and will send updates to site Principal Investigators.

A Trial Steering Committee of independent researchers, including: a service user-researcher, a clinical academic, a social scientist and a statistician, will be set up and meet at least annually during the course of the study to provide independent oversight and advice. The steering committee will advise on development of the study intervention and trial procedures. The committee will also review serious adverse events or other concerns regarding the safety of the trial.

A Data Monitoring Committee is not planned for this feasibility trial, which is not collecting interim data and has no pre-planned stopping criteria. The study management team will ask the steering committee to review this plan before the start of the feasibility trial in the second year of the study and will recruit a DMC if the TSC advises this.

14. Ethical requirements and patient and public involvement

Ethics: UCL will act as sponsor for the study.

We have obtained approvals for the study from an NHS Research Ethics Committee and HRA. The R&D teams of both involved NHS Trusts will confirm capacity and capability to deliver the study before beginning any recruitment of study participants. We will provide annual reports to the overseeing REC during the course of the study. Amendments to the study plans and the proposed intervention required following preliminary testing of the intervention are being submitted for REC approval as substantial amendments before implementation.

Following ethical approval, we will register the trial protocol with the ISRCTN trials register.

Patient and public involvement: Members of the McPin Foundation service user-researcher advisory group were consulted in the initial planning of the study and reviewed the funding application. The study researcher employed by the McPin Foundation was explicitly recruited as a researcher with lived experience of mental health problems; she has reviewed all of the study documents including the study questionnaires, topic guides and information sheets. Our working group includes 6 service user-researchers and 5 practitioners from mental health services, who are advising on the development of the study intervention and trial outcome measures and procedures, and dissemination plans at the end of the study. The McPin researcher is leading on qualitative data collection and analysis, with input from working group members in developing a qualitative coding frame. Co-applicant Vanessa Pinfold brings expertise in facilitating patient and public involvement in research and will advise on study plans throughout.

15. Monitoring, Auditing and Training

The Chief Investigator will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality.

The Chief Investigator will inform the sponsor should he have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

The Chief Investigator will review and provide assurances of the training and experience of all staff working on this study. Appropriate training records will be maintained in the study files.

16. Finance

The study is funded by a research grant from the National Institute for Health Research School for Social Care Research.

The excess treatment costs of delivering the study intervention will be met by the participating NHS Trusts (Barnet, Enfield and Haringey Mental Health NHS Trust and Camden and Islington NHS Foundation Trust). A service-level agreement between the two Trusts, identifying roles and responsibilities of each organisation and confirming funding for study excess treatment costs, has been signed by both parties.

The CIs, PIs and trial management members have no financial conflicts of interests.

17. Insurance

University College London holds insurance against claims from participants for injury caused by their participation in the trial. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this trial is being carried out in a hospital, the hospital continues to have a duty of care to the participant of the trial. University College London does not accept liability for any breach in the hospital's duty of care, or any negligence on the part of hospital employees. This applies whether the hospital is an NHS Trust or otherwise.

18. Publication policy

The funders require, within 30 days of the end of the study, an End of Project Report, and a brief, accessible "Findings" document. A publications plan for additional publications in peer-reviewed journals and other publications will be developed by the Study CIs in discussion with the study management group. All proposed publications will be discussed with and reviewed by the Sponsor prior to publishing other than those presented at scientific forums/meetings.

19. Intellectual property

All intellectual property rights and know-how in the protocol and in the results arising directly from the study, but excluding all improvements thereto or clinical procedures developed or used by each participating site, shall belong to UCL. Each participating site agrees that by giving approval to conduct the study at its respective site, it is also agreeing to effectively assign all such intellectual property rights ("IPR") to UCL and to disclose all such know-how to UCL with the understanding that they may use know-know gained during the study in clinical services and teaching to the extent that such use does not result in disclosure of UCL confidential information or infringement of UCL IPR.

20. Supporting documents

A Risk Assessment and a Schedule of Events form for the Community Navigator Study accompany this protocol but are provided as separate documents.

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