ISRCTN10771821 https://doi.org/10.1186/ISRCTN10771821

Community navigators study

Submission date
03/04/2017

Recruitment status
No longer recruiting

Registration date
07/04/2017

Overall study status
Completed

Last Edited
07/06/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
People with mental health problems are often vulnerable to loneliness, which affects their quality of life and can impede recovery. Loneliness can be defined as a negative experience arising due to the difference between someone's desired and achieved quantity and/or quality of social relationships. Loneliness has been associated with many negative health outcomes in the general population such as shorter life expectancy. It also predicts the onset of anxiety and depression, and leads to worse outcomes for those who are anxious or depressed. In addition, people with mental health problems are often particularly vulnerable to loneliness. The aim of this study is to develop and test a programme of support to increase community connections and reduce loneliness for people with complex anxiety or depression.

Who can participate?
Adults who are using participating mental health services who are feeling lonely.

What does the study involve?
After agreeing to take part in the study, participants complete some questionnaires assessing their social relationships, quality of life and mental health. They are then randomly allocated to one of two groups. Those in the first group receive standard care from their clinical teams and are also offered a pack of written information about community resources and activities within their area. Those in the second group receive a programme of support from a 'Community Navigator'. This involves 10 meetings with the Community Navigator over six months, to help people review their current relationships, activities and interests and make a plan with the aim of reducing loneliness. There is a budget of £100 per person available to help put these plans into action. Participants receiving support from a Community Navigator are also invited to attend up to three group meetings, which provide opportunities to meet other participants, discuss the programme and their progress, and share resources and experiences. After six months, all participants are asked to complete the same questionnaires as at the start. In-depth feedback is also collected through interviews with 20 of the participants receiving support from a Community Navigator, the Community Navigators themselves, and 10 other involved people.

What are the possible benefits and risks of participating?
Support from a Community Navigator may reduce people's feelings of loneliness and improve quality of life and health. Reading through the written information about local resources and community activities may also be useful. Participants will be involved in a study which will help

to find out more about what kind of support is helpful for people with anxiety or depression who are experiencing feelings of loneliness. It is possible that participants will not find receiving support from the Community Navigator or the written information about local resources helpful and this could be disappointing. Working to increase their community connections may be difficult for participants. They will remain under the care of NHS clinical services and receiving standard care throughout the programme, so expert help and support with any distress will be available. It is possible that people may be disappointed when their meetings with a Community Navigator end after 10 sessions.

Where is the study run from?
1. Complex Depression, Anxiety and Trauma Service, St Pancras Hospital (UK)
2. Barnet Complex Care Team, Edgware Community Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2016 to February 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Brynmor Lloyd-Evans
b.lloyd-evans@ucl.ac.uk

Study website
https://www.ucl.ac.uk/psychiatry/research/epidemiology/community-navigator-study/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
31617

Study information

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

Study 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 or anxiety who use specialist 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. This support will be in addition to treatment as usual from a secondary mental health service.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England - Cambridge Central Research Ethics Committee, 26/07/2016, ref: 16/EE/0255

Study design
Randomised; Both; Design type: Treatment, Psychological & Behavioural, Complex Intervention, Qualitative

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Study not assigned to a MH Clinical Studies Group; UKCRC code/ Disease: Mental Health/ Unspecified mental disorder

Interventions

Participants are randomised to one of two groups. Randomisation will be conducted by an independent statistician in the UCL Division of Psychiatry, who is not connected to the study team. Allocation of participants in the feasibility trial (n=40) will be by block randomisation, stratified by study site. There will be unequal allocation between treatment arms, with 30 participants in the treatment group and 10 in a control group. Due to limitations in the researcher resources available, participants' allocations will not be concealed from the research team.

Intervention arm: Participants will be offered 10 meetings with a Community Navigator over a six-month period with the aim of increasing community connections and reducing loneliness. Each participant may access a budget of up to £100 on goals agreed with their Community Navigator to facilitate access to and participation in social activity, and to develop network connections. The intervention comprises three main components:
1. 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
2. Support to develop and use an action plan to increase connectedness. This will be person centred and include: providing information about available activities and sources of support locally; practical help to access activity; access to financial support from a budget; emotional support to overcome barriers to increasing social connectedness
3. Participants will be invited to attend up to three meetings for all participants which provide opportunities to meet co-participants, discuss the programme's aims and progress, and share information about helpful local resources and experiences

Control arm: Participants will receive treatment as usual and will be offered a pack of written information about community resources and activities within their area.

The total duration of treatment and follow-up will be six months from baseline.

Intervention Type

Other

Primary outcome measure

Feasibility measures:
1. Recruitment duration is recorded as the time period from recruitment of the first trial participant to meeting the trial recruitment target (40 participants)
2. Recruitment rate is recorded as the number of participants screened, the number of those screened who are eligible, and the number of eligible participants who consent to participate in the study by four months
3. Attrition rate is recorded as the number of participants who consent to participate that remain in the study until the end of follow up at six months
4. Number of adverse events recorded in each study arm until the end of follow up at six months
5. Intervention take-up rate for those in the intervention arm, where the minimum threshold for intervention take-up is three sessions with a Community Navigator
6. Implementation of the intervention is recorded as the proportion of participants that

maintained engagement with a Community Navigator and the number of sessions of support provided
7. Process evaluation is undertaken through qualitative interviews at the end of treatment with treatment group participants, Community Navigators and other stakeholders as well as Community Navigators' records of sessions and feedback from treatment group participants after two of their sessions with a Community Navigator

Secondary outcome measures
Potential primary and secondary outcomes for a future definitive RCT are being measured to assess acceptability, response and completeness:
1. Loneliness is measured using the de Jong Gierveld loneliness scale (11 items) at baseline and six months
2. Depression severity is measured using the Patient Health Questionnaire (PHQ-9) at baseline and six months
3. Anxiety severity is measured using the Generalized Anxiety Disorder Questionnaire (GAD-7) at baseline and six months
4. Social network is assessed with the abbreviated Lubben Social Network Scale (LSNS-6) at baseline and six months
5. Social capital is measured with the Resource Generator UK (RG-UK) at baseline and six months
6. Activity over the previous week is measured using the Time Budget Diary, with additional questions on whether activities were done with others or alone and, if with others, whether this was online or face-to-face at baseline and six months
7. Wellbeing is measured with the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and six months
8. Health-related quality of life is measured with the EQ-5D-5L at baseline and six months
9. Mental health-related quality of life is assessed on the Recovering Quality of Life Questionnaire brief version (ReQoL-10) at baseline and six months
10. Information is sought from Trust Informatics teams regarding participants' current diagnosis, care cluster, attended and missed face-to-face appointments with their clinical team, 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 are sought for the six months prior to baseline and at six month follow up for the intervention period since baseline.
11. Records of participants' use of social care services are sought for the six months prior to baseline and at six month follow up for the intervention period since baseline

Overall study start date
01/03/2016

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Current male and female service users of participating services (Camden and Islington Complex Depression Anxiety and Trauma Team or the Mood Anxiety and Personality Stream of the Barnet Complex Care Team)
2. Aged 18 or over (there is no upper age limit for this study)
3. Service users currently receiving multi-disciplinary support (e.g. care co-ordination and medical input, and access to psychology support) will be prioritised to help explore whether community navigation support is a useful addition within these services

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40 participants in the trial, plus an additional 13 participants involved in qualitative interviews

Total final enrolment
59

Key exclusion criteria
1. Lacks capacity to consent to participate;
2. Poses a risk of harm to others such that meetings with a researcher or community navigator are not advised by staff from participating clinical services;
3. Is unable to communicate in English;
4. Is currently an inpatient at a mental health or general hospital;
5. Do not meet a threshold level for loneliness on a brief screening questionnaire.

Date of first enrolment
20/04/2017

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Complex Depression, Anxiety and Trauma Service
Camley Building
St Pancras Hospital
4 St Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
Barnet Complex Care Team
Dennis Scott Unit
Edgware Community Hospital
Burnt Oak Broadway
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United Kingdom
HA8 0AD

Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The funders require, within 30 days of the end of the study, an End of Project Report, and a brief, accessible “Findings” document. Publication in a high-impact peer reviewed journal is also planned, with intent to publish by February 2019. Planned publication of the trial protocol in a peer-reviewed journal before the end of participant recruitment.

Intention to publish date
28/02/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Brynmor Lloyd-Evans (b.lloyd-evans@ucl.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	09/02/2017	07/04/2017	No	Yes
Protocol article	protocol	23/10/2017		Yes	No
Results article		29/05/2020	22/04/2021	Yes	No
Results article	qualitative results	26/11/2020	22/04/2021	Yes	No
Dataset		27/09/2019	07/06/2023	No	No
HRA research summary			28/06/2023	No	No