ISRCTN13205972 https://doi.org/10.1186/ISRCTN13205972

The Community Navigator trial to reduce loneliness and depression in adults with depression that does not respond to drug treatment

Submission date
24/06/2022

Recruitment status
No longer recruiting

Registration date
08/07/2022

Overall study status
Ongoing

Last Edited
28/11/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
About a third of people with depression are not helped by anti-depressants and can be termed "treatment resistant" (TRD). Talking therapies are also of limited benefit for this group. Among people with TRD only 2-3 out of 10 recovers over a few years. They are enduringly unwell and often extremely lonely. More research and new types of support are urgently needed for this group. Our research team has previously developed and tested the feasibility of a programme of support, the Community Navigator programme, in addressing loneliness for people with complex depression and anxiety.

In this study, we propose a full trial in four areas of England to test the effectiveness of the Community Navigator programme, in reducing loneliness and depression for people with TRD in secondary care.

Who can participate?
Adults aged 18 years or older, with treatment-resistant depression

What does the study involve?
This is a 33-month trial with a built-in review point after the first six months. 306 people will be allocated at random to get support from a Community Navigator to increase their social activities and community engagement in addition to their usual community mental health team care; or to carry on receiving treatment as usual. We will ask all the participants to complete research questionnaires with a researcher when they agree to take part, eight months later (once the Navigator support has ended), and again six months after that. Our main question is whether people in the group offered the Community Navigator support are less depressed at eight months follow-up than people in the comparison group. We will also assess loneliness, anxiety and people's personal recovery at each time point, and look at whether the programme

is good value for money. A peer researcher will do in-depth interviews with people receiving the programme, the Navigators and their supervisors, to understand how any benefits for people are achieved, and what helps the programme work well in an NHS context.

What are the possible benefits and risks of participating?
Possible benefits of participating: We hope that having support from a Community Navigator will reduce 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. People in both groups will be involved in a study which will help to find out more about what kind of support is helpful for people with long-term depression who are experiencing feelings of loneliness.

Potential disadvantages of participating: It is possible that people will not find receiving support from the Community Navigator or the written information about local resources helpful, and this could be disappointing. Making a plan to increase your social connections with others could be very useful but some participants may find it challenging.

Where is the study run from?
Camden and Islington NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2021 to December 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

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

Study website
https://www.ucl.ac.uk/priment/our-collaborations/community-navigator-trial

Contact information

Type(s)
Principal Investigator

Contact name
Dr Brynmor Lloyd-Evans

ORCID ID
http://orcid.org/0000-0001-9866-788X

Contact details
Division of Psychiatry
University College London
Maple House
149 Tottenham Court Rd
London
United Kingdom
W1T 7NF

-
b.lloyd-evans@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Gergely Bartl

ORCID ID
http://orcid.org/0000-0002-5947-1304

Contact details
Division of Psychiatry
University College London
Maple House
149 Tottenham Court Rd
London
United Kingdom
W1T 7NF
-
g.bartl@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309178

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 52174, NIHR131647, IRAS 309178

Study information

Scientific Title
Randomised controlled trial of the Community Navigator programme to reduce loneliness and depression for adults with treatment resistant depression in secondary mental health services

Study objectives
People in the group offered the Community Navigator support will be less depressed at eight months follow-up than people in the comparison group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/03/2022, South Central - Oxford B Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 207 1048199; oxfordb.rec@hra.nhs.uk), ref: 22/SC/0064

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Depression

Interventions
Current interventions as of 28/11/2024:

This is a researcher-blind, randomised controlled trial with two arms. Staff in participating NHS services will briefly describe the study to potentially eligible service users and refer participants who are interested in taking part and agree to be referred to the study research team. A study researcher will provide an information sheet and discuss the study further with potential participants; then take formal consent from those who wish to take part. All consenting, potential participants will then be screened by researchers for loneliness and meeting treatment resistant depression criteria. Baseline measures will then be completed with those who are eligible, who will then be enrolled in the study and allocated at random to the treatment or the control group. The Trial Manager or administrator will inform the person's GP and care team that they are taking part in the trial, and will inform the participant which trial arm they are allocated to, and will inform the Community Navigators' supervisors of all participants randomized to the intervention arm, who require allocation to a Community Navigator.

We aim to recruit 306 service users to take part in the trial, from four NHS sites in London, Birmingham and Yorkshire. We anticipate this recruitment will take 16 months, from June 2022 to September 2023. Update: Recruitment was slower than planned. To address these two new London sites we brought on to meet our recruitment target, and we applied for an extension which was given. We had 6 recruitment sites, 4 of which were in London and recruited 314 participants by 31 July 2024.

Each participant receiving the study intervention will receive up to ten 1:1 meetings with a Community Navigator as well as up to four “meet-ups” open to all participants over an 8-month period. The "meet-ups" will run alongside the intervention, facilitated by the Community Navigators. Participants will receive the study intervention in addition to routine care from a specialist community mental health team (CMHT). The control group will receive routine CMHT care plus written information about local social resources. Routine care for both trial groups includes reviews by a psychiatrist and, typically, regular meetings with a care coordinator and where indicated, psychological therapy.

Assessments for all participants will be performed by blinded researchers at the time of consent (baseline), 8-month (end of treatment) and 14 month (six months after end of treatment). Baseline measures will be performed at the screening visit. Additional depression and loneliness ratings will be collected through a self-completed online form or through a phone or video call with a study researcher at 4 and 11 months.

We will collect qualitative data from selected, consenting participants and intervention providers at two stages: a) Qualitative study 1: during the internal pilot phase, to understand any barriers to trial recruitment and intervention engagement, using an anonymised online survey for all participants who agree to be contacted about this (Qualitative study 1a) and semi-structured interviews with 20 participants from the treatment group (Qualitative study 1b); and b) Qualitative study 2: with 20 intervention group participants later in the trial, once they have completed their 8 month end-of-treatment interview, using semi-structured interviews to explore experiences of the programme and how perceived benefits were achieved, and to identify core and local contextual factors affecting delivery of the programme in an NHS context. This will inform development of guidance to support future scale-up in the event of a positive trial result. Participant interviews will be conducted by a study peer researcher with lived experience of mental health difficulties, who will also lead the analysis.

When seeking consent to take part in the study, we will ask all participants if they would like to receive a report of study findings, and will send one to all participants who request this.

Previous interventions:

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Intervention Type
Other

Primary outcome measure
Depression severity (PHQ-9) at 8 months (end-of-treatment)

Secondary outcome measures
1. Depression severity (PHQ-9); Timepoint(s): baseline, 4, 11, and 14 months
2. Number of patients achieving a 20% reduction in PHQ-9; Timepoint(s): Baseline, 8 and 14 months
3. Number of patients who achieve remission of depressive symptoms, defined as a PHQ-9 score of <10; Timepoint(s): Baseline, 8 and 14 months
4. Loneliness (ULS-8); Timepoint(s): Baseline, 4, 8, 11, and 14 months
5. Anxiety (GAD-7); Timepoint(s): Baseline, 8 and 14 months
6. Process of Recovery (QPR); Timepoint(s): Baseline, 8 and 14 months
7. Four-item Multiple Identities Scale (MIS); Timepoint(s): Baseline, 8 and 14 months
8. Brief Rosenberg self-esteem scale (B-RSES); Timepoint(s): Baseline, 8 and 14 months
9. Self-stigma (DISC-12 sub-scale); Timepoint(s): Baseline, 8 and 14 months
10. Lubben Social Network Schedule (LSNS-6); Timepoint(s): Baseline, 8 and 14 months
11. EuroQol EQ-5D 5 level (EQ-5D-5L); Timepoint(s): Baseline, 8 and 14 months

12. Recovering Quality of Life (ReQoL); Timepoint(s): Baseline, 8 and 14 months
13. Client Service Inventory (CSRI); Timepoint(s): Baseline, 8 and 14 months
14. Daytime Activities Questionnaire; Timepoint(s): Baseline, 4, 8, 11, and 14 months

Overall study start date
01/09/2021

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age 18+ years
2. Meet ICD-10 diagnostic criteria for depression assessed using the Clinical Interview Schedule - Revised (CIS-R) interview
3. Have had at least two reported courses of anti-depressants without symptom remission, confirmed by the participant
4. Score of 2 or more on 6-item De Jong Gierveld Loneliness Scale (DJG-6)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 306; UK Sample Size: 306

Total final enrolment
314

Key exclusion criteria
Current exclusion criteria as of 28/11/2024:

1. Are due to be discharged from the mental health team within the trial intervention period (8 months)
2. Currently using mental health inpatient services
3. Identified by involved clinicians or clinical records as having a primary diagnosis of a serious mental illness other than TRD, defined as schizophrenia or other non-mood psychotic disorders (ICD-10 codes F20-29 or equivalent) or bipolar disorder (ICD-10
code F31 or equivalent), or a diagnosis of dementia (ICD-10 codes F00-F03 or equivalent) or mild cognitive impairment (ICD-10 code F06.7 or equivalent)
4. Lacks capacity to consent to participate

5. Does not understand English well enough to give informed consent and engage with the study intervention
6. Has a care coordinator who supervises the Community Navigators

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Previous exclusion criteria:

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2. Currently using mental health inpatient services
3. Identified by involved clinicians or clinical records as having a primary diagnosis of a serious mental illness other than TRD, defined as schizophrenia or other non-mood psychotic disorders (ICD codes F20-29) or bipolar disorder (ICD code F31)
4. Lacks capacity to consent to participate
5. Does not understand English well enough to give informed consent and engage with the study intervention
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Date of first enrolment
15/07/2022

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Pancras Hospital
Camden and Islington NHS Foundation Trust
St. Pancras Way
London
United Kingdom
NW1 0PE

Study participating centre
West Park Hospital
Tees, Esk and Wear Valleys NHS Foundation Trust
Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Study participating centre
Birmingham and Solihull Mental Health NHS Foundation Trust
Unit 1
50 Summer Hill Road
Birmingham
United Kingdom
B1 3RB

Study participating centre
St Anns Hospital
Barnet, Enfield and Haringey Mental Health NHS Trust
St Anns Road
London
United Kingdom
N15 3TH

Study participating centre
Central & North West London NHS Foundation Trust Headquarters
Greater London House
Hampstead Road
London
United Kingdom
NW1 7QY

Study participating centre
North East London NHS Foundation Trust
West Wing
C E M E Centre
Marsh Way
Rainham
United Kingdom
RM13 8GQ

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust

Sponsor details

St Pancras Hospital
4 St Pancras Way
London
England
United Kingdom
NW1 0PE
+44 20 7450 8507
sponsor.noclor@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.candi.nhs.uk/

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

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
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
28/02/2026

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.0	22/03/2022	05/07/2022	No	Yes
Protocol file	version 1.0	04/02/2022	05/07/2022	No	No
HRA research summary			28/06/2023	No	No
Protocol article		06/10/2023	10/10/2023	Yes	No