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Improving quality of life and health outcomes of patients with psychosis through a new structured intervention for expanding social networks: SCENE (Work Package 5)

Submission date
04/03/2019

Recruitment status
No longer recruiting

Registration date
26/03/2019

Overall study status
Completed

Last Edited
02/10/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
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 to the general population, and compared to other groups with long-term health conditions. Social isolation in turn, is associated with worse outcomes including poor quality of life.
We are interested in testing an intervention to expand patients' social networks and to see whether it improves their quality of life. The intervention involves receiving support from a mental health professional to try an activity of their choice and to meet new people. The clinicians (named 'social contacts coaches') will receive specific training and instructions on how to motivate and support patients. A similar intervention was found to be beneficial for patients in Italy and has been adapted to the UK context through a number of earlier studies including a survey, focus groups, a case series and a feasibility trial.
In the present study we will recruit 576 patients with psychosis who are socially isolated from community-based NHS services across England (both urban and rural). We will randomly allocate them either to receiving social contacts coaching or information about local options for activities only. We are primarily interested in whether the active support improves quality of life compared to receiving information, but we are also looking to see whether it increases time spent in social activities, improves social situation or mental health symptoms and reduces feelings of loneliness or use of health services.

Who can participate?
Adult patients with a diagnosed psychosis-related condition and mental health professionals can take part.

What does the study involve?
Those interested in taking part will first meet with a researcher to discuss the study, ask questions and confirm agreement to participate by signing a consent form.

The researcher will then ask the participant demographic questions such as age, current living situation and employment status. To assess whether the intervention would be suitable for them they will go through questionnaires about social contacts, activities, quality of life and psychological symptoms. They will also ask them about their health service use.
This interview is expected to last for no more than 45 minutes. If the participant is eligible to receive the intervention, they will be enrolled in the study. If not, they will receive £15 as a thank you for their time and resume care as usual.

People who are eligible and accept to participate in the study will either receive active support to meet new people or receive information about local opportunities for social activities. There will be a 50% chance of receiving either the active support or the information. This will be based solely on chance rather than individual characteristics. Participants in the information group will receive a booklet with information about activities in their local area. They will then be contacted after 6 month, 12 months, and 18 months to meet with a researcher and complete the same questions about social contacts, quality of life, symptoms etc. Every time they complete these questionnaires participants will receive £15 as a thank you.

Participant in the active support group, we will be given an appointment to meet their social contacts coach. As part of this intervention, the social contacts coach, who will be a trained mental health professional (e.g. a psychologist, psychiatrist, occupational therapist, nurse, or social worker), will support the participant to take part in one or more social activities, i.e. activities with other people. Participation in the intervention will involve meeting with the social contacts coach once a month, for six months (i.e. 6 times in total).

Once they have completed the sessions with the social contacts coach over 6 months, a member of the research team will contact the participant at 6 month, 12 months, and 18 months to complete the same questions about social contacts, quality of life, symptoms etc. Every time they complete these questionnaires they will receive £15 as a thank you. Participants who have received the social contacts coaching will also be invited to an individual interview to learn about their thoughts, feelings and experiences of the intervention. These interviews will be audio-recorded and participants will receive £20 as a thank you for their time.

What are the possible benefits and risks of participating?
We believe that participation in this research is safe and do not expect any harm or injury to result from taking part. There is a chance that participants may become distressed during the interviews, in which case the researcher will stop the sessions and provide appropriate support. Taking part in the study may help socially isolated individuals with psychosis to expand their social activities and meet more people by working with a trained social contacts coach. If the coaching helps it may have a positive effect on their quality of life.

Where is the study run from?
The study is run from East London NHS Foundation Trust but is a collaboration between a number of different NHS Trust and Universities across the UK.

When is the study starting and how long is it expected to run for?
October 2018 to December 2023

Who is funding the study?
NIHR Central Commissioning Facility (CCF) (UK)

Who is the main contact?
Agnes Chevalier, agnes.chevalier@nhs.net

Study website
http://www.scene.elft.nhs.uk/

Contact information

Type(s)
Public

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
40824

Study information

Scientific Title
A randomised controlled trial of a structured intervention for expanding social networks in psychosis

Acronym
SCENE (Work Package 5)

Study objectives
A structured intervention for expanding social networks (aka social contacts coaching) for patients with psychosis will result in improved quality of life compared to an active control condition (i.e. information on local options for social activities).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2019, London - Hampstead Research Ethics Committee (Royal Free Hospital, Pond St, Hampstead, London NW3 2QG; nrescommittee.london-hampstead@nhs.net; 02071048127), ref: 19/LO/0088

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions

Consent & baseline:
Potentially eligible patients will be identified by members of their treating clinical team (depending on the local Trust policy this may include clinical studies' officers), who will introduce the study and if interest is shown, request their verbal permission to pass their contact details to a member of the research team. Informed consent will be sought from all patients to participate in the study, which will include permission to access medical records to retrieve socio-demographic and clinical characteristics.
Eligibility will continue to be assessed during baseline where researchers will ascertain whether patients meet the inclusion criteria of "a score of 5 or less on the MANSA and less than three social contacts in the previous week" If the service user is not eligible for the study they will still be compensated £15 for their time. They will also be reassured that they will resume care as usual, e.g. with their Community Mental Health Team. If participants are eligible, they will be invited to take part in the study.

Intervention:
Clinicians (named "social contacts coaches") should meet patients six times over the six-month intervention period, around once per month. The meetings should focus on the patient's motivation to expand their social networks, their preferences for how to do this, local options for doing this and plans for how to achieve it in practice.
The intervention will start with two initial meetings, each lasting about 60 minutes, and ideally within the first month. The main aim of these initial meetings is to explore preferences, discuss options for activities and agree a way forward. The follow-up meetings should last at least 20 minutes each and include discussion around progress and the provision of support as required. Follow-up meeting may take place over the phone as long as the initial meeting and at least one other meeting remain face to face.
The intervention will be delivered by clinicians (minumum NHS band 4 or equivalent experience) from a range of background including psychologists/assistant psychologists, social workers, nurses, support workers and medical doctors. Clinicians will be trained in the intervention in one session of up to three hours, normally in a group format.

Control group:
Patients in the control group will be provided with information about local options for social activities by the researcher in the form of an activity booklet. This group is intended to control for the provision of information on social activities in addition to routine care and clinician attention to their social isolation.
Usual mental health treatment, including care-coordination, medication, and psychological therapies, will not be affected by participation in this study, neither in the intervention nor in the control group.

Randomisation procedures:
Patients will be randomised to either the intervention or control. The allocation ratio will be 1:1. Randomisation will be stratified by NHS Trust, ensuring balanced numbers of patients in each group at each NHS Trust. Permuted blocked randomisation with block sizes of m=6, 4 and 2 will be used within each stratum. Patients will be allocated to clinicians based on locality and availability i.e. not randomly. The randomisation will be carried out remotely by the Pragmatic Clinical Trials Unit at Queen Mary, University of London. One researcher per site will be given a login to the system in order to complete randomisation at that site.

Outcome assessments:
Outcomes will be assessed at 6 months, 12 months and 18 months by a researcher masked to allocation. The primary outcome will be subjective quality of life, measured on the Manchester Short Assessment of Quality of Life (MANSA) at the end of the intervention (6 months after

recruitment). We are also interested in whether the primary outcome is medicated by number of social contacts in the previous week at 6 months.

Intervention Type
Other

Primary outcome measure
The primary outcome will be the subjective quality of life, measured on the Manchester Short Assessment of Quality of Life (MANSA) at the end of the intervention (6 months after recruitment). Timepoint(s): 6 months (primary outcome), 12 months and 18 months follow-up

Secondary outcome measures
Assessed at 6 months, 12 months and 18 months
1. Psychopathological symptoms Positive And Negative Syndrome Scale
2. Social situation (SIX)
3. Feeling of loneliness (UCLA Loneliness Scale)
4. Time spent in social activities (Time Use Survey)
5. Health-related quality of life (EQ-5D-5L)
6. Service use (Client Service Receipt Inventory)

Overall study start date
01/10/2018

Completion date
31/12/2023

Eligibility

Key inclusion criteria
PATIENTS:
1. 18-65 years old
2. Diagnosis of psychosis-related condition (ICD-10 F20-29)
3. Capacity to provide informed consent
4. Ability to communicate in English
5. Limited social network size (three or less social contacts with non-first degree relatives in the previous week)
6. Low quality of life (Score 5 or less on MANSA quality of life assessment)

CLINICIANS:
1. Mental health professional with experience of providing mental health care (e.g. psychiatrists, clinical psychologists, nurses, occupational therapists), minimum NHS Band 4 or equivalent experience
2. Aged 18 and over
3. Capacity to provide informed consent
4. Ability to communicate in English

Participant type(s)
Mixed

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600

Total final enrolment
577

Key exclusion criteria
PATIENTS:
1. Primary problem of current drug addiction
2. No capacity to provide written informed consent
3. An inpatient on a psychiatric ward at the time of recruitment

Date of first enrolment
01/03/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
East London NHS Foundation Trust
United Kingdom
E1 8DE

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
United Kingdom
DL2 2TS

Study participating centre
Devon Partnership Trust
United Kingdom
EX2 5AF

Study participating centre
Somerset Partnership NHS Foundation Trust
United Kingdom
TA6 4RN

Study participating centre
Cornwall Partnership NHS Foundation Trust
United Kingdom
TR15 2SP

Study participating centre
Oxford Health NHS Foundation Trust
United Kingdom
OX3 7JXT

Study participating centre
Leeds and York Partnership Trust
United Kingdom
LS15 8ZB

Study participating centre
Gloucestershire Health and Care NHS Foundation Trust
Gloucester
United Kingdom
GL3 4AW

Study participating centre
Humber Teaching NHS Foundation Trust
Hull
United Kingdom
HU10 6ED

Sponsor information

Organisation
East London NHS Foundation Trust

Sponsor details
20-24 Commercial Street
London
England
United Kingdom
E1 8DE
02076855949
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01q0vs094

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0615-20009

Results and Publications

Publication and dissemination plan
Dissemination activities will be influenced and supported by our Lived experience advisory panel (LEAP). Throughout all phases of the research, we will disseminate information about the activities of the programme through social media (twitter: @study_scene) and a project-specific website (http://scene.elft.nhs.uk/) in order to reach a wider public audience. When results become available, they will be disseminated through scientific publications in peer-reviewed open access journals; presentations at national and international conferences and to professional and non-professional audiences at appropriate events. Workshops for NHS Trusts and patient organisations will be delivered in collaboration with the LEAP. The LEAP will also be actively involved in developing lay summaries of the findings to send to participants.

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon reasonable request from Dr Domenico Giacco (d.giacco@qmul.ac.uk). Participants are made aware at the point of consent that their data may be shared with researchers in other organisations to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. They are told this information will not identify them nor could it be combined with other information in a way that could identify them. Applications for datasets will be considered on a case-by-case basis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		04/12/2018		No	No
Protocol file	version v3.0	21/09/2020	26/02/2021	No	No
Protocol article		13/12/2021	15/12/2021	Yes	No
Results article		13/03/2023	15/03/2023	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan	version 1.0	15/09/2023	25/09/2023	No	No