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Feasibility trial of a structured intervention for expanding social networks in psychosis

Submission date
30/05/2018

Recruitment status
No longer recruiting

Registration date
11/12/2018

Overall study status
Completed

Last Edited
07/08/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Psychosis affects a large number of people (1-2% of the population), can last for decades and cause much distress to patients. Although patients who have psychosis receive medication, practical support and sometimes talking therapies, these treatments have limited benefit and many patients remain socially isolated. Previous studies have social isolation is associated with poor quality of life. The aim of this study is to test in a small sample of patients (36) with psychosis whether it is possible to engage patients in a newly developed intervention to increase their social contacts, and to see how its benefits can be assessed compared to the care that patients usually receive. This small study will help with the design of a larger trial to receive a definitive answer of whether the intervention is more beneficial than usual care.

Who can participate?
Patients aged 18 to 65 with a diagnosis of psychosis who have less than two social contacts outside home, work or services and who have a poor quality of life

What does the study involve?
Nine clinicians in three NHS mental health Trusts (East London NHS Foundation Trust, Devon Partnership NHS Foundation Trust and Tees, Esk and Wear Valleys NHS Foundation Trust) deliver the intervention (social contacts coaching) to 36 patients overall. The patients are randomly allocated to receive either the intervention or only information about events and social groups in their area. People who receive the intervention receive support from a mental health professional to try an activity of their choice, which involves meeting new people. All patients and clinicians are interviewed about their experience of receiving or delivering the intervention. Patients are also interviewed about their social contacts and activities, symptoms and quality of life before and after the intervention.

What are the possible benefits and risks of participating?
There may be benefits towards reducing social isolation for both patients in both groups. However, this has not been studied yet and cannot be guaranteed. Risks of participating are minimal as all patients will keep receiving their standard care and procedures are in place to respond to arising distress due to participation and to preserve confidentiality of participants.

Where is the study run from?
The lead team is at East London NHS Foundation Trust, which covers three boroughs (Newham, Tower Hamlets and Hackney) of London. Other sites are within the areas covered by the Devon Partnership NHS Foundation Trust and the Tess, Esk and Wear Valleys NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
February 2018 to February 2019

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

Who is the main contact?
1. Agnes Chevalier (Programme Manager)
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2. Domenico Giacco (co-lead investigator)
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
38036

Study information

Scientific Title
Feasibility trial of a structured intervention for expanding social networks in psychosis

Acronym

SCENE (Work Package 4)

Study objectives
Psychosis affects a large number of people (1-2% of the population), can last for decades and cause much distress to patients and carers. Although patients receive medication, practical support and sometimes talking therapies, these treatments have limited benefit and many patients remain socially isolated. Previous studies have shown that small social networks are associated with poor quality of life. The trialists would like to test the feasibility of an intervention to expand patients' social networks and consequently improve their quality of life. In this specific study they will carry out a feasibility study, further refining the intervention, in order to gain more systematic practical experience of its provision within the NHS.

The study will be carried out at different sites in order to make the intervention applicable to different (urban and rural) areas. The study sites will be East London, North East of England (York and surrounding area), and Devon.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Surrey Research Ethics Committee, 14/05/2018, IRAS ID: 243201, REC ref: 18/LO/0520

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental health/ Organic, including symptomatic, mental disorders

Interventions
Patients will be randomised to either the intervention or control. The allocation ratio will be 2:1 in favour of the intervention. Randomisation will be stratified by NHS Trust, ensuring balance between groups in the patient numbers from each NHS Trust. Blocked randomisation with a block size of m=3 will be used within each stratum. A fixed block size of m=3 is appropriate in this trial as the feasibility of intervention and study procedures is of primary interest and not intervention effects. Should blocked randomisation be used in the full trial a variable block size would be utilised. The randomization will be carried out remotely by the Pragmatic Clinical Trials Unit at Queen Mary, University of London.

11 clinicians will be asked to deliver the intervention ('social contacts coaching') to a small number of patients. 36 participants with psychosis will be randomised to receive either the intervention or information about events and social groups in their area (24:12). The intervention group will receive support from a mental health professional to try an activity of their choice, which involves meeting new people.

Type and frequency of meetings
Patients will be identified from mental health teams' caseloads and will be offered the intervention if they do not show substantial risk to self or others and this should be monitored as per routine clinical practice. The clinician delivering the intervention will not be the treating clinician of the patient.
Clinicians should meet patients six times over the six-month intervention period; about once per month.
The intervention should start with a sufficiently long first two meetings (about 60 minutes) in the first month to explore preferences, discuss options in detail and agree on the way forward. The following meetings should discuss progress and provide support as required. They should last at least 20 minutes. Further contacts of clinicians with patients, as needed via telephone, text messages, Skype or other electronic means, will be encouraged. Such contacts may also replace face-to-face contacts, but the initial meeting and at least one more meeting will be face-to-face. The location of these meetings can vary and depend on patient preference and local circumstances (including patients' homes, community places and offices of services).

Content of meetings
The meetings should focus on the patient's motivation to expand social networks, their preferences for how to do this, local options for doing this and plans for how to achieve it in practice. This may include temporary support through the intervention (e.g. reminders, initial accompanying). The planned activities should be a way to expand social networks, e.g. leisure activities in groups rather than going to the cinema on their own. This will usually mean establishing new contacts, but could also be engaging in new joint activities with previous contacts (outside on-going friends and close family). The intervention will not address potential difficulties in already existing on-going relationships (e.g. with close family).
The meetings should start with a review of progress and should end with an agreement on actions to be taken. This will then be reviewed and possibly revised at further meetings. Normally, the agreement should not specify more than one type of concrete activity at a time. If a patient expresses interest in more than one activity, they should be asked to choose one to prioritise. If there is no substantial progress after three months with one type of activity, an agreement should be made to switch to a different activity. There will be some flexibility about when exactly the switch should be considered and agreed. The switch should be agreed by both patient and clinicians in a face-to-face meeting.

Who will deliver the intervention
The intervention will be delivered by employed NHS clinicians who are clinically qualified (e.g. psychiatrists, psychologists, nurses, occupational therapists) and have experience in delivering psycho-social interventions.

Training of clinicians
Clinicians will be trained in the intervention in one session of up to three hours, flexibly in either a group format or individual format by a senior member of the core research team. When and if required, depending on the previous experience, additional one-to-one training can be provided. During the training they will acquire knowledge of the structure and aims of the intervention, i. e. number of sessions, frequency of sessions and procedures to help the patients to reach out to social activities. They will also be taught simple motivational interviewing techniques. Scenarios in which barriers for the patient in engaging in new social contacts may appear and strategies to overcome them will be discussed.
Knowledge about the local context will be helped by a list of possible local options for low cost activities in the local area available to the patient that involve contacts with other people. This list will be provided by the research team. Clinicians will also be expected to and supported in

obtaining a good knowledge about the options and encouraged to network in the given community to generate more options for relevant activities. Learning progress will be assessed during the training and in the subsequent supervision, provided by senior members of the research team, which will be organised flexibly in order to identify the ideal frequency. At the end of the case studies, clinicians who have delivered the intervention will receive an in-depth interview and will be encouraged to provide suggestions for further refinement of the intervention, of the training and of the supervision arrangements.

Further support of clinicians
Clinicians will receive updates on changes in options for activities from the local research team and from participating clinicians themselves through networking. They will also be supervised through regular phone calls (at least once a month or more if and as required) either locally or centrally from the study team in London.

Recording of intervention sessions
For each clinician, we will aim to audio-record two interventions sessions (if the patients consent to this). They will be helpful to understand what are the topics and activities discussed during the intervention sessions and to identify ways to help motivation and commitment of patients to social activities in order to help specify training guidelines and obtain examples to be used for a training package.

Control group
Patients in the control group will be provided with comprehensive information about local options for social activities by the researcher. This condition is intended to control for the provision of information and non-specific attention through a professional in addition to routine care. Also, the mere provision of information should be regarded as good practice independent of additional targeted interventions, so that patients in the control group should receive it too. The usual treatment, including care-coordination, medication, and psychological therapies, will not be affected, neither in the intervention nor in the control group.

The trialists will then interview patients and clinicians about their experience of receiving or delivering the intervention. Patients will also be interviewed about their social contacts and activities, symptoms and quality of life before and after the intervention. The data collected will help to see whether the definitive intervention is more beneficial than normal care and to gain further and more systematic practical experience with the intervention in the NHS in preparation for a full randomised controlled trial.

Intervention Type
Behavioural

Primary outcome(s)
Quality of life measured by the Manchester Short Assessment for Quality of Life (Priebe et al., 1999) at baseline and at 6 months

Key secondary outcome(s))
1. The number and quality of social contacts on each day of the previous week will be measured using Social Contacts (SCA) (Giacco et al., 2016), including detailed questions about social activities as developed in the ongoing PGfAR VOLUME (on volunteering in mental health) and including questions of the Time Use Survey (Priebe et al., 2016) at baseline and at 6 months
2. Positive and negative symptoms assessed using the Positive and Negative Syndrome Scale (PANSS, Kay 1991 and Clinical Assessment Interview for Negative Symptoms (CAINS, Kring et al.,

2013) at baseline and at 6 months
3. Loneliness assessed using UCLA-8 (Hays and DiMateo, 1987) at baseline and at 6 months

Completion date
28/02/2019

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 and low quality of life (Score less than 5 on MANSA quality of life assessment and less than 7 consecutive days with social contacts in the previous week)

Clinicians:
1. Mental health professional with experience of providing community mental health care (e.g. psychiatrists, clinical psychologists, nurses, occupational therapists)
2. Aged 18-65 years old
3. Employed by participating NHS Trusts
4. Capacity to provide informed consent
5. Ability to communicate in English

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
36

Key exclusion criteria
Patients:
1. Does not meet inclusion criteria
2. Primary problem of current drug addiction

3. No capacity to provide written informed consent
4. An inpatient on a psychiatric ward at the time of recruitment

Clinicians:
1. Does not meet inclusion criteria

Date of first enrolment
07/06/2018

Date of final enrolment
24/09/2018

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre
Devon Partnership NHS Trust
Wonford House
Dryden Road
Exeter
United Kingdom
EX2 5AF

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

Sponsor information

Organisation
Noclor, East London NHS Foundation Trust

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Domenico Giacco (d.giacco@qmul.ac.uk). Data will be pseudo-anonymised, whereby all participants will be assigned a participant ID number and this will be used for all data processing purposes. No person-identifiable data will be shared. The data will be available until November 2022, and will only be shared with other researcher for the purpose of systematic reviews and meta-analyses.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/08/2020	07/08/2020	No	No
HRA research summary			28/06/2023	No	No
Protocol file	version V2	30/04/2018	02/04/2019	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes