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Assessing volunteering in mental health care for people with psychosis

Submission date
22/07/2015

Recruitment status
No longer recruiting

Registration date
23/07/2015

Overall study status
Completed

Last Edited
19/02/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
People living with mental illness in the community frequently become extremely socially isolated. It has been previously shown that social isolation is associated with worse mental and physical outcomes in the longer term. This trial seeks to examine whether spending time on weekly bases with a volunteer companion alleviates these patients social isolation and improves outcomes.

Who can participate?
Patients aged between 18-65, diagnosed with schizophrenia or a related disorder and being socially isolated.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 (intervention group) meet with a volunteer weekly to spend at least an hour together. The patient chooses what they do during this time but the volunteer introduces a range of possible social activities, such as going out for tea and cake, or the cinema. Those patients in group 2 have a one-off meeting with a researcher to discuss the different possibilities of engaging in free or low-cost social activities and groups in the local area. Volunteer companions are training on their role and supported throughout the trial. Both patients and volunteers are assessed at four points during the trial, i. e. at the start, after 6 months, at the end of the 12-month trial, and, finally, 6 months after the trial has ended. Qualitative interviews are further carried out to explore their opinions and experiences of participating in the trial.

What are the possible benefits and risks of participating?
Within this study there are two groups of participants that we need to consider with regards to potential risks and benefits - the volunteer participants, and the patient participants. Main risk that may occur are: emotional burden; maintaining patient participant confidentiality; ending the relationship; abuse of both the volunteer participant and the patient participant. Main benefits involve an opportunity to widen one's social sphere, and to decrease one's social isolation in patients; for volunteers gains include gaining experience in working with someone with mental health illness; receiving training in mental health awareness, listening skills, equality and diversity.

Where is the study run from?
Newham Centre for Mental Health, London (UK)

When is the study starting and how long is it expected to run for?
July 2015 to February 2016

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

Who is the main contact?
Dr Hana Pavlickova

Contact information

Type(s)
Public

Contact name
Dr Hana Pavlickova

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19248

Study information

Scientific Title
An exploratory randomised controlled trial assessing volunteering in mental health care for people with psychosis

Acronym
VOLUME6

Study objectives

This study aims to examine whether spending time on weekly bases with a volunteer companion alleviates social isolation and improves patient outcomes for people living with a mental illness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Camden & Kings Cross, 20/05/2015, ref: 15/LO/0674

Study design
Randomised; Interventional; Design type: Treatment

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Schizophrenia, Psychosis; Disease: Schizophrenia, Psychosis

Interventions
Befriending scheme: Patient participants will be individually matched with a volunteer companion. During the 12 months of the intervention, the patient and companion volunteer will meet on a weekly basis and spend at least an hour together. Although the time together will be spent according to the patient's preferences, the volunteer will be proactive in introducing a range of social activities from going out for tea and cake, visiting a cinema, or various social events available for free, or little money in the local area. Patients will be followed for 12 months during the intervention, plus for another 6 months of follow-up, adding up to 18 months.

Intervention Type
Behavioural

Primary outcome measure
Time use; Timepoint(s): Baseline; 6 months; 12 months (i.e. end of the intervention); 18 months (i.e. 6 months follow-up)

Secondary outcome measures
1. Assessment of therapeutic relationship STAR; Timepoint(s): 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)

2. Attitudes to mental health; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
3. Beck Depression Inventory BDI-II; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
4. CAINS; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
5. CSRI; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
6. EQ-5D-5L; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
7. PANSS; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i. e. 6 month follow-up)
8. Self-esteem; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
9. Social contacts; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)
10. Subjective Quality of Life; Timepoint(s): Baseline, 6 month, 12 month (i.e. end of the intervention), 18 months (i.e. 6 month follow-up)

Overall study start date
01/10/2014

Completion date
01/09/2017

Eligibility

Key inclusion criteria
For patient participants:
1. A diagnosis of schizophrenia or a related disorder (ICD-10:F20-29)
2. Being socially isolated i.e. spending on average less than 60 mins a day in social activities as measured by the TUS (Time Use Scale)
3. Willingness to receive regular one-to-one input from a volunteer participant over a period of 12 months
4. Aged between 18-65
5. Sufficient spoken and written English to converse with a volunteer participant on a regular basis and ability to fill in any necessary paperwork and forms
6. Being in the care of the community mental health team for a minimum of two months
7. Capacity to provide informed consent

For volunteer participants:
1. 18 or more years of age
2. Willingness to provide regular one-to-one input to a patient with mental illness over a one year period
3. Willingness to participate in appropriate training and supervision
4. Sufficient command of English to be interviewed/fill out forms in English and to regularly converse with the patient
5. DBS checks show no major criminal convictions (e.g., sexual offences)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
Planned Sample Size: 159; UK Sample Size: 159; Description: We will recruit 106 patient participants, where 53 patient participants will be allocated to an intervention group, and 53 patient participants will be in the control group. Additionally, 53 volunteer participants will be recruited to become the companion for the patient participants in the intervention group.

Total final enrolment
124

Key exclusion criteria
For patient participants:
1. Severe physical disability sufficient to prevent them in participating in community activities.
2. Learning disability
3. Having received a one to one volunteer input scheme in the last 2 years in the community (e. g., befriending, companion, peer support)
4. Currently receiving inpatient care from mental health care services
5. Evidence of history of physical violence
6. Currently in another research study

For volunteer participants:
1. Having received care for a mental health illness from secondary or primary care services in the last 12 months
2. Current professional role in secondary mental health service
3. Severe physical disability sufficient to prevent them in participating in community activities
4. Lack of understanding of the responsibilities and characteristics of the volunteer role despite having received appropriate training
5. Unspent convictions of fraud, theft, violent assault or sexual offenses as identified on the DBS check

Date of first enrolment
24/07/2015

Date of final enrolment
01/03/2016

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Newham Centre for Mental Health
Glen Road
London
United Kingdom
E13 8SP

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
R&D Office
Queen Mary University of London
Barts & London School of Medicine The QMI building
5 Walden Street
London
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United Kingdom
E1 2EF

Sponsor type
University/education

ROR
https://ror.org/026zzn846

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 results of the study will be disseminated as publications in peer review scientific journals, a NIHR final report, and as Conference presentations and posters. In addition, research findings in the form of a lay report will be made available through the VOLUME website, and also through the Institute of Voluntary Research.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan

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?
Protocol article	protocol	03/08/2016		Yes	No
Results article	results	01/09/2020	19/02/2021	Yes	No
HRA research summary			28/06/2023	No	No