

# Assessing volunteering in mental health care for people with psychosis

<b>Submission date</b> 22/07/2015	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 23/07/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/02/2021	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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**  
Newham Centre for Mental Health  
Glen Road  
London  
United Kingdom  
E13 8SP

## 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

England

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?
<a href="#">Protocol article</a>	protocol	03/08/2016		Yes	No
<a href="#">Results article</a>	results	01/09/2020	19/02/2021	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No