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A research study in Bosnia and Herzegovina to test an intervention called Volunteer Support, designed to improve care for people living in the community with severe mental illness

Submission date
09/11/2018

Recruitment status
No longer recruiting

Registration date
20/11/2018

Overall study status
Completed

Last Edited
06/12/2022

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
Volunteer Support involves a volunteer, such as a student or member of the community, spending time with a person living in the community with mental health difficulties. The volunteer and patient will meet every 2 weeks for a period of 6 months, and they will do joint social activities which they will decide on together. They can also meet with other pairs of patients and volunteers and spend time together as a group. This Volunteer Support aims to improve the patient's social interactions and engagement with the community. This study aims to find out whether Volunteer Support can help to improve care for people living with severe mental illness in Bosnia and Herzegovina. More specifically, the researchers want to find out how patients and volunteers experience Volunteer Support when it is used on a regular basis. They also want to find out if Volunteer Support improves outcomes like quality of life and symptoms.

Who can participate?
Patients aged 18 and older with severe mental illness

What does the study involve?
All patients are randomly allocated into two groups: one group receives Volunteer Support and one group (the control) does not receive Volunteer Support (both groups receive their usual treatment). The two groups of patients are compared to see if Volunteer Support makes a difference to outcomes like quality of life and symptoms. Patients in the Volunteer Support group are also interviewed to see how they experienced the intervention.

What are the possible benefits and risks of participating?
For patients, they will be taking part in testing an intervention which might lead to improved quality of life, social functioning and symptoms. The study will benefit volunteers who take part in terms of the training and supervision they will receive to enable them to implement the intervention. For all participants involved in the study, their suggestions and experiences might

be incorporated into further adaptations of Volunteer Support, so that it is tailored to the needs of patients, carers and clinicians in the context of the mental health care system in Bosnia and Herzegovina. Severe mental illnesses cause a high burden for societies with high levels of distress and high costs to individuals who are affected. This is particularly worse in low and middle-income countries such as Bosnia and Herzegovina, where there is a lack of human and financial resources for specialised mental health services in the community. The testing of Volunteer Support will provide evidence for interventions for people with severe mental illness in the community. It is unlikely that any significant ethical, legal or management issues will arise from this study, but some potential risks might be: within the research assessments and interviews that take place across both studies, questions will be raised with participants that might trigger feelings of distress or anxiety. Participants may experience anxiety in trying a new intervention. Throughout the intervention-testing period, individuals will continue to receive their routine care, including any medication, in addition to the test intervention. The intervention can be stopped at any point. The intervention to be tested (Volunteer Support) has an evidence base for effectiveness. There may be risks for volunteers who are supporting someone with mental illness, including the emotional burden and maintaining patient confidentiality. The researchers will minimise these potential risks by providing in-depth training to volunteers to help them understand what severe mental illness, how to manage the volunteer-patient relationship and how to keep in regular contact with the volunteer coordinator. There will be ongoing support and supervision for volunteers throughout the intervention period.

Where is the study run from?
Clinical Centre University of Sarajevo (Bosnia and Herzegovina)

When is the study starting and how long is it expected to run for?
August 2017 to August 2020 (updated 03/03/2021, previously: March 2021)

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

Who is the main contact?
Dr Francois van Loggerenberg, f.vanloggerenberg@qmul.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Francois van Loggerenberg

ORCID ID
http://orcid.org/0000-0001-5317-7983

Contact details
Unit for Social and Community Psychiatry
Queen Mary University of London
Newham Centre for Mental Health
London
United Kingdom

E13 8SP
+44 (0)20 7540 4380 Ext: 2339
f.vanloggerenberg@qmul.ac.uk

Type(s)
Scientific

Contact name
Dr Francois van Loggerenberg

Contact details
Unit for Social and Community Psychiatry
Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)20 540 4380 Ext: 2312
f.vanloggerenberg@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16/137/97

Study information

Scientific Title
Testing the effectiveness, acceptability and feasibility of Volunteer Support in severe mental illness in Bosnia and Herzegovina: a randomised controlled trial

Study objectives
To test the acceptability, feasibility and effectiveness of Volunteer Support against usual treatment.
The specific research questions are :
1. How can Volunteer Support be used to support community mental health care in Bosnia and Herzegovina?
2. How is Volunteer Support experienced by patients and volunteers?
3. How do patient outcomes change when Volunteer Support is used?

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. The Clinical Centre University of Sarajevo School of Medicine Research Ethics Committee (Eticki komitet), 18/09/2018
2. Queen Mary Ethics of Research Committee, 30/10/2018, ref: QMERC2018/66

Study design
Interventional single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life

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
Patients with severe mental illness (including psychosis)

Interventions
72 patients will be recruited, and each patient will be randomly allocated to either a control or intervention group. Randomisation will be done by UK based research team using STATA statistical software and allocations communicated to the unmasked researchers in Bosnia team. Patients will be randomised to either the intervention or control groups so that each patient will either receive Volunteer Support OR receive their usual treatment.

Masking: randomisation will take place after recruitment of participants and completion of baseline assessments. Follow-up assessments at 6 and 12 months will be completed with participants by masked researchers. Measures are in-place to ensure that researchers completing follow-up research assessments remain masked to participant allocation.

Patients allocated to the intervention group will receive Volunteer Support delivered by a volunteer every 2 weeks. The intervention will be over 6 months during which patients will receive 6-7 Volunteer Support sessions. Volunteer Support is where a volunteer (such as a student or member of the community) spends time in the community with someone experiencing mental health difficulties. The focus of this intervention is joint social activities (e. g. walking in the park, playing sport) and each patient will be paired with one volunteer. There is flexibility for patient-volunteer pairs to spend time in groups with other patient-volunteer pairs.

Patients allocated to the control group will receive their usual treatment over the 6 month period.

Intervention Type

Mixed

Primary outcome measure
Quality of life, measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 months (post intervention) and 12 months

Secondary outcome measures
1. Symptoms, measured using the Brief Psychiatric Rating Scale (BPRS) at baseline, 6 and 12 months
2. Quality of life, measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 and 12 months
3. Objective social situation, measured using the Objective Social Outcomes Index (SIX) at baseline, 6 and 12 months
4. Service use, measured using adapted Client Service Receipt Inventory (CSRI) at baseline, 6 and 12 months
5. Self esteem, measured using the Self-esteem rating scale at baseline, 6 and 12 months
6. Stigma, measured using the Internalized Stigma of Mental Illness Inventory (ISMI) at baseline, 6 and 12 months

Overall study start date
01/08/2017

Completion date
20/08/2020

Eligibility

Key inclusion criteria
1. Patients with a primary diagnosis of severe mental illness (ICD-10 F2)
2. Aged 18 years and older
3. Capacity to provide informed consent
4. Scores 5 or below on the MANSA scale
5. Illness of over 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
72 patients (36 volunteers)

Total final enrolment

Key exclusion criteria
1. Does not meet inclusion criteria
2. Primary diagnosis of substance-use disorder, learning disability, dementia, organic psychosis
3. Diagnosis of bipolar disorder
4. An inpatient at the time of recruitment
5. Participating in another study conducted by this or another research group

Date of first enrolment
01/12/2018

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Bosnia and Herzegovina

Study participating centre
Clinical Centre University of Sarajevo
Bolnička 25
Sarajevo
Bosnia and Herzegovina
N/A

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
4 Newark St
Whitechapel
London
England
United Kingdom
E1 2AT

Sponsor type
University/education

Website
https://www.qmul.ac.uk/

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 statistical analysis plan is being written and the trialists are planning publication(s) of a large protocol paper describing the work of their Research Group, including this study, and are considering writing more detailed protocol papers. They intend to publish the quantitative and qualitative findings from this study by August 2020. Regarding dissemination, this study is part of a research group which also aims to build sustainable research capacity. The dissemination plan therefore aims to inform research, policy and practice. The trialists plan to disseminate findings across Bosnia and Herzegovina and across the wider regional network of South Eastern Europe. Dissemination will include publications, attending conferences, and using platforms like Twitter and the Group website.

Intention to publish date
31/07/2021

Individual participant data (IPD) sharing plan
The trialists will ensure that the study dataset is available for sharing on request following the publication of the main research papers. This is to ensure the scientific impact of the project is

maximised. Prior to making the dataset available to interested individuals, the dataset will be pseudonymised and any potentially identifiable data removed. For publications that require data to be accessible, they will comply with this as guided by FAIR principles.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/06/2021	16/06/2021	Yes	No
Protocol article		14/06/2019	11/08/2022	Yes	No