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

Submission date
01/03/2019

Recruitment status
No longer recruiting

Registration date
04/03/2019

Overall study status
Completed

Last Edited
06/03/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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. Two volunteers will meet small groups of three to six patients, meeting every 2 week for a period of 6 months, with a focus on one or two of the following tasks i) increasing social activity /interactions; ii) engaging in productive, e.g. income-generating, activities; iii) providing practical support for accessing and utilising available professional services and care; and iv) referrals to such services if and when appropriate. It will be up to each group of patients and volunteers to decide which of these tasks to focus on.
This study aims to find out whether Volunteer Support can help to improve care for people living with severe mental illness in Uganda. More specifically, we want to find out how patients and volunteers experience Volunteer Support when it is used on a regular basis. We also want to find out if Volunteer Support improves outcomes like quality of life and symptoms of patients.

Who can participate?
Patients with a primary diagnosis of severe mental illness, aged 18-65 years, able to communicate in Luganda or English can participate.

What does the study involve?
30 patients will be recruited to the Volunteer Support intervention and 30 patients will be recruited to a control condition, against which patient outcomes in Volunteer Support will be compared.
Patients who are recruited into the intervention group will receive Volunteer Support every 2 weeks over 6 months, where 2 volunteers will meet small groups of three to six patients. The intervention will focus on one or two of the following tasks i) increasing social activity /interactions; ii) engaging in productive, e.g. income-generating, activities; iii) providing practical support for accessing and utilising available professional services and care; and iv) referrals to such services if and when appropriate. It will be up to each group of patients and volunteers to

decide which of these tasks to focus on.
Patients in the control group will receive their usual treatment over the 6 month period.

What are the possible benefits and risks of participating?
Severe mental illnesses cause high levels of distress to affected individuals. In countries such as Uganda there is often a lack of human and financial resources for specialised mental health services in the community. This study will provide evidence on how to include effective and long-lasting local based interventions for community based mental health programs in the country. Overall, the study will build both mental health and research capacity within Uganda. Additionally, for patients who will be involved in testing the intervention, this might lead to improved quality of life, social functioning, and symptom reduction. Volunteer participants might gain experience and knowledge about supporting someone with mental illness which might reduce stigma towards mental illness.
We do not predict any significant risks from participating in this study; however it is possible that whilst completing the research assessments or qualitative interviews, the questions asked might trigger feelings of distress or anxiety. To minimise this risk; researchers with experience working with severe mental illness were employed, research assessments can be stopped at any point, and further support can be provided to the participant if necessary.
Participants may also experience anxiety in trying new interventions. Throughout the intervention-testing period, individuals will continue to receive their routine care, including any medication. The interventions can be stopped at any point.

Where is the study run from?
1. Jinja Regional Referral Hospital, Rotary Road, Jinja, Uganda
2. Mityana District Hospital, Masaka, Uganda

When is the study starting and how long is it expected to run for?
December 2018 to March 2021

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

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

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
16/137/97

Study information

Scientific Title
Testing the effectiveness, acceptability and feasibility of Volunteer Support in severe mental illness in Uganda: a non-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 Uganda?
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. Makerere University College of Health Sciences, School of Medicine Research Ethics Committee, approved 19/09/2018, Ref: 2018-096
2. Uganda National Council for Science and Technology, approved on 01/11/2018, Ref: SS 4807
3. Queen Mary Ethics of Research Committee (Hazel Covill, Room W117, Finance Department, Queens' Building, Queen Mary University of London, Mile End Road, London E1 4NS; 020 7882 7915; h.covill@qmul.ac.uk), approved 30/10/2018, Ref: QMERC2018/67

Study design
Interventional multi-centre non-randomised controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients with severe mental illness (including psychosis)

Interventions
30 patients will be recruited to the Volunteer Support intervention and 30 patients will be recruited to a control condition, against which patient outcomes in Volunteer Support will be compared.

Patients who are recruited into the intervention group will received Volunteer Support every 2 weeks over 6 months, where 2 volunteers will meet small groups of three to six patients. The intervention will focus on one or two of the following tasks i) increasing social activity /interactions; ii) engaging in productive, e.g. income-generating, activities; iii) providing practical support for accessing and utilising available professional services and care; and iv) referrals to such services if and when appropriate. It will be up to each group of patients and volunteers to decide which of these tasks to focus on.

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

Intervention Type
Behavioural

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

Key secondary outcome(s))
1. Symptoms, measured using the Brief Psychiatric Rating Scale (BPRS) at baseline, 6 and 12 months
2. Objective social situation, measured using the Objective Social Outcomes Index (SIX) at baseline, 6 and 12 months
3. Service use, measured using adapted Client Service Receipt Inventory (CSRI) at baseline, 6 and 12 months
4. Stigma, measured using the Self-Esteem Rating Scale at baseline, 6 months and 12 months
5. Adherence to medication, using the Medication Adherence Rating Scale (MARS) at baseline, 6 and 12 months

Completion date
12/06/2020

Eligibility

Key inclusion criteria
1. Primary diagnosis of severe mental illness (ICD-10 F20-29, F31, F32)
2. Aged 18-65 years old and over
3. Capacity to provide informed consent assessed by UBACC score of ≥14
4. Able to communicate in Luganda or English
5. Scores 5 or below on the MANSA scale

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
70

Key exclusion criteria
1. Primary diagnosis of substance-use disorder, organic psychosis and/or a neurocognitive disorder
2. Currently an inpatient at the time of recruitment
3. Participating in another study conducted by this or another group

Date of first enrolment
01/12/2018

Date of final enrolment
15/03/2019

Locations

Countries of recruitment
Uganda

Study participating centre
Jinja Regional Referral Hospital
Rotary Road
Jinja
Uganda
N/A

Study participating centre
Mityana District Hospital
Mityana
Uganda
N/A

Sponsor information

Organisation
Queen Mary University of London

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

The combined sets of all data from all countries will be held at QMUL in anonymised form. Data sharing with external interests will be considered only after the publication of the findings that reflect the given data. The datasets will be available upon request from Stefan Priebe (s.priebe@qmul.ac.uk). The data collected will be both quantitative and qualitative. The duration of availability of data has not yet been decided. During the course of the study, data will be shared internally within the Group using an online data collection platform called REDCap, for basic descriptive and comparative analysis. The method for sharing the data externally (if required) will be decided in due course.
Informed consent will be obtained from all participants involved in the study. All participants are assigned a patient ID at the point of enrolment and all subsequent data collected will be linked to this ID, without any link to identification data following Good Clinical Practice.

IPD sharing plan summary
Other

Study outputs

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