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A research study in Uganda to test a Family Involvement intervention, designed to improved 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
The Family Involvement intervention has been developed from existing approaches called Trialogue and Psychoeducation. A key part of these approaches is bringing together several people living with mental health difficulties, their family members and mental health professionals into regular meetings. These different groups meet as equals to discuss topics that they have previously agreed on, share experiences and to learn from one another.
This study aims to find out whether Family Involvement can help to improve care for people living with severe mental illness in Uganda. More specifically, we want to find out how patients, family members/friends, and health professionals experience Family Involvement when it is used on a regular basis. We also want to find out if Family Involvement improves outcomes like quality of life and symptoms of patients and reduces the burden experienced by family members.

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 Family Involvement intervention and 30 patients will be recruited to a control condition, against which patient outcomes will be compared.
Patients who are recruited into the Family Involvement intervention will receive this at their routine clinic or agreed community location once per month. 1-2 family members/friends will be recruited for each patient, who will attend the monthly Family Involvement meetings with their relatives. 6-12 clinicians will be recruited to help facilitate the Family Involvement meetings. The Family Involvement intervention is based on principles of Trialogue and psychoeducation. It involves bringing together several patients, 1-2 of their family members/friends and 1-2 mental health professionals in monthly meetings, as equals so that they may discuss pre-agreed topics,

share experiences and for mutual learning.
Patients recruited to 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. Family members and friends might benefit from having space to share their experiences and learn from other patients and families, which might lead to an improved ability to provide care for their family member or friend with 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. Masaka Regional Referral Hospital, Alex Ssebowa Road, Masaka, 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

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
16/137/97

Study information

Scientific Title
Testing the effectiveness, acceptability and feasibility of Family Involvement in severe mental illness in Uganda: a non-randomised controlled trial

Study objectives
To test the acceptability, feasibility and effectiveness of Family Involvement against usual treatment.
The specific research questions are:
1. How can Family Involvement be used to support community mental health care in Uganda?

2. How is Family Involvement experienced by patients, family members/friends and professionals?
3. How do outcomes change when Family Involvement 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 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 Family Involvement intervention and 30 patients will be recruited to a control condition, against which patient outcomes will be compared.

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Patients recruited to 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. Objective social functioning, measured using Objective Social Outcome Index (SIX) at baseline, 6 and 12 months
2. Symptoms, measured using Brief Psychiatric Rating Scale (BPRS) 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 Internalized Stigma of Mental Illness Inventory (ISMI) at baseline, 6 and 12 months
5. Medication adherence, measures using the Medication Adherence Rating Scale (MARS) at baseline, 6 months and 12 months

Completion date
29/06/2020

Eligibility

Key inclusion criteria
1. Patients with a primary diagnosis of severe mental illness (ICD-10 F20-29, F31, F32)
2. Aged 18-65 years
3. Capacity to provide informed consent assessed by UBACC Score of ≥14;
4. Able to communicate in Luganda or English
5. Can identify a family member or friend
6. 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
118

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

Date of first enrolment

01/12/2018

Date of final enrolment
15/03/2019

Locations

Countries of recruitment
Uganda

Study participating centre
Masaka Regional Referral Hospital
Alex Ssebowa Road
Masaka
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
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/06/2019	24/09/2021	Yes	No