

A research study in Colombia 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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/06/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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. Two volunteers will meet small groups of three to six patients, meeting every 2 weeks for a period of 6 months, with a focus on increasing social activities/interactions e.g. visiting parks, museums, and going to cafes. As music and art plays a strong role in the Colombian culture, the social activities may involve producing art and music.

This study aims to find out whether Volunteer Support can help to improve care for people living with severe mental illness in Colombia. 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.

Who can participate?

Anyone with a primary diagnosis of severe mental illness (ICD-10 F20-29, F31, F32) who is aged 18-65 years.

What does the study involve?

30 patients will be recruited and will receive the Volunteer Support intervention, where 2 volunteers will meet small groups of 3-6 patients every 2 weeks for 6 months. The focus of this intervention is to increase social activities and interactions e.g. visiting parks, museums, and going to café. As music and art play a strong role in the Colombian culture, the social activities may involve producing art and music.

What are the possible benefits and risks of participating?

Severe mental illnesses cause high levels of distress to affected individuals. In countries such as Colombia 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 Colombia. 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 and trained, research assessments can be stopped at any point, and further support can be provided to the participant if necessary.

Where is the study run from?

1. Clinica La Inmaculada, Cra. 7 #6970, Bogotá, Cundinamarca, Colombia
2. San Ignacio University Hospital, Cra. 7 #40-62, Bogotá, Cundinamarca, Colombia
3. ACEPEF (Colombian Association of Schizophrenia Patients and their Families), cl.52a #27a-54, Bogotá, Cundinamarca, Colombia
4. Asociación Colombiana de Bipolares, Carrera 8 D No. 106 - 50 Barrio Francisco Miranda, Bogotá, Cundinamarca, Colombia

When is the study starting and how long is it expected to run for?

December 2018 to May 2020 (updated 03/03/2021, previously: March 2021)

Who is funding the study?

National Institute for Health Research

Who is the main contact?

Dr Francois van Loggerenberg, f.vanloggerenberg@qmul.ac.uk

Contact information

Type(s)

Scientific

Contact name

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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 Volunteer Support in severe mental illness in Colombia: A non-controlled trial

Study objectives

To test the acceptability, feasibility and effectiveness of Volunteer Support.

The specific research questions are:

1. How can Volunteer Support be used to support community mental care in Colombia?
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. IRB of Javeriana University, approved 19/09/2018, Ref: 2018/122
2. Ethics Committee of the Hospital Departamental Psiquiátrico Universitario del Valle, Cali, approved 08/10/2018
3. Ethics Committee of Clínica La Inmaculada, approval 16/07/2018
4. Ethics Committee of Clínica Fray Bartolomé: approval 14/11/2018

5. 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: QMERC2018/59

Study design

Interventional multi-centre non-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 and will receive the Volunteer Support intervention, where 2 volunteers will meet small groups of 3-6 patients every 2 weeks for 6 months. The focus of this intervention is to increase social activities and interactions e.g. visiting parks, museums, and going to café. As music and art play a strong role in the Colombian culture, the social activities may involve producing art and music.

Intervention Type

Behavioural

Primary outcome(s)

Quality of Life, measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 months 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 Internalized Stigma of Mental Illness Inventory (ISMI) at baseline, 6 and 12 months.

Completion date

13/05/2020

Eligibility

Key inclusion criteria

1. Primary diagnosis of severe mental illness (ICD-10 F20-29, F31, F32)
2. Aged 18-65 years
3. Capacity to provide informed consent
4. Willing to engage with a volunteer

5. Scores 5 or below on the MANSA scale

6. Illness of over 6 months

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

55

Key exclusion criteria

1. Primary diagnosis of substance-use disorder
2. Diagnosis of dementia or organic psychosis;
3. An inpatient at the time of recruitment
4. 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

Colombia

Study participating centre

Clinica La Inmaculada

Cra. 7 #6970

Bogotá

Colombia

N/A

Study participating centre
San Ignacio University Hospital
Cra. 7 #40-62
Bogotá
Colombia
N/A

Study participating centre
ACPEF (Colombian Association of Schizophrenia Patients and their Families)
cl.52a #27a-54
Bogotá
Colombia
N/A

Study participating centre
Asociación Colombiana de Bipolares
Carrera 8 D No. 106 - 50 Barrio Francisco Miranda
Bogotá
Colombia
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 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?
Results article		06/05/2021	10/05/2021	Yes	No
Protocol article		14/06/2019	11/08/2022	Yes	No
Protocol article	programme method	13/09/2021	05/06/2024	Yes	No