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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

Registration date
04/03/2019

Overall study status
Completed

Last Edited
06/06/2024

Condition category
Mental and Behavioural Disorders

[ ] 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. 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 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. ACPEF (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

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

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
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 measure
Quality of Life, measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 months and 12 months.

Secondary outcome measures
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.

Overall study start date
01/08/2017

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30 patients (20 volunteers)

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
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N/A

Sponsor information

Organisation
Queen Mary University of London

Sponsor details

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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
We 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 aim to inform research, policy

and practice. We plan to disseminate the findings across Colombia and across two wider networks, LatinCLEN and Red Maristan, that supports research and teaching of young mental health researchers across the region. Dissemination will include publications, attending conferences, and using platforms like Twitter and our Group website.

Intention to publish date
31/07/2021

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