ISRCTN11440755 https://doi.org/10.1186/ISRCTN11440755

A research study in Colombia to test a Family Involvement intervention, 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
07/12/2022

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 Colombia. 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 bass. We also want to find out if Family Involvement improves outcomes like quality of life and symptoms for patients.
We will therefore recruit 30 patients to take part in this study. Patients will attend meetings once per month over a 6 month period. In each group, there will be 5 patients, 1-2 family members/friends for each patient and 1-2 mental health professionals.
We will interview patients, family members/friends and clinicians at the end of the study to see how they experienced the intervention.

Who can participate?
Patients with a primary diagnosis of severe mental illness, aged 18-65 years can participate.

What does the study involve?
The Family Involvement Intervention will be tested in an open non-controlled trial with 30 patients. The patients will receive Family Involvement at an agreed community location once per month over a 6 month period. 1-2 family members/ friends will be recruited for each patient. These participants will attend the month 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 mutual learning.

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

When is the study starting and how long is it expected to run for?
December 2018 to September 2020 (updated 03/03/2021, previously: 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

Protocol serial number
16/137/97

Study information

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

Study objectives
To test the acceptability, feasibility and effectiveness of Family Involvement.
The specific research questions are:
1. How can Family Involvement be used to support community mental health care in Colombia?
2. How is Family Involvement experienced by patients, family members/friends and professionals?
3. How do patient outcomes change when Family Involvement 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 University Hospital of Valle, approved 08/10/2018
3. Ethics Committee of Clínica La Inmaculada, approved16/07/2018
4. Ethics Committee of Clínica Fray Bartolomé: approved 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

Primary study design
Interventional

Study design
Interventional multicentre non-controlled trial

Study type(s)
Quality of life

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

Interventions
The Family Involvement Intervention will be tested in an open non-controlled trial with 30 patients. The patients will receive Family Involvement at an agreed community location once per month over a 6 month period. 1-2 family members/ friends will be recruited for each patient. These participants will attend the month 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 mutual learning.

Intervention Type
Behavioural

Primary outcome(s)
Quality of Life, measured using the Manchester Short Assessment of Quality of Life (MANSA) measured 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

Completion date
17/09/2020

Eligibility

Key inclusion criteria
1. Primary diagnosis of severe mental illness (ICD F20-29, F31, F32)
2. Aged 18-65 years old
3. Illness of 6 months or over
4. Scores 5 or below on the MANSA scale
5. Capacity to provide informed consent.

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
80

Key exclusion criteria
1. Primary diagnosis of substance-use disorder
2. Diagnosis of dementia or organic psychosis
3. 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
Colombia

Study participating centre
Clinica La Inmaculada
cra.7 #6970
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

Study participating centre
San Ignacio University Hospital
cra.7 #40-62
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

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