ISRCTN83333181 https://doi.org/10.1186/ISRCTN83333181

A research study in Colombia to test an intervention called DIALOG+, designed to improve care for people living in the community with severe mental illness

Submission date
09/11/2018

Recruitment status
No longer recruiting

Registration date
20/11/2018

Overall study status
Completed

Last Edited
24/09/2026

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
DIALOG+ is an intervention delivered on a tablet or smartphone using an app. It is designed to help mental health professionals to improve the structure of their routine meetings with patients. It also helps to improve communication with patients during these meetings. Patients are first asked about how satisfied they are with eight areas of their lives (e.g. physical health, family relationships, leisure activities) and three areas of the treatment they are receiving (e.g. practical help, meetings), which is called the DIALOG scale. The patient then chooses up to three areas to discuss in more depth with their health professional. The clinician then discusses each area chosen by patients, using four steps that focus on solutions to the identified problems. This study aims to find out whether DIALOG+ can help to improve care for people living with severe mental illness in Colombia. More specifically, the researchers want to find out how patients and health professionals experience DIALOG+ when it is used during their routine meetings. They also want to find out if DIALOG+ improves outcomes like quality of life and symptoms.

Who can participate?
Patients aged 18-65 with severe mental illness (psychosis, bipolar disorder and/or severe depression)

What does the study involve?
All patients are randomly allocated into two groups. Patients in the DIALOG+ group use the app with their clinicians once per month for a period of 6 months. The other group (the control) do not use DIALOG+ (both groups receive their usual treatment). The two groups of patients are compared to see if DIALOG+ makes a difference to outcomes like quality of life and symptoms. Patients in the DIALOG+ group are also interviewed to see how they experienced the intervention.

What are the possible benefits and risks of participating?
For patients, they will be taking part in testing an intervention which might lead to improved

quality of life, social functioning and symptoms. The study will also benefit clinicians who take part in terms of the training and supervision they will receive to enable them to implement the intervention. For all participants involved in the research, their suggestions and experiences might be incorporated into further adaptations of DIALOG+, so that it is tailored to the needs of patients, carers and clinicians in the context of the mental health care system in Colombia. Severe mental illnesses cause a high burden for societies with high levels of distress and high costs to individuals who are affected. This is particularly worse in low and middle-income countries such as Colombia, where there is a lack of human and financial resources for specialised mental health services in the community. In recent years, the Ministry of Health in Colombia has been developing a new model of care to improve care for people with severe mental illness in the community. The testing of DIALOG+ will therefore contribute to this work by providing evidence for interventions for people with severe mental illness in the community. It is unlikely that any significant ethical, legal or management issues will arise from this study, but some potential risks might be: within the research assessments and interviews that will take place across both studies, questions will be raised with participants that might trigger feelings of distress or anxiety. Participants may experience anxiety in trying a new intervention. Throughout the intervention-testing period, individuals will continue to receive their routine care, including any medication, in addition to the test intervention. The intervention can be stopped at any point. The intervention (DIALOG+) to be tested has an evidence base for effectiveness.

Where is the study run from?
1. San Ignacio University Hospital (Columbia)
2. Clinica La Inmaculada (Columbia)
3. Clinica Fray Bartolome (Columbia)
4. Hospital Departamental Psiquiátrico Universitario del Valle ESE (Columbia)

When is the study starting and how long is it expected to run for?
August 2017 to September 2020 (updated 07/07/2021, previously: October 2020; updated 03/03/2021, previously: March 2021)

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

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

Contact information

Type(s)
Public

Contact name
Dr Francois van Loggerenberg

ORCID ID
https://orcid.org/0000-0001-5317-7983

Contact details
Unit for Social and Community Psychiatry
Queen Mary University of London

Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)20 7540 4380 Ext: 2339
f.vanloggerenberg@qmul.ac.uk

Type(s)
Scientific

Contact name
Dr Francois van Loggerenberg

Contact details
Unit for Social and Community Psychiatry
Newham Centre for Mental Health
London
United Kingdom
E13 8SP
+44 (0)20 540 4380 Ext: 2312
f.vanloggerenberg@qmul.ac.uk

Additional identifiers

Protocol serial number
16/137/97

Study information

Scientific Title
Testing the effectiveness, acceptability and feasibility of DIALOG+ in severe mental illness in Colombia: a randomised controlled trial

Study objectives
To test the acceptability, feasibility and effectiveness of DIALOG+ against usual treatment.
The specific research questions are :
1. How can DIALOG+ be used to support community mental health care in Colombia?
2. How is DIALOG+ experienced by patients and professionals?
3. How do patient outcomes change when DIALOG+ is used?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. IRB of Javeriana University, 19/09/2018, ref: 2018/122
2. Ethics Committee of the University Hospital of Valle, 08/10/2018
3. Ethics Committee of Clínica La Inmaculada,16/07/2018
4. Ethics Committee of Clínica Fray Bartolomé, 14/11/2018
5. Queen Mary Ethics of Research Committee (QMERC2018/59): positive opinion received 30/10/2018

Primary study design
Interventional

Study design
Interventional multi-centre cluster randomised controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients with severe mental illness (including psychosis, bipolar disorder and severe depression)

Interventions
Recruitment will take place at University Hospital of Valle, Clínica La Inmaculada, Clínica Fray Bartolomé and San Ignacio Hospital.
14 clinicians will be recruited. For each clinician, the research team will recruit 12 of their patients and then each clinician-patient cluster will be randomly allocated to a control or intervention group. Randomisation will be done by the UK-based research team using STATA statistical softwareand allocations and communicated to the unmasked researchers in the Colombia team. Clinician-patient clusters (12 patients per clinician) will be randomised to either the intervention or control groups so that each clinicians will be either delivering DIALOG+ OR delivering usual treatment to their patients.

Masking: randomisation will take place after recruitment of participants and completion of baseline assessments. Follow-up assessments at 6 and 12 months will be completed with participants by masked researchers. Measures are in-place to ensure that researchers completing follow-up research assessments remain masked to participant allocation and to minimise risk of contamination in clinicians allocated to the control group.

Patients allocated to the intervention group will receive DIALOG+ at their routine outpatient clinic appointments once per month. This will be delivered by their usual clinician using an app on a tablet computer. The intervention will be over 6 months during which patients will receive 6-7 DIALOG+ sessions. DIALOG + is a technology mediated intervention, which involves a structured patient assessment covering satisfaction with eight life domains and three treatment domains (DIALOG scale) and a four-step solution focused therapy approach to address patient concerns (+). DIALOG+ aims to make routine meetings between clinicians and patients therapeutically effective.

Patients allocated to the control group will complete the DIALOG scale at their routine outpatient clinic appointments once per month over the 6 month period.

Intervention Type
Mixed

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

Key secondary outcome(s)

Measured at baseline, 6 months (post intervention) and 12 months:
1. Objective social functioning, measured with the objective social outcome index (SIX)
2. Symptoms, measured with the Brief Psychiatric Rating Scale (BPRS)
3. Service use, measured with adapted Client Service Receipt Inventory (CSRI)

Completion date
02/10/2020

Eligibility

Key inclusion criteria
1. Primary diagnosis of severe mental illness (psychosis, bipolar disorder and/or severe depression) ICD F20-29, F31, F32
2. Aged 18-65 years old
3. Attending clinic for at least 6 months
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
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
173

Key exclusion criteria
1. Does not meet inclusion criteria
2. Primary diagnosis of substance-use disorder
3. Diagnosis of dementia or organic psychosis
4. An inpatient at the time of recruitment
5. Participating in another study being conducted by this or another research group

Date of first enrolment
01/12/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
Colombia

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

Study participating centre
Clinica La Inmaculada
Cra. 7 #6970
Bogota
Colombia
N/A

Study participating centre
Clinica Fray Bartolome
Cra. 65 #66
Bogota
Colombia
N/A

Study participating centre
Hospital Departamental Psiquiátrico Universitario del Valle ESE
Calle 5 No. 80-00, Santiago de Cali
Cali
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 trialists will ensure that the study dataset is available for sharing on request following the publication of the main research papers. This is to ensure the scientific impact of the project is maximised. Prior to making the dataset available to interested individuals, the dataset will be pseudonymised and any potentially identifiable data removed. For publications that require data to be accessible, the trialists will comply with this as guided by FAIR principles.

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	11/08/2022	Yes	No
Other publications	Qualitative study of experiences	22/04/2024	24/09/2026	Yes	No