

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

Submission date 05/12/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/12/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/05/2025	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

DIALOG+ is an intervention delivered on a tablet 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 life (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 the patient, using a four-step approach that focuses 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 Argentina. 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?

Any patient receiving care at one of the study sites who has a primary diagnosis of severe mental illness (specifically an anxiety disorder) and who is aged 18-65

What does the study involve?

Patients use the DIALOG+ App within their routine clinical appointments once per month for a period of 6 months. This is delivered by their usual clinician using an app on a tablet computer. The intervention is over 6 months during which patients receive 6-7 DIALOG+ sessions. The researchers also interview patients and clinicians who have used DIALOG+ to see how they experienced the intervention.

What are the possible benefits and risks of participating?

Severe mental illnesses cause high levels of distress to affected individuals. In countries such as

Argentina 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 Argentina. Additionally, for patients who will be involved in testing the intervention, this might lead to improved quality of life and symptom reduction. Mental health professionals will also benefit in terms of the training and supervision they will receive to enable them to implement the intervention.

The researchers do not predict any significant risks from participating in this study; however, it is possible that whilst completing the research assessment or qualitative interviews, the questions asked might trigger feelings of distress or anxiety. To minimise this risk, researchers with experience working with people with severe mental illness were employed. Additionally, research assessments can be stopped at any point, and further support can be provided to the participant if necessary. Participants might also experience anxiety in trying new interventions. Through the intervention-testing period, individuals will continue to receive their routine care, including any medication. The intervention can be stopped at any point.

Where is the study run from?

1. Fundación Humanas (Argentina)
2. Las Heras (Argentina)
3. Centre of Neuropsychiatry and Neurology of Behavior (CENECON) (Argentina)

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

December 2019 to March 2022 (updated 20/09/2021, previously: December 2021 (updated 12/07/2021, previously: July 2021; updated 08/03/2021, 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

Study website

<http://www.qmul.ac.uk/nihr-ghrg>

Contact information

Type(s)

Public

Contact name

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Scientific

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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 DIALOG+ in severe mental illness in Argentina: a non-controlled trial

Study objectives
To test the acceptability, feasibility and effectiveness of DIALOG+.
The specific research questions are:
1. How can DIALOG+ be used to support community mental health care in Argentina?
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. Approved 08/10/2019, Universidad Buenos Aires Ethics Committee (Prof. Marín Rafael Seoana, Marcelo T. de Alvear 2270, Buenos Aires, Argentina; Tel: +54 (0)11 5285-2751; Email: sectaquini@fmed.uba.ar)
2. Approved 21/11/2019, 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; Tel: +44 (0)20 7882 7915; Email: h.covill@qmul.ac.uk), ref: QMERC2019/78

Study design

Interventional single-centre non-controlled study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

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 (specifically anxiety disorders)

Interventions

At least 5 clinicians and 40 patients will be recruited. Patients will receive DIALOG+ at their routine clinical 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+). DIALOG+ aims to make routine meetings between clinicians and patients therapeutically effective.

Intervention Type

Behavioural

Primary outcome measure

Quality of life measured using the Manchester Short Assessment of Quality of Life (MANSA) measured at baseline and 6 months

Secondary outcome measures

1. Objective social functioning measured using the Objective Social Outcome Index (SIX) at baseline and 6 months
2. Symptoms measured using the Brief Psychiatric Rating Scale (BPRS) at baseline and 6 months
3. Service use measured using adapted Client Service Receipt Inventory (CSRI) at baseline and 6 months
4. Patients' experience of the DIALOG+ intervention assessed using qualitative interviews at 6 months

Overall study start date

01/12/2019

Completion date

01/03/2022

Eligibility

Key inclusion criteria

Current inclusion criteria as of 18/12/2020:

1. Primary diagnosis of an anxiety disorder
2. Aged 18-65 years old
3. Capacity to provide informed consent
4. Score of 5 or below on the MANSA scale
5. Receiving care from a participating health care provider

Previous inclusion criteria:

1. Primary diagnosis of severe mental illness as defined by ICD10: F20-9, F31, F32
2. Aged 18-65 years old
3. Capacity to provide informed consent
4. Score of 5 or below on the MANSA scale
5. Receiving care from a participating health care provider

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

40 patients (5 healthcare providers)

Key exclusion criteria

1. Diagnosis of dementia or organic psychosis as determined by their health providers
2. Primary diagnosis of substance use disorder
3. Severe learning difficulties or severe cognitive disability

Date of first enrolment

22/05/2021

Date of final enrolment

01/08/2021

Locations

Countries of recruitment

Argentina

Study participating centre

Fundación Humanas

Santos Dumont 3454

Buenos Aires

Argentina

C1427EIB

Study participating centre

Las Heras

Av. Las Heras 2492

Buenos Aires

Argentina

C1425ASS

Study participating centre

Centre of Neuropsychiatry and Neurology of Behavior (CENECON)

Paraguay 2155

Buenos Aires

Argentina

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Sponsor information

Organisation

Queen Mary University of London

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Sponsor type

University/education

Website

<http://www.qmul.ac.uk>

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**

The researchers intend to publish the quantitative and qualitative findings from this study by March 2021. Regarding dissemination, this study is part of a research group which also aims to build sustainable research capacity. The dissemination plan therefore aims to inform research,

policy and practice. The researchers plan to disseminate findings across Argentina. Dissemination will include publications, attending conferences, and using platforms like Twitter and the group website.

Intention to publish date

31/07/2022

Individual participant data (IPD) sharing plan

The datasets 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 between the research group using an online data collection platform called REDCap. 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 enrollment and all subsequent data collected will be linked to this ID, without any link to identifiable 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 file	version V1.0	18/06/2019	10/01/2020	No	No
Results article		19/05/2025	20/05/2025	Yes	No