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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

Registration date
16/12/2019

Overall study status
Completed

Last Edited
20/05/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact information

Type(s)
Public

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Type(s)
Scientific

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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 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

Study type(s)
Quality of life

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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
C1121ABG

Sponsor information

Organisation
Queen Mary University of London

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 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?
Results article		19/05/2025	20/05/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V1.0	18/06/2019	10/01/2020	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes