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

Submission date
08/07/2019

Recruitment status
No longer recruiting

Registration date
08/07/2019

Overall study status
Stopped

Last Edited
06/12/2022

Condition category
Mental and Behavioural Disorders

[X] 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
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 Peru. More specifically, the aim is to find out how patients and health professionals experience DIALOG+ when it is used during their routine meetings, and to find out if DIALOG+ improves outcomes like quality of life and symptoms.

Who can participate?
Patients aged 18-65 with a primary diagnosis of severe mental illness receiving care at one of the study sites

What does the study involve?
Patients use the App within their routine clinical appointments once per month for a period of 6 months. Patients and clinicians who have used DIALOG+ are also interviewed 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 Peru 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 Peru. 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. No significant risks are expected from participating in this study, but 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. Carabayllo CMHC (Peru)
2. San Gabriel Alto CMHC (Peru)
3. Honorio Delgado CMHC (Peru)
4. La Victoria CMHC (Peru)

When is the study starting and how long is it expected to run for?
July 2019 to May 2020 (updated 03/03/2021, previously: March 2021; updated 11/08/2020, previously: November 2020; updated 14/04/2020, previously: September 2020; updated 05/11/2019, previously: July 2020)

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
https://www.qmul.ac.uk/nihr-ghrg/

Contact information

Type(s)
Public

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Type(s)
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 Peru: 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 Peru?
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 10/06/2019, Universidad Peruana Cayetano Heredia Ethics Committee (Dra. Frine Samalvides Cuba, Av. Honorio Delgado 430, Lima, Peru; Tel: +511 319-0000 ext 201352; e-mail duict@oficinas-upch.per), ref:103031
2. Approved 03/06/2019, 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: QMERC2019/43

Study design
Interventional single-centre non-controlled study

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, bipolar disorder and severe depression)

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) 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
01/07/2019

Completion date
28/05/2020

Reason abandoned (if study stopped)
The study was unable to complete due to COVID-19 restrictions

Eligibility

Key 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)

Total final enrolment
40

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

15/07/2019

Date of final enrolment
15/01/2020

Locations

Countries of recruitment
Peru

Study participating centre
Carabayllo CMHC
Micaela Bastidas 433, Carabayllo
Lima
Peru
15313

Study participating centre
San Gabriel Alto CMHC
Leoncio Prado S/N, Villa María del Triunfo
Lima
Peru
15811

Study participating centre
Honorio Delgado CMHC
Eloy Espinoza, Urb 709, San Martín de Porres
Lima
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15102

Study participating centre
La Victoria CMHC
Jr. Antonio Bazo S/N, La Victoria
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Sponsor information

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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
The researchers 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 aims to inform research, policy and practice. The researchers plan to disseminate findings across Peru. Dissemination will include publications, attending conferences, and using platforms like Twitter and the 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. 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 enrolment 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			08/07/2019	No	No