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A research study in Colombia to test the acceptability and feasibility of an intervention called DIALOG+, adapted to improve care for people in primary care with poor physical and mental health

Submission date
27/11/2020

Recruitment status
No longer recruiting

Registration date
01/12/2020

Overall study status
Completed

Last Edited
16/11/2023

Condition category
Other

[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 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 be adapted to be used to improve care for people in primary care with physical conditions and poor quality of life 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 other symptoms in order to plan for larger definitive trials if indicated.

Who can participate?
Adults in primary care who have at least one common chronic condition (such as diabetes, hypertension, chronic obstructive pulmonary disease, cardiovascular disease, rheumatologic or infectious diseases etc) and who have a low quality of life

What does the study involve?
The initial stage of this study involves a suggested adaptation of DIALOG+ from other trials that have been conducted. Potential minor adaptations may include suggested modifications to the number of domains addressed, item wording and training examples. DIALOG+ will be adapted to primary care settings to enable wider use with patients with chronic physical and mental health

conditions with assessments before and 3 months after the intervention. The adaptation process will be through stakeholder consultation based on actual experience of using the intervention. The results will provide insight into refining the training process and implementing the intervention across healthcare settings.

What are the possible benefits and risks of participating?
DIALOG+ is a resource-oriented and evidence-based intervention which makes use of existing personal and social resources to improve the quality of life of patients with mental illness. The intervention is low cost, using routine meetings between patients and clinicians without the need for additional referrals or services. The researchers will adapt DIALOG+ for primary care to improve reach and enable a larger patient population to benefit. Additionally, the study focuses on a new and vulnerable population – those with comorbid (simultaneously present) chronic physical and mental health problems. Research has shown that comorbid physical and mental health problems are common, resource-intensive and result in a poor quality of life for billions of people worldwide.
A potential benefit for all participants is that their suggestions and experiences might be incorporated into further adaptations, which will tailor the intervention to the needs of patients and clinicians in the context of the primary care system in Colombia. Additionally, for patients who will be involved in testing the DIALOG+, this might lead to improved quality of life, social functioning, and symptoms. The study will also benefit clinicians involved in terms of the training they will receive. Clinicians involved in the DIALOG+ study will be provided with training and supervision to enable them to implement the intervention.
The researchers do not foresee any significant ethical, legal or management issues arising from this study. Within the research assessments and qualitative 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 new interventions. Throughout the intervention-testing period, participants will continue to receive their routine care, including any medication, in addition to the intervention. The intervention can be stopped at any point. The use of DIALOG+ in mental health care settings has an evidence base for effectiveness and the researchers believe this is easily transferable across to physical health care too without any additional risks. To minimise the impact of potential risks, risk management strategies have been outlined in the study protocol.

Where is the study run from?
Javesalud IPS, Bogota (Colombia)

When is the study starting and how long is it expected to run for?
November 2019 to February 2022 (updated 02/09/2021, previously: November 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

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Type(s)
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Additional identifiers

Protocol serial number
16/137/97

Study information

Scientific Title
Testing the acceptability and feasibility of DIALOG+ in patients with common chronic conditions and poor mental health in primary care in Colombia: a non-randomized study with before and after design

Study objectives
The study aims to test the feasibility and acceptability of and adapted DIALOG+ intervention for patients with comorbid physical and mental health conditions in primary care.

The specific research questions are:
1. How can DIALOG+ be used to support community mental and physical healthcare in the regional primary care context?
2. How is DIALOG+ experienced by patients and health professionals?
3. How do patient outcomes change when the intervention is used?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/12/2020, Comité de Investigaciones y Ética Institucional, Facultad de Medicina, Pontificia Universidad Javeriana (Institutional Research and Ethics Committee, Faculty of Medicine, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio, Carrera 7 # 40-62, piso 2, Bogotá, Colombia; +57 (0)1 3208320 Ext 277; ciei@husi.org.co), ref: FM-CIE-1239-20
2. Approved 26/10/2020, Comité de Investigaciones y Ética Institucional, Facultad de Medicina, Pontificia Universidad Javeriana (Institutional Research and Ethics Committee, Faculty of Medicine, Pontificia Universidad Javeriana, Hospital Universitario San Ignacio, Carrera 7 # 40-62, piso 2, Bogotá, Colombia; +57 (0)1 3208320 Ext 277; ciei@husi.org.co), ref: FM-CIE-1113-20
3. Approved 27/01/2021, 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, UK; +44 (0)20 7882 7915; h.covill@qmul.ac.uk), ref: QMERC20.101

Primary study design
Interventional

Study design
Non-randomized study with before and after design

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Chronic conditions such as diabetes, hypertension, chronic obstructive pulmonary disease (COPD), cardiovascular disease (CVD)

Interventions
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.

Once enrolled, patients will receive DIALOG+ at their routine primary care appointments, around once per month. This will be delivered by the healthcare worker using an app on a tablet computer. The intervention period will be 3 months, during which patients will attend up to three DIALOG+ sessions.

Data collection with all participants will take place at baseline and following the 3-month intervention period. At baseline, the researchers will collect socio-demographic information from all participants, which, for patient participants, will include clinical characteristics.

A subset of participants will be invited to attend a qualitative interview after the end of the intervention (3 months) in order to capture the individual experience of the intervention; including barriers and facilitators of attending intervention sessions, suggested adaptations and the practical delivery of the intervention.

In addition to the research data collection described above the research and clinical support staff keep a record of their intervention sessions. These reports will include the date, duration of interventions and the topic of discussion. This information is also captured within the DIALOG+ app and can be retrieved by the research staff. The aim is to record at least one session per patient, which will be scored for adherence.

Intervention Type
Behavioural

Primary outcome(s)
1. Quality of life measured using the Manchester Short Assessment (MANSA) at baseline and 3 months
2. Depression measured using the Patient Health Questionnaire (PHQ-8) at baseline and 3 months
3. Anxiety measured using Generalised Anxiety Disorder assessment (GAD-7) at baseline and 3 months
4. Objective social functioning measured using objective social outcomes index (SIX) at baseline and 3 months
5. Physical health symptoms measured using The Short Form (36) Health Survey (SF-36) at baseline and 3 months

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Diagnosis of ≥1 common chronic condition such as diabetes, hypertension, COPD, CVD, etc
2. Quality of life score measured on the MANSA ≤5.5
3. Capacity to provide informed consent
4. Able to speak and understand the local language
5. Attending the outpatient clinic for at least six months
6. Live within a 20 km radius of the clinic
7. Aged 18-65 years old

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
31

Key exclusion criteria
1. Unable or unwilling to provide informed consent
2. Does not meet inclusion criteria

Date of first enrolment
01/01/2021

Date of final enrolment
01/11/2021

Locations

Countries of recruitment
Colombia

Study participating centre
Javesalud IPS, Sede Santa Beatriz
Dirección: Calle 127 # 17 A – 81, Bogotá
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Study participating centre
Javesalud IPS, Sede Toberín
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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 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?
Results article		16/11/2023	16/11/2023	Yes	No
Protocol article		30/09/2021	04/10/2021	Yes	No