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A research study in Pakistan to test an intervention called DIALOG+, designed to improve care for people living in the community with common mental disorders

Submission date
05/06/2019

Recruitment status
No longer recruiting

Registration date
06/06/2019

Overall study status
Completed

Last Edited
16/06/2023

Condition category
Mental and Behavioural Disorders

[ ] 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 more 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 common mental disorders (mild-to-moderate anxiety and depression) in Pakistan. More specifically, the aim is to find out how patients and health professionals experience DIALOG+ when it is used during their routine meetings. The researchers also want to find out if DIALOG+ improves outcomes like quality of life and symptoms.

Who can participate?
Patients aged 18-65 enrolled for individual counselling with the Pursukoon Zindagi Program who have mild to moderate anxiety and/or depression symptoms

What does the study involve?
Patients receive DIALOG+ at their routine counselling appointments once per month. This is delivered by their counsellor using an app on a tablet computer. The intervention takes place over 6 months during which patients 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. Patients and counsellors in the DIALOG+ group are also interviewed to see how they experienced the intervention.

What are the possible benefits and risks of participating?
Common mental disorders including mild to moderate anxiety and depression can cause distress to affected individuals. In countries such as Pakistan 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 Pakistan. Additionally, for patients who will be involved in testing the intervention, this might lead to improved quality of life, social functioning 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 interviews, the questions asked might trigger feelings of distress or anxiety. To minimise this risk, researchers with experience working with people with depression and anxiety are employed, research assessments can be stopped at any point, and further support can be provided to the participant if necessary. Participants may also experience anxiety in trying new interventions. Through the intervention-testing period, individuals will continue to receive their routine care, including any medication. The interventions can be stopped at any point.

Where is the study run from?
1. Interactive Research and Development (Pakistan)
2. The Indus Hospital (Pakistan)

When is the study starting and how long is it expected to run for?
June 2019 to 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 common mental disorders in Pakistan: 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 Pakistan?
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 28/02/2019, Interactive Research and Development Ethics Committee (Institutional Review Board (IRD-IRB), IRD Admin Office, 4th Floor, The Indus Hospital Research Center, Main

Korangi crossing, Karachi, Pakistan; Tel: +92 (0)300 8272693; Email: irb@ird.global), ref: IRD_IRB_2019_02_005
2. Approved 16/05/2019, 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: QMERC2019/21

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
Common mental disorders (mild-moderate depression and anxiety)

Interventions
4 counsellors, and 40 patients who are eligible to receive the Pursukoon Zindangi (Peaceful Life) counselling programme will be recruited. Patients will receive DIALOG+ at their routine counselling appointments once per month. This will be delivered by their counsellor 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) at baseline and 6 months

Key secondary outcome(s))
1. Objective social functioning measured using Objective Social Outcome Index (SIX) at baseline and 6 months
2. Symptoms measured using Aga Khan University Anxiety and Depression Scale (AKUADS) at baseline and 6 months

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Score of 20-60 on the AKUADS scaled for the symptoms of mild to moderate anxiety and depression

2. Aged 18-65 years old
3. Lives within a 20 km radius of the clinic where recruitment will take place
4. Capacity to provide informed consent
5. Score of 5 or below on the MANSA scale
6. Able to communicate in Urdu
7. Enrolled for individual counselling with the Pusukoon Zindagi (Peaceful Life) programme

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
44

Key exclusion criteria
1. Does not meet inclusion criteria
2. Primary diagnosis of substance-use disorder; organic psychosis and/or neurocognitive disorder
3. Participating in another interventional study by this or another research group

Date of first enrolment
03/06/2019

Date of final enrolment
30/09/2019

Locations

Countries of recruitment
Pakistan

Study participating centre
Interactive Research and Development
4th Floor, Woodcraft Building Plot 3 & 3-A Sector 47 Korangi Creek Road

Karachi
Pakistan
75190

Study participating centre
Indus Health Network: The Indus Hospital, Korangi
Plot C-76, Sector 31/5, Opposite Crossing Darussalam Society Sector 39 Korangi
Karachi
Pakistan
75190

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 generated during and/or analysed during the current study are available from the corresponding author on reasonable request. The combined sets of all data from all countries 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 with the Group using an online data collection platform called REDCap, for basic descriptive and comparative analysis. 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 article		14/06/2019	11/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes