

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/06/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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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 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

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

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 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 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

Overall study start date

01/06/2019

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

40 patients (4 counsellors)

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

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Sponsor information

Organisation

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Sponsor type

University/education

Website

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ROR

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 Pakistan. Dissemination will include publications, attending conferences, and using platforms like Twitter and the Group website.

Intention to publish date

31/12/2023

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