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A research study in Pakistan to test a family involvement intervention, designed to improve care for people living in the community with common mental health conditions

Submission date
03/06/2019

Recruitment status
No longer recruiting

Registration date
05/06/2019

Overall study status
Completed

Last Edited
06/12/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The Family Involvement intervention has been developed from existing approaches called Trialogue and psychoeducation. A key part of these approaches is bringing together several people living with mental health difficulties, their family members and mental health professionals into regular meetings. These different groups meet as equals to discuss topics that they have previously agreed on, share experiences and to learn from one another. This study aims to find whether Family Involvement can help to improve care for people living with common mental health conditions (mild-to-moderate depression and anxiety) in Pakistan. More specifically the aim is to find out how patients, family members/friends, and health professionals experience of Family Involvement improves outcomes like quality of life and symptoms for patients.

Who can participate?
Patients aged 18-65 years with mild-to-moderate depression and/or anxiety, who are enrolled in individual counselling on the Pursukoon Zindangi program

What does the study involve?
The patients receive the Family Involvement intervention at an agreed community location once per month over a 6-month period. One or two family members/ friends are recruited for each patient. These participants attend the monthly Family Involvement meetings with their relatives. Three counsellors are recruited to help facilitate the Family Involvement meetings. The Family Involvement intervention is based on principles of Trialogue and psychoeducation. It involves bringing together several patients, one or two of their family members/friends and one or two mental health professionals in monthly meetings, as equals, so that they may discuss pre-agreed topics, share experiences and mutual learning. Patients, family members/friends and clinicians are interviewed at the end of the study to see how they experienced the intervention.

What are the possible benefits and risks of participating?
Common mental health conditions including depression and anxiety 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. Family members and friends might benefit from having space to share their experiences and learn from other patients and families, which might lead to an improved ability to provide care for their family member or friend with mental illness. No significant risks are expected from participating in this study, but it is possible that whilst completing the research assessments or interviews, the questions asked might trigger feelings of distress or anxiety. To minimise this risk, researchers with experience working with mental health disorders will be employed, research assessments can be stopped at any point, and further support can be provided to the participant if necessary. Participants might also experience anxiety trying new interventions. Throughout the intervention-testing period, patients 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. Interactive Research and Development (Pakistan)
2. The Indus Hospital (Pakistan)

When is the study starting and how long is it expected to run for?
May 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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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
16/137/97

Study information

Scientific Title
Testing the effectiveness, acceptability and feasibility of family involvement in common mental health conditions in Pakistan: a non-controlled trial

Study objectives
To test the acceptability, feasibility and effectiveness of Family Involvement against usual treatment.
The specific research questions are:
1. How can Family Involvement be used to support community mental health care in Pakistan?
2. How is Family Involvement experienced by patients, family members/friends and professionals?
3. How do outcomes change when Family Involvement 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 trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Common mental health conditions (including mild to moderate depression and anxiety)

Interventions
The Family Involvement Intervention will be tested in an open non-controlled trial with 30 patients. The patients will receive Family Involvement at an agreed location once per month over a 6 month period. 1-2 family members/friends will be recruited for each patient. These participants will attend the monthly Family Involvement meetings with their relatives. 3 counsellors will be recruited to help facilitate the Family Involvement meetings. The Family Involvement intervention is based on principles of Trialogue and psychoeducation. It involves bringing together several patients, 1-2 of their family members/friends, and 1-2 mental health professionals in monthly meetings, as equals, so that they may discuss pre-agreed topics, share experiences and mutual learning.

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 AKUAD Scale for the symptoms of anxiety and depression
2. Aged 18-65 years old
3. Capacity to provide informed consent
4. Living within a 10 km radius of the clinic where recruitment will take place
5. Enrolled for individual counselling with Pursukoon Zindagi (Peaceful Life) Program
6. Scores 5 or below on the MANSA scale

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
73

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
27/05/2019

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 finding 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 within 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 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		19/10/2021	26/04/2022	Yes	No
Protocol file		26/02/2019	14/06/2019	No	No