

# 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

<b>Submission date</b> 03/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/06/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/12/2022	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The Family Involvement intervention has been developed from existing approaches called Triologue 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 Triologue 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](mailto:f.vanloggerenberg@qmul.ac.uk)

## Contact information

### Type(s)

Public

### Contact name

Dr Francois van Loggerenberg

### ORCID ID

<https://orcid.org/0000-0001-5317-7983>

### Contact details

Unit for Social and Community Psychiatry  
Queen Mary University of London  
Newham Centre for Mental Health  
London  
United Kingdom

E13 8SP  
+44 (0)207 540 4380 Ext: 2339  
f.vanloggerenberg@qmul.ac.uk

### **Type(s)**

Scientific

### **Contact name**

Dr Francois van Loggerenberg

### **ORCID ID**

<https://orcid.org/0000-0001-5317-7983>

### **Contact details**

Unit for Social and Community Psychiatry  
Queen Mary University of London  
Newham Centre for Mental Health  
London  
United Kingdom  
E13 8SP  
+44 (0)207 540 4380 Ext: 2339  
f.vanloggerenberg@qmul.ac.uk

## **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 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 Dialogue 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?
<a href="#">Results article</a>		19/10/2021	26/04/2022	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>		26/02/2019	14/06/2019	No	No