

# Improving community-based mental health care in India and Pakistan

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		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 09/02/2022	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 10/01/2025	<b>Condition category</b> 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

About 5-8% of the world's population suffer from a Severe Mental Illness (SMI), presenting a major challenge worldwide. SMI causes significant distress to affected people, families and wider communities, generating high costs through loss of productivity and ongoing healthcare use. The burden is greatest in low- and middle-income countries (LMICs), where there may be a lack of financial resources and qualified staff to provide extensive specialised services.

This study will explore, adapt and test a low-cost, generic approach (DIALOG+) that makes use of existing resources to improve community-based care for patients with psychosis and reduce the need for institutionalisation in India and Pakistan. DIALOG+ is an app-mediated intervention that has been shown to improve mental health outcomes. The research will also develop a participatory arts work that will focus on giving voice to people with psychosis and their experiences as well as engage local communities, opening conversations about mental illness. The overall aim of the study is to test the effectiveness and cost-effectiveness of DIALOG+ in improving the quality of community-based care for patients with psychosis in India and Pakistan.

### Who can participate?

Patients aged over 18 years with a diagnosis of psychosis, currently not receiving inpatient treatment, with a duration of illness greater than 2 years

### What does the study involve?

The study will be conducted in India and Pakistan with 210 patients and 15 clinicians within each country. A clinician and their respective patients will be randomly divided into two groups. The study will involve clinicians using the app-based intervention called DIALOG+ in their routine sessions with patients. In one group the DIALOG+ app will be used to structure the conversation that takes place during the session. This involves going through a patient's satisfaction level on various life domains and then discussing them further using a four-step solution-focused approach. In the second group, clinicians will only use the app to complete the satisfaction scale with patients.

Data will be collected at baseline, at 6 months after the intervention, and at 12 months. Data collection will include different tools to measure quality of life, symptom severity, objective social functioning, economic/cost-effectiveness data and health alliance. Further interviews will take place with patients and clinicians at the end of the intervention period (6 months) to gain a

more in-depth understanding of the experience of using DIALOG+. Data will be analysed to help the researchers understand how effective and accepted the DIALOG+ intervention was in the sample population.

What are the possible benefits and risks of participating?

The burden of severe mental illness is greatest in LMICs where there are neither sufficient financial resources nor qualified staff to provide extensive specialised services. Individuals with chronic psychosis in particular fail to receive adequate care.

This study aims to repurpose an effective and low-cost intervention (DIALOG+), which can be integrated within community care to improve outcomes for patients with chronic psychosis. Making use of existing resources to improve community-based care for patients with psychosis is not only a priority in its own right but can aid transferability of the intervention to other LMICs, where people with psychosis experience similar situations.

Overall, the study will build both mental health and research capacity in Pakistan and India. A potential benefit for all participants involved in the research is that their suggestions and experiences might be incorporated into the culturally-specific adaption of DIALOG+ for use in these countries. Additionally, for participants who will be involved in the testing of the modified intervention, this might lead to improved quality of life, social functioning, and symptoms. The study will also benefit the clinicians involved as they will be provided with training and supervision to enable them to implement the intervention. Clinicians will also have the opportunity to get involved in the research process and attend training seminars as part of the capacity-building activities.

There are no risks associated with taking part in the study. If patients feel any level of anxiety or distress whilst answering any research questions, there are relevant protocols and procedures in place to deal with any such situation and the research team is qualified and trained to handle the situation appropriately.

Where is the study run from?

Queen Mary University of London (UK)

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

September 2020 to March 2024

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

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## Contact information

**Type(s)**

Principal investigator

**Contact name**

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Scientific

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## Additional identifiers

National Institute for Health and Care Research (NIHR)

200824

## Study information

### Scientific Title

Improving outcomes for people with psychosis in Pakistan and India – enhancing the Effectiveness of Community-based care (PIECES)

### Acronym

PIECES

### Study objectives

Approximately 5-8% of the world's population suffer from a Severe Mental Illness (SMI) presenting a major challenge worldwide. SMI causes significant distress to affected people, families and wider communities, generating high costs through loss of productivity and ongoing healthcare use. The burden is greatest in low- and middle-income countries (LMICs), where there are neither a lack of financial resources nor qualified staff to provide extensive specialised services. Within LMICs, an estimated 69%-89% of people with SMI experience a treatment gap, adding to other significant social inequalities. This treatment gap is most pronounced for people with psychosis, particularly chronic psychosis, where 75% of all individuals fail to receive

adequate care, despite a high financial burden and reduced quality of life (QoL). This project focuses on two LMICs, namely India and Pakistan. Lack of mental health services and widespread poverty means that mental health issues often remain undiagnosed, misdiagnosed, or untreated within both countries. LMICs therefore need effective, appropriate and low-cost forms of care that utilise and strengthen existing personal and social resources available to individuals, their families and communities. Reducing the treatment gap for individuals with psychosis by providing low-cost, effective interventions is an urgent priority. The principal question addressed within the study is whether a low-cost, generic approach (DIALOG+) that makes use of existing resources is effective and cost-effective in improving community-based care for patients with psychosis.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Approved 28/10/2020, Queen Mary University London's Research Ethics Committee (Empire House, Queen's Building, Queen Mary University of London, Mile End Road, London, E1 4NS, UK; +44 (0) 20 7882 7915/6947; research-ethics@qmul.ac.uk), ref: QM28\_10\_20
2. Approved 16/02/2021, IRD International Review Board in Karachi, Pakistan (15 Beach Road # 02-01, Singapore, 189677; +65 (0)6372 8778; info@ird.global), ref: IRD\_IRB\_2021\_01\_005
3. Approved 23/10/2020, Schizophrenia Research Foundation's Ethics Committee in Chennai, India (Mental Health Centre, R/7A, Main Road, Anna Nagar (West Extn), Chennai, India; +91 (0)44 2615 1073, 26153971; info@scarf.org), ref: SRF-CR/14/OCT-2020

## **Study design**

Cluster randomized controlled trial and a mixed-methods process evaluation

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Improving the quality of life for individuals with long-term psychosis (duration of >2 years)

## **Interventions**

This is a cluster randomised control trial where clinicians and their respective enrolled patients will form clusters that will be randomised into a treatment and active control arm. The total duration of the intervention will be 12 months from the date of randomisation.

DIALOG+ intervention:

Clinicians allocated to intervention, per country n = 7 (total n = 14)

Patients allocated to intervention, per country n = 105 (total n = 210)

The intervention is designed to be implemented within routine meetings between clinicians and patients. The intervention is a technology-assisted resource-orientated approach. It involves a structured patient assessment (DIALOG) covering satisfaction with eight life domains and three treatment aspects. This is followed by a four-step solution-focused therapy (+ component) approach to address patient concerns. Clinicians will receive one and a half hours of face-to-face training and will be provided with training manuals and materials. DIALOG+ sessions will be one per month as per routine clinical practice for patients with psychosis.

## Active control:

Clinicians allocated to control, per country n=7 (total n=14) Patients allocated to control, per country n=105 (total n=210)

Patients will continue to receive standard treatment including routine meetings with clinicians. To control for the addition of a tablet computer in the consultation and for repeated quality of life assessments, patients will complete the DIALOG scale at the end of each session. They will not however discuss the results with clinicians or complete the four-step solution-focused component. Active control sessions will be once per month as per usual routine clinical practice for patients with psychosis.

## Intervention Type

Behavioural

## Primary outcome(s)

Subjective quality of life measured using the Manchester Short Assessment of Quality of Life (MANSA) at baseline, 6 and 12 months

## Key secondary outcome(s)

1. Hospitalisation measured using the Client Service Resource Inventory (CSRI) at baseline, 6 and 12 months
2. Symptoms measured using the Brief Psychiatric Rating Scale (BPRS) at baseline, 6 and 12 months
3. Negative symptoms measured using the Scale for the Assessment of Negative Symptoms (SANS) at baseline, 6 and 12 months
4. Objective social situation measured using the Objective Social Outcomes Index (SIX) at baseline, 6 and 12 months
5. Therapeutic alliance measured using the Helping Alliance Questionnaire (HAQ-II) at baseline, 6 and 12 months
6. Health-related quality of life measured using EQ5D-3L at baseline, 6 and 12 months
7. Service use measured using the Client Service Receipt Inventory (CSRI) at baseline, 6 and 12 months

## Completion date

11/03/2024

## Eligibility

### Key inclusion criteria

Patients with a diagnosis of psychosis, currently not receiving inpatient treatment, with a duration of illness greater than 2 years

Patients:

1. Diagnosis of psychosis
2. Aged over 18 years
3. Capacity for informed consent
4. Can speak and understand the local language
5. Has a low quality of life (<5 on the MANSA)

Clinicians:

1. Any professional background or lay community worker
2. Regular contact with patients with psychosis

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patients:

1. Dementia and/or significant cognitive impairment and/or severe learning disability
2. Organic psychosis or drug-induced psychosis if given as the primary diagnosis
3. Unable to provide informed consent

Clinicians:

1. Does not have regular contact with individual(s) with chronic psychosis
2. Unable to speak either Urdu or Tamil

**Date of first enrolment**

07/03/2022

**Date of final enrolment**

31/12/2022

**Locations**

**Countries of recruitment**

India

Pakistan

**Study participating centre**

**Schizophrenia Research Foundation**

R/7a, N Main Rd, Kailash Colony

Sector A

Anna Nagar West Extension

Chennai

India  
600101

**Study participating centre**

**Karwan e Hayat**  
Karachi Port Trust Hospital  
East Wharf  
Karachi  
Pakistan  
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**Study participating centre**

**Jinnah Postgraduate Medical Center (JPMC)**  
Rafiqi Sarwar Shaheed Rd  
Karachi Cantonment  
Karachi  
Pakistan  
75510

## **Sponsor information**

**Organisation**

National Institute for Health Research

**ROR**

<https://ror.org/0187kwz08>

## **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

Research data will be retained and archived in accordance with the Research Governance Framework and IM&T Information and security policies. Records will be archived as per Queen Mary University of London procedures and kept for 20 years in the Trust Modern Records Centre. The PI (Bird) will be the custodian of the data.

The data will also be stored at the main study site in India (SCARF) where Ramachandran will be the custodian of the data, and the main study sites in Pakistan (Postgraduate Medical Centre and Karwan-e Hayat) where Pasha will be the custodian of the data. This will be done according to the local regulations for data storage and protection.

### IPD sharing plan summary

Stored in non-publicly available repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		26/01/2023	27/01/2023	Yes	No
<a href="#">Protocol article</a>	protocol for the economic evaluation	08/01/2025	10/01/2025	Yes	No
<a href="#">Other files</a>	version 1.0	01/12/2023	10/07/2024	No	No
<a href="#">Statistical Analysis Plan</a>	version 3.21	06/02/2024	20/03/2024	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes