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Improving community-based mental health care in India and Pakistan

Submission date
04/02/2022

Recruitment status
No longer recruiting

Registration date
09/02/2022

Overall study status
Completed

Last Edited
10/01/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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)
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
NIHR200824

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 is 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)
Rafiqui 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?
Protocol article		26/01/2023	27/01/2023	Yes	No
Protocol article	protocol for the economic evaluation	08/01/2025	10/01/2025	Yes	No
Other files	version 1.0	01/12/2023	10/07/2024	No	No
Statistical Analysis Plan	version 3.21	06/02/2024	20/03/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes