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Translating evidence for early intervention in psychosis (TRANSLATE) in low and lower-middle countries (LMIC): implementation and evaluation

Submission date
09/09/2025

Recruitment status
Recruiting

Registration date
22/10/2025

Overall study status
Ongoing

Last Edited
03/08/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is about helping young people in Pakistan and Sri Lanka who are experiencing psychosis for the first time. Psychosis is a mental health condition that affects how people think, feel, and behave. In many low- and middle-income countries, people often wait a long time before getting treatment—sometimes over two years. This delay can seriously affect their quality of life, education, and ability to work.

In countries like the UK, early intervention services help people get treatment quickly, which leads to better outcomes. This study aims to set up similar early intervention services in Pakistan and Sri Lanka. It also wants to understand why some people don't respond well to treatment (a condition called treatment resistant schizophrenia) and whether we can predict who might be at risk.

Who can participate?
People in Pakistan and Sri Lanka who are experiencing psychosis for the first time may be invited to take part in the study. The research team will work with local mental health services to identify potential participants.

What does the study involve?
Participants will receive care through the new early intervention services. The team will collect information about their health, treatment, and progress over time. Some participants may also be asked to provide additional information to help researchers understand why some people don't respond to treatment.

What are the possible benefits and risks of participating?
The main benefit is receiving care earlier than usual, which can lead to better recovery and

improved quality of life. There may be some risks, such as feeling uncomfortable when answering personal questions or sharing health information, but the research team will take steps to protect participants' privacy and wellbeing.

Where is the study run from?
Keele University (UK)

When is the study starting and how long is it expected to run for?
April 2024 to February 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
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Contact information

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Study information

Scientific Title
Translating evidence for Early Intervention in Psychosis (TRANSLATE) in Low and Lower-Middle Countries (LMIC): Implementation and Evaluation

Acronym
TRANSLATE

Study objectives
1. To evaluate the implementation of Early Intervention in Psychosis (EIP) services in maintaining engagement with the services, achieving remission in First Episode of Psychosis, and other relevant implementation outcomes.
2. To assemble a cohort of FEP within the EIP service and identify potential predicting factors of Treatment Resistant Schizophrenia at one-year follow-up.
3. To develop a prognostic model for estimating an individual's risk of treatment resistance at one year and to undertake the validation of the model's predictive performance.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 11/06/2025, Keele University’s Research Ethics Committee (Keele University, Keele, Newcastle Under Lyme, ST5 5GB, United Kingdom; +44 1782 733937; health.ethics@keele.ac.uk), ref: 1028

2. Approved 28/03/2025, Kyber Medical University - Institute of Public Health and Social Sciences (KMU, Phase-5, Hayatabad, -, Pakistan; +91-5892867; drshaista.iph@kmu.edu.pk), ref: KMU/IPHSS /Ethics/2025/TE/260

Primary study design
Observational

Study design
Observational cross sectional cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
First episode psychosis and treatment resistant schizophrenia

Interventions
Patients with a diagnosis of First episode Psychosis (FEP) will be recruited. The participants will be assessed at the baseline and follow up in 1, 3,6, and 12-month period with pre identified tools. All participants will receive care following the clinical guidelines developed for the management of FEP in the study settings. The package of care will include evidence-based pharmacotherapy, cognitive behaviour therapy and other psychosocial interventions. The treatment will be provided by trained psychiatrists and psychologists. The supervising psychiatrist will decide the choice of medication, dosage and other interventions after involving patients and families in the treatment according to the clinical practice guidelines adopted for management of First Episode Psychosis in Pakistan and Sri Lanka. Each participant will be allocated a care coordinator to coordinate the services to ensure the receipt of services that prescribed to given for each patient. The patients will be followed up for one year to estimate the rates of remission, engagement with the service and other clinical outcomes during the study.

The duration of observation and total duration of follow-up will be 12 months for each participant. This study is not aimed at testing the efficacy related to the individual drugs or other interventions, these are well established. Our aim is to assess the implantation effectiveness of the Early Intervention in Psychosis services in resource poor settings.

Intervention Type
Other

Primary outcome(s)
1. Disengagement from service is measured using clinic records and care coordinator notes at 1, 3, 6, and 12 months
2. Remission is measured using PANSS (score ≤3) or YMRS (score ≤12) at 1, 3, 6, and 12 months

Key secondary outcome(s)
1. Change in occupational and social functioning is measured using WHODAS 2.0 at 1, 3, 6, and 12 months
2. Psychopathology symptom severity is measured using PANSS, YMRS, and HDRS at 1, 3, 6, and 12 months
3. Family burden is measured using the Family Burden Scale at 3 and 12 months

4. Perceived stigma is measured using the Modified Internalized Stigma of Mental Illness tool (ISMI) at 12 months
5. Blood pressure is measured using clinic records at 1, 3, 6, and 12 months
6. BMI is measured using clinic records at 1, 3, 6, and 12 months
7. Cardiovascular disease risk is measured using WHO-STEPS at 12 months
8. Appropriateness is measured using the Intervention Appropriateness Measure tool (IAM) at 12 months
9. Feasibility is measured using the Feasibility Intervention Measure at 12 months
10. Acceptability is measured using the Applied Mental Health Research Group tool at 12 months
11. Fidelity of CBT delivery is measured using the Revised Cognitive Therapy Scale (CTS-R) at 12 months
12. Implementation cost is measured using administrative data logs collected over the one-year period

Completion date
01/02/2029

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 03/08/2026:
1. Patients aged 16-40 years
2. Residing within the study districts
3. Diagnosed with First-ever psychotic episode who have not received antipsychotic medication previously, or if they already have used antipsychotic medications, it was for no longer than six weeks

Previous key inclusion criteria:
1. Patients aged 18-35 years
2. Residing within the study districts
3. Diagnosed with First-ever psychotic episode who have not received antipsychotic medication previously, or if they already have used antipsychotic medications, it was for no longer than six weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
40 Years

Sex

All

Total final enrolment
0

Key exclusion criteria
1. Those with an overt learning disability
2. Those with severe substance abuse (except nicotine dependence)
3. Those with organic illness associated with psychotic symptoms

Date of first enrolment
01/09/2025

Date of final enrolment
31/01/2029

Locations

Countries of recruitment
Pakistan

Sri Lanka

Study participating centre
Deaprtment of Psychiatry, Ayub Medical Teaching Institution
Main Mansehra Road
Abbottabad
Pakistan
Kyber Pakhtunkhwa Province

Study participating centre
Deapartment of Psychiatry and Behavioural Sciences
Faisalabad Medical University, Allied/ District Head Quarters Hospital -Faisalabad, Mall Road
Faisalabad
Pakistan
38000

Study participating centre
Department of Psychiatry, Balochistan Institute of Psychiatry and Behavioural Sciences (BIPBS) , Quetta
Balochistan Institute of Psychiatry and Behavioral Sciences (BIPBS), Behind BMC Hospital, Berwery Road
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Pakistan
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Study participating centre
Department of Psychiatry, Medical Teaching Institute, Lady Reading Hospital, Peshawar
Soekarno Rd, Pipal Mandi
Peshawar
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Study participating centre
Institute of Public Mental Health and Behavioural Sciences, Khyber Medical University, Peshawar
KMU Main Campus, Phase 5, Hayatabad
Peshawar
Pakistan
Kyber Pakhtunkhwa Province

Study participating centre
National Hospital Galle
Karapitiya
Galle
Sri Lanka
00

Study participating centre
Department of Psychiatry, Jinnah Postgraduate Medical Center (JPMC)
Rafiqui, Sarwar Shaheed Rd, Karachi Cantonment
Karachi
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75510

Sponsor information

Organisation
Keele University

ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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 will be available upon request from Professor Saeed Farooq - s.farooq@keele.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes