



THE HOPE

Traditional healers working with primary care and mental health for early intervention in psychosis in adolescent: intervention and feasibility.

Sponsor reference: MR/T040378/1

End of Study Report December 2024

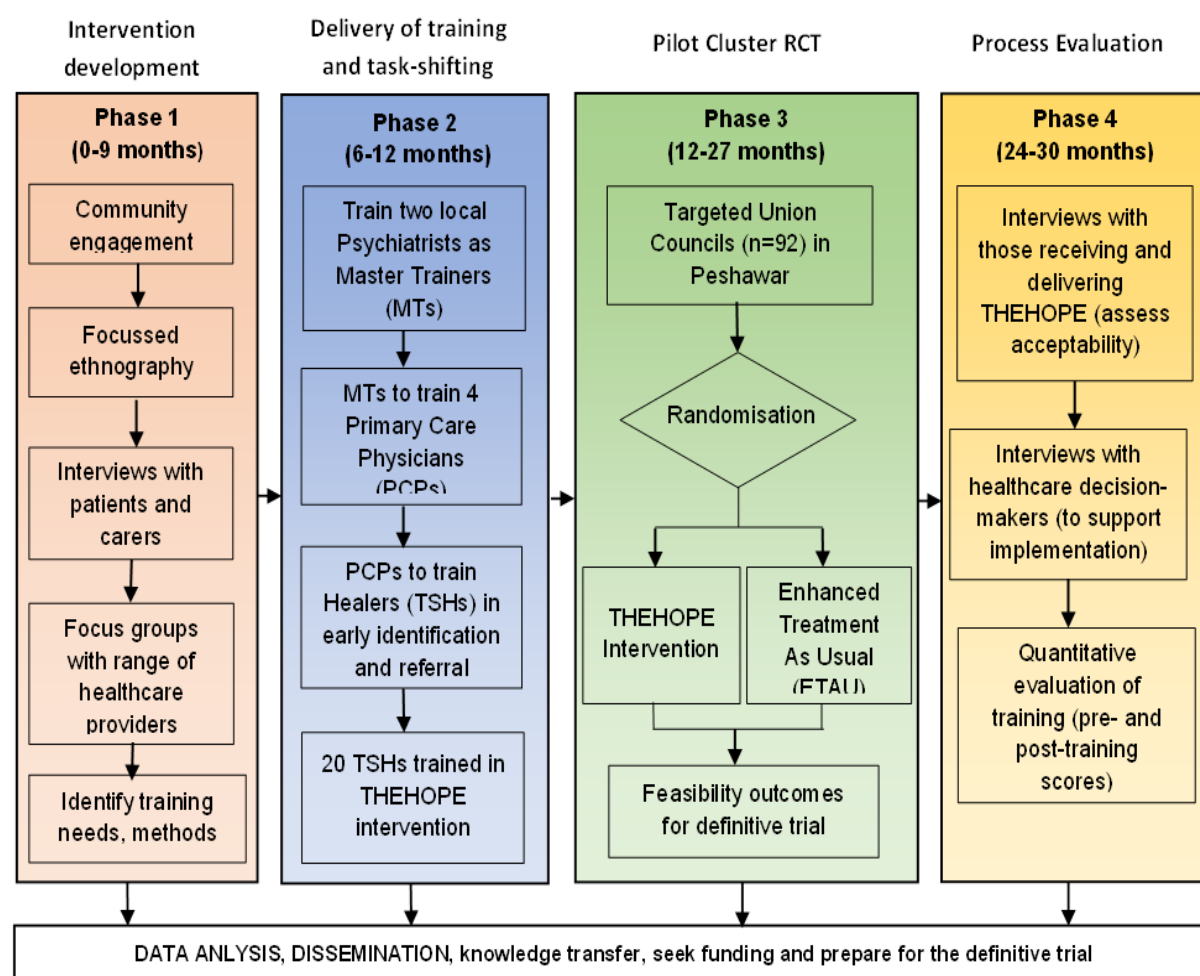
Executive Summary: This report is to confirm the completion and close out of The HOPE feasibility study. This document will inform the study steering committee on the following.

- Progress across each work phase & objectives achieved
- Community Engagement & Patient and Public Involvement
- Impact & Dissemination

Overview of The HOPE: Spread across four phases, THE HOPE is a feasibility study of Traditional HEalers working with primary care and mental Health for early interventiOn in psychosis in young PErson. THE HOPE programme aim to develop a culturally appropriate and context-bespoke service level intervention for early identification, referral and management of First Episode Psychosis (FEP) in the adolescent population in Peshawar, Khyber Pakhtunkhwa (KP) in Pakistan and evaluate its feasibility for implementation. Detailed overview of the overall study is attached.



THE HOPE Study
Overview - April 202



Progress across each work phase

Phase 1: (0-9 months) March 2022 – December 2022 - Completed Qualitative & Ethnographic study leading to Intervention Development

- Extensive community fieldwork and mapping exercise was carried out from July 2022 – August 2022 to compile a database of 350 TSH across Khyber Pakhtunkhwa (KPK) Pakistan.
- Data collection tools for qualitative interviews, focus groups and ethnographic framework were developed in close consultation with patients, public and community members.
- Data collection for focused ethnographies, qualitative interviews and focus groups took place from August 2022 – Jan 2023.
 - Focused ethnographies TSH, patients & carers: n= 15
 - Qualitative interviews with TSH, patients & carers: n= 25
 - Focused Group Discussion TSH, patients, Carers (female & male) & Healthcare professionals (PCP): n=6
- Brief report attached.



THEHOPE-Highlight
s of Ethnography ar

Phase 2: (6-12 months) Sept 2022 – March 2023 - Completed Delivery of training and task-shifting

Separate training workshops have been arranged across four groups.

1. Psychiatrist
2. Primary Care Physicians
3. Traditional Healers
4. Research Assistants

Please see the report attached with details on training workshops for each category.



THEHOPE Capacity
development & CEI

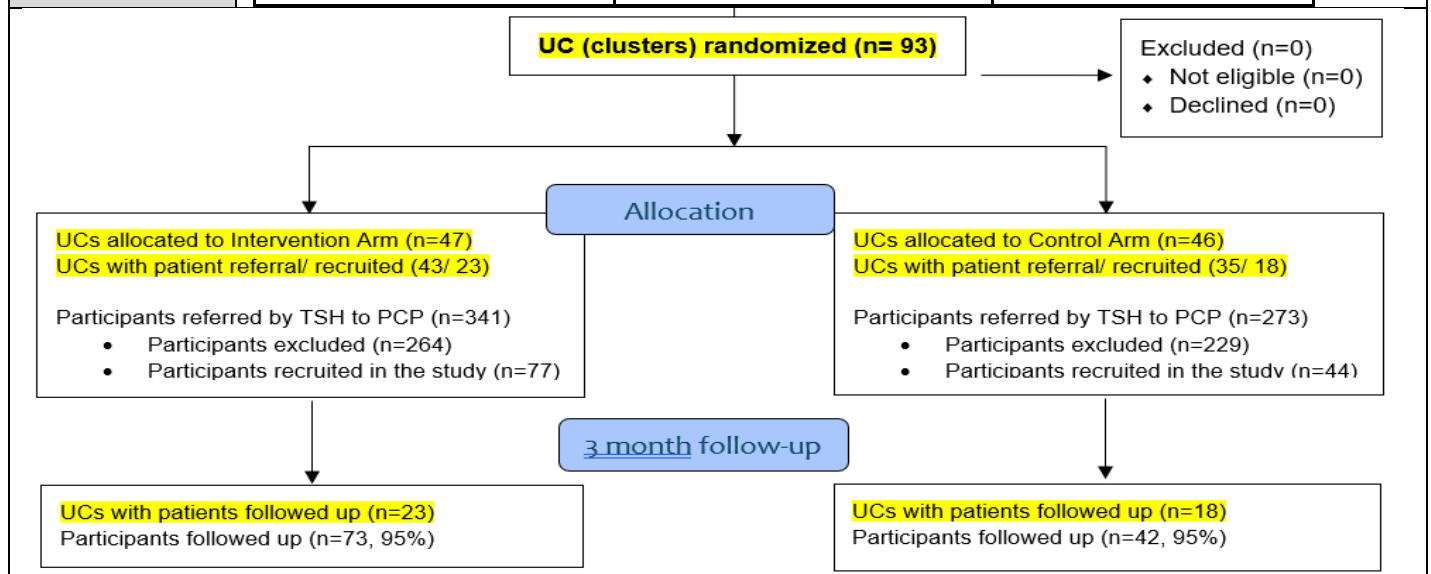
Phase 3: (12-24 months) May 2023 – May 2024 - Completed Feasibility Cluster Pilot RCT

Ethics Approvals	<ul style="list-style-type: none"> • Favorable ethics approval received from Keele University (ref: MH210177), Khyber Medical University Ethical Review Board (ref: DIR/KMU-EB/IG/001005) and National Bioethics Committee Pakistan (Ref: No.4-87/NBC-840/22/621).
Trial Registration and Protocol	<ul style="list-style-type: none"> • Trial was registered on ISRCTN register Feb 2023: https://doi.org/10.1186/ISRCTN75347421 • The protocol is published in BMJ open: DOI: 10.1136/bmjopen-2023-072471
Trial Duration	<ul style="list-style-type: none"> • 1st May 2023 – 30th April 2024 • Lady Reading Hospital and Hayatabad Medical Complex, Peshawar, are the two main trial sites.

Randomization & Recruitment

Randomization was completed at the Union Council level and allocated using a 1:1 ratio to either intervention arm (THE HOPE) or Enhanced Treatment as Usual (ETAU) and stratified by urban/rural setting. In total 93 UCs have been randomized. The recruitment of participants completed over 12 months recruitment period from 1st May 2023- 30th April 2024. In total the trial has recruited n= 121 participants from n=614 referrals from the TSH across both arms.

Month	Total Screened	Total Enrolled
May (2023)	48	12
June	50	5
July	58	6
August	58	12
September	57	8
October	33	6
November	73	17
December	51	15
January (2024)	42	16
February	21	06
March	26	06
April	97	12
Total	614	121



Progression criteria and feasibility findings

	Recruitment to the trial	TSH engagement in study	Completion rates for the trial follow-up
Green	≥ 130 patients recruited over 12 months	>85% of TSHs consented, participated in training and worked with psychiatric services in referring the suspected cases	≥ 80% of participants complete follow-up assessments at 3 months
Amber	90-130 participants recruited	70%–85% of TSHs consented, participated in training and worked in referring suspected cases	70-80% of participants complete 3-month follow-up assessment
Red	<90 patients recruited	<70% of TSHs consented/ participated	< 70% of participants complete 3-month follow up assessment
Trial feasibility findings	121 participants recruited in 12 months	95% (38/40) TSH engagement	95% (115/121) of participants completed 3-month follow-up

THE HOPE was effective, fostering collaboration between traditional healers and healthcare providers. Stakeholders unanimously supported its continuation, highlighting its unprecedented potential to improve mental health care access and reduce stigma.

Key feasibility progression criteria were met: high recruitment and retention & TSH engagement in the study. Key feasibility findings were presented at the Global Mental Health Symposium held in Pakistan in December 2024 (copy attached). Detailed findings will be published in peer reviewed journal.



The HOPE
Feasibility Trial_Key |

Data & Safety Monitoring	<ul style="list-style-type: none"> Regular monitoring visits from the CI of the study and independent trial monitors No major findings or protocol deviation identified. Data and Safety Monitoring Board meeting was arranged on 2nd Nov to review the data with no concerns highlighted from the members. Copy of ppt slides from and minutes of the meeting attached. DSMB decided not to have further in-person meetings upon receipt of satisfactory data management and safety updates from The Hope team in May 2024.
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Phase 4: (24-30 months) May 2024 – October 2024 - Completed Process Evaluation

We followed the MRC framework for the process evaluation which focuses on 'context', 'implementation', and 'mechanisms of impact'. We identified mechanisms and contextual factors that had its impact on the intervention development work. The qualitative study included semi structured interviews with relevant stakeholders including.

1. Psychiatrists and PCPs
2. Traditional and Spiritual Healers

3. Carers
4. Patients
5. Policy Makers

Key questions for process evaluation:

1. Acceptability of educational materials and delivery
2. Burden of training
3. Appropriateness of the Intervention
4. Quality of Implementation
5. Acceptability of Intervention
6. Satisfaction of Stake Holders
7. Overall satisfaction with the intervention
8. Barriers and facilitators to early detection and collaboration with mental health services
9. Barriers and Facilitators in Implementation
10. Sustainability of THEHOPE

The key findings of the process evaluation were presented at the Global Mental health Symposium held in Pakistan in December 2024. Copy of the presentation attached. Detailed findings will be published in a peer reviewed journal.



THEHOPE process
evaluation-key findi

Community Engagement & Patient and Public Involvement

Community engagement for the Hope project was conducted in three phases:

1. First phase: Psychosis Awareness among the general community in Khyber Pakhtunkhwa (KPK) – 10 sessions
2. Second phase: Meetings with Traditional and Spiritual Healers
3. Third phase: Mental Health Awareness among the general community in KPK – 18 sessions.

In addition, a Lived Experience Advisory Panel (LEAP) has been established to promote active cooperation between the community, people with lived experience of psychosis as a patient or carer and the researchers. Regular meetings of the research team and principal investigators were arranged with the LEAP members to provide their valuable input on study design, documents, trial processes and strategies for engagement with the wider communities.

Detailed report attached:



CEI &
PPI_THEHOPE_FinalF

Impact and Dissemination

Published papers:

- Traditional healers working with primary care and mental health for early intervention in psychosis in young persons: protocol for the feasibility cluster randomised controlled trial.
<https://pubmed.ncbi.nlm.nih.gov/37451736/>
- Early intervention in psychosis and management of first episode psychosis in low- and lower-middle income countries (LMIC): a systematic review. (published in Schizophrenia Bulletin) DOI: [10.1093/schbul/sbae025](https://doi.org/10.1093/schbul/sbae025).
- Quarterly newsletters <https://www.keele.ac.uk/globalhealth/research/hope/#newsletters>

Guidelines & Manuals:

- Guidelines for Early Intervention in Psychosis

- A Family Physicians guide to Psychosis (Manual for Primary Care Physicians)
- A Guidebook on Psychosis for Traditional and Spiritual Healers (Guide for Traditional and Spiritual Healers)

Draft papers/manuscript:

- Developing and adapting guidelines for early intervention in psychosis using the ADAPTE framework
- Causes of Delayed Diagnosis and Treatment of First Episode Psychosis in Lower- and Middle-Income Countries: Learning for Pakistan. (Qualitative paper).
- Equitable Partnership: Patient and Public Involvement & Engagement and Community Engagement in Mental Health Research- An Example from a Low and Middle-Income Country
- Identification and Mapping of Spiritual healers
- Key Feasibility Findings of The HOPE
- Process Evaluation of The HOPE

Psychosis Awareness Video:

- The HOPE team developed a psychosis awareness video, which was presented at the GMH symposium on December 4th and 5th at Islamabad, Pakistan.

Media Coverage:

- A TV talk show at Khyber News, program name "studio 2" and News 21 featured Prof Saeed Farooq, to raise awareness about mental health issues and discuss various related concerns. Prof Saeed Farooq provided a comprehensive overview of the Hope project and its objectives. He highlighted the importance and need for youth mental health in LMIC.
- Prof. Jalil Khan, the lead of THE HOPE project, appeared on a live state television program (PTV National Live) to discuss psychosis and the project itself. Ishfaq Tariq, the project manager, also elaborated on the project's aims and objectives. Prof Jalil delved into mental health issues, with a particular focus on First Episode Psychosis in young individuals. He also highlighted the negative consequences of delayed psychosis detection.

Events & Conferences:

- The feasibility findings of The HOPE, Guidelines for First Episode Psychosis, and manuals for Primary Care Physicians and Traditional and Spiritual Healers were disseminated at the **Global Mental Health Symposium held in Islamabad in December 2024, Islamabad**. The event was organized by the NIHR funded CONTROL project and talks included from mental health professionals across the globe.



- Khyber Medical University hosted a **Seminar on Early Intervention for Severe Mental Illness on 11th Dec 2024**, focused on the critical importance of early intervention for severe mental illness, particularly in adolescents. Organized by the HOPE team, Institute of Public Mental Health & Behavioral Sciences (IPMH&BS), and Keele University, the event was led by **Principal Lead, Prof Jalil Khan and Dr M Firaz Khan**, and chaired by the **Vice-Chancellor, Prof Dr Zia ul Haq**. **Keynote speaker and Chief Investigator, Prof, Saeed Farooq**, highlighted the growing burden of psychiatric illnesses in low- and middle-income countries. He emphasized the urgent need for early diagnosis, prompt treatment, and collaborative efforts among all stakeholders. A significant milestone was announced: the release of the first-ever clinical guidelines for managing the First Episode Psychosis (FEP) in Low- and Middle-Income Countries (LMICs). Other speakers at

the seminar underscored the importance of advancing research and quality initiatives in mental health. The event was attended by a diverse group of experts, including traditional healers, reflecting a commitment to a holistic approach to mental healthcare. The seminar was featured in **THE News, The Frontier Post, Mashriq** and other local newspapers.

- **Global Mental Health Symposium Feb 2024** at Keele organized by Prof Saeed Farooq and team (report attached). Overall, 119 people attended the symposium, with 65 attendees on day one and 54 attendees on day two of the event. The symposium hosted guests from a variety of national and international organisations including the World Health Organisation, NIHR, HealthNet TPO, Agha Khan University, Centre for Mental Health and Addiction Canada, and Kent and Medway Medical School. There were 31 speakers across the two days, presenting on a range of topics including early intervention in psychosis, capacity building in low- and middle-income countries (LMICs), implementation research in LMICs, mental health and Tuberculosis, and mental health in conflict/post-conflict settings.



- The Hope team Co-Investigators and research team participated with oral and poster presentations at the **fourth International Public Health Conference** at IPH&SS, KMU, (April 16th-19th).
- Prof Saeed Farooq presented The HOPE study at the International Conference on Health Research at Rehman Medical Institute, Peshawar, (26th April-28th April, 2024).
- Dr Abdul Jalil Khan presented The HOPE ethnographic study at the **WONCA South Asia Region Conference May 2024 in Sri Lanka**.
- **Public mental health symposium was organized by IMH&BS, KMU on 15th Feb, 2024.** Centered around the introduction of Public mental health with the focus on youth mental health, featuring mental health experts and collaborative strategies for effective solutions. A plenary session was held to address the growing need for public mental health and destigmatization of mental health issues. Experts in psychiatry, mental health, and public health discussed strategies to effectively tackle these challenges. The symposium highlighted the role of research projects like HOPE in advancing understanding and intervention strategies.