ISRCTN75347421 https://doi.org/10.1186/ISRCTN75347421

Traditional healers working with primary care and mental health for early intervention in psychosis in young persons

Submission date
09/01/2023

Recruitment status
No longer recruiting

Registration date
11/01/2023

Overall study status
Completed

Last Edited
28/01/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims:
One-in-ten people experience a psychotic episode (delusion, hallucination) before 18 years of age. These experiences can be upsetting and, without adequate treatment, can have serious long-term effects (e.g. reduce quality of life, disrupt education, reduce long-term employment). Early treatment after a psychotic episode is vital to reduce long-term effects.
People living in Low- and Middle-Income Countries (LMICs) (e.g. Pakistan) experience poorer access to care compared to those in Higher Income Countries (e.g. UK, USA). It can take over 2 years for someone living in an LMIC to be diagnosed and treated for psychotic episodes. This is double the time it takes for someone in the UK.
Previous research about psychotic episodes in the Peshawar district of Pakistan found that people with mental health issues often sought help from traditional and spiritual healers (TSHs). These issues are commonly linked to superstition and/or spirits. Seeking help from TSHs is a key cause of delay in treatment for psychotic episodes.
Collaboration between TSHs and primary care has shown to improve healthcare provision for health conditions, such as HIV/AIDS, but the same has not been evaluated for psychotic episodes, up to now.
The proposed programme of research, called THE HOPE (traditional healers working with primary care and mental health for early intervention in psychosis), seeks to develop a new way of detecting and treating psychotic episodes among adolescents in Peshawar, Pakistan. This research will strengthen collaboration between TSHs and primary care to improve healthcare for patients reporting these issues. By working with TSHs the researchers will develop a new approach that is culturally sensitive and acceptable to local populations.

Who can participate?
Participants (aged 14 to 25 years) residing in one of the 93 union councils in district Peshawar 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 6 weeks.

What does the study involve:
The cluster allocation of the union council will determine the treatment path for each

participant. Potential participants will be verbally informed about the trial and those who agree to participate will be given a full written information sheet about the study by a research assistant (RA) (written information sheets read by RA for those who can't read) about the study. Those willing to participate will be requested to complete the baseline sociodemographic data and a suicide risk screen by a RA. The RA will refer all suspected cases from TSH and PCP to the psychiatrists assigned to each arm who will independently assess patients within 48 hours of referral, without knowing the diagnosis (by PCP) or impression of TSH. Those diagnosed with FEP will be started on treatment in collaboration with participating PCPs or TSH (if the patients and family want to continue treatment by TSH) in the intervention arm, while those in the control arm will be provided with treatment as usual. The treatment will be based on recent guidelines for the treatment of first-ever psychotic episodes adopted for the purpose of the study. Follow-up data will be collected 12 weeks later by the RAs.

What are the possible benefits and risks of participating:
Those who take part may not receive any direct benefit. However, the information from this study will help THE HOPE research team to develop an intervention to support the care of adolescents with psychosis in the community. This will provide future developments in the area of community-based treatment in psychiatry programs and help in improving the practice of evidence-based psychiatry.
There are no anticipated risks involved for those who decide to take part in this study. The study includes sharing personal experiences, which some may find uncomfortable. Participants are under no obligation to answer any questions that make them feel uncomfortable. The information received from the participant will not be used in any way that might cause any harm. Participants will be informed that if there is any problem throughout participation the trained mental health professionals will be available for help. Participants will be informed of their right to withdraw from the study at any time if they find the supervision of treatment or any other part of the study is causing a problem.

Where is the study run from?
93 union councils in district Peshawar, Khyber Pakhtunkwa (KP) (Pakistan)

When is the study starting and how long is it expected to run for?
September 2019 to December 2024

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Saeed Farooq, s.farooq@keele.ac.uk

Study website
https://www.keele.ac.uk/globalhealth/research/hope/

Contact information

Type(s)
Principal Investigator

Contact name
Prof Saeed Farooq

ORCID ID
http://orcid.org/0000-0003-2088-6876

Contact details
School for Primary
Community and Social Care
Keele University
Newcastle-under-Lyme
Keele
United Kingdom
ST5 5BG
+44 (0)1782 734973
s.farooq@keele.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MR/T040378/1

Study information

Scientific Title
Traditional healers working with primary care and mental health for early intervention in psychosis in young persons: protocol for the development of intervention and feasibility cluster randomised controlled trial

Acronym
THE HOPE

Study objectives
This study will evaluate the the feasibility and acceptability of THE HOPE intervention by investigating the acceptability of task sharing, training procedures and to establish pathways for referral and management of FEP. Specifically the study will aim to answer the following research questions;
1. Does involving traditional healers and primary care in early detection and treatment of First Episode Psychosis (FEP) leads to earlier detection and better management of First Episode Psychosis (FEP) compared to treatment as usual in a low and middle income country (LMIC) setting?
2. Is it feasible and acceptable to establish care pathways for early detection and management of first episode psychosis in young person (FEP) for evidence based management of FEP?

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Approved 16/08/2021, Keele University Faculty of Medicine and Health Sciences Research Ethics Committee (Keele University, Staffordshire, ST5 5BG, UK; +44 (0)1782 732000; health.ethics@keele.ac.uk), ref: MH210177
2. Approved 15/11/2022, National Bio Ethics Committee Pakistan (Health Research Institute, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad, Pakistan; +92 (0)51 9224325; nbcpakistan@nih.org.pk), ref: 4-87/NBC-840/22/621

Study design
Pragmatic feasibility cluster pilot randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice, Other therapist office

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact detail to request a participant information sheet

Health condition(s) or problem(s) studied
First episode psychosis

Interventions
93 union councils in district Peshawar, Pakistan will be randomised using a 1:1 ratio to either intervention arm (THE HOPE) or Enhanced Treatment as Usual (ETAU) and stratified by urban /rural setting. The randomisation will be done by a statistician who is not part of the study team using computer-generated random numbers.

THE HOPE is an organizational/service level intervention with the following essential components:
1. A cascade model of training and task shifting from psychiatrists to Primary Care Physicians (PCP), and from PCP to TSH for early detection and treatment of FEP in adolescents.
2. Linking TSH and PCP with mental health professionals for early identification and referral of FEP and establishing community pathways for effective management of FEP. A group of TSH in the intervention arm will be linked with one PCP working in the nearest primary health care (PHC) facility who are trained in early identification and referral of FEP in young persons (see below). The TSH and PCPs will work collaboratively in establishing care pathways for the optimum management of FEP in young persons.

The cascade training in the intervention will consist of the following:
Training for Psychiatrists:
First, a team of psychiatrists with extensive experience in early intervention in psychosis and

child and adolescent psychiatry in the UK and Pakistan will train local psychiatrists in the early detection and treatment of FEP. The researchers will train two psychiatrists who will act as Master Trainers (MTs). These master trainers in turn will train PCPs. They will use face-to-face teaching, case studies and direct clinical supervision. The training will be based on recent guidelines such as NICE guidelines on early detection and management of psychosis in young people adopted for the local settings. MhGAP guidelines on the Training of Trainers (https://www.who.int/mental_health/mhgap/training_manuals/en/) will be used for training master trainers and quality assured by Khyber Medical University (KMU) University.

Training for Primary Care Physicians (PCPs):
Secondly, these MTs will train PCPs using interactive methods. PCPs in both arms will be trained in the mhGAP treatment guidelines while those in the intervention arm will receive additional training in early detection and management of FEP by MTs as described above.

Training for traditional healers:
Thirdly, these PCPs will train TSH for identification, referral and working collaboratively with PCPS and health services for effective management of FEP. The information gained from ethnographic and qualitative studies will inform the contents, format and methodology for training TSH. Based on our experience of working with traditional healers in the STOPS+ programme, the training will mainly focus on the following topics: overcoming barriers in working with psychiatric services, symptoms and signs of FEP and differentiating these from normal behaviours expected in adolescence, attitudes and behaviours towards people with psychosis, avoiding harmful practices, respecting individual autonomy, preventing gender-based discrimination and information about referral pathways.
The training will be delivered in a workshop. Two main educational tools used in workshops will be (i) case vignettes of typical patients for identification of suspected cases of FEP which have been successfully used in previous research with lay health workers and (ii) a video in the local language that will deliver the key messages on topics mentioned above.
The researchers have used this model of task shifting and cascade training in our previous research and will use a similar approach in implementing the intervention.

Control arm: Enhanced Treatment as Usual (ETAU)
The Enhanced Treatment As Usual (ETAU) will include treatment as usual provided in the local mental health services, enhanced by WHO mhGAP (mental health gap action programme) training for PHC physicians. The traditional and spiritual healers (TSH) in the control group will also be given generic training about good mental health care. Training will be of a similar duration to that for the intervention but the content will not include materials on early intervention in psychosis.

Intervention Type
Other

Primary outcome measure
This will be a feasibility cluster RCT. Key feasibility outcomes will include:
1. The total number of cases recruited in a 12-month period, with a minimum sample size of 90 during the 12-month period
2. Total number of cases referred by TSH and primary care physicians to psychiatrists and the proportion of suspected FEP in the referred cases during the recruitment period
3. The number of FEP cases suspected by TSH and PCPs during the 12-month period

4. The likelihood of the confirmed diagnosis of FEP based on interview diagnosis by a psychiatrist during the 12-month period and Duration of Untreated Psychosis (DUP) in those meeting criteria for FEP during the 12-month recruitment period

Secondary outcome measures

In addition to feasibility outcomes, the study will aim to measure the following clinical outcomes:
1. Psychopathology is measured by Brief Psychiatric Rating Scale (BPRS), Young Mania Rating Scale (YMRS), Hamilton Depression Rating Scales (HDRS), Clinical Global Impression Scale (CGI) for measuring improvement in symptoms and remission rates at baseline and 12-week post-baseline
2. Occupational and social functioning is measured using the global assessment of functioning (GAF) at baseline and 12-week post-baseline
3. Duration of untreated psychosis will be measured using the Comprehensive Assessment of At Risk Mental States (CAARMS) at baseline
4. Quality of life is measured using EuroQol-5 at baseline and 12 weeks post-baseline
5. Family burden is measured using the Perceived Family Burden Scale (PFBS) at baseline and 12 weeks post-baseline
6. Stigma measured using the Internalized Stigma of Mental Illness (ISMI) at baseline and 12 weeks post-baseline
7. Physical health is measured by weight and Body Mass Index at baseline and 12 weeks post-baseline
8. Substance abuse is measured using the Drug Abuse Screening Test (DAST-10) at baseline and 12 weeks post-baseline
9. Response to antipsychotics treatment is measured by Change in Psychiatric Rating Scale (BPPRS) from baseline to 4 weeks after starting antipsychotics
10. Adherence to antipsychotic treatment is measured by Medication Adherence Rating Scale (MARS) at 3 months follow up
11. Rates of disengagement defined as a participant's refusal to engage with treatment or not responding to contact requests for a consecutive 4 weeks period during follow-up while still residing within the study site catchment area, will be measured at 3 months follow-up
12. Service utilisation metrics measures will be used as a measure of the acceptability of the intervention at baseline and 12 months follow-up. These will include patients screened for suspected psychosis out of all those presenting at different contact points, the median time taken in screening, frequency and duration of contacts, median length of time to treatment from assessment to starting treatment and proportion of cases identified as At-Risk Mental State (ARMS) for FEP out of total accepted cases, the willingness of TSH to work with health services (indicated by the number of TSH approached, consented and completing training programme)
13. The acceptability of trial procedures will also be assessed through adherence to trial procedures and completion of the assessments at baseline and 12 weeks
14. Fidelity of intervention: first-episode psychosis services fidelity scale, modified and adapted for the local settings will be used to assess the degree to which mental health teams deliver evidence-based care for FEP, measured at baseline and follow up
15. The Client Service Receipt Inventory (CSRI) will measure direct and indirect costs at baseline and follow up to estimate health economic costs from the payer and provider perspective. The researchers will estimate mean, median and quartile costs at each timepoint

The progression criteria for the definitive trial:
In view of the lack of similar studies in this area, it is not possible to suggest clear progression criteria to guide the decisions about the feasibility to proceed to a definitive trial in future. The researchers suggest following a priori progression criteria in order to guide the feasibility of a

future definitive trial. The trial findings in the light of the following criteria will be presented to the trial steering committee which will advise about the feasibility of proceeding to the definitive trial.
Red: i.e., the progression to a definitive trial using the proposed intervention and procedures is not feasible. Recruitment below 90 in total (45 in both arms) over 12 months period, less than 70% of recruited sample completed all follow-up visits and less than 70% of TSH in both arms consented, participated in training, and worked with psychiatric services in referring the suspected cases.
Amber: i.e., the progression to a definitive trial using the proposed intervention is feasible but would require modifications in the intervention, recruitment or follow-up procedures. Recruitment of 90-130 participants in total over 12 months period, 70-80 % of recruited sample completed all follow-up visits and 70-85% of TSH in both arms consented, participated in training, and worked with psychiatric services in referring the suspected cases.
Green: i.e. the progression to a definitive trial using the proposed intervention is feasible without changes in the intervention, recruitment or follow-up procedures.

Overall study start date
01/09/2019

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Patients aged 14 to 25 years
2. Residing in one of the union councils in district Peshawar
3. First-ever psychotic (FEP) episode diagnosis made at interview by psychiatrists using a Composite International Diagnostic Interview based on the International Classification of Diseases, 11th revision (ICD-11) criteria for schizophrenia, persistent delusional disorder, acute and transient psychotic disorders, schizoaffective disorder, mood disorders (mania, severe depressive episode, bipolar affective disorder) with psychotic symptoms
4. Have not received antipsychotic medication previously, or if they already have used antipsychotic medications, it was for no longer than 6 weeks.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
14 Years

Upper age limit
25 Years

Sex
Both

Target number of participants
90

Total final enrolment
121

Key exclusion criteria
1. Evidence of overt learning disability
2. Organic brain damage or pervasive developmental disorder
3. Severe substance abuse (except nicotine dependence)
4. Young person or parent not willing to provide informed consent

Date of first enrolment
02/05/2023

Date of final enrolment
31/07/2024

Locations

Countries of recruitment
Pakistan

Study participating centre
Lady Reading Hospital, Peshawar
Soekarno Rd
Pipal Mandi
Khyber Pakhtunkhwa
Pakistan
25000

Study participating centre
Khyber Medical University, Peshawar
Phase V
Hayatabad
Peshawar
Khyber Pakhtunkhwa
Pakistan
25100

Sponsor information

Organisation

Medical Research Council

Sponsor details
Medical Research Council 2nd Floor
David Phillips Building
Polaris House
North Star Avenue
Swindon
England
United Kingdom
SN2 1FL
+44 (0)1793 416200
international@mrc.ukri.org

Sponsor type
Research council

Website
https://mrc.ukri.org/

ROR
https://ror.org/03x94j517

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study results would be shared with local communities, service users, traditional healers and health administrators. Throughout the study period, the researchers will hold several information-sharing and dissemination meetings involving different stakeholders to discuss the findings from different phases of the study and trial findings. The researchers will also produce training manuals used for health care professionals and TSH and these will be shared widely with relevant local and international health and policy agencies. The findings of the study will also be presented in local and international research and health-service research. At least three publications are planned which will be published in open-access resources. Manuscripts with the pilot trial results will be submitted for publication in peer-reviewed journals and presented at academic conferences. Trial results will be disseminated to patients with a summary sheet outlining the trial findings in lay language. The researchers will also disseminate their findings through social media such as Twitter accounts.

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The datasets generated during/or analyzed during the current study will be available on request from Professor Saeed Farooq (s.farooq@keele.ac.uk). The data sharing plan has been uploaded as an additional file to the record.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	Data management plan		11/04/2023	No	No
Protocol article		14/07/2023	17/07/2023	Yes	No