ISRCTN12146586 https://doi.org/10.1186/ISRCTN12146586

Mental Health and Transgender (MenTra): integrating mental health services into primary care settings; a mixed-methods study of the mhGAP intervention

Submission date
06/10/2025

Recruitment status
Not yet recruiting

Registration date
08/10/2025

Overall study status
Ongoing

Last Edited
18/11/2025

Condition category
Mental and Behavioural Disorders

[X] 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

Transgender people often experience high levels of stress, discrimination, and exclusion, which can lead to common mental health problems such as depression, anxiety, and suicidal thoughts. Unfortunately, most transgender individuals in Pakistan do not have access to supportive or inclusive mental health care. The Mental Health and Transgender (MenTra) study aims to find practical ways to bring mental health services closer to the transgender community by training general practitioners (GPs) in primary healthcare clinics to identify and manage depression and anxiety using the World Health Organization's Mental Health Gap Action Programme (mhGAP) guidelines. This is a pilot feasibility study, meaning it will test whether this approach can work in real-world clinics before running a larger trial. The study will involve 144 transgender participants in Peshawar who show signs of depression or anxiety. GPs trained in mhGAP will provide three short, weekly sessions of focused psychological support based on cognitive behavioural therapy (CBT). Researchers will measure symptoms of depression (PHQ-9) and anxiety (GAD-7) at the start, after 2 months, and again after 4 months. The study will also assess how easy it is to recruit and retain participants, whether the intervention is acceptable, and how well GPs follow the mhGAP guidelines. The findings will help improve access to mental health care for transgender people in Pakistan and provide lessons for expanding similar inclusive services in other low-resource setting

Who can participate?

The study will involve transgender adults aged 18 years or above who are living in Peshawar, Khyber Pakhtunkhwa, Pakistan. Participants must self-identify as transgender and express interest in improving their mental wellbeing through participation in a brief, structured psychological program delivered within primary care settings. To be eligible, potential participants must:

1. Screen positive for symptoms of both depression and anxiety, defined as a score of 3 or higher on the Patient Health Questionnaire-2 (PHQ-2) and Generalized Anxiety Disorder-2 (GAD-2) screening tools.

2. Be residents of Peshawar who are able to attend sessions at one of the participating general practitioners (GP) clinics.
3. Be able to understand the study procedures and provide written informed consent in Urdu, Pashto, or English.

What does the study involve?
Transgender adults residing in Peshawar will be informed about the MenTra study. Trained Gurus (Transgender community head/leader within each trans network or group) will provide a brief introduction to the purpose of the study and screen interested individuals using short mental health questionnaires (PHQ-2 and GAD-2) in the presence of the research team. Individuals who screen positive symptoms of depression and anxiety will be referred to the MenTra Research Assistant (RA) for further assessment.
The Research Assistant will explain the study in detail, provide the participant information sheet, and arrange a convenient time and date for the potential participant to review and sign the written informed consent form. Following consent, the RA will assign the participant to the nearest GP clinic to confirm eligibility through standardized screening tools and collect baseline demographic and clinical data, including depression and anxiety scores (PHQ-9 and GAD-7). Eligible participants will then be scheduled to attend three weekly face-to-face sessions of a brief psychological intervention delivered by mhGAP-trained General Practitioners. Each session will last approximately 45–60 minutes and will include:
Session 1: Psychoeducation about depression, anxiety, and suicidal ideation; understanding mental health and treatment options.
Session 2: Building coping skills, stress management techniques, and cognitive restructuring.
Session 3: Problem-solving skills, relapse prevention, and personalized strategies for ongoing emotional wellbeing.
All sessions will be conducted in a safe, inclusive, and confidential GP clinical setting. Participants who require additional support will be referred to mental health professionals for further care.
Follow-up assessments will be carried out by trained RAs, who are independent of the intervention delivery, 2 months and 4 months after the intervention. These assessments will measure changes in depression, anxiety, and overall wellbeing. In total, each participant will be involved in the study for approximately four months.
A subset of participants, along with selected GPs and Gurus, will also be invited to participate in qualitative interviews to share their experiences, perceptions of the intervention, and feedback on feasibility and acceptability. These insights will help refine the mhGAP model for broader implementation. Throughout the study, strict confidentiality, voluntary participation, and participant wellbeing will be prioritized. The MenTra study aims to develop an evidence-based, culturally sensitive, and inclusive model of mental health care for transgender individuals in Pakistan's primary care system.

What are the possible benefits and risks of participating?
Those who take part in this study may not receive direct personal benefits. However, participation may contribute to valuable knowledge that could improve future mental health services for transgender individuals in Pakistan and similar contexts. The information gained will help the MenTra research team evaluate and refine the integration of the WHO mhGAP intervention within primary care settings, aiming to make mental health services more accessible, inclusive, and sensitive to the unique needs of transgender communities.
Participants may experience indirect benefits such as receiving mental health screening and access to trained general practitioners (GPs) who provide structured psychological support using mhGAP guidelines, early identification and management of symptoms of depression, anxiety, or suicidal ideation, enhanced understanding of their mental health through psychoeducation and coping strategies discussed during sessions and a sense of empowerment and inclusion by

contributing to research that seeks to reduce stigma and improve care for transgender populations.
If this intervention proves effective, findings may inform public health policies and lead to broader implementation of culturally adapted mental health programs within primary care settings across Pakistan and beyond.
There are no anticipated risks involved for those who decide to take part in this study. Participants are under no obligation to answer any questions asked during the study that make them feel uncomfortable. The information received from the participants and data generated during the course of study will not be used in any way that might cause any harm. Participants will be informed of their right to withdraw from the study at any time. The withdrawal from the study will not affect their routine care seeking.

Where is the study run from?
Khyber Medical University (Pakistan)

When is the study starting and how long is it expected to run for?
June 2025 to December 2026

Who is funding the study?
Health Research Institute, National Institute of Health Pakistan (Pakistan)

Who is the main contact?
Dr Saima Aleem, Saima.aleem@kmu.edu.pk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SG-23/R4-168

Study information

Scientific Title
Mental Health and Transgender (MenTra): a feasibility trial of integrating mental health services into primary care settings using the mhGAP intervention

Acronym
MenTra

Study objectives
The Mental Health and Transgender (MenTra) study is designed as a pilot feasibility trial to explore the integration of the WHO's mhGAP intervention for common mental health disorders into routine primary care services for transgender populations.

Specifically, this mixed-methods study aims to: (1) assess the prevalence and levels of depression, anxiety, and suicidal ideation among transgender individuals; (2) pilot the delivery of the mhGAP intervention within primary healthcare facilities (GP Clinics); and (3) conduct a comprehensive process evaluation to assess the feasibility, acceptability, and fidelity of intervention delivery.

Findings from this pilot will inform the design and conduct of a future large-scale trial evaluating the effectiveness of mhGAP-based integration in improving mental health outcomes among transgender populations.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/09/2025, Khyber Medical University Ethics Committee (Phase V Hayatabad, Peshawar, 25000, Pakistan; +92 (0)919217258; dr.zohaibkhan@kmu.edu.pk), ref: Dir/Ethics/KMU /2025/09/183

Study design
Quasi-experimental pilot feasibility trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression and anxiety among transgender individuals

Interventions
Intervention:
The intervention comprises the integration of WHO's mental health Gap Action Program (mhGAP) protocols into primary care practice (GP Clinics). General practitioners will be trained to identify, diagnose, and manage common mental disorders among transgender individuals. The intervention emphasizes brief, structured psychological support, including three sessions of focused cognitive-behavioral therapy delivered one week apart.

mhGAP Intervention:
The mhGAP intervention package emphasizes evidence-based, low-intensity psychological therapies, and continuous monitoring. The adaptation for transgender populations includes sensitization to minority stress, stigma, and gender-affirming communication. A supervision system led by psychiatrists will reinforce adherence to mhGAP protocols and ensure quality of care.
A brief mhGAP intervention grounded in the principles of Cognitive behavioral approach will be specifically tailored for transgender population. It will consist of three weekly face-to-face sessions, each lasting 45 to 60 minutes. Each session will address a distinct agenda: Session 1 will cover psychoeducation about common mental health condition, suicidal ideations and its treatment, Session 2 will focus on coping skills and strategies, and lastly Session 3 will introduce problem-solving techniques. Following these sessions, formal booster sessions will be planned, depending on client need.
The intervention resources will consist of (a) a Master trainer's manual to guide GPs through the implementation of each intervention session; (b) a handbook to be used by the GPs in which sessions details along with character examples to demonstrate how each intervention strategy can be implemented by clients in their life; (c) flyers to aid the intervention delivery by GPs and (d) a hand out/ workbook that uses graphical illustrations to demonstrate intervention strategies to clients and helps them keep a record of intervention strategies practiced by them at home throughout the week.

Training of Gurus and GPs:
Community Gurus will receive three days of training on identifying depression and anxiety using PHQ-2 and GAD-2, with tools translated into local languages and validated through mock sessions. Their role is limited to community sensitization and participant screening. Their role will remain focused on identifying at-risk individuals and referring them to trained GPs for further management. Training modules will adopt interactive, competency-based approaches to enhance retention and skill application.
A Training of Trainers (ToT) model will be adopted for the mhGAP intervention training of general practitioners (GPs). Two-day training will be conducted for a group of Master Trainers, including clinical psychologists. The training will cover three core sessions of the mhGAP

intervention.
Following the Training of Trainers (ToT) phase, General Practitioners (GPs) will participate in an intensive five-day mhGAP training facilitated by the Master Trainers. This training will prepare GPs to integrate mental health into routine primary care, with a strong emphasis on early identification and brief intervention. It will also improve their clinical competencies in the assessment, diagnosis, and management of depression, anxiety, and suicidal ideation.
To ensure accuracy and competence, the training will incorporate active learning methods, daily skill tests, and supervised role plays. Following the main training, General Practitioners (GPs) will deliver the intervention to a simulated client as part of on-site or in-field training. Upon completion of this phase, refresher trainings will be scheduled every three months to consolidate learning, address implementation barriers, and maintain intervention quality.

Intervention Delivery Procedure:
Following referral, participants will undergo baseline assessment using GAD-7 and PHQ-9. GPs will then provide the mhGAP-guided intervention over three consecutive weeks. Fidelity to intervention protocols will be monitored through supervisory visits, structured checklists, and refresher training. Post-intervention assessments will be conducted at 2 months and 4 months to capture both short- and medium-term effects.

Intervention Type
Behavioural

Primary outcome(s)
1. Depressive symptoms measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline (pre-intervention), 2-month follow-up, and 4-month follow-up
2. Anxiety symptoms measured using the Generalized Anxiety Disorder-7 (GAD-7) at baseline (pre-intervention), 2-month follow-up, and 4-month follow-up

Key secondary outcome(s))
Feasibility and process outcomes:
1. Recruitment rate: number and proportion of eligible participants who consent and enroll, measured at baseline.
2. Retention rate: number and proportion of participants completing both follow-up assessments at 2 and 4 months.
3. Treatment adherence: number and proportion of participants attending all three scheduled mhGAP-based CBT sessions. Participants missing no more than one session are classified as “adherent”; others as “non-adherent.” Measured at 4 months post-intervention, based on GP session logs.

Completion date
19/12/2026

Eligibility

Key inclusion criteria
1. Adults (aged ≥18 years)
2. Self-identifying as transgender
3. Residing in district Peshawar
4. Possessing a valid national identity card
5. Positive screen for both depression and anxiety, defined as scores ≥3 on the Patient Health Questionnaire-2 (PHQ-2) and Generalized Anxiety Disorder-2 (GAD-2)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Individuals already engaged in ongoing psychiatric or psychological treatment at study onset will be excluded to avoid confounding treatment effects

Date of first enrolment
19/03/2026

Date of final enrolment
19/06/2026

Locations

Countries of recruitment
Pakistan

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

Sponsor information

Organisation
Health Research Institute, National Institute for Health Pakistan

Funder(s)

Funder type
Government

Funder Name
Health Research Institute Pakistan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated or analysed during this pilot study will be available on request from Dr Saima Aleem (saima.aleem@kmu.edu.pk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes