







### CONTNEWS

The Quarterly Newsletter of the CONTROL Research Programme

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## TRIAL UPDATE



#### **CONTROL Definitive Trial**

In the current quarter, till 28 March 2025, a total of 137 participants have been recruited into the definitive trial, with 68 participants having completed their 8-week follow-up. Four additional recruitment centers were activated: Prime Hospital and Al-Khidmat Hospital on January 21, 2025, followed by Kuwait Teaching Hospital (March 5, 2025) and Dr. Rafiq Tanooli clinic (March 10, 2025).

External monitoring visits to KMU and on-site monitoring visits at recruitment centers were conducted as part of ongoing trial oversight. Dr. Naveed Afzal performed monitoring visits at Emergency Satellite Hospital Nahaqi (February 24, 2025), Khyber Teaching Hospital (February 26, 2025), Alfalah Center, and Begum Zari Chest and TB center (both on March 10, 2025). Dr. Imran Gillani conducted visits at DHQ Haripur (February 27, 2025), TB Center Kangra, and Civil Hospital Kalabat (both on March 20, 2025). The independent monitors were accompanied by Dr. Shaista Rasool, Dr. Rubab Farooqi, Dr. Zarmina Fahim, Dr. Asma Habib, and Dr. Aiman Niaz. A second external monitoring visit at KMU was conducted by Dr. Naveed Afzal on March 18, 2025.

Internal monitoring visits were also conducted by Dr. Shaista Rasool, Dr. Zarmina Fahim, and Dr. Asma Habib at Alfalah center and Begum Zari Chest and TB center (February 18, 2025), and by Dr. Rubab Farooqi, Dr. Aiman Niaz, and Dr. Asma Habib at Prime Hospital (February 20, 2025).

These monitoring visits confirmed satisfactory trial progression and adherence to protocols at all recruitment centers

# Advancing Skills in CBT for DOTS Facilitators





The Directly Observed Treatment Short-course (DOTS) facilitators participated in a refresher training program on Cognitive Behavioral Therapy (CBT). This intensive training was conducted across two blocks: the first from December 19th to 21st, 2024, and the second on January 3rd and 4th, 2025. The initial session of the first day, facilitated by Saara Khan, the Intervention Development Coordinator and a certified CBT Master Trainer, was dedicated to experiential learning through role-playing exercises and constructive feedback. This focused approach enabled participants to enhance their proficiency in delivering effective CBT interventions. Notably, Nazia Gul (KTH) and Chan Zaib (Dr. Rafique Tanooli Private Clinic) led impactful role-playing scenarios conducted in Urdu.

This linguistic accessibility significantly enhanced the practical application of CBT techniques, ensuring facilitators are well-prepared to confidently implement these skills within diverse real-world contexts.



This comprehensive training initiative represents a critical advancement in strengthening the provision of mental health support for tuberculosis (TB) patients by equipping frontline DOTS facilitators with essential counseling competencies.

# **Enhancing Counseling Skills Through Motivational Interviewing**

The second day of the continuing professional development workshop for Directly Observed Treatment, Short-course (DOTS) facilitators, led by Faryal Fazal, a certified Master Trainer in Cognitive Behavioral Therapy (CBT), concentrated on Motivational Interviewing (Session 2). This pivotal session emphasized the application of effective communication strategies to enhance the empowerment of individuals undergoing treatment for tuberculosis (TB).





The training incorporated interactive role-playing scenarios, featuring compelling performances by Nadia Jalal from the Multi-Drug Resistant TB unit at Lady Reading Hospital (MDR TB LRH) and Tahzeem Akhtar from the TB Centre in Kangra. Their delivery in Urdu and Pashto ensured critical cultural sensitivity and broad accessibility for participants.



experiential These exercises instrumental were in strengthening the facilitators' capacity guide to patients toward positive behavioral modifications, thereby fostering improved treatment adherence and enhanced psychological well-being.

#### Strengthening Problem-Solving Skills in CBT Training

The third day of the Cognitive Behavioral Therapy (CBT) refresher training for Directly Observed Treatment, Short-course (DOTS) facilitators, under the guidance of Rafia Khalil, a certified CBT master trainer, concentrated on the pedagogical application of problem-solving role-play methodologies. This session aimed to fortify the fundamental tenets and preserve the systematic framework inherent in Cognitive Behavioral Therapy. DOTS facilitators actively participated in experiential learning exercises, with notable demonstrations of practical competencies through interactive role-play scenarios presented by Asad Ullah from the Tuberculosis Centre (TBC) Gunj and Mushtag Ali from Civil Hospital, Khalabat, Their enactments underscored the efficacious implementation of CBT techniques, thereby cultivating a more robust groundwork for the provision of mental health support to individuals treatment for tuberculosis. undergoing instructional module represents a significant progression towards augmenting the self-assurance and proficiency of facilitators in the seamless integration of mental health care within the established TB treatment protocols.







# Refining Cognitive Restructuring Skills

The fourth and fifth days of the Cognitive Behavioral Therapy (CBT) refresher training for DOTS facilitators, under the guidance of Zumar Malik, a certified CBT master trainer, focused on cognitive restructuring. This fundamental CBT technique empowers patients to identify, critically evaluate, and reframe maladaptive thought patterns. Notably, Gul Muhammad from Al-Khidmat Hospital and Sikandar Khan from Al-Falah Hospital delivered exemplary therapist-patient role-plays. Their enactments effectively illustrated practical methodologies for guiding individuals toward more rational and adaptive cognitive frameworks. These demonstrations underscored the applied utility of cognitive restructuring technique, ensuring facilitators are adept at providing crucial mental health support to individuals undergoing treatment for tuberculosis.

These interactive sessions served to fortify the clinical competencies and self-efficacy of the facilitators, thereby promoting enhanced mental health outcomes within the context of TB care. Furthermore, a comprehensive five-day CBT training initiative was successfully undertaken for two newly appointed DOTS facilitators representing Alfalah Hospital and Lady Reading Hospital (LRH). Conducted on the 13th, 14th, 15th, 20th, and 21st of February 2025, these intensive sessions equipped the new facilitators with foundational skills essential for their roles.





# Onsite CBT Training at TB Facilities in Haripur & Peshawar

Following the efficacious completion of the CBT training program, the subsequent phase of on-site practical training had formally commenced at designated tuberculosis (TB) facilities within the Haripur and Peshawar districts, spanning the period from January 10th to January 19th, 2025. Certified CBT Master Trainers are currently engaged in intensive mentorship with Tuberculosis Health Workers (TBHWs), providing direct, experiential guidance to enhance their proficiency in the delivery of CBT interventions. This approach ensures that TBHWs acquire a robust and nuanced understanding of CBT methodologies, thereby empowering them to effectively address the mental health needs of TB patients as an integral component of the definitive trial. By synergistically integrating theoretical knowledge with real-world application, this strategic initiative serves to fortify the capabilities of frontline healthcare professionals, thereby establishing a foundation for sustainable integration of mental health interventions within the continuum of TB care





#### Mastering CBT for Enhanced Patient Support

The necessity for periodic refresher training was identified as crucial for augmenting the knowledge base, resolving ambiguities, and developing robust conceptual understanding among Tuberculosis Health Workers (TBHWs) involved in the CONTROL study. In response to this exigency, a targeted refresher program was conducted on March 6-7 and March 13-14, 2025, at Khyber Medical University. The format and structural design of sessions facilitated focused interaction during role-playing exercises and enabled tailored guidance provision for each participant.





Core content areas included a General Information Sheet and the Patient Health Questionnaire-2 (PHQ-2), the cultivation of effective therapeutic and communication skills, the application of techniques to establish rapport, the strategic assignment and review of homework to reinforce learning, and the structured delivery of Cognitive Behavioral Therapy (CBT) sessions. DOTS facilitators actively engaged in these role-playing scenarios, providing a secure and structured environment for the experiential acquisition of essential CBT techniques.

CBT Master Trainers and a clinical research fellow provided comprehensive and nuanced feedback, both acknowledging participant proficiencies and opportunities for further development. This interactive and personalized approach served to effectively bridge the theoretical-practical divide, thereby empowering fDOTS facilitators with the requisite confidence to implement CBT principles effectively within their routine clinical practice.

# CONTROL Definitive Trial Recruitment and Monitoring Updates





Recruitment for the CONTROL definitive trial officially began on November 18, 2024, across three pilot centers—Khyber Teaching Hospital, Emergency Satellite Hospital Nahaqi (Peshawar), and District Headquarter Hospital (Haripur). These sites were selected for their prior involvement in the pilot phase and readiness in terms of staff training and infrastructure.



A staggered rollout strategy followed:

- On December 23, 2024, four additional sites were activated: TB Center Kangra Colony, Civil Hospital Kalabat Township, Alfalah Medical Centre, and Begum Zari TB and Chest Hospital.
- On January 21, 2025, Prime Hospital and Al-Khidmat Hospital were added.
- In March 2025, Kuwait Teaching Hospital (March 5) and Dr. Rafiq Tanoli Clinic (March 10) joined the recruitment network.

As of March 18, 2025, a total of 122 participants have been recruited and randomized into trial arms, with 54 participants completing the 8-week follow-up.



# CONTROL STUDY External and Internal Monitoring Visits

To ensure trial fidelity and adherence to protocols, multiple monitoring visits were conducted across participating sites:

- Dr. Naveed Afzal carried out independent monitoring at:
  - Emergency Satellite Hospital Nahaqi (Feb 24)
  - Khyber Teaching Hospital (Feb 26)
  - Alfalah Medical Centre & Begum Zari Center (Mar 10)
  - Khyber Medical University (KMU) (Mar 18)
  - Dr. Imran Gillani monitored:
    - DHQ Haripur (Feb 27)
    - o TB Center Kangra & Civil Hospital Kalabat (Mar 20)
  - Internal monitoring visits were conducted by:
    - Dr. Shaista Rasool, Dr. Zarmina Fahim, and Dr. Asma Habib at Alfalah and Begum Zari Centers (Feb 18)
    - Dr. Rubab Farooqi, Dr. Aiman Niaz, and Dr. Asma Habib at Prime Hospital (Feb 20)

The monitoring confirmed satisfactory trial implementation with strict adherence to study protocols at all centers

#### **Process Evaluation Updates**

In January 2025, process evaluation team developed the process evaluation protocol for the CONTROL trial and finalised version of the protocol was submitted to BMC Trials on March 19, 2025.

In February 2025, the team began the expert validity process for the Applied Mental Health Research Group (AMHR) tool, adapted for the CONTROL study and created a Google Form for Round 1, involving 15 experts from various fields, including CBT, psychiatry, public health, research, and medical education. Based on their feedback and quantitative assessments using the Content Validity Index (CVI) and Content Validity Ratio (CVR), the AMHR tool was revised. Team then developed a second Google Form for Round 2, which was sent to the same panel for further evaluation. After additional analysis of the CVI and CVR scores, the tool was finalized, and a certified language expert translated the final version into Urdu for linguistic and contextual accuracy.

In March 2025, tailored topic guides for qualitative interviews to explore the CONTROL trial's implementation processes were developed. These guides were designed for various respondent groups, including patients (control and intervention arms), trial staff, DOTS facilitators, and medical officers. The patient interview guides were refined based on feedback from Dr. Ghazala, a representative of the Patient and Public Involvement and Engagement (PPIE) group. Since December 2024, the team had also been collecting fidelity data for the process evaluation, which includes audio recordings of randomly selected CBT sessions. All recording, storage, and management activities are meticulously documented.

#### Future directions:

- Conduct cognitive interviews with end users (patients) to assess the clarity and comprehensibility of the AMHR tool.
- Hold a consultation meeting with the PPIE Research User Group to review and discuss the qualitative interview topic guides.
- Share all finalised topic guides with the CONTROL trial leads for review and feedback.
- Develop a detailed field plan for conducting the qualitative interviews

#### **CAPACITY DEVELOPMENT**



#### Dr. Amir Wahab

Dr. Amir Wahab, originally from Swat and currently residing in Peshawar, recently completed his FCPS in Psychiatry from Lady Reading Hospital, Peshawar. He earned his MBBS from Al Nafees Medical College, Islamabad (2016-17) and has since been dedicated to clinical research in mental health.

He previously served as a Clinical Research Fellow in THE HOPE clinical trial and has been working in the same capacity for the CONTROL trial since September 2022. Alongside his research contributions,



He is currently pursuing a Master of Health Research at IPH, Khyber Medical University, further strengthening his expertise in the field

#### **Dr. Muhammad Sohaib**

Muhammad Sohaib, a PhD Public Health Scholar at the School of Medicine, Keele University, specializes in neglected tropical diseases, mental health, and stigma-related health outcomes. He holds a Master's in Public Health and an MS in Epidemiology and Biostatistics from Khyber Medical University, Pakistan, a Master's in Drug Toxicology and Safety Pharmacology from of Bradford, UK, the University and postgraduate diplomas in Health Economics, Clinical Trials, and GIS Mapping.



With extensive experience in quantitative and qualitative research, Sohaib has contributed to multiple peer-reviewed publications and community-based interventions. He previously worked as a Health Communication Officer at the Directorate General Health Services, KP, Pakistan.

Currently, as a PhD scholar under the CONTROL project (funded by NIHR), he is researching stigma in comorbid tuberculosis and depression, aiming to inform policy and intervention strategies for vulnerable populations in low-resource settings.

#### NIHR SPARC Awardee-Bushra Bibi

During the NIHR SPARC placement, Bushra undertook the systematic review module titled "The principles and methods of systematic review" University of Central Lancashire, UCLan. This comprehensive course spanned 12 sessions over four months, enhancing her understanding of evidence synthesis methods. She actively contributed to the Rapid Conversion Evidence Summaries (RaCES) team, where she developed a mini-review of a systematic review, now scheduled for publication in the Journal of Tuberculosis and Lung Diseases. This experience sharpened her skills in evidence appraisal and research writing. Throughout the placement, Bushra engaged in a wide range of seminars and workshops organized by the Research Facilitation and Delivery Unit (RFDU),

- How to develop a research question
- Provocation seminar series 2: disbelief and disregard healthcare for people with energy-limited conditions
- Thrive Centre postgraduate seminar and workshop
- ARCFEST quarterly event
- NIHR Academy members' conference 2024

Bushra Bibi with
Colette Miller
(Research Capacity
Delivery Manager and
SPARC supervisor)

including:

Bushra also collaborated with the stroke rehabilitation team on the DARE project, contributing to Urdu translations and supporting the development of audio-based multilingual instructions in a stroke rehabilitation app.

Beyond academic involvement, she joined societies at UCLan and explored several cultural aspects, and built personal and professional connections.

Mark Goodall (NIHR)

Research Fellow and

RaCES team member)

This placement significantly improved her research and communication skills, expanded her professional network, and deepened her expertise in systematic reviews, research writing, and networking.

Bushra's Hikig adventures with Mountaineering Society UCLan



#### NIHR SPARC Awardee-Maryiam Rahim

Mariyam Rahim worked under the supervision of Professor Ivonne Trapala (CTU Director) and Professor Martyn Lewis (CONTROL trial statistician), with additional mentorship from Professor Jonathan Hill at KEELE University, UK. The placement was strategically structured to develop her expertise in clinical trial methodologies, operational conduct, and statistical analysis. She collaborated closely with Sarah Lawton, Senior Trial Manager, to explore trial strategies and management processes. In addition to her work at the CTU, she contributed to two rehabilitation science trials led by Professor Hill, gaining hands-on experience in applied trial research.





A key component of her placement was regular participation in monthly Patient Public Involvement and Engagement (PPIE) meetings, where she observed how patient feedback shapes research design and care planning for musculoskeletal conditions. She also engaged in Keele Postgraduate Research Association (KPA) seminars, presenting her work, participating in scholarly discussions, and receiving valuable feedback. For professional development, she presented her research proposal at a postgraduate seminar in September 2024 and attended the UK Research in Musculoskeletal Epidemiology (UK-RiME) conference. She contributed to a Delphi study on "Quality Indicators for Community Musculoskeletal Services," helped develop a WHO scoping review protocol, and successfully secured grant funding. Her role in the TRANSLATE project's qualitative team further deepened her expertise, particularly in topic guide development and collaborative research.

Guided by Professor Hill, she developed a PhD research proposal during the SPARC placement. His mentorship was key in refining her research questions, methodology, and funding strategy. After several revisions and critical feedback, she submitted her proposal to various European funding bodies and was awarded full PhD funding. This accomplishment stemmed from the comprehensive training and exposure gained through the SPARC placement, which served as a pivotal step in her transition from master's study to doctoral research and fostered lasting professional networks in the field.

### COMMUNITY ENGAGEMENT INITIATIVE



# NIHR CEI Guiding Principles Pilot Project Completion

The "Art for Impact" CEI pilot project successfully operationalized NIHR's CEI Guiding Principles within a culturally diverse and complex setting in Khyber Pakhtunkhwa, Pakistan, embedded in ongoing CONTROL study CEI activities. The project, completed on 15<sup>th</sup> January 2025, ensured inclusive participation, cultural relevance, and shared decision-making across all phases by engaging local and Afghan refugee communities from the outset. A key achievement was the co-creation of the animated video "Gul Makkai ke Kahani" by the community to raise awareness on TB and mental health.

The participatory approach enabled early and continuous input from the CONTROL PPIE advisory group, shaping content that reflected community preferences. Co-creation workshops empowered community members, especially women and refugees, to lead discussions, make creative choices, and guide messaging strategies. The project embraced flexibility by offering multiple art forms and adapting to feedback, ultimately selecting animated video as the most suitable medium.

Significant impacts included enhanced awareness among community members, two real-life TB diagnoses resulting from the video, and strengthened trust and credibility for research initiatives. The pilot also fostered professional growth for the team and laid a foundation for future CEI-based collaborations and funding opportunities.

Despite security and cultural challenges, the team's culturally sensitive, gender-responsive, and adaptive methods enabled safe and effective implementation. The pilot was showcased at the CONTROL Global Mental Health Symposium and received recognition from academic and community leaders. Its outcomes serve as a replicable model for CEI in similar settings, promoting sustainable, community-led solutions for public health awareness and engagement.

## Strengthening Community Awareness via Story of Gul Makkai



The community-driven awareness video, "Gul Makai Ki Kahani (The Story of Gul Makai)," developed as part of the NIHR Community Engagement and Involvement (CEI) Guiding Principles pilot project, is now live on the @CONTROL\_NIHR YouTube channel! Created entirely with insights and contributions from the community, this powerful video is now available for everyone to watch and share.

Watch here: <a href="mailto:youtube.com/@control\_nihr">youtube.com/@control\_nihr</a>

The video presents the story of an Afghan girl caught between the battle of TB and depression, just days before her wedding. Despite the weight of stigma and silence, she finds the strength to rise above her struggles. Her journey transforms from pain to purpose as she begins sharing her story, breaking the taboos surrounding TB and mental health. Through the strong support of Lady Health Visitor and her voice and courage, she becomes a symbol of resilience and hope, inspiring others to speak up, seek help, and stand tall against the stigma.

By integrating local perspectives, the video serves as a powerful tool for raising awareness, educating, and strengthening community-driven action. It highlights the effectiveness of participatory approaches and reinforces the role of community-led solutions in creating meaningful and sustainable change.

## Community Voices Driving Impact: Feedback on CEI Awareness Video



Collecting feedback from community members is essential to ensuring that the NIHR CEI Guiding Principles pilot project remains true to its core ethos: by the community, for the community. In line with this commitment, the CEI team visited the Naguman Afghan Refugee Camp during the second week of January 2025 to screen the awareness video "Gul Makkai Ki Kahani" for camp residents.

The video was received with great enthusiasm, with community members expressing deep appreciation for its powerful storytelling and the authentic representation of their voices and experiences. Many attendees shared the video with friends and family, significantly extending its reach and impact. The visit also provided an opportunity to gather meaningful feedback, which was thoughtfully documented and will serve to guide and strengthen future CEI initiatives.





# CONTROL CEI Team Meeting With Afghan PPIE Advisory Group Members

The CONTROL CEI team convened a meeting with Afghan members of the PPIE advisory group on 13 February 2025 to share PPIE and CEI updates. During the meeting, members were informed that the final report of the CEI pilot, detailing the project's activities, outcomes, and reflections, had been formally submitted to the NIHR. The Project Manager acknowledged the pivotal role played by the advisory group, emphasizing that their insights were integral to the development of culturally grounded outputs.

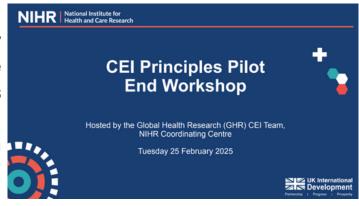


The conversation also addressed the pressing issue of the potential repatriation of Afghan refugees back to Afghanistan. Members expressed concern regarding the uncertainty surrounding this transition and its implications for continued community engagement. In response, the CEI team facilitated a discussion on how future CEI initiatives might evolve to remain relevant and impactful amid this changing context.

The discussion also focused on the CEI activities for the next quarter to facilitate the recruitment in the CONTROL definitive trial and to facilitate TB patients residing in different refugee camps.

#### **NIHR CEI Pilot End Workshop**

THE NIHR CEI Principles Pilot End Workshop was held on 25th February 2025, where 11 pilot projects were showcased. Each project assigned five minutes of time and three slides only focusing on methodology, lessons learnt, and challenges.





From Asia, three projects were selected to pilot the guiding principles.

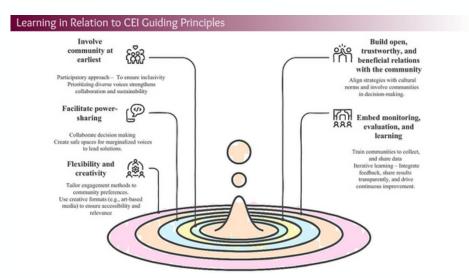
Dr. Saima Aleem, Co-Lead of the NIHR CEI Pilot project from the CONTROL study, presented Art for Impact.



#### Art for Impact: Community-Driven Creations for Tuberculosis and Mental Health Awareness

NIHR CEI GUIDING PRINCIPLES PILOT PROJECT



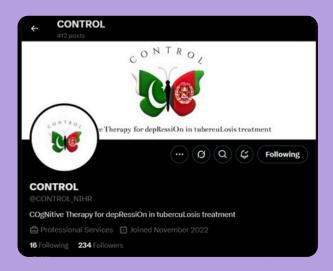


NIHR CEI Global team appreciated all the projects and teams and mentioned that the projects will be showcased on the official website, and their team is currently identifying the principles that have come out as strongest in each of the pilots, and will choose two examples for each of the principles to demonstrate the principle in practice.

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