The CONTROL

(COgNitive Therapy for depRessiOn in tubercuLosis treatment)

to improve outcomes for depression and TB in Pakistan and Afghanistan

Funded by: RIGHT3, NIHR

Reference: NIHR201773

“Two-days Workshop on Tools Training for CONTROL Team”

Date: June 24th & 25th, 2025

Facilitators: Dr. Amir Aziz, Dr. Amir Wahab, Dr. Rubab, Faryal

Participants: Research Assistants

Report writing: Dr. Shawana Bangash (Research Assistant)

Report Reviewed by: Dr. Rubab Farooqi

Overview Summary

A comprehensive training session on tools was conducted on 24th and 25th June, 2025, to enhance the competencies of the CONTROL trial team in essential procedures and data collection methodologies. This intensive two-day training program was designed to reinforce critical skills in diagnostic assessment, informed consent processes, and standardised data collection tools, which are fundamental to the successful implementation of the CONTROL trial.

The training aimed to ensure consistency in trial procedures, enhance data quality, and strengthen the team's capability to effectively manage complex mental health assessments. The sessions were structured to provide both theoretical knowledge and hands-on practical experience, enabling team members to apply their learning in real-world clinical settings with confidence and precision.

The training program emphasised the importance of maintaining ethical standards, ensuring participant safety, and collecting high-quality data that would meaningfully contribute to the advancement of mental health research. Special attention was given to cultural sensitivity and linguistic accessibility, with materials and discussions conducted in English and Urdu to accommodate the diverse backgrounds of the team members and study participants.

Objectives of the Training

- To ensure a comprehensive and consistent understanding of the CONTROL trial's rationale, methodology, and assessment flow.
- To provide in-depth theoretical and practical training on the use of various assessment tools.
- To standardize the administration of tools across English and Urdu versions.
- To strengthen informed consent practices and ethical engagement with participants.
- To foster teamwork and mutual learning among facilitators and field implementers.
- To ensure alignment of data collection practices with the protocol and regulatory standards.

Day 1 - June 24, 2025

Opening Session: Overview of the CONTROL Trial
Time: 9:00-9:30 AM

Facilitator: Dr. Rubab Farooqi (Trial Coordinator)

Dr. Rubab welcomed the participants and provided a comprehensive introduction to the CONTROL trial. She revisited the rationale behind the study, emphasizing the significance of addressing mental health issues through integrated care models. The session elaborated on trial phases, the recruitment process, and the key assessment time points. Participants were reminded of their roles and responsibilities, timelines, and the ethical significance of standardized assessments.

Session 1: PHQ-2 and EuroQoL EQ-5D
Time: 10:00-11:00 am
Facilitators: Dr. Amir Aziz and Dr. Amir Wahab

- **PHQ-2:** This brief screening tool for depression is used at the initial contact point. The facilitators walked through the purpose of each question, cultural sensitivity, and scoring criteria.
- **EuroQoL EQ-5D:** This session emphasized the importance of assessing health-related quality of life. Participants practiced both English and Urdu versions and discussed contextual relevance.

Activities:

- Interactive role-play to simulate patient interactions.
- Discussion on handling incomplete responses and clarifying ambiguous items.

Tea Break

Time: 11:00-11:30 AM

Session 2: PHQ-9 and Harvard Trauma Questionnaire (HTQ)
Time: 11:30-12:30 am

Facilitators: Dr. Amir Aziz and Dr. Amir Wahab

This session expanded on the PHQ-2 screening to the more detailed PHQ-9 scale, which quantifies depressive symptoms.

- **HTQ:** Focused on assessing trauma exposure, the facilitators elaborated on its structure and how to handle emotionally charged responses. Cultural and linguistic challenges in trauma-related discussions were addressed.

Practice:
Participants conducted mock interviews, switching roles between assessor and participant, followed by group feedback sessions.

Session 3: WHO-DAS 2.0
Time: 12:30-2:00 pm

Facilitators: Dr. Amir Aziz and Dr. Amir Wahab

Participants were introduced to the WHO Disability Assessment Schedule (12-item version), which evaluates six domains of functioning. Emphasis was placed on probing techniques and clarifying item interpretations.

Outcome:
Participants gained fluency in navigating between subjective self-reports and structured questioning techniques.

Hands-on Training & Debriefing
Each session incorporated real-time demonstrations, peer practice, and facilitator-led feedback. The day concluded with an open forum where participants reflected on their learning and discussed field-level implementation challenges.

Lunch Break

Time: 2:30 PM onwards

Day 2 - June 25, 2025

Facilitators

Dr. Amir Aziz
Clinical Research Fellow, CONTROL Program
Lead Facilitator for Diagnostic Assessments and Data Collection Tools

Faryal
Research Coordinator
Co-facilitator for Assessment Scales and Practical Training Sessions

Session 1: Diagnostic Assessment and Inclusion/Exclusion Criteria

Time: 9:00-10:00 AM
Facilitators: Dr. Amir Aziz & Faryal

Training commenced with a comprehensive review of the diagnostic criteria and assessment protocols essential for participant screening in the CONTROL trial. Dr. Amir Aziz provided

an in-depth presentation on the diagnosis of bipolar disorder according to the ICD-10 criteria, emphasising the importance of accurate diagnostic assessment for trial eligibility.

The key topics covered included:

- **Bipolar Disorder Diagnosis (ICD-10)**: Detailed examination of diagnostic criteria, mood episodes classification, and differential diagnosis considerations
- **Suicidal Risk Assessment**: Implementation of mhGAP (Mental Health Gap Action Programme) protocols for assessing current suicidal tendencies and developing appropriate safety plans
- **Exclusion Criteria Identification**: Recognition of severe mental illness forms, learning disabilities, and substance abuse disorders (excluding nicotine dependence) that would preclude trial participation
- **Inclusion and Exclusion Criteria Assessment**: Systematic approach to participant screening ensuring appropriate trial enrolment.

The participants engaged in case study discussions and practiced applying the diagnostic criteria through interactive scenarios. This session reinforced the critical importance of a thorough assessment to ensure participant safety and research integrity.

Session 2: Informed Consent Procedures

Time: 10:00-11:00 AM
Facilitators: Dr. Amir Aziz & Faryal

This session focused on the ethical foundations of clinical research through comprehensive informed consent processes. Dr. Amir Aziz led the participants through the essential elements of valid informed consent, emphasising both the legal requirements and ethical considerations specific to mental health research.

The session covered:

- **Elements of Informed Consent**: Detailed review of information disclosure, comprehension assessment, and voluntary participation principles
- **Appropriateness Assessment**: Evaluation of participant capacity to provide informed consent and identification of situations requiring additional safeguards
- **Demonstration and Practice**: Role-playing exercises in obtaining informed consent, with emphasis on clear communication and participant understanding
- **CONTROL Program Specific Consent**: Detailed discussion of trial-specific consent elements, including intervention descriptions, potential risks and benefits, and data management procedures

The participants practiced consent procedures through structured role-plays and received feedback on communication techniques and documentation requirements. Special attention was paid to cultural considerations and language barriers that might affect the consent process.

Tea Break

Time: 11:00-11:30 AM

Session 3: Standardized Assessment Scales - Part I

Time: 11:30-12:30 PM
Facilitators: Dr. Amir Aziz & Faryal

This session introduced the participants to the critical assessment tools used throughout the CONTROL trial to measure various aspects of mental health and functioning. The facilitators provided comprehensive training on three essential scales.

Zarit Burden Interview Scale:

- Overview of caregiver burden assessment and its relevance to the CONTROL trial
- Administration procedures and scoring methodology
- Interpretation of results and clinical implications
- Cultural adaptations for local context

Patient Health Questionnaire-9 (PHQ-9):

- Presentation of both English and Urdu versions
- Depression screening and severity assessment protocols
- Scoring interpretation and clinical decision-making based on results
- Discussion of sensitivity and specificity in the target population

Harvard Trauma Questionnaire (HTQ):

- Trauma exposure assessment methodology
- Administration techniques for sensitive topics
- Role-play exercises with peer feedback
- Hands-on practice sessions to build confidence

Participants engaged in extensive hands-on practice, working in pairs to administer the scales and receiving individualised feedback from the facilitators. This practical approach ensured competency development and confidence-building.

Session 4: Standardized Assessment Scales - Part II

Time: 12:30-1:30 PM
Facilitators: Dr. Amir Aziz & Faryal

The fourth session continued the assessment tools training with a focus on stigma measurement.

Internalised Stigma of Mental Illness (ISMI) scale:

- Comprehensive overview of stigma concepts and their impact on mental health outcomes
- Detailed presentation of ISMI components and subscales
- Administration techniques for sensitive stigma-related questions
- Interpretation of scores and clinical significance
- Discussion of cultural factors affecting stigma perception in the local context

This session emphasised the importance of creating a safe, nonjudgmental environment when discussing stigma-related topics. Participants practiced empathetic communication techniques and learned to recognise the signs of distress that might arise during stigma assessments.

Session 5: Service Utilization Assessment

Time: 1:30-2:30 PM
Facilitators: Dr. Amir Aziz & Faryal

The final session before lunch focused on service utilisation measurement.

Service Recipient Inventory (SRI):

- Overview of healthcare service utilization tracking
- Detailed review of SRI components and data collection procedures
- Discussion of local healthcare systems and service categories
- Practice in completing SRI forms and identifying service utilization patterns
- Integration of SRI data with other trial outcomes

The participants learned to systematically document various types of healthcare services and their associated costs, ensuring comprehensive capture of resource utilisation data throughout the trial period.

Lunch Break

Time: 2:30 PM onwards

Advanced Data Collection Techniques and Quality Assurance

The training focused on advanced aspects of data collection, quality assurance procedures, and problem-solving strategies for challenging assessment scenarios. The sessions included

refresher training on data management protocols, inter-rater reliability exercises, and discussions of common challenges encountered in previous trial phases.

Practical Application and Competency Assessment

Emphasised practical application through extensive role-playing exercises, competency assessments and collaborative problem-solving sessions. The team members demonstrated their proficiency in all assessment tools.

Data Management and Documentation Standards

A comprehensive review of data management procedures, including electronic data capture systems, quality control measures, and adverse event reporting protocols. Participants received updated guidelines on documentation standards and learned about recent protocol modifications.

Hands-On Practice Sessions

Hands-on practice was integral to the training program throughout both days. Participants engaged in the following activities:

- **Peer-to-Peer Assessment Practice**: Team members practiced administering all assessment tools with colleagues, receiving real-time feedback and guidance
- **Scenario-Based Learning**: Complex case scenarios were presented to challenge participants' problem-solving abilities and decision-making skills
- **Inter-Rater Reliability Exercises**: Standardization activities to ensure consistency across team members in assessment administration and scoring
- **Cultural Adaptation Practice**: Role-plays incorporating cultural and linguistic considerations relevant to the study population

The practical sessions fostered collaborative learning and built confidence among the team members. The facilitators provided individualised feedback and additional coaching as needed to ensure competency achievement.

Closing Remarks

The CONTROL Refresher Training concluded with reflective discussions on key learning outcomes and preparation for upcoming trial activities. Dr. Amir Aziz emphasised the critical importance of maintaining high standards of data collection and participant care throughout the trial implementation.

Participants expressed appreciation for the comprehensive training format and felt well-prepared to continue their roles in the trial. The collaborative atmosphere enhanced team cohesion and established clear protocols for addressing the challenges that may arise during data collection activities.

Conclusion

The June 2025 CONTROL Training successfully achieved the objectives of enhancing team competencies in essential trial procedures and data collection methodologies. This

comprehensive two-day program strengthened the team's capacity to deliver high-quality research outcomes while maintaining ethical standards and participant safety.

The training reinforced the importance of standardised procedures, cultural sensitivity, and collaborative teamwork in conducting meaningful mental health research. Team members emerged from the training with enhanced confidence, updated knowledge, and renewed commitment to the success of the CONTROL trial.

On-Site Training Activities

On-site training of research assistants was conducted on 30th June and 1st July at the following locations:

- RHC Nahaki
- KTH (Khyber Teaching Hospital)
- Prime Hospital
- Alfalah Center
- TBC Gunj
- LRH MDR TB (Lady Reading Hospital MDR TB Unit)

These on-site training sessions ensured the practical application of refresher training content in real clinical settings and provided additional support for research assistants working directly with the study participants.