The CONTROL

(COgNitive Therapy for depRessiOn in tubercuLosis treatment)

to improve outcomes for depression and TB in Pakistan and Afghanistan

Funded by: RIGHT 3 NIHR

Reference: NIHR201773

“Site Initiation Visit (SIV) Training”

14th – 16th October 2024

EXECUTIVE SUMMARY

Capacity development is an integral component of the CONTROL study, as the research team comprises early career researchers as Research Assistants, qualitative and quantitative researchers, data input administrators, DOTs facilitators, master's students, Ph.D. scholars, and Postdoc Fellows. Developing their knowledge, skills, and attitudes will, in turn, contribute to the quality of project deliverables.

The Site Initiation Visit (SIV) training was conducted as part of the preparation for the upcoming CONTROL definitive trial. The training aimed to ensure that the participating sites were well-prepared and fully compliant with the study protocol, ethical standards, and regulatory guidelines. This three-day training session was arranged at the Khyber Medical University and facilitated by Dr. Shaista Rasool and Dr. Rubab Farooqi. The training was structured to provide comprehensive training on the clinical trial process, discuss the roles and responsibilities of site team members, and review the study protocol in depth. This report will narrate the proceeding of a three-day SIV training.

INTRODUCTION

Site Initiation Visits (SIVs) are critical to the success of clinical trials, as they ensure that the site is prepared and compliant with the study protocol. The SIV is the final preparatory step before the start of the trial and confirms that the site has the necessary resources, trained staff, and understanding of the protocol to conduct the study effectively.

Activity Background

The SIV training was conducted from October 14th to 16th, 2024, at the ORIC Committee Room. Khyber Medical University. It aimed to train site coordinators, assessors, and psychologists from TB sites in Peshawar and Haripur. The sessions focused on clinical procedures, ethical considerations, and data management practices essential for the trial. Interactive discussions, demonstrations, and Q&A sessions ensured participants could engage with the material and seek clarification. This comprehensive training was key for all participants to be ready for their roles, ensuring the trial's success and data quality.

Objectives

The main objectives of the training were:

- To review the study protocol and ensure that all sites understood their responsibilities.
- To verify that all site staff were adequately trained on clinical trial procedures and data collection.
- To confirm compliance with ethical guidelines and regulatory requirements.
- To enhance the sites' preparedness for participant enrollment and data management.

Facilitators

- Dr. Shaista Rasool — Post-Doc Fellow & Lead Clinical Trial, CONTROL
- Dr. Rubab Farooqi — Administrator & Clinical Trial Coordinator, CONTROL

Participants

The participants were key members from various centers, including site coordinators, assessors, and psychologists. The participants included the following team members from their respective centers:

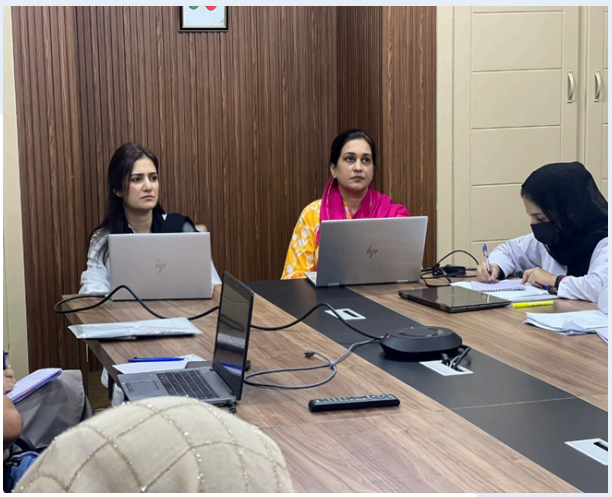
Hospital/Location	Site coordinator (SC)	Assessor (A)	Psychologist (Psy)
Lady Reading Hospital Peshawar	Awais	Sidra	Nagina
Khyber Teaching Hospital Peshawar	Mahnoor Majid	Ayesha Afridi	Mehwish
Kuwait Teaching Hospital Peshawar	Rida	Mahnoor Ahmad	Maryam Rehman
Civil Hospital Khalabat Township Haripur	Asad	Sardar	Naeem Jan
RHC Nahaqi Peshawar	Somia	Salman	Uzma
Al-Khidmat Hospital Peshawar	Kanwal	Tahira	Shireen Arbab
DHQ Hospital Haripur	Mehboob	Shafaq Zahoor	Sundus

TBC Kangra Colony Haripur	Mahnoor Razak	Shumaila	Laraib
PRIME Hospital Peshawar	Maria Marjan	Tuba	Rubab Ellahi
Irfan General Hospital Peshawar	Hessam	Rabia Ali Afridi	Younus
Dr. Rafiq Tanoli Clinic Haripur	Aftab Sahar	Faisal Afridi	Riffat Ahmed
PPM (Gunj) Peshawar	Zeeshan Khan	Maimoona, Sardar	Maria

Workshop proceeding

Day 1 – 14th October 2024

The first day of the Site Initiation Visit (SIV) training started with an introductory session led by Dr. Shaista Rasool and Dr. Rubab Farooqi. Participants were welcomed, and the objectives of the training were outlined, establishing a collaborative atmosphere. The initial discussions focused on the clinical trial's overall objective, design, and scope. Key aspects such as ethical considerations, informed consent, and good clinical practice (GCP) were emphasized.



This was followed by training on participant enrolment, accurate documentation, and maintaining confidentiality. Case studies were used to stress the importance of data integrity and the proper reporting of adverse events. The day ended with an interactive question-and-answer session for participants to clarify any doubts.

Day 2 – 15th October 2024

The second day focused on clinical trial management, quality assurance, and audit readiness. The participants were introduced to monitoring tools and checklists to ensure adherence to study protocols and were trained in identifying and correcting discrepancies in clinical documentation.

Participants practiced problem-solving in these scenarios, which helped them understand how to apply their training to real-life situations. The session also focused on data collection techniques, with practical examples and training on electronic data capture (EDC) systems, including error correction and data validation.

Day 3 – 16th October 2024

The final day of the training focused on reporting requirements, adverse event documentation, and serious adverse event (SAE) reporting, along with timelines and communication with the ethics committee and regulatory bodies.

Role-playing activities were conducted to help participants practice responding to different clinical situations, reinforcing quick decision-making and effective communication. The training concluded with a summary of the main points and a final question-and-answer session to address any last concerns. Feedback from participants was collected to ensure they were confident and well-prepared for their upcoming roles in the clinical trial.

Conclusion

Overall, the training was successful in achieving its objectives, equipping the site staff with the knowledge and confidence needed to perform their roles efficiently. The feedback from participants indicated that they felt prepared to apply their training in their work, contributing to the success of future clinical trials. This training highlighted the importance of continuous learning and collaboration in clinical research and underscored the commitment of the team to upholding high standards of practice and participant safety.