The CONTROL

(COgNitive Therapy for depRessiOn in tubercuLosis treatment)

to improve outcomes for depression and TB in Pakistan and Afghanistan

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Workshop on the Overview of the CONTROL Trial

Procedures and

Quantitative Data Collection Tools

25th October – 1st November 2023

Khyber Medical University

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EXECUTIVE SUMMARY

Capacity development is an integral component of the CONTROL study as the research team comprised early careers researchers as research assistants, qualitative and quantitative researchers, data input administrators, and DOTs facilitators. CONTROL's holistic capacity development approach empowers team members to bring a higher level of expertise, efficiency, and a constructive mindset to their work, ultimately enhancing the overall success and impact of the project.

Under the capacity development module, a comprehensive work package 2 data collection tool workshop was held from 25th October to 1st November 2023, at the Senate Hall, Admin Block Khyber Medical University (KMU), which aimed to familiarize research assistants and CBT master trainers with the upcoming pilot trial, providing them with an in-depth understanding of the trial and to offer a practical, hands-on experience with the translated tools, information sheets and consent forms in native languages. This report is a narrative description of the activities conducted during the workshop.

INTRODUCTION

Facilitator:

- Dr. Muhammad Firaz Khan, (CONTROL Clinical Trial Coordinator)
- Dr. Abdul Jalil, Associate (Head of Department-Family Medicine, KMU)
- Dr. Amir Wahab, (CONTROL Clinical Research Fellow)
- Dr. Amir Aziz, (CONTROL Clinical Research fellow)
- Dr. Zeeshan Kibria (CONTROL Project Manager, Pakistan)
- Dr. Shaista Rasool, (CONTROL Post-Doc fellow)
- Ms. Fatima (Clinical Psychologist, Lady Reading Hospital Peshawar)
- Dr. Rubab Farooqi (CONTROL Administrator)

Training Day, Date & Venue

The six-day training on the awareness regarding CONTROL pilot trial procedures and quantitative data collection tools was held on 25th to 27th October 2023, 30th to 31st October 2023, and on 1st November 2023, in Senate Hall at Khyber Medical University (KMU), Peshawar.

Significance Of the Workshop:

Before the commencement of the pilot study, this training covered conducting data collection in the native language, handling patient interactions, understanding fundamental research ethics, adhering to data collection protocols, and mastering the use of digital data collection equipment. For newly recruited research assistants, hands-on practice was emphasized to ensure a thorough grasp of the methodologies. The aim was to translate this

acquired knowledge into practical actions, especially during their fieldwork for work package 2, encompassing both pilot and definitive data collection stages.

Day 1 Proceedings:

The session commenced with the recitation of the Holy Quran by Dr. Fayaz Ahmad. Dr. Zeeshan Kibria opened the session by highlighting **the aim and objective of CONTROL as a project** and the need to have training sessions on data collection tools, research ethics, and standard operating procedures (SOPs).

Dr. Muhammad Firaz Khan initiated the session with his introduction and encouraged participants to introduce themselves, fostering an ice-breaking interaction between them. This

marked the beginning of an interactive session. He explained the main objective of this pilot trial and educated the research team about the criteria for recruiting participants for the pilot trial, including the inclusion and exclusion criteria. He mentioned that, initially, participants need to undergo screening on the three tools mentioned below:

- PHQ-2
- PHQ-9
- WHO DAS 2.0 (12 items)

Furthermore, he provided a detailed explanation, specifying that individuals with a cut-off score of 3 or higher on the PHQ-2 would be included in the study. Participants with a score of 10 or above on the PHQ-9 and a score of 16 or above on the WHO DAS 2.0 would be eligible to participate in the study.

Dr. Amir Aziz, CONTROL Clinical Research Fellow delivered an insightful presentation focused on WHODAS 2.0 (12 items). He highlighted the significance of the WHO DASS tool and explained that its primary purpose is to measure depression, anxiety, and stress levels in patients. Moreover, he guided the proper technique for posing questions to patients

in the field while using this tool, along with a detailed discussion of its translation into Urdu/Pashto.

Hands-on Activity:

The research assistants and psychologists were divided into six distinct groups, with each group assigned specific roles for engaging in role-playing exercises. Within each group, one research assistant assumed the position of the interviewer, while the other played the role of the interviewee. Both research assistants within a pair practiced utilizing the PHQ-9 and WHODAS 2.0 assessments as part of these exercises. To ensure the quality and accuracy of the role-playing sessions, a psychologist provided supervision and guidance to each group, overseeing their activities, and contributing valuable insights to the training process. This structured approach aimed to enhance the proficiency of the research assistants and psychologists in administering the assessments and fostering a collaborative and effective learning environment.

Feedback:

The day 1 session wrapped up with a feedback segment, during which the research assistants were encouraged to reflect on their understanding of the tools and their translated versions.

This provided an opportunity to evaluate their comprehension and gain insights into any areas that might need additional clarification or enhancement. The interactive feedback session was also aimed to foster open communication and ensure that the research assistants felt confident and well-equipped in the utilization of the tools, addressing any potential concerns or uncertainties.

Day 2 Thursday, Oct 26, 2023

Day 2 commenced with a **recap** of day 1 by **Dr. Amir Wahab** followed by the overview of the content to be covered on day 2 including the Generalized Anxiety Disorder scale (GAD-7), Harvard trauma questionnaire (HTQ), Zarit Burden Interview Scale, Internalised Stigma of Mental Illness ISMI Presentation and discussion on Zarit Burden Interview scale (English and URDU).

The first half of the session was facilitated by **Dr. Muhammad Firaz Khan** and **Ms. Fatima Ruby**, (Clinical Psychologist), introducing the GAD-7 tool—a widely utilized self-report scale for diagnosing and assessing the severity of anxiety disorders. Dr. Firaz explained that the GAD-7 is widely used as a screening tool to identify individuals who may be experiencing symptoms indicative of generalized anxiety disorder. It consists of seven questions that assess the frequency and severity of common anxiety symptoms over the past two weeks. He shared that psychiatrists often employ the GAD-7 for preliminary assessments, aiding in the early detection of anxiety disorders and facilitating timely interventions. He also mentioned that commonly used cut-off scores might categorize individuals as having minimal,

mild, moderate, or severe anxiety. These categories help in tailoring the treatment plans to the specific needs of each patient.

Later, during the second half of the session**, Dr. Amir Wahab** guided participants through an in-depth exploration of the **Harvard Trauma Questionnaire (HTQ)**. During his presentation, he shared that HTQ is designed to comprehensively assess trauma and its psychological impact. It covers a range of traumatic experiences and associated symptoms, allowing for an understanding of an individual's trauma history. He elaborated that the widespread use of the HTQ in research studies contributes to a better understanding of the prevalence and impact of trauma on public health. It allows researchers to identify patterns, risk factors, and the overall burden of trauma within populations. Further, **Dr Amir Wahab** also discussed that **EuroQoL EQ5D** is a versatile instrument used to measure and quantify health-related quality of life across various settings, contributing valuable data for healthcare research, decision-making, and policy development. He navigated through its components, facilitating a discussion that encompassed both its English and Urdu translations. To enhance participant engagement and

comprehension, **Dr. Amir Wahab** further conducted an interactive segment, ensuring a robust grasp of the material.

Dr. Firaz, during the third half of the session, elaborated on the **Internalized Stigma of Mental Illness ISMI**, mentioning it as a 29-item questionnaire measuring self-stigma among persons with psychiatric disorders. Dr. Firaz explained each item/question of ISMI to the team, illustrating how to conduct questions with patients in the field. He and Ms. Fatima conveyed the method in both Urdu and Pashto languages, guiding them on the appropriate approach to communicating with patients effectively.

Dr. Amir Aziz, introduced the **Zarit Burden Tool**, providing the audience with a detailed insight into its significance and application. Afterward, he conducted a detailed explanation of each question and its translations, thereby ensuring that all participants attained a comprehensive understanding of the intricacies embedded in the **Zarit Burden Tool**. This approach not only served to elucidate the tool's content but also fostered a more inclusive and enriched learning experience for all attendees.

Ms. Fatima conducted an engaging and interactive session, about every tool discussed in the session and precisely explained each question with the assistance of research assistants who provided translations.

Mock Activity:

All the facilitators led mock activities to simulate real-world scenarios, providing a controlled environment for practice, learning, and skill development. **Dr. Firaz and Ms. Fatima** collaborated to identify and address any discrepancies or inconsistencies in the translations. All participants actively participated in a discussion regarding their translations of the tools. This interactive session provided an opportunity for everyone to share their interpretations, facilitating the identification and rectification of inconsistencies in everyone's translations. Their joint efforts not only helped address discrepancies but also promoted the development of improved and revised translated versions through collective input and collaboration.

Day 3- Friday, Oct 27, 2023

On the third day, training on screening and diagnosis of bipolar disorder using ICD 10 guidelines, assessment of current suicidal tendency using MhGAP protocol, other forms of severe mental illness, evidence of learning disability or severe substance abuse (except nicotine dependence), Medication adherence rating (MARS), and Client Service Receipt Inventory (SRI) was continued by **Dr. Firaz, Dr. Amir Aziz, and Ms. Fatima Ruby.** They elaborated on the significance of all the tools and the way of asking them from the patients in a very detailed manner.

Dr. Firaz shared that the ICD10 provides a standardized way for healthcare professionals to identify and categorize bipolar disorder based on its distinct features and characteristics. He

also explained that by using the Medication Adherence Rating Scale, healthcare providers can identify potential issues related to medication adherence, tailor interventions to address specific barriers, and ultimately improve patient's treatment outcomes. It serves as a valuable tool in assessing and addressing adherence behavior, which is crucial for the effective management of various medical conditions. He explained that Client Service Receipt Inventory (SRI), is used to collect information on service utilization, income, accommodation, and other cost-related variables.

Role-Play:

The session proceeded to conduct a hands-on exercise that involved role-playing, wherein psychologists from the CONTROL program were invited to demonstrate their engagement with a patient exhibiting various conditions. The purpose of the demonstration was to highlight effective interaction methods, diagnostic strategies, crucial indicators to observe, and relevant questions to pose during encounters with patients presenting these conditions.

Dr. Firaz explained that the careful assessment of inclusion and exclusion criteria is essential for the scientific rigor, ethical conduct, and overall success of research studies and clinical trials. It contributes to the validity of the study, the safety of participants, and the meaningfulness of the results obtained. **Dr. Firaz**, placed special emphasis on the importance of informed consent, explaining its fundamental components, ensuring its suitability, and illustrating the procedure for obtaining informed consent. Furthermore, a thorough discourse unfolded, specifically on the informed consent protocols within the framework of the CONTROL program. This discussion offered comprehensive insights into the meticulous execution of informed consent procedures within the program.

Day 4- Monday, Oct 30, 2023

Digital data collection

The adoption of digital data collection in research addresses several needs, including efficiency, data quality, accessibility, and adaptability. These advantages make digital tools

invaluable for researchers across various disciplines. The fourth-day session was led by **Mr. Raheel (Data Information Officer KMU)** and **Dr Zeeshan Kibria.**

Mr. Raheel introduced the session by acquainting participants with digital data collection platforms, focusing on ODK (Open Data Kit). He covered various aspects, including the platform's user interface, step-by-step installation procedures, functionality and discussed strategies to minimize risks associated with digital data collection, and highlighted how utilizing such platforms can enhance the benefits of data collection, such as efficiency, accuracy, and accessibility.

Mr. Raheel also explained the importance of data protection, emphasizing protocols and measures in place to ensure the security and safety of collected data. This involved discussing encryption, user access control, backup procedures, and other safety protocols to safeguard sensitive information collected through these digital platforms.

A dummy Open Data Kit (ODK) sample questionnaire was prepared, and the code was distributed to all team members. Under the supervision of **Mr. Raheel** and **Dr. Zeeshan Kibria,** each participant entered dummy data into the questionnaire to practice using ODK on their respective devices. This hands-on session provided practical experience and familiarized the team with the ODK tool, ensuring proficiency in its usage.

Day 5- Tuesday, Oct 31, 2023

Ethics and Confidentiality:

Dr. Abdul Jalil (Associate Professor, Family Medicine) facilitated the research ethics session. He explained that it is essential for protecting participants, maintaining the credibility of research, ensuring global standards, complying with the law, upholding the integrity of the research process, garnering public support, and contributing to the long-term impact of scientific endeavors. Researchers, institutions, and the broader scientific community must prioritize and uphold ethical principles in all stages of the research process.

Dr Jalil elaborated that researchers must obtain voluntary informed consent from participants before involving them in a study. Participants should be provided with sufficient information about the study's purpose, procedures, potential risks, and benefits, allowing them to make an informed decision about their participation. Researchers should treat participants with respect, acknowledging their autonomy and dignity. This includes protecting their privacy, maintaining confidentiality, and considering their cultural and social context.

Dr Jalil explained to the research team that **Good Clinical Practice (GCP)** is a set of international ethical and scientific quality standards that guide the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials or studies involving human participants.

Moreover, the team received detailed insights into the importance of data protection, which encompasses the safeguarding of data integrity and privacy. Confidentiality was emphasized to ensure the non-disclosure of sensitive information, while safety was underscored as a priority to safeguard the well-being of both participants and researchers. Also, the concept of

monitoring was explained, involving systematic oversight to uphold the quality and ethical conduct of research activities. Together, these principles form a cohesive framework that fosters the responsible and ethical execution of research studies and other data-driven initiatives.

Standard Operating Procedures in the CONTROL project:

The second half of the session was continued by **Dr. Shaista Rasool** and **Dr. Rubab Farooqi**, on Standard Operating Procedures (SOPs).

The contents of the SOPs were as follows:

1. SOP001-Informed consent
2. SOP002-Screening and eligibility
3. SOP003-Baseline and follow-up procedures
4. SOP005-Data protection and confidentiality
5. SOP006-Adverse events

SOP001-Informed consent: Dr. Shaista Rasool conveyed to the research team the significance of obtaining informed consent. She emphasized that consent is communicated in local languages. She outlined the procedure, stating that no individual can be recruited as a participant without obtaining their consent.

SOP002-Screening and eligibility: Dr. Shaista explained the procedures and criteria for screening individuals or participants to determine their eligibility for the CONTROL study. It also included guidelines on how to assess and verify certain qualifications, characteristics, or requirements to ensure that individuals meet the necessary criteria before they can proceed to the next stage.

SOP003-Baseline and follow-up procedures: Dr. Shaista explained that in the upcoming pilot study, participants will undergo baseline assessments before the intervention is administered. Follow-up assessments will then occur at specified intervals after the baseline to monitor changes or outcomes. She elaborated that these procedures are essential for understanding the natural progression of a condition, the effectiveness of an intervention, or the impact of various factors over time. She said this contributes to the overall reliability and validity of study

findings by providing a comprehensive view of participant experiences and outcomes.

SOP005-Data protection and confidentiality: Dr Rubab shared with a research team that, there are laws and regulations, such as the General Data Protection Regulation (GDPR) in the European Union or the Health Insurance Portability and Accountability Act (HIPAA) in the United States, outline specific requirements for data protection and confidentiality. These regulations often include guidelines on data collection, storage, processing, and the rights of individuals regarding their personal information. She said that professionals and organizations handling sensitive data are typically required to implement measures such as encryption, access controls, and secure storage to uphold data protection and confidentiality standards. Breaches of these principles can lead to legal consequences, damage to reputation, and loss of trust.

SOP006-Adverse events were explained by **Dr. Firaz**, that adverse events generally refer to unexpected and undesirable occurrences or side effects associated with a particular process, procedure, or, in some contexts, medical treatments or interventions. He explained that in various fields, including healthcare, clinical trials, pharmaceuticals, and research, SOPs are documents that outline step-by-step instructions and guidelines to ensure consistency and standardization in various processes. SOP006-Adverse events would likely

describe the procedures and protocols to be followed when adverse events occur. He gave an example to the research team that, in the context of clinical trials or healthcare, an adverse event could include unexpected side effects or complications experienced by participants. The SOP would guide the individuals involved in managing and reporting these events, ensuring that proper documentation and protocols are followed to maintain the safety of participants and the integrity of the study.

Day 6- Wednesday, Nov 1, 2023

The **sixth & last day** of the session was led by **Dr Zeeshan Kibria.** He explained **SOP-007-Safety procedures that** in research they are crucial to ensure the well-being of researchers, participants, and the environment. These procedures are typically outlined in Standard Operating Procedures (SOPs) and are designed to mitigate risks associated with various research activities. The specific safety procedures may vary depending on the nature of the research, the field of study, and the potential hazards involved.

SOP-008- Data Transfer, was also explained by **Dr. Zeeshan** that in clinical trials, "data transfer" refers to the process of moving or transmitting data from one location or entity to another. Clinical trials involve the collection of a significant amount of data, including patient information, study outcomes, laboratory results, and other relevant data points. Data transfer is a critical aspect of managing and analyzing this information, and it involves the movement of data between various stakeholders (who are related to the Trial).

Role and responsibilities:

In the second half of the session roles and responsibilities were discussed among the research team. **Dr. Shaista Rasool** explained the responsibilities of **site coordinators** and that they must play a crucial role in the meticulous documentation and management of various

stages in the clinical trial process. This includes recording the dates of pre-screening, consent, and screening on study-specific recruitment and maintaining a screening log, emphasizing the secure storage of identifiable information. The **coordinator** will maintain comprehensive participant files, securely filing documents such as demographics forms, consent forms, pre-screening and screening forms, encounter forms, and any other forms in a locked filing cabinet at the ORIC KMU office. Moreover, the coordinator documents randomization, baseline, and follow-up assessments on study-specific logs, ensuring accuracy and completeness.

Coordinating participant appointments with DOTS facilitators and providing reminders one day before appointments are essential responsibilities, documented on encounter forms. Specific tasks involve overseeing electronic data submissions by assessors daily and securing hard data appropriately. For pre-screening, screening, baseline assessment, and intervention/control sessions, the coordinator will record key information and will ensure effective communication and appointment scheduling. Moreover, the **coordinator** will track follow-up assessments, maintain records of Serious Adverse Effects, and be empowered to make decisions under SOPs for SAEs, demonstrating a commitment to participant safety and data integrity.

Dr. Firaz has allocated responsibilities among the **psychologists**, stating that those participating in **CONTROL** trials bear crucial duties in guaranteeing the thorough screening and effective supervision of participants. They will methodically assess participants against eligibility criteria, furnish comprehensive information about the trial through participant information sheets, and secure informed consent during the recruitment phase. Furthermore, psychologists will actively oversee the data collection process, managing both baseline and 8 & 24-week follow-up assessments. Their specific tasks encompass providing guidance during recruitment, evaluating participants against eligibility criteria, and supervising assessors throughout the data collection phase. Psychologists will play an essential role in recognizing the necessity for assessor training, ensuring assessors' proficiency in data collection tools. They need to possess ample knowledge to assist assessors facing challenges and, when required, organize on-site refresher training sessions. The psychologists will maintain thorough records of on-site training in designated logs and promptly inform the site coordinator of any Serious Adverse Events, thus contributing to the overall safety and integrity of the trial.

Dr. Shaista Rasool also addressed the responsibilities of **assessors** within the study, emphasizing their specific roles aimed at ensuring the seamless progress of assessments and the overall success of the trial. Assessors are charged with the completion of both baseline and follow-up assessments, with a requirement to electronically submit all assessments by the end of each day. Their designated tasks encompass coordinating participant appointments with the site coordinator, confirming appointments one day before screening, baseline, and follow-up assessments, as well as appointments for mhGAP/CBT sessions. Assessors will meticulously fulfill baseline assessments, along with the 8 and 24-week follow-up assessments. They will collaborate with the site coordinator to put details of these assessments into the

study-specific log. Following each CBT/mhGAP session, assessors will diligently complete and submit encounter forms in coordination with the site coordinator. Moreover, assessors hold a pivotal role in promptly informing the site coordinator of any Serious Adverse Events, thereby contributing to the vigilance and safety measures implemented in the trial.

Feedback:

The sixth day was concluded with a concise 15-minute feedback session during which participants offered a summary of the entire six-day program. Through an anonymous survey, participants shared valuable feedback, providing insights not only on each presenter's sessions but also on the overall workshop experience.

"Agenda"

Day 1- Wednesday, Oct 25, 2023

Time	Session	Resource Person
08:30-09:00 am	Pre-test	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL)
09:00-09:30 am	Introduction to the trial team, brief background, introduction, and the rationale, objectives, and research questions	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL)
10:00-11:00 am	The CONTROL trial flow diagram and assessments at various time points (screening, baseline, 8th week, and 24th week)	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL)
11:00-11:30 am	**Tea Break**	
11:30-12:30 pm	Presentation and discussion on PHQ2 & PHQ9 (English and URDU) Hands-on 1:1 practice	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL)
12:30-2:00 pm	WHO DAS 2.0 (12 items) Presentation and discussion on WHO DAS 2.0 (12 items) (English and URDU) Hands-on 1:1 practice	Dr. Amir Aziz (Clinical Research fellow in the CONTROL)

Day 2- Thursday, Oct 26, 2023

Time	Session	Resource Person
09:00-10:00 am	Generalized Anxiety Disorder scale (GAD-7) Presentation and discussion on GAD-7 (English and URDU) Hands-on 1:1 practice	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL) Ms. Fatima (Clinical Psychologist)
10:00-11:00 am	Harvard trauma questionnaire (HTQ) Presentation and discussion on HTQ (English and URDU)	Dr. Amir Wahab (Clinical Research fellow in the CONTROL)
11:00-11:30 am	**Tea Break**	
11:30- 12:30 pm	Zarit Burden Interview Scale Presentation and discussion on Zarit Burden Interview scale (English and URDU) Hands-on 1:1 practice	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL) Ms. Fatima (Clinical Psychologist)
12:30-01:30 pm	Internalised Stigma of Mental Illness ISMI Presentation and discussion on ISMI (English and URDU) Hands-on 1:1 practice	Dr. Amir Aziz (Clinical Research fellow in the CONTROL)
01:30-02:30 pm	Presentation and discussion on EuroQoL EQ5D (English and URDU) Hands-on 1:1 practice	Dr. Amir Wahab (Clinical Research fellow in the CONTROL)

Day 3- Friday, Oct 27, 2023

Time	Session	Resource Person
09:00-11:00 am	Diagnosis of bipolar disorder (ICD10), assessment of suicidal tendency (currently suicidal) (mhGAP), other forms of severe mental illness, have evidence of learning disability or severe substance abuse (except nicotine dependence). data collection tools (MARS,SRI)	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL program)
11:00-11:30 am	**Tea Break**	
11:30- 12:30 pm	Assessment of inclusion and exclusion criteria	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL program)
12:30-01:30 pm	Informed consent: element of informed consent, appropriateness, demonstration of obtaining informed consent, detailed discussion on the informed consent of the CONTROL program	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL program)

Day 4- Monday, Oct 30, 2023

Time	Session	Resource Person
09:00-11:00 am	Introduction to digital data collection platforms (ODK), the user interface and installation procedures, alleviating risk and enhancing the digital data collection benefits, data protection, security, and safety protocols	Data Information Officer KMU
11:00-11:30 am	**Tea Break**	
11:30- 01:30 pm	1:1 practice on a dummy questionnaire uploaded on the ODK.	Dr. Zeeshan Kibria(Project Manager in the CONTROL) Data Information Officer KMU

Day 5- Tuesday, Oct 31, 2023

Time	Session	Resource Person
09:00-11:00 am	Research ethics (general introduction, relevant concepts of research ethics, Research and clinical trials, evaluation risk and benefits, GCP and conduct of research, data protection, confidentiality safety and monitoring)	Dr. Abdul Jalil (Associate Prof. Family Medicine KMU)
11:00-11:30 am	**Tea Break**	
11:30- 12:00 pm	SOP001-Informed consent	Dr. Shaista Rasool (Post-doc fellow CONTROL)
12:00-12:30 pm	SOP002-Screening and eligibility	Dr. Shaista Rasool (Post-doc fellow CONTROL)
12:30-01:00 pm	SOP003-Baseline and follow up procedures	Dr. Shaista Rasool (Post-doc fellow CONTROL)
01:00-01:30 pm	SOP005-Data protection and confidentiality	Dr. Rubab Farooqi, Administrator CONTROL
01:30-02:00 pm	SOP006-Adverse events	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL program)

Day 6- Wednesday, Nov 1, 2023

Time	Session	Resource Person
09:00-09:30 am	S007-Safety procedures	Dr. Zeeshan Kibria(Project Manager in the CONTROL)
09:30-10:00 am	SOP008-Data transfer	Dr. Zeeshan Kibria(Project Manager in the CONTROL)
10:00-11:00 am	Roles and responsibilities of Site coordinator	Dr. Shaista Rasool (Post-doc fellow CONTROL)
11:00-11:30 am	**Tea Break**	
11:30- 12:30 pm	Roles and responsibilities of psychologist	Dr. Shaista Rasool (Post-doc fellow CONTROL)
12:30-01:30 pm	Roles and responsibilities of Assessor	Dr. Muhammad Firaz Khan (senior clinical research fellow in the CONTROL program)