INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East

Study Protocol

Protocol Version 3.0

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LIST OF ACRONYMS

AAU	Addis Ababa University
ACASI	Audio-Computer Assisted Self-Interview
AHRI	Armauer Hansen Research Institute
CAB	Community Advisory Board
CAPI	Computer Assisted Participant Interview
CI	Confidence Interval
COC	Certificate of Competency
CONSORT	Consolidated Standards of Reporting Trials
DASS	Distress, Anxiety and Depression Score
DSMB	Data and Safety Monitoring Board
EAB	External Advisory Board
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
INNOVETH	Innovative Health Interventions for Ethiopian Migrant Domestic Workers in the Middle East IRB Institutional Review Board
LSHTM	London School of Hygiene and Tropical Medicine
LTFU	Lost to Follow Up
MDWs	Migrant Domestic Workers
MSRH	Mental, Sexual and Reproductive Health
MoH-E	Ministry of Health, Ethiopia
MoLS	Ministry of Labour and Skills, Ethiopia
OsloMet	Oslo Metropolitan University
PI	Principal Investigator
PIS	Participant Information Sheet

QALYs	Quality-Adjusted Life Years
QoL	Quality of Life
RD	Risk Difference
RQ	Research Question
RR	Risk Ratio
SPHMMC	St. Paul Hospital Millennium Medical College
SHG	Self Help Groups
SRH	Sexual and Reproductive Health
SOPs	Standard Operating Procedures
UAE	United Arab Emirates
WHO	World Health Organisation

1. LIST Of INVESTIGATORS AND PARTICIPATING INSTITUTIONS

1.1 Investigators

The project leaders are qualified individuals by education and training. They are responsible for the whole aspect of the project. All further key collaborators are also qualified by education and training to perform their assigned tasks and discharge their responsibilities.

TABLE 1: LIST OF INVESTIGATORS AND COLLABORATORS INVOLVED IN THE STUDY

Name	Credentials	Institution	Role and responsibilities	Email
Dr. Kassahun Habtamu	BSc, MSc, PhD	School of Psychology, AAU	PI: leads technical investigator and coordinates the process evaluation of the INNOVETH trial, with a focus on the design and application of qualitative methods. He will also support capacity building efforts (PhD and Postdoc mentorship)	Kassahun.habtamu@aau.edu.et
Dr. Berhanu Seyoum	BSc, MSc, PhD	AHRI	Co-PI: co-leads the capacity development component of the project including PhD and supports trial implementations	berhanu.seyoum@ahri.gov.et
Prof Dawit Shawel	BSc, MSc, PhD	Oslo Met	Co-PI: co-leads the development, implementation and evaluation of training manuals for different aspects of the trial, including training for empowerment workers, and module developers. He will also contribute to the development of early career researchers (PhDs, Postdocs)	daab@oslomet.no
Dr M Sanni Ali	DVM, MSc, PhD	LSHTM	Co-PI: Co-leads and coordinates design, implementation & reporting on protocol. Also, leads development of the statistical analysis plans and trial analyses. He will also support capacity building efforts (PhD and Postdoc mentorship).	sanni.ali@lshtm.ac.uk
Dr Samrawit Solomon	MD, MPH	St. Paul's Hospital Millenium Medical College, SPHMMC	Co-PI and PhD student: She will co-lead the development and implementation of the intervention, clinical trial, SOPs, training manuals for the trial, including empowerment workers, and module developers. She is expert in sexual and reproductive health (SRHR), and Gender	samrawit.solomon@sphmmc.edu.et
Dr Seid Muhie Yimam	BSc, MSc, PhD	Hub of Computing and Data Science (HCDS)	Collaborator: Co-leads development of data collection tools, mobile applications and supervision on capacity development on data science and artificial intelligence.	seid.muhie.yimam@uni-hamburg.de

Dr Abdu Seid Kedir	BSc, MSc, PhD	Center for clinical research and prevention, Frederiksberg Hospital	Collaborator: Leads the economic evaluation component and supports the implementation and the process evaluation of the project. He will also support capacity building efforts (PhD and Postdoc) mentorships.	abdukkedir@gmail.com
Mr. Yosef Addisu	BSc, MSc	Sefed Software systems	Data manager: Leads the development of data collection tools and data management. Also supports the development of the mobile application for the intervention.	email.to.yoseph@gmail.com
Mr. Dawit Ketema	BSc, MSc	Wollo University	App support: supports the development of mobile apps, risk stratifications telegram bot, data collection tools and data management. Also supports the development of the mobile application for the intervention.	userdavek@gmail.com
Dr.Haimanot Disassa	DVM, MSc	AAU	Coordinator: Coordinates data collection and implementation of the trial. He also supports stakeholder engagement and involvement workshops.	haimanot.disassa@aau.edu.et
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Aziza Oumer	Bsc, Msc	Bahir Dar University	PhD student: She contributes to digitalisation of project tools; manuscript write up, publications on data science and artificial intelligence	aziz86umer@gmail.com
Sintayehu Simie	Bsc, Msc	University of Gonder	PhD student: She contributes to risk stratification study, data analysis, manuscript write up, and publications on mental health epidemiology	simies952@gmail.com

1.2 Signatures

Study Title: INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East.

The following project leaders have approved the protocol version **[1.0 (dated 15.06.2026)]** and confirm hereby to conduct the project according to the current version of the World Medical Association Declaration of Helsinki , and principles of Good Clinical Practice (GCP), and other essential ethics guidelines for clinical studies as well as all national legal requirements as applicable in each collaborating countries.

Project PI and Co-PIs

- I have read this protocol and agree that it contains all necessary details for carrying out this study. I will conduct the study as outlined herein and (pending developments) will complete the study within the time plan.
- I will ensure that all individuals and parties contributing to this study are qualified and I will implement procedures to ensure integrity of study tasks and data
- I will provide copies of the protocol and all pertinent information to all individuals responsible for me who assist in the conduct of this study. I will discuss this material with them to ensure they are fully informed and trained regarding their activities within the study conduct.
- I will use only approved informed consent forms and will fulfil all responsibilities for submitting pertinent information to the Independent Ethics Committees responsible for this study.
- It is understood that this protocol will not be disclosed to others without prior written authorisation, except where required by applicable local laws.

TABLE 2: SIGNATURES OF CORE RESEARCH TEAM

Project PI- Addis Ababa University (**AAU)**

Name	Kassahun Habtamu	
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Role	Principal Investigator	
Signature		Date:

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Signature		Date:

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Signature		Date:

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Signature		Date:

Project co-lead – London School of Hygiene and Tropical Medicine **(LSHTM)**

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Signature		Date:

Project collaborator– University of Hamburg, Hub of Computing and Data Science **(HCDS)**

Name	Seid Muhie Yimam	
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Role	Collaborator	
Signature		Date:

Project collaborator–Center for Clinical Research and Prevention, Frederiksberg Hospital

Name	Dr Abdu Seid Kedir	
Title	PhD	
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Phone	+ 45 31847979	
Role	Collaborator	
Signature		Date:

1.3 Roles of Participating institutions

TABLE 3. ROLE OF PARTICIPATING INSTITUTIONS AND THEIR CONTACT PERSON

Institution	Contact person	Role in the study
Addis Ababa university	Dr. Kassahun Habtamu	Overall project supervision. AAU is the lead institution with responsibility for scientific, financial oversight and governance of the INNOVETH Consortium.
St. Paul's Hospital Millenium Medical College (SPHMMC)	Dr Samrawit Solomon	Study coordination. Hosting the clinical trial data, support the development of interventions, their implementation and all research work.
Armauer Hansen Research Institute (AHRI)	Dr. Berhanu Seyoum	Capacity building: lead capacity building component of the project (PhDs) including support to early career researchers and post-docs. It will also support the trial implementation.
Oslo Metropolitan University (OsloMet)	Prof Dawit Shawel	Co-lead the development of intervention manuals development for app content on mental, sexual and reproductive health. Support training manuals development for Empowerment Workers (EWs) and Migrant Domestic Workers (MDWs). Also provide support in the capacity building (PhD student supervision).
London School of Hygiene and Tropical Medicine (LSHTM)	Dr M Sanni Ali	Co-lead the trial design and management. Support technical working group in all aspects of the study methodological and statistical oversight, data analysis, data collection, implementation and process evaluation.
University of Hamburg, Hub of Computing and Data Science (HCDS)	Dr Seid Muhie Yimam	Co-lead the data science component of the project. Support INNOVETH in the digitalisation and automation of data collection and intervention tools. Leads the mobile applications development and data science team.
Center for clinical research and prevention, Frederiksberg Hospital	Dr Abdu Seid Kedir	Lead the economic evaluation component of the project. Will also support the implementation and the process evaluation of the trial.
Sefed Software systems	Mr. Yoseph Addisu	Data base management: co-lead, the data base management, mobile applications, software developments and digital skill interventions.

1.4 Sponsoring Institution

Addis Ababa University: AAU serves as the lead institution for the INNOVETH Consortium, holding primary responsibility for its scientific direction, financial oversight, and overall project governance.

2. SUMMARY

Migration is a complex phenomenon with profound health implications. Every year, more than 350,000 Ethiopian women migrate to the Middle East legally, and many others illegally, seeking domestic work. Economic crisis, rising unemployment, and internal conflict contribute to this massive migration. Nevertheless, MDWs in the Middle East are subject to overwork; mental, sexual and reproductive health challenges; and limited healthcare access. Studies on MDWs are mostly exploratory or cross-sectional; longitudinal and intervention studies are lacking. Thus, this implementation science protocol outlines a study to develop, implement, and evaluate a multi-component health intervention for Ethiopian MDWs in the Middle East. The intervention integrates peer-support, digital skills training, self-help groups, and community empowerment, guided by risk stratification and using a mobile application. A cluster randomized controlled trial (RCT) will assess the intervention's population-level impact and cost-effectiveness over 24 months. A process evaluation will run in parallel to explore mechanisms of implementation and identify strategies for better optimization.

The study has three research questions (RQs):

RQ1 – What individual and work characteristics predict psychological distress among Ethiopian MDWs in the Middle East?

To address this question, a cross-sectional survey will be conducted among MDWs in selected Middle East countries using a 21-item validated psychological distress scale (Depression, Anxiety and Stress Scale [DASS-21] as the outcome measure.

RQ2 – What is the effectiveness and impact of INNOVETH interventions among Ethiopian MDWs in the Middle East?

Under this research question, we aim to conduct pre-departure assessment, baseline survey, midline evaluation, and endline evaluation of the INNOVETH implementation. Process evaluation will also be conducted as the intervention proceeds.

Pre-departure assessment: a survey will be conducted among MDWs before their departure to the Middle East countries.

Baseline assessment: a cross-sectional survey will be conducted among Ethiopian MDWs three months after they migrate to the Middle East countries.

Midline evaluation: an interim survey will be conducted after 12 months of MDWs' departure.

Impact evaluation: after 24 months of implementing the intervention, we will conduct an endline survey to assess programme population-level effects.

Process evaluation: the process evaluation will document intervention implementation, perceptions of feasibility and acceptability of the intervention throughout the trial period.

RQ3 – What is the cost-effectiveness of the INNOVETH interventions

Under this research question, we will assess the cost-effectiveness of the INNOVETH project, including providing guidance on maximal costs for a given level of effectiveness. Cost-effectiveness will also be interpreted against relevant willingness -to-pay (WTP) thresholds to determine value for money. Further, we will also examine the overall benefits of INNOVETH intervention in terms of quality of adjusted life.

Generally, this project aims to improve mental, sexual reproductive health of Ethiopian MDWs in the Middle East. Results will be shared via peer-reviewed journals, policy briefs, stakeholder workshops, and open-access platforms. The project period is 4 years (Nov 2025 to October 2029) with a total budget of €1.5 million Euro funded by the Wellcome Trust (UK) through the Transdisciplinary Approaches to Mobility and Global Health Joint Call.

3. BACKGROUND

3.1 Migration and Health

Migration is a dynamic and complex global phenomenon that shapes the political, economic, demographic, and socio-cultural situations of nations, communities, and individuals [1]. According to the latest available evidence, there were 281 million international migrants worldwide in 2020 [2], accounting for 3.6% of the global population. Migration is triggered by several factors such as political instability, economic difficulties, and environmental disasters [3]. Modernisation, globalisation, stronger social networks, and the desire for a better life are also key facilitators of migration [4]. The effects of migration are multifaceted and can have significant consequences for both the sending and receiving countries [5]. One of the sectors shaped by migration is domestic work [6]. Reports showed that there are 11.5 million migrant domestic workers (MDWs) worldwide [7], representing 7.7% of the global estimate of 150.3 million migrant workers. The Arab States are among the major global destinations for MDWs, accounting for 27.4% of the 11.5 million MDWs worldwide [7]. Nearly three-quarters of the MDWs in the Arab States are women. Most of them are from Asian and African countries such as Sri Lanka, the Philippines, Bangladesh, Nepal, Indonesia, Ethiopia, and Kenya [8]. MDWs provide indispensable services in the destination countries [9]; nonetheless, they are confronted with vulnerabilities, leading to violations of their human and labor rights [10]. Evidence also shows that domestic workers often lack access to timely and appropriate health services.

Ethiopia is one of the major source countries for MDWs to the Middle East. Due to the economic crisis, high unemployment rate, internal conflict, and war, many are still forced to leave Ethiopia to seek employment abroad [11]. In the stakeholder engagement and involvement activity for Phase I grant of this project, the Ministry of Labour and Skills (MoLS) of Ethiopia reported that between July 2023 and May 2024, over 314,000 people, most of them were women, migrated to the Middle East using the legal channel and a lot more using illegal routes. MoLS also has a plan to send more than 700,000 domestic workers to different Middle East countries per year.

A recent phenomenon shaping the migration dynamics in Ethiopia is return migration [12]. According to official reports from the Ethiopian Ministry of Women and Social Affairs, over 70,000 MDWs are being deported from the different Gulf States every year. A significant number of other MDWs are also voluntarily returning. Several factors contributed to return migration [13], including adverse social and cultural environments, emotional maladjustment, serious health problems, and lack of skills to fulfil employers' needs. Most Ethiopian MDWs return before or without achieving their migration objectives.

Several studies documented the adverse experiences of Ethiopian MDWs in the Middle East. These include human rights violations [14], sexual abuse [15], denial of salary, lack of access to healthcare, overwork, and sleep deprivation [16], deportation [17], detention and confinement [18], physical and mental health problems, and stigma and discrimination [19,20]. Migration has also led to social, psychological, and economic crises, affecting not only the migrants themselves but also their families and communities [21]. A preliminary analysis of the scoping review we conducted in Phase I of this project showed a higher prevalence of both mental (24%-51%) and physical (20%-40%) health issues. Higher prevalence of anxiety, depression, stress-related disorders and physical ailments were reported. During our stakeholder meeting, participants with lived experience of MDW shared their experience, stating, “The emotional, mental and physical challenges we experience, including depression, sleep deprivation, overwork, and inadequate meals, are overwhelming.” Most of the studies conducted in MDWs are either qualitative or cross-sectional surveys, mainly among migrant returnees. To the best of our knowledge, there are no studies on Ethiopian MDWs in destination countries nor on interventions that mitigate the negative experiences of MDWs.

In the last few years, a new bilateral agreement was signed between the government of Ethiopia (GoE) and some of the Gulf States on recruiting MDWs. The agreement requires the GoE to offer qualified MDWs who meet certain specific criteria, including medical and physical fitness, to carry out specific tasks. Host countries then imposed comprehensive pre-migration medical screening, covering a wide range of conditions such as tuberculosis (TB), HIV, mental, sexual and reproductive health (MSRH). Twelve private health facilities in Addis Ababa were certified by the Gulf Medical Council to do the screening. Only those deemed medically fit are allowed to travel. Our preliminary analysis of the pre-screening electronic medical data in Phase I showed substantial variability of MDWs in their socio-demographic characteristics such as age, marital status, geographical origin, education, previous migration and domestic work experience, suggesting variable risk profile among MDWs. Regardless, limited awareness of their legal and medical entitlements, coupled with their socioeconomic standing and nature of their work renders MDWs a vulnerable, hard-to-reach population [22].

However, MDWs maintain their pre-migration social connections with their recruitment agencies, peers from the same origin, and families through mobile calls or social media [23], also highlighted during our visit to local employment agencies. These social networks, in combination with the big health data generated during the migration process and technology [24], could be used to provide targeted health and psychosocial interventions tailored to the needs of MDWs. MDWs depart from their residence, interact with employment agencies, complete the medical check-up in Addis Ababa, and then move to their employer in the Middle East. See figure 1 below.

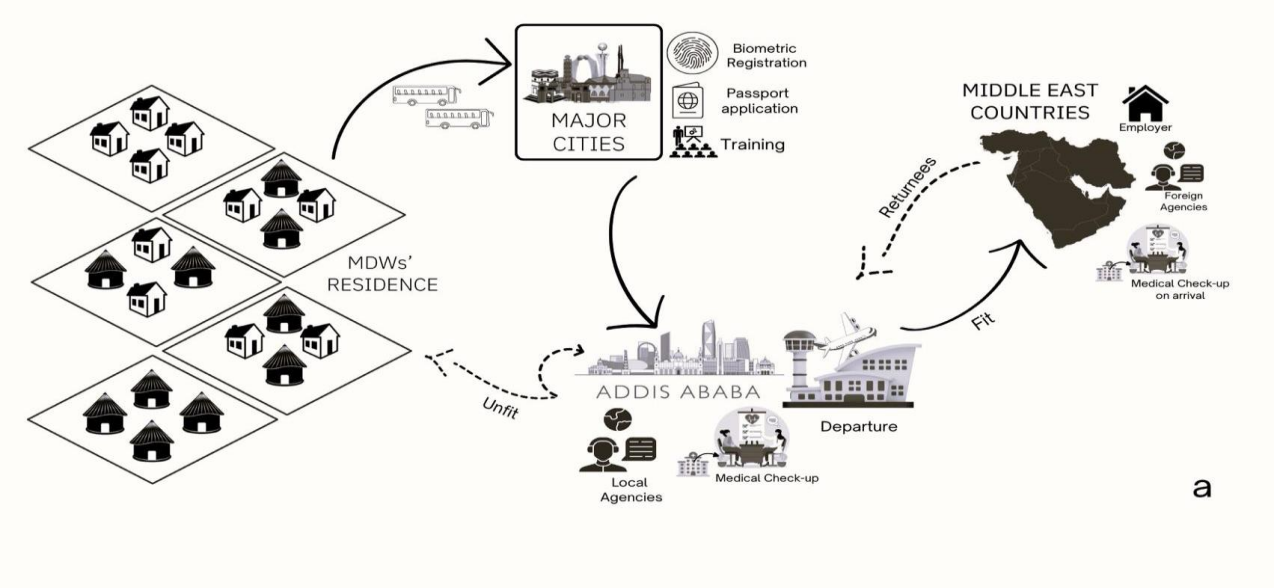


FIGURE 1: OVERVIEW OF MDWS' MIGRATION PATHWAY TO THE MIDDLE EAST

3.2 The INNOVETH study

Fostering community identity and empowering MDWs can be difficult, particularly where MDWs are marginalised, hidden and have low social cohesion. MDWs are heterogeneous in age, education, marital status, domestic work experience and work transitions; all these factors are likely to influence their levels of peer support, behavioural risk, and health service use.

The INNOVETH intervention is specifically designed to reach women while abroad for domestic work and isolated from their families and community. We propose to evaluate our INNOVETH intervention in a pragmatic cluster randomised controlled trial (RCT) nested within the labour migration programme in Ethiopia. We aim to determine the population impact and cost-effectiveness of the intervention among MDWs, in terms of the proportion of women who reported psychological distress using a validated psychological distress scale.

During Phase I of this project, we developed an intervention which aims to provide risk-differentiated support to engage with prevention and care services as well as to strengthen social cohesion and community empowerment among MDWs. This support is provided with a mobile application with pre-departure digital skills training. It aims to empower MDWs with:

- Regular, risk-differentiated and structured one-to-one contact with peers (through mobile Apps) that nudges individuals and their networks to stay healthy.
- Strengthened solidarity and space to discuss problems, issues, and norms (through strengthening their social networks and participation in self-help groups)
- Conduit to facilitate transfer of information through the system and supporting programmatic response.

4. RESEARCH OBJECTIVES AND QUESTIONS

4.1 Research Objectives

The overarching aim of this pragmatic implementation-oriented project is to develop and evaluate a complex mental, sexual and reproductive health (MSRH) intervention package including peer-support, digital skills training, self-help groups, counselling, and mobile health application for Ethiopian MDWs in the Middle East.

The specific objectives of the project include:

1. Develop, refine, and validate a risk-stratification tool for MDWs on MSRH to tailor the intervention.
2. Refine, pilot test and implement the intervention, and evaluate its feasibility and acceptability.
3. Evaluate the impact of the intervention in improving MSRH of MDWs and strengthening their empowerment and social networks.
4. Evaluate the cost and cost-effectiveness of the INNOVETH intervention.

4.2 Research Questions

The project has the following four research questions.

1) What individual and work-related characteristics predict the risk of MSRH in MDWs post-migration?
2) How effective is the INNOVETH intervention compared to the usual care (a 21-day pre-departure training (certificate of competence) with respect to MSRH post-migration?
3) What is needed, in terms of support among MDWs to achieve optimal MSRH post-migration? To what extent does our intervention achieve this?
4) What is the cost and cost-effectiveness of the interventions?

4.3 Overall Hypothesis

We hypothesise that MDWs' MSRH challenges vary based on sociodemographic characteristics; use of MSRH services; and host family characteristics. For example, younger, less educated, first-time migrants in larger or abusive host families may face higher mental health risks. Clusters of MDWs with specific health challenges could be identified and risk-stratified based on their socio-demographic characteristics utilising data science methods. Based on previous experience and evidence, we also hypothesise that a theory-based complex intervention, adapted to the Ethiopian migrant context, combining skills training, peer support, counselling, MDW community empowerment, and innovative technology, can enhance adherence to MSRH services that will lead to improved health and well-being cost-effectively. Figure 2 below outlines how the four questions and the hypothesis relate to one another as well as project related work packages.

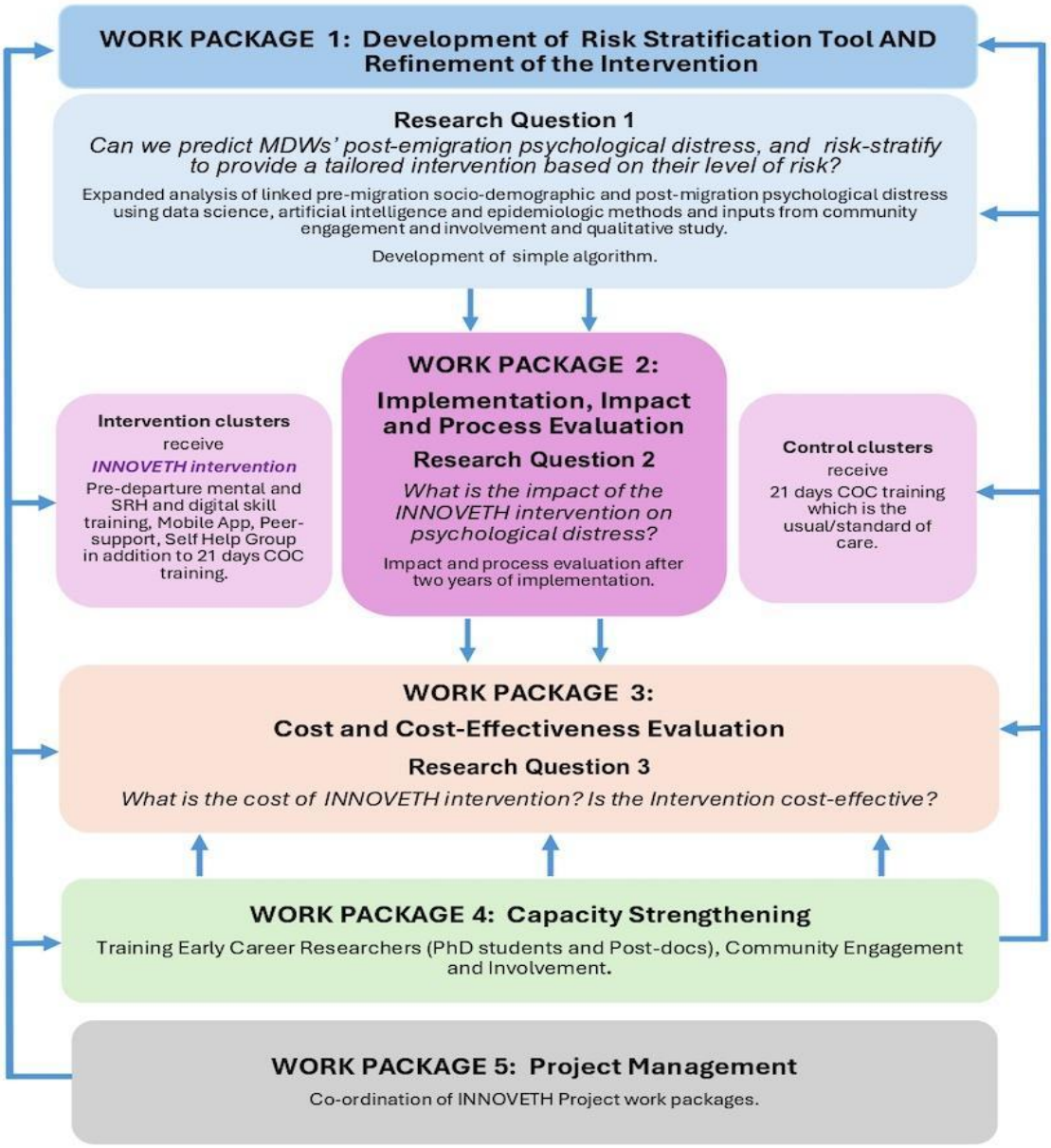


FIGURE 2: OVERVIEW OF RESEARCH QUESTIONS AND ACTIVITIES

[1]**Primary endpoint** defined as % of MDWs who have psychological distress after 24 months measured using the 21-item Depression, Anxiety and Stress Scale.

[2]**Secondary endpoints** defined as 1) % MDWs who have psychological distress after 12 months; 2) % MDWs who have a) depression, b) anxiety and c) stress at 24 months; 3) %MDWs who have self-reported sexual and/or reproductive health problems and sought healthcare services; 4) %MDWs who have self-reported sexual, emotional or physical violence; 5) %MDWs who have self-reported physical injury 6) % MDWs who self- reported pregnancy; 7) knowledge and attitude of MDWs on MSRH and services 8) % MDWs who changed their employer during the two years due to conflict, and 9) the overall well-being of MDWs, measured in terms of quality of life (QoL) at 24 months.

5. RQ1 – RESEARCH DESIGN AND METHODS

What individual, sociodemographic and migration - related characteristics predict psychological distress among MDWs in the Middle East?

5.1 Risk stratification study

We will develop a risk prediction model (risk stratification) that uses pre-departure socio demographic and migration-related characteristics to predict psychological distress during the first 2 months of post-emigration among Ethiopian MDWs in Middle East countries.

5.2 Methods

5.2.1 Design: Cross sectional survey

We aim for at least 10–20 outcome events per predictor parameter (EPV). A minimum of 400 MDWs are required to run the predictive model. The potential participants will be recruited from licensed agencies in Addis Ababa with support from the MOLS, NGOs, and training centers. A 25–30-minute structured questionnaire will be used to collect socio-demographic data, migration experience, and the 21 DASS questions. We will conduct a structured assessment 2-3 months after arrival to collect predictors and outcome variables.

5.2.2 Inclusion criteria

- Age 18 and/or older
- Living or working on the study site (for at least 2 months)

5.2.3 Exclusion criteria

- Newly arriving MDWs who has not lived in the study site for 2 months
- Non-domestic migrant workers

5.2.4 Analysis: logistic regression model

Regression coefficients will be converted into a points-based system, where each predictor is assigned points and summed to generate a total individual risk score. Based on the total score, individuals will be classified into three risk categories:

- Low risk (<10%–15%)
- Moderate risk (15%–30%)
- High risk (>30%)

5.3 Ethical considerations in relation to RQ1

Informed consent will be obtained to participate in the study. Strict confidentiality measures will be implemented, with no data shared with recruitment agencies or employers. Safety protocols will be established to respond appropriately to cases of distress, suicidal ideation, or violence. To minimize harm, sensitive questions will be placed later in the data collection process, and privacy will be ensured at all stages.

6. RQ2, RQ3 and RQ4– RESEARCH DESIGN AND METHODS

RQ2: How effective is an added, adapted peer-led support and self-help groups intervention combined with mobile application (INNOVETH) compared to the usual 21-day COC (certificate of competence) training alone?

6.1 INNOVETH trial overview

The trial will consist of two arms: an intervention arm and a control arm. Participants in the intervention arm will receive enhanced training packages on MSRH topics and digital literacy, enabling them to access resources and support through the INNOVETH mobile application while in destination countries. The INNOVETH App, which will contain information similar to that available on the existing "Mengede" app (developed by MoLS), will be installed for the intervention group before departure. This package is designed to be implemented at all stages of the migration journey: before, during, and after departure.

The control arm will receive the usual care provided by the government, along with basic training on mobile application use. This training will also facilitate post-migration data collection from the control group. All MDWs, regardless of trial arm, can access the "Mengede" app.

6.2 Specific trial objectives

1) To determine the effectiveness of the INNOVETH intervention (peer support and self-help groups based on mobile application) to reduce the proportion of MDWs with MSRH problems post-migration.

2) To identify the support needed for Ethiopian MDWs to achieve optimal MSRH post-migration and to find out the extent to which the intervention achieves this.

3) To determine the cost and cost-effectiveness of the intervention.

6.3 Theory of Change

This project draws inspiration from the peer-led microplanning model developed by the Avahan India AIDS Initiative, which optimised female sex workers (FSW) programme coverage through trained peer educators using a risk-based vulnerability algorithm [25,26]. Similarly, the AMETHIST intervention in Zimbabwe, a peer-led support initiative for FSWs through the structured risk algorithm, successfully reduced HIV transmission [24,27,28, 29, 30]. Building on this evidence and leveraging pre-migration medical screening and socio-demographic data among Ethiopian MDWs in the Middle East, we propose a theory-based, risk-differentiated intervention, tailored to Ethiopian MDWs. This approach aims to enhance social cohesion, empower communities, and improve MSRH outcomes among Ethiopian MDWs in the Middle East. Figure 3 below shows the INNOVETH theory of change.

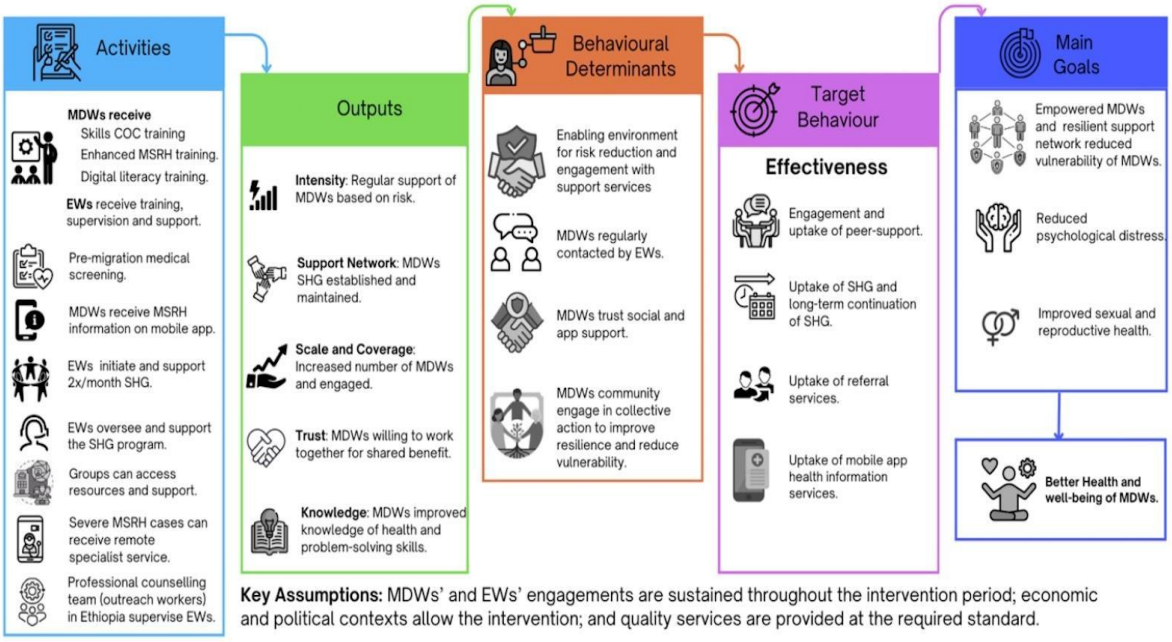


FIGURE 3: THEORY OF CHANGE FRAMEWORK

6.4 Trial Endpoints

6.4.1 PRIMARY ENDPOINT

The primary outcome is a composite psychological distress index including depression, anxiety, and stress among MDWs. This is the proportion (%) of MDWs recruited to the survey who have psychological distress after 24 months, measured using the 21-item DASS [31]. This primary endpoint data will be collected through cross-sectional surveys conducted across all clusters of Ethiopian MDWs after 24 months of risk stratified intervention.

6.4.2 SECONDARY ENDPOINTS

1) % MDWs who have psychological distress after 12 months.

2) % MDWs who have a) depression, b) anxiety and c) stress at 24 months.

3) % MDWs who have self-reported sexual and/or reproductive health problems and sought healthcare services.

4) % MDWs who have self-reported sexual, emotional, or physical violence.

5) % MDWs who have self-reported physical injury.

6) % MDWs who have self-reported pregnancy.

7) Knowledge and attitude of MDWs on MSRH and services.

8) % MDWs who changed their employer during the two years (contract period) due to conflict.

9) The overall well-being of MDWs, measured in terms of quality of life (QoL) at 12 months and 24 months.

10) Perceived levels of peer support among MDWs.

11) Acceptability and perceived quality of health services.

6.4.3 PROCESS EVALUATION ENDPOINTS

To document implementation of the intervention, understand its mechanisms of action, and contribute to interpretation of trial results, a comprehensive process evaluation will be conducted throughout the trial period.

Indicators of implementation

Intervention

1) Number of empowerment workers hired and trained
2) Weekly individual supervision meeting and monthly collective support meeting with all empowerment workers.
3) Number of modules, number of mobile applications, number of training sessions prepared, number of peer support provided

Self-Help Groups (SHGs)

1) Number of EWs trained to initiate and support 2x/month Self Help Group (SHG) in 6-month cycles.
2) Number of EWs retained in post over 2 years.
3) Number of Outreach Workers (Ows) employed to oversee and troubleshoot SHG programme.
4) Biweekly supervision SHG meetings by outreach workers for the first three months with monthly supervision from 3 months to 12 months.

6.4.4 COST ANALYSIS ENDPOINTS

a. Total and incremental economic cost
   i. Estimate total and incremental costs for routine care alone vs. routine plus INNOVETH intervention.
   ii. Costing will follow a health system perspective (or societal, if applicable).

b. Unit cost measures

i. Average costs per person reached/ contact

ii. Average costs per person per service delivered.

c. Variation by service delivery sites and over time (program maturity)

i. Assess whether total costs, cost profiles and unit costs evolve over time due to programme learning effects and as staff get more efficient at their roles.

ii. Longitudinal nature of INNOVETH provides an opportunity for econometric analysis of cost determinants.

d. Key cost drivers

i. Identify major cost contributors including program management, service delivery inputs, and location.

e. Discounting

i. Costs will be discounted at 3% annually, consistent with the cost-utility analysis

6.4.5 COST EFFECTIVENESS AND COST-UTILITY ENDPOINTS

Cost-effectiveness

Costs associated with developing, adapting, delivering, and maintaining the intervention will be included, as well as staff costs for training, moderating the online forum (application), and providing telephone counselling. To compare costs and outcomes between the intervention and control groups, an incremental cost-effectiveness ratio (ICER) will be calculated.

Cost-utility

The incremental cost-effectiveness ratio (ICER) will be compared to relevant WTP thresholds to determine whether the intervention provides good value for money within the Ethiopian health system context. Further, the overall benefits of the intervention will be assessed in terms of quality-adjusted life years (QALYs), which will serve as the primary outcome for the cost-utility analysis. QALYs will be estimated using the EQ-5D-5L instrument, a generic utility-based health status measure developed by the EuroQol Group, applying the Ethiopian value set (32]. This approach captures the overall improvement in well-being resulting from reductions in the frequency and severity of psychological distress attributable to the intervention.

6.4.6 DETERMINANTS OF TARGET BEHAVIOURS

This protocol examines the key behavioural determinants influencing the target outcome behaviors essential to the intervention's success: engagement with support services, trust in digital application, psychological resilience, and reduced vulnerability to health risks. We will assess individual, social, and structural factors—such as self-efficacy, social support, digital literacy, and perceived institutional trust—that may act as barriers or facilitators to these outcomes (Table 4).

TABLE 4: DETERMINANTS OF TARGET BEHAVIOUR AMONG ETHIOPIAN MDWS IN THE MIDDLE EAST

Target Outcome Behaviour	**Individual Factors**	**Social Factors**	**Structural Factors**
Engagement with support services	Self-efficacy, mental health literacy	Social support from peers and family	Accessibility of services, agency cooperation
Trust in the digital application	Digital literacy, previous app experience	Recommendations from trusted peers	Perceived institutional trust (government/ MoLS, Agency)
Psychological resilience	Coping skills, mood situations	Peer support network strength	Availability of psychosocial resources
Reduced vulnerability to health risks	Health knowledge, risk perception	Influence of social norms	Legal protection, employer oversight

6.5 Study locations

The study will be conducted both in Ethiopia and in destination countries including the Kingdom of Saudi Arabia, United Arab Emirates and Qatar. Potential migrants come to Addis Ababa, the capital city of Ethiopia, for pre-migration comprehensive medical screening, to meet their local recruitment agencies, and to travel to their respective destination country. We will recruit participants in Addis Ababa, in collaboration with recruitment agencies, when they come for these services. The study will run through SPHMMC, Ethiopia which provides tertiary care in the country including MSRH services. We will provide digital literacy training and collect pre-migration data while MDWs are in Addis Ababa, before their travel. In the destination countries, we will collect baseline data, implement the intervention package (peer support, self-help group, mobile application, and remote specialist counselling services) and collect midline and endline

data. Twenty-four districts designated as migration hotspots will be randomised to the INNOVETH intervention or usual care. Randomisation will be restricted on a range of key factors such as district population size, the proportion of MDWs migrating from the district each year, language and culture. The study sites will be drawn from purposively selected migration hotspot districts and zones in Ethiopia. Randomisation will be done among the following twenty-four migration hotspots: Assela, Shashemene, Jimma city, Limmu, Asendabo, Agaro,Kombolcha, Bati, Kemisse, Dessie, Hayke, Were ilu, Debre Birhan, Ataye, Worabe, Dalocha, Welkite, Butajira, Hossana, Wolaita-Sodo, Bodity, Assosa, Addis Ababa and Shagar City (Figure 4).

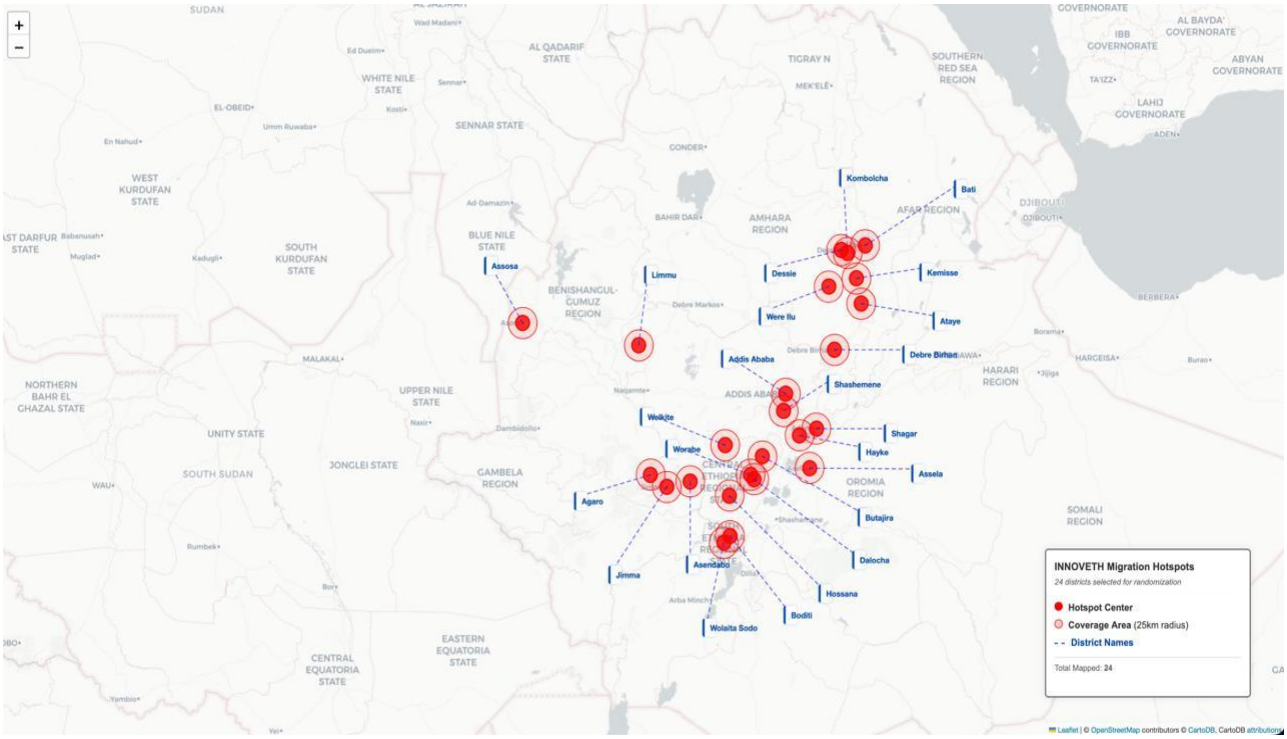


FIGURE 4: INNOVETH TRIAL SITES 24 MIGRATION HOTSPOTS

6.6 Standard of care and the INNOVETH intervention

The implementation and impact evaluation will be based on a pragmatic, two-arm cluster RCT with a process evaluation. The standard of care (usual care) refers to the national migration program. MDWs in the same district speak the same language and have similar culture. This will enable the use of existing social connections, ease building new networks among MDWs, minimize culture and communication barriers, develop efficient peer-led SHGs, and facilitate intervention implementation. The recruitment strategy will ensure a representative and scalable approach, while addressing logistical challenges associated with a mobile population. Selected 24 districts will be randomly assigned to the intervention and usual care, with 12 clusters in each group.

From each cluster, we will recruit MDWs (n=200 per cluster) willing to e-consent (electronic consent) to participate in the study. MDWs in the intervention clusters will receive: i) a pre-departure skills training, ii) peer-led support, iii) SHG, and iv) a Mobile application with MSRH content, in addition to the basic information provided in the 'Mengede' app. MDWs in the control clusters receive pre-departure training on use of the mobile application and information included in the 'Mengede' app but without any MSRH information. Outcomes will be measured at pre-departure, baseline (2 months), midline (12 months), and endline (24 months) of recruitment. The mobile application's analytics functionality will track user engagement and collect data for impact evaluation.

6.6.1. *USUAL CARE*

In the labour and skills office in the nearby district office, potential MDWs will provide their fingerprints, and a CV is created for them on the labour market information system (LMIS). Authorised institutions provide MDWs COC after completing a standard 21-day training consisting of how to navigate destination countries and a review of existing rules and procedures (the usual care). This mandatory 21-day COC skills training is provided by the technical and vocational Education and Training (TVET) colleges and certified private training institutions. Unlike first-time migrants, the duration of the COC training is 6 days for re-migrants. Upon completion of the training and passing the examination, they will be issued with a COC from the MoLS. With this certificate, they travel to Addis Ababa and connect with one of the foreign employment agencies, who had partner employment agency in the destination countries. When a host family chose the MDWs for employment, they will complete pre-departure medical screening in one of the 12 certified private hospitals or diagnostic centers in Addis Ababa. This certification is done by the Gulf Medical Council in the Middle East.

All MDWs undergo routine medical screening to ensure 'fitness' for travel. Those who are 'unfit' to travel, will receive tailored basic health consultation linked to nearby health institutions for follow-up treatment. The result of the pre-departure medical screening is electronically recorded and transmitted to the destination countries as well as the MoLS system. Those MDWs who are deemed "fit" to travel will complete the visa application through their employment agency and will travel to their destination. Upon arrival or within a few days, they will be subject to the same medical checkup, and this information is retained in the destination countries. In case of pregnancy or positive diagnosis for HIV or TB, they will be returned to Ethiopia. Currently, all MDWs can access the "Mengede" app, an app developed by the MOLS, post-migration. This app is integrated into the 'Telebirr' app, a mobile payment service app developed by Ethio Telecom, the state-owned telecommunication and internet service provider in Ethiopia.

As part of the INNOVETH project, we will develop INNOVETH digital skills training supported with mobile application that integrates MSRH information in text and audio. However, the app for the control cluster is similar to the intervention app but only providing information available on the "Mengede" app.

6.6.2. *INNOVETH INTERVENTION*

The intervention starts with an enhanced training package of psychosocial education on resilience and mental health, comprehensive sexual and reproductive health (SRH) education, and digital literacy training to equip MDWs with access to resources and support through a mobile application in their destination.

The intervention package is designed to be implemented at all stages of the migration journey: before, during and after departure. The intervention will also leverage the mobile application to deliver educational materials in text and audio formats, which will only be available for the app in the intervention group. When MDWs visit their employment agency for routine pregnancy check in 48 hours before departure, we will install the INNOVETH mobile application, provide MDWs with training on digital literacy and using the mobile application to access health education, and link them with EWs for peer support. EWs will receive an intensive one-week training to enable them to support MDWs based on their specific needs and risk profiles and take a diary to record relevant data. This ensures personalised and scalable support tailored to each MDW's risk level. A group of 40-50 MDWs in the intervention arm will be linked to a trained EW for individualised peer support.

EW will also invite some of the MDWs to join an SHG, which includes 5-10 MDWs who will meet every two weeks. Each SHG will identify their own priorities, discuss topics and activities such as saving money, and receive support towards these. The SHGs will strengthen social networks and MDWS' resilience, develop ownership of the intervention and community empowerment, and uptake of MSRH services. The risk stratification tool and the intervention package will be refined iteratively and validated through expert consensus meetings and MDWs community and stakeholder engagement and involvement.

Trained EWs will contact fellow MDWs regularly through virtual or in-person meetings, assess their vulnerability on a quarterly basis, record data on each contact, and adjust the frequency of contact with MDWs guided by data collected at their previous contact and MDW's level of risk: weekly for those at the highest risk and monthly for those at the lowest risk. EWs will also support MDWs on mobile applications and respond to crises such as workplace conflict, abuse, or health emergencies. EWs will work closely with their supervisors based in Ethiopia and discuss the data, risk stratification, and topics for discussion at the subsequent contact. They will also refer MDWs experiencing moderate to severe mental health issues, to specialised MSRH services at St. Paul's hospital Millennium Medical College in Ethiopia via telephone. Figure 5 summarises the intervention package.

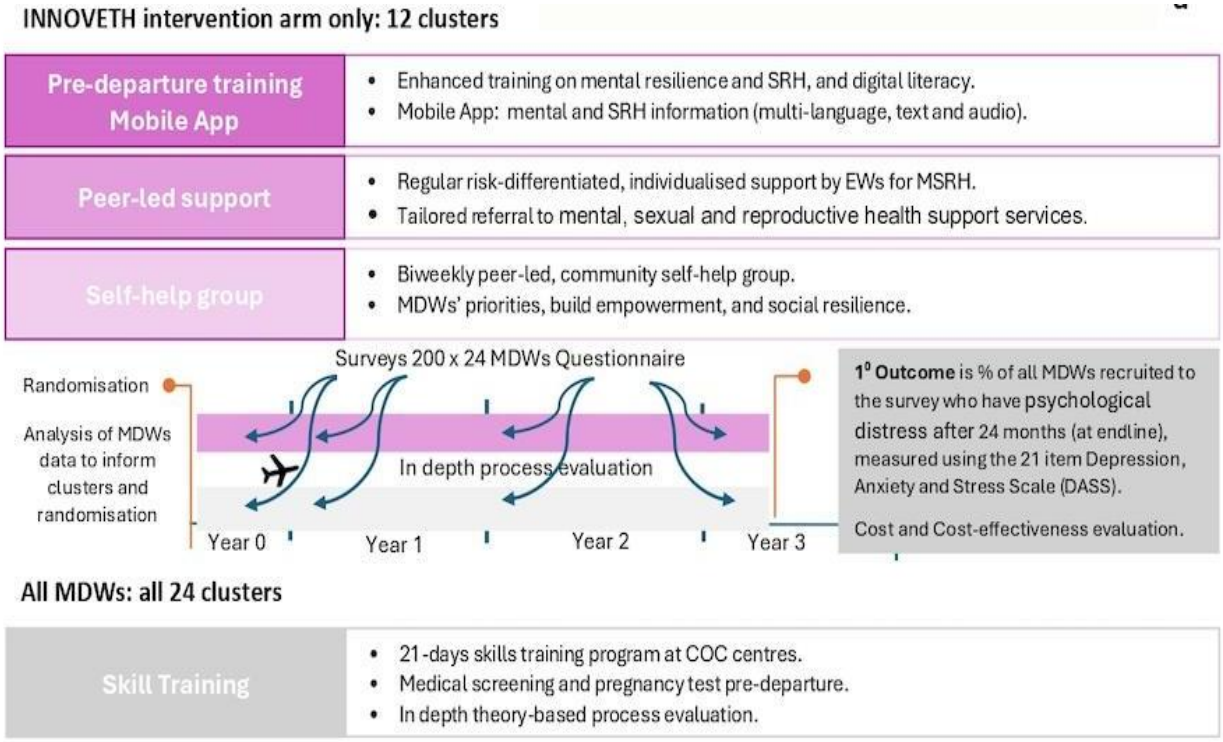


FIGURE 5: INNOVETH TRIAL OVERVIEW

6.7 Trial Design

The trial is a cluster RCT. A two-arm, cluster RCT design will be used for this study to prevent information contamination (spillover effects).

6.7.1. *CLUSTER DEFINITION*

Cluster refers to a district, administrative and geographical migration hotspot in Ethiopia where MDWs originate.

6.7.2. *RANDOMISATION*

Twenty-four districts will be randomised (1:1) to receive the INNOVETH intervention or standard care. To maximise transparency and buy-in from key stakeholders, the research team will invite MoLS, district representatives and representatives of MDWs and employment agencies. Imbalance between arms will be minimised by using restricted randomisation and matching of clusters using 2025 district level migration data.

6.7.3. *MEASUREMENT OF PRIMARY AND SECONDARY ENDPOINTS*

Endpoint data will be collected from the sources described in Table 5 below

TABLE 5: TRIAL ENDPOINTS

Primary Endpoint	**Data Source**
% of all MDWs recruited to the survey who have psychological distress after 24 months measured using the 21-item Depression, Anxiety and Stress Scale.	Survey
Secondary Endpoints	**Data Source(s)**
1) % MDWs who have psychological distress after 12 months.	Survey
2) % MDWs who have a) depression, b) anxiety and c) stress at 24 months.	Survey
3) % MDWs who have self-reported sexual and/or reproductive health problems and sought healthcare services.	Survey
4) % MDWs who have self-reported sexual, emotional or physical violence.	Survey
5) % MDWs who have self-reported physical injury.	Survey
6) % MDWs who self-reported pregnancy.	Survey
7) knowledge and attitude of MDWs on MSRH and services.	Survey, Process data
8) % MDWs who changed their employer during the two years due to conflict, and 9) the overall well-being of MDWs, measured in terms of quality of life (QoL) at 24 months.	Survey, Process data
Cost effectiveness Endpoints	**Data Source**
1) Estimate total and incremental economic cost (Usual care vs. Routine plus INNOVETH intervention. 2) Unit cost measures i) Average costs per person reached/contact (usual care alone or usual care INNOVETH intervention) ii) ii) Average costs per person per service	Survey and financial report.

3) Variation by service delivery sites & over time (program maturity) 4) Assess whether total costs, cost profiles and unit costs evolve over time due to programme learning effects and as staff get more efficient at their roles. 5) Longitudinal nature of INNOVETH provides an opportunity for econometric analysis of cost determinants. 6) Key cost contributors & other cost factors (program management, service delivery inputs, location). 7) An incremental cost-effectiveness ratio (ICER) will be calculated by comparing costs and outcomes between the intervention and control groups. 8) The ICER will be compared to relevant willingness-to-pay thresholds to determine whether the intervention provides good value for money. 9) The overall benefits of the intervention will be assessed I terms of quality-adjusted life years (QALY).	

6.7.4. *SURVEY DESIGN, METHODS AND PROCEDURES*

We will conduct cross-sectional surveys at four timepoints: pre-departure, baseline (1-2 months post-departure), midline (12m) and endline (24m). Data will be collected on socio-demographic and behavioural characteristics, MSRH, physical health, utilisation of health services, economic characteristics, and QoL using an Audio-Computer Assisted Self-Interview (ACASI) techniques, which will be uploaded on a custom developed mobile application, is believed to improve quality data collection, reporting of sensitive behaviours and exposures such as mental and sexual health, abuse, and sexual risk-taking. It has been tested in humanitarian settings of low- and middle-income countries [33]. In addition to obtaining data, the pre-departure survey will familiarise MDWs with the ACASI and facilitate post departure.

6.7.4.1. Inclusion and Exclusion Criteria

All clusters will be included in the survey. In each cluster, random sample of 200 MDWs deemed "fit'' to travel to the Middle East will be selected. Eligibility will be determined by research staff on arrival at employment agency sites. Research staff will check that each recruit reporting for enrolment meets the eligibility criteria and can answer the eligibility questions, understand the

purposes of the study and can provide e-consent. Research staff will review the e-consent forms. If the participant acknowledges full understanding of her participation in the survey, she will be enrolled. The survey itself further contains questions that will check eligibility (such as current age and whether she has complete documents to migrate).

Inclusion criteria:

- Age: 18 years and older
- "Fit" to travel to the Middle East Countries including Saudi Arabia, UAE, and Qatar.

Exclusion criteria

- Non-domestic migrant workers
- "Fit" to travel to the Middle East Countries outside Saudi Arabia, UAE, and Qatar.

Recruitment sites

Participants will be approached through selected foreign employment agencyand TVET networks and invited to participate in the study. The recruitment will be conducted following MDWs pre-migration medical screening. The research team will identify a central location where MDWs report they would be happy to go and take the training as part of the study. The locations will be selected for easy accessibility, relative discreetness, and availability of enough space to arrange e-consent as well as a private room or headphones to prevent information leakage during ACASI. Informal interviews were conducted during the development of risk stratification tools to assist in determining suitable location in each of the employment agency offices. From the randomised clusters, MDWs will be randomly selected over a one-month period to allow enough time to conduct both qualitative and quantitative studies. MDWs will complete all study procedures and will then be provided with mobile applications on their phone and group training on using the mobile application (control districts) and digital literacy skills (intervention clusters).

Data collection tools

The survey will consist of a behavioral questionnaire self-administered on tablets and/or mobile phones using ACASI. To reduce the risk of audio leakage, headphones will be provided. The questionnaire will also include specific questions about social networks to enable social network analysis. Both the questionnaire and informed consent forms will be developed in English and then translated into the local languages—Amharic and Afaan Oromo. The materials will be prepared in an Excel spreadsheet and subsequently converted into ACASI format (see Annexes 1.1–1.4). Each questionnaire will be labeled with a unique Participant ID (PTID) and linked to pre-migration medical screening data through a Computer-Assisted Personal Interview (CAPI) log. This log will connect each individual's PTID with their corresponding pre-migration medical screening record (Annex 2).

Multiplicity

MDWs will be provided with QR code with their labour ID to avoid duplication of respondents in the survey.

6.8 Intervention monitoring and process evaluation framework

The INNOVETH pragmatic cluster randomised control trial will test an enhanced package of intervention/activities on population level reductions of the risk of psychological distress and improved SRH well-being among MDWs. To document implementation of the intervention, understand its mechanisms of action, and contribute to interpretation of trial results, a comprehensive process evaluation will be conducted throughout the trial period (Annex 3.1 and Annex 3.2).

6.8.1. *HOW WILL THE INNOVETH INTERVENTION LEAD TO POSITIVE CHANGE?*

Integrating peer-support and Self-Help Groups into the usual care using mobile application is hypothesised to lead to its intended outcomes. Nesting within the trial, we will conduct a comprehensive process evaluation to document implementation of the intervention, understand its mechanisms of action, and contribute to interpretation of the trial findings. EWs conduct quarterly psychological health risk assessment and use this evidence to provide risk-differentiated support to MDWs.

EWs will also encourage MDWs to join SHGs on Telegram or Whatsapp as well as custom mobile applications, strengthen support networks, individual and group-based problem-solving skills, and increase MDWs capacity to work together to identify shared priorities and collectively act to address these. Delivery of peer-support and SHG will create an enabling environment in which MDWs are reached according to their need, equipped to address determinants of their vulnerability to mental health and actively engage in the services provided.

6.8.2. *ASSESSING IMPLEMENTATION OF INNOVETH*

Enhanced resilience, MDWs community support and service use will improve their MSRH and wellbeing. However, for the designed effect to occur as proposed, intervention components must be delivered as intended with adequate quality and intensity, and local contexts must allow sufficient feasibility and acceptability. Hence, effective implementation of an intervention requires ongoing evaluation and adaptation to local circumstances [34]. For effective implementation, we will strictly adhere to the intervention protocol, maintain meticulous records, actively engage key stakeholders, and provide extensive training to intervention providers. A process evaluation will be conducted to ensure fidelity, enhance intervention quality, and identify core components that maximise impact. In line with the Medical Research Council Guidelines for Process Evaluation [35], we have developed a framework (figure 6) to document and assess 1) Implementation 2) Mechanism of action, and 3) Contexts. We will monitor delivery and uptake of

each intervention component over time, examining ease of delivery and participation rate, MDWs experiences, perceptions, and satisfaction levels.

A mixed methods study will be used for the process evaluation. Quantitative data will be collected using surveys and process data. The mobile application also will monitor user interactions, providing insights into cultural and contextual factors affecting intervention delivery. We will also collect a qualitative data 1) in-depth interviews with MDWs (n=60), EWs (n=25), trainers and key stakeholders (n=15) including recruitment agencies and health facilities; 2) focus group discussions (FGDs) with MDWs (n= 48) and EWs (n=8); 3) document reviews; and 4) observation related to the design and implementation of the intervention. Data will be analysed thematically.

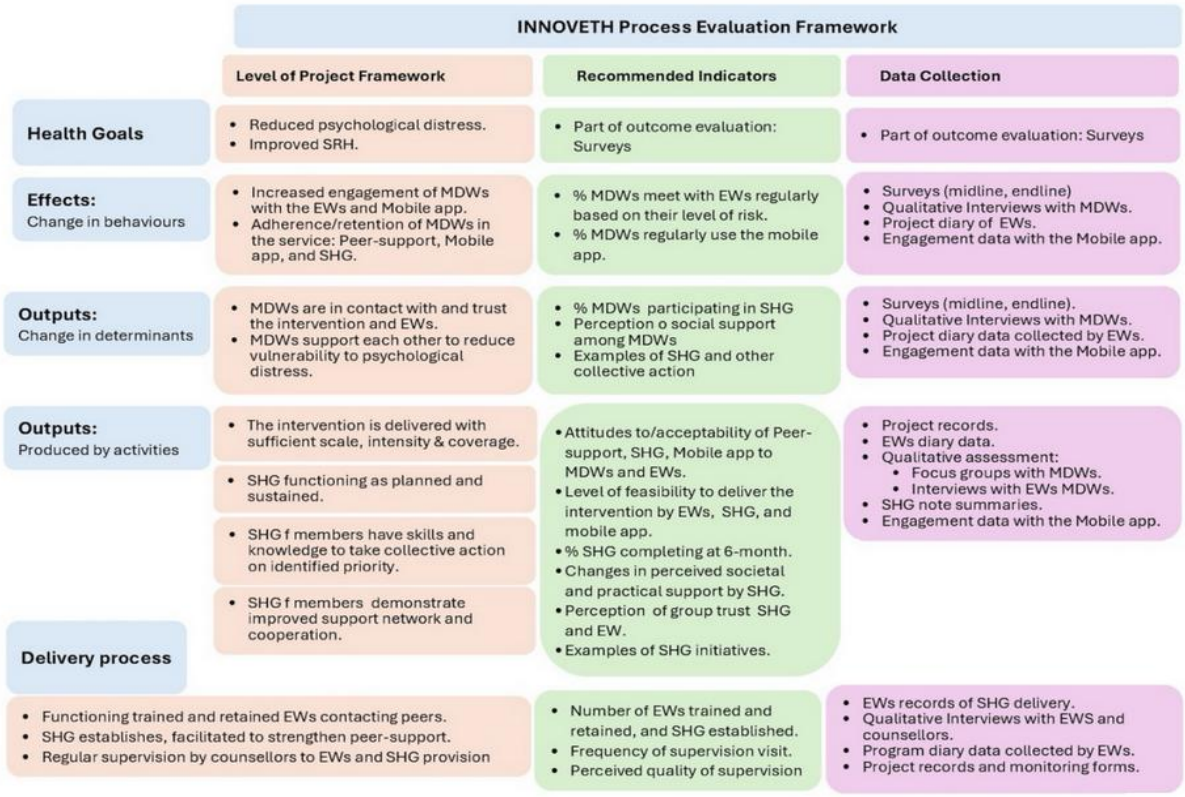


FIGURE 6: INNOVETH TRIAL PROCESS EVALUATION FRAMEWORK

6.10 Process evaluation data collection

6.10.1. CHECKLISTS

A prospective record will be maintained of if/when planned activities (as per protocol) are implemented.

6.10.2. STAFF AND TRAINING RECORDS

Routine programme documentation on start-up activities of the project, including the number of staff hired and deployed, and how many attended all relevant trainings. These will be reviewed annually and at the end of the project if staff retention/performance considered to be an issue affecting the delivery of intervention components.

6.10.3. SELF-HELP GROUP RECORDS

Empowerment workers will be *given recording sheets* on which to record all contact with peers as outlined in the training manual.

6.10.4. QUALITATIVE DATA

The data collection will include process endpoints related to intervention uptake in the intervention arm. Participants will be asked to provide written informed consent for participation in the survey and qualitative interviews. The qualitative interview topic guides and the participant information sheet are included as attachments (Annex 4.1–4.9).

- In-depth interviews and focus group discussion with MDWs: In-depth interviews with MDWs will be conducted at three intervals across the project (baseline, mid-line and endline) in both intervention and control clusters. MDWs will be purposively selected for specific attributes such as high or low levels of engagement in activities (in intervention clusters), experience as peer educators or MDWs care supporters, users and non-users of services, and different ages and types of domestic work. Interviews will explore perceptions of community cohesion and social support among MDWs, perceptions of available services including mobile application, and positive and negative experiences of the intervention (or reasons for choosing to participate or not) in intervention sites.

- Semi-structured interviews with EWs: Semi-structured interviews with staff at intervention (including any staff who have left the programme) will be conducted to elicit perceptions of the feasibility and acceptability of the intervention and their own levels of satisfaction and perspectives on its quality. Specific issues will be probed, such as ease of delivering the enhanced package, particularly challenges faced in increasing MDWs mobilisation and self-help groups.

- Semi structured interviews with key stakeholders: Semi structured interviews with key stakeholders, including INNOVETH/SPHMMC management and staff, and representatives of other partner organisations such as MoLS, MoH, and services to which referrals were made.

- Project diary: A calendar or diary will be kept by a member of the INNOVETH research team to record any events (particularly external) that may affect ability of the intervention to be delivered as planned. Police crackdowns, local festivities, and other health promotion campaigns should all be noted, with a description of their activities and effect. Internal events that have bearing on implementation (such as break-down of the app) will also be noted to help contextualise other collected information.

6.11 Data management

SPHMMC will be the data coordinating centre. This unit is headed by an experienced data manager. Data management and security standards will be equivalent for routine programme data and data collection in surveys, though there will be significant differences in the way data is collected. For survey, data will be collected using ACASI with assistance from a trained EWS. Data validity checks will be built into the ACASI platform. Data will be backed up daily into "cloud storage". Laptop computers on which project data is stored must always be password-locked and kept in secure storage when not in use. Teams will return to SPHMMC at the end of each week to download data into a password protected database accessible only to the project data manager and named study personnel, on a central computer. This will be backed up daily.

The consent forms will be kept separately from survey data. Printed consent forms will be stored in a locked room. For programme data, one hard-copy file linking participants' names with ID numbers, and contact/locator information will be maintained by the project coordinator and stored in a secure locked cabinet separate from participant data. Other hard-copy data will be stored separately in participant files and locked in a file cabinet located in a secure room accessible only to key study personnel. Data will be anonymised, cleaned, entered, and analysed.

6.12 Statistical considerations

6.12.1 SAMPLE SIZE CALCULATIONS

The sample size is based on pragmatic considerations. Outcomes will be assessed after 2 years of implementation through respondent-driven sampling surveys (n=200 per cluster) conducted within each cluster. Analyses will be adjusted accordingly. With 24 clusters, assuming outcome prevalence of 30% [19], we have 80% power to detect a 33% difference in % MDWs who have psychological distress between the intervention and control arms in 1:1 ratio. We used Hayes and Bennett's approach for cluster RCT to calculate sample size and power [36]. In Table 6 we show power calculations, considering different baseline prevalence of the outcome and effect sizes. The number of clusters and individuals per site is fixed (at 24 and 200, respectively) as it is not feasible to conduct a larger trial.

TABLE 6: INNOVETH PROJECT POWER CALCULATION

PROPORTIONS: UNMATCHED											
1-type I	power	z_a	z_b		π_0	% reduction	π_1	cluster size	k	# clusters per arm*	* to be conservative, round up
0.95	**0.37**	1.96	-0.332	2.651	**20.00%**	**20%**	16.00%	**150**	**0.25**	11.04	12
0.95	**0.73**	1.96	0.6128	6.619	**20.00%**	**30%**	14.00%	**200**	**0.25**	10.43	11
0.95	**0.94**	1.96	1.5548	12.35	**20.00%**	**40%**	12.00%	**200**	**0.25**	10.13	11
0.95	**0.995**	1.96	2.5758	20.57	**20.00%**	**50%**	10.00%	**200**	**0.25**	10.00	11
0.95	**0.4**	1.96	-0.253	2.913	**30.00%**	**20%**	24.00%	**200**	**0.25**	10.05	11
0.95	**0.78**	1.96	0.7722	7.465	**30.00%**	**30%**	21.00%	**200**	**0.25**	10.46	11
0.95	**0.96**	1.96	1.7507	13.77	**30.00%**	**40%**	18.00%	**200**	**0.25**	10.02	11
0.95	**0.999**	1.96	3.0902	25.5	**30.00%**	**50%**	15.00%	**200**	**0.25**	10.88	11
0.95	**0.45**	1.96	-0.126	3.365	**40.00%**	**20%**	32.00%	**200**	**0.25**	10.82	11
0.95	**0.8**	1.96	0.8416	7.849	**29.00%**	**30%**	20.30%	**150**	**0.25**	11.66	12
0.95	**0.98**	1.96	2.0537	16.11	**40.00%**	**40%**	24.00%	**200**	**0.25**	10.89	11
0.95	**0.999**	1.96	3.0902	25.5	**40.00%**	**50%**	20.00%	**200**	**0.25**	10.25	11
0.95	**0.45**	1.96	-0.126	3.365	**50.00%**	**20%**	40.00%	**200**	**0.25**	10.45	11
0.95	**0.83**	1.96	0.9542	8.492	**50.00%**	**30%**	35.00%	**200**	**0.25**	10.69	11
0.95	**0.98**	1.96	2.0537	16.11	**50.00%**	**40%**	30.00%	**200**	**0.25**	10.48	11
0.95	**0.999**	1.96	3.0902	25.5	**40.00%**	**50%**	20.00%	**200**	**0.25**	10.25	11

6.12.2 STATISTICAL ANALYSIS

Primary analysis will be based on intention-to-treat principle, using cluster summaries to account for clustering. Cluster summaries of individual MDWs data will be calculated, then the mean of the cluster summaries will be calculated for each group. For unadjusted analysis, we will fit a linear regression model on the cluster summaries at the endline, with treatment dummy and cluster summaries at baseline as regressors. We will use the p-value and confidence intervals for the coefficient of the treatment dummy. To address the possibility of confounding, we will conduct adjusted analysis using the 'two-step' method of Hayes and Moulton [36,37]: i) We will fit individual logistic regression model with the primary outcome as the dependent variable and age (specified a priori) and other variables, that appeared imbalanced post-randomisation, as independent variables to generate predicted probabilities for each MDWs. The mean of the predicted probabilities will be interpreted as predicted prevalence for each cluster. ii) We will calculate the 'residual' risk difference (RD) by subtracting the predicted prevalence from the observed prevalence in each cluster. We will then fit a linear regression model on the residuals to calculate adjusted RD and associated 95% confidence interval.

We will use descriptive statistics to assess whether there was balance across the two arms in key socio-demographic and potentially confounding variables at endline surveys. Results will inform those variables to be adjusted for in the adjusted analysis, with particular attention paid to variables that are known a priori to be associated with the endpoints of interest. We will also explore and report response rates across the arms. Full details of the adjustment strategy will be included in a statistical analysis plan finalized before the data are analysed. To generate an adjusted model, we will fit an individual-level logistic regression model with the primary outcome as the dependent variable, and age and any other confounders as independent variables. This model will be used to generate predicted probabilities for each MDW. For each cluster, we will calculate the weighted arithmetic mean of the predicted probabilities. The mean of the predicted probabilities will be interpreted as the predicted prevalence for each cluster. The strength of evidence against the null will be assessed using an unpaired t-test. Alongside the RCT, we will conduct an economic evaluation following Drummond et al's approach [38]. Data on resource use and health outcomes will be collected at baseline, midline and endline. Costs associated with developing, modifying, delivering, and maintaining the intervention; staff costs related to training, moderating the online forum (application), and telephone consultation for counselling will be included. To compare costs and effects between the intervention and control groups an ICER will be calculated. The overall benefits of the intervention will be assessed in terms of QALYs, which is the primary outcome for the cost effectiveness analysis.

6.12.3 COSTING ANALYSIS

The costing objective is to measure and analyse economic costs of scaling up the integrated model of peer-led support, self-help-groups, and mobile application for MDWs. Economic costs include financial costs representing actual expenditure on goods and services and volunteer time and/or donated goods for which there were no financial transactions.

i) Prospective costing study

a. The prospective nature of INNOVETH provides an opportunity for us to examine costs over time as it is not limited by the short nature of most studies. Specifically, we will:
   i. Assess the changing cost structure of mental health service.
   ii. Cost variation with programme evolution and scale.

ii) Top-down costing approach.

a. Comprehensive access to data (expenditures, time sheets, M&E etc) to facilitate allocation of program expenditures to sites and then to activities
b. Costs will be disaggregated and categorised by activities and input type.
   i. Startup, capital and recurrent costs
c. Approach captures total cost better though less precise for disaggregating costs at the activity level.
d. First allocating out specific expenditures that could be clearly tracked to sites, then by M&E outputs such as persons reached, distances etc
e. All expenses prior to first person reached by INNOVETH will be treated as start-up costs and together with capital costs annualised at 3% discount rate

iii) A bottom-up approach

This will supplement costing (more site level data collection) to ensure robustness of cost allocation

a. Data for baseline cost analysis in all 24 clusters
b. Includes interviews with site program staff.
c. Time and motion analysis

iv) Cost data analysis

a. Data will be entered and analysed in a Microsoft Excel spreadsheet.

6.13 Ethical considerations

This protocol will be reviewed and approval by independent institutional review boards (IRB) at all participating institutions, including those in Ethiopia (AAU, SPHMMC, and AHRI), London School of Hygiene and Tropical Medicine (UK), and Oslo Metropolitan University (Norway). This will include, according to each IRB's requirements, approval prior to the initiation of research, on-going adverse risk monitoring, periodic review, and final study reporting. Support letters will be sought from the Ministry of Health and MoLS to implement the study. The DATA will be collected through ACASI, a data collection method where participants listen to recorded questions via headphones and input answers directly onto a device, enhancing privacy for sensitive topics like health, violence, or behavior. It reduces interviewer bias and improves data accuracy, particularly in low-literacy settings. INNOVETH project has a referral plan to support any participant who needs urgent referral due to health and legal issues (Annex 5). All study staff will undergo GCP, GDPR and health ethics training courses (certificates attached). We will consider the following ethical issues to be addressed throughout the study.

6.13.1. *PARTICIPANT INFORMED CONSENT*

Study participants will be recruited under good clinical practice by experienced researchers trained and certified in health ethics, Good Clinical Practice (GCP) and Safeguarding. The study participants (MDWs) will be trained to read and/ or listen the informed consent and provide their e- consent through ACASI. Study participants will be provided a digital function to ask any questions they may have regarding the study. More specifically, throughout the research project, the following processes will be followed as far as consent is concerned. Detailed information about the research and study procedures will be provided to participants in languages accessible to MDWs (Annex 1.1–1.3). Standard guidelines for non-literate participants (those who do not read) will be followed, as specified in the SOP for the trial team (Annex 6.1).

6.13.2. *COMPENSATION*

Study participants will not receive any financial compensation for taking part in the interview, to ensure that participation is entirely voluntary and the responses are not unduly influenced. However, the project will attempt to provide menstrual sanitary pads to the MDWs departing to the middle east. EWs will receive compensation to cover their time and travel expenses incurred in supporting the recruitment and supporting in project implementation measures, as an appreciation for vital their contribution.

6.13.3. *CONFIDENTIALITY*

The research team will ensure that all research data collected are numbered with a unique ID and not named. A link log which links the unique ID to participants' name will be kept by the project coordinator at SPHMMC in a locked and secure place, separate from the questionnaire/interview data.

Names, addresses and other identifying information of the participants will be required at the study sites for follow up purposes, and will be kept separately. Only the coordinator, data manager and investigators will have access to this information. We will be collecting private information from participants. However, only necessary personal information will be collected and de-identified where possible. Data will be stored in locked cabinets and password protected computers which only project staff can access. All staff, who have access to these records, will be asked to sign statements agreeing to protect the security and confidentiality of identifiable information with strict confidentiality procedures in place (Annex 7). Identifying information will be removed from all data prior to analysis and dissemination of research findings. An electronic copy of anonymized data will be kept for 7 years at SPHMMC. After 7 years the hard copies of the data will be deleted while unidentified data will be maintained for future research use.

6.13.4. *POTENTIAL BENEFITS*

The potential benefits of this research project to various stakeholders are anticipated to be as follows:

- Key local, national and international stakeholders will be involved in the implementation of the research project as members of community level and country level advisory groups. Capacity will be developed among policy makers, planners, and service providers in the development, delivery and scaling up of the intervention. This includes training in specific aspects of the intervention, and access to a range of workshops and meetings that will be organized by the INNOVETH project.
- MDWs will benefit through receipt and participation in health interventions, self-help groups and peer-support interventions.
- Consumers of the research products (such as research funders, policy makers, other researchers and NGOs) will benefit through gaining new knowledge. The networks and partnerships that are established through this process will provide a platform for the sustained strengthening of health and wellbeing of MDWs and research beyond the life of INNOVETH.

6.13.5. *POTENTIAL RISKS*

We generally feel that the risks associated with this research project will be minimal. Nevertheless, we will minimize potential risks by ensuring that participants are cognizant of all risks and benefits prior to voluntary participation. The potential risks and our strategies for minimizing them are discussed below.

Psychological distress in the interview process

Participants may find discussions of personal and community issues distressing. These risks will be reduced by using skilled and highly experienced EWs and counsellors who can establish good rapport with the participants prior and during the research process. Discussing personal information may be particularly more distressing among people who have migration experiences and these risks will be mitigated by establishing good rapport with the participants prior and during the intervention process. Referral to health care services, employment agencies and Ethiopian embassies or consulates will be made when specific mental health needs and legal right violations are identified.

Least restriction or coercion to participate

We need to ensure that all participants are fully informed of the study procedures. Informed consent will be sought and recorded in ACASI. The ACSI will also address non-literate participants.

Burden on local communities (stakeholders)

There may be a potential burden of the project on local communities, including time required from practitioners, policy makers and community participants. This will be identified during the study planning phase and will be kept to a minimum.

Inequitable distribution of treatment

Every effort will be made to ensure fair implementation of the research project, with particular attention to the needs of marginalised and vulnerable groups. Indeed, INNOVETH is focused on improving participation of vulnerable groups in improving the health and wellbeing of MDWs.

6.13.6. INNOVETH TRIAL DATA AND SAFETY MONITORING BOARD

A Data and Safety Monitoring Board (DSMB) has been established and will meet at the outset of the trial virtually using ZOOM, and then semi-annually. The DSMB will approve the overall protocol, assessments, and consent forms. The DSMB will receive all reports of data breach, events, as will the IRBs overseeing this study. Meetings of the DSMB can be scheduled, as needed, to discuss and resolve potential risks. The DSMB will review semi-annually, all accrued data to assess that study objectives are being met, and to ensure that benefit exceeds harm. The DSMB will review and approve the statistical analysis plans prior to the analysis.

6.13.7. INNOVETH EXTERNAL ADVISORY BOARD

The trial has established an external advisory board (EAB) comprising of eleven board members. One MDW and one community stakeholder from the trial communities will also be invited. The main aim of this established EAB is to support and provide strategic guidance, stakeholder engagement, ethical oversight, and contextual relevance of interventions, and research and capacity building activities.

The EAB functions in an advisory capacity to the main trial team, which will be endeavoured to respond appropriately to the issues raised. The EAB will assist trial staff in developing culturally and linguistically appropriate materials for study participants such as study specific fact sheets and informed consent forms. All members of the INNOVETH Advisory Board and the INNOVETH project management team who are involved in coordinating the Advisory Board activities in Ethiopia and destination countries in the Middle East will have separate SOP.

6.13.8. TRIAL MODIFICATION AND DISCONTINUATION

The study may be modified or discontinued at any time by the IRBs as part of their duties to ensure that research participants are protected. Interim analyses are planned at 12-month post intervention implementation using the midline data.

6.13.9. PROTOCOL DEVIATIONS AND EXCEPTIONS

The investigators should not implement any deviation from, or changes of, the protocol without prior review and documented approval from the Ethical Committee of an amendment, except where necessary to eliminate an immediate hazard(s) to trial participants. The investigators should document and explain any deviation from the approved protocol and file waivers received from the SPHMMC Ethics, if applicable.

7. PROJECT MILESTONES

TABLE 7: INNOVETH PROJECT MILLSTONES

Timeline	Milestones
2025-in preparation for Award	Wellcome Trust funding in place Project launch Human resource recruitment Project overview and scoping review papers write up Protocol development for ethics application
Month 6	SOPs developed External advisory board formed Risk stratification study started Protocol development and regulatory approval in place Stakeholders' engagement and involvement workshop Selection and randomisation of 24 migration hotspot clusters for intervention App development and testing Paper reviews, risk stratification follow up
Month 12	Tool development (questioner in ACASI) Translation and piloting MSRH manuals developed and piloted Volunteers' recruitment and training Participant enrolment Survey (predeparture) Mobile App dvt, pilot and testing Scoping review, programme overview, and risk stratification submitted for review
Month 24	Intervention pilot Second stakeholders meeting Data Analysis of data, modifications peer learning and self-help group Interventions and process evaluation Risk stratification study data analysis and intervention modelling Semi-annual EAB and DSMB board meetings held Survey (predeparture, baseline and midline) Continued process evaluation Costing data collected Midline survey Scoping review, programme overview, and risk stratification paper for published

Month 36	Endline Surveys Data Analysis Modelling of cost effectiveness Disseminations Paper write up
Month 48	Publications (primary outcome paper, process evaluation paper, and costing papers) Follow up project developed Update intervention model including models based on study findings PhDs and follow-up
Month 60	INNOVETH papers and policy briefs published Final impact papers published Papers on and cost effectiveness published

8. DISSEMINATION STRATEGIES

The project plans for sharing research findings within the scientific community through presentations at conferences/workshops and via peer reviewed publications. Active policy dialogue meetings in Ethiopia and Gulf countries, where government and donor representatives will be invited. We will share experiences, data and evidence generated by the research project and challenge policy bias and policy incoherence in a constructive evidence-based dialogue - striving towards political commitment for allocation of financial resources to improve health care needs of MDWs.

The project will also disseminate key findings through publications in high-impact, peer-reviewed international, regional and national journals. A minimum of 12 peer-reviewed scientific articles will be produced, covering the key themes of the project such as barriers and facilitators to health services, psychosocial interventions, sexual and reproductive health, digital interventions, peer-support frameworks, and policy recommendations for improving health and social service delivery. Public and stakeholder engagement will be prioritized through collaboration with partners, government agencies, NGOs, and people with lived experience the user advisory group, facilitating direct communication with policymakers and target populations. Findings will be shared at international and regional conferences. Our partnerships with higher education and healthcare institutions and NGOs enable dissemination to healthcare providers and social workers and other key practitioners. The project will also utilize newspapers, social media, and short documentary films highlighting MDWs' experiences and the intervention's impact.

9. REFERENCES

1. Jiang Z, Wang Y, Guo F, Gollan PJ (2018). Vocational experiences and quality of life of migrants: Overview and future research. Soc Indic Res. 139:403-414. doi:10.1007/s11205-017-1727-9.
2. IOM (2022). World migration report, Geneva, Switzerland. https://publications.iom.int/books/world-migration-report-2022. Accessed on 10 March 2023.
3. Castelli, F. (2018). Drivers of migration: why do people move? J Travel Med. 25:1-11. doi: 10.1093/jtm/tay040.
4. Ferwerda J, Gest J (2021). Pull factors and migration preferences: Evidence from the Middle East and North Africa. IMR. 5:431-459. d oi: 10.1177/0197918320949825.
5. Helms B, Leblang D (2019). Global migration: Causes and consequences. In Oxford Research Encyclopedia of Politics. doi: 10.1093/acrefore/9780190228637.013.631.
6. Durekova, P. (2015). A Global Action Programme on Migrant Domestic Workers and their Families. https://colilink.org/20.500.125 92/3sqp3d. Accessed on 22 December 2024.
7. ILO (2021). Global Estimates on Migrant Workers and Migrant Domestic Workers: Results and Methodology. Geneva. https://www. ilo.org/publications/ilo-global-estimates-international-migrant- workers-results-and-methodology. Accessed on 22 December 2024.
8. Auwal, MA (2010). Ending the Exploitation of Migrant Workers in the Gulf, 34 Fletcher F. World AFF. 87.https://www.researchgate.ne t/publication/281146755. Accessed on 10 March 2023.
9. Gallotti M, Branch IL (2015). Migrant domestic workers across the world: Global and regional estimates. International Labour Organization: Geneva, Switzerland. 1-8.
10. Girmachew, AZ (2018). Ethiopian female domestic labour migration to the Middle East: patterns, trends, and drivers. ABD. 11:16-19. doi: 10.1080/17528631.2017.1342976.
11. The Freedom Fund (2023). Ethiopia hotspot report. The Freedom Fund. https://freedomfund.org/wpcontent/uploads/EthiopiaHotspotReport_2023_FINAL.pdf. Accessed on 10 March 2023.

12. Kuschminder K, Ogahara Z, Rajabzadeh I (2021). Evaluations of return within a mass deportation: Ethiopians' experiences of return after expulsion from Saudi Arabia. Int Migr. 59:167-185. doi: 10.111 1/imig.12742.

13. Girmachew, A. (2021). Understanding the forced repatriation of Ethiopian migrant workers from the Middle East. Friedrich Ebert Stiftung Flight and Migration Competence Center. Addis Ababa. http s://coilink.org/20.500.12592/4fvcxs. Accessed on 10 February 2025.

14. Felegebirhan, BM (2019). Potential Migrants: the Overlap between Migration and Human Rights in Ethiopia. EJHR. 4:95-123.

15. Gezie LD, Worku A, Kebede Y, Gebeyehu A (2019). Sexual violence at each stage of human trafficking cycle and associated factors: a retrospective cohort study on Ethiopian female returnees via three major trafficking corridors. BMJ open. 9:e024515. doi: 10.1 136/bmjopen-2018-024515.

16. Fernandez B (2018). Health inequities faced by Ethiopian migrant domestic workers in Lebanon. Health Place. 50:154-161. doi: 10.10 16/j.healthplace.2018.01.008.

17. de Regt M, Medareshaw T (2016). Deported before experiencing the good sides of migration: Ethiopians returning from Saudi Arabia. ABD. 9:228-242. doi: 10.1080/17528631.2015.1083178.

18. Mengiste TA, Abebe T (2023). Ethiopian girls narratives of risk and governance of circular migration to the Arabian Gulf. Child Soc.1:17. doi: 10.1111/chso.12791.

19. Habtamu K, Minaye A, Zeleke WA (2017). Prevalence and associated factors of common mental disorders among Ethiopian migrant returnees from the Middle East and South Africa. BMC Psychiatry. 17:144. doi: 10.1186/s12888-017-1310-6.

20. Gelaye KA, Sisay MM, Akalu TY, et al (2021). Common mental disorders among seasonal migrant farmworkers in Northwest Ethiopia. BMC Psychiatry. 21:1-8. doi:

    10.1186/s12888-021-03068-7.

21. Getachew, D (2016). The interplay between migration and change in the social capital of sending communities: Experiences from Raya Kobo woreda, North Wollo. Thesis: Addis Ababa University.

22. Kumar R, Jamil R (2020). Labor, Health, and Marginalization: a culture centered analysis of the challenges of male Bangladeshi migrant workers in the Middle East. Qual Health Res. 30:1723-1736. doi: 10.1177/1049732320922180.

23. Busza J, Teferra S, Omer S, Zimmerman C (2017). Learning from returnee Ethiopian migrant domestic workers: a qualitative assessment to reduce the risk of human trafficking. Glob Health.13:71. doi: 10.1186/s12992-017-0293-x.

24. Cowan FM, Machingura F, Ali MS, et al (2024). AMETHIST a risk- differentiated, community-led intervention to strengthen uptake and engagement with HIV prevention and care cascades among female sex workers in Zimbabwe: a cluster randomized trial. Lancet Glob Health. 12:e1424-e1435. doi: 10.1016/S2214-109X(24)00235-3.

25. Tanser F, BärnighausenT, Dobra A, Sartorius B (2018). Identifying corridors of HIV transmission in a severely affected rural South African population: a case for a shift toward targeted prevention strategies. Int J Epidemiol. 47:537-549. doi: 10.1093/ije/dyx257.

26. National AIDS Council (2014). Malawi Biological and Behavioural Surveillance Survey 2014., Lilongwe: Malawi Ministry of Health. http s://www.aidsmalawi.org.mw/wp-content/uploads/2024/06/2019-2020_Malawi_BBSS_Report_FINAL. pdf. Accessed on 20 February 2025.

27. Cowan FM, Machingura F, Chabata ST, et al (2022). Differentiated prevention and care to reduce the risk of HIV acquisition and transmission among female sex workers in Zimbabwe: study protocol for the 'AMETHIST' cluster randomized trial. Trials. 23:209. doi: 10.1186/s13063-022-06119-w.

28. Fortunate M, Gracious M, Memory M, et al (2024). We carried her in a wheelbarrow to the clinic: Process evaluation of the AMETHIST intervention combining micro planning with self-help groups to improve HIV prevention and treatment among female sex workers in Zimbabwe (Pre-print BMC Health Ser Res). doi: 10.21203/rs.3.rs-4341475/v1.

29. UNFPA (2025). Minimum Initial Service Package (MISP) for SRH in Crisis Situations | United Nations Population Fund. https://www.unfp a.org/resources/minimum-initial-service-package-misp-srh-crisis- situations.Accessed 24 January 2025.

30. WHO (2021). Mental health crisis services: promoting person- centred and rights-based approaches.https://www.who.int/news- room/fact-sheets/detail/mental-health-strengthening-our-response. Accessed 24 January 2025.

31. Lovibond PF, Lovibond SH (1995). The structure of negative emotional states: comparison of the depression anxiety stress scales (DASS) with the Beck depression and anxiety inventories. B ehav Res Ther. 33:335-343. doi: 10.1016/0005-7967(94)00075-u.

32. Welie AG, Gebretekle GB, Stolk E, et al (2020). Valuing Health State: An EQ-5D-5L Value Set for Ethiopians. ViH RI. 22:7-14. doi: 10.1016/j.vhri.2019.08.475.

33. Falb K, Tanner S, Asghar K, et al (2016). Implementation of Audio- Computer Assisted Self-Interview (ACASI) among adolescent girls in humanitarian settings: feasibility, acceptability, and lessons learned. Confl Health. 10:32. doi: 10.1186/s13031-016-0098-1.

34. Hayes RJ, Moulton LH (2009). Cluster Randomised Trials (1st ed.). Chapman and Hall/CRC. doi: 10.1201/9781584888178.

35. Rogers PJ, Woolcock M (2023). Process and implementation evaluation methods. CID Faculty Working Paper Series. 433.

36. Hayes R, Bennett S (1999). Simple sample size calculations for cluster randomized trials. Int J Epidemiol. 8:319-326. doi: 10.1093/ij e/28.2.319.

37. Moore GF, Audrey S, Barker M, et al (2015). Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 3 50:1258. doi: 10.1136/bmj.h1258.

38. Drummond MF, Sculpher MJ, Claxton K, et al (2015). Methods for the economic evaluation of health care programmes. Oxford, UK: Oxford University Press.

39. Edejer TT, Edejer TT (2003). Making choices in health: WHO guide to cost-effectiveness analysis. https://iris.who.int/handle/10665/42699. Accessed 24 February 2025

10. ANNEXURES

ANNEX 1: INNOVETH TRIAL INFORMED CONSENT

Version: _____Ref. No: IRERC_____ Date_____

Study/Project Title: "**INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East**"

Principal Investigator: Dr. Kassahun Habtamu, Associate Professor, Addis Ababa University

Phone number(s): +251 911 697732

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

- You are invited to take part in this research study because you are preparing for migration to the Middle East as a domestic worker.
- The purpose of this study is to design and evaluate a health intervention to improve the mental, sexual, and reproductive health (MSRH) of Ethiopian Migrant Domestic Workers (MDWs).
- This intervention includes pre-departure skills training, peer-support, self-help groups, and use of a mobile health application.
- We cannot promise direct personal benefit, but the study may improve access to health services and support systems for you and other workers like you.
- Some procedures may cause discomfort (for example, survey questions on sensitive topics). You may choose not to answer any question.
- You may refuse to participate or withdraw at any time without penalty. This will not affect your right to migrate legally or to receive medical care.
- Participation is fully voluntary.

PURPOSE OF THE STUDY

You are being requested to participate in a study that seeks to better understand and improve the health and wellbeing of Ethiopian Migrant Domestic Workers (MDWs) who are preparing to travel to the Middle East for employment. We know that many MDWs face important health challenges, including issues related to mental health, sexual and reproductive health, both before they migrate and after they arrive in the destination countries. This study aims to gather information on these challenges so that we can identify better ways of supporting workers like you.

As part of the study, we are also developing and testing a health intervention designed especially for MDWs. This intervention combines several components, including individual counselling sessions, training in digital literacy, peer-support from other workers with similar experiences, and participation in self-help groups. These elements are intended to help you manage stress, protect your health, and strengthen your support networks. By doing this, the study hopes to improve resilience, wellbeing, and access to essential healthcare services among MDWs. In addition, we will carefully evaluate how effective and cost-effective the programme is, so that the lessons learned can be shared with policymakers, agencies, and health providers to improve services for many more Ethiopian workers in the future.

STUDY DESIGN AND ANALYSIS

This study will be carried out among Ethiopian Migrant Domestic Workers (MDWs) who are preparing to travel to the Middle East for employment. Participants will be recruited through pre-migration health screening clinics and partner organizations in Addis Ababa and the surrounding regions.

Those who agree to participate will be assigned randomly into two groups. One group will receive the new tailored health interventions, which include counselling, digital literacy training, peer-support, and participation in self-help groups. The other

group will continue to receive the routine information and support services that are normally provided before departure. By comparing the experiences and health outcomes of these two groups, we will be able to see what added benefits the new interventions bring.

Data for the study will be collected at different points in time: before migration, shortly after migration, and at follow-up intervals of 12 and 24 months. Information will be gathered through questionnaires, interviews, and where relevant health assessments. The research team will analyse this data to identify changes in mental health, sexual and reproductive health, and overall wellbeing.

By comparing the results between those who received the tailored interventions and those who did not, we will be able to measure both the effectiveness and the cost-effectiveness of the interventions. This evidence will be shared with policymakers, labor agencies, and health authorities to assist in designing better, sustainable support systems for Ethiopian MDWs in the future.

STUDY PROCEDURES AND DURATION

If you agree to participate in this study, you will be requested to take part in several activities designed to understand and support the health and wellbeing of Ethiopian migrant domestic workers:

- **Questionnaire Completion:** You will complete a detailed questionnaire on your background, health status, work experience, and overall wellbeing. This will be done using a tablet or mobile phone and is expected to take approximately 25 minutes for a module.
- **Health Information Collection:** You may be asked to provide relevant health-related information, such as previous TB or HIV test results and responses to mental health screening questionnaires.
- **Intervention Group Activities:** If you are assigned to the intervention group, you will:
  - Receive enhanced pre-departure training covering mental health, sexual and reproductive health, and digital skills.
  - Be paired with a trained peer-support worker ("Empowerment Worker") who will provide guidance and support through mobile contact and group sessions.
  - Be invited to participate in a self-help group comprising 5-10 migrant domestic workers, either via WhatsApp/Telegram or in-person meetings.
  - Use a mobile application to access health-related information and connect with peers.
- **Control Group Activities:** If you are assigned to the control group, you will receive the standard pre-departure training offered by the recruitment agency.
- **Follow-up Duration:** The study will follow participants for a total of 24 months after departure, with follow-up surveys conducted at 1-2 months, 12 months, and 24 months to monitor wellbeing and health outcomes.

RISKS AND DISCOMFORTS

Participation in this study may involve some risks or discomforts. You may feel emotional discomfort when answering questions related to mental health, experiences of violence, or sexual and reproductive health issues. Sharing your experiences in group sessions may sometimes feel sensitive or personal. However, all information shared will be kept confidential, and you will be supported throughout the process. If you experience any distress or emotional difficulty during the study, you will be referred to appropriate counselling and health services to ensure you receive the care and support you need.

BENEFITS AND/OR COMPENSATION

By participating in this study, you may gain valuable knowledge and skills related to mental health, sexual and reproductive health, and digital literacy. You will also have the opportunity to receive peer support and join self-help groups, which can help strengthen your resilience and overall wellbeing. Your participation will contribute to improving health interventions for Ethiopian MDWs in the future, helping others benefit from better services and support.

ALTERNATIVE PROCEDURES OR TREATMENTS

Participation in this study is entirely on a voluntary basis. You have the option to decline participation or withdraw from the study at any time without any negative consequences. If you choose not to participate, you will still receive the standard pre-departure training and health services provided by your recruitment agency. You are free to access any other health services, counselling, or support available in your community at any time, regardless of whether you join this study.

CONFIDENTIALITY

All information you provide during this study will be kept strictly confidential. Your data will be assigned a unique research identification number (ID), and your name will not appear in any reports, publications, or presentations. All study data will be securely stored and accessible only to the research team. While the overall results of the study may be shared with policymakers, recruitment agencies, and other stakeholders to inform better health interventions, your identity will remain completely anonymous.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely on a voluntary basis. You are free to decide whether or not to join, and you may choose to withdraw at any time without any consequences. Deciding not to participate or withdraw from the study will not affect your access to medical care, pre-departure services, or your migration process in any way.

IN THE EVENT OF INJURY, PROBLEMS OR QUESTIONS

If you have any questions about the study, its procedures, or your participation, you may contact **Dr. Kassahun Habtamu** at the School of Psychology, Addis Ababa University, Ethiopia. You can reach him through phone at **+251 911 697732** or email at **kasshabmek@gmail.com**. If you have concerns regarding your rights as a participant, or if you experience any problems related to the study, you may contact the **Institutional Review Board (IRB) at Addis Ababa University**. The IRB will provide guidance and support to address your concerns. Phone: 0111-2238734

INDIVIDUAL INFORMED CONSENT FORM

Study Title: "INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East"
Principal Investigator: Dr. Kassahun Habtamu, Associate Professor, Addis Ababa University
Phone: +251 911 697732

Background

You are invited to participate in a research study because you are preparing to migrate to the Middle East as a domestic worker. The purpose of this study is to improve the mental, sexual, and reproductive health of Ethiopian Migrant Domestic Workers (MDWs) through training, peer support, self-help groups, and a mobile health application. If you take part, you will be asked to complete questionnaires about your health, wellbeing, and experiences, provide health information such as past TB/HIV results, and depending on your group, either receive enhanced pre-departure training with peer-support and digital tools or the standard training usually provided. Follow-up surveys will be conducted at 1-2 months, 12 months, and 24 months after migration. Some questions may feel sensitive, and if health samples are collected, you may experience minor discomfort. However, you may benefit from new knowledge, skills, and peer support, and your participation will help improve services for other MDWs in the future. Your information will remain confidential and identified only by a research ID; results will be shared with policymakers but without revealing your identity. Participation is voluntary, and you may refuse or withdraw at any time without affecting your migration process or access to care.

Consent Statement

Having read and been informed of the above information, I voluntarily agree to participate in this study. I understand the purpose, procedures, possible risks, and benefits, and I know that my participation is voluntary and I may withdraw at any time without consequences for my migration or medical care.

Please initial each statement:

[ ] I agree to participate in this study.
[ ] I agree to complete surveys and interviews.
[ ] I agree to be contacted for follow-up interviews after migration.
[ ] I understand that my participation is voluntary and I may withdraw at any time.
[ ] I understand that my information will be kept confidential.

Participant's Name : _____Signature:_____Date:_____

Staff conducting Consent : _____ Signature:_____Date:_____

Witness : _____ Signature:_____Date:_____

ANNEX 2: CAPI LOG SHEET

Version: _____Ref. No.: IRERC _____Date: _____

Study/Project Title: ***"INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East"***

Principal Investigator: Dr. Kassahun Habtamu, Associate Professor, Addis Ababa University

Phone number(s): +251 911 697732

Purpose: This document is used to record and monitor electronic interviews conducted under the above-named research study. It supports supervision, data quality assurance, and compliance with approved ethical standards.

Interview Information

Screening date: _____

Informed consent date:_____

Interview Date: _____

ACASI ID: _____
Form Name and Version: _____
Form Instance ID: _____
Participant Identification Number (PTID): _____
Study Site (District/Woreda): _____

Interview Start Time (auto-generated): _____

Interview End Time (auto-generated): _____

GPS Data Recorded: ☐ Yes ☐ No

Interview Status: ☐ Complete ☐ Incomplete

Upload Status: ☐ Uploaded ☐ Pending

Supervisor Comments:

_____

_____

_____

_____

_____

_____

2. Roles and Responsibilities

Enumerator

- Conduct interviews using the approved electronic data collection application.
- Ensure accurate and complete recording of questionnaire responses.
- Protect the confidentiality of all participant information.
- Upload completed interviews when connectivity is available.
- Report technical issues or protocol deviations to the field supervisor.

Supervisor

- Review interview records for completeness and consistency.
- Document observations and follow-up actions where required.
- Ensure adherence to approved study procedures.

3. Data Handling and Storage

Interview data are stored electronically and transmitted to the central study database through secure procedures. No personal identifiers are recorded in this log.

4. Confidentiality and Ethics Agreement

By completing this log, I acknowledge that the interview was conducted in accordance with the approved study protocol and ethics guidelines. I agree to:

- Maintain strict confidentiality of all study and participant information.
- Use participant identification codes in place of names or direct identifiers.
- Follow approved procedures for electronic data collection and storage.
- Report any concerns or irregularities immediately to the Study Coordinator.

5. Supervisor Verification

Reviewed by (Supervisor Name): _____

Signature: _____ Date: _____

ANNEX 3: PROCESS EVALUATION TOOLS

Introductoin:

INNOVETH trial is a multi-site, cluster randomised controlled trial evaluating a complex MSRH intervention designed to improve the health, safety, and wellbeing of Ethiopian migrant domestic workers in the middle east. This Process Evaluation Framework outlines the methodology for assessing the implementation of the INNOVETH intervention within the parent cluster randomised controlled trial. This framework provide a structure for assessing progress at each stage. Indicators and tools are provided to guide data collection along the hypothesised pathway from provision of the intervention activities to their intended outcomes. This framework provides a structured approach for assessing progress at each stage of the INNOVETH trial. It establishes a systematic pathway from intervention activities to intended outcomes, supported by clearly defined indicators and data collection tools. The process evaluation is designed to track:

- Whether activities were conducted as planned
- The experience of delivering intervention components
- Participant perceptions and responses
- The relationship between implementation and outcomes

By documenting these dimensions across the four-year project timeline, the evaluation will generate critical insights into how the intervention functions in real-world settings, for whom it is most effective, and under what circumstances.

Measured as part of the Process Evaluation

(1) Activities:
Wheather INNOVETH implementation preparations were adequate in terms of financial and human resources, materials, training content, timing ?
Were there any delays to implementation and if so, why?
Did activities occurr according to the intervention design?
Were all intervention components delivered?
How did timing of implementation compare to plans?
Was implementation of activities feasible?

(2) Outputs:
What was the scale/ reach/ intensity of each intervention activity?
How many and what type of DMWs participated in each component of the intervention?
What challenges to implementation emerged? Were these overcome? (how?)
How did participants experience and perceive the INNOVETH package of services?
What changes in social support, implementors and participants believe did or did not results from the intervention?

(3) Determinants:
Has health awareness of MDWs increased?
Did engagement with outreach and community mobilisation increased?
Is there evidence of change in social dynamics among MDWs, e.g. active engagment?
Encoraged to participate in EWs sessions?

(4) Behavioural Change:
Did MSRH service uptake and retention increase?
Are MDWs in better position to protect themselves from MSRH conditions?
Has MDWs vulnerability decreased?

INNOVETH - Process Evaluation Framework– PROGRAMME INDICATORS

Domain	Indicator	Definition / Measurement	Data Source	Frequency	Target
REACH	Recruitment	# of eligible MDWs who consent/ approached	Screening	Weekly	>80%
	Demographic Representativeness	Comparison of participant demographics (age, district in Ethiopia, host country)	Baseline Survey; MoLS data	Post-recruitment	80%
	Retention Rate	# completing post-intervention follow-up / # randomized to intervention	Trial Database	Post-intervention	>80%
FIDELITY	Content Fidelity	% of core training modules delivered in full per session	Session Fidelity Checklist, SOP	Per session	>90%
	Process Fidelity	% of sessions adhering to key methodological principles (e.g., participatory, safe space)	Fidelity Checklist	Per session / Monthly	>85%
	Quality of Delivery	Mean score on facilitator self-assessment of quality (1-5 scale)	Session Fidelity Checklist	Per session	>4.0
DOSE	Intervention Dose	Total # of contact hours delivered / Planned # of contact hours	Attendance	Monthly	100%
	Participant Dose Received	Mean # of sessions attended per participant	Attendance Records	Post-intervention	>75% of sessions
	Digital Engagement	% of participants active on digital platform (>1 login/week)	Digital Platform Analytics	Weekly	>70%
MECHANISMS	Acceptability	Mean score on acceptability items (e.g., relevance, comfort) in post-intervention survey (1-5 scale)	Survey data	Post-intervention	>4.0

Domain	Indicator	Definition / Measurement	Data Source	Frequency	Target
	Self-Efficacy Change	Mean change in General Self-Efficacy Scale (GSES) score from baseline to follow-up	Trial Outcome Measures	Baseline & Follow-up	Positive change ($p<0.05$)
	Peer Connection	# of participants reporting new supportive contact with another fellow MDWs	Post-intervention Survey; Interview Themes	Post-intervention	>60%
CONTEXT	Policy Environment Stability	Indicator of major disruptive policy change in host country during intervention period	process evaluation	Monthly	No major disruptions
	Partner Organisation Functionality	Rating of partner agencies support (1-5 scale) in monthly check-in	Partner Engagement report	Quarterly	>4.0
ADAPTATION	Planned Adaptations	# of pre-approved contextual adaptations implemented	Implementation report	As implemented	As needed
	Unplanned Adaptations	# of deviations from manual requiring post-hoc review	Unplanned Adaptation Form	As occurs	Minimised
UNINTENDED CONSEQUENCES	Adverse Events Related to Participation	# of SAEs/SARs deemed possibly/probably related to trial participation	SAE/SAR	Immediate	0
	Positive Spillover	Evidence of knowledge sharing with non-intervention MDWs (qualitative indicator)	FGD & IDI	Post-intervention	Documented if present

Process Evaluation Tools

NAME	DESCRIPTION	WHEN
Records	Retrospective records per planned implementation	Throughout the project
Staff & Training Records	Routine program documentation on number of staff hired and deployed, including EW or Peer educators, Nurses, etc.	HR records analysed annually
Monitoring Forms	Forms include: • Project diaries, Risk stratification tools, Tracking forms • Attendance records and supervision reports	Tasks will be compiled monthly to ensure the progress
Project Diary	The project diary will be kept in the form of excel spreadsheet tracking events (particularly external) in each site that may affect ability of the intervention to be delivered as planned. External events could include political developments, security concerns, police crackdowns, fuel shortages, other health promotion campaigns etc. These can be highly localised or affect the whole country; all incidents or occurrences that appear to influence the INNOVETH activities should be noted, with description of their effect. Internal events that have bearing on implementation (such as increased funding, or break-down of project vehicles) could also be noted to help contextualize other information collected. The tool will be populated through two approaches: (1) scheduled quarterly open-ended interviews to follow-up previously reported events and identify new ones; and (2) ad-hoc information received by "word of mouth" through program staff and/or emerging from regular program staff meetings.	Quarterly Intervention & Comparison Dataset: excel Spreadsheet with narrative summaries
Focus Groups	FGD should be arranged to explore the experiences of members to date, focusing on (1) process of setting up group (2) activities conducted and perceived achievements (3) challenges and how these have been addressed (4) support and relationships between SHG members and between SHG and other MDWs and (5) interactions between EW, SHG and MDWs. 4 SHG in each qualitative research site will be selected purposively. The same SHG in each site will undergo a second FGD after 9- 12 months.	Selected SHG should undergo an FGD after 1 month of establishment and a second time 9-12 months later, conducted on a rolling basis (i.e. different SHG can hold FGDs at different times based on date of establishment) Intervention Dataset: 16 focus group notes
Qualitative Interviews with MDWs	In each qualitative research site, about 6 MDWs will be purposively selected at each site based on level of engagement with EWs to explore awareness, perceptions, and experience of INNOVETH interventions.	At the start and 9-12 months later Intervention Dataset: 72 interview transcripts
Qualitative Interviews with EW	Semi structured interviews with purposively selected 6 EW per qualitative research site based on performance e.g. active or high or low facilitation rate / high vs low performing. At the qualitative research sites, any EW who drop out from the program should receive an "exit interview" if possible.	At the start and 9-12 months later Intervention Dataset: 36-50 interview transcripts
Qualitative Interviews with Agencies, TVET	Semi structured interviews with all agencies working in the selected qualitative research intervention sites.	At the start and 9-12 months later Intervention Dataset: 14-18 interview transcripts
Qualitative Interviews with INNOVETH staff	Semi-structured interviews with project PI, Co PIs, Project manager, clinic staff, counselor and PhD students to document perceptions of INNOVETH implementation across both intervention and control sites.	Dataset: 12 interview transcripts

ANNEX 4: QUALITATIVE STUDY INFORMED CONSENT FORM

Participant Information Sheet (PIS)

Addis Ababa University, College of Education and Language Studies Institutional Research Ethics Committee (IREC) Ref No:

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of the Study: INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East

We would like to invite you to participate in this research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

This study is being funded by the Wellcome Trust through the Transdisciplinary Mobility and Global Health-joint call and the study is being conducted by a consortium of higher learning institutions, including Addis Ababa University, Armauer Hansen Research Institute, Oslo Metropolitan University, London School of Hygiene and Tropical Medicine and St.Paul's Hospital Millennium Medical College.

Aims of the research : This study is intended to document implementation of the INNOVETH intervention, understand its mechanisms of action, and contribute to interpretation of the trial findings. The study is also aimed to understand stakeholders' perceptions of feasibility and acceptability of the intervention throughout the trial period.

Who are we recruiting?

We are including a range of people who we think can give us information on the implementation of the INNOVETH intervention, its mechanisms of action as well as its feasibility and acceptability. We will be interviewing migrant domestic workers, empowerment workers, trainers and key stakeholders, including recruitment agencies, health facilities and representatives from the Ethiopian Ministry of Labor and Skills and Ministry of Health. We will conduct focus group discussions with migrant domestic workers and empowerment workers.

What will happen if you agree to take part?

One of our data collectors will either come to your place of work or your home and ask you some questions. The questions will be asking about your own experiences and knowledge of implemntation of the INNOVETH intervention, how its works, and its feasiblity and acceptability. If you are a migrant domestic worker, we may ask you to take part in the same interveiew or focus group discussion at 12 months and 24 months follow-up periods after the intervention. The interviews will take from 45 minutes to 60 minutes and the focus group discussions will take from 60-90 minutes.

Risks of being in the study

We do not expect that the interview or focus group disucssion will cause you any difficulties. On rare occasions, people might be upset by the questions that are being asked. If you are distressed by the questions then you do not have to answer the question and the interview or focus group discussion can be stopped.

Possible benefits

We hope that the information obtained will help to improve the health and wellbeing of migrant domestic workers in Ethiopia and other similar countries. It will also help to refine the INNIVETH intervention and understand how to scale it up. Once the study is completed, we will let you know what we found, either by inviting you to a meeting or giving you a leaflet.

What we will do with your data?

The audio as well as the transcribed data will not include your name so nobody except the project co-ordinators and project data manager will know that the information belongs to you. We will keep the transcribed dta in a locked cupboard and the audio data password protected.

If you take part in a tape-recorded interview or focus group discussion, we will make sure that the tapes do not include your name or identifying information. The tapes will be kept in a locked cupboard. Once the interview tapes have been written down, and the data has been analysed, the tapes will be cleared.

After the end of this study, the information you tell us may be used by other researchers, but they will not be able to identify you in any way.

Main researchers:

Dr Kassahun Habtamu, Dr M Sanni Ali, Dr Samrawit Solomon, Dr Berhanu Seyoum and Professor Dawit Shawel. You can contact us at our office in Addis Ababa University, Main Campus on telephone number +251-911-697732, from Monday to Friday during working hours or in St.Pauls' Hospital Millennium Medical College on telephone number +251-911-459050.

It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. If this study has harmed you in any way, you can contact the Institutional Ethics Review Committee of the College of Education and Language Studies, Addis Ababa University, using the details below for further advice and information:

Institutional Ethics Review Committee, College of Education and Language Studies, Addis Ababa University

Telephone number: 0111-2238734

You may withdraw your data from the project at any time up until it is transcribed for use in the final report.

If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

Consent form

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of the Study: INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East

Addis Ababa University, College of Education and Language Studies Institutional Ethics Review Committee (IERC) Ref No:

Thank you for considering taking part in this research. The person organizing the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up until they are published.

I consent to the processing of my personal information for the purposes explained to me. I understa ☐ t such information will be handled in accordance with the terms of the national data protection rules.

If I am selected to be interviewed in more detail, then I consent to that interview being audio-taped. ☐

The information you have submitted will be published as a report. Please note that confidential ☐ d anonymity will be maintained and it will not be possible to identify you from any publications.

I agree that the research team may use anonymized data for future research. ☐

Participant's Statement:

I, _____, agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signature _____ Date_____

Witness Statement (in an event that participant is not literate):

I, _____, agree that the research project named above has been explained to _____ (participant) to her/his satisfaction and that she/he agrees to take part in the study. Both the notes written above and the Information Sheet about the project have been read to her/him, and she/he understands what the research study involves.

Signature_____Date_____

Investigator's Statement:

I, _____, confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signature_____Date_____

ANNEX 5: QUALITATIVE STUDY TOPIC GUIDES

Qualitative interview guide on implementation of the INNOVETH intervention

(For Migrant Domestic Workers)

Introduction

As part of the INNOVETH project, we are implementing an intervention package consisting of peer support, self-help group, pre-migration skills training, mobile application and psycho-social counselling. This intervention package is aimed to improve mental, sexual and reproductive health among migrant domestic workers and thereby enhance their empowerment and resilience. We would like to understand your perceptions of the feasibility, acceptability, effectiveness and impact of the intervention; your own levels of satisfaction and your perspectives on quality of the intervention and its implementation.

1. What is your overall impression of the INNOVETH intervention or support services?
    - How comfortable do you feel participating in the INNOVETH intervention package?
    - To what extent does the intervention package meet your needs?
    - What do you like or dislike about the specific components of the INNOVETH intervention?
    - Would you recommend this intervention package to a friend? If, yes why? If no, why not?
    - What were the most/least helpful aspects of the INNOVETH intervention?
2. How did you find the pre-migration skills training on raising awareness about the destination country, enhancing skills and addressing gaps in the COC training?
    - What parts of the training content were new for you?
    - How clear was the explanation provided by the trainers?
    - What did you think of the way that the training was delivered?
    - How relevant was the training for enhancing skills?
    - Was the time provided for the pre-migration skills training enough? Would you describe how?
    - What could be improved about the training?
    - What else could be done to improve the content and way of delivery of the training?
3. How did you get the mobile application? Can you tell me about your experience of using it? Can you show me how you've been using the app/making use of information generated from it?
    - Did you find it helpful? Can you tell me more/why this was the case?
    - Overall, how do you feel about the mobile app, why is this? Is it useful for you, how?
    - Did you find it easy to use? Why was that? Can you give me some examples?
    - What were the challenges of using the mobile app? Can you give me some examples/tell me more about this?
    - What can be improved about the mobile app?
4. I would like to know more about the peer support you received as part of the INNOVETH intervention. Did you receive the peer support provided by empowerment workers?
    - What kinds of support did you receive from empowerment workers? Did you find the support helpful? Can you tell me more about how it is helpful?
    - How do you feel about the competency and confidence of the empowerment workers in providing support for you?

- In what situations and ways empowerment workers provided support for you?
- Do you feel that empowerment workers have time and skills to provide support for you?
- What strengths and limitations do you think empowerment workers have?
- What can be improved about the support provided by empowerment workers?

5. Did you involve or participate in self-help groups? If yes, how? If no, why not?
    - What benefits did you get from participating in self-help groups?
    - In what situations and ways participating in self-help groups benefit you?
    - Did you have time to participate in self-help groups?
    - What strengths and limitations do you think self-help groups have?
    - What can be improved about self-help groups?
6. Have you been referred to a mental, sexual or reproductive health support services in St. Paul's Hospital Millennium Medical College due to moderate or severe problems? If yes, what kinds of support services did you receive?
    - How did you get the referral? Did you find it helpful? Can you tell me more/why this was the case?
    - Was it easy to access this service?
    - Did you have the time to receive the support services?
    - Did the healthcare professionals give you enough time? How can you describe their approach and support?
    - What strengths and limitations do you see in the support services? How can it be improved?
7. Overall, which aspects of the INNOVETH intervention or support services do you like and which aspects you do not like? Why is this the case?
    - Are you satisfied with the INNOVETH intervention components or support services?
    - What can be changed or improved to enhance the intervention package?
    - How could the INNOVETH intervention be adapted to make it easier to implement in your daily life or setting?
8. What factors, such as resources, staff, time, might be barriers or facilitators to using this intervention in the future? How does the INNOVETH intervention fit into your current routine or work environment?

Focus-group discussion guide on implementation of the INNOVETH intervention

(For Migrant Domestic Workers)

Introduction

As part of the INNOVETH project, we are implementing an intervention package consisting of peer support, self-help group, pre-migration skills training, mobile application and psycho-social counselling. This intervention package is aimed to improve mental, sexual and reproductive health among migrant domestic workers and thereby enhance their empowerment and resilience. We would like to understand your perceptions of the feasibility, acceptability, effectiveness and impact of the intervention; your own levels of satisfaction and your perspectives on quality of the intervention and its implementation.

1. What is your overall impression of the INNOVETH intervention or support services?
    - How comfortable do you feel participating in the INNOVETH intervention package?
    - To what extent does the intervention package meet your needs?
    - What do you like or dislike about the specific components of the INNOVETH intervention?
    - Would you recommend this intervention package to a friend? If, yes why? If no, why not?
    - What were the most/least helpful aspects of the INNOVETH intervention?
2. How did you find the pre-migration skills training on raising awareness about the destination country, enhancing skills and addressing gaps in the COC training?
    - What parts of the training content were new for you?
    - How clear was the explanation provided by the trainers?
    - What did you think of the way that the training was delivered?
    - How relevant was the training for enhancing skills?
    - Was the time provided for the pre-migration skills training enough? Would you describe how?
    - What could be improved about the training?
    - What else could be done to improve the content and way of delivery of the training?
3. How did you get the mobile application? Can you tell me about your experience of using it? Can you show me how you've been using the app/making use of information generated from it?
    - Did you find it helpful? Can you tell me more/why this was the case?
    - Overall, how do you feel about the mobile app, why is this? Is it useful for you, how?
    - Did you find it easy to use? Why was that? Can you give me some examples?
    - What were the challenges of using the mobile app? Can you give me some examples/tell me more about this?
    - What can be improved about the mobile app?
4. I would like to know more about the peer support you received as part of the INNOVETH intervention. Did you receive the peer support provided by empowerment workers?
    - What kinds of support did you receive from empowerment workers? Did you find the support helpful? Can you tell me more about how it is helpful?
    - How do you feel about the competency and confidence of the empowerment workers in providing support for you?
    - In what situations and ways empowerment workers provided support for you?

- Do you feel that empowerment workers have time and skills to provide support for you?
- What strengths and limitations do you think empowerment workers have?
- What can be improved about the support provided by empowerment workers?

5. Did you involve or participate in self-help groups? If yes, how? If no, why not?
    - What benefits did you get from participating in self-help groups?
    - In what situations and ways participating in self-help groups benefit you?
    - Did you have time to participate in self-help groups?
    - What strengths and limitations do you think self-help groups have?
    - What can be improved about self-help groups?
6. Have you been referred to a mental, sexual or reproductive health support services in St. Paul's Hospital Millennium Medical College due to moderate or severe problems? If yes, what kinds of support services did you receive?
    - How did you get the referral? Did you find it helpful? Can you tell me more/why this was the case?
    - Was it easy to access this service?
    - Did you have the time to receive the support services?
    - Did the healthcare professionals give you enough time? How can you describe their approach and support?
    - What strengths and limitations do you see in the support services? How can it be improved?
7. Overall, which aspects of the INNOVETH intervention or support services do you like and which aspects you do not like? Why is this the case?
    - Are you satisfied with the INNOVETH intervention components or support services?
    - What can be changed or improved to enhance the intervention package?
    - How could the INNOVETH intervention be adapted to make it easier to implement in your daily life or setting?
8. What factors, such as resources, staff, time, might be barriers or facilitators to using this intervention in the future? How does the INNOVETH intervention fit into your current routine or work environment?

Semi-structured interview guide on implementation of the INNOVETH intervention

(For Empowerment Workers)

Introduction

As part of the INNOVETH project, we are implementing an intervention package consisting of peer support, self-help group, pre-migration skills training, mobile application and psycho-social counselling. This intervention package is aimed to improve mental, sexual and reproductive health among migrant domestic workers and thereby enhance their empowerment and resilience. We would like to understand your perceptions of the feasibility, acceptability, effectiveness and impact of the intervention; your own levels of satisfaction, as providers of part of the intervention, and your perspectives on quality of the intervention and its implementation.

1. What is your overall impression of the INNOVETH intervention or support services?
    - How comfortable do MDWs feel about participating in the INNOVETH intervention package and specifically in the peer support service?
    - How comfortable do you feel providing the peer-support components of the INNOVETH intervention package?
    - To what extent does the INNOVETH intervention package meet the needs of MDWs?
    - What do MDWs like or dislike about the specific components of the INNOVETH intervention? What do you like or dislike about the peer support service?
    - Would you recommend INNOVETH intervention package in general and the peer support service in particular to a friend or a colleague? If yes, why? If no, why not?
    - What were the most/least helpful aspects of the INNOVETH intervention package, and more specifically the peer support service?
2. How did MDWs get the mobile application? Can you tell me about theirr experience of using it? Can tell me how they have been using the app/making use of information generated from it?
    - Did MDWs find it helpful? Can you tell me more/why this was the case?
    - Overall, how do you feel about the mobile app, why is this? Is it useful for MDWs, how?
    - Did you find it easy to use? Why was that? Can you give me some examples?
    - What were the challenges of MDWs in using the mobile app? Can you give me some examples/tell me more about this?
    - What can be improved about the mobile app?
3. I would like to know more about the peer support you provided to MDWs as part of the INNOVETH intervention. Did you receive the peer support provided by empowerment workers?
    - What kinds of support did you provide? Did you find the support helpful to MDWs? Can you tell me more about how it is helpful?
    - In what situations and ways you provided peer support for MDWs?
    - Do you feel that you have enough time and skills to provide the peer support for MDWs?
    - Do you feel that MDWs have enough time and interest to receive the peer support?
    - What strengths and limitations do you think the peer support you provided to MDWs have?
    - What can be improved about the peer support you provided to MDWs?
4. Do you think that MDWs involve or participate in self-help groups? If yes, how? If no, why not?

- What benefits did MDWs get from participating in self-help groups?
- In what situations and ways participating in self-help groups benefit MDWs?
- Did MDWs have enough time and interest to participate in self-help groups?
- What strengths and limitations do you think self-help groups have?
- What can be improved about self-help groups?

5. Did you refer MDWs to a mental, sexual or reproductive health support services in St. Paul's Hospital Millennium Medical College due to moderate or severe problems? If yes, what kinds of support services did MDWs receive?
    - How did you refer MDWs? Did you find it helpful for MDWs? Can you tell me more/why this was the case?
    - Was it easy for you to refer and MDWs to access the service?
    - Did MDWs have the time and interest to receive this support services?
    - Did the healthcare professionals give MDWs enough time? How can you describe the healthcare professionals' approach and support?
    - What strengths and limitations do you see in this support services? How can it be improved?
6. Overall, which aspects of the INNOVETH intervention or support services do MDWs like and which aspects they do not like? Why is this the case?
    - Are you satisfied with the INNOVETH intervention components or support services?
    - What can be changed or improved to enhance the intervention package?
    - How could the INNOVETH intervention be adapted to make it easier to implement in MDWs daily life or setting?
7. What factors (such as resources, staff, time) might be barriers or facilitators for MDWs to use this intervention in the future? How does the INNOVETH intervention fit into MDWs current routine or work environment?

Focus group discussion guide on implementation of the INNOVETH intervention

(For Empowerment Workers)

Introduction

As part of the INNOVETH project, we are implementing an intervention package consisting of peer support, self-help group, pre-migration skills training, mobile application and psycho-social counselling. This intervention package is aimed to improve mental, sexual and reproductive health among migrant domestic workers and thereby enhance their empowerment and resilience. We would like to understand your perceptions of the feasibility, acceptability, effectiveness and impact of the intervention; your own levels of satisfaction, as providers of part of the intervention, and your perspectives on quality of the intervention and its implementation.

1. What is your overall impression of the INNOVETH intervention or support services?
    - How comfortable do MDWs feel about participating in the INNOVETH intervention package and specifically in the peer support service?
    - How comfortable do you feel providing the peer-support components of the INNOVETH intervention package?
    - To what extent does the INNOVETH intervention package meet the needs of MDWs?
    - What do MDWs like or dislike about the specific components of the INNOVETH intervention? What do you like or dislike about the peer support service?
    - Would you recommend INNOVETH intervention package in general and the peer support service in particular to a friend or a colleague? If yes, why? If no, why not?
    - What were the most/least helpful aspects of the INNOVETH intervention package, and more specifically the peer support service?
2. How did MDWs get the mobile application? Can you tell me about theirr experience of using it? Can tell me how they have been using the app/making use of information generated from it?
    - Did MDWs find it helpful? Can you tell me more/why this was the case?
    - Overall, how do you feel about the mobile app, why is this? Is it useful for MDWs, how?
    - Did you find it easy to use? Why was that? Can you give me some examples?
    - What were the challenges of MDWs in using the mobile app? Can you give me some examples/tell me more about this?
    - What can be improved about the mobile app?
3. I would like to know more about the peer support you provided to MDWs as part of the INNOVETH intervention. Did you receive the peer support provided by empowerment workers?
    - What kinds of support did you provide? Did you find the support helpful to MDWs? Can you tell me more about how it is helpful?
    - In what situations and ways you provided peer support for MDWs?
    - Do you feel that you have enough time and skills to provide the peer support for MDWs?
    - Do you feel that MDWs have enough time and interest to receive the peer support?
    - What strengths and limitations do you think the peer support you provided to MDWs have?
    - What can be improved about the peer support you provided to MDWs?
4. Do you think that MDWs involve or participate in self-help groups? If yes, how? If no, why not?

- What benefits did MDWs get from participating in self-help groups?
- In what situations and ways participating in self-help groups benefit MDWs?
- Did MDWs have enough time and interest to participate in self-help groups?
- What strengths and limitations do you think self-help groups have?
- What can be improved about self-help groups?

5. Did you refer MDWs to a mental, sexual or reproductive health support services in St. Paul's Hospital Millennium Medical College due to moderate or severe problems? If yes, what kinds of support services did MDWs receive?
    - How did you refer MDWs? Did you find it helpful for MDWs? Can you tell me more/why this was the case?
    - Was it easy for you to refer and MDWs to access the service?
    - Did MDWs have the time and interest to receive this support services?
    - Did the healthcare professionals give MDWs enough time? How can you describe the healthcare professionals' approach and support?
    - What strengths and limitations do you see in this support services? How can it be improved?
6. Overall, which aspects of the INNOVETH intervention or support services do MDWs like and which aspects they do not like? Why is this the case?
    - Are you satisfied with the INNOVETH intervention components or support services?
    - What can be changed or improved to enhance the intervention package?
    - How could the INNOVETH intervention be adapted to make it easier to implement in MDWs daily life or setting?
7. What factors (such as resources, staff, time) might be barriers or facilitators for MDWs to use this intervention in the future? How does the INNOVETH intervention fit into MDWs current routine or work environment?

Interview guide on implementation of the INNOVETH intervention
(For Trainers, Project Staff and Key Stakeholders)

Introduction

As part of the INNOVETH project, we are implementing an intervention package consisting of peer support, self-help group, pre-migration skills training, mobile application and psycho-social counselling. This intervention package is aimed to improve mental, sexual and reproductive health among migrant domestic workers and thereby enhance their empowerment and resilience. We would like to understand your perceptions of the feasibility, acceptability, effectiveness and impact of the intervention; your own levels of satisfaction and your perspectives on quality of the intervention and its implementation.

1. What is your overall impression of the INNOVETH intervention package or support services?
    - How comfortable do MDWs feel participating in the INNOVETH intervention package (peer support, self-help group, pre-migration skills training, mobile application and psycho-social counselling?
    - How comfortable do you feel leading or coordinating the different components of the INNOVETH intervention package? How comfortable do feel providing training to MDWs or empowerment workers?
    - To what extent does the intervention package meet MDWs needs?
    - What do you like or dislike about the specific components of the INNOVETH intervention? What MDWs like or dislike about the specific components of the INNOVETH intervention?
    - Would you recommend this intervention package to a MDWs in the future? If, yes why? If no, why not?
    - What were the most/least helpful aspects of the INNOVETH intervention?
2. How did you find the pre-migration skills training provided by the IINVETH project to MDWs in terms of raising awareness about the destination country, enhancing skills and addressing gaps in the COC training?
    - What parts of the training content were new for MDWs? How did you see the quality of the training material?
    - How clear and appropriate the methods of delivery of the training were to MDWs? What did you think of the way that the training was delivered?
    - How relevant was the training for enhancing the skills of MDWs?
    - Was the time provided for the pre-migration skills training enough? Would you describe how?
    - What could be improved about the pre-migration skills training?
    - What else could be done to improve the content and way of delivery of the training?
3. How do you feel about the mobile application? Can you tell me about MDWs experience of using it? Can you tell me how MDWs have been using the app?
    - Did MDWs find it helpful? Can you tell me more/why this was the case?
    - Overall, how do you feel about the mobile app, why is this? Is it useful for MDWs, how?
    - Did MDWs find it easy to use? Why was that? Can you give me some examples?
    - What were the challenges of MDWs in using the mobile app? Can you give me some examples/tell me more about this?
    - In your opinion, what can be improved about the mobile app?

4. I would like to know more about the peer support we provided to MDWs as part of the INNOVETH intervention. How do you feel about the peer support we provided to MDWs by empowerment workers?
    - What kinds of support did MDWs receive from empowerment workers? Did MDWs find the support helpful? Can you tell me more about how it is helpful?
    - How do you feel about the competency and confidence of the empowerment workers in providing support for MDWs?
    - Do you feel that empowerment workers have enough time and skills to provide support for MDWs?
    - What strengths and limitations do you see from the peer support? What were the strengths and limitations of the empowerment workers?
    - What can be improved about the peer support and empowerment workers?
5. How do you feel about the self-help group component of the INNOVETH intervention package?
    - What benefits did MDWs get from participating in self-help groups? In what situations and ways participating in self-help groups benefit MDWs?
    - Do you think that self-help groups are feasible and acceptable?
    - Did MDWs have time to participate in self-help groups?
    - What strengths and limitations do you think self-help groups have?
    - What can be improved about self-help groups?
6. How do you feel about the referral mental, sexual or reproductive health support services (we provided as part of the INNOVETH intervention package) in St. Paul's Hospital Millennium Medical College due to moderate or severe problems of MDWs? What kinds of support services did MDWs receive?
    - How did MDWs get the referral? Did MDWs find it helpful? Can you tell me more/why this was the case?
    - Was it easy for MDWs to access this service?
    - Did MDWs have the time to receive the support services?
    - Did the healthcare professionals give MDWs enough time? How can you describe the healthcare professionals' approach and support?
    - What strengths and limitations do you see in these support services? How can it be improved?
7. Overall, which aspects of the INNOVETH intervention or support services do MDWs like and which aspects they do not like? Why is this the case?
    - Are MDWs satisfied with the INNOVETH intervention components or support services?
    - Are you satisfied with the INNOVETH intervention components or support services?
    - What can be changed or improved to enhance the intervention package?
    - How could the INNOVETH intervention be adapted to make it easier to implement in MDWs daily life or setting?
8. What factors (such as resources, staff, time) might be barriers or facilitators for MDWs to use the INNOVETH intervention in the future? How does the INNOVETH intervention fit into MDWs current routine or work environment?

ANNEX 6: INNOVETH DIARY

ID		Contact date and type					Safety and referral record	
EW	MDW	Week	Date	In person	Tel.	Chat/ SMS	Urgent concern identified (yes/no)	Referal made (yes/no)

Location: (1) Saudi Arabia___ (2) UAE___ (3) Qatar _____

Wellbeing and Safety check

- Psychological distress ____Yes _____No
- Workplace exploitation/abuse _____ Yes _____No
- Social isolation _____ Yes _____No
- Financial stress _____ Yes _____No
- Health concerns _____ Yes _____No

EW Notes

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ANNEX 7: TRACKING FORM

EW ID: _____

MDW ID	Enrollment date	Baseline Completed (yes/no)	Follow-up date	Status (Active/withdrawn/Lost)	Reason if withdrawn/lost

Retention & Safety Monitoring

Mark if applicable:

- Missed ≥2 meetings _____
- Difficult to reach _____
- Requested withdrawal _____
- Adverse event reported _____
- Referred for support _____

EW Notes

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Research team note

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ANNEX 8: RISK ASSESSMENT TOOL

Risk stratification tool-template

ID		Date	Risk factors	Criteria			Score	Contact schedule
EW	MDW			Low (0)	Moderate (1)	High (2)		
			Younger age					
			Low education					
			First time migrant					
			Large host family					
			Abusive host family					
			Medical history					

ANNEX 9: INNOVETH REFERRAL FORM

This referral form/procedure is envisioned to facilitate referrals as a means of ensuring the possible holistic approach to the needs of MDWs.

5.1 Health related issues

The referral procedures prioritize immediate safety assessment, documentation, and referred to health facilities to receive health services (psychological support (counseling), and health assessment) by mental health experts in Ethiopia.

Key referral procedures that should be considered to identify emotional distress among MDWs.

- Screening and Identification of anxiety, depression, or distress
- In case of urgent risks, provision of onsite initial counseling support by mid-level health professionals (e.g., community nurses).
- Refer the MDW to the health facility to receive a comprehensive counseling and health assessment after securing consent (ensure confidentiality).
- Complete documentation of the referral paper with the required MDW information (can be adapted from MoH mental health form)
- Linkage with health facility that provide the mental health services (case management) and proper follow-up.

Basic biodata and location

Name, Age, Passport No, Address (phone/Region/District), Employer/Country

1. Referring body /individual

   Name, Role, Date, Signature

2. Reason for referral: Emotional distress symptoms (e.g., anxiety, depression, insomnia); Severity of illness (mild/moderate/severe); Risk (e.g., self-harm)
3. History: Duration of the illness, triggering factors (work stress, isolation, insomnia), any previous support provided
4. Receiving service: Clinic/Hospital/Helpline (if available)
5. Referral urgency: Emergency/Routine; Transport needs
6. Best way(s) to contact the individual_____
7. Informed consent

   Date, Signature

Note: The person making the referral should only share relevant information for providing the services requested by the individual

5.2 Legal and right related issues

This referral procedure addresses contract violations, unlawful treatment, passport withholding, non-payment of wages, physical/verbal abuse, or restriction of movement.

Key referral procedures:

- Initial documentation – Record the MDW's complaint using a simple intake log (date, issue type, persons involved).
- Immediate safety – If abuse or threat is alleged, separate the MDW from the employer/agency pending assessment.
- Informed consent – Explain limits of confidentiality (e.g., mandatory reporting if minor at risk).
- Referral pathway –
    - *Contract/wage issues* → Ministry of Labor or foreign employment agency
    - *Passport withholding* → Immigration / Embassy of MDW's home country
    - *Physical/sexual assault* → Police + legal aid NGO + health facility (forensic)
    - *No clear violation* → Legal aid hotline or paralegal
- Documentation – Complete the referral form (Section 7.2 form below) and keep a confidential copy.
- Follow-up – Contact MDW within 72 hours to confirm service access.

Referral form for legal/rights issues (additional fields):

- Type of legal issue (violence / passport / wages / contract / movement / other)
- Any prior complaint filed (with whom, date)
- Embassy notified? (Y/N – which embassy)
- Employer/Agency name (if relevant)
- Referred to (e.g., Labor Office, Legal Aid, Embassy, Police)
- Referral date & case reference number

ANNEX 10: SOPs_ INNOVETH main trial

Standard Operating Procedures (SOP) for INNOVETH trial team

This pack contains the Standard Operating Procedures (SOPs) for the INNOVETH cluster-randomized controlled trial. INNOVETH is an intervention dedicated to improving the mental, sexual, and reproductive health of Ethiopian migrant domestic workers (MDWs) in the Middle East. Each SOP below follows the standard structure and addresses critical aspects of trial conduct.

Each SOP follows this structure: SOP ID & Title; Purpose; Scope; Roles & Responsibilities; Definitions; References; Required Tools/Forms; Procedure (stepwise); Quality Control & Documentation; Deviations & a corrective and preventive action (CAPA); Training & Competency; Version Control & Change History.

SOP-01: Trial Governance, Oversight & Decision-Making

Purpose: Define the governance structure (Funder, Principal Investigator, Co-Investigators, Trial Steering Committee, Data Safety & Monitoring Board, Project Management Team, and any external advisory committees), meeting schedules, decision-making authorities, and escalation procedures. Ensure trial integrity, participant safety, regulatory compliance, and high-level oversight of the INNOVETH protocol.

Scope: Applies to all trial leadership and participating consortium institutions (Addis Ababa University, OsloMet, LSHTM, St. Paul's Hospital Millennium Medical College, AHRI).

Roles & Responsibilities:

- **The PI institution (Addis Ababa University):** Ultimate authority for trial conduct and funding. Ensures regulatory compliance, provides resources, and acts as custodian of the trial master file.
- **Principal Investigator (PI – Dr. Kassahun Habtamu):** Holds overall scientific and ethical responsibility for the trial. Signs off on major protocol amendments, safety decisions, and communications with regulators and funders.
- **Trial Steering Committee (TSC):** Provides strategic oversight of the trial. Composed of the PI, Co-Investigators (Co-PIs) and collaborators. Reviews trial progress, approves major decisions (e.g. protocol changes), and mitigates risks.
- **Co-Investigators:** Lead investigators from partner institutions (e.g. LSHTM, OsloMet, SPHMMC, AHRI). Provide domain expertise (statistics, public health, clinical, Epidemiology, mental health, sexual and reproductive health, etc.) and monitor study activities in their areas of responsibility.
- **Assistant Trial Manager (TM)/Data collection Coordinator):** Day-to-day data collection lead, coordinating across sites. Prepares meeting agendas, progress reports, and communications. Manages timelines and resource allocation.
- **Data Safety & Monitoring Board (DSMB):** Independent experts who meet regularly (at least quarterly) and ad hoc for safety concerns. Reviews serious concerns and events (SAEs) and interim safety analyses, advising the PI and the team on participant safety.

- **Project Management Team (PMT):** Core working group (TM, data manager, app development team, coordinators, steering committee members, PhD's and Post docs) that meets bi-weekely to coordinate activities, track milestones, and resolve operational issues.

- **Site Leads/ CO-PI's:** Local leads at each study location or agency. Ensure SOPs are followed on the ground, supervise field staff, and escalate issues to the TM/PI.

- **Advisory Committee:** External stakeholders and experts who provide high-level guidance and stakeholder perspectives. Aligns trial vision with community expectations and policy; meets periodically as needed.

Definitions: (Include key terms used in governance.)

- **The PI institution:** Institution legally responsible for the trial (AAU).
- **Trial Steering Committee (TSC):** Oversight committee of PI/Co-Is and collaborators.
- **DSMB:** Independent safety monitoring group.
- **Quorum:** Minimum attendance required for committee meetings.
- **Conflict of Interest:** Financial or other interests that could bias judgment.
- **Major Decision:** Protocol changes or unblinding requests.
- **Minor Decision:** Operational or logistical changes.
- **Ad-hoc Review:** Unscheduled meeting convened for urgent issues (e.g. safety signals).

References: INNOVETH Protocol v1.0; Grant agreement; International Conference on Harmonisation–Good Clinical Practice (ICH-GCP) guidelines; Ethiopian National Research Ethics Guidelines.

Required Tools/Forms: TSC and DSMB charters; meeting agenda and minutes templates; issue/decisions log; conflict of interest disclosure form.

Procedure:

1. **Establish Governance Bodies:** Form the TSC and DSMB with written charters specifying membership, roles, and meeting schedules. Ensure at least one independent member on the DSMB.

2. **Meeting Preparation:** Circulate agendas and briefing materials (progress reports, safety summaries) at least 3 working days before each TSC/DSMB meeting. Ensure confidentiality of documents.

3. **Documentation:** During meetings, record minutes, decisions, action items with owners and deadlines. Finalize and upload minutes to the secure repository within 3 working days of each meeting.

4. **Action Tracking:** Maintain a log of action items. The PMT mainly the post-doc and Site Leads are responsible for following up. Escalate any overdue or critical items immediately to the PI and The PI institution.

5. **Escalation Protocol:** For any urgent safety issue, convene the DSMB ad hoc. Implement DSMB recommendations promptly.

6. **Annual Reviews:** Annually review governance effectiveness (meeting frequency, membership). Update charters and SOPs as needed, with Core team approval.

Quality Control & Documentation: Maintain a full audit trail of all governance activities: meeting notices, pre-reads, minutes, and action logs. Submit a quarterly governance report (including decisions and compliance issues) to the PI institution and Funder.

Deviations & CAPA: Any unresolved governance conflict or missed safety escalation must be logged. The PI assigns a Corrective and Preventive Action (CAPA) within 5 working days, documenting root cause and remediation steps.

Training & Competency: All governance committee members receive an induction pack covering INNOVETH objectives, the protocol, and key SOPs. Mandatory training includes Good Clinical Practice (GCP) & research ethics and conflict of interest management. Refresher training on governance roles and SOPs is required annually.

Version Control & Change History: Record the SOP version number, date, and summary of changes on the cover page. Archive previous versions. Any changes to governance structure (e.g. new committee members or policies) must be documented in the change history and communicated to all stakeholders.

SOP-02: Participant (MDW) Identification, Eligibility & Recruitment

Purpose: Standardize the identification, screening, and enrolment of Migrant Domestic Workers (MDWs) to ensure unbiased recruitment, voluntariness, and accurate documentation of recruitment sources.

Scope: All staff involved in recruitment at partner agencies, pre-departure training centers, health clinics, and study field teams.

Roles & Responsibilities:

- **Recruitment Lead:** Oversees recruitment strategy and targets for each cluster; ensures SOP adherence.
- **Screening Staff:** Conduct eligibility assessments using the protocol criteria; complete and maintain the electronic Screening Log.
- **Agency Staff:** Provide lists of potential MDWs and facilitate introductions. Must not exert pressure or coercion. Refer undecided individuals to study staff.
- **Data Manager:** Maintains the centralized ODK/REDCap screening/enrolment database and issues unique study IDs for enrolled participants.

Definitions:

- **Eligible MDW:** A female applicant enrolled at a participating recruitment agency, aged ≥18 years, medically cleared ("fit to travel"), travelling for domestic work, has completed the required Certificate of Competency (COC) for overseas migration, and provides informed consent.
- **Ineligible MDW:** Any applicant who does not meet one or more inclusion criteria (e.g. age, medical fitness, COC, etc.) or meets exclusion criteria.
- **Vulnerable Subgroup:** MDWs at higher risk (first-time migrants, those with disabilities, history of mental health issues, etc.) who may require additional support.

- **Recruitment Cluster:** A defined geographic district in Ethiopia used for cluster-randomization. MDWs in a cluster share similar language and culture, facilitating group interventions.

References: INNOVETH Protocol (Sections 3–4 on eligibility and recruitment); Ethiopian migration/labour regulations; Funding agreement.

Required Tools/Forms: Approved recruitment scripts; electronic Eligibility Checklist (ODK/REDCap); Screening Log; Referral Form for ineligible individuals (to social services, medical care, etc.).

Procedure:

1. **Cluster Assignment:** Use the pre-defined list of randomized clusters (districts) to determine which agencies and communities to approach. Each cluster has a target number of MDWs (e.g. 200 per district).

2. **Approach Potential MDWs:** In private settings at the agency or training center, use the standardized script (in Amharic, Afaan Oromo) to introduce the study. Emphasize voluntary participation and the right to decline without affecting their employment or services.

3. **Screening:** Obtain verbal agreement to screen. Administer the digital Eligibility Checklist. Verify documentation (e.g. COC for migration, age, health clearance). If any criteria are unclear, consult the Site Lead.

4. **Ineligible Candidates:** If ineligible (or unwilling), refer them to appropriate services (healthcare etc.) as needed. Record the reason for ineligibility and any referrals made. Do **not** enroll them.

5. **Enrollment:** For eligible and consenting MDWs, proceed to the informed consent process (see SOP-03). Assign a study ID immediately upon consent. Record the enrolment date.

6. **Record-Keeping:** Document all recruitment attempts (approaches made), including date, cluster, outcome (enrolled, refused, ineligible), and any issues. Enter this data into the electronic Screening Log daily.

7. **Target Monitoring:** The Data Manager generates weekly recruitment reports by cluster. If a cluster is lagging behind targets, the Recruitment Lead explores additional strategies (e.g. engaging alternate agencies) and reports to the Assistant TM.

Quality Control & Documentation: The Data Manager reconciles screening logs and enrolment records monthly. The Site Lead reviews 10% of logs randomly for completeness and accuracy. All screening entries are timestamped and saved on servers.

Deviations & CAPA: Any breach of recruitment procedures (e.g. evidence of coercion, missing screening data) is logged. The Site Lead immediately halts the implicated staff member, conducts an investigation, and implements retraining within 1 week. A formal CAPA (e.g. refresher training, updated materials) is documented and tracked to closure.

Training & Competency: All recruiters undergo interactive training (role-play and scenarios) on ethical recruitment and the SOP. Language and cultural competency training is provided. Recruitment staff must pass the post-training exam before engaging with participants and have annual refresher sessions.

Version Control & History: Maintain a log of any changes to recruitment scripts, eligibility criteria, or SOP procedures. Updated SOP versions are dated, and obsolete versions are archived.

SOP-03: Electronic Informed Consent Procedures (Written, Audio & Low-Literacy)

Purpose: Ensure voluntary, fully informed consent from all MDW participants, with adapted procedures for low-literacy individuals and sensitive modules (e.g. mobile app surveys).

Scope: All personnel obtaining consent at agencies, pre-departure centers, or during follow-up (field staff, Trainers, Empowerment Workers when applicable).

Roles & Responsibilities:

- **Principal and Co-Investigators:** Review and approve all consent materials (forms, scripts) and any major modifications.
- **Site Lead:** Verifies that the consent process is conducted privately, with approved materials in the correct language. Monitors consent quality.
- **Empowerment Worker (EW):** May explain study details to peers but **must not** personally obtain consent from MDWs they directly supervise (to avoid undue influence).
- **Data Manager:** Secures consents (paper or audio records) separately from data, and logs consent status in the REDCap consent register.

Definitions:

- **Informed Consent Form (ICF):** Document outlining study purpose, procedures, risks/benefits, confidentiality, voluntary nature, and contact information. Available in Amharic & Afaan Oromo.
- **E Consent:** A recorded electronic informed consent form with audio option will be provided for electronic informed consent.
- **Assent:** Agreement by a minor (if any under 18) with guardian consent (not expected, as MDWs must be ≥18).
- **Re-consent:** Obtaining consent again if the protocol changes materially or after a set interval (e.g. annually).

References: INNOVETH Protocol (Consent section); Institutional IRB approvals; Ethiopian Personal Data Protection Proclamation No. 1321/2024 (data privacy); Funders' guidelines on consent.

Required Tools/Forms: Approved ICF templates; Audio consent scripts; Comprehension Checklist (5 questions); Consent tracking log (paper/electronic).

Procedure:

1. **Preparation:** Conduct consent in a private, quiet setting. Use the participant's preferred language (Amharic/ Oromomiffa). Present the appropriate ICF version or audio script. Provide pictorial aids if helpful.

2. **Information Delivery:** Clearly explain study purpose, procedures, duration, risks/benefits, confidentiality, data use, and compensation (if any). Emphasize voluntariness and the right to withdraw at any time without penalty. Encourage questions.

3. **Comprehension Check:** After explanation, administer the 5-question checklist to assess understanding. Re-explain any misunderstood concepts. If the participant still cannot demonstrate adequate understanding, do not enroll them.

4. **Documenting Consent:**

    - *E consent:* Conduct an electronic informed consent as a recorded conversation (device encrypted; no personal identifiers stored on it). Complete an audio consent log with recording ID and date.

5. **Post-Consent:** Log the consent in the ODK/ REDCap register and assign the permanent study ID.

6. **Re-Consent:** If any major protocol change occurs (as defined by the PI) ,re-consent all previously enrolled participants before resuming that activity. Also, re-consent at defined milestones (e.g. annually).

Quality Control & Documentation: The Data Manager reviews the consent log weekly. A supervisor randomly audits 10% of consent forms/records each month for completeness (signatures, dates, witness). Discrepancies are corrected or noted as deviations.

Deviations & CAPA: Any missing signatures, witness errors, or incomplete ICF sections are immediately flagged. The Site Lead must promptly act to correct. A corrective note is added to the participant's file. Repeat issues trigger retraining of staff.

Training & Competency: All consent staff receive annual training on the consent process, including role-plays for low-literacy scenarios. Staff must demonstrate proficiency (e.g. through observed mock consents) before conducting actual consents.

Version Control & History: All ICFs and consent materials carry a version number and date. Superseded versions are withdrawn from use. SOP updates and reasons (e.g. regulatory changes) are documented in the SOP history log.

SOP-04: Randomization & Allocation Concealment (Cluster RCT)

Purpose: Detail the generation and concealment of cluster (district) allocation to prevent selection bias and contamination, and outline procedures for permissible unblinding requests.

Scope: Independent Statisticians, Data Managers, Trial Manager, and site staff requesting allocations.

Roles & Responsibilities:

- **Independent Statistician/ data manager:** Creates the randomized allocation list of clusters (stratified/blocked per SAP), and safeguards the master allocation file.

- **Data Manager:** Implements allocation in the secure ODK/REDCap randomization module. Sets user permissions so only unblinded central staff can access sequence information.

- **Site Staff:** When a new cohort is ready, they request cluster allocation through ODK/REDCap. They do **not** access the randomization sequence file.

- **CO-PI's& assistant Trial Manager (TM):** Oversees the randomization system setup and audits logs.

Definitions: Cluster (district) allocation sequence, stratification factors, block size, allocation concealment.

References: INNOVETH Protocol (Randomization section); Statistical Analysis Plan; DSMB charter (for unblinding rules); ICH-GCP.

Required Tools/Forms: Randomization log; Request records (date/user); ODK/REDCap randomization module with audit trails; Sealed envelope backup kits.

Procedure:

1. **Sequence Generation:** The Independent Statistician generates the cluster allocation list (e.g. 12 interventions, 12 control), stratifying by region/language as planned. The list is held confidentially.

2. **System Setup:** The Data Manager programs the ODK/REDCap randomization module with the allocation sequence, restricting view/edit rights. Only the Statistician or Data Manager can upload changes.

3. **Allocation Request:** When a new cluster's cohort is ready, the Site Lead submits a randomization request via ODK/REDCap (by cluster ID). The system automatically assigns that cluster to intervention or control, logging the user ID and timestamp.

4. **Documentation:** The Data Manager updates the cluster master list with the allocation result. No information on future allocations is shared with field staff. Avoid any pre-randomization communication across clusters to prevent contamination.

5. **Unblinding:** Unblinding of a cluster's allocation is only allowed per protocol (e.g. in a medical emergency). Any unblinding must be documented, authorized by the PI, and reported immediately to the DSMB.

6. **Emergency Backup:** In case of system failure, prepare sealed, opaque, sequentially numbered envelopes (prepared centrally by the Statistician) containing cluster allocations. Envelopes are only opened by the PI in the presence of a witness, and the action is logged.

Quality Control & Documentation: The Trial Manager conducts quarterly audits of randomization logs and ODK/REDCap audit trails to detect any unauthorized access or discrepancies. Findings are reported to the TSC.

Deviations & CAPA: Any breach of allocation concealment (e.g. unauthorized access to the sequence) is immediately reported to the DSMB and The PI institution. An investigation is launched and a CAPA plan (e.g. system security fix, retraining) is implemented.

Training & Competency: Data Managers are trained on REDCap randomization modules and access controls. Site staff receive instruction on requesting allocation without bias or premature knowledge.

Version Control & History: Document any changes to the randomization algorithm, block sizes, or stratification factors. All versions of the randomization plan and SAP are archived.

SOP-05: Intervention Delivery & Fidelity (EWs, SHGs, Mobile App)

Purpose: Standardize the delivery of the INNOVETH intervention components – enhanced pre-departure training, Empowerment Worker (EW) support, Self-Help Group (SHG) facilitation, and mobile app onboarding – and ensure consistent fidelity monitoring across clusters.

Scope: All trainers, Empowerment Workers, SHG facilitators, mobile app coordinators, and their supervisors.

Roles & Responsibilities:

- **Trainers:** Deliver the enhanced pre-departure curriculum (mental, sexual and reproductive health [MSRH], digital literacy) according to the facilitator guides. Keep attendance records and deliver key messages consistently.

- **Empowerment Workers (EWs):** Provide individualized peer support based on MDW risk levels. Maintain scheduled contacts (in-person or via phone/Telegram/WhatsApp), record each interaction (date, mode, topics) in the EW diary (digital log), and make timely referrals for high-risk needs.

- **SHG Facilitators:** Form support groups of 5–10 MDWs (ideally via Telegram/WhatsApp). Lead biweekly meetings using the standard agenda, ensure confidentiality, and document sanitized meeting notes and any referrals or issues.

- **Mobile App Coordinator:** Installs and registers MDWs on the INNOVETH app during training. Demonstrates app features (health info, ACASI surveys, quick-exit function). Sets up privacy (PIN, code words). Records app user IDs linked to study IDs.

- **Supervisors:** Observe at least one training session and one EW-SHG interaction per cohort (virtually). Complete fidelity checklists for each component and provide feedback to the responsible staff within 72 hours.

Definitions:

- **Fidelity Threshold:** ≥85% of planned content/actions completed as per facilitator guides.

- **Red-flag:** Any missed high-risk contact or report of abuse/harm that triggers immediate safety protocol (SOP-06).

- **EW Digital Diary:** Secure electronic log where EWs note each participant interaction (date, medium, summary, referrals).

References: Facilitator Guides; EW Training Manual & ToR ; Risk Tool and Action Matrix ; INNOVETH App Manual.

Required Tools/Forms: Attendance sheets for training; session fidelity checklists; EW digital contact logs; SHG meeting logs; app onboarding checklist; referral form; crisis referral cards.

Procedure:

1. **Pre-Departure Training:** Schedule and conduct training sessions per the enhanced curriculum. Each session is observed by a supervisor or senior trainer. Record attendee names and fidelity checklist scores.

2. **EW Assignment:** At enrolment, assign each MDW to an Empowerment Worker. Note the MDW's preferred safe contact method (SMS, call, WhatsApp) and time.

3. **EW Contacts:** Tailor contact frequency to risk level (e.g. Low=monthly, Medium=weekly, High=immediate/regular). Document each EW contact in the digital diary (include summary and any action taken). If a red-flag risk arises (e.g. GBV disclosure), immediately activate SOP-06.

4. **Self-Help Groups (SHGs):** Form SHGs of MDWs (similar language/cluster) to meet biweekly. Facilitators use the standard agenda (peer support, problem-solving). Keep brief confidential notes on key discussion points and any safety issues. Refer members in need to services (using referral form) and log it.

5. **App Onboarding:** During training, install the INNOVETH mobile app on each MDW's phone. Set a security PIN and explain the quick-exit feature. Guide MDWs through the app's sections (MSRH content, anonymous surveys [ACASI]). Ensure MDWs can log in and that data sync is functional. Record the app user ID alongside the study ID.

6. **Fidelity Monitoring:** Supervisors observe a sample of each intervention component (at least one training session and 10% of EW/SHG interactions) and complete the fidelity checklist. Provide constructive feedback and coaching to staff within 72 hours of observation.

7. **Remediation:** If fidelity in any component drops below 85%, implement corrective actions (e.g. booster training for staff, review of materials) and re-evaluate within 2 weeks.

Quality Control & Documentation: Supervisors sign off on each fidelity form. The TM compiles monthly fidelity summary reports by cluster and component, highlighting any deviations. All attendance sheets, checklists, and logs are filed securely.

Deviations & CAPA: Missed sessions, incomplete logs, or unsafe contacts are immediately reported to the Site Lead. The Site Lead and TM devise a CAPA plan (e.g. extra session, retraining EW) and track its completion. Major fidelity failures are escalated to the TSC.

Training & Competency: Trainers must undergo a "Training of Trainers" (ToT) certification program on the enhanced curriculum. EWs complete a one-week intensive training and certification. Refresher trainings (curriculum updates, digital tools) occur quarterly for all intervention staff.

Version Control & History: All curricula, digital content, and app builds are version-controlled. New editions of the app or training materials are tested before release. Maintain a distribution log for digital materials. Document reasons for any content changes in the change history.

SOP-06: Safety Monitoring & Adverse Event (AE/SAE) Reporting (MSRH, GBV, Mental Health)

Purpose: Detect, document, respond to, and report Adverse Events (AEs) and Serious Adverse Events (SAEs) affecting MDWs, prioritizing participant safety and survivor-centered care. Include procedures for urgent cross-border incidents.

Scope: All INNOVETH contacts (pre-departure sessions, EW communications, SHG meetings, app/ACASI surveys).

Roles & Responsibilities:

- **All Staff:** Any team member who learns of an AE/SAE must report it immediately (by phone) to the Clinical Supervisor and Trial Manager, following confidentiality protocols.
- **Trainers/EWs:** Provide immediate first-line support in case of distress or harm disclosure (listen empathetically, provide basic first aid if needed), then initiate referral (health center, counseling).
- **Clinical Supervisor (SPHMMC):** Oversees clinical triage. Authorizes SAE classification and ensures appropriate actions are taken.
- **Assistant Trial Manager (TM):** Ensures all AEs/SAEs are reported within IRB/funder timelines. Maintains the AE/SAE tracking database (pseudonymized).
- **Data Manager:** Enters AE/SAE data into the secure database, linking cases to participant IDs (pseudonymously). Prepares data for safety reports.

Definitions:

- **Adverse Event (AE):** Any untoward medical occurrence reported by a participant or observed by staff, whether or not related to the study intervention.
- **Serious Adverse Event (SAE):** An AE that results in death, is life-threatening, requires hospitalization or prolongation of hospitalization, causes disability/incapacity.
- **Red-Flag:** A critical situation (e.g. report of sexual violence, suicidal intent) requiring immediate action.
- **Time-Sensitive Windows:** For example, initiating PEP within 72 hours after a reported sexual exposure.

References: INNOVETH Protocol safety section; Ethiopian national IRB/ethics reporting regulations; Funders' safety reporting requirements (see DSMB charter).

Required Tools/Forms: AE/SAE report form; "Red-Flag" quick-check form; Referral forms (health, legal, psychosocial); Incident log; MDW safety card with emergency contacts.

Procedure:

1. **Identification:** If an MDW reports or displays a potential AE/SAE (e.g. injury, GBV, mental crisis), the first staff member on scene documents initial facts (what/when/where). Use a non-leading, respectful approach (avoid unnecessary detail or blame).

2. **Immediate Response:** Ensure participant's immediate safety and privacy. For medical issues, call emergency services or a health facility. For mental health crises, provide supportive listening and confidential referral to counseling. Do not probe with repetitive questioning.

3. **Reporting:**

    - *For any SAE:* Notify the Clinical Supervisor within 2 hours of discovery, and the PI & CO-PI within 24 hours.

    - *Documentation:* Complete the AE/SAE report form as soon as possible (within 24 hours). Assign a unique tracking ID. Enter details in the AE log.

    - *Confidentiality:* Do not include personal identifiers in forms or app notes. Use only study ID and initials in electronic systems.

4. **Referral & Follow-Up:** Arrange referral (e.g. hospital, mental health services, police) as needed. Document the referral plan in the AE form. Follow up to verify that care was received and record outcomes (keep this in the confidential case file, separate from research data).

5. **Safety Check-ins:** For any ongoing AE/SAE case, conduct welfare check-ins at defined intervals (e.g. daily, weekly). The EW or Site Lead ensures the MDW is safe and that referrals are completed. Update the AE log with status.

6. **Aggregate Review:** Hold a weekly safety review meeting (including the Trial Manager, Clinical Supervisor, and representatives of PMT). Discuss all reported AEs/SAEs to identify patterns or clusters. Provide aggregated summaries to the DSMB quarterly (or ad hoc if urgent).

7. **Cross-Border Incidents:** If an MDW in the Middle East experiences an urgent problem (e.g. abuse abroad), the TM and PI discuss for a crisis support. Follow pre-arranged protocols with local partner organizations.

Quality Control & Documentation: Perform a 100% audit of all SAE reports (trial monitoring team). Maintain an SAE log with dates, outcomes, and actions. Submit monthly summary AE trend reports (de-identified) to the TSC and IRB.

Deviations & CAPA: Any late report or incomplete form is logged as a deviation. The responsible staff undergo immediate retraining. Process improvements (e.g. more accessible reporting channel) are implemented to prevent recurrence.

Training & Competency: All staff complete annual training on safety and AEs, including survivor-centered care for GBV victims. Role-play drills (e.g. responding to disclosure of abuse or suicidal ideation) are held every six months. The Clinical Supervisor and the counsellors trains EWs.

Version Control & History: Record any updates to SAE definitions, reporting timelines, or referral protocols. All changes (with dates and author) are documented in the SOP history section.

SOP-07: Data Management, Security & Privacy (DPIA Linked)

Purpose: Ensure secure, accurate, and privacy-preserving handling of all trial data (paper and electronic), implementing the Data Protection Impact Assessment (DPIA) measures and compliance with data protection laws.

Scope: All data collection and management activities, including screening logs, consent forms, survey data (ODK/REDCap, ACASI), mobile app data, EW/SHG logs, referral and AE records.

Roles & Responsibilities:

- **Data Manager:** Designs and oversees data flow. Implements databases (ODK/REDCap), user accounts, backups, and audit trails. Periodically reviews data quality and access logs.
- **Site Data Officers:** Handle secure collection of paper CRFs, perform timely scanning/upload to the central server, and destroy paper after archiving.
- **PI/CO-PIs:** Approve all external data sharing (following ethics approvals) and manage data transfer agreements.
- **App developer:** Responsible for technical security of the INNOVETH mobile app (TLS encryption in transit, AES-256 at rest, regular patching). Maintains a breach response plan.

Definitions: PII (Personally Identifiable Information); Pseudonymized Data; Master Link File (file linking PII to study IDs, held separately); Data Breach; Audit Log (records of data access/downloads).

References: INNOVETH DPIA summary; Ethiopian Personal Data Protection Proclamation No. 1321/2024; INNOVETH Protocol; Wellcome Trust data policies.

Required Tools/Forms: Data Flow Diagram; Data Dictionary; Access Control Matrix; Breach Report Template; Encryption SOP (for devices).

Procedure:

1. **Data Minimization:** Collect only essential data. Use unique study IDs on all datasets; store PII (names, contact info) in a separate, highly restricted Master Link File.
2. **Data Collection:**
    - *Paper Forms:* Keep paper forms if available(e.g. ICFs, referral forms) locked at site until scanned. Scan/upload to encrypted server within 7 days of data collection. Destroy papers only after quality checks and double-entry verification (if used).
    - *Electronic Data:* ODK/REDCap entries and app/ACASI data are transmitted over TLS to secure servers and encrypted at rest. Mobile app data are pushed to the central database daily.
3. **Access Control:** Assign role-based permissions (data manager, EW, data entry staff, etc.). Review access lists quarterly. Use strong passwords and two-factor authentication. Maintain an audit log that records all user logins, data exports, and form deletions.
4. **Data Quality & Validation:** Implement real-time range and logic checks in data entry forms. The Data Manager runs weekly discrepancy reports. Critical fields are double-entered or source-verified (e.g. baseline questionnaires). Monthly data consistency checks are performed.

5. **Backups & Recovery:** Perform daily incremental and weekly full backups of all datasets to an off-site encrypted storage. Quarterly disaster recovery drills (restore from backup) are conducted to verify integrity.

6. **Data Sharing:** Governed by Data Sharing Agreements (DSAs) approved by ethics committees. Only de-identified datasets (no PII) are shared with external analysts. Any data request is logged and reviewed by the PI/Trial Manager.

7. **Breach Response:** If a data breach is suspected (e.g. unauthorized access), immediately contain the breach (change passwords, isolate servers). The Data Manager must notify the PI within 24 hours, who in turn informs the IRB and relevant authorities per the DPIA and legal requirements. A breach incident form is completed.

Quality Control & Documentation: Generate monthly data quality dashboards (missingness, outliers) and review in PMT meetings. Quarterly audits compare source documents to database entries (10% sample of key outcomes). All audit logs and backup logs are reviewed and signed off.

Deviations & CAPA: Unauthorized data access, corrupted data, or missing records are logged as incidents. A root-cause analysis is performed, and CAPAs (e.g. additional encryption, staff retraining) are implemented with timelines.

Training & Competency: All study staff sign confidentiality agreements. Mandatory training on data protection and DPIA requirements is provided at induction, with annual refreshers. Field staff are trained on secure data handling (locking laptops, not storing PII on personal devices).

Version Control & History: Track changes to data systems: updates to the data dictionary, CRFs, REDCap forms, or app version. Document each change (date, description, reason) in the version history.

SOP-08: Risk Stratification Tool Use & Tailoring

Purpose: Standardize administration, scoring, and response actions of the INNOVETH risk stratification tool to ensure consistent identification of MDWs' risk levels and timely tailored support.

Scope: Screening staff, Empowerment Workers, Clinical Supervisors, and Data Manager.

Roles & Responsibilities:

- **Screening Staff/EWs:** Administer the risk tool at specified time points; score or record responses accurately (paper or app-based).

- **Clinical Supervisor:** Reviews and verifies high-risk (RED-flag) cases flagged by the tool, and approves immediate plans.

- **Data Manager:** Monitors risk score distributions, configures automated alerts in the system (e.g. SMS to EWs for high-risk triggers), and produces monthly risk reports.

Definitions: Risk categories (Low/Medium/High); Red-flag criteria (e.g. active abuse, suicidal intent); Action Matrix (pre-defined actions by risk level).

References: Risk Stratification Tool (form, action matrix, scoring guide); INNOVETH Protocol; IRB approvals.

Required Tools/Forms: Risk tool form (paper and mobile app version); Scoring reference guide; Action Matrix template; Automated alert configurations.

Procedure:

1. **Administration Timing:** Administer the risk tool at enrolment (pre-departure), at 1-month post-departure, quarterly thereafter, and any time a participant discloses new risk information.

2. **Administration Method:** In a private setting, verbally administer the tool questions or allow self-completion via ACASI for low-literacy MDWs. Ensure confidentiality.

3. **Scoring & Alerts:** Use the numeric scoring guide to calculate a risk score. The mobile app automatically categorizes the MDW into Low/Medium/High risk and sends alerts to the assigned EW if a threshold is crossed.

4. **Action Matrix:** Follow the pre-defined response for each category:

    - *Low Risk:* Standard monthly EW check-ins; no urgent action.

    - *Medium Risk:* Schedule weekly EW contact with enhanced counseling.

    - *High Risk:* Initiate immediate safety planning. The Clinical Supervisor is notified, and a referral is arranged (e.g. SPHMMC or local hospital).

5. **Documentation:** Record all risk scores, red-flag triggers, and responses in the EW diary and app notes. Maintain a secure log of referrals made and outcomes (with participant consent) in the study database.

6. **Reassessment:** Repeat the tool if contact is missed, if the MDW reports new issues, or per schedule. Adjust the intervention plan accordingly.

7. **Quality Assurance:** Supervisors review a random 10% sample of risk tool administrations each month for scoring accuracy and proper action. Any discrepancies trigger retraining of the administering staff.

Quality Control & Documentation: Data Manager includes risk category summaries in monthly reports to the TM. Track response times for Red-flag cases (goal: <24 hours). Maintain a registry of all high-risk cases and their outcomes.

Deviations & CAPA: If a tool is administered incorrectly (wrong scoring) or a high-risk flag is missed, the case is reviewed immediately. The responsible staff receive retraining, and the participant is assessed without delay. All incidents are documented and corrective action implemented.

Training & Competency: Train staff on tool administration with role-play. Conduct inter-rater reliability exercises. Provide annual re-certification in risk tool use.

Version Control & History: The risk tool and action matrix are versioned documents. Log any changes (e.g. modified cutoffs) in Annex C, and update the app content accordingly.

SOP-09: Monitoring, Audit & Quality Assurance

Purpose: Define the monitoring and audit processes (on-site and remote) and quality assurance (QA) activities to protect participant safety and data integrity throughout the trial.

Scope: All trial sites, data management, field teams (EWs, trainers).

Roles & Responsibilities:

- **Monitoring Lead (Designated person):** Plans and oversees all monitoring activities.
- **Monitors/Auditors:** Conduct on-site visits and/or remote reviews. Verify source data, consent forms, and protocol adherence. Prepare monitoring reports.
- **Site Lead:** Ensures timely response to monitoring findings and implements CAPAs.
- **Quality Assurance (QA) Team:** (if separate) conducts independent audits to assess compliance with SOPs and GCP.

Definitions: Site Initiation Visit (SIV), Monitoring Visit (MV), Source Data Verification (SDV), Major Audit Finding (MAF), Corrective Action/Preventive Action (CAPA).

References: INNOVETH Monitoring Plan; ICH-GCP (Section on Monitoring); Funders' compliance guidelines.

Required Tools/Forms: Monitoring visit checklist; Monitoring report template; Issue log; CAPA plan template.

Procedure:

1. **Risk-Based Monitoring:** Assign clusters/sites to risk categories (higher recruitment or complex sites = higher risk). Plan more frequent monitoring (e.g. monthly remote checks) for high-risk sites, and regular on-site visits for others (e.g. quarterly).
2. **Site Initiation Visit (SIV):** Before enrolment starts at a new location, confirm site readiness: verify staff training, supplies, ethics approvals, and understanding of SOPs. Document any site-specific adaptations.
3. **Source Data Verification (SDV):** During monitoring, select a random sample of critical variables (at least 10% of records for baseline and primary outcomes) and compare source documents (ICFs, CRFs) against the database entries for accuracy.
4. **Remote Monitoring:** Use online dashboards (REDCap status, recruitment rates, data completeness) to spot anomalies (e.g. missing data, unusual distributions). Follow up on any issues via phone or video calls.
5. **Reporting:** Within 5 working days of a visit, the monitor issues a written report listing findings (major/minor), observations, and recommended CAPAs. Sites have 10 days to submit a CAPA response. The monitor reviews CAPAs and confirms closure.
6. **Audit Preparation:** Maintain a complete Trial Master File at each site. Ensure all essential documents (consent forms, ethics approvals, training logs) are organized for potential audits by the PI institution or regulators.

7. **Continuous QA:** The TM and PMT review monitoring summaries monthly. Track trends (e.g. recurring errors, protocol deviations) and address systematically.

Quality Control & Documentation: A consolidated monitoring log is maintained by the TM. Monthly monitoring summaries (recruitment, data issues, CAPA status) are circulated to the TSC. Performance metrics (e.g. data query resolution time) are tracked for process improvement.

Deviations & CAPA: Significant or repeated findings (e.g. major data discrepancies, GCP violations) are escalated to the PI and TSC. Systemic issues trigger broader CAPAs (e.g. revised SOPs, re-training, or site suspension if needed). A quarterly trend analysis of findings informs protocol amendments if required.

Training & Competency: All monitors must be trained in GCP, these SOPs, and the trial's data systems. They conduct at least two mock monitoring exercises before independent monitoring. Refreshers on new regulations or protocol changes are provided as needed.

Version Control & History: Any changes to monitoring tools or schedules are documented and versioned. The Monitoring Plan and SOP are updated concurrently when major changes occur.

SOP-10: Protocol Deviations, Violations & CAPA

Purpose: Establish procedures for identifying, documenting, reporting, and correcting protocol deviations and violations, and for implementing corrective and preventive actions (CAPAs) to uphold trial integrity.

Scope: All trial personnel (field staff, data team, site personnel).

Roles & Responsibilities:

- **Any Staff Member:** Promptly report observed or potential deviations/violations to their Site Lead.
- **Site Lead:** Classify the event (minor deviation vs. major violation), record details, and initiate immediate CAPA for minor issues.
- **Trial Manager (TM)/PI:** Review all deviations and violations. Major violations (with impact on safety/data integrity) are reviewed by the PI and reported to the IRB and The PI institution as required.
- **QA/Monitoring Team:** May identify deviations during reviews and ensure they are entered into the deviation log.

Definitions:

- **Protocol Deviation:** An unintentional deviation from the approved protocol or SOP (no significant harm expected).
- **Protocol Violation:** A significant or intentional deviation that affects safety or data validity.
- **CAPA (Corrective and Preventive Action):** Steps taken to correct a deviation and prevent recurrence.

References: INNOVETH Protocol; ICH-GCP (sections on deviation/violation handling); IRB/ethics guidance.

Required Tools/Forms: Deviation/Violation report form; CAPA plan template; Central deviation log (electronic).

Procedure:

1. **Detection & Reporting:** When a deviation/violation is discovered, complete a report form within 24 hours. Include a description, date/time, and individuals involved. Submit the report to the Site Lead.

2. **Assessment:** The Site Lead and TM assess severity. Classify as minor (e.g. late data entry, missed non-critical visit) or major (e.g. informed consent not obtained, eligibility breach, data falsification).

3. **Notification:**

    - *Minor Deviations:* Document locally.

    - *Major Violations:* Notify the PI immediately. The PI determines if regulatory reporting is required (e.g. IRB notification within specified timelines).

4. **CAPA Development:** Conduct a root-cause analysis for each event. Draft a CAPA plan detailing corrective steps, responsible person, and timeline. For example, retraining staff, revising procedures, or enhancing oversight.

5. **Implementation & Verification:** Implement the CAPA. The Site Lead monitors progress. After completion, verify effectiveness (e.g. through monitoring). Close the CAPA only when the issue is resolved.

6. **Trend Monitoring:** Quarterly, the TM reviews the deviation log across sites to identify patterns (e.g. recurrent informed consent issues) and implements systemic improvements.

Quality Control & Documentation: Maintain a centralized deviation/violation log. Track CAPA status and outcomes. The PI reviews the log monthly and reports key issues to the TSC. Include deviation summaries in monitoring reports.

Deviations & CAPA: Repeated minor deviations escalate to retraining or process change. Repeated violations may trigger disciplinary action or site suspension. Effectiveness of CAPAs is evaluated and documented after one month of implementation.

Training & Competency: All staff receive training on what constitutes a deviation/violation and how to report. Case-based exercises at induction help staff practice identification and reporting of deviations.

Version Control & History: Record all changes to this SOP. Any new deviation categories or reporting requirements (e.g. per updated IRB guidelines) are dated and logged in the history section.

(SOP-11 through SOP-15, which cover areas such as communication, logistics, data transfer, etc., remain to be completed because are highly relevant).

Annexes & Templates (placeholders)- planned to be developed

- **Annex A:** Facilitator Guides & manuals (Enhanced Pre-Departure Training)
- **Annex B:** Empowerment Worker (EW) Training Manual & Competency Checklist
- **Annex C:** Risk Stratification Tool (Form, Action Matrix, Scoring Guide, Sample Vignettes)
- **Annex D:** Consent Forms (Amharic, Oromoiffa), Audio Consent Scripts, Witness Forms, Enrolment Checklist
- **Annex E:** INNOVETH App User Manual (ACASI Questionnaire, DPIA Summary, Onboarding Checklist)
- **Annex F:** EW Digital Diary Template, SHG Meeting Log, Referral Form, AE/SAE Reporting Form
- **Annex G:** Referral Directory (Ethiopia & Destination Countries; NGO and Embassy Contacts)
- **Annex H:** Monitoring Visit Checklist, Fidelity Checklist, Supervision Forms
- **Annex I:** Data Flow Diagram, Data Dictionary, Access Control Matrix, Data Breach Report Form
- **Annex J:** Crisis Response Checklist and Safety Plan Template
- **Annex K:** Budget Templates & Costing Workbook
- **Annex L:** Ethics Approvals, IRB Correspondence, DSMB Charters
- **Annex M:** Communication Scripts, Recruitment Scripts, Public Messaging Templates

ANNEX 11: RESEARCHERS CONFIDENTIALITY AGREEMENT

INNOVETH researchers Confidentiality Agreement form

I, _____, agree to maintain confidentiality of all Project information, discussions, participant-related information, project documents, and unpublished findings obtained through my participation in the INNOVETH Project.

I understand that:

- Confidential information must not be shared without authorization.
- Participant identities and sensitive information must remain protected.
- Digital files and communications should be securely handled.

This obligation remains valid during and after my participation in the Project team.

Name: _____

Signature: _____

Date: _____

ANNEX 12: PROCEDURES FOR MDWs MAPPING

Community mapping for MDWs is a tool that facilitates identification of social networks, hotspots, and explore resources for health interventions (e.g., mental, sexual and reproductive health supports) especially in hard-to-reach settings.

The following phases will be followed to map MDWs community**.**

1. **Preparation phase**

- Specify the objective (what we want) to map (e.g., social networks, recruitment routes, service gaps, etc).
- Decide geographic area to cover (Region, district, city, transit hubs) and MDWs to cover
- Recruit MDWs trainers, self-help groups, peer-support groups, outreach volunteers, and their plan roles.

2. Engagement phase

- Identify key actors such as groups of MDWs, social networks, faith-based groups, recruitment agencies, and embassies
- Prepare discussion forum (meetings) to explain the purpose, and build trust.
- Obtain informed consent and data use agreement.
- Prepare digital tools targeted to MDWs routes and/or meeting places (e.g., churches, parks, bus stations).

3. Mapping and data collection phase

- Gather small groups of MWDs to jointly draw a map of their community (e.g., homes, medical services, Embassy, police stations, etc)
- List groups of MDW, informal networks, support groups/associations, and convenient gathering places with their places, contact persons, and schedule.

4. Data verification and analysis phase

- Transfer hand-drawn maps into digital maps and label spatial points with coded information (e.g., risk level, service access).
- Meet with selected MDWs and Verify data and update maps accordingly.
- Analyze patterns and identify clusters of high-risk locations, service gaps, and key hubs such as bus stops, churches, parks and others where support can be placed.

5. Feedback sessions and joint planning phase

- Present findings of the mapping to the selected MDWs and discuss on critical issues specific to MDWs.
- Prepare joint action plan and decide on short-term responses (e.g., peer support hubs, orientation sessions and advocacy demand).
- Produce simple MDWs maps that can be utilized by the MDWs themselves to locate service access, and where to get other assistances.

6. Follow-up phase

- Integrate into existing programmes (e.g., health care services, and labour review planning for MDWs)
- Update mapping after occurrence of major events (e.g., policy changes, major migration flows).

ANNEX 13: DATABASE SCREEN SHOTS

Version: _____Ref. No.: IRERC _____Date: _____

Project Title: ***"INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East"***

Principal Investigator: Dr. Kassahun Habtamu, Asst Prof, AAU: Phone number(s): +251 911 697732

Purpose: This document provides anonymized screenshots of the electronic study database used to store and manage data collected through the study's electronic data collection system. The screenshots are provided for documentation, monitoring, and audit purposes.

Description of the Database Interface

The database stores submitted electronic interview records and associated system-generated metadata. Access to the database is restricted to authorized study personnel through role-based permissions.

Description of Database Content

The database screenshots display the following information:

- Questionnaire name and version
- Form instance identification number
- Enumerator identification code
- Interview date
- Study site (district or woreda)
- Interview completion status
- GPS data indicator
- Data upload date and time

Data Security and Confidentiality Statement

The database is hosted on a secure server with restricted, role-based access. All data transmission from field devices to the database is encrypted. No personal identifiers are displayed in the database views intended for documentation. Data handling procedures comply with the approved study protocol and institutional ethics guidelines.

Prepared by (Data Manager): _____ Signature: _____ Date: _____

ANNEX 14: PAYMENT FORMATS

Empowerment workers (EWs) payment form

Version: _____Ref. No: IRERC_____ Date_____

Study/Project Title: "INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East"

Principal Investigator: Dr. Kassahun Habtamu, Associate Professor, Addis Ababa University

Phone number(s): +251 911 697732

Purpose: This document outlines the key roles, responsibilities, and payment terms for **Empowerment Workers** engaged in the above-named research study.

Participant Information

Name: _____

Role: Empowerment Worker Labor ID Number (if applicable):_____

Start Date:_____ Signature: _____Date: _____

2. Roles & Responsibilities

1. To serve as the key liaison and support person for assigned Migrant Domestic Worker (MDW) participants, guided by the study's risk stratification.
2. Attending all mandatory training and regular supervision meetings.
3. Maintaining accurate, timely, and confidential records of all participant contacts.
4. Conducting proactive, supportive outreach to assigned MDW participants based on their risk level.
5. Facilitating participation in intervention components (peer support groups, digital training sessions).
6. Providing basic motivational support, health information, and guidance using the study materials.
7. Monitoring participant well-being and identifying any signs of increased psychological distress/risk.
8. Immediately documenting and referring any participant identified as being at severe psychological risk to the designated study Nurse at St. Paul following the safety protocol

Payment Procedure:

1. Submit a completed and signed Monthly Timesheet & Expense Log to the Study Coordinator by the 5th of the following month.
2. Payment will be processed via bank transfer within 15 working days of submission.
3. All payments are subject to tax deductions as required by local law.

5. Confidentiality & Ethics Agreement

By signing below, I acknowledge that I have received and understood the study protocol and ethics guidelines. I agree to:

- Maintain the strict confidentiality of all participant information.
- Perform my duties diligently and according to the training provided and protocol.
- Report any concerns or adverse events immediately to the study coordinator.

For Official Use Only – Study Coordinator and finance personnel Verification

- Total Agreed Monthly Stipend: _____
- Payment Method: Bank Transfer ☐ Cash payment ☐ Mobile payment ☐
- Verified by (Study Coordinator): _____Signature_____Date:_____
- Approved by (finance personnel): _____Signature: _____ Date: _____

Study Nurse payment form

Version: _____Ref. No: IRERC_____ Date_____

Study/Project Title: "**INNOVETH: Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East**"

Principal Investigator: Dr. Kassahun Habtamu, Associate Professor, Addis Ababa University

Phone number(s): +251 911 697732

Purpose: This document outlines the key roles, responsibilities, and payment terms for Nurses engaged in the above-named research study.

1 Participant Information

Name: _____

Role: Study Nurse ID Number (if applicable):_____

Start Date:_____ Signature: _____Date: _____

2. Roles & Responsibilities

- Provide professional clinical oversight and support within the research framework,
- ensuring participant safety receiving and prioritizing referrals from Empowerment Workers.
- Conducting confidential, professional assessments and providing short-term supportive and follow up on counseling.
- Determining the need for, and facilitating, referrals to external, specialized mental health services as per the study protocol.
- Providing guidance and back-up support to Empowerment Workers on health-related queries (within scope).
- Participating in clinical supervision and study team meetings.
- Maintaining strict confidentiality and detailed, secure records of all clinical interactions and referrals.
- Attending all mandatory training and supervision meetings.
- Maintaining accurate, timely, and confidential records of all participant contacts.
- Providing basic motivational support, health information, and guidance.
- Monitoring participant well-being and identifying any signs of increased psychological distress/risk.
- Immediately documenting and referring any participant identified as being at severe psychological risk to the designated clinical coordinator at St. Paul following the SOP

Payment Procedure:

1. Submit a completed and signed Monthly Timesheet & Expense log to the Study Coordinator by the 5th of the following month.
2. Payment will be processed via bank transfer within 15 working days of submission.
3. All payments are subject to tax deductions as required by local law.

5. Confidentiality & Ethics Agreement

By signing below, I acknowledge that I have received and understood the study protocol and ethics guidelines. I agree to:

- Maintain the strict confidentiality of all participant information.
- Perform my duties diligently and according to the training provided and SOP available.
- Report any concerns or adverse events immediately to the study (clinical) coordinator.

For Official Use Only – Study Coordinator and finance personnel Verification

- Total Agreed Monthly Stipend: _____
- Payment Method: Bank Transfer ☐ Cash payment ☐ Mobile payment ☐
- Verified by (Study Coordinator): _____Signature_____Date:_____
- Approved by (finance personnel): _____Signature: _____ Date: _____

ANNEX 15: LOCATOR INFORMATION FORM

Section A Project Identification	INNOVETH Trial_____
Full Project Title:	Innovative Health Intervention for Ethiopian Migrant Domestic Workers in the Middle East: INNOVETH
Short Title:	INNOVETH Trial
Lead Applicant:	
Collaborators:	1. [Name, Organisation, Country] 2. [Name, Organisation, Country]
Funder/Sponsor:	Wellcome Trust
Project Dates:	Start: Nov 2025 End: //_____

Section B: Ethics Review Classification	
Type of Research:	☐ Intervention (Clinical Trial) ☐ Social Science Research ☐ Laboratory Based ☐ Secondary Data ☐ Other: _____
Involves NHS?	☐ Yes ☐ No
Involves Human Participants?	☐ Yes ☐ No *If No, justification must be provided*
Vulnerable Groups? (Tick all that apply)	☐ Migrant workers
Sensitive Topics? (Tick all that apply)	☐ Sexual behaviour ☐ Illegal activities (e.g., undocumented status) ☐ Experience of violence/trauma ☐ Mental health ☐ Other: _____
Geographical Location:	Primary: middle east Data Analysis: AAU, St Paul, LSHTM & others

Section B: Ethics Review Classification	
Previously submitted to LSHTM Ethics Committee?	☐ Yes (Ref: _____) ☐ No
Previously submitted to other REC?	☐ Yes (Ref: _____) ☐ No

Section C: Attachments Checklist	Included?
Core Documents	
1. Ethics Application Form (online)	☐
2. Full Research Protocol	☐
3. Process Evaluation Framework	☐
4. Participant Information Sheets (PIS)	☐
- PIS for MDWs (Main Trial) - Amharic & English	☐
- PIS for MDWs (Process Evaluation Interviews) - Amharic & English	☐
- PIS for Facilitators/Staff	☐
5. Consent Forms	☐
- Consent Form for MDWs (Main Trial) - Amharic & English	☐
- Consent Form for MDWs (Process Evaluation) - Amharic & English	☐
6. Data Collection Tools (Questionnaires, Topic Guides)	☐
7. Letters of Support/Agreement from collaborating organisations	☐

Section C: Attachments Checklist	Included?
8. CV of Lead Applicant	☐
Additional Documents (if applicable)	
9. NHS/HRA Approval (if applicable)	☐ N/A
10. External Ethics Approval (from host countries)	☐ *Pending/Attached*
11. Data Management Plan (DMP)	☐
12. Indemnity/Insurance Confirmation	☐
13. Peer Review Report (if grant funded)	☐
14. Translation Certificates (for PIS/CF in Amharic)	☐

ANNEX 16: INNOVETH STUDY QUESTIONNAIRES

ELIGIBLITY QUESTIONS

ELIG 1. Have you read the information sheet and signed the consent form?

• Yes (1)

• No (0)

ELIG 2. Are you travelling to the Middle East for Domestic Work

• Yes (1)

• No (0)

ELIG 3. Are you travelling to one of the following countries: Saudi Arabia, UAE, Kuwait, and Qata?

• Yes (1)

• No (0)

ELIG 4. How old are you?

• Number pad

ELIG 5. How long have you lived in the area (where you come from)?

• Less than 3 months (0)

• 3 to 6 months (1)

• More than 6 months (2)

ELIG 6. Which language do you undesrtand?

• Amharic (0/1)

• Afan Oromoo (0/1)

• None (0/1)

SECTION A: SOCIODEMOGRAPHIC VARIABLES

A1. Which year were you born?

A2. What is the highest level of education that you have completed?

• Never attended school (0)

• Elementary school 1-8 (1) •
Secondary 9-10 (2)

- Secondary 11-12 (3)
- 10 plus 3, College, Certificate, Diploma(4)
- Degree, or above (5)

A3. What is the main language you speak at home?

- Amharic (0)
- Afan Oromo (1)
- Tigrinya (2)
- Welaita (3)
- Gurage (4)
- Silte (5)
- Other (specify)

A4. What other languages can you speak in addition to the main language you use at home? (multiple answers allowed)?

- Amharic (0/1)
- Afan Oromo (0/1)
- Tigrinya (0/1)
- Arabic (0/1)

English (0/1)

- Other (specify) ----------

A5. What is your current marital status?

- Never been married (0)
- Married, and we live together (1),
- Married, and we live separately for work or family reasons (2),
- Not married, but i am cohabiting (3)
- Not married, but i have a boyfriend (4)
- I am divorced or separated (5)
- My husband has died (6)

A6. How many children do you have?

A7. How many people normally live in your household? (include all children, adults and yourself)

- 1-2 people (0)
- 3-4 people (1)
- 5-6 people (2)
- 7-8 people (3)
- 9-10 people (4)
- More than 10 people (5)

A8. How many children under age 18 years do you support, regardless of whether they live in the household with you?

A9. During the past 6 months, how many other household members had a regular income (earned money on a monthly or weekly basis)?

A10. What was your main occupation before migration?

- Have no job (0)
- Student (1)
- Daily laborer (2)
- Domestic worker (3)
- Private firm employee (4)
- Government employee (5)
- Farming (own or for family) (6)
- Trade (own or for family) (7)
- Other, specify (8) _____

A11. What was your parents' major source of income before migration?

- No parent or care taker (0)
- Private firm employee (1)
- Daily laborer (2)
- Government employee (3)
- Farming (own or for family) (4)
- Trade (own or for family) (5)
- Other, specify (6) _____

A12. Do you have the following items in your household?

• Electricity (0/1)

• Refrigerator (0/1)

• Stove (electric, gas, or wood) (0/1)

• Drinking tap water in the house (0/1)

• Livestock (goats, sheep, cattle, donkeys) (0/1)

• Bicycle (0/1)

• Motorcycle/Bajaj (0/1)

• Car/truck in working condition (0/1)

• Phone (cell or landline) (0/1)

• Radio (0/1)

• Television (0/1)

• A flush toilet (0/1)

• Pit latrine (0/1)

• Wash machine (0/1)

A13. Which of the following documents do you currently have?

• Kebele ID (0/1)

• Fayida (0/1)

• Birth Certificate (0/1)

• Health Card (0/1)

• Passport (0/1)

• Driving licence (0/1)

A14. Do you have an account in a bank or other financial institution or other mobile money banking services that you use? [Banks, Telebirr, e-Birr, M-Pesa]

• Yes (1)

• No (0)

A15. Who helped you to find th current job (the dometsic work in the Middle East)?

• Family (0/1)

• Agency (0/1)

• Friends/Neighbors (0/1)

• Broker (0/1)

• Internet (0/1)

• None of the above (ask for a detailed description) (0/1) If other, please,specify_____

A16. How much did you pay for the job/travel?

• less than $20 (0)

• $20-$50 (1)

• $50-$100 (2)

• $100-$200(3)

• More than $200 (4)

• I don't know (5)

A17. From whom did you get this job information?

• Close friend (1)

• Friend (2)

• Acquaintance/Colleague (3)

• Stranger (4)

• Relative(5)

• Other (6)

A18. Which of the following best describes your situation regarding access and use of a mobile telephone/cellphones?

• I have a smartphone and I use it (0)

• I have a non-smartphone mobile telephone and I use it (1)

• I share a mobile telephone with a family member/ relative (2)

• I share a mobile telephone with another person not a relative or a family member) (3)

• I do not use a mobile telephone at all (4)

A19. Who paid when you buy your current phone?

- Myself (0)
- Family (1)
- Friend/other migrant (2)
- Agency (3)
- Government (3)
- Other (specify) (4)

A20. Do you use your mobile phone for any financial transactions?

- Yes (1)
- No (0)

A21. Do you use the Internet?

- Yes (1)
- No (0)

A22. During the last one month, how often did you use the internet (data/bundles/wifi)?

- Almost every day (0)
- At least once a week (1)
- Less than once a week (2)
- Not at all (3)

A23. Which apps do you use? (multiple answers)?

- Whattsapp (0/1)
- Telegram (0/1)
- Facebook / Facebook Messenger (0/1)
- Viber (0/1)
- IMO (0/1)
- Other (specify)
- None

A24. How often do you use your Telegram?

- Never (0)
- Sometimes (1)

• Always (2)

A25. How often do you use your TikTok?

• Never (0)

• Sometimes (1)

• Always (2)

A26. How often do you use Whattsup?

• Never (0)

• Sometimes (1)

• Always (2)

A27. How often do you use IMO?

• Never (0)

• Sometimes (1)

• Always (2)

Think about your household food supply

A28. In the past four weeks, did you worry that your household would not have enough food?

• Yes (1)

• No (0)

A29. How often did this happen in the past four weeks?

• Always(1)

• Sometimes (2)

• Never (3)

Think about the quality of food in your household n the past 4 weeks

A30. In the past four weeks, were you or any household member not able to eat the kinds of food you preferred because of a lack of resources?

• Yes (1)

• No (0)

A31. How often did this happen in the past four weeks?

• Always(1)

• Sometimes (2)

• Never (3)

Think about whether you had adequate food in your household in the past 4 weeks

A32.Did you or any household member go to sleep at night hungry because there was not enough food?

• Yes (1)

• No (0)

A33. How often did this happen in the past four weeks?

• Always(1)

• Sometimes (2)

• Never (3)

The next questions are about your domestic work experience/migration. All your answers are private and confidential

A34. Have you ever been employed as a Domestic Worker in Ethiopia, before?

• Yes (1)

• No (0)

A35. How old were you when you first start domestic work?

A36. For how many years have you been employed or worked as a a domestic worker in Ethiopia?

SECTION B: Migration Experiences

B1. Have you ever migrated abroad for domestic work other than your current migration?

• Yes (1)

• No (0)

B2. Is this migration your:

• First time travelling for domestic work (0)

• Second time (1)

• Third time or more (2)

B3. If you re-migrate for a second or more rounds; what was/were your reason/s for re-migration?

• Disappointed by family who abused the money I sent for saving (0/1)

• No opportunity to do business here (0/1)

- I finished the money I brought (0/1)
- Stigma and discrimination (0/1)
- No or weak support system from the local administration (0/1)
- Instability and conflict in your locality (at home place) (0/1)
- Opportunities, services and facilities in the destination (0/1)
- If other, please specify (0/1) _____

B4. What was your age when you first migrated abroad for domestic work?

- Number pad

B5. Were you below 18 years old at any point during your previous migration process?

- Yes (1)
- No (0)

B6. How did you organize your travel the last time?

- Through a licensed foreign employment agency in Ethiopia (0)
- Through an informal broker/agent (1)
- Through relatives/friends abroad (2)
- By myself (self-organized) (3)
- Other (specify) (4)

B7. How long did you stay in the destination country in your most recent migration?

- Less than 6 months (0)
- 6–11months (1)
- 1–2 years (2)
- 3–4 years (3)
- 5 years or more (4)

B8. Which of the following were reasons for you to return to your home country in your recent migration?

- To live with my family (0/1)
- Deportation (0/1)
- Contract terminated (0/1)
- Insufficient payment (0/1)

- Denial of salary (0/1)
- Strict control by police (0/1)
- Health problem/sickness (0/1)
- Family pressure (0/1)
- Completion of term/end of contract (0/1)
- Economic crises at the destination country (0/1)
- Due to COVID-19 pandemic (0/1)
- Family pressure (0/1)
- If other, please specify (0/1) _____

B9. Who covered the expense to return to your home country?

- NGOs (0)
- Foreign government (1)
- Ethiopian government (2)
- Myself (3)
- Family/relatives (4)
- Friends (5)
- Other (specify)_____

B10. What was the destination country for your most recent migration?

- Saudi Arabia (0)
- United Arab Emirates (1)
- Kuwait (2)
- Qatar (3)
- Lebanon (4)
- Jordan (5)
- Bahrain (6)
- Oman (7)
- Other (specify)

B11. Who initiated you into migration?

- Parents (0)
- Relatives (1)
- Neighbors (2)
- Self (3)
- Friends/peers (4)
- Family/relatives/friends from abroad (5)
- Broker (6)
- Others from abroad (7)
- Other, specify (8) _____

B12. How did you organize your travel in the current migration?

- Through a licensed foreign employment agency in Ethiopia (0)
- Through an informal broker/agent (1)
- Through relatives/friends abroad (2)
- By myself (self-organized) (3)
- Other (specify) (4)

B13. How long did this travel take since you registered, for official CV? (in months)

- Number pad

B14. What was your main job abroad?

- Live-in domestic worker (in a private home) (0)
- Live-out domestic worker (1)
- Cleaner in company/hotel (2)
- Nanny/childcare worker (3)
- Elderly care (4)
- Other (specify) (5)

B15. How many hours per day did you work abroad in most days?

- Less than 8 hours (0)
- 8–10 hours (1)
- 11–14 hours (2)

- 15 hours or more (3)

B16. Did you have at least one day off per week abroad?

- Yes, every week (0)
- Sometimes (not every week) (1)
- Rarely (2)
- Never (3)

B17. Did you keep your own passport with you?

- Yes, every week (0)
- Sometimes (not every week) (1)
- Rarely (2)
- Never (3)

B18. How do you describe your sleeping condition?

- Own room with a door (0)
- Shared room with other workers/family (1)
- Sleeping in living room or kitchen (2)
- Other (specify) (3)

B19. How often did you get enough food to eat every day?

- Always (0)
- Often (1)
- Sometimes (2)
- Rarely (3)
- Never (4)

B20. How safe do/did you feel in the employer's home?

- Very safe (0)
- Safe (1)
- Sometimes (2)
- Neither safe nor unsafe (3)

- Unsafe (4)
- Very unsafe (5)

B21. What is your residence (before migration):

- Rural (1)
- Urban (0)

B22. Did you get the following opportunities after returning back home in your recent migration?

- Started business by myself (0/1)
- Got support from the government/NGO (0/1)
- Got support from family/community (0/1)
- Reunite with family (0/1)
- Got freedom of movement (0/1)
- Have stable life (0/1)
- Other, specify _____

B23. Did you get the following support from the government or an NGO up on your return in your recent migration?

- Counseling and rehabilitation (0/1)
- Training (life skills and technical) (0/1)
- Financial support (seed money, transport fee, cash for subsistence (0/1)
- Arrangement of a work place (container, shop, market place) (0/1)
- Food and accommodation (0/1)
- Healthcare services (0/1)
- Other, specify _____

B24. Did you experience the following challenges after returning home in your recent migration?

- Stigma and discrimination (0/1)
- Considering you as “mentally unstable” (0/1)
- Unable to get the money you sent (family, friends or relatives denied the money you sent) (0/1)
- Unable to pay ones debt (0/1)
- Betrayal by wife/husband/boy or girl friend (0/1)
- Lack of support to start business (0/1)

- High interest rate for the money you borrowed (0/1)
- Conflict of life style and habits (0/1)
- Other, specify _____

SECTION C: SOCIAL COHESION AND PEER SUPPORT

J1. In general, how would you describe your relationship with other migrant domestic workers?

- Very Good (0)
- Good (1)
- Neither good nor bad (2)
- Bad (3)
- Very bad (4)
- No relationship with other migrant domestic workers (5)
- Don't know (6)

J2. How many migrant domestic workers do you consider close friends? (By close we mean you could talk to them about your personal problems)

- Number pad

J3. My colleagues will support me if I have personal problems while abroad

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)
- I don't have colleagues (5)

The next few questions will ask about peer support

J4. It helpful to receive information from a peer educator /empowerment worker - a colleague who is also a MDW and trained to support her colleagues who are MDWs on metal, sexual and reproductive health?

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)
- I don't have colleagues (5)

J5. While abroad, how often would you like to meet a peer educator (by whatsapp or social media)

- Once a week (0)
- Every two weeks (1)
- Once a month (2)
- Other (3), _____

J6. What would you like the peer educator/empowerment worker to talk you about?

- Mental health (0/1)
- Sexuala nd reproductive health (0/1)
- Contraception (0/1)
- Cervical cancer screening (0/1)
- Stigma and discrimination (0/1)
- Importance of testing regularly for HIV and STI (0/1)
- Finance (0/1)
- Migrant domestic worker rights (0/1)
- Legal issues for migrant domestic workers (0/1)
- Sexual and gender based violence (0/1)
- Self help groups (0/1)

J7. Right now, how many people can you count on for help if you have a problem?

- None (0)
- 1 to 2 (1)
- 3 to 5 (2)
- 6 to 10 (3)
- More than 10 (4)

J8. Of these people, how many are women who have worked, or plan to work, as domestic workers in another country?

- None (0)
- A few (1)
- About half (2)

• Most (3)

• All (4)

J9. In the past 12 months have you partcipated in any group-based activity to support social and/or economic needs?

• Yes (1)

• No (0)

J10a. Is Person nickname [1] from your home district (woreda)? /Is this woman from your home district or area?

• Yes (0)

• No (1)

• Don't know (2)

J10b. Has Person nickname [1] ever worked as a domestic worker in another country, or is she also planning to go soon?/Has this woman worked as a domestic worker outside Ethiopia, or is she planning to go soon?

• She has worked abroad (0)

• She is planning to go abroad (1)

• No (2)

J29c. How often do you communicate with Person nickname [1] now?/ How often do you talk to this woman now?

• Every day (0)

• Several times a week (1)

• About once a week (2)

• Less than once a week (3)

• Not in last 3 months (4)

J29d. In the past 6 months, has Person nickname given you emotional help, such as listening or comforting you? / In the past six months, has this woman listened to you or comforted you if you were sad or worried?

• Yes (0)

• No (1)

J29e. In the past 6 months, has Person nickname given you information about migration, your rights, or how to handle stress?/ In the past six months, did this woman give you information about working abroad, your rights, or how to cope with stress?

• Yes (0)

• No (1)

J29f. Would you like to add another woman like this? You can add up to 3 women total./ Do you want to add another woman like this? You can add up to three. If “No” or if 3 contacts reached, go to Q12.

• Yes (0)

• No (1)

J29g. Of the women you listed, how many know each other well? / Of the women you listed, do any of them know each other well? Choose “none,” “a few,” or “all or almost all.”

• None of them (0)

• A few of them (1)

• All or almost all of them (2)

J30. Among people you feel close to, how many can you talk to if you feel sad, worried, or stressed about migration? / Of those you are close to, how many can you talk to about feeling sad or worried about migration?

• None (0)

• A few (1)

• About half (2)

• Most (3)

• All (4)

J31. Of people you feel close to, how many can you talk to about sexual or reproductive health? / Of those you trust, how many can you talk to about women’s health, such as sexual or reproductive health?

• None (0)

• A few (1)

• About half (2)

• Most (3)

• All (4)

J32. Do you know a woman in your home area who has returned from working abroad, and often helps or gives advice to others about migration? / Do you know a woman from your area of residence, who has come back from working abroad, and who others go to for advice about migration?

• Yes (1)

• No (0)

SECTION L: SOCIAL NETWORK QUESTIONS

L1. How many migrant domestic workers do you know personally who live in the middle east where you know their name and they know yours?

L2. How many of those migrant domestic workers whom you know personally have you had contact in the last month?

O4a. Now, thinking of these [number from previous question sn3] women whom you know and had contact:
a. How many of them are aged <25 years?
b. How many of them are aged 25 years or more?
c. How many of them had previous migration?
d. How many of them have lived three two or more years
d.How many of them have smart phone?
e. How many of them are family members?
f. How many of them are married?
g. How many of them are in the same country as your destination?
h. How many of them have completed high school?
i. How many do you think have motivated you to migrate?
j. How many do you think are from your woreda?
j. How many do you think you can seek support from?

SECTION C: FAMILY AND SOCIAL SUPPORT

C1. Which family members do you currently have?

- Parents alive (at least one) (0/1)
- Parents not alive (both) (0/1)
- Husband/partner (0/1)
- Children (0/1)

C2.With whom did you live most of the time before leaving?

- Parents (0)
- Husband/partner (1)
- Alone (2)
- With children (3)
- Relative (4)
- With employer/host (5)

C3. If you have been married/in relationship, how long (in years) have you been married?

• Numeric

C4. Who mainly cares for your children while you are abroad?

- Husband/partner (0)
- Parents (1)
- Other relatives (2)
- Friends/neighbors (3)
- Other (specify) (4)
- Not applicable (no children) (5)

C5. If you have been abroad before, how often do you communicate with your close family (parents, partner, or children) while abroad?

- Every day (0)
- Several times per week (1)
- Once a week (2)
- 1–3 times per month (3)
- Less than once a month (4)
- Never (5)

C6. How would you rate the emotional support you receive from your family (how much they listen, encourage, and comfort you)?

- Very Good (0)
- Good (1)
- Fair (2)
- Poor (3)
- Very Poor (4)

C7. Did you attend pre-departure training before your migration?

- Yes, 21-day training (new migrant) (0)
- Yes, 6-day training (returnee) (1)
- Other training (specify) (2)
- No training (3)

C8 Which topics you remember learning about?

- Domestic work skills (cleaning, cooking, childcare) (0/1)
- Rights as a worker (0/1)
- Contract and salary information (0/1)
- Language (Arabic or others) (0/1)
- Health and safety at work (0/1)
- Mental health and stress management (0/1)
- Sexual and reproductive health (0/1)
- Use of digital devices and internet (0/1)
- Other (specify) _____

Answer the following questions only if you have been abroad before

C9. Approximately how many Ethiopian women migrants did you regularly communicate with (at least once a month) you in the destination country?

- None (0)
- 1-4 (1)
- 5-9 (2)
- 10 or more (3)

C10. Did you participate in any migrant support or social group (online or in-person)?

- Yes, online group (0)
- Yes, in-person group (1)
- Yes, both (2)
- No (3

C11. If you re-migrate for a second or more rounds; what was/were your reason/s for re-migration?

- Disappointed by family who abused the money I sent for saving (0/1)
- No opportunity to do business here (0/1)
- I finished the money I brought (0/1)
- Stigma and discrimination (0/1)
- No or weak support system from the local administration (0/1)
- Instability and conflict in your locality (at home place) (0/1)
- Opportunities, services and facilities in the destination (0/1)

- If other, please specify (0/1) _____

C12. Do you think that the following factors contributed to your migration? Organise in the forms of C21

C13a. Unemployment (lack of job opportunities)

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31b. Family pressure

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31c. Peer pressure

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31d.Society expects you to migrate (migration is a culture in the community)

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31e.Corrupted or impartial system in the government

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31f. Reduction of land size in the locality

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31g. Hearing success stories of previous migrants

- Not a factor at all (0)

- Somehow a factor (1)
- Really a factor (2)

C31h. Unable to access education and low quality of education

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31i. Failing in your education

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31j. Death of family members/parents

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31k. Problems within your family (such as poverty, conflict and large family size)

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31l. Instability/conflict in your locality

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31m. Early/forced marriage

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31n. Being deceived by brokers

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31o. Government and NGOs offer opportunities to returnees than to jobless youths living here

- Not a factor at all (0)
- Somehow a factor (1)
- Really a factor (2)

C31p. If there were other factors contributing to your migration, please specify_____

- xxxxxxxxx

C14. Do you think that you had the following opportunities here in your home country before your migration?

- Have job (0/1)
- Have own business (0/1)
- Have access to education (0/1)
- Have supportive family (0/1)
- Have supportive local administration (0/1)
- Have supportive community environment (0/1)
- Have resources (land, money etc) (0/1)
- Other, please specify (0/1) _____

How much did you experience the following challenges during your stay abroad (at the destination)?

C33a. Difficulty to adjust to a different culture, religion and way of life

- Never (0)
- Rarely (1)
- Soemtimes (3)
- Always (2)

C33b. Difficulty to communicate due to language problem

- Not experienced at all (0)
- I experienced it some how (1)

• I experienced it very much (2)

C33c. Working for long hours for employers (labor exploitation)

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33d. Forced to work for others (parents, daughter, son or other relatives of employers)

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33e. Salary denial

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33f. Detention or imprisonment

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33g. Confiscation of your passport, documents or recorded address

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33h. Physical violence such as dragging, hitting, pushing, beating, slapping, punching, threatening with a weapon, burning, cutting with knife, etc.

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33hi. Verbal violence such as insults, belittling, constant humiliation, intimidation, threats of harm

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33j. Sexual violence (for females only) such as forced to have sex, had had sexual violence because of a fear if you were not complaint to it, forced to do something sexual that you found humiliating

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33k. Restricted freedom such as locked in a house or no access to family, agency or colleague, or never had been free to do what you wanted?

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33l. Faced physical or mental health problems

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33m. Denial of access to healthcare services

• Not experienced at all (0)

• I experienced it some how (1)

• I experienced it very much (2)

C33n. If there are others, please, specify

• xxxxxxxxxxxxxx

How often did you get the following opportunities during your stay abroad (at the destination)?/ Similar Choices /

C34a. Good treatment from employers

- Never (0)
- Rarely (1)
- Sometimes (2)

- Usually (3)
- Always (4)

C34b. Enough salary

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34c. Exposure to a different culture and way of life

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34d. Learning new skills

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34e. Developing better working habit

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34F. Supporting your family (sending remittance)

- Never (0)

- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34g. Saving money

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34h. Having better access to services and facilities (health, technology, shopping etc)

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34i. Developing strong sprit and endurance

- Never (0)
- Rarely (1)
- Sometimes (2)
- Usually (3)
- Always (4)

C34j. If there are other opportunities you got there, please, specify

- xxxxxxxxxxx

C35. What mode of transport did you use during your previous migration?

- By plane (0)
- By vehicle (1)
- On foot (2)

• By Boat (3)

• Mixed: (underline two or more that apply to you) Plane, Vehicle, Boat and on Foot (4)

C36. Did you experience the following challenges during your previous migration (while travelling)?

• Detention or imprisonment (0/1)

• Being stranded/Delay (0/1)

• Document Confiscation (0/1)

• Forced to give money as ransom (0/1)

• No infomration about job conditions (0/1)

• Traveling for long hours and for many days on foot (0/1)
• Caught by traffickers (for ransom, sexual abuse or labor exploitation) (0/1)

• Sleeping in the forest/desert (0/1)

• Hunger and thirst (0/1)

• Drown in the sea (0/1)

• Denial of access to travel by broker or guardian (0/1)

• Threatened by wild animals (0/1)

• Physical health problem such as injury, wound, etc., due to hazardous travel or accident (0/1)
• Physical violence such as dragging, hitting, pushing, beating, slapping, punching, threatening with a weapon, burning, cutting with knife, etc. (0/1)
• Verbal violence such as insults, belittling, constant humiliation, intimidation, threats of harm (0/1)
• Sexual violence such as forced to have sex, had had sex with broker because of fear of punishment if you were not complaint, forced to do something sexual that you found humiliating (0/1)
• Other, specify _____

Depression, Anxiety and Stress Scale (DASS-21)

Please read/ listen to the following statement and choose a number 0, 1, 2, 3 to indicate how much the statement applied to you over the past week.

D1. I found it hard to wind down.

• Did not apply to me at all (0)
• Applied to me to some degree, or some of the time (1)
• Applied to me to a considerable degree, or a good part of the time (2)
• Applied to me very much, or most of the time (3)

D2. I was aware of dryness of my mouth

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)

- Applied to me very much, or most of the time (3)

D3. I couldn't seem to experience any positive feeling at all.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D4. I experienced breathing difficulty (e.g. excessively rapid breathing, breathlessness in the absence of physical exertion).

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D5. I found it difficult to work up the initiative to do things.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D6. I tended to over-react to situations.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D7. I experienced trembling (e.g. in the hands).

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D8. I felt that I was using a lot of nervous energy.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D9. I was worried about situations in which I might panic and make a fool of myself.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D10. I felt that I had nothing to look forward to.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D11. I found myself getting agitated.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D12. I found it difficult to relax.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D13. I felt down-hearted and blue.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D14. I was intolerant of anything that kept me from getting on with what I was doing.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D15. I felt I was close to panic.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D16. I was unable to become enthusiastic about anything.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D17. I was unable to become enthusiastic about anything.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D18. I felt that I was rather touchy.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D19.I was aware of the action of my heart in the absence of physical exertion (e.g. sense of heart rate increase, heart missing a beat).

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D20. I felt scared without any good reason.

- Did not apply to me at all (0)
- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)

D21. I felt that life was meaningless.

- Did not apply to me at all (0)

- Applied to me to some degree, or some of the time (1)
- Applied to me to a considerable degree, or a good part of the time (2)
- Applied to me very much, or most of the time (3)
-

The standard WHO-5 Well-Being Index questions

Please think about the last two weeks. For each statement, choose the answer that best describes how you have felt. Response options for every item (0–5)

D22. I have felt cheerful and in good spirits.

- At no time (0)
- Some of the time (1)
- Less than half of the time (2)
- More than half of the time (3)
- Most of the time (4)
- All of the time (5)

D23. I have felt calm and relaxed.

- At no time (0)
- Some of the time (1)
- Less than half of the time (2)
- More than half of the time (3)
- Most of the time (4)
- All of the time (5)

D23. D24. I have felt active and vigorous.

- At no time (0)
- Some of the time (1)
- Less than half of the time (2)
- More than half of the time (3)
- Most of the time (4)
- All of the time (5)

D25. I woke up feeling fresh and rested.

- At no time (0)
- Some of the time (1)
- Less than half of the time (2)
- More than half of the time (3)
- Most of the time (4)
- All of the time (5)

D26. My daily life has been filled with things that interest me

- At no time (0)
- Some of the time (1)
- Less than half of the time (2)
- More than half of the time (3)

- Most of the time (4)
- All of the time (5)

SECTION E: EQ-5D -5L– QUALITY OF LIFE

Please indicate which statement best describes your health status today

E1. Do you have problems in walking about?

I have no problems in walking about (1)
2. I have slight problems in walking about (2)
3. I have moderate problems in walking about (3)
4. I have severe problems in walking about (4)
5. I am unable to walk about (5)

E2. Do you have problems in self-care?

1. I have no problems washing or dressing myself (1)
2. I have slight problems washing or dressing myself (2)
3. I have moderate problems washing or dressing myself (3)
4. I have severe problems washing or dressing myself (4)
5. I am unable to wash or dress myself (5)

E3. Do you have problems performing usual activities (e.g., work, study, housework, family or leisure activities)?

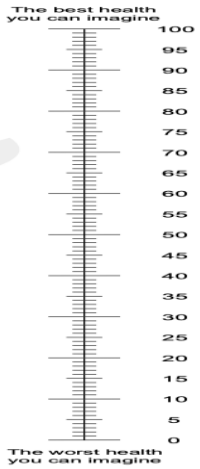
1. I have no problems doing my usual activities (1)
2. I have slight problems doing my usual activities (2)
3. I have moderate problems doing my usual activities (3)
4. I have severe problems doing my usual activities (4)
5. I am unable to do my usual activities (5)

E4. Do you have pain/discomfort?
1. I have no pain or discomfort (1)
2. I have slight pain or discomfort (2)
3. I have moderate pain or discomfort (3)
4. I have severe pain or discomfort (4)
5. I have extreme pain or discomfort (5)

E5. Do you have anxiety/depression?
1. I have no anxiety or depression (1)
2. I have slight anxiety or depression (2)
3. I have moderate anxiety or depression (3)
4. I have severe anxiety or depression (4)
5. I have extreme anxiety or depression (5)

E6. We would like to know how good or bad your health is TODAY. This scale is numbered from 0 to 100. 100 means the best health you can imagine. 0 means the worst health you can imagine. Mark an X on the scale

to indicate how your health is TODAY. Now, please write the number you marked on the scale in the box below



Section I - WORK RELATED STIGMA AND DISCRIMINATION

I1. Because of my work as a domestic worker (in ethiopia or aborad), I have lost respect or standing in the community.

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)
- I don't know (888)

I2. Because of my work as a domestic worker, I think less of myself.

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)
- I don't know (888)

I3. Because of my work as a domestic worker, I have felt ashamed.

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)
- I don't know (888)

I4. Because of my work as a domestic worker, people have talked badly about me.

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)

- I don’t know (888)

I5. Because of my work as a domestic worker I have been verbally insulted, harassed, and/or threatened

- Never (0)
- Once (1)
- A few times (2)
- Often (3)
- I don't know (888)

I6. I confronted, challenged, or educated someone who was stigmatising and/or discriminating against me.

- Never (0)
- Once (1)
- A few times (2)
- Often (3)
- I don't know (888)

I7. My interactions with close friends have not changed since I’ve decided to travel for doemstic work.

- Strongly agree (1)
- Agree (2)
- Disagree (3)
- Strongly disagree (4)
- I don’t know (888)

SECTION K: SUBSTANCE USE DISORDER

K1. How often do you chew chat?

(0) Never (Skip to Questions XXX)
(1) Monthly or less
(2) 2 to 4 times a month
(3) 2 to 3 times a week
(4) 4 or more times a week

K2. How often do you us shisha?

(0) Never (Skip to Questions XXX)
(1) Monthly or less
(2) 2 to 4 times a month
(3) 2 to 3 times a week
(4) 4 or more times a week

SECTION G: SRH KNOWLEDGE

The next few questions ask you to think about your sexual and reproductive knowledge

G1. Can a woman become pregnant if she has sexual intercourse only one time, without protection?

- Yes (1)

- No (0)
- Not sure (888)

G2. Have you ever heard of infections that can be passed from one person to another during sex (sexually transmitted infections)?

- Yes (1)
- No (0)
- Not sure (888)

G3. Can a healthy-looking person have HIV or another sexually transmitted infection?

- Yes (0)
- No (1)
- Don't know (2)

G4. Have you ever been tested for HIV?

- Yes (0)
- No (1)
- Not sure (888)

G5. Which of these can protect against both pregnancy and sexually transmitted infections (STIs) if used correctly?

- Condom (0/1)
- Pills (0/1)
- Injection (0/1)
- Withdrawal ('pulling out') (0/1)
- Traditional herbs or drinks (0/1)
- Don't know (888)

G6. Do you know that using condoms correctly every time you have sex can reduce the chance of getting HIV?

- Yes (0)
- No (1)
- I am not sure (2)
- Don't know (3)

G7. If a condom breaks during sex, is there any contraception a woman can take within a few days to reduce the chance of pregnancy?

- Yes (1)
- No (0)
- Don't know (2)

G8. Where you come from, do you know any place in your home area where you can get contraception or family planning services?

- Yes(0)
- No (1)
- Donot know (2)

G9. Is it true that a woman cannot get pregnant if she has sex during her monthly bleeding (period)?

• True (0)
• False (1)
• Donot know (2)

G10. When does a women most likely pregnant during the monthly period?

• During menstration (0)
• The first week after menstration (1)
• The second week after menstration (2) •
A week before menstration (3)
• Donot know (4)

G11. Which contraceptive methods have you heard of?

• Male condom (0/1)
• Birth control pills (0/1)
• Injectable (0/1)
• Implant (0/1)
• IUD (loop) (0/1)
• Emergency contraception (0/1)
• Traditional methods (withdrawal, calendar, herbs, etc.)(0/1)
• Other (specify) (0/1) _____

• Don't know (888)

G12. modern family planning methods like pills, injections, or implants usually make a woman permanently unable to have children in the future?

• Yes (0)
• No (1)
• Donot know (2)

G13. In the country where you are going for work, do you think migrant workers have the right to get care for sexual and reproductive health problems (for example, contraception, STI treatment, pregnancy care)?

• Yes (0)
• No (1)
• I am not sure (2)

• Donot know (3)

G14. If you want to avoid pregnancy while you are abroad, how confident are you that you can do so?

• Very confident (0)
• Somewhat confident (1)
• Not confident (2)

• Not at all confident (3)
• Not sure (4)

G15. If you go to a health facility for contraception or STI treatment in the area where you come from, do you think the health workers should keep your information confidential and not tell you to employer or broker or family without your permission?

• Yes (0)
• No (1)
• I am not sure (2)
• Donot know (3)

SECTION F: SRH Outcomes

The next few questions ask you about sexual and reproductive health- all information will be kept confidential /

F1. Have you ever had sexual intercourse (sex)?

• Yes (1)

• No (0)

• Prefer not to say (888)

F2. How old were you when you first had sexual intercourse?

• 12 years or younger (0)

• 13–15 years (1)

• 16–17 years (2)

• 18–19 years (3)

• 20 years or older (4)

• I donot remember (5)

• Prefer not to say (888)

F3. In the last 12 months, have you had sexual intercourse with anyone?

• Yes (1)

• No (0)

• Prefer not to say (888)

F4. In the last 12 months, with how many different men have you had sexual intercourse with?

• None (0)

- One (1)
- Two (2)
- Three or more (3)
- Prefer not to say (888)

F5. Have you ever been pregnant?

- Yes (1)
- No (0)
- Not sure (2)

F6. How old were you at your frist pregnancy?

- 12 years or younger (0)
- 13–15 years (1)
- 16–17 years (2)
- 18–19 years (3)
- 20 years or older (4)
- I donot remember (5)
- Prefer not to say (888)

F7. Have you ever used anything to delay or avoid getting pregnant?

- Yes (1)
- No (0)

F8. How many times have you been pregnant, including miscarriages and abortions?

- Number pad

F9. At the time of your most recent pregnancy, did you want to become pregnant then, later, or not at all?

- Wanted to be pregnant then (0)
- Wanted to be pregnant later (1)
- Did not want to be pregnant at all (2)
- Prefer not to say (888)

F10. What was the outcome of your most recent pregnancy?

- Live birth (baby born alive and survived) (0)

- Baby born alive but died later (1)
- Miscarriage (lost the pregnancy naturally) (2)
- Induced abortion (pregnancy ended on purpose with medicines or procedure) (3)
- Stillbirth (baby born dead after about 7 months of pregnancy or more) (4)
- Prefer not to say (888)

F11. Have you ever had an induced abortion?

- Yes (1)
- No (0)

F12. Where was the abortion care obtained?

- Health facility (1)
- Pharmacy (0)
- Traditional provider (888)

F13. Would you like to have (a/another) child?

- Yes (1)
- No (0)
- Not sure (888)

F14. Have you ever experienced an unintended pregnancy?

- Yes (1)
- No (0)

F15. Do you plan to use any method to avoid pregnancy while you are abroad?

- Yes, I plan to use a method (0)
- No, I do not plan to use a method (1)
- I am not sure yet (2)
- Prefer not to answer (3)

F16. In the last 3 months, have you used any method to prevent pregnancy?

- No (0)
- Yes, always (1)
- Yes, sometimes (2)

• No sex in the last three months (3)

F17. Which method/s have you used in the last 3 months to prevent pregnancy? (You may choose more than one)

• Male Condom: (Men can put a rubber sheath on their penis before sexual intercourse) (0/1)

• Female Condom: (Women can place a sheath in their vagina before sexual intercourse) (0/1)

• IUCD: (Women can have a loop or coil placed inside them by a doctor or a nurse which can prevent pregnancy for one or more years) (0/1)

• Injectables: (Women can have an injection by a health provider that stops them from becoming pregnant for one or more months) (0/1)

• Implants: (Women can have one or more small rods placed in their upper arm by a doctor or nurse which can prevent pregnancy for one or more years) (0/1)

• Pill: (Women can take a pill every day to avoid becoming pregnant) (0/1)

• Emergency Contraception (Morning-after pill, an emergency measure, within three days after they have unprotected sexual intercourse, women can take special pills to prevent pregnancy) (0/1)

• Lactational Amenorrhea Method (LAM): (Up to six months after childbirth, before the menstrual period has returned, women use a method requiring frequent breastfeeding day and night) (0/1)

• Withdrawal: (Men can be careful and pull out before climax) (0/1)

• Other modern methods (0/1), including male/female sterilization (0/1)

• Other traditional methods(0/1)

F18. Have you ever taken a morning after pill?
The morning after pill is a pill women can take after sex has occurred to prevent a pregnancy

• Yes (1)

• No (0)

F19. Do you know where you could get contraception or family planning methods if you need them in the area where you come from?

• No (0)

• Yes (1)

• I am not sure (2)

• Prefer not to say (888)

F20. Have you ever received information bout sexual and reproductive health information, in the area where you come from

- No (0)
- Yes (1)
- I am not sure (2)

F21. In the last 12 months, have you ever discussed contraception OR family planning with a health staff?

- No, I didnot (0)
- Yes, I did, and we discussed contraception/family planning (1)
- Prefer not to say(2)

F22. In the last 3 months, was there any time when you wanted to avoid pregnancy, but you were not using any method to prevent pregnancy?

- No (0)
- Yes, always (1)
- I did not have sex in the last 3 months (2)
- Prefer not to say (888)

F23. What was the reason that you did not use any method to prevent pregnancy at the last time you were pregnant?

- I was worried about side effects or health problems (0/1)
- I wated to be preganant (0/1)
- My husband/partner did not want me to use a method (0/1)
- I was afraid my employer, broker, or others would find out (0/1)
- I did not know where to get methods (0/1)
- Methods were too expensive or difficult to get (0/1)
- My religion or beliefs do not allow it (0/1)
- My culture or tradition do not allow it (0/1)
- I did not think I could get pregnant (0/1)
- Other reason, specify _____
- Prefer not to say (888)

F24. When you think about using any method to prevent pregnancy, who decides?

- Mostly me (0/1)
- Mostly my husband/partner (0/1)

• My husband and me decide jointly (0/1)

• Someone else (for example, broker, employer, family) (0/1)

• Prefer not to say (888)

F25. Does your husband or regular partner support the use of contraception to prevent pregnancy?

• No, he is against it (0)

• Yes, he supports it (1)

• He does not care either way (2)

• I do not have a husband or regular partner (3)

• Prefer not to say (888)

Answer the following Questions if you have travelled to the middle East before

F26. Have you ever had sexual intercourse, while abroad?

• Yes (1)

• No (0)

• Prefer Not To Say (2)

F27. Have you had unconsented sexual intercourse while abroad?

• Yes, I was pressured (1)

• Yes, I was forced (1)

• No (0)

• Prefer Not To Say (2)

F28. Have you been pregrant, while abraod?

• Yes (1)

• No (0)

F29. When you were working abroad, was there any time when you want to avaoid pregnancy, but you were not using any method to prevent pregnancy?

• No (0)

• Yes (1)

• I did not have sex while abroad (2)

• Prefer not to say (888)

F30. What was the main reason you did not use any method to prevent pregnancy?

- I was worried about side effects or health problems (0/1)
- I wanted to be pregnant (0/1)
- My husband/partner did not want me to use a method (0/1)
- I was afraid my employer, broker, or others would find out (0/1)
- I did not know where to get methods (0/1)
- Methods were too expensive or difficult to get (0/1)
- My religion or beliefs do not allow it (0/1)
- My culture or tradition do not allow it (0/1)
- I did not think I could get pregnant (0/1)
- Other reason, specify _____
- Prefer not to say (888)

F31. Did you know where you could get contraception or family planning methods if you needed them while abroad?

- No (0)
- Yes (1)
- I am not sure (2)
- Prefer not to say (888)

F32. Were you worried that your employer, agent, or other people would find out that you are using contraception while you were abroad?

- No (0)
- Yes, a little worried (1)
- Yes, very worried (2)
- Prefer not to say (888)

F33. Were you able to accessed any contraception when you need them while you were abroad?

- No (0)
- Yes (1)

SECTION H: SEXUAL AND GENDER BASED VIOLENCE AND ACCESS TO SERVICES

Now let's talk about violence and access to services

H1. Have you ever had a verbal violence such as insults, belittling, constant humiliation, intimidation, threats of harm

• No (0)

• Yes (1)

H2. Have you ever had a husband/partner hit, slap, kick, push, shove or otherwise physically hurt you?

• No (0)

• Yes (1)

H3. Have you ever had a broker/ agency/ employer hit, slap, kick, push, shove or otherwise physically hurt you?

• No (0)

• Yes (1)

H4. In the past three months, how many times has this happened to you?

• It hasn't happened to me (0)

• Once (1)

• Twice (2)

• Three times (3)

• Four times (4)

• 5 or more times (5)

H5. Did you ever tell anyone about this?

• Yes (1)

• No (0)

H6. If yes, whom did you tell?

• Police (0/1)

• Neighbor (0/1)

• Friend (0/1)

• Family member (0/1)

• Traditional leader/court (0/1)

• Religious leader(s) (0/1)

• Other _____ (0/1)

H7. Has anyone ever forced you to have sex?

• Yes (1)

• No (0)

H8. Did you ever tell anyone about this unwanted sexual experience?

• Yes (1)

•No (0)

H9. If yes, whom did you tell?

• Police (0/1)

• Neighbor (0/1)

• Friend (0/1)

• Family member (0/1)

• Traditional leader/court (0/1)

• Religious leader(s) (0/1)

• Other _____ (0/1)

H10. After the unwanted sexual experience, did you seek any healthcare services to protect yourself against HIV or other infections or pregnancy?

• Yes (1)

• No (0)

H11. If yes, where did you access these healthcare services?

• Health post/center (0/1)

• Family Planning Clinic, such as Merystops (0/1)

• Private Clinic (0/1)

• Government Hospital (0/1)

• Private Hospital (0/1)

• Other (0/1)

H12. With what kind of person did this happen?

• Husband/long term boyfriend/partner (0/1)

• Broker/Agency worker (0/1)

• Employer (0/1)

• Family member (0/1)
•Other/Unknown (0/1)

ANNEX 17: INNOVETH BUDGET OVERVIEW

INNOVETH Budget Overview

Budget category	Amount (EUR)
Staff	804,032.00
Equipment	14,417.00
Training & CPD	7,500.00
Materials and consumables	4,000.00
Access charges	9,897.00
Travel and subsistence	163,500.00
Public engagement and patient involvement	22,000.00
Fieldwork expenses	301,650.00
Overheads	118,765.00
Other	54,000
Grand Total	**1,499, 761**