ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCES
SCHOOL OF PUBLIC HEALTH

Title: Effectiveness and Implementation Determinants of the DINKNESH App Compared to Paper-Based Assessment Tools for Palliative Care: A Mixed-Methods Cluster Randomized Trial in Addis Ababa, Ethiopia

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MASTER OF PUBLIC HEALTH
RESEARCH PROJECT SUBMISSION FORM

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Full Title of the Research Project	**Effectiveness and Implementation Determinants of the DINKNESH App Compared to Paper-Based Assessment Tools for Palliative Care: A Mixed-Methods Cluster Randomized Trial in Addis Ababa, Ethiopia**
Duration of Project	**8 months (November 2025-June 2026)**
Study Area	**Addis Ababa, Ethiopia**
Total Cost of the Project	**232,760 ETB**
Source of Budget	**DINKNESH Project**
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1. Summary

Background: Although the National Palliative Care Strategic Plan in Ethiopia supports the integration of palliative care into primary health care, delivery of palliative care at the primary care level remains low. Routine identification of patients with palliative needs is largely based on unstructured clinical judgment. There is limited empirical evidence from Ethiopian primary care settings evaluating whether structured digital tools can improve systematic patient identification.

Objective: The primary objective of this study is to evaluate the comparative effectiveness of the DINKNESH App in increasing the rate of identification of patients requiring palliative care, compared with paper based care. The secondary objective is to explore the implementation determinants (enablers and barriers).

Methods: In this study, a mixed method cluster randomized trial will be used. The trial will be over a 6 weeks comparison period involving 12 randomly selected primary healthcare clusters in Addis Ababa. 6 Clusters will get the intervention (DINKINESH App), and the other 6 will be using paper based. The main outcome is the identification rate of patients needing palliative care. Quantitative data will be extracted from DINKNESH App logs in the intervention arm and standardized paper-based records in the control arm. Models with adjustment for clustering will be used to compare identification rates between study arms. Findings from quantitative analyses will be triangulated with qualitative insights from healthcare workers to contextualize observed differences in identification and to explain how and why the DINKNESH App influenced care practices.

Expected Outcome: The study will determine whether the use of DINKNESH App increases palliative care identification rates in primary care and provide qualitative insights into implementation barriers.

Work Plan and Estimated Budget: The total intervention and data collection is for 6 weeks from April to May 2026 followed by analysis and report submission by June 2026. The total budget estimate for the research is 232,760 ETB. Funding mainly comes from the DINKNESH Project .

2.Introduction

2.1 Background

Palliative care is an approach that improves the quality of life of patients and their families who are facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and correct assessment and treatment of pain and other problems, whether physical, psychosocial or spiritual [1]. In low and middle income countries, traditional palliative care models are often centralized in tertiary settings creating a significant equity gap. The WHO highlights the need of adopting decentralized primary palliative care models. These models use the task shifting concept where basic palliative care responsibilities like systematic identification and symptom management are shifted from specialists to primary health care workers and community health teams to overcome the workforce and geographic barriers[2,3].

Globally, the need for palliative care is increasing, driven by the growing burden of non-communicable diseases, chronic infectious conditions, and improved survival with advanced illness. Sub-Saharan Africa is experiencing a particularly rapid rise in palliative care needs due to increasing cardiovascular disease, cancer, chronic respiratory disease, and HIV, with most patients receiving ongoing care within primary health care settings [1,3]. In Ethiopia, the expanding burden of chronic disease has heightened the importance of early identification and timely management of palliative care needs within routine primary care, where most patients first present and are followed longitudinally [1,4].

In line with this, the Federal Ministry of Health of Ethiopia published the comprehensive National Palliative Care Strategic Plan (2025–2029) [4]. This policy explicitly calls for the integration of palliative care into primary health care and the use of community health workers as key providers of basic palliative services. In Ethiopia, this is important as most palliative care services are concentrated more in specialized tertiary settings creating a significant gap even for the urban population[5].

Despite this policy direction, routine primary care practice faces implementation

challenges. Systematic identification of patients requiring palliative care remains low, with care processes often described as fragmented and reliant on unstructured clinical judgment rather than standardized assessment approaches[3]. The WHO recommends the use of digital decision support systems to assist health workers in strengthening clinical decision making[7]. In this context, integrating digital application like DINKNESH App into primary care workflow offers a targeted approach to supporting more systematic identification of patients with palliative care needs within routine primary care.

2.2.Statement of the Problem

Palliative care identification remains low in primary healthcare settings across Addis Ababa as evidenced by routine service reports from the Addis Ababa Health Bureau [8]. Currently, palliative care is primarily delivered through family health teams operating from health centers, with scheduled home visits conducted. During these encounters, routine standard care lacks formalized, standardized identification protocol for palliative care and instead relies largely on subjective clinical judgment and memory-based decision making[3,4]. This results in inconsistent identification of patients with palliative care needs.

The implications of under identification is substantial. Globally, a large proportion of individuals who could benefit from palliative care do not receive it, leading to unmanaged symptoms, reduced quality of life, caregiver burden, and increased use of acute health services [1,9]. This gap is most pronounced in low and middle income countries. In sub Saharan Africa and Ethiopia specifically, the rapid rise in non communicable diseases alongside persistent communicable diseases has substantially increased the population living with serious health-related suffering, intensifying the demand for early identification within primary care systems [1,9].

Qualitative studies from Ethiopia and similar settings indicate that primary healthcare workers often feel overburdened and insufficiently trained to systematically assess

palliative care needs, particularly in the absence of standardized tools integrated into routine workflows [3,6].

Digital decision support tools have been proposed as a means of improving knowledge and reducing subjectivity in clinical decision making. The DINKNESH App was developed to address this procedural gap by digitizing validated tools, including the Supportive and Palliative Care Indicators Tool (SPICT) for patient identification, the Integrated Palliative care Outcome Scale (IPOS) for symptom assessment decision support tools for symptom and management . A pilot usability assessment among health center healthcare workers was conducted and demonstrated acceptable feasibility and usability of the application. However, without a controlled comparison against routine non-standardized care, it remains unclear whether the use of a digital tool meaningfully improves identification rates or adherence to palliative care protocols.

Generating comparative evidence is important to justify adoption and potential scaleup of digital palliative care tools. The WHO Global Strategy on Digital Health also emphasizes that effectiveness, implementation feasibility, and contextual fit must be demonstrated beyond pilot studies where challenges such as connectivity limitations, usability barriers, and variable technological self-efficacy among healthcare workers may affect real world performance [7,10].

2.3. Rationale and Significance

2.3.1. Policy Significance

This study directly reinforces the national strategic plan for the delivery of palliative care within primary health centers by providing health-care workers with a practical, structured tool to identify patients with palliative care needs during routine care. By supporting systematic identification at the primary care level, the intervention enables earlier recognition of palliative needs and more consistent use of validated assessment tools, thereby reinforcing and strengthening the integration of palliative care into everyday primary health-care practice[9].

2.3.2. Clinical and Practice Significance

The study findings have direct and immediate implications for patient care and family health teams performance in Addis Ababa and similar urban primary care settings. Health care workers will be supported to systematically identify patients with palliative care needs and apply validated tools such as the SPICT and IPOS more consistently in everyday practice[3].This reduces the risk of clinician overwhelm. In addition, information from the workflow assessment provides feedback directly to the DINKNESH team, allowing improvement of the App to ensure optimal appropriate integration into our healthcare environment.

2.3.3. Methodological and Academic Significance

The findings will strengthen the evidence base on whether structured digital tools meaningfully improve identification of palliative care needs at the primary care level and inform future implementation research and evaluation in similar health system context. By using a CRCT, the study provides a rigorous comparison between a structured digital identification approach and routine standard care under real world primary healthcare conditions.

3. Literature Review

Digital tools are an important way to improve the efficiency and quality of palliative care services.This literature review synthesizes current evidence to frame the DINKNESH App intervention, focusing on comparing its systematic approach to current practice and identifying the barriers needed to ensure its long term success in Ethiopia. The review draws on global, regional and local evidences to describe existing primary palliative care delivery, implementation gaps, and the role of structured digital decision support tools in strengthening routine care processes.

Palliative care by the WHO is a comprehensive approach aimed to improve quality of life for patients and their families facing life threatening illness [1,3]. The new present model for palliative care states need of integration early in the course of chronic illness unlike the traditional service delivery of specialized end-of-life approach and shifts it towards primary palliative care[2,3]. Primary palliative care requires task shifting and relying on non specialist health care workers to perform initial systematic screening and referral as depending on specialized services alone won't meet the massive global need [3].

While Ethiopia's National Palliative Care Strategic Plan provides the official mandate for integrated primary Palliative Care, an implementation gap exists. Inconsistency in LMIC palliative care is specifically characterized by the failure to initiate a needed clinical assessment or intervention despite patient eligibility [8] and a lack of adherence to the standardized protocol[11]. Evidence suggests that without standardized protocols, healthcare workers rely on ad hoc, memory based identification, which results in fragmented documentation and missed opportunities for care. The App addresses this primary process deficiency by replacing subjective judgment with an evidence based digital tool they can use when coming in contact with chronic disease patients with potential need of palliative care [3, 6].

Magnitude and Global/Regional Distribution

The unmet palliative care scale is significant. According to the WHO, an estimated 56 million people worldwide require palliative care annually, yet only about 14% of those in need currently receive it, with the largest unmet burden being in low and middle income countries [1]. The rising prevalence of non-communicable diseases, particularly cancer, is rapidly accelerating the demand for palliative care in Sub Saharan Africa [5][13]. This trend confirms that addressing palliative care is no longer just a clinical issue but a very important public health issue that requires decentralized models.

Local Context and Policy Mandate

The problem is indeed felt in Ethiopia, where specialized palliative care services are mostly concentrated in tertiary settings in urban places like Addis Ababa which creates a massive challenge in achieving equitable access for the wider whole population [4]. This uneven distribution shows that current service delivery is inequitable. The National Palliative Care Strategic Plan provides the official mandate for integrating palliative care into primary care settings and leveraging existing community cadres[5]. By operationalizing this policy direction through a structured digital identification tool, the DINKNESH App directly supports national goals for health system strengthening and decentralization[5].

Causes, Risk Factors, and Determinants of Systemic Failure

The process under routine standard care is fragmented. Documentation relies on ad hoc and inadequate paper based records, which fail to enforce systematic patient assessment, thereby limiting coverage and data quality [5]. Furthermore, global strategies on digital health emphasize that implementation success depends on addressing organizational readiness, which includes overcoming persistent infrastructure deficits, such as unreliable

network connectivity, and providing adequate management support [14]. These systemic vulnerabilities create high organizational risk for any new intervention.

Individual factors pose direct risks to implementation fidelity. Studies confirm that HCW level barriers include insufficient training and confidence in complex tasks like pain management [12], high perceived workload, and, critically, low technological self-efficacy (confidence in using the App). Without addressing these individual determinants, the App risks being abandoned. The risk is that the new systematic approach may simply be perceived as an additional burden, thereby sabotaging the intervention's intent [14].

Effectiveness of mHealth as a Systematic Protocol

The DINKNESH App is designed to function as a logic gate helping healthcare workers to use the systematic process for delivering palliative care. This strategy is supported by literature showing that mHealth interventions significantly improve process outcomes in Sub saharan Africa. Reviews demonstrate increased documentation, timely follow-up, and patient tracking fidelity across various health programs [12,15]. By guiding the health care worker through the screening tools (SPICT/ECOG) and action documentation, the App is hypothesized to boost the service delivery rate, providing the necessary evidence of comparative efficacy [16].

Methodological Rigor and CRCT Justification

To rigorously evaluate the comparative effectiveness of the DINKNESH App under real world primary healthcare conditions, a cluster randomized controlled trial (CRCT) design was chosen. CRCTs are particularly appropriate for interventions delivered at the facility or team level, where individual randomization is neither feasible nor methodologically sound due to the high risk of contamination between providers operating within the same health facility[22]. In this study, family health teams within primary healthcare clusters

function as the unit of intervention delivery, making cluster level randomization essential to preserve internal validity.

The CRCT framework also strengthens external validity by evaluating effectiveness under pragmatic implementation conditions rather than artificial experimental settings[17,20]. This is particularly important in low resource primary care contexts like ours, where system-level constraints, workload variation, and team dynamics substantially influence intervention performance. Accordingly, this design permits appropriate statistical handling of correlated observations within clusters, ensuring valid inference for the rate-based primary outcome[22,23].

4. Conceptual Framework

4.1. Narrative Description

The conceptual framework for this study is adapted from the Logic Model approach, showing the input up to the anticipated outcomes, while also taking into account the contextual factors that influence implementation[21].

A determinant part is added from the consolidated framework for implementation research [20]. In the determinant part, we try to see the contextual factors that currently influence palliative care delivery that will be covered by the qualitative part. First is the inner setting (Facility factors) that includes the structural environment of the health center, where we hypothesize that infrastructure challenges, such as internet reliability, and workload pressure may act as barriers. The second is the characteristics of individuals (HCW Factors) that focuses on the characteristics of the users themselves, specifically looking into how the HCWs' technological self-efficacy and baseline palliative care knowledge affect their adoption of the tool. Finally it's the outer setting (External environment) that provides the background context with the existing national guidelines that the App aims to reinforce..

When we look at the input, it includes the DINKNESH App, and a comprehensive healthcare training for both technical usage and basic palliative care assessment tools. These resources are supported by weekly supervision. The essential research setup includes 12 healthcare clusters and 6 weeks of the intervention.

The second in line in the Logic Model is the activities and these are the clinical intervention activities which is deployment of the App in 6 intervention clusters with training and support over 6 weeks period, and research evaluation activities which is a Cluster Randomized

Controlled Trial comparing intervention and control clusters, with systematic data collection (App logs, paper forms) and qualitative process evaluation through focus group discussions and in depth interviews.

Then is the activities that bring about immediate, measurable outputs that include rates of patient identification with palliative care need and clinical action documentation from both intervention and control arms, transcribed discussions of HCW implementation experience and comparative outputs showing statistical differences between intervention and control clusters.

These outputs lead to three categories of outcomes which are the short-term outcomes that include a proven increase in systematic patient identification rates and documented clinical action, medium-term outcomes which include detailed insights into implementation factors including barriers/enablers and long-term outcomes which is Policy recommendations for national integration of the DINKNESH App within Ethiopia's primary healthcare system.

4.2. Diagrammatic Presentation

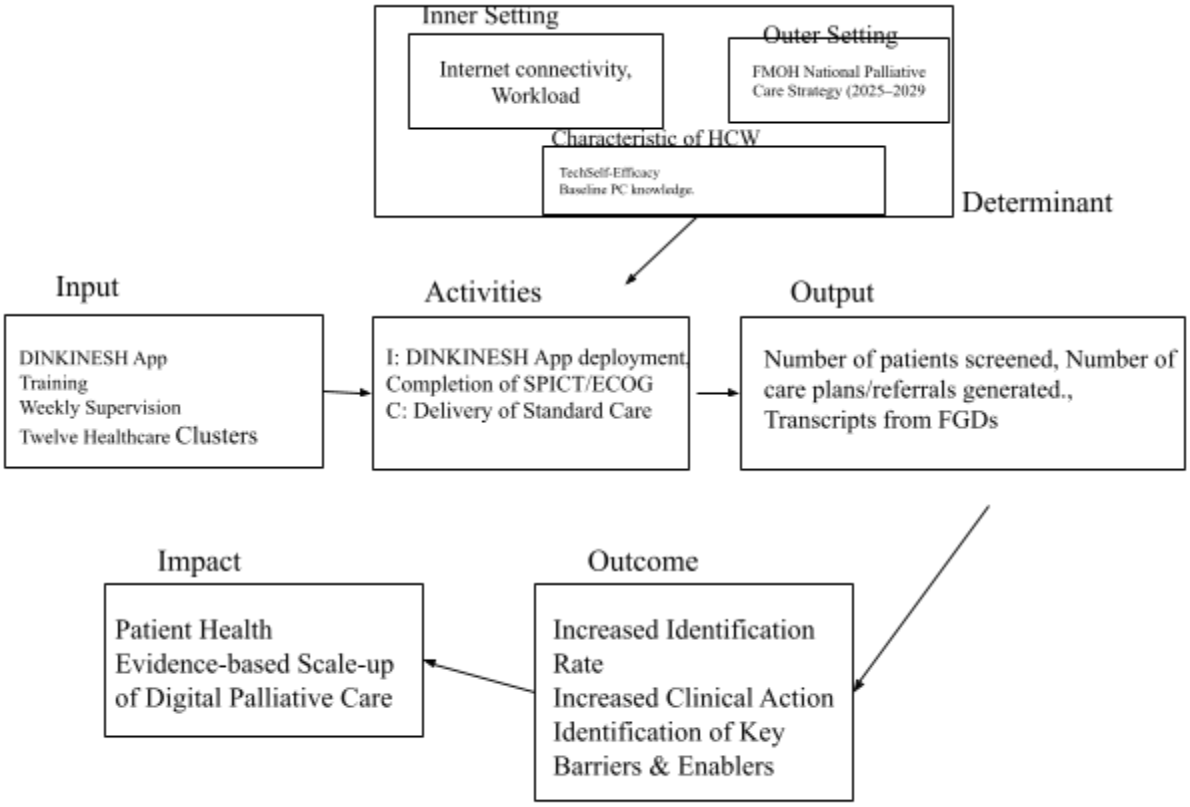

Diagram 1: Conceptual Framework from Logic Model Approach and some adaptation of CFIR

5.Objectives

5.1. General Objective

● To evaluate the effectiveness of the DINKNESH App in improving palliative care patient identification and to explore determinants of its implementation among family health teams' health extension workers in primary healthcare clusters of Addis Ababa, Ethiopia.

5.2. Specific Objective

● (Primary) To compare the rate of palliative care identification among patients with chronic conditions between intervention clusters utilizing the DINKNESH App and control clusters utilizing standard paper-based documentation over the study period.

●(Secondary) To explore the real-world determinants of implementation specifically the barriers and facilitators affecting the adoption, utilization, and integration of the DINKNESH App

6. Methods

6.1. Study Setting

The study will be conducted in Addis Ababa, Ethiopia, targeting primary healthcare facilities within the city's administration. The sampling frame for this study consists of the 95 health centers currently reporting functional palliative care service delivery out of the 101 total health centers in the city. From this pool, 12 eligible health centers are selected to serve as the study clusters.

The research will leverage the existing Family Health Team (FHT) structure attached to these health centers. These teams are officially mandated to conduct systematic home-based visits within their respective catchment areas to provide a range of community-based health services.

6.2. Study Design

The primary aim is to assess the comparative rate of identification of patients with palliative care needs using DINKNESH App via a Cluster Randomized Controlled Trial , while concurrently gathering data on implementation determinants to inform future scale up .

It will use a mixed-methods cluster randomized controlled trial with two parallel arms, which are Intervention and Control. The CRCT design helps to minimize contamination. It will be a pragmatic CRCT with a 6 weeks intervention period. As the primary outcome is the process of care measure, changes are expected to be observed early following implementation.

To isolate the specific effect of the intervention from the effect of general education, Health Care Workers in both arms will receive an initial, brief baseline training session on standardized palliative care assessment. Following this training, the intervention group will proceed to use the DINKNESH application and the control paper based for the 6

weeks intervention period. Consequently, the study will measure and compare the rate of patient identification.

The qualitative component will use a post intervention exploratory design based on Focus Group Discussions with healthcare workers to understand experiences, challenges, and enablers of integrating the App into routine palliative care.

6.3. Source and Study Population

6.3.1. Source Population

Quantitative arm:

- All adult patients receiving home-based primary health services within the catchment areas of the 95 eligible health centers in Addis Ababa during the study period.

Qualitative arm:

- All healthcare providers(part of the family care team) involved at the household visits under the participating facilities

6.3.2. Study Population

Quantitative arm:

- Adult patients with chronic illnesses who are encountered by HCWs under the family health team during the active comparison period in facilities randomized to either the Intervention or Control group, and who meet the inclusion criteria.

Qualitative arm:

Health care workers:

○ Health care workers who directly engaged in palliative care patient identification and who are also available for FGDs

Inclusion Criteria

●For patients(Quantitative Part):

○ Adults aged 18 years or older

○ Currently diagnosed with one or more chronic conditions and receiving home-based follow-up care from a participating Family Health Team within the catchment area of a selected study cluster

○ Willing to provide verbal informed consent, or has a primary caregiver willing to provide proxy consent

● For healthcare workers:

○ Staff members of the Family Health Team at the selected clusters

○ Involved in delivering or supervising palliative care services during the study period

○ For the qualitative part: Participated in the DINKNESH App implementation process and is willing to participate in a Focus Group Discussion (FGD)

Exclusion Criteria

● For patients

○ Patients whose clinical condition prevents both self-participation and proxy participation in the assessment process

○ Patients already formally identified and referred for palliative care prior to the study period

● For healthcare workers:

○ Staff members planning to be absent for more than 1 day during the six-week active study period

○ Healthworker not present during the training session

6.4. Sample Size Determination

The sample size for this cluster randomized trial is determined using standard approaches for cluster-randomized trials with proportion (binary) outcomes, aligned with Hayes and Bennett (1999). This study specifically screens individuals with known chronic conditions, the primary endpoint is evaluated as the proportion of chronic patients identified as requiring palliative care.

The calculation is based on estimating the difference in identification proportions between the intervention and control arms. Based on literature, we estimate the baseline identification proportion of palliative care needs among chronic patients in routine care P1 to be 5% (0.05). We hypothesize that the DINKNESH App will increase systematic identification by a factor of 3, resulting in an expected proportion (P2) of 15% (0.15) in the intervention arm.

To detect this difference with 85% power ($Z_{1-\beta} = 1.04$) and a 5% significance level ($Z_{1-\alpha/2} = 1.96$), we calculated the unadjusted sample size and then applied a Design Effect (DE) to account for facility-level clustering. We estimated an ICC of 0.03, supported by methodological standards for primary care practice-level clustering.

Each cluster is defined as two Family Health Team (FHT). Based on routine service data, two FHT encounters approximately 120 individuals that have underlying chronic conditions over a six-week period. Thus, the expected average cluster size (m) of eligible chronic patients over the six-week study period is 120.

Then, the required design effect is 4.57. Multiplying the unadjusted individual sample size (approximately 157.5 per arm) by this design effect requires approximately 720 chronic patients per arm. Dividing this by the average cluster size (m = 120) yields exactly 6 clusters per arm. This results in a total of 12 clusters included in the study. This provides a total expected denominator of 1,440 routine chronic patient encounters over the six-week study period.

$$n = (Z1\text{-}\alpha/2 + Z1\text{-}\beta)^2 \times (p1(1-p1)) + (p2(1-p2)) \times (1 + (m-1)\rho) / (p1 - p2)^2 \times m$$

- ($Z_{1\text{-}}\beta = 1.04$) and a 5% significance level ($Z_{1\text{-}}\alpha/_2 = 1.96$)

- Baseline identification proportion (P1): 0.05 (5%)
- Expected identification proportion (P2): 0.15 (15%)
- Difference in proportions: 0.1
- Average chronic patient encounters per cluster (m): 120 (over 6 weeks)
- Design Effect (DE): 1 + (m-1)*ICC = 1 + (119 *0.03) = 4.57
- Clusters per arm (c): 6 (12 total)
- Total N= 1440

6.5. Sampling Method

In this study, we will use multistage sampling aligned with the principles of a cluster randomized controlled trial. In the first stage, the clusters are health centers within Addis Ababa that have palliative care services through Family Health Teams. Of the 101 health centers, 95 currently deliver palliative care and will form the sampling frame. A complete list of eligible facilities will be obtained from Addis Ababa regional health bureau.To make sure the selected clusters are representative of the city, we will use stratified random sampling, stratifying facilities by patient volume. After this, these facilities will be randomly allocated to either the intervention or control group using a computer-generated sequence managed by an independent person so that there's allocation concealment. A total of 12 clusters(6 per arm) will be included in the study.

In the second stage, all patients currently diagnosed with a chronic illness and receiving follow-up home-visit care from the Family Health Teams within the selected cluster

catchment areas will be included consecutively. This population forms the denominator for the study's proportion-based primary outcome, representing the total reach of the implementation environment. Given that the screening is integrated into routine clinical care, verbal informed consent will be sought from each identified patient (or their proxy caregiver) for the research use of their data. This verbal consent will be witnessed and documented. The numerator will then be defined as the subset of these chronic patients who are successfully screened and identified for palliative care needs using either the DINKNESH App (intervention) or standard paper-based tools (control). This multistage approach ensures that the study captures real-world implementation fidelity while minimizing selection bias among the target chronic patient population.

For the qualitative component, we'll purposely identify healthcare providers and key stakeholders from facilities assigned to the intervention arm. Participants will be chosen based on their direct involvement in the rollout or oversight of the palliative care App, ensuring diversity across roles. Data will be collected through FGD organized by professional category to foster open dialogue and reduce hierarchical influence. The number of FGDs will be guided by thematic saturation, typically reached after four to six FGDs.

6.6. Data Collection

We will use a mixed method to collect both quantitative and qualitative data, ensuring a comprehensive evaluation of the DINKNESH App's impact. For the quantitative part, data will be extracted from the DINKNESH app backend logs in the intervention arm and paper-based forms in the control arm, measuring the health care workers' documented patient identification rates and clinical action taken. All data collectors will be trained appropriately to ensure ethical conduct and will conduct weekly site visits to document the number of chronic patients visited and screened, ensure data integrity and adherence to the study protocol across all eight clusters.

For the qualitative component, we will conduct FGDs with health care workers

purposely selected from the intervention arm. This purposive identification is designed to ensure maximum variation in experience and professional role to gather both hands-on user experiences and health facility insights. The FGDs will explore user experiences, perceived usability of the App, and contextual enablers and barriers (systemic, human, and technological) affecting the App's integration into routine workflows. In depth interviews will also be made in selected identified patients in both intervention and control to compare their experiences. All discussions will be audio-recorded with consent, transcribed verbatim, and translated from Amharic into English by experienced translators.

6.7. Data Management

All data will be managed with strict attention to confidentiality. Data generated by the DINKNESH App (Intervention Arm) will be automatically uploaded to a cloud server accessible only to the core research team. In the control arm, data will be recorded on standardized paper logs.Prior to analysis, data cleaning will be standardized across both arms, including automated range checks, consistency reviews, and manual outlier detection. Each participant and facility will be assigned a unique study ID to maintain anonymity throughout.

Qualitative data from Focus Group Discussionswill be audio recorded, transcribed verbatim, and checked against recordings for accuracy. Transcripts will be de-identified immediately upon transcription and imported into qualitative analysis software for systematic coding.

All data, whether quantitative or qualitative, will be securely stored, regularly backed up, and retained in line with institutional data protection protocols.

6.8. Data Analysis

We will have a mixed-methods design, analyzing quantitative and qualitative data separately and then integrating the findings during interpretation to generate a comprehensive understanding of the DINKNESH App's effectiveness and Implementation.

The primary effectiveness outcome for analysis is defined as the number of patients identified as having palliative care needs by family health teams during routine home visits over 6 weeks study period. This outcome will be operationalized as the number of individuals identified as requiring palliative care divided by the total number of chronic patient encounters conducted within each cluster.

In alignment with the study objectives, quantitative analyses will address the identification of patients with palliative care needs (primary outcome)

Quantitative data will be cleaned up and analyzed using standard statistical software Stata. Models with adjustment for clustering at the facility level will be used. This approach accounts for the clustered study design and enables valid comparison of identification rates between intervention and control arms.The model will test if the DINKNESH App process led to a significantly higher rate of patient identification and documented action compared to the Control arm.

For the Qualitative part, We will analyze the transcripts from the Focus Group Discussions using thematic analysis. This involves systematically reading the transcripts and categorizing recurring quotes and ideas into specific themes. This analysis will tell us the exact process issues that need fixing before the DINKNESH App can be scaled up

nationally.

Findings from quantitative analyses will be triangulated with qualitative insights from healthcare workers and identified patients with palliative care need to contextualize observed differences in identification and clinical action, and to explain how and why the DINKNESH App influenced routine care practices.

7. Ethical Consideration

Ethical approval for this study will be obtained from the Research Review Ethics Committee of Addis Ababa University, College of Health Sciences. In addition, an official support letter will be secured from the Addis Ababa City Administration Health Bureau (AAHB). To ensure full institutional accountability and successful implementation, administrative permission will be obtained from the respective sub city health office heads and the facility managers of the 12 selected health centers. These stakeholders will be engaged throughout the process to ensure the study aligns with facility-level workflows and regional health priorities.

Before data collection, all participants will be fully informed about the study's purpose, procedures, potential risks, and benefits. Written informed consent will be obtained from all Health Care Workers and formal verbal informed consent will be obtained from all eligible chronic patients prior to the screening process. For patients who are unable to provide consent due to their clinical condition, proxy consent will be obtained from their primary caregiver. Participation will be entirely voluntary, and individuals will have the right to withdraw from the study at any stage without any negative consequences or loss of standard care benefits.

Confidentiality will be strictly maintained throughout the study. No personal identifiers will be collected or linked to the data. Each participant and facility will be assigned a unique study code to ensure anonymity. Given the use of an mHealth application, enhanced security measures will be implemented. All data including App backend logs, Audio recordings will be encrypted, password-protected, and stored securely on a server accessible only to authorized members of the research team. Audio recordings from Focus Group Discussions and in depth Interview will be transcribed, anonymized immediately, and stored securely, with identifying information removed to protect participant privacy.

All ethical principles outlined by Addis Ababa University and the Addis Ababa City Health Bureau will be rigorously followed to ensure respect for participants, data integrity, and institutional accountability

8. Dissemination of Result

The findings of this study will be submitted and presented to Addis Ababa University. The results will also be conveyed to the health office accountable, stakeholders, and health centers. An effort would be made to present it at various seminars, research conferences, and workshops. Finally, an attempt will be made to publish it in high impact journals. The study findings will be given to the Addis Ababa Health Bureau, as well as other relevant stakeholders.

9. Work Plan

No	Activities to be Done	Responsible Bodies	Schedule 2025-2026															
			Nov.2025		Dec.2025		Jan.2026		Feb.2026		Mar2026		Apr2026		May2026		Jun2026	
1	Proposal Writing	PI																
2	Proposal Feedback	Advisors																
3	Proposal Defense and Correction	PI																
4	Ethical Clearance Approval	IRB, PI																
5	Budget Arrangements	Advisors																
6	Preparation of Data Collection, Recruitment and Training of Data Collectors/Supervisors	PI, Team																
8	Training of Participants	PI, Team																

7	Necessary Modification	PI																
9	Data collection	PI, Team																
10	Data Analysis and Interpretation	PI																
11	Report Write Up and Submission	PI																
12	Thesis Evaluation	Advisors																
13	Thesis Defense	PI																
15	Monitoring the overall activities	PI																

Table 1: Work Plan

11. Budget Plan

No	Expenses	Measurement in Units/No.	Unit Price (ETB)	Total (ETB)
I. LOGISTICS + PERSONNEL COSTS FOR TRAINING				
1.	Compensation for Trainers	4 Trainers	1500/person/day For 3 days	18,000
2.	Venue + Daily Refreshments & Catering	24 HCW - 2HCW per health center - 24 HCW for 2 days and - 12 HCW for 3 days 4 trainer Total = 28 People - 28 people for 2 days	900/person/day For 3 days	64,800

		- 16 people for the 3rd day		
3.	Compensation for Trainee	24 HCW 2HCW per health center 24 HCW for 2 days and 12 HCW for day 3	600/person /day For 2 days - for 24 people 600/person /3rd day for 12 people	36,000
4.	Stationary(Photocopying & Tool Printing) and Supplies	Patient Consents,and other Notebooks, Pens, Batteries, Audio Recording	-	5,000
5.	Tablets	2 * 6 Tablets = 12 Tablets (2 Tablets per Health center)	- (will use existing DINKNESH tablets)	-
6.	Software Support Team Compensation	2 Team Members	For 3 months	12,000
II. DATA COLLECTION				

7.	SIM Card Purchase	12 SIM Cards	100/per SIM Card	1,200
8.	Internet Package for 2 months	12 Packages	400/per month For 2 months	9600
9.	Local Transportation (PI Supervision)	5 * 6 HC (Every 2 weeks in between monitoring) = 30 Trip within 2 months - Intervention Group	200/trip For 2 months	12,000
		5 * 6 HC (Every 2 weeks - in between monitoring) = 30 Trip within 2 months - Control Group	200/trip For 2 months	
10.	Local Transportation (Data Collector/ Quantitative)	9 * 6 Trips (Weekly Data Collection)= 54 trip within 2 months - Intervention Group	200 /trip For 2 months	21,600
		9* 6 Trips(Weekly data collection) = 54 Trip within 2 months - Control Group	200/trip For 2 months	

11.	Local transportation for X amount of indepth interview in identified patient houses for PI and Qualitative Data collector	2* X Trips	- For 1 month	5,000
12.	Data Collector/ Facilitator Payment	Quantitative Data collection+ Qualitative Data Collection for 2 month	5000/month For 2 months	10,000
13.	Qualitative Discussion Costs	1 FGD Session Refreshments/Session - Intervention Group 12 HCW	600/person /day	14,400
		1 FGD Session Refreshments/Session - Control Group 12 HCW	600/person /day	
III. DISSEMINATION				
15.	Printing and Binding Thesis	3 Copies	-	2,000

IV. TOTAL EXPENSES (Sub-Total)				211,600
16.	Contingency (10% of Sub-Total)	10% * 211,600	-	21,160
V. GRAND TOTAL				**232,760**

Table 2: Budget plan

I. References

1. World Health Organization. Global Atlas of Palliative Care. Geneva: WHO; 2020.
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II. Annexes

Annex I: Participant Study Information Sheet

(For HCWs)

Title of Study: Effectiveness of the DINKNESH Clinical Decision Support for Palliative Care and Determinants of Implementation : A Cluster Randomized Trial in Addis Ababa, Ethiopia

Principal Investigator: Meheret Yeshitila

Institution: Addis Ababa University, School of Public Health, Department of Epidemiology and Biostatistics

Contact Information: +251919373034 or meheretyeshitila3@gmail.com

1. Introduction

I am giving you this information to invite you to participate as a Health Extension Worker(HEW) in a research study we are conducting about improving palliative care identification. Before you decide, you are welcome to talk about this study with anyone you feel comfortable with and take as much time as you need to think about it. As we go

through this form, if there are any words or ideas that are not clear, please ask me to stop and explain them.

2. Purpose of the Research

   The purpose of this research is to evaluate methods for documenting and identifying patients in palliative care over a two-month active period. We aim to understand how effectively patients with life-limiting chronic illnesses can be systematically identified in family health team practice .This study will also identify the real-world barriers and enablers affecting the App's successful integration. The ultimate goal is to provide evidence for the scale-up of systematic palliative care.

3. Participant Selection

   You are being invited to participate because you are a Health Extension Worker currently involved in family health teams at a primary healthcare facility in Addis Ababa that has been randomly selected for this study.

4. Voluntary Participation

   Your participation is completely voluntary. You can refuse to participate or withdraw at any time without penalty. Your decision will not affect your employment, supervision, or current standing at your facility.

5. Description of the Process If you agree to participate:

   - You will receive training on systematic palliative care assessment and be asked to utilize a clinical decision support resource for patients with chronic conditions over a two-month active period. Additionally, you will be required to obtain verbal informed consent from these patients prior to their evaluation.
   - At the conclusion of the study, you will be asked to participate in a Focus Group Discussion (FGD) to share your experiences with the assessment process."

6. Risks

   There is no physical risk from participating in this study. The main risks are:

   - Breach of Confidentiality: Your answers on FGDs could be sensitive.
   - Increased Workload: Using a new system may initially increase your workload over the two months. We will protect your anonymity and data security as

explained below, and the App is designed to minimize added responsibilities.

7. Benefits You will not receive any direct financial benefit from participating, but will receive training and potential stipends to cover data costs. The main benefits are:
    - Knowledge Gain: You will receive specialized training, and your knowledge increase will be measured.
    - Improved Service: The App is expected to provide clinical decision support that could improve the systematic nature of your patient management.
    - Policy Impact: Your participation is vital to make evidence-based decisions regarding national scale-up, ensuring future digital tools are user-friendly and effective in Ethiopia.
8. Confidentiality

    All information collected will be kept strictly confidential. Your name will not be used in any report or publication. A unique identification number will be used instead. The data will be stored securely on encrypted servers, and only the principal investigator and authorized study staff will have access. Your facility's name will be anonymized in publications where required to protect cluster identity.

9. Reimbursement

    You will not be paid, but participants may receive compensation for related expenses (e.g., airtime/data costs) or a small token of appreciation.

10. Right to Refuse or Withdraw

    You have the right to refuse to participate or choose to withdraw your consent at any time, for any reason, without any penalty. Your decision will not affect your employment or your job duties.

11. Who to Contact

    If you have questions about this study, contact:

- Principal Investigator: Meheret Yeshitila
- Phone Number: +251919373034
- Email: meheretyeshitila3@gmail.com

If you have ethical concerns, contact:

- Addis Ababa University, College of Health Science, Institutional Review Board (IRB)

Annex II: Informed Consent Form

(For HCWs)

Title of Study: Effectiveness of the DINKNESH Clinical Decision Support for Palliative Care and Determinants of Implementation : A Cluster Randomized Trial in Addis Ababa, Ethiopia

Participant ID Number: ___

Consent Statement

I have read the information sheet for this study. I have been given the opportunity to ask questions, and they have been answered to my satisfaction. I understand the purpose of the study, and the potential risks and benefits.

I understand that my participation is voluntary and that my refusal to participate or decision to withdraw will not affect my employment, duties, or professional standing in any way. I understand that my work performance data will be reviewed, but my identity will be kept confidential.

I voluntarily agree to participate in this study.

Participant’s Name: _____ Signature _____ Date: __ / __/ 2026GC

Name of HEW: _____ Signature: _____ Date: __/ __ / 2026GC

Witness (if applicable): _____ Signature: _____ Date: __ / __ / 2026GC

(For patients)

Patient Verbal Consent Script

“ Before I start today's visit, I want to tell you about a study our health center is part of.

We are part of a research study that is testing a better way to identify patients who may need extra support for their illness. During this visit, I will ask you some additional questions about your symptoms, feelings, and daily needs. This will take about 5 to 10 extra minutes.

I will collect your answers here. Your information will be kept private. Your name will not appear anywhere in the research. You will not be paid for participating.

Your participation is completely voluntary. If you do not want to participate, your regular care today continues exactly as normal. Nothing will change. You can also stop answering at any time during the visit.

Do you have any questions? Do you agree to participate?"

Annex V: Palliative Care Assessment Tools

Supportive and Palliative Care Indicators Tool (SPICT)

The SPICT is used to help identify people whose health is deteriorating. Assess them for unmet supportive and palliative care needs.

Look or any general indicators of poor or deteriorating health.

Status	Assessment Indicator
☐	Unplanned hospital admission(s).
☐	Performance status is poor or deteriorating, with limited reversibility. (eg. The person stays in bed or in a chair for more than half the day.)

☐	Depends on others for care due to increasing physical and/or mental health problems.
☐	The person's carer needs more help and support.
☐	Progressive weight loss; remains underweight; low muscle mass.
☐	Persistent symptoms despite optimal treatment of underlying condition(s).
☐	The person (or family) asks for palliative care; chooses to reduce, stop or not have treatment; or wishes to focus on quality of life.

Look for Clinical Indicators of Life-Limiting Conditions

Category	Clinical Indicators
Cancer	☐ Functional ability deteriorating due to progressive cancer. ☐ Too frail for cancer treatment or treatment is for symptom control.

Dementia/ Frailty	☐ Unable to dress, walk or eat without help. ☐ Eating and drinking less; difficulty with swallowing. ☐ Urinary and faecal incontinence. ☐ Not able to communicate by speaking; little social interaction. ☐ Frequent falls; fractured femur. ☐ Recurrent febrile episodes or infections; aspiration pneumonia.
Neurological disease	☐ Progressive deterioration in physical and/or cognitive function despite optimal therapy. ☐ Speech problems with increasing difficulty communicating and/or progressive difficulty with swallowing.

	☐ Recurrent aspiration pneumonia; breathless or respiratory failure. ☐ Persistent paralysis after stroke with significant loss of function and ongoing disability.
Heart/ Vascular disease	☐ Heart failure or extensive, untreatable coronary artery disease; with breathlessness or chest pain at rest or on minimal effort. ☐ Severe, inoperable peripheral vascular disease.
Respiratory disease	☐ Severe, chronic lung disease; with breathlessness at rest or on minimal effort between exacerbations. ☐ Persistent hypoxia needing long term oxygen therapy. ☐ Has needed ventilation for respiratory failure or ventilation is contraindicated.

Kidney disease	☐ Stage 4 or 5 chronic kidney disease (eGFR < 30ml/min) with deteriorating health. ☐ Kidney failure complicating other life limiting conditions or treatments. ☐ Stopping or not starting dialysis.
Liver disease	☐ Cirrhosis with one or more complications in the past year: diuretic resistant ascites; hepatic encephalopathy; hepatorenal syndrome; bacterial peritonitis; recurrent variceal bleeds. ☐ Liver transplant is not possible.
Other conditions	☐ Deteriorating with other conditions, multiple conditions and/or complications that are not reversible; any treatment available will have a poor outcome.

Review Current Care and Care Planning

Status	Action Item
☐	Review current treatment and medication to ensure the person receives optimal care; minimise polypharmacy.

☐	Consider referral for specialist assessment if symptoms or problems are complex and difficult to manage.
☐	Agree a current and future care plan with the person and their family. Support carers.
☐	Plan ahead early if loss of decision-making capacity is likely.
☐	Record, share, and review care plans.

ECOG Performance Status Tool

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours

3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

IPOS Integrated Palliative Outcome Scale

Item #	Assessment Area	Detailed Content / Question
1	Main Concerns	What have been your main problems or concerns? (Open-ended/Not scored)

2	Physical Symptoms	Scoring for 10 core symptoms: 1. Pain 2. Shortness of breath 3. Weakness or lack of energy 4. Nausea (feeling sick) 5. Vomiting (being sick) 6. Poor appetite 7. Constipation

		8. Sore or dry mouth 9. Drowsiness 10. Poor mobility
3	Patient Anxiety	Have you been feeling anxious or worried about your illness or treatment?
4	Family Anxiety	Have any of your family or friends been anxious or worried about you?
5	Depression	Have you been feeling depressed?
6	Peace	Have you felt at peace?
7	Sharing Feelings	Have you been able to share how you are feeling with family or friends?
8	Information	Have you had as much information as you wanted?

9	Practical Problems	Have any practical problems (financial or personal) been addressed?
10	Respondent	Who completed this questionnaire? (Patient, Staff, or both)

Annex VII: Interview Guide for Healthcare providers

Study Title: Effectiveness and Implementation Determinants of the DINKNESH App Compared to Paper-Based Assessment Tools for Palliative Care: A Mixed-Methods Cluster Randomized Trial in Addis Ababa, Ethiopia

Target Participants: HCW from Intervention Clusters (Purposively Sampled).

Time Allotment: 60-90 minutes.

Objective: To explore HCWs' experiences, perceptions, and contextual factors (enablers and barriers) affecting the uptake and use of the DINKINESH App.

Section A: Introduction, Context, and Consent (5 minutes)

Facilitator: Welcome, thank you for taking the time to share your experience with the DINKINESH App. We are here to understand what worked and what didn't work over the last 6 weeks . There are no right or wrong answers, your honest feedback is vital to scale up this service.

- Review informed consent and confidentiality protocols (especially regarding anonymity and cluster identity).
- Ground Rule: Encourage equal participation and emphasize that we are here to discuss the system and the App, not individual performance.
- Confirm willingness to be audio-recorded.

Section B: Usability, Engagement, and Initial Experience (15 minutes)

(Focus: User experience, satisfaction, clarity of the tool.)

1. When you first started using the DINKINESH App, what were your immediate feelings or thoughts about incorporating it into your daily chronic care routine?
2. How easy or difficult was the App to learn and use initially, particularly regarding the interface and navigation?

- Probe (Usability): Were the screening tools (SPICT, ECOG, IPOS) clear? Did the App save you time or cost you time?

3. What was the most useful feature of the App, and what was the most frustrating or confusing part?

Section C: Workflow Integration and Process Determinants (30 minutes)

(Focus: Systemic barriers, technical challenges, and adherence)

4. Can you describe how the DINKINESH App changed the order or routine of your chronic care patient follow-up visits? Did the App force you to do things you normally skip?
    - Probe (Systematic Action): Was the process of documenting a referral or a counseling session clearer with the App?
5. Regarding Technical Barriers: What were the most common technological difficulties you faced while using the App (e.g., poor internet connectivity, battery life, App freezing)?
    - Probe (Connectivity): Did lack of reliable internet/data coverage impact your ability to use the App in real-time during a patient visit?
6. Regarding Supervisory and Organizational Support: How did your facility manager or supervisor support you during the 6 weeks implementation period?
    - Probe (Systemic Enablers): Did you receive sufficient guidance or reminders? Was there any conflict between App use and other facility reporting requirements?
7. Regarding Workload and Time: Did the App ultimately increase or decrease your perceived workload? Was the time spent using the App compensated or recognized in any way?

Section D: Capacity, Sustainability, and Recommendations (20 minutes)

(Focus: Capacity building, attitudes, and future scalability.)

8. Thinking about the training you received, how well did it prepare you to use the App and understand the principles of systematic palliative care screening?
    - Probe (Knowledge Gain): Did you feel more confident identifying palliative care needs after using the App than you did before the study?
9. If the DINKINESH App were rolled out nationally tomorrow, what is the single biggest factor that would make HCWs continue using it for the next year? (The "Enabler")
10. Conversely, what is the single biggest factor that would cause HCWs to abandon the App and revert to paper records? (The "Barrier")
11. Final Recommendation: If you could give the DINKINESH team one piece of advice on how to improve the App for future national use, what would it be?

Annex IX: Interview Guide for Patients

Study Title:Effectiveness and Implementation Determinants of the DINKNESH App Compared to Paper-Based Assessment Tools for Palliative Care: A Mixed-Methods Cluster Randomized Trial in Addis Ababa, Ethiopia

Method: In-Depth Interview

Time Allotment: 30–45 minutes

Objective: To explore patients' experiences of the care they received, their perception of the screening process , and their satisfaction

Section A: Introduction and Consent (5 minutes)

Facilitator: Thank you for agreeing to speak with me. I am a researcher from Addis Ababa University. We are trying to improve how patients like you are cared for in home to home visits. Recently, your health care worker used a new system (an App on their phone) to ask you questions about your health and symptoms. I would like to hear your honest thoughts about that visit. This is not a test, and your answers will not affect your medical care. Everything you say is confidential.

- Review informed consent.
- Confirm willingness to be audio recorded.

Section B: Experience of the Consultation (10 minutes)

(Focus: Patient-centeredness, communication, and time)

1. Think back to your last visit with the nurse/health worker when they used the phone/tablet to ask you questions. Can you describe how that visit felt compared to usual visits?

2. Did you feel the health worker was paying attention to you, even though they were using a device?
    - Probe: Did the phone create a barrier, or did it seem to help them ask better questions?
3. The health worker asked you detailed questions about your physical symptoms (pain, tiredness) and your feelings (worry, sadness). How did it feel to be asked these specific questions?
    - Probe: Was it helpful to discuss these things? Did any question make you uncomfortable?

Section C: Perception of Action and Support (15 minutes)

(Focus: Outcome of the screening)

4. After the health worker finished the questions on the phone, what happened next? What advice or help were you given?
    - Probe: Were you referred to a hospital? Were you given new medicine? Did they just talk to you?
5. Do you feel that the action taken (referral/counseling) addressed your main problem?
6. Did you understand why the health worker made that decision? Was the plan explained clearly to you?

Section D: Satisfaction and Recommendations (10 minutes)

(Focus: Overall satisfaction and future preference)

7. Overall, how satisfied were you with the care you received during that visit?
8. If you come back for your next follow-up, would you prefer the health worker to use this system again to check your symptoms, or go back to the old way? Why?
9. Is there anything you would change about how the health worker interacted with you?

Annex XI: CV of PI and Primary Advisor

CV of PI

Meheret Yeshitila Amare

MD, MPH Candidate

WORK EXPERIENCE

mDoc September 2025-Present	Clinical AI Officer I provide clinical input in performances, medical writing and overall flow
Creofam LLC Dec. 2024 - June 2025	Project Manager Successfully managed projects with tight deadlines and limited resources. Coordinated team members to ensure tasks were completed on time
Lancet General Hospital March 2024- Nov. 2024	General Practitioner I provided comprehensive care for patients with a wide range of conditions at the inpatient ward.

Tikur Anbessa Hospital Oct.. 2022- Oct. 2023	Research Assistant Collected and analyzed research data and conducted comprehensive literature reviews.

EDUCATION

Addis Ababa University Sep. 2024 - Present	Master's of Public Health (with specialty in Epidemiology and Biostatistics)
Addis Ababa University Feb. 2024	Doctor of Medicine

CV of Primary Advisor:

https://storage.googleapis.com/msgsndr/ijwfUsqUtc26ZIwSTkV5/media/69455bb90fb2962c7f537c5c.pdf

Annex XII: Assurance of Principal Investigator

I, the undersigned agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide timely progress report to my advisor and seek the necessary advice and approval from my primary advisors in the module of the research. I will communicate timely to my advisors all stakeholders involved in the study including any source of funding for this research.

Name of the student: Meheret Yeshitila

Date: November 28, 2025

Signature: 

Approval of the primary Advisor

Name of the primary advisor: Dr. Adamu Addissie

Date: November 28, 2025

Signature: