



# BMJ Open Study protocol for key interventions to improve the follow-up adherence postcervical precancerous lesion treatment in Ethiopia: a pragmatic randomised controlled trial

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## ABSTRACT

**Introduction** The follow-up adherence after treatment for a positive screening test is critical for preventing the development of screen-detected abnormalities in cervical cancer. Yet, this poses a major challenge in developing countries like Ethiopia, emphasising the urgency for intervention strategies. Our trial aims to assess which strategies would be effective in improving adherence to follow-up after suspicious cervical lesion treatment in Ethiopia. Thus, the objective of this study is to evaluate key interventions to improve the follow-up adherence rate among women treated for suspicious cervical lesions in primary healthcare settings in Ethiopia.

**Method and analysis** We will employ a pragmatic randomised control trial study design, using Consolidated Standards of Reporting Trials guidelines for reporting and a Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist for developing the protocol, to evaluate intervention effectiveness. These interventions are: (a) structured nurses-led telephone call reminders, (b) home-visit reminders led by health extension workers and (c) application-based automated short message service text reminders. The standard care involves only receiving oral follow-up advice and a baseline follow-up card. The planned start date is 1 November 2024, with an anticipated end date of 1 November 2025. Our study will include women aged 30–49 who are HIV-negative and those over 25 who are HIV-positive, and who have been treated for suspicious cervical lesions after a positive visual inspection with acetic acid (VIA) screening, as per Ethiopian Ministry of Health guidelines for cervical cancer screening eligibility. The required sample size is 460, with 115 participants per arm. Study participants in the intervention group will receive the stated interventions plus the standard care, while the control group will receive only the standard care. The interventions will be delivered three times annually: 4 months from baseline, then at 8 months and finally at 12 months before the appointment due date. The primary outcome of our study is the proportion of adherence to follow-up recommendations, which will be measured by rescreening (VIA) after 1 year (11–13 months after the first

## STRENGTHS AND LIMITATIONS OF THE STUDY

- ⇒ Recruitment may take some time, especially for the mobile application-based SMS-reminder intervention arm as internet and mobile access may be limited in rural Ethiopia.
- ⇒ Comparisons between the intervention arms will not be done; doing so would require a much larger sample size.
- ⇒ The study provides innovative and contextually feasible intervention strategies to improve the follow-up adherence level to contribute to the WHO's cervical cancer elimination target by 2030.
- ⇒ The pragmatic design of the trial enhances the generalisability of the results to real-world settings across Ethiopia.
- ⇒ By evaluating key interventions, this study aims to identify effective and practical strategies for improving follow-up adherence.

screening). Descriptive statistics,  $\chi^2$  test (Fisher's exact test), binary logistic regression analysis and intention-to-treat will be used to describe and interpret the results.

**Ethics and dissemination** The trial protocol has been approved by the institutional review board of Addis Ababa University with protocol number (008/24/SPH). Trial results will be disseminated to study participants, national and international audiences through workshops, conferences and publications in reputable journals.

**Trial registration number** [NCT06515301](https://www.clinicaltrials.gov/ct2/show/study/NCT06515301).

## INTRODUCTION

Despite being highly preventable, cervical cancer ranks as the fourth leading global cancer in 2020, with over 90% of the 342 000 deaths occurring in developing countries.<sup>1</sup> In Ethiopia, cervical cancer ranked second most common, with an incidence of 21.5 per 100 000,<sup>2</sup> exceeding the WHO's 2030 target of 4 per 100 000.<sup>3</sup> Persistent human



papillomavirus infection, mainly types 16 and 18, causes 70% of cervical cancer,<sup>4</sup> making prevention through vaccination, screening and treatment crucial.<sup>5</sup> WHO aims to eliminate cervical cancer by 2030, targeting 90% vaccination, 70% screening and 90% treatment coverage.<sup>3</sup> Ethiopia's Ministry of Health adopted WHO-recommended screening guidelines,<sup>6</sup> using visual inspection with acetic acid (VIA) as the primary method for women aged 30–49, screened positive cases receive immediate same-day treatment, followed by recommended follow-up visits after 1 year for HIV negative and after 6 months for HIV positive women.<sup>6</sup> To meet WHO goals, screening coverage must increase from 3% to 70%, a significant 23.3-fold rise.<sup>7</sup>

Cervical cancer screening's effectiveness relies on rigorous post-treatment follow-up for precancerous lesions, given the high recurrence risk of cervical intraepithelial neoplasia.<sup>8,9</sup> In developing nations like Ethiopia, a significant number of women treated for precancerous cervical lesions do not attend follow-up appointments, with reported loss to follow-up rates ranging from 41% to 69%.<sup>10–12</sup> This poses a major challenge to cervical cancer reduction efforts, contradicting prevention and treatment guidelines.<sup>5,6</sup>

Despite recommendations for follow-up after precervical cancer treatment, adherence remains low in developing countries.<sup>13–17</sup> In Nigeria, losses to follow-up were 47.2%, often due to poor education and geographical barriers.<sup>17</sup> In Kenya, 39% of positive cases missed scheduled visits, particularly HIV-positive women.<sup>18</sup> Cameroon and Côte d'Ivoire also faced high loss to follow-up rates.<sup>19,20</sup> In Ethiopia, despite limited prior research, a 2022 study in Addis Ababa found a 27.5% follow-up adherence level.<sup>21</sup> In 2016, 48.9% of HIV-positive women failed to return for 1-year follow-up. Additionally, high rates of missed follow-up were observed: 70.2% in Addis Ababa, 62.2% in Oromia and 61.4% in southern Ethiopia.<sup>22</sup> A 2024 study in Addis Ababa and Oromia reported only 44.7% of women returned for post-treatment follow-up visits.<sup>12</sup> This highlights the crucial need for developing intervention strategies aimed at improving adherence to follow-up.

Implementing contextual intervention strategies involving healthcare professionals, community-based mechanisms and technologies like e-health could improve follow-up adherence in Ethiopia. As of 2023, mobile phone access in Ethiopia stands at about 44% and is growing rapidly, ensuring significant connectivity.<sup>23,24</sup> The increasing penetration of smartphones further improves access to SMS and digital services. The Ethiopian government, through the Ministry of Innovation and Technology, is working to enhance digital connectivity, while the Ministry of Health is actively promoting digital health to strengthen health communication and outreach.<sup>25</sup> E-health interventions effectively increase cervical cancer screening knowledge and uptake in urban and rural areas globally.<sup>26–28</sup> For instance, in Tanzania, SMS-based interventions increased cervical cancer screening uptake.<sup>29</sup> Despite improving screening outcomes, the impact of

e-health interventions on follow-up adherence to suspicious cervical lesion treatment remains unknown in Africa, especially in Ethiopia.

Healthcare professionals' recommendations increase cervical cancer screening uptake in studies across Ethiopia and Africa.<sup>30,31</sup> For instance, a 2019 trial in Addis Ababa demonstrated that one-on-one health talks can increase women's cervical cancer screening uptake.<sup>32</sup> Building on this, we aim to implement patient tracking mechanisms to evaluate their effectiveness in enhancing adherence to post-treatment rescreening recommendations. Currently, there is no structured reminder strategy in place. Leveraging community-based mechanisms like health extension workers (HEWs), especially in rural Ethiopia, presents a promising approach to enhance follow-up adherence by efficiently locating and tracking women who test positive. With over 85% of Ethiopian women residing in rural areas,<sup>33</sup> it's imperative to adopt locally feasible intervention strategies. This method has demonstrated effectiveness in improving maternal and child healthcare utilisation in Ethiopia<sup>34</sup> and similar African settings.<sup>35</sup> Hence, customising cervical cancer screening interventions to fit local communities is essential. This underscores the importance of investigating this approach as an intervention in the present study. It's vital to explore various comprehensive interventions, including country-specific strategies and e-health integration, to address follow-up adherence after suspicious cervical lesion treatment.

In this study, a pragmatic randomised controlled trial will evaluate interventions in real-world settings, enabling broader applicability nationwide. Our interventions, including health professional tracking, community-based tracking and e-health interventions, target improved follow-up adherence after treatment for suspicious cervical lesions. This study aims to design culturally tailored, contextually feasible interventions, setting a precedent for effective real-world implementation in Ethiopia.

## Hypothesis

We hypothesised that structured nurse-led telephone call reminders, HEW-led home reminder visits and app-based automated SMS reminders to improve follow-up adherence among women treated for suspicious cervical lesions in rural settings of Ethiopia.

## Study objectives

### General objective

To evaluate key interventions to improve the follow-up adherence rate after 1 year among women treated for suspicious cervical lesions in primary healthcare settings in Ethiopia.

### Specific objectives

1. To evaluate the effect of structured nurses-led telephone call reminders on follow-up adherence among

women treated for suspicious cervical lesions compared with standard care.

2. To evaluate the effect of home-reminder visits led by HEWs on follow-up adherence among women treated for suspicious cervical lesions compared with standard care.
3. To investigate the effect of app-based automated SMS reminders on follow-up adherence among women treated for suspicious cervical lesions compared with standard care.

## METHOD AND ANALYSIS

### Study design and setting

A pragmatic randomised controlled trial study design will be used. The study will be conducted in screening facilities in rural Ethiopia. Fifteen health centres and three primary hospitals from Oromia, southern Ethiopia and central Ethiopia will be included. Cervical cancer screening and treatment for suspicious cervical lesions using either cryotherapy or thermal ablation are available in all of the facilities as part of a see-and-treat approach. Currently, all facilities are providing the service.

### Sample size and statistical power

The sample size for the intervention is determined based on assumptions of a 95% CI, 80% power and a follow-up adherence proportion of 27.9% in the standard group, as reported in a previous study in Addis Ababa, Ethiopia.<sup>21</sup> We anticipate a 19% increase in outcomes with the intervention.<sup>36</sup> Accounting for a 10% loss to follow-up rate, the final sample size required is 460. With an equal allocation of sample size to each intervention and control arm, 115 participants will be assigned to each arm. Therefore, the sample size will be allocated as 115 for each of the three intervention arms and 115 for the control arm.

### Participants

We will recruit women treated for suspicious cervical lesions by VIA in 18 primary healthcare facilities. The principal investigator and health facility focal persons will be responsible for the recruitment based on eligibility criteria. Women who test positive on cervical cancer screening and receive treatment will be included in the study. Conversely, women with a history of hysterectomy, a diagnosis of other histologically invasive cervical cancer, suspicious cervical cancer cases, pregnancy, prior screening history or vaginal bleeding and those who do not consent to participation will be excluded. To ensure adequate enrolment, health facility staff will actively inform eligible women about the study. Recruitment progress will be monitored regularly to address any barriers and ensure the target sample size is met.

### Randomisation procedure and trial arms

In this intervention study, a pragmatic randomised controlled trial will be used to assess the effectiveness of three intervention strategies as well as the current standard care.

The degree of pragmatism is evaluated using the Pragmatic-Explanatory Continuum Indicator Summary (PRECIS-2) tool across nine domains, each rated on a 5-point Likert scale. Scores range from 1 (more exploratory) to 5 (more pragmatic), with high scores indicating greater pragmatism.

The randomisation will be based on facility level. A total of 18 primary healthcare facilities (3 primary hospitals and 15 health centres) in the peripheral cancer care settings of Ethiopia will be randomly assigned to one of the four arms (figure 1). Random numbers will be generated using a computer by an independent statistician. Based on sample size calculations, all eligible women in the intervention health facilities will receive the intervention alongside standard care, while women in follow-up at the control health facilities will receive standard care only. Both intervention and control groups in each arm will be followed for 12 months if participants are HIV-negative or 6 months if HIV-positive. Subsequently, follow-up adherence levels will be measured and compared with the standard care at the end of the follow-up period.

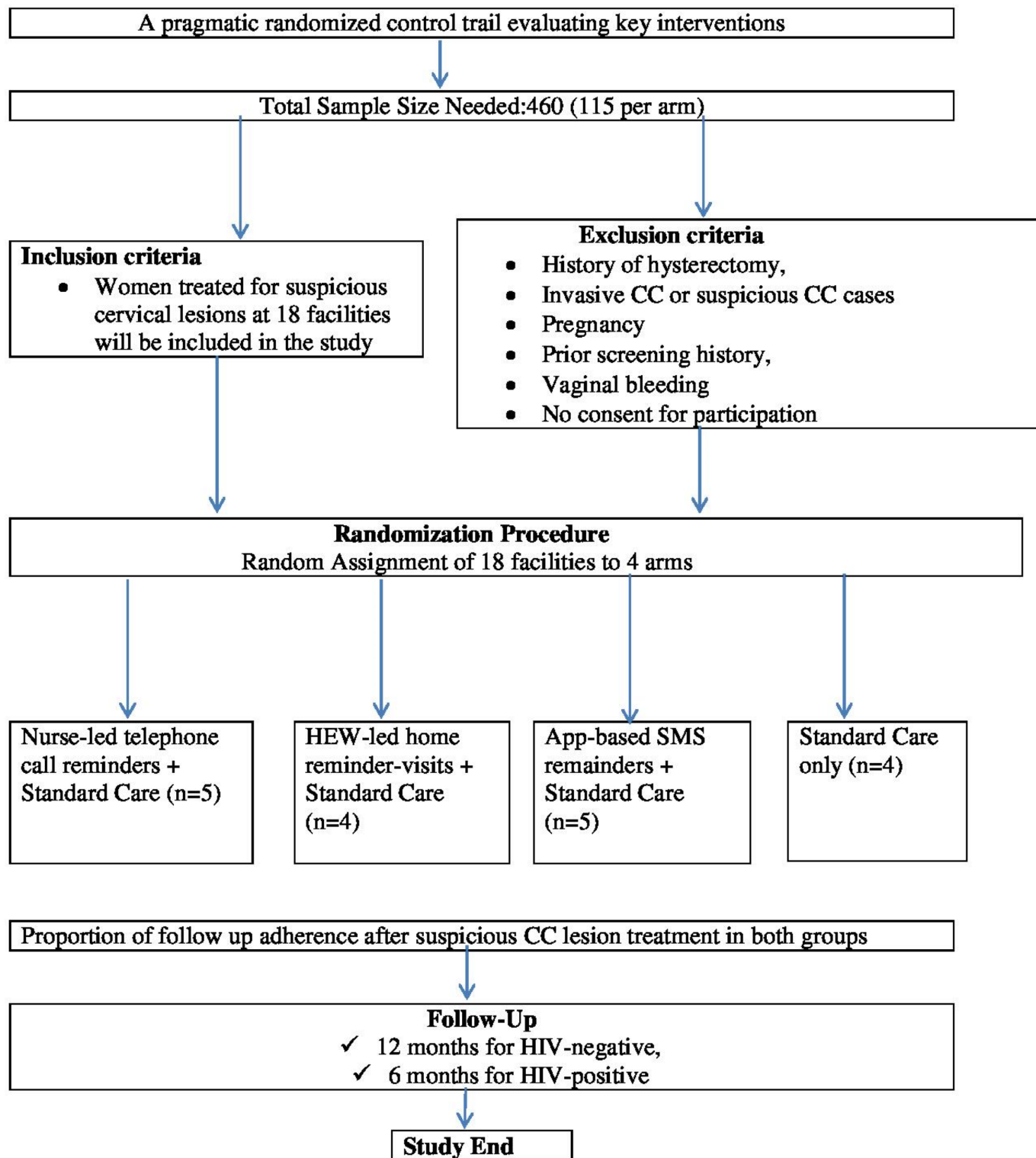
Due to the nature of the study, participants will not be aware of which intervention arm their assigned facility belongs to. Data analysts will remain blinded to the group allocation during the analysis phase. Only the principal investigator and health facility screening focal persons will know the intervention assignments for each facility, as they are responsible for implementing the intervention and managing the allocation process at the facility level.

The intervention arms are: (1) nurse-led intervention plus standard care, (2) HEW-led house-to-house visits plus standard care and (3) app-based SMS intervention plus standard care (table 1). Intervention implementation involves three phases: baseline assessment, intervention adaptation or development and implementation, and evaluation of effectiveness. Stakeholder meetings in the second phase will inform intervention design.

### Key interventions

**Arm 1: (structured nurses/midwives-led telephone reminders plus standard care)**

Trained nurses and midwives, main caregivers in Ethiopian cervical cancer screening units, have proven effective in promoting cervical cancer screening uptake. Our hypothesis posits that their active intervention via telephone reminders will enhance follow-up adherence after suspicious cervical lesion treatment. In this arm, five primary healthcare facilities will be randomly selected for the intervention. Eligible women treated for suspicious cervical lesions and scheduled for post-treatment follow-up will be tracked by nurses and midwives throughout the follow-up period. They will receive proactive phone call reminders from these healthcare professionals, reminding them of their scheduled follow-up visits. The intervention will be administered three times: initially 4 months after recruitment and then every 4 months for a year for HIV-negative women and every 2 months for 6 months for women



**Figure 1** Consolidated Standards of Reporting Trials flowchart illustrating the enrollment, allocation, intervention, follow-up and end stages for interventions aimed at improving follow-up adherence to postcervical precancerous lesion treatment in Ethiopia.

living with HIV. The planned start date is 1 November 2024, with an anticipated end date of 1 November 2025.

**Arm 2: (home reminder visits led by HEWs plus standard care)**

HEWs serve as vital community navigators, dedicating their time to community outreach. They effectively counsel

and connect women to maternal healthcare services from the community to health posts and health centres. This method has shown effectiveness in addressing public health issues in Ethiopia and similar African settings. We hypothesise that employing community-based

**Table 1** Description of the interventions in the study

Intervention	Description
Nurse-led telephone call	Nurses proactively make phone calls to remind women about their appointment dates. The message orientation that the nurse will deliver is: "Dear (Women's first and last name), your follow-up appointment is scheduled for DD/MM/YYYY in the Ethiopian calendar at (facility name). We kindly remind you to return for rescreening, as adhering to your follow-up appointment is essential for your health and tracking your progress."
HEW-led house-to-house visits	Health extension workers visit women at their homes to remind them about their follow-up appointments.
App-based SMS intervention	Women will receive SMS text reminders via mobile application about their appointment dates. The key content of the text message reads as "Dear (patient first name and last name), this is a kind reminder that your follow-up appointment is scheduled for DD/MM/YYYY in the Ethiopian calendar. Thank you! (Facility name)." The messages are sent in the patient's preferred language: Amharic, English or Oromifa.
Standard care	Women will not receive any additional intervention beyond being told to return after 1 year or 6 months, depending on their HIV status, along with appointment care at baseline.

interventions through HEWs will improve follow-up adherence levels after suspicious cervical lesion treatment by women.

In this approach, women treated for suspicious cervical lesions will be personally visited and monitored by HEWs and women's developmental armies in their homes. These visits aim to actively remind women of their scheduled post-treatment follow-up appointments. A brief orientation will be provided to the HEWs on the intervention's content, purpose and importance; however, no additional specialised training is necessary since they have recently received refresher training on cervical cancer screening and follow-up. The door-to-door visits will occur three times: initially, at 4 months (for HIV-negative women) and 2 months (for HIV-positive women) after recruitment, followed by subsequent visits every 2 months for 6 months for HIV-positive individuals and every 4 months for 12 months for those HIV-negative. The planned start date is 1 November 2024, with an anticipated end date of 1 November 2025.

### Arm 3: app-based automated SMS reminders plus standard care

The application will be collaboratively developed by IT companies in partnership with the Developing International Research Collaboration In Ethiopia to Support Oncology at Primary Health Care level (DINKNESH) project, funded by Martin Luther University. This app aims to digitise patient follow-up data and referral systems. Among its primary goals is to assess whether using the app enhances the follow-up adherence rate after suspicious cervical lesion treatment.

As part of this initiative, women will receive SMS-based reminders for their post-treatment follow-up visits. The intervention will consist of three rounds, with each woman receiving three SMS text reminders about her follow-up date. The first texts will be sent 4 months and 2 months after recruitment for HIV-negative and HIV-positive women, respectively. Subsequently, reminders will be sent every 2 months for 6 months for HIV-positive women and every 4 months for 12 months for HIV-negative women.

The planned start date is 1 November 2024, with an anticipated end date of 1 November 2025.

### Standard care

In this arm of the study, we will select four primary health-care facilities situated in peripheral cancer care settings. Women, who have been treated for suspicious cervical lesions and have scheduled post-treatment follow-up appointments, following the guidelines outlined by the Ministry of Health and current clinical practices of the country, will serve as the control group. These women will be orally informed about their follow-up appointment dates and will receive a post-treatment follow-up card at baseline. Apart from this information and routine care, no additional interventions will be provided to the women in this arm of the study. The planned start date is 1 November 2024, with an anticipated end date of 1 November 2025.

To ensure intervention fidelity in our study on improving follow-up adherence for cervical cancer screening, we will implement several steps. We will provide training for data collectors and supervisors, along with orientation for HEWs and nurses on the study's aims and protocols. Standard operating procedures for intervention delivery, including home visits and SMS reminders, have been established. Regular monitoring and supervision will ensure adherence to these protocols, minimising deviations. All intervention activities will be documented.

### Data monitoring and oversight

The study protocol has been approved by the Addis Ababa University Institutional Review Board (008/24/SPH), and the follow-up data for the trial will be reported every 6 months.

The data monitoring will be overseen by a supervisory team, consisting of two members, the principal investigator and the research team, which includes nine members. The principal investigator, along with the supervisory team, will ensure the safety of participants and the integrity of the study. Regular weekly meetings will be



held to review trial progress, assess emerging issues and ensure adherence to the protocol. Any concerns related to participant safety, data integrity or trial conduct will be promptly addressed during these meetings. Furthermore, the study will undergo periodic audits to assess compliance with the protocol, and the audit process will be independent of both the investigators and the sponsor.

### Patient and public involvement

Recognising the crucial role of patients and key stakeholders in research and intervention studies, we actively involved various stakeholders from conceptualisation to implementation. We collected feedback from these groups and made necessary adjustments for intervention and questionnaire development. Experienced data collectors will be recruited from primary healthcare facilities after receiving training about the study's aims and scope. Additionally, supervisors, designated to the selected intervention facilities, will be recruited and trained to monitor data collection and follow-up throughout the intervention period.

### Outcome measures

The proportion of adherence to follow-up recommendations in the intervention and standard group after suspicious cervical lesion treatment. Follow-up adherence will be measured by rescreening (VIA) after 1 year (11–13 months after first screening). We will use objective measurement through review of the comprehensive records maintained within the cervical cancer screening follow-up registry. Accordingly, women who fail to return for their scheduled follow-up visit after being treated for a suspicious cervical lesion will be categorised as 'Lost to Follow-Up', while those who do attend will be categorised as 'Follow-Up Adherent'.<sup>22 29</sup>

### Data management and statistical analysis

Data will be collected using standardised pretested questionnaires in 18 primary healthcare facilities and recorded in the Research Electronic Data Capture (REDCap) database. A double data entry method will be used. Regular audits and checks for inconsistencies or outliers will ensure data integrity. Data will be cleaned before analysis, and documentation of data management processes will be maintained. Confidentiality will be upheld by anonymising participant data. The data will be analysed using SPSS V.23 and R-software. Tables, figures, frequency (proportion), mean (SD) and median (IQR) will be employed to summarise the results. To compare the intervention effect, the  $\chi^2$  test (Fisher's exact test) and binary logistic regression analysis using crude odds ratio and adjusted odds ratio will be used. To account for potential participant discontinuation or deviation from the protocol, data will be collected based on the reasons for discontinuation or deviation from the intervention protocols. This will enable us to identify factors influencing participant retention. Intention-to-treat analysis will be applied to analyse the follow-up data. All analysis

procedures will strictly adhere to the Consolidated Standards of Reporting Trials guidelines for analysing randomised controlled trials (RCT) and pragmatic RCT studies.

### DISCUSSION

Our study aims to tackle the issue of follow-up adherence after treatment for suspicious cervical lesions. By evaluating and implementing effective interventions, our research holds the potential to significantly enhance follow-up rates, thereby bolstering the success of cervical cancer screening programmes. The pragmatic design of our trial will allow generalisations within Ethiopia, reflecting the real-world effectiveness of our intervention strategies. We will provide contextually and locally tailored interventions designed for the Ethiopian context, aimed at improving follow-up adherence after suspicious cervical lesion treatment. This is essential for reducing the morbidity and mortality associated with cervical cancer, ultimately contributing to the WHO's 2030 target to eliminate cervical cancer as a public health concern.

### Ethics and dissemination

After the proposal underwent extensive revision and supervision, the trial protocol was approved by the institutional review board of Addis Ababa University with protocol number (008/24/SPH). The trial results will be published in peer-reviewed international journals and submitted to the study's funders. Verbal and written informed consent will be obtained from all participants. A copy of the consent form is available as a supplementary file. Participants' data will be stored securely and anonymised to protect confidentiality. No adverse events or unintended effects are expected from the study. However, any unsolicited or spontaneously reported concerns related to the intervention will be documented and reviewed. If any participant expresses dissatisfaction or discomfort with the intervention, the issue will be addressed promptly by the research team. The research team will ensure that participants' rights and well-being are protected throughout the study. Any protocol amendments or modifications will be communicated to Institutional Review Board (IRB), trial registries, journals, funders and participants, as relevant.

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**Contributors** ADM, the principal investigator, led the study's conception and execution, as well as the development of the trial protocol. ADM is the guarantor. MG, the primary supervisor, provided an extensive revision of the trial protocol, contributing significantly to conceptualisation and design. SG offered valuable input

during the final protocol review, contributing to both design and execution. MMA, AS, EG and SR contributed to the study methodology and provided comments to the protocol. ESK actively participated in the study conduct and design, providing valuable feedback. AA contributed insights to refining methodology and execution during the final protocol review. EJK, the main supervisor, was involved in the conceptualisation and execution, meticulously reviewing the trial protocol.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design or conduct or reporting or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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