



**PELVIC ORGAN PROLAPSE AMONG WOMEN IN SIDAMA REGION, ETHIOPIA:
PREVALENCE, RISK FACTORS, AND EFFECT OF PELVIC FLOOR MUSCLE
TRAINING**

BY

MELESE SIYOUM DESTA (BSc, MSc)

**A DISSERTATION SUBMITTED TO THE PUBLIC HEALTH ACADAMIC AND
SERVICE DIRECTORATE, COLLEGE OF MEDICINE AND HEALTH SCIENCES,
HAWASSA UNIVERSITY IN PARTIAL FULFILMENT OF THE REQUIREMENTS
FOR THE DEGREE OF DOCTOR OF PHILOSOPY IN PUBLIC HEALTH**

APRIL, 2025

HAWASSA, ETHIOPIA

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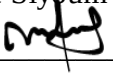
APRIL, 2025

HAWASSA, ETHIOPIA

DECLARATION

I hereby declare that this PhD dissertation is my original work and has not been presented for a degree in any other university, and all sources of materials used for this dissertation have been duly acknowledge.

Name: Melese Siyoun

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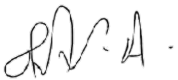
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This is to certify that the dissertation titled “**Pelvic Organ Prolapse among women in Sidama Region, Ethiopia: prevalence, risk factors, and effect of pelvic floor muscle training**” submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy (PhD) with specialization in Public Health, the Graduate Program of the School of Public health, and has been carried out by Melese Siyoum Desta (ID. No. PhD PuHeR/0004/13), under my/our supervision. Therefore, I/we recommend that the student has fulfilled the requirements and hence hereby can submit the dissertation to the school.

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ABBREVIATIONS

APR	Adjusted Prevalence Ratio
BMI	Body Mass Index
CI	Confidence Interval
cRCT	Cluster Randomized Controlled Trial
CONSORT	Consolidated Standards of Reporting Trials
CVI	Content Validity Index
D-W HDSS	Dale-Wonsoho Health and Demographic Surveillance Site
HDSS	Health and Demographic Surveillance System
HEP	Health Extension Program
HSTP I	Health Sector Transformation Plan I
HSTP II	Health Sector Transformation Plan II
ICC	Intra-Class Correlation Coefficient
IQR	Interquartile Range
ICS	International Consistency Society
IUGA	International Urogynecology Association
MEGLM	Mixed-Effects Generalized Linear Models
MoH	Ministry of Health
NICE	National Institute for Health and Care Excellence
NIH	National Institutes of Health
PFMT	Pelvic Floor Muscle Training
POP	Pelvic Organ Prolapse
POP-Q	Pelvic Organ Prolapse Quantification
POP-SS	Pelvic Organ Prolapse Symptom Score
P-QoL	Prolapse-Quality of Life
PROs	Patient-Reported Outcomes
RCT	Randomized Controlled Trial
RH	Reproductive Health
SD	Standard Deviation
S-POP	Simplified Pelvic Organ Prolapse Quantification
VIF	Variance Inflation Factor

SCIENTIFIC ENVIRONMENT

This PhD dissertation is part of the Public Health PhD program led by the Public Health academic and service directorate, College of Medicine and Health Sciences at Hawassa University, Ethiopia. The program comprises coursework modules, which were completed with this research. The key collaborators for this project include the Worldwide Fistula Fund, the University of Minnesota, and Maternal Health, all of whom provided essential financial and logistical support. The Yirgalem Hamlin Fistula Center acted as a referral site for POP cases, offering free services to patients, while selected health centers in the Sidama region facilitated patient examination and recruitment.

My supervisors for this dissertation were Dr. Ayalew Astatkie (Associate Professor at Hawassa University) as the primary supervisor, with co-supervision from Dr. Wondwosen Teklesilasie (Associate Professor at Hawassa University) and Dr. Rahel Nardos (Associate Professor at the University of Minnesota), a urogynecologist specialized in female pelvic medicine and reconstructive surgery. Their combined expertise was instrumental in shaping the research design, execution, and analysis, ensuring that the study adhered to high academic standards while addressing significant public health needs. Dr. Biniyam Sirak, a urogynecologist at Yirgalem Hamlin Fistula Center, provided valuable clinical insights and support throughout the research process. Additionally, Professor Theresa Spitznagle from the Worldwide Fistula Fund offered her expertise in Urogynecology, enhancing the academic rigor of the study through mentorship and guidance on clinical methodologies.

The research was conducted within the Health and Demographic Surveillance System (HDSS) of Hawassa University.

WHAT IS THIS DESSERTATION ABOUT?

This study investigated pelvic organ prolapse (POP) among women in the Sidama National Regional State of Ethiopia, focusing on three primary objectives across three papers. The research is grounded in emphasizing the importance of understanding knowledge through women's subjective experiences and cultural contexts. It recognizes that health issues like POP are not merely clinical conditions but also social phenomena shaped by various factors, including cultural beliefs and access to healthcare. A significant aspect of this approach is the commitment to utilizing locally available resources, such as middle-level health professionals, to enhance healthcare delivery and empower communities.

Paper I centered on the translation and cultural adaptation of the Pelvic Organ Prolapse Symptom Score (POP-SS) into the *Sidaamu Afoo* language. The aim was to evaluate the psychometric properties of the adapted questionnaire among women with symptomatic POP. The original POP-SS, developed in English, consists of seven items that assess various symptoms related to POP. By translating this tool, we ensure it is culturally acceptable and comprehensible for the local population, facilitating accurate assessment and diagnosis.

Paper II aimed to determine the prevalence of POP in the Dale and Wonsho districts, alongside identifying risk factors. This community-based cross-sectional study utilized both subjective and objective measurements to provide a comprehensive understanding of POP prevalence among women in this region and contributing factors. By identifying risk factors, the study informs public health strategies and interventions to reduce POP.

Paper III evaluated the effect of pelvic floor muscle training (PFMT) on alleviating prolapse symptoms and improving quality of life among women diagnosed with symptomatic POP stages I-III. Conducted as a cluster-randomized controlled trial, this study assesses how structured PFMT delivered by trained midwives over six months can enhance women's health outcomes. The findings offer evidence for PFMT as an effective non-invasive intervention for managing POP.

Overall, this research seeks to fill critical gaps in understanding POP in the Sidama region, contributing to improved clinical practices and health outcomes for affected women. By providing culturally appropriate assessment tools, establishing prevalence data, and validating effective

interventions, this research lays a foundation for ongoing public health initiatives aimed at addressing POP. The insights gained from this study will continue to inform healthcare providers, policymakers, and researchers in their efforts to enhance women's health services in Sidama and similar contexts.

Recognizing that POP is a multifaceted issue influenced by both biological factors and social determinants indicates that addressing it requires not only clinical interventions but also consideration of cultural beliefs and access to healthcare. By focusing on using locally available resources such as middle-level health professionals, this study aims to improve accessibility and effectiveness of care for women experiencing POP.

LIST OF ORIGINAL PAPERS

1. Siyoum M, Teklesilasie W, Nardos R, Sirak B, Astatkie A. Reliability and validity of the Sidaamu Afoo version of the pelvic organ prolapse symptom score questionnaire. *BMC Women's Health*. 2023;23(1):324
2. Siyoum M, Nardos R, Teklesilasie W, Astatkie A. Prevalence and risk factors of pelvic organ prolapse among women in Sidama region, Ethiopia: A community-based survey. *Women's Health*. 2024;20:17455057241265078.
3. Siyoum M, Nardos R, Sirak B, Spitznagle T, Teklesilasie W, Astatkie A (2025) Effect of Midwife-Led Pelvic Floor Muscle Training on Prolapse Symptoms and Quality of Life in Women with Pelvic Organ Prolapse in Ethiopia: A Cluster-Randomized Controlled Trial. *PLoS Med* 22(3): e1004468. <https://doi.org/10.1371/journal.pmed.1004468>

ABSTRACT

Background: Pelvic organ prolapse (POP) is a condition characterized by the descent of pelvic vaginal compartment and the surrounding organs. It's impact on a woman's quality of life can be substantial, resulting in psychological distress, social isolation, and physical complications. POP is a prevalent condition affecting millions of women worldwide. Despite its widespread occurrence, the true prevalence remains uncertain due to inconsistencies in diagnostic methods and reporting practices. Pelvic floor muscle training is a recommended first-line treatment for managing POP, but its effectiveness in low-income setting is understudied.

Objectives

This study aimed to enhance the understanding of pelvic organ prolapse symptom assessment, its prevalence and risk factors, and the management of mild to moderate pelvic organ prolapse among women in the Sidama Region, Ethiopia.

Methods

A total of 100 women with symptomatic prolapse completed the POP-SS questionnaire during the first round of interviews, with 61 completing a second round for test-retest reliability assessment. Content validity was evaluated using the content validity index and the construct validity was assessed through exploratory factor analysis. Known group validity was determined using the Kruskal-Wallis test. Internal consistency reliability was assessed using Cronbach's alpha, and test-retest reliability was evaluated using the intraclass correlation coefficient to assess the stability of the questionnaire over time (Paper I).

A community-based cross-sectional survey was conducted in the Dale-Wonsho Health and Demographic Surveillance Site from March to October 2023. A multi-stage stratified cluster sampling method was employed to select a representative sample of 816 women. Anatomical prolapse was diagnosed using the standardized pelvic organ prolapse quantification (POP-Q) method. Symptomatic prolapse was assessed through patient-reported symptoms, allowing for the identification of women experiencing significant discomfort or functional impairment. A complex survey-based modified Poisson regression was used to identify risk factors associated with prolapse (Paper II).

Furthermore, a parallel-groups, two-arm cRCT was conducted in the Dale-Wonsho Health and Demographic Surveillance Site. A total of 187 women with symptomatic POP stages I-III from eight kebeles/clusters were randomized by cluster to receive either midwife-led pelvic floor muscle training plus lifestyle counselling (intervention group) or lifestyle counselling alone (control group). The primary outcomes included changes in prolapse symptom score (POP-SS) and prolapse quality of life (P-QoL). Mixed-effects generalized linear models were utilized to determine the effect of pelvic floor muscle training on prolapse symptoms and prolapse quality of life (Paper III).

Results

The pelvic organ prolapses symptom score questionnaire was successfully translated into *Sidaamu Afoo*, demonstrating good content validity (0.88) and high internal consistency ($\alpha = 0.79$). Test-retest reliability was also strong (ICC = 0.83). Exploratory factor analysis revealed two factors (physical and functional) explaining 70.6% of the variance, with significant loadings for each item. Known group validity showed a significant difference in median prolapse symptom scores across different prolapse stages (Kruskal-Wallis $\chi^2 = 17.5$, $p < 0.001$) (Paper I).

In Paper II, among the 815 women surveyed, 779 (95.6%) underwent pelvic examinations. Anatomical prolapse (stages II-IV) was observed in 241 (30.90%, 95%CI: 24–38.7%) participants. The overall prevalence of symptomatic prolapse in the total sample was 189 (24.27%, (95% CI: 19.98–29.16%). Significant risk factors for anatomical prolapse included higher parity (APR: 1.17; 95%CI: 1.1-1.24), prolonged heavy lifting (APR: 1.26; (95%CI: 1.14-1.4), and prolonged labor (APR: 1.32; 95%CI: 1.1-1.56). Factors associated with symptomatic prolapse included early childbirth (APR for age at first birth < 18 years: 1.29 (95%CI: 1.1-1.52) and prolonged heavy lifting (APR: 1.16 (95%CI: 1.10-1.28).

In the intervention study (Paper III), 187 women were randomized to the intervention (n=86) and control (n=101) groups. At six months, the intervention group showed significantly greater improvements in prolapse symptoms compared to the control group, with a mean change difference of -4.11 (99% CI: -5.38, -2.83). Significant improvements were also observed in the intervention group across various domains of the prolapse quality of life scale: -8.86 (99% CI: -13.84 -3.89) in physical domain; -11.18 (99% CI: -15.03, -7.32) in psychological domain, and -9.01 (99% CI: -10.49 -5.54) in personal relationship domain. A higher proportion (83.72%) of

women in the intervention group perceived their condition as "better" after the intervention, compared to 41.57% in the control group.

Conclusions

The *Sidaamu Afoo* version of the POP-SS tool is valid and reliable for assessing pelvic organ prolapse symptoms. The prevalence of anatomical and symptomatic prolapse is notably high in the Sidama Region, with identified risk factors necessitating community-based education and interventions. Moreover, midwife-led PFMT combined with lifestyle counselling significantly improves symptoms and quality of life in women with mild to moderate POP, highlighting its potential for integration into maternal and reproductive health programs in low-resource settings. In addition, routine screening and campaigns are needed to identify the cases early.

1. INTRODUCTION

1.1. Background

The term "pelvic organ" pertains to the vaginal compartments along with nearby structures such as the bladder, rectum, uterus, cervix, and bowel. Prolapse is defined as the descent or slipping of an organ from its normal position (1). Pelvic Organ Prolapse (POP) is a type of pelvic floor disorder in women, characterized by the descent of one or more vaginal walls, the cervix, uterus, bladder, or rectum into the vaginal canal (2) . The pelvic organs are typically supported by the levator ani muscle and the surrounding connective tissue attachments. However, injury to the levator ani muscle or its nerve supply (the pudendal nerve), as well as damage to the connective tissues, can result in the downward displacement of these organs (3, 4).

Pelvic Organ Prolapse (POP) affects millions of women worldwide, and the prevalence reaches up to 50% when diagnosed through pelvic examination (5). Until the mid-1990s, POP lacked standardized diagnostic definitions. The Pelvic Organ Prolapse Quantification (POP-Q) System, endorsed by the International Continence Society (ICS), the American Urogynecology Society (AUGS), and the Society of Gynecologic Surgeons (SGS), was introduced to provide a standardized method for describing and staging pelvic organ prolapse (6-8) . The POP-Q system objectively measures POP by assessing the support of vaginal segments and staging prolapse from 0 to 4 as follows: Stage 0: Points Aa, Ba, Ap, and Bp are all at -3 cm, while points C and D are at or above total vaginal length (TVL) - 2 cm. Stage I: The criteria for Stage 0 are not met, and the leading edge of the prolapse is more than 1 cm above the hymen. Stage II: The leading edge of the prolapse is positioned between 1 cm above and 1 cm below the hymen. Stage III: The leading edge is more than 1 cm beyond the hymen but less than TVL - 2 cm from the hymen. Stage IV: The leading edge of the prolapse is more than TVL - 2 cm beyond the hymenal remnant (6, 9, 10). However, it focused solely on anatomical changes, which posed challenges in classifying prolapse severity and correlating it with symptoms. Even it was challenging to classify which stage is abnormal.

In 2001, the National Institute of Health (NIH) defined vaginal support as normal only in the complete absence of prolapse (stage 0) and considered any descent as abnormal (11). This

definition, although clinical, was not widely accepted due to the lack of large epidemiological studies correlating prolapse symptoms with anatomical changes (2, 11).

The POP-Q system offers specificity and objective quantification of prolapse, making it a valuable tool in clinical assessments. However, its complexity led to the development of a simplified version, known as S-POP, in 2006. The S-POP system uses fewer measurement points while still maintaining the ordinal POP-Q stages, providing a more streamlined approach to prolapse evaluation (9, 12) .

By 2010, increased knowledge about POP led to recommendations that the definition should consider symptoms in addition to anatomical changes (2). As a result, the International Urogynecology Association (IUGA) and the International Continence Society (ICS) defined POP as the descent of one or more structures, including the anterior vaginal wall, posterior vaginal wall, uterus, or vaginal vault, in conjunction with relevant symptoms (13). They developed a document that encompasses all required elements for a diagnosis-like symptoms, signs, clinical assessment, functional investigation of POP, imaging investigations, terminology for conservative and surgical management. They recommended an interval review (5-10 years) to keep the document updated and widely acceptable (1).

Older terms like cystocele, rectocele, uterocele, and enterocele are currently considered meaningless because they describe the protruding organ behind the affected structure of vaginal support. The current definition preferred to characterize the site affected as anterior prolapse, posterior or apical (3, 13). Pelvic Organ Prolapse can be asymptomatic, but common symptoms include a sensation of something descending from the vagina, vaginal discomfort, and a feeling of heaviness in the lower abdomen. Other symptoms may involve difficulty emptying the bladder or bowels. Symptoms often worsen with standing or physical activity (14). Management options range from conservative treatments, such as lifestyle modifications, pessary use, and pelvic floor muscle training, to surgical interventions (1, 13, 15, 16) .

1.2. Problem Statement

Pelvic organ prolapse is a common condition that affects women of all ages and parity (17) but establishing its exact prevalence is challenging due to variations in diagnostic methods and criteria (3, 4, 8) . Objectively, POP affects up to 65% of women worldwide (18, 19) with higher risks in

low- and middle-income countries . Risk factors for POP include both non-modifiable (family history, ethnicity, older age) (20, 21) and modifiable factors such as obesity, underweight, heavy lifting, chronic medical problems (like diabetes mellitus, chronic cough, constipation), parity, mode of delivery) risk factors have been identified (1, 13, 15, 16) .

Even though mortality is uncommon in POP, it often coexists with other pelvic floor disorders, significantly impacting women's quality of life. Studies indicate high co-occurrence with overactive bladder in 50%, stress urinary incontinence, and fecal incontinence (22, 23) . Similarly, hydronephrosis was observed in 3.5% to 30.6% of cases (24). POP has also a psychological impact in which women suffer from depression (25, 26). Stigma and discrimination due to POP were reported to result in a psychological burst (27, 28). POP can lead to a vaginal bulge, difficulties with urination, and sexual dysfunction, all of which negatively impact quality of life (3, 29). The relationship status and sexual desire might not improve even by surgery (30, 31).

If POP is left untreated, can lead to several complications. These include erosion of prolapse tissues, procidentia, and vaginal perforation with evisceration (32, 33). Procidentia is a severe form of prolapse where the uterus or other organs protrude significantly from the vagina. Additionally, untreated prolapse can result in urinary and fecal incontinence, urinary tract infections, and kidney damage due to obstruction of urine flow. Sores on the cervix and an increased risk of infections are also possible complications (23) .

Moreover, sometimes the treatment of POP by itself, especially surgical interventions, can also have complications. Infection is a common risk with any surgical procedure (3, 34). Other possible side effects include irritation and bleeding, pain, including pain during sexual intercourse (dyspareunia), and ulceration. Although rare, mesh erosion can occur, leading to additional complications. Furthermore, there is a risk of recurrence after surgery, which contributes to the overall failure rate of treatment (30, 31).

Women with POP often delay seeking treatment due to embarrassment, stigma, and fear of discrimination (27). Even in developed countries, women are ashamed of disclosing POP even to

a health professional and suffer from the problem (35). In low-income countries, delays in seeking treatment are common, even for severe prolapse (21, 36, 37).

In Ethiopia, Previous studies have indicated that the prevalence of POP ranges from 1% to 56.3%, depending on the diagnostic methods and study settings (38, 39). Most prior research has been conducted in health facility settings (36, 37, 40) , and the others were conducted using the symptomatic approach for POP diagnosis (38). Both approaches have a high probability of underestimating the prevalence of POP. A study from Dabat district, northern Ethiopia (39), deserves acknowledgment for revealing the difference in the prevalence of POP when diagnosed by symptom score (28%) and thorough pelvic examination (56.3%). However, it used the simplified techniques (i.e. not the standard POP-Q) to quantify degree of prolapse. In addition to the universally identified risk factors, there are additional risk factors that are expected to increase the prevalence of POP. Women in Ethiopia are prone to a high number of vaginal deliveries, early marriage and early childbirth, heavy lifting/carrying, and low body mass index (BMI) (39-42) .

Evidence from high-income countries shows that pelvic floor muscle exercises can alleviate symptoms of pelvic organ prolapse and enhance health-related quality of life (43-45) . However, there is a lack of evidence from low-income countries including Ethiopia. The Ethiopian Reproductive health Strategy clearly stated that the prevalence of POP remains high in Ethiopia and low-income countries that needs comprehensive strategy to be addressed (46). In addition, while diagnosing and monitoring treatment outcome needs valid tool both for clinical and research purposes, we did not get published Sidaamu Afoo version of POP-SS.

The difficulties in accurately diagnosing and measuring the prevalence of Pelvic Organ Prolapse (POP), along with cultural stigma, a lack of validated assessment tools, and the recommendation to manage every women at general hospital, highlight the urgent need for comprehensive research in this field. Moreover, the effectiveness of PFMT can vary significantly based on cultural beliefs, healthcare access, lifestyle and social support systems (47).

This thesis aims to fill these critical gaps by locally adapting and validating a questionnaire to assess POP symptoms, determining prevalence using standardized measurements, and evaluating the effectiveness of pelvic floor muscle exercises in alleviating prolapse symptoms and improving

quality of life. By focusing on these objectives, this research aspires to provide valuable insights into the epidemiology of POP and inform future interventions that can enhance women's health outcomes in the region.

2. LITERATURE REVIEW

2.1. Prevalence of Pelvic Organ Prolapse

Determining the population prevalence of Pelvic Organ Prolapse (POP) is quite challenging, as it varies significantly depending on the diagnostic methods used and the characteristics of the study population (48). In general, a review of the literature shows that anterior prolapse is two times more common than posterior prolapse and three times common than apical prolapse (3, 21). Most women with POP are asymptomatic and the actual prevalence may differ when diagnosed by symptom (patient self-report) and thorough pelvic examination (4, 5, 49). For instance, systematic reviews and meta-analyses reveal varying pooled prevalence (18, 19). A systematic review published by the International Urogynecology Consultation Committee in 2022 indicated that the reported prevalence of POP varies significantly, ranging from 1% to 65%. This variation depends on whether the diagnosis is based on symptoms (1% to 31%), pelvic examination (10% to 50%), or a combination of both methods (20% to 65%) (19). But another systematic review and meta-analysis published in 2024, show that the worldwide prevalence of POP was 25% when determined by symptoms and 41.8% on pelvic examination (18). This shows that the existing evidence varies widely. It was noted that most existing population-based surveys lack physical examination data, and that white women from higher-income countries are disproportionately represented in the current literature (19).

In Netherland, a study that assessed the entire population of a small town reported that 40% of women aged 45 to 85 years had POP stage II and above on pelvic examination, but only 12% of them were symptomatic (50). Similarly, a community-based study in East Lebanon shows that 49.8% of women aged 15-60 years had stage $\geq$ II POP (51). Prolapse stage $\geq$ II was detected in 27.1% of general female population (52), and among 29.5% of women in the United Arab Emirates (53). In Maryland, among women older than 40 years and appointed for surgery, POP beyond the

hymen was observed in 24.8% of cases (54). Different studies in China show that the prevalence of symptomatic POP (confirmed stage II and above) was 9.1% (55) among rural women who complain symptoms, 15.8% (56) among obese women and 9.6% among adult women (57). These results may be underestimates since non-symptomatic cases were not examined (55). A narrative review on POP prevalence and diagnosis concludes that many women suffering from POP may remain undiagnosed may not seek medical attention for various reasons (8).

In low-income settings, the prevalence of POP is higher due to presence of additional risk factors. A review of different literature from 16 low and middle-income countries reported that the mean prevalence of POP is 19.7% which ranges from 3.4 to 56.4% (58). Another review of POP in low-resource countries published in 2023 concluded that POP predominantly affects younger women in these settings (59). In a rural community in the Gambia, among women who underwent pelvic examinations, 46% had prolapse stage >I, yet only 13% of those with moderate to severe prolapse reported experiencing symptoms (60). A varying prevalence was reported by different studies. For example, the reported prevalence in Nepal ranges from 8% (61) to 60.9% (62), in Tanzania 64.6% (63), Brazil 52.3% (20), Pakistan 10.3% (21), and Bangladesh 15.6% (64).

In Ethiopia, the prevalence of POP ranges from 1% to 56.3%, depending on the diagnostic methods employed and the study settings. Based on the symptomatic approach, POP was diagnosed among 1% -28% of women. However, pelvic examination of the same population showed that 56.3% of them have at least stage II prolapses (38, 39, 42, 65).

2.2. Factors Associated with Pelvic Organ Prolapse

To date, various studies have identified a range of risk factors associated with the development of POP. These factors are linked to either the weakening of collagen (connective tissue) or damage to the levator ani muscle and its nerve supply. Defects in the collagen and levator-ani muscle are important etiologic factors for the development of POP (8, 66-68) . While all literature agrees on some risk factors like the risk of old age and vaginal birth, there are also contradicting findings on the role of certain factors like physical activity, body mass index, hysterectomy, and race/ethnicity. The findings of various literature were presented as follows.

2.2.1. Sociodemographic and economic risk factors

Age: Aging is one of the most frequently cited risk factors for POP. The impact of age on POP is thought to result from a combination of physiological aging, decreased estrogen levels, and age-related degenerative diseases. Consequently, aging plays a complex role in the development of organ prolapse (23, 66, 69, 70) . Two community-based studies from China show that there is a consistent increase in POP prevalence with increasing age. Compared to 20-29-year-old women, the risk increases almost by two fold for those older than 50 years (55). and more than fourfold for those older than 70 years (56). A community-based study from East Lebanon also shows that POP prevalence dramatically increases with age which reaches up to 75% among 50-59 years women and become plateau phase after that (51). A similar study from Brazil and Pakistan also reported that age 35 years or older increases the risk of POP almost six-fold (20, 21).

In Ethiopia, three studies from the northern part of Ethiopia and two systematic review and meta-analysis studies also confirmed that age greater than 40 years were significantly associated with POP (39, 40, 42). In general, several studies that assess the association of age with POP agree that the risk of POP increase with age.

Level of education: Community-based studies from Turkey and Ethiopia have demonstrated that a lack of formal education is significantly associated with a higher prevalence of POP (71, 72) . This might be due to the high probability of homebirth and increased number of vaginal births among uneducated females (73).

Ethnicity/race: Studies that compared different ethnic groups reported that the risk of POP differs across ethnic groups. A prospective study from Netherland and China that compared prolapse stages reported that apical prolapse is common in China whereas anterior prolapse is common in Caucasians (74). This study showed that ethnicity was a significant predictor of type of prolapse on multivariate analysis. Studies from America that compared white and black women reported that white women are more suffer from POP than black women (75-77) . It is justified that black women commonly have a narrow pubic arch that is protective against POP compared to the gynecoid pelvis (69, 70). However, two studies from Uganda and South Africa show that black women developed more POP than Caucasian women (78, 79). This discrepancy indicates the need for further studies. A community-based study from rural Gambia showed that Wolof ethnicity was

more at risk of POP compared to Mandinka ethnic group (60). This was explained as it is pointing to genetic factor or cultural factor. In Ethiopia, evidence about the effect of ethnicity is not report

2.2.2. Obstetrics and gynecologic risk factors

Vaginal delivery: Similar to aging, vaginal delivery is the commonest risk factor of POP, for which the mechanism of action is identified. Ultrasound-assisted investigations show that during vaginal delivery, direct and indirect injury to the pelvic muscle by compression of the fetal part and neurologic injury from over-stretching of the pudendal nerve is common (3, 8, 70) . In Maryland, a large cohort of women who gave birth showed that vaginal delivery carries a risk compared to cesarean delivery (80). A systematic review and meta-analysis that assess the association between mode of delivery and POP in 2018, showed that vaginal delivery has an higher risk of POP compared to cesarean delivery (81). There are also similar findings from community-based studies from China and Brazil (55, 56, 82) . In general, large-scale cross-sectional studies, and systematic review and meta-analysis studies showed that vaginal delivery has the strongest association with POP as compared to cesarean delivery (82, 83). Studies conducted in Ethiopia were more focused on the effect of parity than the mode of delivery (39, 71) .

Number of childbirth (parity): Several studies were reported that parity was a risk for POP. Community-based studies from China, Lebanon, and Sweden reported that the risk of POP increased at least twice with parity (51, 84) . However, a retrospective review of 1,746 women from Sydney published in 2020 shows that even though vaginal birth affect POP, the number of birth did not associate with POP (49). Studies from developing countries like Nigeria and Ethiopia (where high parity is common) show that POP is associated with high parity (40, 85, 86) .

Forceps Assisted delivery: Forceps-assisted deliveries were associated with POP compared to spontaneous vaginal delivery. Community-based cohort studies from Maryland and Swedish (from 2005-2015), show that the risk of developing POP and the need for surgery is increased among women assisted with forceps compared to those not assisted with forceps (80, 81, 87) . A systematic review and Meta-analysis published by 2021 also reported that forceps delivery is a risk for symptomatic POP (83). Evidence about the effect of instrumental delivery on POP is scarce in Ethiopia.

Prolonged labor: Prolonged and obstructed labor were identified to increase the risk of POP (15). Institution-based studies from Nigeria and Hospitals of the Amhara region, Ethiopia reported that prolonged labor was significantly associated with POP (40, 85).

Homebirth: A study conducted in Nigeria found that unsupervised home deliveries were the most significant predisposing factor for POP (88). Similar evidence was reported from Tanzania (63) and Ethiopia (89) where POP was associated with home delivery. Perineal support from a skilled birth attendant during childbirth is essential for preventing lacerations or tears in the perineum, which are more likely to occur during home deliveries (90). This increased risk may be due to the likelihood of prolonged labor and perineal trauma associated with unsupervised home births.

Age at first delivery: A study conducted in Amhara referral hospitals among patients visiting gynecology clinics found that having a first delivery before the age of 20 is significantly associated with an increased risk of POP (40). Similarly, a prospective study in a tertiary care hospital in northern India showed that early marriage and early pregnancy were associated with POP (91)

Menopause: While the effect of menopause is related to aging, studies have shown that there is a direct relationship between menopause and increased risk of POP irrespective of age and parity. The hormonal change during menopause causes a drop in estrogen hormone and affects the strength of collagen (8, 92). A retrospective study from Nigeria shows a strong association between POP and menopause (85). In Ethiopia, one study conducted in the Gurage zone showed that menopause was associated with pelvic floor disorder (93). However, there is no adequate report specifically on the association of menopause and POP.

Hysterectomy: History of pelvic surgery, especially hysterectomy, was found to risk one of vaginal compartment prolapse. A nationwide study conducted in Denmark revealed that undergoing a hysterectomy, regardless of the surgical approach, is associated with a heightened risk of requiring POP surgery, particularly in the posterior compartment (94-96). The researchers advised that women should be fully informed about the risks of POP and that alternative treatment options should be explored before deciding on a hysterectomy (94). It was evidenced that intraoperative damage to connective tissues, blood supply, and nerves was found to increase central compartment prolapse (8). A follow-up study of women who underwent surgery from 2015-17 in Mekelle, Ethiopia, showed that vaginal repair has an anatomical failure in 34% and symptomatic recurrence in 23% (34).

2.2.3. Lifestyle factors

Carrying heavy objectives: An online survey data collected from 3,934 women, compared the symptom of POP among women categorized by the amount of weight lifting for exercise (<15Kg, 16 –50kg, >50 kg, and inactive women). The proportion of women with symptoms is 7% in a heavy lifting group (>50kg) and 21% among inactive groups (82). Another study conducted among nulliparous women with at least 6-months history of weight lifting reported a relatively low prevalence of POP (97). However, studies from low-income countries and rural China shows that POP is more prevalent among women who perform physical labor (21, 39, 55). One community-based study from Tanzania and two studies (institution-based) from Ethiopia show that carrying heavy objectives for more than five hours was a significant risk factor for POP (40, 63). Even a two-hour daily carrying heavy objective was associated with POP (39).

Obesity: Studies from developed countries show that obesity and overweight were associated with POP. The possible way in which obesity risks to POP is maybe through increasing intra-abdominal pressure (70, 98). Two systematic reviews and meta-analyses of papers from developed countries show that a higher BMI > 24kg/m² was a significant risk factor for primary POP (16, 99). A community-based study from East Lebanon and China also shows that a higher BMI remains a significant risk factor for POP (51, 55). In contrast to the above findings, studies from Democratic Republic of Congo (100) and Ethiopia show that lower BMI(< 18kg/m²) was associated with POP (42, 71). It was justified that chronic under-nutrition may cause poor tissue tensile strength (58). Two recently published systematic review and meta-analysis studies reported that there was no association between POP and BMI (86, 101).

2.2.4. Family history of pelvic organ prolapses (genetic predisposition)

Genetic predisposition may aggravate or impact POP development as the strength of collagen (the main component of connective tissue) that supports pelvic fascia is determined by genetic factors (8). However, there is limited evidence on the role of gene in causing POP. A systematic review and meta-analysis revealed that the existing evidence is primarily based on small sample sizes and is often of low quality(102). Additionally, the genetic contributions to POP are not well understood, indicating that further research is needed to clarify the role of genetics in the pathogenesis of POP (103).

In developed countries, the association between family history and POP was well researched. A population-based study that involved 4628 women diagnosed with POP and their families shows that the risk of developing POP is increasing with the number of family histories affected by POP. History of at least one first-degree relative has increased the risk of POP by two fold, and history of two first-degree relatives increased the risk more than threefold (104). One systematic review and meta-analysis also show that on average, a positive family history of POP increases the risk threefold (105). This is similar to a case-control study that revealed a family history of prolapse has remained associated with advanced prolapse (106). Another study that assessed family history of POP among women who underwent gynecological surgery shows that family history has increased the risk (107). A case-control study from Bahir-Dar also reported that a family history of POP was associated with POP (71).

2.2.5. Medical history

Constipation: Reports from China, Korea, Nigeria, and Ethiopia show a significant association between POP and constipation (56, 71, 85) . However, one observational study and systematic review of papers from developed countries show that there is no association (16, 76). This indicates inconsistencies in the existing literature.

Chronic cough: Studies from rural China and Nigeria reported that chronic cough (>3weeks) was associated with symptomatic POP (55, 85). Intra-abdominal pressure caused by chronic cough and constipation causes excessive strain on the pelvic structure including the pudendal nerve (8, 56).

Diabetes mellitus: Systematic review and meta-analysis of papers from developed countries only, and retrospective study of managed cases at Turkey tertiary hospitals show that diabetes mellitus was a risk factor for POP (16, 108). If there are co-morbidities like diabetes mellitus, there will be poor tissue features through neuropathy and genetic factors that predispose to POP (8, 56). Reports on the effect of chronic medical cases are scarce from Ethiopia.

2.3. Impact of POP on Health-Related Quality of Life

Quality of life (QoL) refers to an individual's perception of their position in life in the context of the culture and value systems in which they live, relative to their goals, expectations, standards, and concerns (109). In healthcare, HRQoL specifically focuses on how health conditions affect a person's ability to live a fulfilling life, encompassing physical, psychological, and social

functioning (110). Pelvic Organ Prolapse is a multifaceted condition that encompasses both physical and functional aspects (111). Consequently, POP can significantly affect the quality of life and psychological well-being of the women it impacts. In fact, prolapse can lead to various urinary, bowel, and sexual disorders, all of which can adversely affect a patient's quality of life. Sexual dysfunctions, in particular, are quite common among women with POP (111). POP patients usually complain problems with sexual desire, arousal, orgasm, and pain, which can lower their quality of life and negatively impact their relationships (31). Social, physical, and psychological constraints caused by POP may have an impact on a patient's interpersonal connections also (112, 113). A study involving 3,114 middle-aged women (ages 50 to 61) found that the presence of POP symptoms was associated with lower quality of life scores across all health domains, including physical mobility, pain, emotional well-being, social isolation, energy levels, and sleep (114). Other similar studies have also reported that POP leads to physical, social, psychological, occupational, household, and sexual limitations in women, resulting in significant symptomatic distress and a diminished quality of life (112, 114). Rural women with POP frequently face divorce due to social stigma and a reluctance to discuss their challenges, particularly regarding daily activities such as childcare, cooking, fetching water, and farming (58, 115). Studies from Ethiopia have indicated that POP significantly impacts women's health-related quality of life, leading to issues such as social rejection, divorce, loss of self-esteem, depression, restlessness, sleep disturbances, and increased susceptibility to reproductive and urinary tract infections (116-118).

Moreover, the primary objective of treatment should be to enhance health-related quality of life by alleviating these symptoms. To create more effective treatment plans, it is crucial to assess the severity of prolapse symptoms and their impact on quality of life (119). Consequently, a thorough clinical evaluation that includes comprehensive history-taking and a pelvic examination is essential for assessing a woman with POP-related symptoms. This evaluation helps determine the effects on her quality of life and guides therapeutic management (120).

2.4. Management options for POP

Pelvic Organ Prolapse management encompasses both conservative and surgical approaches. There is no consensus on a gold-standard treatment due to differences in subjective and objective success rates, therapy-related adverse events, and potential long-term complications (121, 122). Conservative management is often prioritized initially (121, 123), which may be less appealing to

some women due to their perceived inconvenience and slow progress. Recent clinical guidelines recommend that treatment should be provided only to patients with symptomatic prolapse or those with specific medical indications (124, 125). The choice of therapy depends on factors such as patient expectations, symptom severity, quality of life impact, prolapse type and grade, recurrence risk, and potential postoperative complications (125).

2.4.1. Surgical management

Surgical options have evolved with emerging evidence supporting or challenging existing methods (126). Procedures for apical defects include sacrospinous ligament fixation, uterosacral ligament suspension, McCall's culdoplasty, transvaginal mesh, and sacral colpopexy (127). For anterior vaginal wall prolapse, options include paravaginal repair, anterior colporrhaphy, and combined repairs for central and lateral defects (128). Posterior wall defect repairs include midline plication, site-specific techniques, graft/mesh augmentation, trans-anal repair, and sacral colpopexy (129, 130).

While mesh use in anterior and posterior compartment repairs yields good outcomes, it is often abandoned due to high complication rates (131). Obliterative procedures, with higher success rates, are recommended for elderly, medically compromised, or non-sexually active women (132). Sacrospinous ligament suspension has a lower anatomical recurrence rate compared to vaginal hysterectomy with uterosacral ligament suspension (133). Sacrocolpopexy and sacrospinous ligament fixation (SSLF) are effective for apical defects, with sacrocolpopexy providing better anatomical durability and sexual function but higher complication rates, making SSLF a more cost-effective option (134, 135). Colpocleisis, preferred for elderly and non-sexually active women, offers faster recovery, lower morbidity, and higher success rates than vaginal hysterectomy (136). Performing hysterectomy during colpocleisis increases operative time without additional benefits (137). Laparoscopic sacrocolpopexy, though luxurious for low-resource settings, offers better recovery and lower blood loss than open procedures (138). Modified abdominal high uterosacral colpo/hysteropexy, practiced in Ethiopia, is a safe and effective apical prolapse treatment (139).

In developing countries, women seek treatment at an advanced stage of prolapse and are usually managed surgically (21, 37, 85) . Surgical interventions are categorized as reconstructive or obliterative, with obliterative procedures for elderly women who do not desire future fertility. The

procedure includes removal of the descended vaginal compartment and closing of the vagina (the uterus may or may not be removed). Reconstructive surgeries aim to restore normal pelvic anatomy, often involving paravaginal repair and vaginal vault suspension (13, 34). The increasing preference for uterine preservation complicates POP surgery (126). While surgeries can alleviate physical symptoms, they may not improve relationship dynamics or sexual desire (30).

In Ethiopia, among POP surgeries the common surgeries include anterior colporrhaphy (98.6%), vaginal hysterectomy with McCall's culdoplasty (51.8%), and posterior colporrhaphy (97.5%). The scarcity of skills and materials limits the performance of sacrocolpopexy, sacrospinous ligament fixation, and site-specific posterior repair (140). Despite being prevalent, vaginal repair has significant anatomical and symptomatic recurrence rates. Intraoperative damage to connective tissues, blood supply, and nerves was found to increase central compartment prolapse (8). A follow-up study in Mekelle, Ethiopia, indicated a 34% anatomical failure and 23% symptomatic recurrence rate post-vaginal repair (34).

The International Urogynecology Consultation recommends defining surgical success as the absence of bothersome bulge symptoms or the need for retreatment for POP, with a follow-up period of at least 12 months for research purposes. Secondary outcomes like anatomical measures and related pelvic floor symptoms should not determine success. Clinically, success is defined as the absence of bothersome bulge symptoms (141).

2.4.2. Conservative Management

Non-surgical therapies like pessaries, pelvic floor muscle training (PFMT), and lifestyle modifications can relieve symptoms and aid in weight loss for obese individuals. However, severe prolapse cases often require surgical intervention.

A. **Pessary:** is a device inserted into the vagina to support the descending vaginal compartment (13, 142). While it is effective in managing mild degree prolapse, there are risks of infection and irritation. The use of pessary is not well implemented in Ethiopia (except the one under feasibility study in Bahir Dar).

B. Pelvic floor muscle training (PFMT)

Pelvic Floor Muscle Training (PFMT) is a set of exercises aimed at improving the strength, endurance, power, and relaxation of the pelvic floor muscles, either individually or in combination (143). PFMT has been proven effective in relieving POP symptoms and improving pelvic floor strength, coordination and endurance. However, evidence from low-income countries is lacking. Trials from western countries show significant symptom improvement and quality of life enhancement with PFMT.

A review of two trials indicated a 17% improvement in prolapse symptoms compared to control groups (142). A randomized controlled trial on women aged 55 and older with mild symptoms showed a 57% improvement in the PFMT group compared to 13% in control groups (45). A systematic review of 13 studies involving 2,340 patients reported a mean difference of -3.07 (95%CI: -3.91 to -2.23) in prolapse symptom scores favouring the PFMT group (144).

PFMT has also been shown to improve sexual function. A study among 109 Scandinavian-speaking women with POP stages I-III indicated that 39% of women who received lifestyle advice and PFMT reported improved sexual function, compared to 5% who received lifestyle advice only (145). Another multicenter randomized controlled trial across the United Kingdom, New Zealand, and Australia found significantly fewer prolapse symptoms in intervention groups after 16 weeks of individualized pelvic muscle training (43).

There are, however, contradicting findings on the effect of PFMT on improving the prolapse stage. A randomized controlled trial in Norway involving 109 women shows that PFMT improved at least one POP-Q stage in 19% of participants (146). Similarly, a review of 11 RCTs concluded that PFMT is effective in improving POP stage in women with POP-Q stage I-III (19). However, other controlled trials reported that there was no change in the prolapsed stage (43, 147). Other studies reported that the effect of physical exercise on pelvic floor muscle strength is controversial and needs an adequate sample size for generalization (147, 148).

Quality of life is a crucial outcome in evaluating POP treatments. Several researches have investigated the impact of various treatments by assessing quality of life (142, 149). An assessor-blinded pilot study on 29 POP patients for 16 weeks showed dramatic improvements in symptoms like stress urinary incontinence, frequency, post-micturition dribbling, and bowel obstruction,

leading to better overall health and quality of life (150). Two randomized controlled trials also showed that PFMT significantly improved bowel-related quality of life (151, 152).

PFMT is a cost-effective intervention for managing POP and has been recommended as a first-line treatment in the recently updated guidelines from the National Institute for Health and Care Excellence (NICE) (153). Evidence suggests mechanisms by which PFMT may be effective in both preventing and treating POP (154, 155). PFMT is a multimodal intervention that includes education, muscle strengthening, and posture work to optimize pelvic floor function and support. The primary goals are to reduce symptoms, slow disease progression, and improve quality of life.

Despite the proven benefits of PFMT, there is a need for more evidence from low-income countries to confirm its feasibility and effectiveness. In addition, there is a shortage of urogynecologist and other specialists trained to deliver PFMT, which limits access to this treatment specially in low-resource settings. Studies have shown that primary care nurses are in an ideal position to provide PFMT, as they have frequent contact with women (156, 157). While these findings are from developed countries, there is a lack of evidence from Ethiopia and other low-income countries as well.

2.5. Conceptual Framework

Drawing from the findings presented in the literature, the following conceptual framework has been developed (Figure 1). This framework illustrates how various risk factors contribute to POP either by directly damaging the pelvic muscles (including the levator ani muscle and its nerve supply) or by leading to a weakening of collagen to weaken (39, 51, 63, 71, 78, 93, 99, 103, 104, 158).

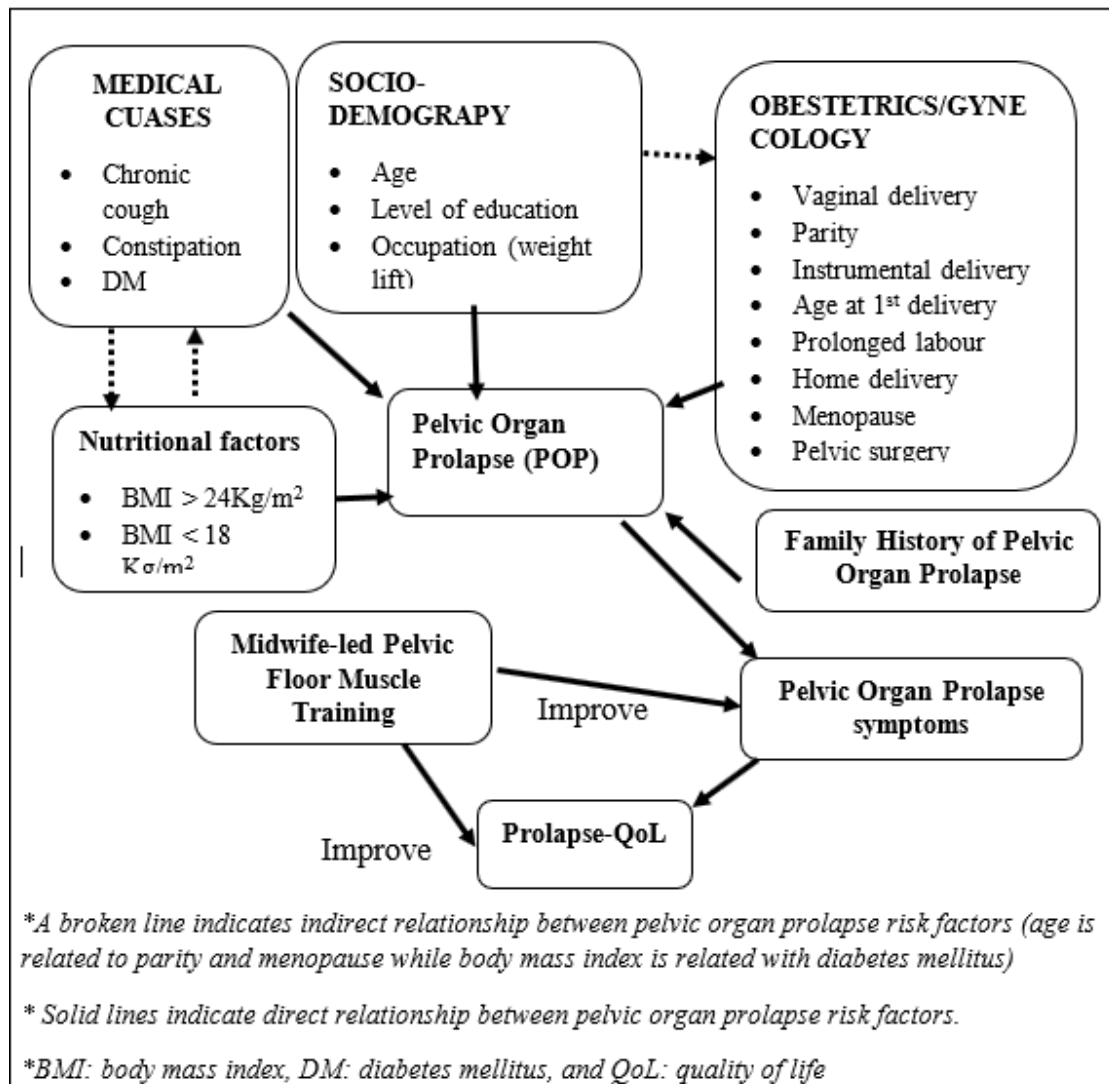


Figure 1: Conceptual framework indicating risk factors and impacts of pelvic organ prolapse. Compiled from related literature, 2022

2.6. Ethiopia's Healthcare Delivery System

Ethiopia's healthcare system is structured into three tiers: primary healthcare units, general hospitals, and tertiary hospitals. The primary healthcare unit (PHCU) consists of health posts, health centers, and primary hospitals. Each health center is linked to five satellite health posts, collectively serving approximately 25,000 people. The Health Extension Program (HEP) optimizes these health posts, categorizing them into comprehensive and basic types. Comprehensive health posts are staffed by health extension workers (HEWs), nurses, midwives, and other professionals, offering a wider range of services. Basic health posts, primarily staffed by

HEWs, focus on preventive and health promotion services, treating conditions such as malaria, pneumonia, and scabies, and referring patients to health centers for higher-level care (159).

Health centers provide both preventive and curative services and act as referral centers and training sites for HEWs. Primary hospitals provide service to about 100,000 people, offering inpatient and ambulatory care, including emergency surgeries. General hospitals serve an average population of 1 million, functioning as referral centers for primary hospitals and training facilities for health officers and nurses. The tertiary level consists of specialized hospitals serving approximately 5 million people, also acting as referral centers for general hospitals (159).

Ethiopia has made significant strides through the Health Sector Transformation Plan (HSTP-I), which run from 2015/16 to 2019/20 (160, 161). This plan led to increased access to healthcare services, with the primary health infrastructure expanding to cover over 90% of the population by 2019. The HEP has notably contributed to improved health indicators, with outpatient attendance rising from 0.27 to 0.9 per capital per year between 2000 and 2019 (162). The country achieved substantial reductions in under-five mortality, maternal mortality, and new HIV infections, attributed to comprehensive health strategies and multisectoral approaches (163).

Despite these successes, health service utilization remains low, particularly among rural populations and socioeconomically disadvantaged groups (164, 165). Barriers include misconceptions about disease, cultural beliefs, poor client satisfaction, and inadequate access to services (159). Health indicators vary significantly based on region, residence, gender, and socioeconomic status, with urban and wealthier populations generally experiencing better health outcomes (166).

The second Health Sector Transformation Plan (HSTP II) is Ethiopia's strategic health plan for the fiscal years 2020/21 to 2024/25 (159). Its primary goal is to enhance the health of the population by accelerating progress toward Universal Health Coverage (UHC), safeguarding individuals during health emergencies, transforming local health systems (woredas), and ensuring the health system is responsive to the needs and expectations of the community. HSTP II aligns with Ethiopia's ten-year development plan and international commitments, including the Sustainable Development Goals (SDGs), setting ambitious yet realistic targets to measure progress (159).

HSTP II outlines 14 strategic directions that encompass major initiatives for the five-year period. The plan focuses on universal health coverage, aiming to provide equitable access to health services; emergency preparedness, protecting populations during health crises; woreda/district transformation, enhancing local health systems to improve service delivery; and health system responsiveness, ensuring the health system meets the expectations of the population (159).

The Ministry of Health (MoH) oversees seven agencies responsible for implementing health-related activities: the Ethiopian Public Health Institute (EPHI), which conducts public health research and emergency management; the Armauer Hansen Research Institute (AHRI), which focuses on biomedical research and capacity building; the HIV/AIDS Prevention and Control Office (HAPCO), which coordinates HIV prevention efforts; the Ethiopian Health Insurance Agency (EHIA), which develops the health insurance system; the Ethiopian Food and Drug Authority (EFDA), which regulates health product safety and quality; the Ethiopian Pharmaceuticals Supply Agency (EPSA), which ensures the supply of quality pharmaceuticals; and the National Blood Bank, which manages blood and blood product availability (159, 167).

The overarching mission of HSTP II is to promote the health and well-being of the Ethiopian population through comprehensive health services. The goals include improving quality of life by enhancing health service accessibility and affordability, and promoting comprehensive care by integrating health promotion, disease prevention, and rehabilitative services across all levels of care (168).

2.6.1. Revised Health Policy (2024)

In conjunction with HSTP II, Ethiopia revised its national health policy to address emerging health challenges and align with socio-economic development goals (167). Key components of the revised policy include a mission to provide and regulate a comprehensive range of health services through a decentralized system, goals to ensure equitable and quality health services for all citizens, and guiding principles emphasizing a primary health care approach that includes all aspects of health care. The revised policy reflects a critical assessment of health challenges and aims to empower communities, ensuring that health services are tailored to local needs while promoting collaboration among health professionals and stakeholders.

Overall, HSTP II represents a significant commitment by Ethiopia to improve health outcomes and address the diverse health needs of its population, leveraging a comprehensive and inclusive approach to health system strengthening.

2.6.2. Reproductive Health Strategy and Pelvic Organ Prolapse (POP)

Ethiopia's third Reproductive Health (RH) Strategy, designed to align with the Health Sector Transformation Plan II (HSTP-II) and the national health policy, aims to enhance the reproductive health status of women, families, newborns, adolescents, and youth. This strategy, which spans the years 2021 to 2025, is grounded in a comprehensive situational analysis of the country's reproductive health performance (46).

A key component of this strategy is its acknowledgment of the knowledge and care gaps related to POP. The strategy notes that "little is known about the prevalence of POP among women in low- and middle-income countries". As a result, POP has been included in to the strategic directions of the RH strategy with specific aims: Enhancing the capacity of health facilities at all levels to identify and refer women with symptomatic POP for appropriate care, introducing comprehensive strategies to prevent the onset of POP, with a focus on education and community awareness; and mandating general hospitals to treat all symptomatic cases of POP, ensuring timely and effective care for affected women (46). These initiatives represent a critical step forward in addressing POP and ensuring that reproductive health services in Ethiopia are comprehensive, inclusive, and responsive to the needs of all women.

2.7. Significance of the study

Understanding the epidemiology of POP holds both clinical and public health importance.

2.7.1. Public Health Importance

Pelvic organ prolapse has significant public health importance as it decreases the quality of life, increase the use of health care resource and decrease productivity (51). It is an important public health issue that needs to be a focus of primary prevention (169). As a result of lifestyle modification, it is expected that the number of elderly populations will increase from time to time, and the POP will become more prevalent shortly and increase economic and public health

burden (5, 7, 8). The increase in life expectancy and improved quality of life increase both the prevalence of disease and the number of treatment-seeking women (8).

To allocate resources to women with POP, an understanding of its incidence/prevalence, risk factors, and clinical implication, natural history, and treatment options is needed to treat and develop preventive strategies. Identifying modifiable risk factors may help for patient counselling and prevention in patients at risk (7). Even it was suggested that since the risk of developing POP is different across settings, the approach to risk factor modification and prevention should also differ (76). So that, to develop the best and most- effective preventive and therapeutic strategies, the prevalence and risk factors at the community level should be defined (51).

The impact of POP extends beyond individual patients to their families and communities. Improved management of POP symptoms through accessible, conservative treatments like PFMT allows women to maintain their roles within families and communities, thereby reducing potential economic and social burdens on households. As its current status, the high cost for treatment and risk of recurrence after surgery makes POP both a health and financial burden (7). POP is currently a common disorder that has a remarkable economic burden on the health system and individuals (69).

2.7.2. Clinical Importance

From a clinical perspective, POP poses significant challenges due to its impact on women's physical health, sexual function, and overall quality of life (51). Advanced stages are associated with secondary complications such as ulcers, bowel symptoms, urinary symptoms, and psychological distress. The relationship status and sexual desire might not improve even by surgery (30, 31). This indicates a need for alternative management options.

However, social stigma often leads to delayed treatment-seeking behavior among women with POP. Many women wait over 12 months before seeking care for severe prolapse due to fear of discrimination or divorce (27, 28). This indicates the need for community-based screenings to identify women with this disorder. Validated tools like the POP-SS facilitate accurate communication between patients and healthcare providers, enabling culturally relevant care that improves diagnostic accuracy and treatment outcomes. This adaptation allows healthcare providers

to identify POP more effectively, make evidence-based treatment recommendations, and potentially integrate POP screening into routine care.

Understanding the epidemiology of POP including its prevalence, risk factors and clinical implications allows for tailored prevention strategies through patient counseling and community education (7). This approach empowers healthcare workers to provide patient-centered care that addresses the unique needs of women with POP. Again, evaluating the effectiveness of pelvic floor muscle training (PFMT) delivered by mid-level professionals at lower-level health facility as treatment option is crucial for improving women's health outcomes related to POP. This strategy ensures access to care, improve compliance to treatment follow-up and reduce the complications related to surgery. PFMT provides a conservative management strategy that avoids the risks associated with surgical interventions, which can lead to complications and longer recovery times. This approach empowers women to manage their symptoms effectively without invasive procedures. PFMT is more viable than surgical treatments, which can be prohibitively expensive, especially in low-resource settings, and it helps reduce the broader financial burden of POP, including lost productivity and decreased quality of life. Delivering this care at lower-level health facility improves access for women in rural areas and reduce the burden on general hospitals. Moreover, currently, the most important outcome of POP treatment is health-related quality of life and patient satisfaction (29, 170). Especially for women giving birth at an older age, the demand for conservative management is imperative (126).

2.8. Justification of the Study

The study on the epidemiology of POP is crucial due to the unique risk factors prevalent in Ethiopia, which contribute to a higher incidence of this condition. Factors such as a high frequency of vaginal deliveries, early marriage, early childbirth, heavy lifting, and low BMI among women in the region significantly increase the vulnerability to POP (39, 40, 42) .

A systematic literature review indicates that while several studies have examined the prevalence and risk factors of POP in Ethiopia, the majority are health facility-based or rely on symptomatic approaches for diagnosis (38). These methodologies likely underestimate the true prevalence of POP, as they fail to capture undiagnosed cases within the community. Many women with POP experience significant pain and limitations in daily activities but often do not seek treatment due

to fears of discrimination and stigma (27). Evidence suggests that approximately 80% of women with severe prolapse in Pakistan and Ethiopia delay seeking care for over a year (21, 37). This highlights the need for a community-based study to more accurately determine the prevalence of POP and its associated risk factors.

The significance of physical examination in diagnosing POP is well-documented, as pelvic examinations can confirm the presence of prolapse and identify potential risk factors for treatment failure (120, 171). Although advanced imaging techniques like magnetic resonance imaging (MRI) offer precise assessment of prolapse stages, clinical evaluations are typically sufficient for pre-surgical staging (172). While the simplified POP-Q system is easier to use, the standard POP-Q is more effective in predicting recurrence (171, 173). Studies have shown that factors such as a larger preoperative genital hiatus and greater postoperative vaginal length are associated with higher recurrence risks following colpocleisis, underscoring the value of using the standard POP-Q for accurate diagnosis. So that, this study used the standard POP-Q, whereas previous studies relied on the simplified techniques.

The effectiveness of any epidemiological study depends on the appropriateness of its assessment tools. The translation and validation of the POP-SS into Sidaamu Afoo addresses language barriers that could impede accurate symptom reporting. By ensuring that this tool is culturally relevant and psychometrically reliable, the study enables more accurate identification of POP cases, facilitating public health strategies to improve women's health in the Sidama region.

In addition to the gap in research on the effects of pelvic floor muscle training (PFMT) for managing prolapse symptoms in low-income countries in general, in Ethiopia, the current practice that encourages referring all women with POP to general hospital is not feasible for all patients. In addition, ideally PFMT is effective if delivered by pelvic physiotherapists. However, since Ethiopia has no such professionals, different models of PFMT service delivery is mandatory. Therefore, this study assessed the effect of midwife-led PFMT on symptom relief and prolapse quality of life among affected women, contributing critical insights into the epidemiology of POP and guiding future interventions to enhance women's health outcomes in the region. Moreover, methodologically, this study is distinguished by its use of a complex

survey analysis aligned with a rigorous sampling design to identify risk factors, a level of rigor that previous studies may have lacked.

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RESEARCH QUESTIONS

1. What are the psychometric properties (reliability and validity) of the Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire translated into *Sidaamu Afoo* for use among women in Sidama National Regional State?
2. What is the prevalence of pelvic organ prolapse among women in Sidama National Regional State?
3. What are the risk factors for pelvic organ prolapse in this population?
4. How does pelvic floor muscle training influence the severity of pelvic organ prolapse symptoms among women in Sidama National Regional State?
5. What improvements in quality-of-life metrics are observed in women with pelvic organ prolapse following participation in pelvic floor muscle training programs?

3. OBJECTIVES

3.1 General Objective

The aim of the study was to enhance the understanding of pelvic organ prolapse symptom assessment, its prevalence and risk factors, and the management of mild to moderate pelvic organ prolapse among women in the Sidama Region, Ethiopia.

3.2. Specific Objectives

1. To translate the pelvic organ prolapse symptom score (POP-SS) into Sidaamu Afoo and assess its psychometric properties, among women in the Sidama National Regional State of Ethiopia (Paper I).
2. To determine the prevalence and identify the risk factors of pelvic organ prolapse (Paper II)
3. To evaluate the effect of midwife-led pelvic floor muscle training on pelvic organ prolapse symptoms and prolapse- specific quality of life among women with POP (Paper III)

4. METHODOLOGY

4.1. Study Area

Sidama National Regional State is situated in the southern part of Ethiopia, approximately 275 kilometers south of Addis Ababa. It is bordered to the north, northeast, and southeast by the Oromia Region, to the south by the Gedeo Zone, and to the west by the Wolaita Zone. Geographically, Sidama lies between latitudes 6°14' N and 7°18' N and longitudes 38°20' E and 39°20' E. According to the data from the Population and Development Bureau (174), the region comprises 30 woredas (districts), 6 town administrations, and one city administration, which is Hawassa, the capital of Sidama. Predominantly situated in the southern highlands of Ethiopia, the elevation in Sidama ranges from 1,000 meters above sea level in the Rift Valley around Lake Abaya in the Loka Abaya woreda to 3,400 meters above sea level at Mount Garamba in the Arbegona woreda. The western part of the region features lower land topography within the Great East African Rift Valley, encompassing parts of Lake Abaya and the entirety of Lake Hawassa.

Sidama's population is rapidly increasing, with an average annual growth rate of 2.9%. According to the report from the Sidama regional health bureau (175), the projected population for 2024 was approximately 4,873,216, consisting of 2,409,318 males (49.44%) and 2,463,898 females (50.56%). The Sidama region is among the most densely populated areas in Ethiopia, facing challenges such as a shortage of arable land and rapid population growth with an average household size of 4.9.

The region has seen progress in its healthcare infrastructure, with the total number of hospitals reaching 25, including 19 governmental and 6 non-governmental facilities. Among the governmental hospitals, five are general hospitals and 14 are primary hospitals. Hospital distribution varies, with 10 woredas and 7 town administrations, including Hawassa City, having hospitals. Notably, Hawassa City has a better hospital distribution than other areas, while 20 woredas lack hospitals. In addition to hospitals, Sidama has 138 health centers, of which 136 are governmental and 2 are non-governmental. The region is also served by 551 government-owned health posts and 161 registered non-governmental clinics. By 2024, health center coverage in the region reached 71%, with 9 woredas meeting their health center needs and 24 woredas, including town administrations, achieving over 50% coverage (175).

Agriculture serves as the primary means of livelihood, with the majority of the population engaged in small-scale farming and agro-pastoralism (73). The region is known for its diverse agricultural production, which includes coffee, enset (false banana), maize, potatoes, and other root crops, as well as livestock rearing. Women play a vital role in the agricultural and economic activities in Sidama, often balancing farm work with household responsibilities

Women participate in all stages of farming, from planting to harvesting, especially with food crops like enset and vegetables. They are heavily involved in the processing of enset, which is labor-intensive and crucial for household food security. In addition to agricultural duties, women manage most household chores, including cooking, cleaning, and childcare. Many women also engage in small-scale trading or selling agricultural products at local markets to supplement household income.

The studies were conducted in the Dale and Wonsho districts of Sidama National Regional State, Ethiopia, from May 2022 to April 2024. The two districts were selected because these are the Health and Demographic Survey Sites of Hawassa university. Both districts are known for their high population density and coffee production. The Dale district has 10 health centers and 33 health posts. Additionally, the Hamlin Fistula Center, which provides free services for fistula cases and pelvic organ prolapse, is located in Yirgalem town, which is surrounded by the Dale district. This center has 25 beds and primarily serves patients with fistula cases.

Wonsho district comprises five health centers and 17 health posts. According to the 2024 report from the Sidama Regional Health Bureau, the total population of Dale district is 254,653, while Wonsho district has a population of 129,730 (175). The Ethiopian Central Statistical Agency indicates that females represent 49.7% of the population in Dale woreda and 49.2% in Wonsho (176). Dale district consists of 36 rural kebeles and two urban kebeles, whereas Wonsho district has 17 rural kebeles and one urban kebele, which are the smallest administrative units in Ethiopia.

In 2017, Hawassa University established its own HDSS site in the Dale and Wonsho districts of the Sidama Region (177). This HDSS site encompasses 10 rural kebeles and two urban kebeles, known collectively as the Dale-Wonsho Health and Demographic Surveillance Site (D-W HDSS). The primary objective of establishing the D-W HDSS was to create a foundational context for clinical trials and to generate longitudinal epidemiological data. In this project, we utilized the

sampling frame from the HDSS to select clusters and households based on a list of house numbers. The Map of the D-W HDSS is obtained from previous study (Figure 2).

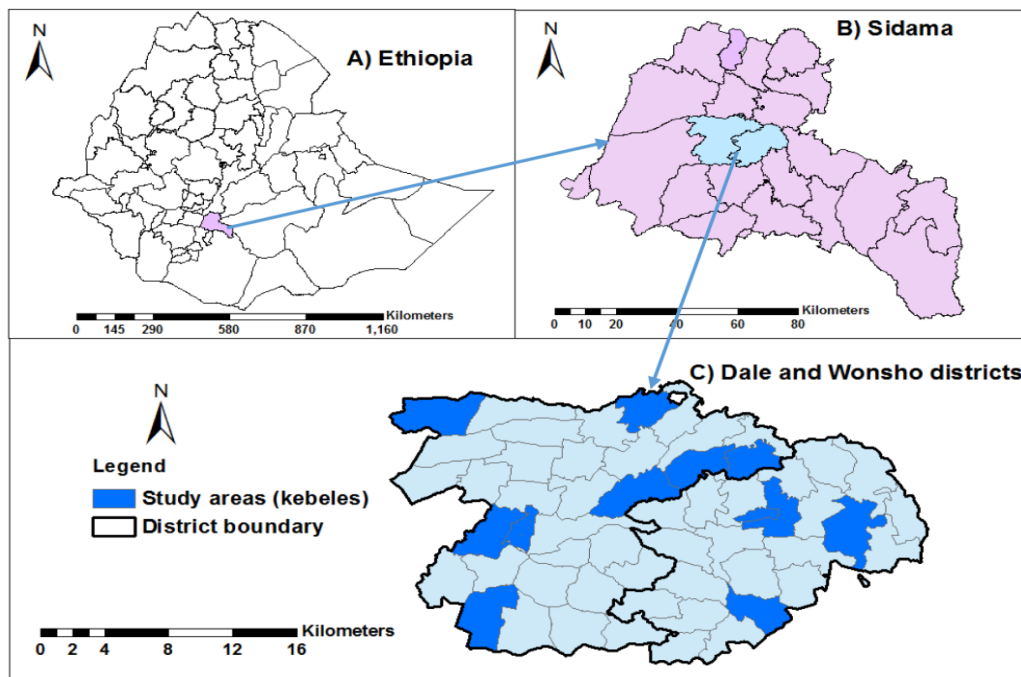


Figure 2: Map Dale-Wonsho Health and Demographic Surveillance system (178).

4.2. Study design and period

For Paper I, a cross-sectional study with repeated measures was conducted to translate the Pelvic Organ Prolapse Symptom Score (POP-SS) into Sidaamu Afoo and to assess the psychometric properties of the questionnaire among women with symptomatic POP. The study took place at Yirgalem General Hospital and the Yirgalem Hamlin Fistula Center in the Sidama Regional State of Ethiopia, from May to July 2022.

For Paper II, a community-based cross-sectional study was conducted within the Dale-Wonsho Health and Demographic Surveillance System (D-W HDSS) in the Sidama National Regional

State of Ethiopia. Data collection took place over eight months, from March 13 to October 28, 2023, utilizing both subjective and objective measures.

For Paper III, a community-based, parallel-groups, two-arm cluster-randomized controlled trial (cRCT) was conducted among women with symptomatic POP stages I-III at the Dale-Wonsho Health and Demographic Surveillance System (D-W HDSS) site. Eligible participants were identified through the baseline survey conducted in Paper II. These cases were then randomized into intervention and control groups based on community clusters. Cluster randomization was chosen to reduce the risk of intervention spillover to the control group and to facilitate the delivery of the intervention at the group level, utilizing nearby health facilities. The enrolment period lasted for eight months, from March 13 to October 28, 2023, with each participant followed for six months post-enrolment. The last participants were enrolled on October 28, 2023, making the final follow-up visit on April 27, 2024.

The clusters were defined as kebeles, which are the smallest administrative units in Ethiopia, similar to neighbourhoods or wards, with populations ranging from 500 to several thousand residents. The size of kebeles varies depending on their location and population density, with urban kebeles typically being smaller than those in rural areas. Each kebele is further divided into smaller units known as *gots* or villages. Kebele administrations play a vital role in population-based surveys and research studies in Ethiopia (179, 180).

4.3. Study Participants

In Paper I, the study participants included women aged 18 and older who presented with symptomatic POP at the gynecology outpatient department of Yirgalem General Hospital and Yirgalem Hamlin Fistula Center. Women who were not fluent in the local language, Sidaamu Afoo, were excluded from the study.

In Paper II, the participants included women who had given birth at least once or were over 18 years old, with their household information recorded in the Health and Demographic Survey database of Hawassa University. Women who were pregnant (either confirmed or suspected), in the immediate postpartum period (within six weeks), unable to participate due to illness, or who had never engaged in sexual contact (virgins) were excluded from the study.

In Paper III, based on the findings from Paper II, women who exhibited at least one symptom of POP and were confirmed to be in stages I-III using the standard POP-Q measurement were included in the study. Women with stage IV prolapses were referred to the Yirgalem Hamlin Fistula Center for further management.

4.4. Sample Size Determination

In Paper I, the sample size was determined following the recommendation of at least 5-10 subjects per item, as outlined by the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) (181, 182). Thus, the estimated sample size was 70 (10 subjects per item). However, to ensure sufficient representation, 100 women were ultimately recruited.

In Paper II, the sample size was calculated using Open-Epi version 3.1 for both the prevalence of POP and its associated risk factors. For the prevalence study, the assumptions included a 56.3% prevalence of anatomical POP, a 7% non-response rate(183), a 95% confidence interval, 5% marginal error, and a design effect of 2. This calculation resulted in a sample size of 813. The sample size for the associated risk factors was estimated based on variables that were significantly associated with anatomical prolapse in a previous study conducted in northern Ethiopia (183). The maximum sample size of 813, determined from the first objective, was considered sufficient to effectively address the remaining objectives outlined in Paper III.

In Paper III, sample size calculations were conducted using Open-Epi version 3.1, with assumptions of a 99% confidence level, 80% power, an exposed-to-unexposed ratio of 1, a mean difference of 3.16 with a standard deviation of 4.78 in the intervention group, and a mean difference of 0.12 with a standard deviation of 3.86 in the control group over six months (43). When adjusted for a 16% rate of refusal and loss to follow-up, resulting in an individual-based total sample size of 111.34. The individual-based sample size calculated for quality of life was 98, based on an assumed mean difference of 2.84 and a standard deviation of 4.78 in the intervention group, and 3.86 in the control group (43). Consequently, a total sample size of 111.3 was utilized for all outcomes, including prolapse symptoms and quality of life measures. The decision to adjust the confidence level to 99% was made to account for multiple comparisons across various outcomes (POP-SS and three P-QoL domains) by lowering the significance level to 0.0125 from the standard 0.05, using the Bonferroni method (41, 184).

To calculate the minimum number of clusters needed, the individual-based sample size was multiplied by the intra-cluster correlation coefficient (ICC). Due to the absence of reported ICC values in previous studies, a typical estimated value of 0.03 (185-187) was used. This calculation suggested a requirement of 1.67 clusters per arm. To ensure sufficient power (188, 189), a total of eight clusters were randomly selected from the 12 available clusters in the D-W HDSS.

To account for the cluster design, a Variance Inflation Factor (VIF) was calculated using the formula: $VIF = 1 + ((n-1) * ICC)$, where “n” is the average cluster size (13.91) and ICC is the intra-cluster correlation coefficient (0.03). This resulted in a VIF of 1.39. The individual-level sample size required was inflated by this VIF to account for the design effect and the total sample size increased to 155, resulting in an expected average of 19.4 participants per cluster. However, during enrolment, a slightly higher number of eligible cases were identified in each cluster. Excluding these additional participants was considered unethical; instead, including all eligible cases was viewed as manageable and likely to enhance the study's precision (185-187). As a result, all eligible cases were included, increasing the total sample size from 155 to 187 participants.

4.5. Sampling Technique and Procedure

In Paper I, all women who visited the gynecology outpatient departments of Yirgalem General Hospital or were admitted to the Yirgalem Hamlin Fistula Center during the study period were assessed for prolapse symptoms using two key questions: whether they experienced a feeling of bulging, pressure, or something coming down from their vagina, or if they noticed a visible mass protruding from the vagina in the past year (190, 191). Women reporting at least one of these symptoms were invited for a pelvic examination to confirm the presence of prolapse. To evaluate test-retest reliability, 61 women with mobile phones were purposefully selected based on accessibility and followed up after two weeks.

In Paper II, the Hawassa University Health and Demographic Surveillance System (HDSS) site was initially divided into two districts, Dale and Wonsho. Representative kebeles were then selected as "clusters" from both districts, with six kebeles chosen from Dale and two from Wonsho using simple random sampling. The number of households in each kebele ranged from 640 to 2,200. To ensure adequate representation from each cluster, an equal number of eligible women 101.6 (rounded up to 102) were selected from each kebele using computer-generated random

numbers based on their house numbers. This adjustment resulted in a total sample size of 816. Thus, the study included two strata (Dale and Wonsho districts), eight clusters (kebeles), and 816 eligible women.

4.6. Randomization and concealment

In this study, the Dale-Wonsho Health and Demographic Surveillance Site (D-W HDSS) served as the research location, comprising eight kebeles from the Dale district and four kebeles from the Wonsho district. To reduce stratum variability and ensure balance across study arms, these kebeles were stratified into two strata based on their geographical locations (Dale and Wonsho districts) (188, 189). An equal number of clusters from each stratum were assigned to the intervention and control groups, ensuring that both arms were similar in important characteristics, thereby minimizing potential confounders.

Cluster randomization was carried out by the staff of the D-W HDSS at Hawassa University, who were independent of the study team. A lottery method was employed to randomly select two out of four clusters from the Wonsho district and assign them to each arm. Similarly, six out of eight clusters from the Dale district were chosen, with three clusters randomly assigned to each arm using the same lottery method. To reduce risk of spillover effects from the intervention, a buffer zone (at least one kebele) was established between the intervention and control clusters (188). Finally, all eligible study participants identified during the baseline survey from each cluster were included in the study (Figure 3).

Following the randomization of clusters, two staff members from the Yirgalem Hamlin Fistula Center, who conducted pelvic examinations to assess the stage of POP, were assigned for recruiting eligible participants for the study. This recruitment process was conducted without any knowledge of the group allocation, maintaining blinding throughout the recruitment of all eligible participants from each cluster. The recruitment was based on a pre-defined criterion: women diagnosed with POP stages I-III who experienced at least one symptom as measured by the POP-SS.

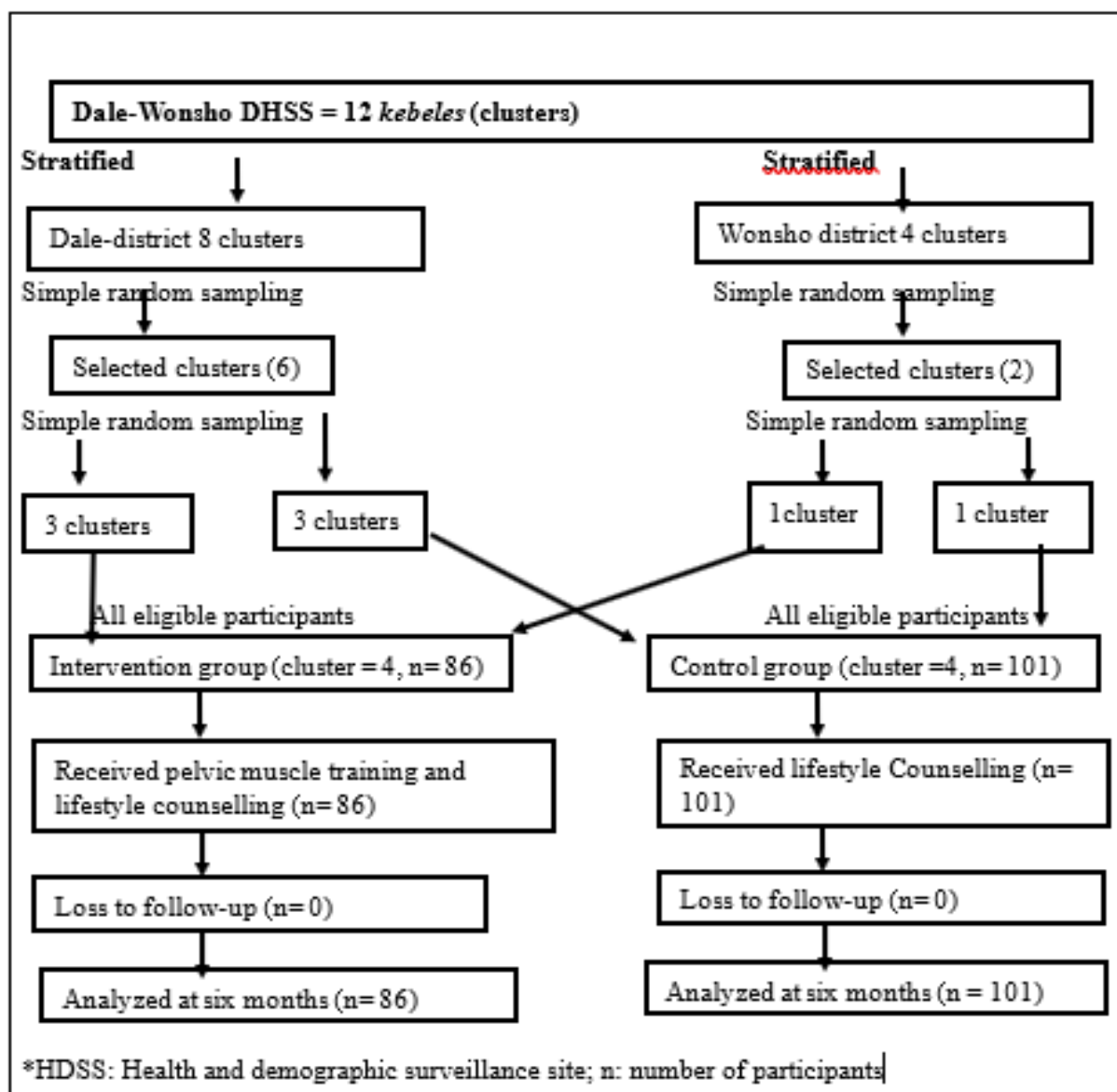


Figure 3: Randomization and sampling procedure used to assess the effect of pelvic floor muscle training on prolapse symptoms and quality of life in Sidama Region, Ethiopia, April 2022 to April 2024

4.7. Blinding (Masking)

In this study, blinding was implemented to the extent possible to minimize bias and enhance the validity of the findings. Participants in the intervention group were aware that they were receiving the pelvic floor muscle training (PFMT) program but were blinded about the control groups. Similarly, participants in the control group knew they were receiving lifestyle counseling but were

blinded to the intervention group's treatment. Healthcare providers delivering the counseling interventions were also blinded to the treatment allocation of the participants. Outcome assessors who collected data at the conclusion of the intervention period were blinded to the treatment allocation of the participants.

Blinding the participants and healthcare providers to the alternative intervention helped prevent potential biases related to expectations and behaviors. Blinding the outcome assessors was particularly important to eliminate detection bias and ensure objective assessment of the study endpoints (192). While it was not feasible to blind the participants to their own treatment, the use of a control intervention and blinding to the alternative arm helped control for potential biases related to participant knowledge of the treatment (193). Blinding of outcome assessors was a key strength of the study design, as it ensured that the assessment of the primary and secondary outcomes was not influenced by knowledge of the participants' treatment allocation (192). This helped to enhance the internal validity of the study findings.

4.8. Description of the Intervention

The intervention took place within the D-W HDSS study area, where each cluster is served by its own health posts staffed by health extension workers. Additionally, five or more clusters are supported by a single health center. These health centers, which employ formally trained healthcare professionals, including midwives, were selected for the intervention because of their ability to provide training and their geographical accessibility to participants, making them more suitable than hospitals.

Each health center in the study area is staffed with at least three degree-holding midwives who are responsible for providing antenatal, delivery, and postnatal care. The health centers are equipped with various rooms, including delivery rooms, cervical cancer screening rooms, and outpatient rooms, which facilitate Pelvic Organ Prolapse Quantification (POP-Q) assessments and ensure confidentiality during individual counselling sessions.

From each selected health facility, two female midwives were trained either in pelvic floor muscle training and patient counselling or solely in counselling for lifestyle modifications, depending on their assigned health facility. The training, which included theoretical education, simulation, and

video aids, was conducted by a fellowship-trained urogynaecologist. Subsequently, the trained midwives implemented the intervention for the women assigned to the intervention arms.

Women in the intervention group received PFMT along with lifestyle advice, while the control group received only lifestyle modification counselling. We translated the Lifestyle Advice Leaflet from the POPPY trial (194) into Sidaamu Afoo, the local language, to enhance understanding and effectiveness during counselling sessions. The lifestyle counselling aimed to educate participants on modifiable risk factors that can contribute to or exacerbate POP. Women were counselled on strategies to prevent and manage constipation, such as increasing fiber intake, staying hydrated, and using the correct posture during bowel movements. Advice was also provided on cough management through treatment of underlying respiratory conditions. Counselling on proper lifting techniques and avoiding heavy lifting when possible was another key component. Women were taught how to lift heavy objects safely by bending at the knees, keeping the back straight, and avoiding straining the abdominal muscles.

In the intervention group, the lifestyle counselling was delivered in conjunction with the PFMT program by the trained midwives. It was an integral part of the overall intervention to address both the symptoms of prolapse as well as the underlying factors that may contribute to its development and progression over time. During the initial visit, pelvic examiners connected eligible women with the assigned midwife based on the POP-Q findings. In a private room, midwives informed the women about their specific stage of POP and the type of prolapse (anterior, posterior, or central). They explained the benefits of pelvic floor muscle exercises, how these exercises function, and provided detailed instructions on the exercises and follow-up schedule in a private setting.

Participants were trained to perform the exercises while sitting or lying comfortably, focusing on pelvic muscle contractions. The regimen included 10 maximum holds for 10 seconds each and 10 fast contractions, with instructions to repeat this at least three times daily (morning, afternoon, and night) (43, 194, 195) . Participants were taught to pre-contract their pelvic floor muscles in response to increases in intra-abdominal pressure through the Knack exercise. This involved performing 10 long squeezes and lift contractions, each held for 10 seconds, followed by 10 short squeezes (1-2 seconds each). They were instructed to notice the release and relaxation of the

muscles after completing the short squeezes and to practice squeezing while lightly coughing for 10 repetitions.

To ensure correct identification and contraction of pelvic floor muscles, participants received internal digital biofeedback during training sessions led by the midwives. Various verbal cues and analogies were used to enhance understanding. For instance, participants were instructed to "imagine you are trying to stop the flow of urine or hold back gas. Squeeze as if you are attempting to slow down or stop your urine mid-stream" (196). This analogy helped participants visualize the specific action required. Throughout the exercises, midwives provided descriptive feedback, encouraging participants to concentrate on lifting the muscles around the vagina and anus, thereby fostering awareness of the muscles engaged during contractions. They would say things like, "As you squeeze, focus on lifting the muscles around your vagina and anus upwards. You should feel a tightening and lifting sensation" (43, 194, 195). This guidance helped participants become more aware of the specific muscles they were engaging during the contractions. Counselling was conducted in Sidaamu Afoo, the local language, following the realist evaluation guideline (194).

Participants were scheduled for five visits at a nearby health facility, occurring at weeks 0, 2, 6, 10, and 15. The frequency of these appointments was adapted from the guidelines of the United Kingdom National Health Service (NHS) (197). The initial appointments were closely spaced to reinforce correct exercise techniques and ensure that participants fully understood the provided advice. Subsequent appointments were spaced further apart to encourage independent home exercise. A 15-week intensive training period with monthly follow-ups was recommended to achieve adequate muscle strength (198). It is often suggested that women continue to practice PFMT as a maintenance strategy. Changes in prolapse symptoms and health-related quality of life were analyzed at the six-month follow-up. This practice is supported by evidence indicating that significant changes in prolapse symptoms and stages often manifest within this period (126, 199).

4.9. Study variables and Measurements

In Paper I, the Sidaamu Afoo version of the Pelvic Organ Prolapse Symptom Score (POP-SS) was evaluated for various psychometric properties, including validity and reliability. Face validity refers to the extent to which the questionnaire appears to measure what it is intended to measure, as perceived by the patients during the adaptation process (200). It also reflects how respondents

or laypeople view the validity of the questionnaire items. While face validity can encourage respondents to answer more accurately, it is considered the weakest method for assessing a questionnaire's overall validity (200, 201). In this study, face validity was evaluated through feedback from ten women diagnosed with Pelvic Organ Prolapse (POP) who were fluent in *Sidaamu Afoo*. Participants were asked to paraphrase each question and explain their understanding, helping to identify any issues with clarity or cultural appropriateness (202). Then women's comments on item clarity and items wording were taken. Modifications were made based on this feedback.

Content validity was evaluated by a panel of six experts (gynecologists) who rated each questionnaire item for relevance and comprehensiveness using a 4-point scale (203, 204). The Content Validity Index (CVI) was calculated, with a value of $\geq 80\%$ indicating acceptable content validity (203, 205). The experts evaluated each item based on its relevance, representativeness, and technical quality.

Exploratory factor analysis was conducted to assess construct validity. The suitability of the data for factor analysis was confirmed using Kaiser-Meyer-Olkin (KMO) statistics (> 0.5) (206) and Bartlett's test of sphericity ($p \leq 0.05$) (207). Factors with eigenvalues > 1 were retained and rotated using the varimax orthogonal rotation method (208). At the same time, we used a scree plot indicating eigenvalues for each factor to identify the number of factors to be retained. Then to estimate factor correlations, the varimax orthogonal rotation procedure was applied and communalities and factor loadings ≥ 0.4 were considered sufficient (209). Items with factor loading ≥ 0.4 on more than one factor were considered to be cross-loading (206).

Convergent validity demonstrates how well different measures of the same construct correlate with one another. It assesses whether tests that are supposed to measure the same concept yield similar results. The goal of convergent validity is to demonstrate that scores on a particular measure are similar to those on other, theoretically related measures. It is evaluated by examining the Average Variance Extracted (AVE > 0.5) and Composite Reliability (CR > 0.7) (210). The reliability coefficient and average inter-item covariance were also analyzed to ensure items within each domain were closely related. Known-group validity was assessed using the Kruskal-Wallis test to compare POP-SS values across different stages of POP. Significant results indicated the questionnaire's ability to differentiate between stages of prolapse (211). Then pairwise multiple

comparisons were done by using Dunn's test to see between which stage of prolapse it can differentiate. A significant level of the test (212) indicates the questionnaires' ability to differentiate between different stages of the prolapse.

In Paper II, the primary outcome variables were anatomical POP and symptomatic POP. Anatomical prolapse was defined as stage $\geq$ II on the Pelvic Organ Prolapse Quantification (POP-Q) system. The POP-Q system measures nine points in and around the vagina with measurements expressed in centimeters to the nearest 0.5cm. this was done by staff of Yirgalem Hamline Fistula center who has special training on fistula and POP management. These measurements are translated into a staging system ranging from Stage 0 to Stage IV based on the leading edge of the prolapse relative to the hymenal remnants and total vaginal length. All measurements are taken at maximum Valsalva, except for total vaginal length (TVL), which is measured at rest. The nine measurement points are as follows (10):

1. **Genital Hiatus (GH):** Measured from the middle of the external urethral meatus to the posterior aspect of the hymenal remnant.
2. **Perineal Body (PB):** Measured from the posterior aspect of the hymenal remnant to the center of the anal opening.
3. **Point C:** The lowest part of the cervix (or vaginal cuff).
4. **Point D:** The highest point of the posterior vaginal wall (posterior vaginal pouch). Both points are measured relative to the plane of hymenal remnants, which is chosen for its clear definition and easy identification.
5. **Total Vaginal Length:** Measured from the hymenal remnant to Point D.
6. **Point Aa:** An arbitrary fixed point on the anterior vaginal wall, located 3 cm back from the middle of the external urethral meatus in normal cases.
7. **Point Ba:** The lowest part of the upper anterior vagina; unlike Point Aa, this point is not fixed and can be located anywhere along the vaginal wall above the first 3 cm (Aa).
8. **Points Ap and Bp:** Corresponding points to Aa and Ba, but located on the posterior vaginal wall.

These measures are translated into a staging system by Urogynecology fellow as follows (10, 213):

- I. **Stage 0:** Points Aa, Ba, Ap, and Bp are all at -3 cm, while points C and D are at or above total vaginal length (TVL) - 2 cm.
- II. **Stage I:** The criteria for Stage 0 are not met, and the leading edge of the prolapse is more than 1 cm above the hymen.
- III. **Stage II:** The leading edge of the prolapse is positioned between 1 cm above and 1 cm below the hymen.
- IV. **Stage III:** The leading edge is more than 1 cm beyond the hymen but less than TVL - 2 cm from the hymen.
- V. **Stage IV:** The leading edge of the prolapse is more than TVL - 2 cm beyond the hymenal remnant (6, 9, 10).

In this study, symptomatic prolapse was defined as having anatomical prolapse (stage $\geq$ II) along with reported prolapse symptoms. Symptoms of POP were collected using the Sidaamu Afoo version of the POP-SS questionnaire (214). The psychometric properties of this questionnaire have been evaluated in the same setting and found to have acceptable reliability and validity (Paper I). It maintains the same structure as the original version, containing seven items with five Likert-scale questions scored from 0 to 4, resulting in a possible total score ranging from 0 to 28 (with higher scores indicating worse symptoms) (14). A response score different from zero indicates the presence of symptoms.

The independent variables for Paper II included sociodemographic characteristics (education level, residence, occupation, ethnicity, age in years, marital status), lifestyle characteristics (smoking habits, body mass index, and average hours of heavy lifting/carrying per day), obstetric and reproductive characteristics (mode of delivery, number of childbirths, place of delivery, history of labor lasting more than 24 hours, age at first marriage, age at first childbirth), as well as medical and surgical history (chronic cough lasting more than three weeks, constipation/infrequent stooling and difficulty passing stool, diabetes mellitus, history of pelvic surgery or trauma, and family history of POP).

Socio-demographic characteristics were measured based on participants response to each item. Heavy lifting hours were measured by the estimated average hours per day the women carry heavy objects like water, big baby, wood, stone, or any types of cements. History of Pelvic surgery was

considered if the women experienced any type of surgery that involved pelvic muscle like episiotomy, hysterectomy, or surgery for pelvic tumours. Prolonged labour was measured by asking women whether or not she has history of labor that lasted more than one day and night (24 hours). Chronic cough was considered if she experienced it for more than three weeks and constipation was considered presented if she has infrequent stooling and difficulty passing stool. BMI was measured at health facilities at the time of pelvic examinations. Participants' weight was measured to ± 0.1 kilogram (Kg) and standing height was measured to ± 0.001 meter using a wall mounted stadiometer. BMI was calculated as weight over height square (kg/m^2). Finally categorized as underweight ($<18.5\text{Kg/m}^2$), normal ($18.5 - 25.5\text{Kg/m}^2$), overweight ($25.5 - 29.9\text{kg/m}^2$) and obesity ($\geq 30\text{Kg/m}^2$) (215).

In Paper III, the primary outcomes were a mean change difference in pelvic organ prolapse symptoms and Prolapse Quality of Life (P-QoL) scores. At the beginning of the study, participants completed both the POP-SS and P-QoL questionnaires to establish baseline scores. For POP_SS measurement, participants rated their symptoms using a scale from 0 (no symptoms) to 4 (very severe symptoms) across seven items, yielding a total score ranging from 1 to 28 (we included participants who experienced at least one symptom). After six months of PFMT, participants were asked to complete the same questionnaires again. The mean change in POP-SS was obtained by subtracting the average POP-SS at the sixth months from the baseline average POP-SS.

Prolapse quality of life (P-QoL) was assessed by using the questionnaire translated from the Amharic version (216). The Amharic version was previously validated in Ethiopia among Amharic speaking women with POP. The tool has three domains: physical function, psychological function, and personal relationships domains. Each domain is assessed separately, with scores ranging from 0 to 100 (where higher scores indicate a poorer quality of life). Each domain corresponds to a specific aspect of quality of life. The tool demonstrates acceptable reliability and validity. The secondary outcome measured was women's perceived change in prolapse symptoms since the intervention began, evaluated using the Patient Global Impression of Change (PGI-I) index, which classifies changes as Better/Improved, No Change, or Worse (217).

Intervention adherence was evaluated based on attendance at appointments (43) and the amount of exercise reported by women during follow-up. Adherence to the training protocol is considered adequate if women complete at least 80% of the training sessions provided by the midwives (218).

4.10. Data Collection Tools and Procedures

The original version of the Pelvic Organ Prolapse Symptom Score (POP-SS) was developed by Hagen and colleagues for English-speaking women (14). The POP-SS consists of seven questions, each using a five-point Likert scale that ranges from zero to four (0 = never felt the symptom, 1 = occasionally, 2 = sometimes, 3 = most of the time, and 4 = all of the time), with higher scores indicating more severe symptoms. Participants are asked how often they have experienced the following symptoms in the past four weeks:

1. A sensation of something descending from the vagina
2. An uncomfortable feeling in the vagina that worsens when standing
3. A heaviness in the lower abdomen
4. A dragging sensation in the lower back
5. Difficulty emptying the bladder
6. A feeling of incomplete bladder emptying
7. A feeling of incomplete bowel emptying

Translation and Cultural Adaptation of POP-SS

Permission to translate the POP-SS was obtained from the original author (14). The translation and cultural adaptation were conducted following the standard method recommended by Beaton et al., (219) which includes forward translation, synthesis, backward translation, expert committee review, and pilot testing. This thorough process ensures that the translated tool accurately reflects the cultural and linguistic context of the target population. In health survey questions, the term back translation is strongly encouraged, as it aids in assessing the translation's quality (220). Translation should not be on a word-for-word basis; instead, it is essential to understand the geographical context, specific concerns, and cultural meanings that the language conveys.

Forward and Backward Translation: Three native Sidaamu Afoo speakers a medical doctor, a reproductive health expert, and a sociologist fluent in English independently translated the POP-SS from English to Sidaamu Afoo. A consensus draft was created by synthesizing these three translations. This draft was then back-translated into English by two independent translators (one

sociologist and one reproductive health expert) who are proficient in both languages. The original and back-translated versions were compared for discrepancies by the principal investigator, the translators, and a public health expert to ensure conceptual equivalence. After making the necessary adjustments, the first *Sidaamu Afoo* version was finalized, with some modifications to the wording resulting in a preliminary version.

Six gynecologists assessed the relevance of each item and rated its suitability. Expert agreement was determined using the CVI (205). To evaluate the equivalence and comprehensibility of the translated *Sidaamu Afoo* version, it underwent face validation and pretesting with ten women who spoke *Sidaamu Afoo* and were admitted to Adare General Hospital and Yirgalem Hamlin Fistula Center with a diagnosis of POP. The data was collected by General practitioners and Health Officer.

The data collection tool for Paper II comprised six sections: sociodemographic characteristics, POP-related lifestyle factors, obstetric and gynecologic history, household wealth index, POP-SS, and objectively measured POP. The questionnaires were developed based on a review of relevant literature (20, 23, 74) . Initially created in English, the tool was then translated into the local language (*Sidaamu Afoo*). The POP-SS was utilized to assess prolapse symptoms by asking participants how frequently they experienced these symptoms over the past four weeks. This questionnaire had previously been translated into the local language and validated in the same study area (214). It demonstrated validity and required 15-20 minutes to complete.

Data were collected using Kobo Toolbox. Eight nurses gathered data through home visits. All study participants were invited to a pelvic examination at a nearby health facility and were given an appointment (date and time) regardless of their symptoms. The collected data were uploaded daily to the European Union Kobo Toolbox Server and monitored by the principal investigator.

Pelvic organ prolapse quantification was conducted by two staff members from the Yirgalem Hamlin Fistula Center, both of whom have specialized training in fistula and POP management. These professionals, referred to as "*Health Officers*" in Ethiopia, guided women to empty their bladders before lying in a lithotomy position. The degree of prolapse was measured using a spatula marked in centimeters to assess nine points in and around the vagina.

Data collectors and field supervisors underwent three days of training on the study's purpose, the use of the Kobo tool, and each item in the questionnaire. Additionally, pelvic floor examiners received training from a urogynaecologist at the Hamlin Fistula Center for one day to minimize discrepancies among examiners. As part of their pre-testing, they performed ten POP-Q assessments under the supervision of the urogynecologist on patients admitted to the Hamlin Fistula Center for POP.

Paper III utilized baseline data obtained from Paper II. All tools were translated from English and Amharic into the local language, Sidaamu Afoo. Based on the results of the POP-Q and POP-SS assessments, women with symptomatic POP stages I-III were interviewed regarding how much the prolapse had impacted their quality of life using the P-QoL tool. The original P-QoL tool consists of 20 items across nine domains (221); however, in a previous effort to adapt the P-QoL for local use (specifically to an *Amharic version*), the dimensions were condensed into three:

1. **Physical Function:** This includes General Health Perception (GHP), Prolapse Impact (PI), Role Limitations (RL), Physical Limitations (PL), and Social Limitations (SL).
2. **Psychological Function:** This encompasses Emotional Disturbances (EMO) and Sleep/Energy Disturbances (SE).
3. **Personal Relationships.**

This tool has been validated in a similar context in northern Ethiopia (222)).

The secondary outcome, which assessed women's perceived change in prolapse, was evaluated using the Patient Global Impression of Change index (PGI-I), a seven-point Likert scale where participants rated their condition from 1 (very much better) to 7 (very much worse). Participants were classified as improved if they scored 1, 2, or 3 on the PGI-I scale, no change if they scored 4, and worse if they scored 5, 6, or 7 (217). At three- and six-months post-intervention, four nurses visited participants' homes to collect follow-up data. During these visits, nurses administered the POP-SS and P-QoL questionnaires (used at baseline), assessed perceived changes using the PGI-I index, and evaluated adherence to the training protocol (218).

4.11. Statistical Analysis

This section details the statistical analyses conducted across the three papers of this PhD work. The analyses were performed using Stata software versions 16 and 17 (StataCorp LLC, College

Station, Texas, USA). Data were initially managed using Epi-Data version 3.1 and Microsoft Excel 2013. The chosen methods reflect the study designs, data structures, and the specific research questions addressed in each paper. Complex sampling designs, cluster randomization, and the need for validity and reliability assessments were all considered in the analytical approach.

Paper I: Data were entered into Epi-Data version 3.1 and subsequently analyzed using Stata version 16. Sociodemographic characteristics were summarized using frequencies, means, and standard deviations. Known-group validity was assessed using the Kruskal-Wallis test to compare POP-SS values across different stages of POP (211). Then, Dunn's test was used for pairwise comparisons to see between which stage of prolapse it can differentiate. A significant level of the test (212) indicates the questionnaires' ability to differentiate between different stages of the prolapse.

To test reliability, Cronbach's alpha was employed to evaluate internal consistency, with values ranging from 0.7 to 0.95 indicating adequacy (181, 223). Additionally, item-total correlations of ≥ 0.5 and inter-item correlations of ≥ 0.3 were examined (224). Test-retest reliability was assessed using the intra-class correlation coefficient (ICC) derived from a two-way mixed-effects model, with an ICC of ≥ 0.7 considered acceptable (225). The data were organized in a long format to facilitate the ICC calculation, utilizing single-rating, absolute agreement, and two-way mixed-effect models. Floor and ceiling effects were deemed present if more than 15% of participants achieved the lowest or highest possible scores, suggesting potential limitations in the questionnaire's ability to discriminate effectively (181).

In Paper II, the dataset was downloaded from the Kobo Toolbox server, exported to Microsoft Excel 2013, and then imported into Stata version 17 for analysis. The analysis took into account the complex sampling design variables, including stratification by district (Dale and Wonsho), clustering by kebele, and appropriate weighting. The weighting variable was created by multiplying the cluster selection weight by the household selection weights. To normalize these weights, each unit's survey weight was divided by the unweighted average of the survey weights. Categorical variables were summarized using frequencies and percentages, while continuous variables were described using means, standard deviations, or medians and interquartile ranges. The wealth index was calculated using principal component analysis (226, 227) based on 28 items.

The relationship between anatomical prolapse, symptomatic prolapse, and potential risk factors was analyzed using complex sample modified-Poisson regression. This method was chosen over logistic regression because when the outcome of interest is common (more than 20%), the odds ratio can overestimate the prevalence ratio (228, 229). Secondly, this model facilitates the direct estimation of prevalence ratios, which are easier to interpret (228, 230). In cross-sectional studies, the prevalence ratio is the preferred measure, capable of being directly estimated by statistical models (228, 229). The prevalence ratio is generally more comprehensible for non-epidemiologists compared to the odds ratio. Furthermore, model-based estimation is more suitable for controlling confounding variables (228, 230). The relative risk estimate of a given covariate is e^{β} (228, 231). In complex sample analysis, although robust standard errors cannot be applied using Stata's `svy` prefix, the inherent robustness of `svy` estimation ensures that Poisson regression adequately accounts for survey design characteristics (232).

Variables with p -values ≤ 0.25 in the bivariable analysis, along with those supported by existing literature, were included in the multivariable model (233). The model was iteratively refined by removing variables that did not significantly affect the overall model fit or the parameters of the remaining variables. This process continued until the model achieved significance and demonstrated good fit. The adjusted Wald test was employed to evaluate the overall significance of the model by comparing the full model to the reduced (null) model (234). The results indicated that the full model was significantly different from the reduced model (anatomical prolapse $p = 0.005$ and symptomatic prolapse $p = 0.034$), suggesting that the variables included in the full model are crucial for explaining the outcome variable. The associations between outcome variables and risk factors were reported as adjusted prevalence ratios (APR) with a 95% confidence interval. Additionally, a multivariable linear regression model was utilized to assess multicollinearity among independent variables, with a variance inflation factor (VIF) of less than five indicating minimal multicollinearity (235).

In Paper III, an intention-to-treat analysis was used. The data analysis followed the complex sampling design that included stratification by district, clustering, and weighting adjustments as outlined in Paper II. While the intervention was randomly assigned at the cluster level, outcomes were assessed at the individual level. A multilevel mixed-effects generalized linear model (MEGLM) was utilized to compare changes from baseline in the POP-SS and each P-QoL domain

at three- and six-months post-intervention in both groups. MEGLM was selected for its ability to account baseline results, flexibility and robustness, which are essential for accurately modelling the complex and diverse data structures commonly encountered in cluster randomized controlled trials (cRCT), resulting in more reliable and interpretable outcomes (236).

The difference in POP-SS between the intervention and control groups was estimated by calculating the mean change from baseline at six months. A Bonferroni correction for multiple measurements (41) was applied to adjust the level of significance to 0.0125, as we assessed the effect of pelvic floor muscle training (PFMT) on four outcomes (POP-SS and three domains of P-QoL). The mean change difference between the intervention and control groups was then reported along with a 99%CI and p-values. This adjustment is essential for maintaining statistical rigor and reducing the risk of Type I errors in the analysis (41).

Initial null models for each outcome variable were fitted to calculate the intraclass correlation coefficient (ICC). Following this, we fitted models that included the intervention variable alongside each outcome variable individually. This allowed us to evaluate the impact of the intervention on each outcome. To assess the effects of confounders and effect modifiers, we examined model fit for each model with added predictors using Pseudo Log-Likelihood values and the adjusted Wald test for the significance of predictors. Higher (less negative) Pseudo Log-Likelihood values indicate better model fit, while a significant Wald test highlights the importance of the predictors (237). This approach enabled us to identify the most suitable models for each outcome. Residual analysis was conducted to evaluate homoscedasticity and normality of residuals using histograms. The reporting of this cluster cRCT was guided by the CONSORT (Consolidated Standards of Reporting Trials) 2010 statement, along with an extension specifically for reporting cluster randomized trials (238, 239).

4.12. Ethical Considerations

This study received ethical approval from the Institutional Review Board of the College of Medicine and Health Sciences at Hawassa University (Ref. No. IRB/157/14). Permissions were also obtained from the Sidama region Public Health Institute, Yirgalem General Hospital, Yirgalem Hamlin Fistula Center, and the respective health centers. Participants provided written

informed consent, with provisions made for those who were unable to read or write; in such cases, their agreement was indicated through a fingerprint after the consent form was read to them.

Due to the sensitive nature of POP, data on self-reported symptoms were collected in private settings within the participants' homes. Pelvic examinations were conducted in delivery rooms to maintain physical privacy and confidentiality. While pelvic examinations can cause some discomfort and psychological distress, these risks were minimized by allowing participants to withdraw from the study at any point during the consent process. Participants were reimbursed for their travel expenses to the health facility for pelvic examinations, receiving 200 Ethiopian Birr (approximately four U.S. dollars at that time).

During the study, 26 participants with stage IV prolapse were referred to the Yirgalem Hamlin Fistula Center for treatment. The research complied with the principles outlined in the Declaration of Helsinki (240), ensuring confidentiality by assigning codes to participants rather than using their names. Access to the key linking these codes to individual identities was restricted to the principal investigator. The study was designed to prioritize participant well-being and minimize risks throughout the research process.

Trial Registration

The trial was registered in the Pan African Clinical Trial Registry (<https://pactr.samrc.ac.za>) database under the registration number PACTR202302505126575.

5. RESULTS

This section presents the key findings from three studies that comprehensively assessed the reliability and validity of the *Sidaamu Afoo* version of the POP-SS questionnaire, determined the prevalence and risk factors of POP in the Sidama Region, and evaluated the effects of a midwife-led pelvic floor muscle training intervention on prolapse symptoms and quality of life.

5.1. Paper I: Reliability and Validity of the Sidaamu Afoo version of the pelvic Organ Prolapse Symptom Score Questionnaire

In this paper published on BMC Women's Health, all 100 women recruited for this study volunteered to participate making a response rate of 100%. Most of the women were from rural areas (91%) and 37 (37%) of the women had stage II prolapse, fifty-five (55%) had stage III prolapse, and eight (8%) had stage IV prolapse.

The translated questionnaire was easily understood by both experts and women with prolapse symptoms, requiring only minor wording modifications. Only few modifications were made to the wording, and no item was suggested to be deleted or added to the scale. The format of the tool is the same as the original scale and its translated versions (seven questions with five response options). The overall CVI was 0.88, indicating excellent content validity, with only one item (item 3) having a CVI score below 0.8.

Bartlett's test of sphericity ($\chi^2 = 412.53$, $p < 0.001$) and the Kaiser-Meyer-Olkin measure of sampling adequacy showed that the POP-SS has adequate common variance ($KMO = 0.66$) for factor analysis. Using the principal component analysis model, the factor analysis extracted two factors (components) based on a minimum eigenvalue of 1. The factors were rotated orthogonally by using a varimax approach to easily interpret factor loadings and identify items that loaded on each factor (component). Two items (*feeling of something coming down from the vagina* and *an uncomfortable feeling or pain in your vagina*) loaded to Factor 1 with factor loadings of 0.87 and 0.92, respectively. Five items (A3, A4, A5, A6, and A7) loaded to Factor 2 with factor loadings ranging from 0.61 to 0.90 (Table 1). Factor 1 explained 44.6% of the common variance, and Factor 2 explained 26 %. Both factors combined explained 70.6% of the

common variance. The eigenvalue was 3.1 for Factor 1 and 1.8 for Factor 2. Communalities for each item ranged from 0.44 to 0.84, indicating adequate commonalities.

Table 1: Factor loadings of the Sidaamu Afoo version of POP-SS, June 2022

Items	Factor 1	Factor 2
A1. A feeling of something coming down from the vagina	0.02	0.87
A2. An uncomfortable feeling or pain in your vagina.	0.01	0.92
A3. A heaviness or dragging feeling in your lower abdomen.	0.74	0.29
A4. A heaviness or dragging feeling in your lower abdomen.	0.74	0.36
A5. A need to strain (push) to empty your bladder	0.90	0.17
A6. A feeling that your bladder has not emptied completely	0.86	0.13
A7. A feeling that your bowel has not emptied completely	0.61	0.27

The overall internal consistency of the POP-SS questionnaire was 0.79. There was no evidence of an increase in this value if an item is deleted. The POP-SS demonstrated high internal consistency, and robust test-retest reliability over a 2-week period, with an ICC of 0.83 (95% CI: 0.50-0.92, $p < 0.001$). The percentage distribution of the responses showed that an answer of zero (0) was given most frequently to one item (A feeling of incomplete bowel emptying (51%). An answer of four (4) was given most frequently to two items (A feeling of something coming down from your vagina (71%) and A feeling of discomfort /pain in the vagina (72%).

Table 2: Internal consistency, item-total correlation, inter-item correlation reliability; and Ceiling and Floor effect score of Sidaamu Afoo version of POP-SS, June 2022

Items	Item-total correlation	Inter-item correlation	Internal consistency	Ceiling (n)	Floor (n)
A1. A feeling of something coming down from the vagina	0.27	0.78	0.79	71	0
A2. An uncomfortable feeling or pain in your vagina.	0.31	0.78		72	2
A3. A heaviness or dragging feeling in your lower abdomen.	0.61	0.72		7	21
A4. A heaviness or dragging feeling in your lower abdomen.	0.67	0.70		12	16
A5. A need to strain (push) to empty your bladder	0.55	0.73		18	25
A6. A feeling that your bladder has not emptied completely	0.54	0.73		17	22
A7. A feeling that your bowel has not emptied completely	0.51	0.74		6	51

Furthermore, the POP-SS scores were able to significantly differentiate between the various stages of prolapse (Stages II to IV) as determined by pelvic examination, with statistical significance established ($p < 0.001$). This means that the questionnaire effectively identified differences in symptom severity among women at different stages of prolapse, particularly distinguishing those in Stage II from those in Stages III and IV.

5.2. Paper II: Prevalence and Risk Factors of Pelvic Organ Prolapse among women in Sidama Region, Ethiopia

In this paper published on Sage Women's Health, a total of 816 women were selected and 815 (99.9%) participated in the interview and were invited for pelvic examination at a nearby health center. One woman did not wish to participate in the study. Among women who were invited, 779 (95.6%) underwent examination to assess for pelvic organ prolapse. The age of the participants ranged from 18 to 85 years with a mean age of 41.5 years and a standard deviation of 12.75 years. Seven hundred and fifteen (87.7%) of the participants were rural residents (Table 3).

Anatomical prolapse (stage $\geq$ II) affected 241 (30.90% [95% CI: 24 – 38.7]) of the population, while symptomatic prolapse (stage $\geq$ II with symptoms) was present in 187 (24.27%; (95%CI: 19.98 – 29.16). Among women with anatomical prolapse, 78.51% reported significant symptoms. The most prevalent symptoms were a feeling of discomfort/pain in the vagina (98.4%) and a sensation of something passing through the vagina (96.8%), with a median symptom duration of 48 months (IQR: 42.1-53.9 months).

Table 3: Sociodemographic and Reproductive Health characteristics of study participants involved in the prevalence of Pelvic organ Prolapse in Sidama Region, Ethiopia, 2024 (weight n=815).

Variables	Category	Frequency	Percent (%)
Districts	Dale	590	72.4
	Wonsho	225	27.6
Residence	Urban	101	12.4
	Rural	714	87.6
Marital Status	Married	739	90.6
	Others©	77	9.4
Level of education	No formal education	572	70.2
	Primary school	161	19.7
	Secondary school and above	82	10.1
Religion	Protestant	715	87.7
	Orthodox	79	9.7
	Others®	21	2.6
Occupation	Employed	35	4.3
	Non-employed	780	95.7
Ethnicity	Sidama	809	99.3
	Others¥	6	0.7
Wealth index	Poorest	166	20.34
	Poorer	170	20.8
	Middle	163	20.1
	Rich	156	19.2
	Richest	160	19.6
Chronic cough (> 3 weeks)	No	567	69.6
	Yes	248	30.4
Constipation	No	607	74.5
	Yes	208	25.5

Table 3: Continued (weight n=815).

Variables	Category	Frequency	Percent (%)
Family history of POP	No	582	71.4
	Yes	233	28.6
History of pelvic surgery	No	665	81.5
	Yes	150	18.5
Body Mass Index (kg/m ²)	< 18.5	248	30.5
	18.5– 24.9	481	59
	≥ 25	86	10.5
Abortion experience	No	745	92
	Yes	70	8
History of homebirth	No	197	24.2
	Yes	618	75.8
A place for the last childbirth	Home	528	64.8
	Health Facility	287	35.2
Prolonged labor	No	472	58
	Yes	343	42
Menopause	No	545	66.8
	Yes	270	33.2

*Note: Others© = never married, widowed, divorced; Others®: Muslim, Catholic; Others¥: Amhara, Gurage Oromo. POP: pelvic organ prolapses.

Modified Poisson regression identified significant risk factors for anatomical prolapse. The identified risk factors are consistent with previous studies: for each additional hour of heavy lifting per day, the prevalence of POP increases by 26% (APR = 1.26, 95% CI: 1.14-1.4), for each additional childbirth, the POP prevalence increases by 17% (APR = 1.17, 95% CI: 1.10-1.24), and prolonged labor (>24 hours) was associated with a 32% higher prevalence of POP (APR = 1.32, 95% CI: 1.1-1.56).

Table 4: Risk factors for anatomical pelvic organ prolapse in Sidama region, Ethiopia, 2024 (weighted n=779)

Variables	Anatomical prolapse (n=779)		CPR (95%CI)	APR (95%CI)
	Yes (%)	No (%)		
Average heavy lifting hours/day			1.34 (1.9 –1.5)*	1.26 (1.14-1.4)**
Childbirth frequency			1.31 (1.2 – 1.4)*	1.17 (1.1 -1.24)**
Chronic-cough (>3weeks)				
No	138(25)	405 (75)	Ref	Ref
Yes	103(44)	134 (56)	1.72 (1. -2.8)*	1.28(0.85 – 1.9)
Prolonged labor (>24hrs)				
No	110 (24)	342 (76)	Ref	Ref
Yes	131(40)	196 (60)	1.65 (1.2 – 2.3)*	1.32 (1.1 -1.56)**
Constipation (>3 months)				
No	163(28)	410 (72)	Ref	Ref
Yes	78(38)	129 (62)	1.3 (1.1 – 1.7)*	1.04 (0.86 – 1.27)
Age at first delivery				
< 18 years	115(49.7)	117 (50.3)	2.17(1.38– 3.4)*	1.57 (0.97-2.56)
>= 18 years	125(23)	421 (77)	Ref	Ref

*: Significant at $P < 0.25$, **: Highly significant ($P < 0.01$); Ref= reference category; CPR crude prevalence ratio, APR= adjusted prevalence ratio, CI= confidence Interval

In symptomatic prolapse cases, a one-unit increase in the average daily heavy lifting hours is associated with a 16% higher prevalence of symptomatic prolapse (APR =1.16; (95% CI: 1.1 - 1.28)). Women who gave birth before the age of 18 years had a 29% higher prevalence of symptomatic prolapse (APR =1.29; (95% CI: 1.1-1.52)).

Table 5: Risk factors associated with symptomatic pelvic organ prolapse in Sidama region, Ethiopia, 2024 (weighted n=241)

Variables	Symptomatic prolapse (n=241)		CPR (95%CI)	APR (95%CI)
	Yes (%)	No (%)		
Average daily heavy lifting			1.18 (1.03 -1.33)*	1.16 (1.1-1.28)**
Childbirth _frequency			1.01(1.– 1.14)*	1.01 (0.97- 1.1)
Chronic-cough (>3weeks)				
No	100 (73)	38 (27)	Ref	Ref
Yes	89(86.3)	14 (13.7)	1.19 (0.98 -1.43)*	1.13(0.99 – 1.3)
Prolonged labor (>24hrs)				
No	85 (78)	25 (22)	Ref	Ref
Yes	104(79)	27 (21)	1.02(0.84 – 1.2)*	0.94 (0.8 -1.1)
Family history of POP				
No	126(75)	42 (25)	Ref	Ref
Yes	64(86.5)	10 (13.5)	1.15 (1.02 – 1.3)*	1.1(0.86 – 1.41)
Age at first delivery				
< 18 years	105(91)	11 (9)	1.35 (1.13 – 1.6)*	1.29 (1.1 -1.52)**
>= 18 years	84(67)	41 (33)	Ref	Ref

*: Significant at $P < 0.25$, **: Highly significant ($P < 0.01$); Ref= reference category; CPR crude prevalence ratio, APR= adjusted prevalence ratio, CI= confidence Interval

5.3. Paper III: Effect of Midwife-Led Pelvic Floor Muscle Training on Prolapse Symptoms and Quality of Life

In this paper published on PLoS Medicine, it was aimed to assess effect of PFMT delivered by mid-level professionals at lower-level health facility. A total of 187 eligible women were randomized to the intervention group (n = 86) or the control group (101). At baseline, a slightly higher number of women in menopause, family history of prolapse, and history of home birth

were observed in the intervention group. Detailed sociodemographic characteristics are presented in Table 6.

Table 6: Sociodemographic and Clinical Characteristics of Trial Participants at Baseline in Sidama Region, Ethiopia (August 2024) (n = 187)

Variables	Category	Control(n=101)	Intervention (n=86)
Number of clusters	Dale	3	3
	Wonsho	1	1
Number of participants	Dale	64	70
	Wonsho	37	16
Clusters	Aposto	21	-
	Megara	-	26
	Dagia	-	16
	Shoye	-	27
	Wayicho	26	-
	Dansha sire	17	-
	Mamana	37	-
	Bokaso	-	16
Age at base line	Median (IQR)	34 (30-37)	50 (35-60)
Age at first Birth	Median (IQR)	18 (17-19)	17 (16-20)
Number of childbirths	(Median (IQR)	4 (4-5)	5 (4-7)
Age at last delivery	Median (IQR)	30 (26-32)	36 (29-42)
Level of Education	No formal education	67 (66.82%)	60 (69.47%)
	Primary school	18 (17.94%)	20 (23.16%)
	Secondary and above	15 (15.25%)	6 (7.38%)
Occupation	Employed	5 (5.38)	5 (5.79%)
	Un-employed	96 (94.62%)	81 (94.21%)
Menopause	Yes	24 (24.22%)	53 (61%)
	No	77 (75.78%)	34 (39%)

Table 6 Continued

Variables	Category	Control(n=101)	Intervention (n=86)
Experience of prolonged labor	Yes	62 (61%)	46 (53.16%)
	No	39 (39%)	40 (46.84%)
History of home birth	Yes	66 (65.47%)	63 (73.16%)
	No	35 (34.53%)	23 (26.84%)
Family history of prolapse	Yes	53 (52.47%)	8 (9%)
	No	48 (47.53%)	78 (91%)
Stage of prolapse	Stage 1	11 (11.21%)	11 (13.16%)
	Stage 2	65 (64.57%)	55 (64.21%)
	Stage 3	24 (24.22%)	19 (22.63%)
Type (site) of prolapse	Anterior only	34 (33.66%)	37 (43.02%)
	Posterior only	15 (14.85%)	10 (11.63%)
	More than one site	52 (51.49%)	39 (45.35%)
Mean Base-line POP-SS	Mean, SD	12.17 ± (4)	13.86 ± (4.4)
Prolapse quality of life (baseline)			
Physical function	Median (IQR)	40.5 (29.7 - 51)	43 (35 – 56.7)
Personal relation	Median (IQR)	44.44 (33 - 55)	44.44 (33 - 55)
Psychological function	Median (IQR)	46.69 (33 - 53)	40 (33 - 53)

*IQR= Inter-quartile range, SD=Standard Deviation; POP-SS = Pelvic organ prolapse symptoms score. ** P-values presented with [‡] indicate Mann-Whitney U test, [©] indicate chi-square test and [®] indicate independent t-test.

The mean baseline POP-SS and prolapse quality of life domain scores were almost similar across the groups. All participants strictly adhered to their allocated treatment and completed the 6-month follow-up, with no losses or crossovers. The PFMT intervention resulted in significant reductions in the POP-SS compared to the control group. The mean change difference in POP-SS scores was -4.11 points (99% CI: -5.38 to -2.83, $p < 0.001$), indicating a substantial improvement in symptoms

among those receiving the intervention. The change in POP-SS was more noticeable in women with prolapse stage-I with a mean change difference of -4.94 (99% CI [-7.38, -2.49]; $p < 0.001$) and stage II with a mean change difference of -2.99 (99% CI [-4.83, -1.13]; $p < 0.001$) as compared to stage III in reducing POP-SS (Table 6).

The intervention also led to notable improvements across all prolapse quality of life domains with a mean change difference of -8.86 (99% CI [-13.84, -3.89]; $p < 0.001$) in the physical domain, -9.01 (99% CI [-10.49, -5.54]; $p < 0.001$) in the personal relationship domain, and -11.18 (99% CI [-15.03, -7.32]; $p < 0.001$) in the psychological domain. Compared to women with stage III prolapse, women with Stage I prolapse experienced the most considerable improvement in all domains of health-related quality of life with a mean change of -34.9 points (99% CI: -42.16, - 27.62, $p < 0.001$) in the physical function, -23.9 points (99% CI: -29.65, - 18.23, $p < 0.001$) in personal relationship function, and -16.8 points (99% CI: -24.34, - 9.26, $p < 0.001$) in the psychological function. Similarly, women with stage II prolapse experienced more improvement than women with stage III prolapse with a mean change of -16 points (99% CI: -22.52, - 10.79, $p < 0.001$) in physical function, and -15.2 points (99% CI: -20.69, - 9.71, $p < 0.001$) in personal relationship function.

Table 7: Adjusted Effect of Pelvic Floor Muscle Training on Prolapse Symptoms and Quality of Life in Sidama Region, Ethiopia, August 2024

Predictors	Category	β (crude)	β (adjusted)	99%CI	P-value
POP-SS					
Intervention	Mean change	- 4.11	-4.11	-5.38, -2.83	< 0.001
Stage	Stage I	-5.22	-4.94	-7.38, -2.49	< 0.001
	Stage II	-3.03	-2.99	-4.83, -1.13	< 0.001
	Stage III	Ref	Ref		
Symptom duration		0.0	0.03	0.005, 0.06	=0.002
prolong labor		1.22	0.80	-0.704, 2.30	=0.17
Physical Function					
Intervention effect	Mean change	- 11.47	-8.86	-13.84, -3.89	< 0.001
Stage	Stage I	-39	-34.9	-42.16, -27.62	< 0.001
	Stage II	-18.37	-16	-22.52, -10.79	< 0.001
	Stage III	Ref	Ref		
Baseline POP-SS		1.45	0.64	0.21, 1.06	<0.001
Personal relationship					
Intervention effect	Mean change	-8.97	-9.01	(-10.49, -5.54)	< 0.001
Stage of prolapse	Stage I	-24.3	-23.9	(-29.65, -18.23)	< 0.001
	Stage II	-15.12	-15.20	(-20.69, -9.71)	< 0.001
	Stage III	Ref	Ref		
Baseline POP-SS		0.83	0.23	(-0.08, 0.55)	0.06
Psychological function					
Intervention effect	Mean change	-11.24	-11.18	(-15.03, -7.32)	< 0.001
Stage of prolapse	Stage I	-18.57	-16.80	(-24.34, -9.26)	< 0.001
	Stage II	-5.53	-5.13	(-9.93, 0.32)	0.006
	Stage III	Ref	Ref		
Baseline POP-SS		0.33	0.02	(-0.43, 0.46)	0.9

**POP-SS = pelvic organ prolapses symptom score, CI= confidence interval, Ref= reference category. ** The regression table shows a combination of four different regression tables (POP-SS and three domains of Prolapse quality of life).*

Additionally, the analysis revealed that higher baseline POP-SS predicts a smaller improvement (or even a worsening) in physical function. Specifically, for every one-point increase in baseline POP-SS, the physical function score increased by 0.64 points (99% CI: 0.21 to 1.06, $p < 0.001$). In terms of perceived improvement, a significantly higher proportion of women in the intervention group (84.2%) reported their condition as "better" compared to the control group (41.7%) ($p=0.0049$).

6. DISCUSSION

This study aimed to translate and validate the Sidaamu Afoo version of the Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire, assess the prevalence and risk factors of POP, and evaluate the impact of midwife-led Pelvic Floor Muscle Training (PFMT) on improving POP symptoms and quality of life among women in Ethiopia. The discussion will begin with an exploration of the methodological aspects, main findings, and policy implications. It will address how these findings can influence clinical practice, policy, and future research, emphasizing the potential for enhancing the management of POP in Ethiopia and similar contexts.

The principal strength of this thesis lies in the validation of a culturally relevant POP-SS assessment tool, the use of standardized measurements for diagnosing both symptomatic and anatomical prolapse, and the innovative approach of utilizing midwives to deliver the intervention. Additionally, the methodological rigor employed in this study represents another important strength. However, there are limitations, particularly regarding reliance on patient self-reports for adherence to treatment. The detail of the methodological discussion is presented here below.

6.1. Discussion of the Main Findings

The Sidaamu Afoo version of the Pelvic Organ Prolapse Symptom Score questionnaire validation involved 100 women, primarily from rural backgrounds, highlighting the demographic context in which the *Sidaamu Afoo* version was validated. The high response rate of 100% underscores the willingness of participants to engage with the research, which is crucial for the generalizability of the findings. This response rate underscores the importance of addressing women's health issues that are often overlooked in similar settings. The varying stages of prolapse (37% stage III, 55% stage II, and 8% stage IV) highlight the diverse experiences faced by women with POP, emphasizing the need for tailored assessment.

The face validity of the questionnaire was confirmed by both experts and participants, indicating that the tool is comprehensible and relevant to the target population. The CVI of 0.88 suggests that the majority of items are relevant and comprehensive (203, 205), although the lower score for one item indicates a potential area for refinement. This high degree of relevance is crucial for ensuring the tool's acceptance and use in clinical practice, where understanding local experiences is key.

The questionnaire's format remains consistent with the original scale and translated versions, which consists of seven questions with five response options. This indicates the *Sidaamu Afoo* version is technically equal and can be used for international comparison.

The internal consistency of the POP-SS, with a Cronbach's alpha of 0.79, demonstrates acceptable reliability (181, 223). The test-retest reliability score of 0.83 further supports the stability of the instrument over time, which is critical for clinical and research applications (225). This was based on a follow-up with 61 women, indicating that the questionnaire consistently measures the same constructs across different instances, which is vital for longitudinal studies and ongoing patient assessments.

The exploratory factor analysis revealed two factors that accounted for 70.6% of the common variance. The factors were well-defined, with factor loadings ranging from 0.61 to 0.92. Factor 1 included items related to feelings of something coming down from the vagina and discomfort, while Factor 2 encompassed other symptoms such as heaviness and the need to strain. The previous versions also showed two factors named physical and evacuation symptoms (241, 242). These findings align with previous research, reinforcing our understanding that POP symptoms can be categorized into physical discomfort and functional impairment. This understanding can guide clinicians in identifying specific symptom clusters when developing treatment plans.

Known group validity was assessed through the Kruskal-Wallis test, which indicated significant differences in symptom scores among different stages of prolapse. The tool effectively distinguished between stages II and III, as well as stage II and IV, but not between stages III and IV. This suggests that the questionnaire is capable of identifying varying levels of symptom severity, which is essential for clinical assessment and treatment planning. Significant differences in symptom scores across stages enable healthcare providers to tailor interventions based on severity, ultimately improving patient outcomes.

The result of this study has significant relevance both for clinical practice and researchers. The ability of the *Sidaamu Afoo* version to differentiate between stages of prolapse, as evidenced by significant differences in symptom scores across groups, highlights its utility in clinical settings. This criterion validity is essential for practitioners in tailoring interventions based on the severity of symptoms. Furthermore, the identification of two distinct factors through factor analysis provides insight into the symptom dimensions, suggesting that the questionnaire captures both

physical discomfort and functional impairment associated with POP. These findings highlight the importance of culturally adapted assessment tools in improving the management of POP. By providing a reliable and valid instrument, healthcare providers can better understand the symptom burden faced by women, ultimately leading to improved patient-centered care.

The current study revealed a prevalence of 30.90% for anatomical prolapse (stage II or higher) among the 779 women examined. This aligns with other previous studies that report anatomical prolapse rates in Ethiopia (31.8%) (243), Uganda (27.5%) (244) and Turkey (27.1%) (52), indicating the widespread nature of the condition. However, this prevalence is higher than the national estimated prevalences (22.7% to 23.5%) (245, 246) reported in a systematic review and meta-analyses. The systematic reviews and meta-analyses included POP prevalences that were estimated by symptomatic approach which can underestimate the prevalence.

The prevalence of anatomical POP in this study is notably lower than that reported in earlier studies from northern Ethiopia (55.1% - 56.3%) (39, 247) and Tanzania (64.6%) (63). This discrepancy may be attributed to several factors, including differences in measurement techniques and study populations. Previous Ethiopian studies often used the simplified POP quantification (S-POP) method, while the present study employed the standardized pelvic organ prolapse quantification (POP-Q) method, which may introduce variations due to measurement differences. Additionally, the median parity in the Tanzanian study was higher (5, IQR 0-14) compared to the present study's median of 4 (IQR 3-5), as higher parity is a known risk factor for POP. The current study's prevalence was estimated using complex survey analysis, which accounts for the effects of study design, potentially leading to more accurate prevalence estimates. Genetic factors may also play a role in the observed differences, although research on this topic is limited. Two systematic review and meta-analyses have indicated that many studies on POP have small sample sizes and varying quality, which can affect the reliability of their findings regarding effect of genetic factors (102, 104). Overall, the lower prevalence of anatomical POP in this study highlights the importance of standardizing measurement techniques and understanding the influence of genetic and environmental factors in different populations.

The most common stage of prolapse in the present study was Stage II (70.2%), comparable to previous reports from Tanzania (64.6%) (63) and Uganda (63.4%) (244). This suggests that POP is prevalent in the community. The finding that 78.5% of women with anatomical prolapse

reported symptoms underscores the substantial impact of this condition on quality of life. Symptoms such as discomfort and the sensation of something protruding are consistent with findings from other studies, including a systematic review that highlighted the psychological and physical burdens of POP on women (248). The high prevalence of symptomatic prolapse in Sidama suggests that many women may be living with untreated conditions, which could lead to further complications if not addressed. This high symptom burden emphasizes the need for increased awareness and intervention strategies for affected women.

Modifiable risk factors were identified as significant contributors to the development of POP in this study, with each additional hour of heavy lifting increasing the prevalence of anatomical prolapse by 26% and symptomatic prolapse by 16%. This aligns with findings from other studies that have established a clear link between physical strain and pelvic floor disorders (148) and epidemiological studies from Ethiopia (37, 40, 89) , Nepal (249), and Tanzania (63). The pathophysiology behind this association can be explained by the increased intra-abdominal pressure exerted during heavy lifting, which can weaken pelvic support structures over time (48, 63) .

The number of childbirths also significantly influenced the prevalence of prolapse, with each additional childbirth increasing the prevalence of anatomical prolapse by 17%. This is consistent with previous research that indicates trauma to the pelvic floor during delivery can lead to prolapse in China (250), Turkey (52), Pakistan (21), Tanzania (63), Uganda (244), and Ethiopia (37, 89) . Moreover, the finding that women who delivered before the age of 18 had a 29% higher prevalence of symptomatic prolapse highlights the risks associated with early childbirth. Early age at first childbirth is linked to various adverse health outcomes, including increased risk of obstetric complications and long-term pelvic floor disorders (243). Younger women may have underdeveloped pelvic support structures, making them more susceptible to injury during childbirth, which can result in prolapse later in life.

Prolonged labor, defined as lasting more than 24 hours, was also associated with a 32% increased prevalence of anatomical prolapse. Extended labor can cause significant stress on pelvic support tissues, leading to damage that may not be immediately apparent but manifests as prolapse over time. This finding is supported by other studies that have documented the complications associated with prolonged labor, including increased risk of pelvic floor dysfunction (245, 251).

The implications of these findings are significant for public health and clinical practice. The high prevalence of both anatomical and symptomatic prolapse, coupled with the identified risk factors, calls for urgent public health interventions. Community-based education programs focusing on lifting techniques, reproductive health, and safe childbirth practices could empower women and healthcare providers to reduce the incidence of POP.

Furthermore, healthcare professionals should be trained to recognize the signs and symptoms of POP, particularly in women with identified risk factors. Early intervention and management strategies can improve the quality of life for affected women and may prevent the progression of the condition.

The findings of this study underscore the effectiveness of midwife-led pelvic floor muscle training (PFMT) in improving POP symptoms and enhancing quality of life among women experiencing POP. As healthcare systems increasingly pivot towards community-focused models that prioritize prevention (126), this research highlights the critical need for effective conservative management strategies for pelvic floor dysfunction.

Our results demonstrate that women received PFMT Plus lifestyle modification counselling experienced significant reductions in POP-SS, with a mean change difference of -4.11 (99% CI: -5.38, -2.83) compared to the control group. Similarly, significant quality of life improvements was observed in the intervention groups with a mean change difference of -8.86 in the physical domain, -9.01 in the personal relationship domain, and -11.18 in the psychological domain. This aligns with previous literature indicating that PFMT is a clinically- and cost-effective approach for managing POP, as established by a review of 11 RCTs (19). The recent updates to the National Institute for Health and Care Excellence (NICE) guidelines further support the implementation of PFMT as a first-line treatment for urinary incontinence, emphasizing its provision in primary care settings (153).

However, the limited availability of trained healthcare professionals, such as physiotherapists and specialist, poses a significant barrier to widespread adoption of PFMT (252). As an alternative, the existing evidences suggests that PFMT delivered by nurses can be as effective as that provided by physiotherapists (156, 157). This highlights the potential for integrating PFMT into routine care provided by primary healthcare professionals. This approach can enhance accessibility and

compliance among women who may face barriers to specialized services. The delivery of PFMT is crucial for maximizing its benefits, particularly in community settings where access to specialized care is limited.

The mechanisms underlying the effectiveness of PFMT in treating POP are multifaceted (154, 155). Women learn to consciously contract their pelvic floor muscles in anticipation of increases in intra-abdominal pressure "performing the Knack". Additionally, regular strength training enhances the structural support of the pelvic floor over time (253, 254). These mechanisms are supported by anatomical and biomechanical principles, whereby voluntary contractions of the pelvic floor muscles help stabilize pelvic organs, reducing symptoms and improving quality of life (125, 255).

The reduction in prolapse symptoms contributes to enhancements in various quality of life domains. Alleviating prolapse symptoms enables women to engage in physical activities more comfortably, improving their overall physical health and fitness (256). Similarly, improved pelvic health can enhance sexual function and intimacy, leading to stronger personal relationships and increased overall satisfaction (257). Reducing the burden of prolapse symptoms can significantly enhance mental well-being, alleviating anxiety and depression associated with living with POP (258).

Identifying women who are most likely to benefit from PFMT is essential for optimizing clinical outcomes (44). Our analysis revealed that women with Stage I and II prolapse experienced more pronounced improvements in both prolapse symptoms and quality of life compared to those with Stage III prolapse. This suggests that intervention at an early stage may yield better outcomes, highlighting the importance of timely identification and referral of women at risk of developing more severe symptoms. Women with Stage I and II prolapses typically have stronger pelvic floor muscles that can respond more effectively to PFMT (259). The severity of symptoms tends to be less pronounced in earlier stages of prolapse, allowing for more noticeable improvements with conservative treatments like PFMT. Studies have shown that earlier intervention can lead to better outcomes, as the pelvic floor muscles are still capable of significant recovery (258). The therapeutic approach must consider individual patient factors, including symptom severity, quality of life impacts, and personal expectations, to tailor interventions effectively (125).

Overall, the observed mean change difference in POP-SS is both statistically significant and clinically meaningful, exceeding the minimally important change of 1.5 (260). Additionally, there was a significant improvement in symptoms such as vaginal discomfort/pain and the sensation of a protruding mass, which are critical indicators for prolapse treatment targets (258). The substantial reduction in these key symptoms underscores the importance of pelvic floor muscle training (PFMT). These symptoms are closely linked to the physical support provided by the pelvic floor muscles. Strengthening these muscles through PFMT may result in a more pronounced reduction in these specific symptoms compared to others that may be less directly affected by muscle strength or that involve more complex physiological changes.

6.2. Policy and Program Implications

This dissertation sought to address the critical gap in effective pelvic organ prolapse (POP) management within the Sidama region of Ethiopia. The key findings, the robust psychometric properties of the Sidaamu Afoo POP-SS, the alarmingly high prevalence of POP coupled with specific modifiable risk factors, and the significant reduction in prolapse symptoms achieved through midwife-led PFMT hold profound implications for policy, practice, and future research. To contextualize these findings and outline actionable steps for translating them into improved care for women in the Sidama region, this discussion proceeds in two parts. First, it will provide a broad overview of the policy landscape for addressing POP within the Ethiopian health system. Second, it will focus specifically on the programmatic and research implications arising directly from the findings of this dissertation, outlining actionable steps for translating these results into improved care for women in the Sidama region.

Addressing POP effectively within the Ethiopian health system requires consideration of several key policy areas. Recognizing POP as a significant women's health issue warrants supporting the implementation of culturally relevant assessment tools such as the validated Sidaamu Afoo version of the POP-SS. This tool is important for fostering trust and encouraging women to engage with healthcare services, it improves access to care and ensure that assessments reflect the unique experiences of women from diverse backgrounds (261) .

Comprehensive training programs for healthcare providers on the use and interpretation of such symptom assessment questionnaires also have the potential to improve diagnostic accuracy and

the application of appropriate interventions. A systematic review highlights the growing importance of patient-reported outcomes (PROs) in clinical practice, identifying key challenges and facilitators in their implementation. While training programs can enhance the integration of PROs into patient care, their effectiveness often depends on factors such as provider engagement, ongoing support, and tailored training initiatives (262). Furthermore, establishing feedback mechanisms and context-specific strategies is crucial for maximizing the benefits of PROs in clinical settings (263). This facilitates better monitoring of treatment effectiveness and enhances the overall quality of care provided to patients (264, 265).

Furthermore, as underscored by the high prevalence of undiagnosed POP (Paper II), community-based screening initiatives can effectively reduce stigma and encourage women to seek timely care. These initiatives facilitate early identification and intervention, significantly improving health outcomes. Raising awareness and promoting education about POP, particularly in rural and underserved communities, is vital policy consideration. Such initiatives can empower women to seek timely care and reduce the stigma associated with the condition. Community education programs have proven instrumental in normalizing discussions around POP and encouraging women to seek help (266). Research indicates that stigma is a significant barrier to accessing care, often leading to delays in diagnosis and treatment (37). Therefore, an integrated approach that combines community education with healthcare provider training is essential to reduce stigma and improve access to care for women with POP. Finally, supporting resource allocation for further research on POP is crucial to validate assessment tools in diverse populations and settings, improve diagnostic tools, enhance treatment outcomes, and reduce disparities in care. Ultimately, this approach will not only enhance the quality of life for women affected by POP but also ensure that healthcare resources are utilized efficiently and effectively across various populations (264, 267).

The implications of the current interventional study extend beyond clinical practice into health policy. Given the increasing prevalence of POP among women, it is worth integrating PFMT into routine care recognizing its effectiveness as a first-line conservative treatment for POP. The focus on non-invasive procedures at lower-level health facilities, delivered by mid-level health professionals, is necessary to enhance accessibility and reduce the burden on specialized care facilities. This approach aligns with the need for effective management strategies that prioritize conservative treatments.

The unique contributions of this dissertation now allow for targeted action within this broader policy context. The successful validation of the Sidaamu Afoo POP-SS directly enables its implementation in clinical settings and research projects throughout the Sidama region, enhancing the accuracy and cultural relevance of POP assessments. The prevalence findings call for targeted interventions to address modifiable risk factors, such as promoting institutional delivery to prevent prolonged labor, access to family planning for birth spacing, and reducing strenuous physical labor during lifting weights. These interventions should be integrated into existing maternal and reproductive health programs, leveraging established infrastructure and mid-level health worker networks. Crucially, the demonstration that midwife-led PFMT significantly reduces prolapse symptoms (Paper III) offers a scalable and cost-effective strategy for expanding access to POP treatment. This requires the development of a comprehensive training program for midwives and other primary healthcare professionals, equipping them with the skills and knowledge to deliver PFMT effectively and to provide culturally sensitive counselling to women. Furthermore, to ensure sustainability, PFMT should be focused and be prioritized in the standard curriculum for midwifery training programs. Moving forward, these findings underscore the need for specific changes to clinical guidelines and standard operating procedures. The findings support a multi-pronged approach that encompasses screening, prevention, and management, with a focus on empowering midwives and communities to address this neglected women's health issue.

In conclusion, this dissertation provides compelling evidence to support the integration of evidence-based POP care into the Ethiopian health system. By focusing on culturally appropriate tools, targeted interventions, and task-shifting to midwives and, a significant impact can be made on the lives of women in the Sidama region and beyond. Non-specialists can effectively administer PFMT with appropriate training and support, addressing the shortage of specialized physiotherapists (156, 157). Expanding the role of midwives in delivering PFMT could improve compliance and outcomes, as they are often more accessible to women than specialized physiotherapists. This approach could alleviate the burden of surgery and enhance the overall management of pelvic floor dysfunction.

6.3. Methodological Discussion

I. Study Design

In this PhD research, we used cross-sectional study design (Paper I and Paper II) and cluster randomized control trial study (Paper III). Each study was designed to address specific research questions within the broader context of understanding and mitigating POP in Sidama region, Ethiopian. The design choices were based on the need to ensure methodological rigor while balancing practical constraints related to resource availability, population characteristics, and data collection logistics.

The strengths of the psychometric study design lie in its comprehensive evaluation of measurement properties, use of established statistical methods, cultural and contextual relevance, test-retest reliability, ability to facilitate comparisons across studies, identification of floor and ceiling effects, and guidance for future research. Psychometric studies systematically assess various properties of measurement instruments, including reliability and validity, ensuring that the instrument is appropriate for the target population and context (268). The design employs rigorous statistical techniques, such as exploratory factor analysis, enhancing the credibility of the findings. While adapting the POP-SS into *Sidaamu Afoo*, attention was given to the geographical context, and cultural meanings that language carries. The translation was done by a team of different expertise. The absence of stage I patients in our study is a limitation, as it restricts the ability of the *Sidaamu Afoo* version of the POP-SS to capture the full range of symptom severity associated with different stages of prolapse. This limitation arises because stage I prolapse is often less severe and may not present significant symptoms, leading to fewer women with this stage seeking clinical care. Despite this, the tool remains valid for clinical use in assessing higher degrees of prolapse (stages II and above), where it effectively measures relevant symptoms and impacts on quality of life.

The second study design used in this PhD work is a community-based cross-sectional study. Cross-sectional studies are a form of observational research that examines data from a population at a specific moment in time. This design is commonly employed to assess the prevalence of health outcomes, explore health determinants, and characterize the features of a population (269). They only reveal correlations between variables at a single point in time and cannot establish cause-and-effect relationships. While cross-sectional studies can highlight associations, they often lack the depth needed to thoroughly explore complex relationships.

However, cross-sectional studies offer significant advantages in providing a snapshot view or observation of the health status of the study population at a stated period (269). This information is vital for planning proper health services and assessing the health needs of specific groups or populations. The cost-effectiveness and ease of conducting cross-sectional studies make them valuable tools for generating preliminary evidence that can inform the design of more advanced future studies.

Accordingly, a community-based cross-sectional study was used to determine the prevalence of POP and identify risk factors. The finding was used as a baseline information and followed by interventional study (Paper III). Even though the study cannot establish a cause and effect relationships, the identified POP risk factors which included frequent childbirth, experience of prolonged labour, heavy lifting and early-age childbirth were supported by other literature, indicating its consistence (269).

Thirdly, we employed cRCT design to evaluate the effect of midwife-led pelvic floor muscle training (PFMT) on both POP-SS and P-QoL. The randomized controlled trial (RCT) is considered the gold standard for determining the impact of an intervention on outcomes (270). A cRCT is a specific type of RCT that involves the randomization of groups (clusters) of individuals into either control or intervention conditions (271).

For evaluating certain types of interventions, such as health promotion and educational initiatives, a cRCT is often the only valid approach (272). This design is typically employed when individual-level randomization is impractical, when the intervention logically applies to an entire cluster, or when there is a high risk of information contamination. In our study, we opted for a cRCT because our intervention, pelvic floor muscle training (PFMT), is an educational initiative that carries a significant risk of information contamination if individual randomization were used. Additionally, delivering the intervention at the group or health facility level is more cost-effective and time-efficient than individual randomization. We took the nature of the cluster design into account during sample size calculations and utilized variance inflation factors to address intraclass correlations (ICC). Similarly, complex survey data analysis methods were applied during the data analysis phase.

II. Sample Size

In research, estimating the sample size during the planning phase is essential. A sample size that is too large can lead to unnecessary resource expenditure and may impose an undue burden on participants. Conversely, a sample size that is too small undermines the scientific integrity of the study, as it lacks the statistical power needed to draw reliable conclusions.

In this PhD work, we calculated the sample size for each objective by considering necessary assumptions for each study design. By its nature, psychometric studies typically involve smaller sample sizes, which can limit the generalizability of findings (268); however, this does not diminish the value of results. In our case, the questionnaire validation was conducted with 100 participants, and 61 were included in the test-retest phase. In paper I, we adhered to the recommended standard of 5-10 participants per item for sample size calculation. Even though this the final sample size seems small, it is essential to argue that this size was statistically and practically sufficient for establishing the psychometric properties of the tool.

Complex survey analysis and cRCTs introduce unique challenges for post-hoc power analysis, primarily due to the complexities inherent in their sampling designs and their implications for statistical inference. This complexity complicates the interpretation of post-hoc power analysis since standard formulas for power calculations typically assume simple random sampling (273, 274). Furthermore, post-hoc power analysis relies on observed effect sizes and sample statistics derived from collected data.

Given these unique challenges, several recommendations emerge for researchers conducting complex survey analyses and cRCTs. First, conducting power analyses during the planning phase of a study is essential to ensure adequate sample sizes based on expected effect sizes and desired significance levels. Second, instead of relying on post-hoc power analysis, researchers should consider reporting confidence intervals or effect sizes that provide clearer insights into the data without falling into the pitfalls associated with retrospective calculations (273, 274).

In this PhD research, we adjusted our sample size calculation for a 99% confidence interval, power, effect size, and clustering effects. This adjustment indicates that we considered elements of prospective power analysis. Moreover, we reported effect sizes with a 99% CI and significance level. These approaches ensured that our study was well-designed and adequately powered.

III. Validity

Validity is concerned with how well a study measures what it intends to measure (275). It encompasses two key components: internal validity and external validity. There is no external validity without internal validity, but presence of internal validity does not guarantee the presence of external validity

A. Internal validity

Internal validity is crucial for establishing reliable causal relationships. The primary threats to internal validity are bias, confounding, and chance effects.

Bias: This refers to any systematic error that results in an inaccurate evaluation of the association between an exposure and its effect within the target population (276). Bias in research indicates a deviation from the truth and is primarily categorized into two main types: selection bias and information bias (275, 276). Understanding research bias and its implications is crucial for investigators and policymakers, as bias can be present in all types of research and is challenging to eliminate (277). It can occur at every stage of the research process and significantly affects the validity and reliability of study findings (277). In these studies, the potential sources of bias and measures taken to mitigate them were explicitly declared.

Selection bias

Selection bias is a systematic error that occurs in the process of identifying the study population (277). It occurs when the individuals, groups, or data selected for analysis do not accurately represent the larger population intended for study. This bias can arise from improper selection of participants or inadequate randomization into study groups, leading to results that do not reflect the true characteristics of the population. Non-random sampling, and non-response bias are the common types of selection bias in observational study, while improper randomization and recruitment process are common source of bias in cRCT (271).

Sampling bias: In probability sampling, the greatest potential for sampling bias can be attributed to the non-coverage of survey population elements (277). Non-coverage of the sample frame occurs when certain population elements are systematically excluded from the sources used to create probability frames, resulting in those elements having no chance of being included in the sample. Additionally, sample non-coverage bias may occur during the process of screening

selected units to identify and select eligible survey respondents. In paper I, we included 100 women who understand Sidaamu Afoo and we assumed that they are from different part of the Sidama region.

In paper II, to minimize the risk of sampling bias in survey study, we stratified the study area and randomly selected clusters, ensuring equal chance for both strata. Then households were selected using computer generated house numbers before deploying data collectors. Data collectors and supervisors were trained on how to address the selected households. Finally, the data was weighted during analysis to account for unequal selection probability (278). Survey analysts are generally more focused on consistent estimators rather than purely unbiased estimators. Consistent estimators are those that converge on the true population value as the sample size approaches the population size (278).

Two other significant sources of sampling bias in surveys are non-response bias and volunteer bias. Non-response bias refers to the differences between those who do not respond and those who do respond from the originally selected sample, while volunteer bias pertains to the differences between volunteers and the broader population. Both types of bias can result in similar issues, particularly the risk that the collected data may not accurately represent the entire population, but rather only those individuals who choose to participate (192). In complex survey, if the non-response is high, a class method adjustment weight techniques can be used to account for non-response bias (278). In our study, the response rate was high (greater than 95.6% in Paper II; and 100% in Paper I and III) and the risk of volunteer bias is expected to be minimal since the data was collected from the originally selected households without any replacements.

Among the six bias specific to cRCT identified by the Cochrane handbook for a systematic review of intervention (RoB 2) (271), bias arising from randomization and participant recruitment are related to sampling bias.

Bias in randomization: In individually randomized trials, randomization is a crucial mechanism that mitigates the influence of both known and unknown prognostic factors such as the severity of illness or the presence of comorbidities on the assignment of participants to intervention groups. If prognostic factors affect the assignment of participants to intervention groups, the estimated

effect of the intervention may be biased due to confounding. Confounding occurs when there are common causes influencing both the intervention group assignment and the outcome (239) .

In cluster-randomized trials (cRCTs), bias resulting from the randomization process is often less prevalent than in individually randomized trials. The primary risk of subversion in cRCTs usually stems from the methodologists responsible for implementing the randomization. Because they typically lack motives or knowledge that could lead to manipulation of the allocation, the integrity of the randomization is generally maintained (271). However, because most cRCTs involve a limited number of randomized clusters, chance imbalances in cluster or participant characteristics are more common than in individually randomized trials. Importantly, differences that occur by chance do not necessarily introduce a risk of bias.

To ensure unbiased allocation, randomization of clusters should be conducted carefully and ideally independently. If not, biased allocation may occur, resulting in certain clusters being assigned to specific arms based on factors that could influence the outcome. Randomization can be achieved through different options (239) including: Simple randomization, matching, stratifying or minimization. To minimize the risk of randomization bias in our cRCT study, we employed stratification of the districts, and clusters were selected by simple randomization. Stratifying on location is likely to reduce stratum variability and helped ensure balance across study arm (188, 189). Furthermore, the randomization was conducted by an independent researcher who had no prior information about the participants' background. This approach aimed to prevent biased allocation and ensure that clusters were assigned to intervention and control arms based solely on chance.

By employing geographical stratification and involving an independent researcher in the randomization process, we aimed to minimize the risk of randomization bias and enhance the internal validity of our cRCT study. This approach helps to increase confidence in the estimated treatment effects and the reliability of the study's conclusions. It is important to note that while randomization is a powerful tool to control for known and unknown confounders, chance imbalances in cluster or participant characteristics may still occur, especially in studies with a small number of clusters.

Identification /Recruitment bias: In many cluster trials, clusters are identified and randomized before recruiting participants. In such cases, the allocation of the cluster may be known to the recruiters, potentially influencing who is approached to participate in the trial and how inclusion and exclusion criteria are applied. This can undermine the randomization process and lead to differential recruitment between the two conditions, resulting in post-randomization selection bias. Additionally, participants may refuse consent based on their knowledge of the intervention they are assigned to receive, further contributing to selection differences between groups (279, 280).

If the recruiter possesses knowledge of both the clinical characteristics of the participants and the allocation schedule, biased recruitment can occur (280). To mitigate this source of bias, it is recommended that participant recruitment be completed prior to randomization (43). If pre-randomization recruitment is not feasible, the recruiter should be masked or blinded to the cluster allocation. In this cRCT, it was not possible to recruit participants before randomization because the intervention starts following recruitment (as soon as eligible women is identified through pelvic examination). Therefore, prior cluster randomization was necessary to facilitate training for these midwives in two separate sessions (control and intervention). To minimize bias, the individuals responsible for recruiting study participants were blinded to the allocation schedule.

Information bias

Information bias refers to a systematic error that occurs when there are inaccuracies of information in a study (281). This occurs at the time of data collection. The three main types of information bias are misclassification bias, ecological fallacy and regression to the mean. Misclassification bias is originated when the sensitivity and specificity of the procedure to detect the exposure and outcome is not perfect, exposed or diseased subjects are classified as non-exposed/ or diseased and vice versa (275). The most common causes of misclassification bias are detection bias, observer/interviewer bias, recall bias and reporting bias. Interviewer bias is more common when the disease status is known to interviewer (282). Reporting bias occurs when the participants collaborate with researchers and give response in the direction they perceive as the interest of the researcher. This may result into over reporting or under reporting. Sometimes called social desirability bias (283). Survey data is vulnerable to information bias primarily due to measurement bias. Measurement bias is a systematic bias in the way respondents interpret and respond to

questions. It may be deliberate on the part of the respondent, or the unconscious result of poor questionnaire construction or interviewer training (201).

In our current study, we implemented several strategies to minimize information/measurement bias. We translated and validated the POP-SS tool into the local language (Paper I), ensuring clarity and cultural relevance. The stages of prolapse were objectively measured in centimeters, enhancing the accuracy of our assessments. To address potential biases, we trained both subjective and objective data collectors on the data collection tools. Interviews about women's experiences with POP-SS were conducted in private settings at their homes, which aimed to reduce social desirability bias and encourage honest reporting (the sensitivity nature of the symptoms can induce under reporting). Participants were asked about their experiences within the last four weeks to mitigate recall bias (Paper II and III), and a test-retest was conducted two weeks after the initial interview to further enhance reliability (Paper I). The individual performing pelvic examinations was blinded to participants' reported symptoms until after the examination was completed. This approach helped ensure that the assessment of the condition was objective and unbiased.

Despite these efforts, some risk factors for POP (POP) may not have been accurately measured. Many participants lacked birth certificates, leading to potential inaccuracies in age reporting. Although age is a recognized risk factor for POP in existing literature, our findings did not show a significant relationship between age and POP prevalence. Additionally, factors such as prolonged labor and heavy lifting were significantly associated with POP prevalence; however, these were based on respondents' judgments rather than objective measurements, introducing the possibility of further bias.

Bias due to deviation from intended intervention: Performance bias refers to systematic differences in the care delivered to the intervention and control groups that are unrelated to the intervention being studied. When participants, intervention providers, or trial staff are aware of the allocation, there is an increased risk of performance bias due to contamination, where the intervention may inadvertently be delivered to the control group. In cluster randomized trials, which are often pragmatic in nature, the control arm typically consists of usual care or no intervention (284).

In trials that require adherence to the intervention, the degree of compliance can significantly influence the assessment of the intervention's efficacy, leading to compliance bias. This type of bias tends to skew the estimated effect of the intervention toward the null hypothesis (285). To mitigate performance bias in our study, we implemented several strategies. While participants and midwives delivering the training were aware of their own intervention, they were blinded to the details of the other group's intervention, reducing the risk of bias in how the interventions were delivered. When feasible, we established buffer zones to prevent information contamination between groups. In cases where this was not possible, adjacent clusters were assigned to similar arms to minimize the risk of cross-contamination. Additionally, the research team covered transportation costs to enhance adherence to training sessions, thereby improving compliance among participants.

Adherence to the training protocol was primarily assessed through participants' self-reports. While this method provides valuable insights, it does present a gap in objectively ensuring or measuring adherence. To address this limitation, we also tracked attendance at midwife-led training sessions, which revealed a 100% adherence rate among participants. This approach aligns with recommended practices for measuring adherence, as it offers a more concrete assessment of participation in the training sessions. The training provided to both groups included similar content on lifestyle counselling. This design element helped ensure that participants could not easily identify the differences between the interventions, despite the intervention arm receiving additional training in pelvic floor muscle training (PFMT).

Bias due to missing outcome data: Missing outcome data in cluster randomized trials (CRTs) can lead to bias in the intervention effect estimate. This risk of bias arises even from procedures used to impute missing outcome data and incomplete follow-up (286). Allocation concealment is often not feasible in cRCTs, which can introduce bias through intervention assignment (287). To minimize bias, cRCTs should aim for similar loss to follow-up between groups and always use intention-to-treat analysis (279). Retaining all participants after allocation, regardless of inclusion criteria or receipt of allocated treatment, is important but may dilute the treatment effect (288). Attrition bias can occur if those who drop out have unique characteristics, making the remaining sample unrepresentative of the original sample.

Bias in measurement of the outcome: Errors in the measurement of outcomes can bias intervention effect estimates, commonly known as measurement error for continuous outcomes and misclassification for dichotomous or categorical outcomes (271). In cRCTs, the knowledge of allocation by outcome assessors can influence outcome measurement, particularly when assessments rely on the judgment of the assessor or are self-reported by participants (193). Response bias, a subset of ascertainment bias or detection bias, occurs when the assessment of outcome measures is systematically distorted by investigators or study participants who are aware of treatment allocation (192). This bias can inflate observed variance in statistical analyses, making it less likely to achieve statistically significant results. To mitigate this, standardized data collection protocols and training for study personnel can reduce inter-observer variability. Additionally, blinding study personnel to patient exposure and outcome status, or using different examiners for measuring outcomes and evaluating exposures can further decrease bias (279, 282).

In this cRCT, we provided comprehensive training for data collectors and utilized a standardized questionnaire to ensure consistency in data collection. To further enhance the integrity of our assessments, end-line data collectors were blinded to the intervention allocation, preventing any influence from their knowledge of which participants received the intervention. A significant concern in our study was the potential for response bias, particularly during the end-line assessment (Paper III). Since participants were aware that they are receiving intervention, this awareness could result in over-reporting of the intervention effects.

ii. Confounding

Confounding is often referred to as a “mixing of effects,” wherein the effects of the exposure under study on a given outcome are intertwined with the effects of an additional factor (or set of factors), resulting in a distortion of the true relationship (276, 289). Confounding is a critical issue in epidemiologic research and is described as the confusing or mixing of the influence of one exposure variable on the outcome with the impact of another exposure variable. For confounding to occur, a confounding variable must be related to both the exposure (determinant) and the outcome variables. However, it is essential to note that a confounder cannot be an intermediary variable in the causal pathway leading from exposure to outcome. The presence of confounding variable in the study make it difficult to establish a clear causal link between treatment and outcome unless appropriate methods are used to adjust for the effect of the confounders (275, 276).

To effectively manage confounding in research, researchers should first measure and report all potential confounders, including participant sociodemographic characteristics, diagnostic features, comorbidities, and any other factors that might influence the outcome. Next, it is essential to routinely assess the role of confounding factors and adjust for them in the analysis. During study planning, clear inclusion and exclusion criteria should be established to restrict specific confounding variables. Additionally, multivariable analysis allows for the adjustment of multiple variables simultaneously through mathematical modelling.

In this PhD work, we used a complex survey modified-Poisson regression model in Paper II to adjust for potential confounders. Similarly, in the cRCT, a mixed-effects generalized linear model was used to identify and adjust for confounding variables (Paper III). As a result, we observed slightly reduced effect of PFMT on the domains of pelvic organ prolapse quality of life (P-QoL) after adjusting for stage of POP.

By employing these strategies and measuring adherence through both self-reports and objective attendance data, we aimed to minimize performance bias and ensure that the observed effects of the intervention were attributable to the intervention itself, rather than systematic differences in care delivery. However, it is important to acknowledge that certain unmeasured and residual confounders were not controlled for in our analyses. Specifically, psychosocial factors such as mental health status, social support, and cultural beliefs regarding health may have influenced both the severity of POP symptoms and the perceived effectiveness of the intervention. These variables were not captured in our data collection, potentially leading to biased estimates.

iii. Chance

Chance refers to random variability that can lead to errors in results, potentially causing researchers to incorrectly conclude that an observed effect is significant when it may be due to random fluctuations (290). Chance can be quantified using statistical methods such as confidence intervals (CIs) and significance tests. These tools help assess the likelihood that observed differences are due to chance rather than true effects. By selecting primary outcomes with sufficient power and precision, researchers can reduce sampling variability, resulting in narrower confidence intervals and more accurate estimates (291).

We aimed to minimize the role of chance by ensuring that our primary outcomes were selected with sufficient power and precision to calculate an appropriate sample size. Similarly, in our investigation of midwife-led PFMT, we utilized rigorous statistical tests to evaluate the measured effect sizes, reporting these alongside 99% confidence intervals. Overall, while chance is an inherent aspect of any research study, we took steps to manage its influence through careful study design and robust statistical analysis. As a result, we believe that the role of chance is minimized in our conclusions

B. External validity

The external validity of a study refers to the extent to which its findings can be generalized or applied to populations, settings, or situations beyond the specific context of the study itself (292). It captures the applicability of inferences drawn from a study's sample to a broader population or other target populations. Generalizability is the ability to make inferences based on a sample drawn from a defined population, (293), while transportability refers to the ability to make inferences based on a sample but targeted at a different population (294). The credibility of both generalizability and transportability inferences relies on how well they can address multiple dimensions, such as mechanisms, settings, treatments, outcomes, units, and time. However, it is typically impossible to completely approximate or fully account for external validity in its entirety (292).

The external validity of this PhD research offers insights into its generalizability and transportability, though certain limitations should be acknowledged. The studies were carried out among women aged 18 and older residing in the rural and semi-urban settings of the Dale and Wonsho districts. These districts are located central to the region, practice the typical cultural and socio-economic conditions of the Sidama region, making the findings potentially generalizable within this context. However, caution is necessary when applying these results to other Ethiopian regions, where cultural and linguistic differences exist. The Sidaamu Afoo version of POP-SS may not be effective in regions with different linguistic.

The validation of the Pelvic Organ Prolapse Symptom Score (POP-SS) in *Sidaamu Afoo* enhances its cultural relevance for this population. However, Ethiopia's linguistic diversity presents challenges for generalizing the POP-SS findings to other regions where different languages are

spoken. To improve the broader applicability of this tool, further validation in other Ethiopian languages is necessary.

The effectiveness of the pelvic floor muscle training (PFMT) intervention, delivered by trained midwives, is a key finding of this research. The standardization of training and structured follow-up appointments ensured internal consistency, contributing to the intervention's effectiveness. Nevertheless, the success of PFMT in other settings might vary, particularly where midwives or primary healthcare providers are scarce.

The socio-demographic characteristics of the study population closely align with those of women in other rural and semi-urban areas across the region. This similarity supports the generalizability of the findings to similar populations. However, the exclusion of certain groups, such as pregnant women or those not fluent in *Sidaamu Afoo*, may limit the findings' applicability to the broader female population experiencing POP.

For the questionnaire validation in Paper I, a non-random sample was selected under the assumption that women admitted to Yirgalem Hamlin Fistula Center represent the broader population of the Sidama region. While this assumption holds in many cases, it may not fully capture the experiences of women in more remote areas with limited access to healthcare, thereby affecting the generalizability of the findings. In Papers II and III, participant selection was more robust, based on thorough household listings in the Dale-Wonsho Health and Demographic Surveillance System (D-WHDSS), with sampling weights applied during data analysis to account for unequal selection probabilities. This approach enhances the representativeness of the findings within the D-WHDSS population.

The studies were conducted between March 2023 to October 2023, and the intervention outcome was measured after six months indicating short term effect of the intervention. However, the long-term effect was not measured. Some evidences showed that symptom reduction success rates decrease in the medium and long term as adherence to the training program deteriorates (295).

The consistency of the PFMT intervention across clusters, supported by standardized training, reinforces its external validity. The effect of PFMT observed in this study aligns with results from similar studies conducted in high-income countries, suggesting that PFMT is an effective intervention for women with POP across diverse settings. Yet, future research should explore its effectiveness in various Ethiopian regions to further establish its broader applicability.

While the findings are consistent with similar studies in low-resource settings, the reliance on participants' ability to attend follow-up visits at health facilities may limit the generalizability to populations with different levels of healthcare access. Additionally, the specific resources and training provided in this study may not be available in other settings, potentially affecting the replication of the results. The cluster-randomized controlled trial (cRCT) design minimized spillover effects and enhanced internal validity, but randomization at the cluster level may not fully account for individual-level confounding factors, warranting caution when generalizing these findings.

7. CONCLUSIONS AND RECOMMENDATIONS

The *Sidaamu Afoo* version of the POP-SS questionnaire has strong face, content, construct, convergent, and criterion validity, along with acceptable internal consistency and test-retest reliability. This validated instrument effectively differentiates between various stages of POP, making it valuable for clinical assessments and research. Its clinical implications suggest that it can enhance patient care and contribute to standardized management of POP in the *Sidaamu Afoo-speaking* population, ultimately improving understanding and treatment of this condition in diverse settings.

Anatomical POP affects a substantial portion of women in the Sidama region. The identified risk factors include increased number of childbirths, prolonged labor, early age childbirth, and prolonged heavy lifting works which are consistent with existing literature and can be preventable, highlighting the need for targeted interventions. By addressing these factors through education and clinical practice, healthcare providers can play a crucial role in reducing the burden of POP among women in the Sidama region and beyond. Midwife-led pelvic floor muscle training (PFMT) is an effective intervention for alleviating POP symptoms and enhancing the quality of life among affected women. As healthcare systems increasingly focus on preventive care, integrating PFMT into routine reproductive health services is crucial, especially for women at risk of pelvic floor dysfunction. This study provides robust evidence for the adoption of PFMT as a standard practice in managing POP, demonstrating its acceptance by participants and its significant impact on improving physical, psychological, and relational aspects of life. Implementing PFMT in low-resource settings like Sidama region can be a safe and effective strategy for managing POP.

Recommendations

1. Policy Recommendations

- Develop and validate translations of the Pelvic Organ Prolapse Symptom Score (POP-SS) tool in other Ethiopian languages, to ensure culturally and linguistically appropriate symptom assessment across different regions
- Advocating for routine screenings for POP in primary healthcare centers, especially in rural areas with high prevalence rates, can facilitate early detection and management.
- Supporting the establishment of community-based education campaigns aimed at raising awareness about POP, its risk factors, the benefits of PFMT, and the availability of midwife-led services would be advantageous. Such campaigns can empower communities and encourage early health-seeking behaviors.
- It would be beneficial for policymakers to consider integrating midwife-led pelvic floor muscle training (PFMT) into the existing reproductive health services. This integration is essential for improving symptoms and quality of life for women with mild to moderate POP.
- It is important for policymakers to prioritize the creation and implementation of comprehensive training programs focused on PFMT techniques and counseling strategies, particularly for midwives in rural and underserved areas. Equipping midwives with these skills can enhance their ability to provide effective services in regions where there is a shortage of specialized healthcare providers.
- Policymakers are encouraged to incorporate the specific training protocols and exercise regimens demonstrated in recent studies into the development of national PFMT guidelines. This approach ensures that midwives receive training based on evidence-based practices that have shown positive outcomes.

2. Program/Operational recommendations

- Healthcare practitioners in the Sidama region are encouraged to systematically adopt the Sidaamu Afoo version of the POP-SS Questionnaire in clinical settings to evaluate symptoms effectively and inform treatment decisions
- Sidama Regional Health Bureau and NGOs could take the lead in public health campaigns that raise awareness about pelvic organ prolapse, its risk factors, and available treatments.

Engaging local communities through workshops can empower women to seek care and reduce stigma associated with POP.

- Health Facilities and NGOs may consider implementing targeted interventions aimed at educating women about safe childbirth practices and pelvic health risks associated with heavy lifting. Improving maternal health services to address issues such as prolonged labor can significantly reduce the incidence of POP
- Training centers are encouraged to develop structured training programs for midwives that focus on effectively delivering PFMT. This training could include techniques for assessing POP severity using locally validated version of the POP-SS and guidance on lifestyle counselling to complement PFMT.

3. Recommendations for Future Research

- Healthcare researchers might conduct longitudinal studies assessing the long-term effects of midwife-led PFMT on women's health outcomes beyond immediate symptom relief, including quality of life and functional status over time
- Research institutions and researchers could expand research to include various populations, particularly urban settings and different educational backgrounds, to better understand the tool's applicability and effectiveness.
- Researches that investigate the cost-effectiveness of PFMT compared to other prolapse management strategies are encouraged to inform resource allocation decisions.
- Clinical researchers are encouraged to design studies that incorporate objective measures of adherence to training protocols to identify barriers to compliance and improve patient outcomes

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ORIGINAL PAPERS

PAPER I

RESEARCH

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Reliability and validity of the *Sidaamu Afoo* version of the pelvic organ prolapse symptom score questionnaire

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Abstract

Background Both for clinical and research purposes, it is critical that clinicians and researchers use a tool that is trans-culturally adapted and tested for its psychometric properties. The English version of the Pelvic Organ Prolapse Symptom Score (POP-SS) questionnaire was developed in 2000. Since then it has been translated into other languages and verified. However, the tool has not been adapted for use in *Sidaamu Afoo* language in the Sidama Region of Ethiopia.

Objective This study aimed to translate and adapt the Pelvic Organ Prolapse Symptom Score questionnaire into *Sidaamu Afoo* and evaluate its psychometric properties.

Methods A total of 100 women with symptomatic prolapse completed version-2 of the POP-SS questionnaire during the first round of interviews, and 61 of them completed the questionnaire during the second round of interviews (to establish the test-retest reliability). We adapted the scale translation process recommended by Beaton and his colleagues. The content validity was assessed using the content validity index and the construct validity was done based on exploratory factor analysis using the principal component analysis model. The criterion validity was evaluated by using the Kruskal-Wallis test based on stages of the prolapse established via pelvic examination. The internal consistency reliability of the scale was assessed using Cronbach's alpha value, and test-retest reliability was evaluated using the intraclass correlation coefficient.

Results The questionnaire was successfully translated to *Sidaamu Afoo*, and achieved a good content validity index (0.88), high internal consistency (Cronbach's alpha of 0.79), and test-retest reliability (an intraclass correlation coefficient of 0.83). The exploratory factor analysis revealed two factors based on an eigenvalue of 1. The two factors explained 70.6% of the common variance, and each item loaded well (0.61 to 0.92) to its corresponding factor. There is a significant difference in the median score of prolapse symptoms across different stages of prolapse (Kruskal-Wallis χ^2 , 17.5, $p < 0.001$).

Conclusion The *Sidaamu Afoo* version of the POP-SS tool is valid and reliable. Further studies that involve a balanced number of women in each stage of prolapse are needed to avoid the ceiling and floor effects.

Keywords Pelvic organ prolapse, POP-SS, Reliability, Validity, Psychometric properties, *Sidaamu Afoo*, Ethiopia

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Introduction

Pelvic Organ Prolapse (POP) is the descent of one or more of the vaginal walls, cervix, uterus, bladder, or rectums into or out of the vaginal canal [1–4]. It is a complex disorder with both physical and functional elements [5] which require early treatment and has a substantial influence on the quality of life and psychological well-being of women [5–7]. The overall prevalence reaches up to 50% when diagnosed through vaginal examination [8]. The risk is increased in low and middle-income countries due to early marriage, heavy physical work and poor nutrition [9]. A prevalence of 60.9% was reported from Nepal [10]. A recent community-based study from northern Ethiopia showed that the prevalence of POP was 56.3% on pelvic examination and 26.3% based on symptoms [11]. Overall, it is challenging to establish the population-level prevalence of POP as the prevalence varies widely based on the tool used to diagnose the condition and population (symptomatic or asymptomatic) [12]. Therefore clinicians and researchers need to use a standard tool and criteria to accurately diagnose this disorder [13].

Hagen and colleagues developed a Pelvic Organ Prolapse Symptom Score (POP-SS) tool for English-speaking women in 2000 and published its psychometric properties in 2009 and 2010 [14, 15]. However, to use tools in other languages, they should be translated, cross-culturally adapted and their psychometric properties tested [16–18]. This helps the comparison of outcome measures and the accuracy of measurements [19]. So far, the POP-SS tool has been successfully translated into Turkish [20], Amharic [21], and Chinese [22] versions, and has been found to have acceptable psychometric properties. Evaluation of the international use of the questionnaire shows that the tool is commonly used in high-income countries both for clinical and research purposes and is also in use in low and middle-income countries [23]. The tool was used both for assessment of common prolapse symptoms [14] and for outcome measure after intervention [24]. The POP-SS is a condition-specific and brief index of symptoms that measures the extent of prolapse symptoms. However, in the current study area, its use for the assessment of prolapse symptoms by clinicians is inconsistent and not all items are used for prolapse assessment.

To our knowledge, no published study has evaluated the psychometric properties of this tool in *Sidaamu Afoo*, which is the mother tongue of the majority of the population in the Sidama Region of Ethiopia. Therefore, this study was designed to translate and adapt the POP-SS questionnaire into *Sidaamu Afoo* and evaluate its psychometric properties (reliability and validity) among women with POP symptoms.

Methods and materials

This study involved two phases. Initially, the original tool was translated to the target language, pretested, and data used to assess its psychometric properties other than test-retest reliability were collected. In the second phase, selected participants were interviewed again to evaluate the questionnaire's test-retest reliability.

The original POP-SS questionnaire

The original version of the POP-SS has seven questions with a five-point Likert scale which range from zero to four (0=never felt symptom, 1=occasionally, 2=sometimes, 3=most of the time, and 4=all of the time), a higher score indicating severe symptoms [14]. The participants are asked how often they have had the following symptoms in the last four weeks: (1) A feeling of something coming down from the vagina? (2) Uncomfortable feeling in the vagina that worsens when standing? (3) A heaviness feeling in the lower abdomen? (4) A dragging feeling in the lower back? (5) A difficulty in emptying the bladder? (6) A feeling of incomplete bladder emptying? and (7) A feeling of incomplete bowel emptying? The total score is calculated by summing up all responses to the seven-question. The total score ranges from 0 to 28. If the participant's total response score is greater than zero, she is considered as having symptoms of prolapse.

Translation and cultural adaptation of POP-SS

The permission to translate the tool was received from the primary author of the original POP-SS [14] (Additional File 1). Translation and cultural adaptation of the POP-SS tool was conducted according to the standard method of translation and adaptation recommendation by Beaton et al. [25]. This standard method includes forward translation, synthesis, backward translation, expert committee review, and pilot testing. The translation is not done on a word-by-word basis. Rather, we considered the geographical context, specific concerns, and cultural meanings that language carries. We gave more emphasis to the back translation because it aids in assessing the translation's quality [26].

Forward and backward translation Three native *Sidaamu Afoo* speakers (one medical doctor, one reproductive health expert, and one sociologist) who were fluent in English translated the tool from English to *Sidaamu Afoo* independently. A common draft version of *Sidaamu Afoo* was produced from the three translated versions in consensus between the three translators. This version was back-translated into English by two independent translators who were not involved in the forward translation and were fluent in *Sidaamu Afoo* and English. The original and back-translated versions were checked for any discrepancies by the author. Item number 1, “a feeling of something

coming down from the vagina” in the original version was stated as “a feeling of something coming down from the uterus” in the back-translated version. The authors referred back to the translators and identified that the discrepancy happened at the time of forward translation (as they considered using the term “vagina” embarrassing). After correcting this and other wordings, the first *Sidaamu Afoo* version was produced.

For expert committee review, experts with specialization in gynecology, midwifery, public health, and *Sidaamu Afoo* language reviewed the final forward and backward translations against the original version. For the English word ‘vagina’, a more appropriate word was selected by the committee. Again unnecessarily repeated words were modified (like item number 5, “a difficulty to empty bladder” was stated as “a need to push to completely urinate a urine” on the back-translated version. This was modified as “a need to push to empty bladder”. Then, a pre-final version (version_2) was created. This version was evaluated by six gynecologists from four hospitals for the suitability of each item and relevance for symptom assessment. The agreement was calculated using the Content Validity Index [27].

To evaluate the equivalence and comprehensibility of the translated *Sidaamu Afoo* version, the version_2 tool was also face-validated and pretested among ten women who speak *Sidaamu Afoo* and were admitted to Adare General Hospital and Yirgalem Hamlin Fistula Center with a diagnosis of Pelvic Organ Prolapse (POP). The pretest was conducted by one General Practitioner and one Health Officer working at Yirgalem Hamlin Fistula Center. No change was made after the pretest and version_2 was used as a final version.

Psychometric evaluation

Study participants

The study participants were women aged 18 years and above with symptomatic Pelvic Organ Prolapse who were recruited from the gynecology outpatient department of Yirgalem General Hospital and Yirgalem Hamlin Fistula Center from April to July 2022. Women who were not fluent in *Sidaamu Afoo*, were pregnant (confirmed or suspected), or were early postpartum were excluded.

Sample size

To ensure the statistical robustness of the analysis, the sample size was determined based on the recommendation of at least 5–10 subjects per item as per the Consensus-based Standards for the Selection of the Health Measurement Instruments (COSMIN) [28, 29]. Accordingly, the estimated sample size was 70 (10 subjects per item). However, to ensure the adequacy of the sample (to have adequate data for analysis and to obtain precise estimates), we recruited 100 women.

Sampling procedure

All women who visited the gynecology outpatient departments of Yirgalem General Hospitals or who were admitted to Yirgalem Hamlin Fistula Center during the study period were assessed for the presence of prolapse symptoms by two important questions: whether they had a feeling of bulging/pressure/something coming down from their vagina or; whether they had a visible mass protruding from the vagina in the past one year [21, 30, 31]. All women who had one or both of the above symptoms were considered symptomatic and invited for pelvic examination to confirm the prolapse. At Yirgalem General Hospital the prolapse symptoms were assessed by a General Practitioner in out-patient department and the pelvic examination was performed by a Gynecologist who is blinded to the questionnaire score. The prolapse stage was classified using the simplified POP-Q system [32, 33]. At Yirgalem Hamline Fistula Center, the symptom assessment was conducted by a Health Officer who took training and was working at Fistula Center. The prolapse stage was classified by a urogynaecologist using the standard POP-Q system [34] which is a very specific and objective system for quantifying and describing POP.

To measure the test-retest reliability, 67 women who can be traced after two weeks (those who have a mobile phone) were purposefully selected based on their accessibility. The same data collector and tool (version_2) was used to collect data about prolapse symptoms through telephone interviews. In this interview, patient stability was not checked. A 2-weeks duration for the retest [28] was preferred because if the duration is too short, they may remember their previous response, which may result in an overestimation of the test-retest reliability. On the other hand, if the time is too long, an individual's response may be changed due to other interventions and underestimate the test-retest reliability [35].

Statistical analysis

The collected data were entered into Epi-Data version 3.1 and analyzed using Stata version 16 software [StataCorp LLC, College Station, Texas, USA]. After cleaning and coding the data, sociodemographic characteristics were described by frequency, mean, and standard deviation.

Face validity Face validity, the extent to which the questionnaire is a measure of what it is intended to measure in the opinion of the patient and experts was evaluated by the expert committee through the adaptation process [36]. It is also the degree to which respondents or laypeople believe the questionnaire items are valid. Face validity may drive respondents to answer more accurately, but it is the weakest method of determining a questionnaire's validity [35, 36]. In this study, the face validity was evaluated first by the experts whether the tool is attractive or

not. Then ten women who speak *Sidaamu Afoo* and were admitted to Adare General Hospital and Yirgalem Hamlin Fistula Center with a diagnosis of Pelvic Organ Prolapse (POP) were asked what they thought each question was asking, whether they could paraphrase each question in their terms, and the logic behind their responses [37].

Content validity We evaluated whether the questionnaire could be understood by patients and experts and whether all important and relevant items had been included by the expert panel. Six experts evaluated the comprehensiveness and the relevance using a scale that range from 1 to 4 (1=not relevant, 2=somewhat relevant, 3=quite relevant, and 4=highly relevant) [38, 39]. Experts' agreement on relevancy was calculated using the Content Validity Index (CVI), and agreement $\geq 80\%$ was considered acceptable [27, 38]. These experts evaluated each item for content relevance, representativeness, and technical quality.

Construct validity The construct validity was done based on exploratory factor analysis using the Principal Component Analysis (PCA) model. To run the factor analysis, its appropriateness was determined by Kaiser-Meyer-Olkin (KMO) statistics and Bartlett's test of sphericity. The value of KMO is acceptable if it is >0.5 [40] and Bartlett's test is acceptable if it is significant, p -value ≤ 0.05 [41]. To identify the number of meaningful factors, eigenvalues >1 were considered meaningful and factors were retained for rotation [42]. At the same time, we used a Scree plot indicating eigenvalues for each factor to identify the number of factors to be retained. Then to estimate factor correlations, the varimax orthogonal rotation procedure was applied and commonalities and factor loadings ≥ 0.4 were considered sufficient [43]. Items with factor loading ≥ 0.4 on more than one factor were considered to be cross-loading [40].

Convergent validity To assess how closely a test is related to other tests that measure the same construct (domain), the average inter-item covariance and reliability coefficient were used. Ideally, two tests measuring the same domain (construct) should have high or moderate correlations. A reliability coefficient of ($CR > 0.7$) and Average variance extracted value ($AVE > 0.5$) indicates convergent validity [44]. We used average inter-item covariance and correlation of items within each identified domain.

Criterion validity To evaluate the known-group validity, the median difference of POP-SS values among the three stages of POP was compared by using the Kruskal-Wallis test. Significant Kruskal-Wallis's test indicates the validity of the tool [45]. Furthermore, pairwise multiple comparisons were done by using Dunn's test to see between which

stage of prolapse it can differentiate. A significant level of the test [46] indicates the questionnaires' ability to differentiate between different stages of the prolapse.

Internal consistency and test-retest reliability The tool's internal consistency reliability was evaluated using Cronbach's alpha. Cronbach alpha values between 0.7 and 0.95 [28, 47] indicate adequate internal consistency of the POP-SS questionnaire. Each item's reliability was also analyzed by assessing its item-total correlation and the overall reliability if a specific item is deleted. Item-total correlation of ≥ 0.5 and inter-item correlation of ≥ 0.3 was considered adequate [48].

Test-retest reliability was computed based on the intra-class correlation coefficient (ICC). To check the test-retest reliability, the data were reshaped from wide form to long form as intra-class correlation coefficient (ICC) estimation works with long data) [49]. Single-rating, absolute agreement, and two-way mixed-effect models were used [16, 49, 50]. An ICC of ≥ 0.7 was considered acceptable [28].

Floor and ceiling effects were computed by percentage frequencies of the lowest and highest scores achieved. Accordingly, ceiling and floor effects were considered present if $>15\%$ of participants achieved this score [28]. The presence of ceiling and floor indicates that the tool fails to discriminate patients at the extremes.

Results

Characteristics of study participants

One hundred women volunteered to participate in the study making a response rate of 100%. The age of the participants ranged from 24 to 75 years. Most of the women were from rural areas (91%), can't read and write (91%), were housewives by occupation (84%), and were Protestant by religion (94%). Fifty-five (55%) had stage 3 prolapse and 81 (81%) of the participants had apical prolapse (Table 1).

Face validity

Both the panel of experts and POP symptomatic women who participated in the pre-test study confirmed that the tool is easily understandable. No item was suggested to be deleted or added to the scale. The format of the tool remained the same as the original scale and its translated versions (seven questions with five response options).

Content validity

Six experts evaluated the relevance and comprehensiveness of the questionnaire. The overall content validity index was 0.88 and the Scale Validity index was 0.43. Only One item (item number three) was given an index

Table 1 Characteristics of study participants involved in the validation of the *Sidaamu Afoo* version of the Pelvic organ prolapse symptom score tool, Sidama region, Ethiopia, 2022 (N = 100)

Variables		Frequency (%) or Mean ($\pm$ SD)
Age (mean)		46.9 ($\pm$ 10.6)
Residence	Rural	91 (91%)
	Urban	9(9%)
Religion	Protestant	94 (94%)
	Orthodox Christian	4 (4%)
	Muslim	2 (2%)
Marital status	Single	2 (2%)
	Married	64 (64%)
	Widowed	31 (31%)
	Divorced	3 (3%)
Level of education	Unable to read and write	91 (91%)
	Able to read and write	3 (3%)
	Attended school	6 (6%)
Occupation	Housewife	84 (84%)
	Farmers	14 (14%)
	Others	2 (4%)
Number of childbirths (mean)		6 ($\pm$ 2.23)
Women in menopause	Yes	65 (65%)
	No	35 (35%)
Stage of prolapse	Stage 2	37 (37%)
	Stage 3	55 (55%)
	Stage 4	8 (8%)
Prolapse compartment	Apical	81 (81%)
	Anterior	10 (10%)
	Posterior	3 (3%)
	Vault	6 (6%)

score of <0.8. Similarly, a scale validity index of <0.8 was observed from one expert (expert number 4) (Table 2).

Reliability and item analysis

The overall internal consistency of the POP-SS questionnaire was 0.79 (95% confidence interval of 0.73–0.85). There was no evidence of an increase in this value if an item is deleted. The percentage distribution of the

responses showed that an answer of zero (0) was given most frequently to one item (A feeling of incomplete bowel emptying) (51%). An answer of four [4] was given most frequently to two items (A feeling of something coming down from your vagina [71%] and A feeling of discomfort /pain in the vagina [72%]). Item-total correlation, inter-item correlation coefficient; and floor and ceiling effects are presented in Table 3. Among the 67 women who were chosen for a second-round interview two weeks after the first interview, six of them were not accessible. Hence, only 61 women participated in the re-test interview. The test-retest reliability value was 0.83 (95% CI: 0.50–0.92) (Table 3).

Construct validity

Bartlett's test of sphericity ($\chi^2=412.53$, $p<0.001$) and the Kaiser-Meyer-Olkin measure of sampling adequacy showed that the POP-SS has adequate common variance (KMO=0.66) for factor analysis. Using the principal component analysis model, the factor analysis extracted two factors (components) based on a minimum eigenvalue of (1) The factors were rotated orthogonally by using a varimax approach to easily interpret factor loadings and identify items that loaded on each factor (component). Two items (*feeling of something coming down from the vagina* and *an uncomfortable feeling or pain in your vagina*) loaded to Factor 2 with factor loadings of 0.87 and 0.92, respectively. Five items (*a heaviness feeling in the lower abdomen, a dragging feeling in the lower back, difficulty in emptying the bladder, a feeling of incomplete bladder emptying and a feeling of incomplete bowel emptying*) loaded to Factor 1 with factor loadings ranging from 0.61 to 0.90 (Table 4). Factor 1 explained 44.6% of the common variance, and Factor 2 explained 26%. Both factors combined explained 70.6% of the common variance. The eigenvalue was 3.1 for Factor 1 and 1.8 for Factor (2) The scree plot constructed based on eigenvalues of 1 also indicated two factors (dimensions) of the *Sidaamu Afoo* version of the POP-SS (Fig. 1). Communalities for each item ranged from 0.44 to 0.84, indicating adequate commonalities.

Table 2 Content Validity Index score of pelvic organ prolapse symptom score given for the *Sidaamu Afoo* version, June 2022

Item	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	CVI
A1	1	1	1	1	1	1	1
A2	1	1	1	1	1	1	1
A3	0	1	1	0	1	1	0.68
A4	1	1	1	0	1	1	0.83
A5	1	1	1	1	1	0	0.83
A6	1	1	1	1	1	1	1
A7	1	1	0	1	1	1	0.83
Proportion relevance	0.86	1	0.86	0.71	1	0.86	Mean CVI=0.88

*CVI=Content Validity Index *SVI (Scale Validity Index)=0.43

Table 3 Internal consistency, test-retest reliability; and ceiling and floor effect score of the *Sidaamu Afoo* version of pelvic organ prolapse symptom score, June 2022

Items	Item-total correlation	Inter-item correlation	Internal consistency (95% CI) (A1-A7)	Ceiling (n)	Floor (n)	Test-retest values		
						(ICC3,1)	95%CI	P_value
A1. A feeling of something coming down from the vagina	0.27	0.78	0.79 (0.73, 0.85)	71	0	0.83	(0.50, 0.92)	< 0.001
A2. An uncomfortable feeling or pain in your vagina.	0.31	0.78		72	2	0.66	(0.48, 0.79)	< 0.001
A3. A heaviness or dragging feeling in your lower abdomen.	0.61	0.72		7	21	0.78	(0.63, 0.87)	< 0.001
A4. A heaviness or dragging feeling in your lower abdomen.	0.67	0.70		12	16	0.78	(0.59, 0.88)	< 0.001
A5. A need to strain (push) to empty your bladder	0.55	0.73		18	25	0.81	(0.66, 0.89)	< 0.001
A6. A feeling that your bladder has not emptied completely	0.54	0.73		17	22	0.75	(0.61, 0.84)	< 0.001
A7. A feeling that your bowel has not emptied completely	0.51	0.74		6	51	0.81	(0.65, 0.90)	< 0.001

*(ICC3, 1)=Single rating, Two-way Mixed-effects model (absolute agreement); CI=confidence interval

Table 4 Construct and convergent validities of the *Sidaamu Afoo* version of pelvic organ prolapse symptom score, June 2022

POP-SS Items	Construct validity			Convergent validity		
	Item-loading	Variance (%)	Eigenvalue	Reliability coefficient	Average inter-item covariance	Scale reliability coefficient
Factor 1						
A1. A feeling of something coming down from the vagina	0.02	44.6	3.1		0.89	0.817
A2. An uncomfortable feeling or pain in your vagina.	0.01					
A3. A heaviness or dragging feeling in your lower abdomen.	0.74			0.81		
A4. A heaviness or dragging feeling in your lower abdomen.	0.74			0.80		
A5. A need to strain (push) to empty your bladder	0.90			0.78		
A6. A feeling that your bladder has not emptied completely	0.86			0.80		
A7. A feeling that your bowel has not emptied completely	0.61			0.85		
Factor 2						
A1. A feeling of something coming down from the vagina	0.87	26	1.8	0.71	0.37	0.817
A2. An uncomfortable feeling or pain in your vagina.	0.92			0.71		
A3. A heaviness or dragging feeling in your lower abdomen.	0.29					
A4. A heaviness or dragging feeling in your lower abdomen.	0.36					
A5. A need to strain (push) to empty your bladder	0.17					
A6. A feeling that your bladder has not emptied completely	0.13					
A7. A feeling that your bowel has not emptied completely	0.27					
Total		70.6				

Convergent validity

The correlation of items within each factor (convergent validity) assessed by the internal consistency reliability of each factor has an adequate correlation (scale reliability coefficient) of 0.84 for Factor 1 and 0.82 for Factor 2. The average inter-item covariance was 0.89 in Factor 1 and 0.37 in Factor 2 (Table 4).

Criterion validity: known groups validity

The criterion validity showed that there was a significant difference in the median of POP-SS among the three groups of prolapse stages based on the Kruskal-Wallis

test (Kruskal-Wallis χ^2 , 17.5, $p < 0.001$). In addition, pairwise multiple comparisons showed that the tool can differentiate stage 2 prolapse from stage 3 ($p < 0.001$) and stage 2 from stage 4 ($p = 0.011$), but no significant difference was observed between stage 3 and stage 4 ($p = 0.46$). The median of POP-SS was 12 in stage 2 patients, 18 in stage 3 and 19 in stage 4 participants with POP.

Discussion

The Pelvic Organ Prolapse Symptom Score (POP-SS) tool was successfully translated into *Sidaamu Afoo* language and achieved adequate psychometric properties. The tool

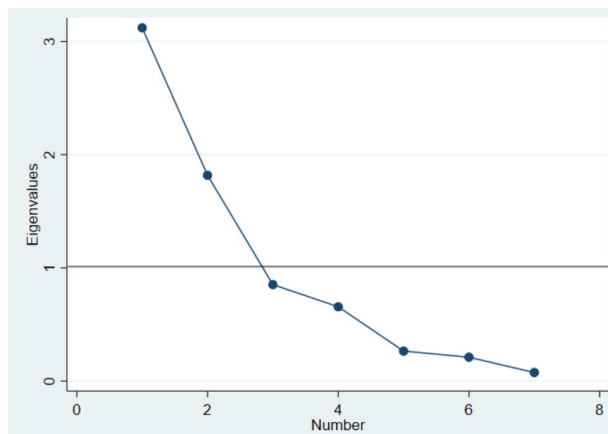


Fig. 1 A scree plot indicating the number of factors to be retained for the Sidaamu Afoo version of the POP-SS questionnaire, June 2022

has a content validity index of 0.88, internal consistency reliability (Cronbach alpha) of 0.79, and test-retest reliability (ICC) of 0.83. Bartlett's test of sphericity was significant and the Kaiser-Meyer-Olkin (KMO) statistics was 0.66 indicating the adequacy of the sample for factor analysis. Factor analysis revealed two factors with a common variance of 70.6% and factor loadings ranged from 0.61 to 0.92. Evaluation of criterion (known-group) validity showed that the current version of POP-SS can differentiate between POP stages. It was able to differentiate between stages 2 and 3, and between stages 2 and 4, but not between stages 3 and 4.

During the translation of this tool, the changes were made more at the level of the meaning of the sentences considering culture rather than more specific word modifications to maintain the original meaning and context. More attention was given to the back-translation as it helps in assessing the translation's quality [26]. These efforts helped to maintain the meaning and purpose of the tool similar to the original version which in turn will help for international comparisons. The evaluation made by a panel of experts and POP symptomatic women suggests maintaining the questionnaire format as it is (i.e., no item was suggested to be deleted or added to the scale). This indicates the current, *Sidaamu Afoo*, version is technically equivalent to the original scale and its translated versions [14, 20–22] in terms of the number of items [7], response options (0 to 4), and outcome measure (a symptom of prolapse). The *Sidaamu Afoo* version had an adequate content validity index (0.88) and Scale Validity Index (0.43). This shows the agreement among experts on the relevance of the items and the comprehensiveness of the overall scale.

The questionnaire also had acceptable internal consistency reliability (Cronbach alpha=0.79). This value is in-line with the values of the original tool (0.72–0.83) based on the source of data used [14] and the Chinese

version (0.78) [22], but slightly lower than the result of the Amharic version (0.86) [21] and higher than the result of the Turkish version (0.71) [20]. Despite the slight difference in the magnitude of the reliability coefficient, all values are greater than the threshold value (0.7) [47], indicating that the tool is internally consistent. The test-retest reliability of the questionnaire was also good (ICC=0.83). This value is similar to the result of the Amharic version (0.81) [21] but lower in size compared to the Chinese and Turkish versions (0.98) [20, 22]. Still, the result of these findings indicates that the scale is consistent over time.

The exploratory factor analysis identified two factors (components) based on a minimum eigenvalue of one. The first factor contains items number three to seven and the second factor contains the first two items: *a feeling of something coming down from the vagina* and *discomfort feeling/pain in the vagina*. The first two items (symptoms) are a direct result of something protruding from the vagina. So, this construct (dimension) can be named protrusion-related symptoms. The remaining five items (symptoms) can occur when the prolapsing part is within the vaginal canal (without protruding out of the vagina) and can be named non-protrusion symptoms.

The number of factors identified is similar to all the previous three versions [20–22]. The original version did not report on factor analysis, but the translated three versions named the two factors as physical and evacuation symptoms. However, the last item (a feeling of not completely emptying the bowel) inconsistently loaded to each factor. In this study, only two items (*a feeling of something coming down from the vagina* and *discomfort feeling/pain in the vagina*) loaded to one factor and the remaining five items loaded to the other factor. This might be because the majority (63%) of the current study participants were women who were diagnosed with advanced-stage of prolapse. In an advanced stage of prolapse, protrusion of mass per vagina and discomfort in the vagina exist always [20, 51–53], but the other symptoms may not exist always. The items in each factor had good factor loadings, indicating a good correlation with the underlying factor. Yong and Pearce suggest that a factor with two variables (items) can be considered reliable if the variables (items) are highly correlated ($r > 0.7$) but fairly uncorrelated with other items [54]. This tool has a convergent validity in terms of Cronbach alpha of 0.84 in Factor 1 and 0.82 in Factor 2. This indicates the items in each factor (construct) are highly correlated. The two factors explained 70.6% of the common variance. This is similar to the Amharic version (71.56%) [21] and higher than the Turkish version 55.9% [20].

Based on the Kruskal-Wallis test, the criterion validity test shows that the *Sidaamu Afoo* version of POP-SS can produce significantly different POP symptom scores

across the different stages of prolapse confirmed by urogynaecologist. Specifically, it was able to differentiate between the early prolapse stage (stage 2) and advanced stages (stages 3, $p < 0.001$; and stage 4, $p = 0.011$). However, no significant difference was observed between the advanced stages (stages 3 and 4, $p = 0.46$). This could be because stages 3 and 4 are sometimes interchangeable depending on the presence of factors aggravating the prolapse like heavy work at the time of diagnosis. Since the management protocol is similar for advanced stages (stages 3 and 4), this tool has clinical importance in diagnosing the patient for POP and monitoring prolapse symptoms. The Turkish and Amharic versions also showed that the highest stage of prolapse had a higher value of POP-SS [20, 21]. Both long-term and short-term follow-up is necessary even after surgery for pelvic floor disorders to evaluate treatment success [12, 55]. Therefore, this tool has importance in diagnosing POP, for patient follow up after treatment and also to compare effectiveness of different treatment options.

The ceiling and floor effect test showed that an answer of zero (0) was given most frequently to one item (*a feeling of incomplete bowel emptying*, 51%). This agrees with the result of the Amharic version of the POP-SS (73) [21]. This score (zero) might be due to the fewer number (3%) of participants with posterior prolapse in this study. Unless the posterior compartment is involved in the prolapse, a feeling of incomplete bowel emptying may not occur. On the other hand, a maximum rating of four [4] was given most frequently to two items (*a feeling of something coming down from your vagina* [71%] and *a feeling of discomfort /pain in the vagina* [72%]). The result of the Turkish version of POP-SS [20] also showed that the ceiling effect was seen in a similar item. In the current study, there is no lower score rating given for item number one (feeling of something coming down from your vagina). This might be again due to the majority of the participants having advanced stages of prolapse.

To our knowledge, this is the first validation of the *Sidaamu Afoo* version of the POP-SS tool. However, it is not free of limitations. This study did not involve women with prolapse stage one because we did not get them during the study period. However, since stage 1 is not considered clinically relevant and most women seek healthcare only when the prolapse is advanced [56], this tool is valid and can be used in clinical settings. The other limitation is that the criterion validity of the tool was evaluated only against the known group validity test, but not compared against other standard tools like the Prolapse-Quality of life tool and Pelvic Floor Distress Inventory (PFDI-20) tool. Thirdly, the lack of participants in stage one and the inclusion of a majority from the advanced stage of prolapse resulted in a considerable number of floor and ceiling effects. It has also produced only two items that

loaded to Factor 2 with lower average inter-item covariance. Further, most (91%) of the study participants can't read and write, so the questionnaire was administered through interviews. The way the questions were communicated during interviews might influence participants' responses in a way that may produce bias.

Conclusion

The *Sidaamu Afoo* version of POP-SS was successfully translated, and it is consistent, valid, and reliable to use for the assessment of pelvic organ prolapse both in research and clinical setups. Further, studies that involve a balanced number of women in each stage of prolapse are needed to evaluate the ceiling and floor effects.

Abbreviations

ICC	Intra-class Correlation Coefficient
POP	Pelvic Organ Prolapse
POP-SS	Pelvic Organ Prolapse Symptom Score

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12905-023-02478-x>.

Additional File 1: Pelvic Organ Prolapse Symptom Score

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Authors' contributions

MS: Conceived the idea, ensured data curation, did the formal analysis, and wrote the main manuscript; WT: Ensured data curation and wrote the manuscript; RN: Ensured data curation and wrote the manuscript; BS: Ensured data curation and wrote the manuscript; AA: Conceived the idea, ensured data curation, did the formal analysis, and wrote the main manuscript. All authors read and approved the final manuscript.

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Data Availability

All data on which the results are based are provided within the manuscript.

Declarations

Ethics approval and consent to participate

This study was one component of a project on 'Epidemiology of Pelvic Organ Prolapse in Sidama Region, Ethiopia'. The study complied with the Declaration of Helsinki and was approved by the Institutional Review Board of the College of Medicine and Health Sciences, Hawassa University (Ref. No. IRB/157/14). Permission was obtained from Yirgalem General Hospital and Yirgalem Hamline Fistula Center. Written informed voluntary consent was obtained from the participants and their legal guardians.

Consent for publication

Not applicable.

Competing interests

All authors declare that they have no competing of interest.

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PAPER II

Prevalence and risk factors of pelvic organ prolapse among women in Sidama region, Ethiopia: A community-based survey

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Abstract

Background: Pelvic organ prolapse is a descent of the vaginal compartments and the surrounding organ due to loss of support of the vaginal tissue. It has a significant psychological, physical, and social impact that affects women's quality of life. However, its true prevalence is unknown due to the variability in the methods used to diagnose the disorder.

Objectives: This study aimed to determine the prevalence of pelvic organ prolapse and its associated risk factors among women in Sidama region, Ethiopia.

Study design: A community-based cross-sectional survey was conducted in the Dale–Wonsho Health and Demographic Surveillance Site, Sidama region, from March to October 2023.

Methods: A multi-stage stratified cluster sampling was used to select a sample of 816 women. Anatomical prolapse was diagnosed based on the standardized pelvic organ prolapse quantification method, and symptomatic prolapse was assessed by patient-reported symptoms. A complex survey-based modified Poisson regression was used to assess the risk factors associated with prolapse.

Results: A total of 815 participated in the interview, and 779 (95.6%) underwent pelvic examination to assess for prolapse status. Anatomical prolapse (Stages II–IV) was observed in 241 (30.9%; 95% confidence interval = 24–38.7) of the participants. The prevalence of symptomatic pelvic organ prolapse was 78.5% (95% confidence interval = 69.1–85.7) among women with anatomical prolapse (189/241). This prevalence falls to 24.27% (95% confidence interval = 19.98–29.16) for the total sample population. Higher frequency of childbirth, prolonged heavy lifting activities, and prolonged labor increased the likelihood of developing anatomical prolapse. Childbirth at an early age and prolonged heavy lifting activities were significantly associated with symptomatic prolapse.

Conclusion: Anatomical prolapse and symptomatic prolapse are high in the study area. Parity, prolonged heavy lifting, prolonged labor, and early age childbirth were associated with pelvic organ prolapse. Community-based education and interventions that focus on the modification of risk factors are needed.

Plain language summary

A study on pelvic organ prolapse confirmed through physical examination and symptoms of prolapse assessed among women in Sidama region of Ethiopia

Why was the study done? Pelvic organ prolapse occurs when one or more vaginal compartments and their surrounding organs drop from their normal position. Imagine the pelvic floor as a supportive sling made of muscles, ligaments, and tissues. These structures usually hold organs, such as vagina, bladder, uterus, and rectum in place. However, when the pelvic floor weakens due to factors, such as pregnancy, childbirth, or menopause, these organs bulge. Symptoms

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may include feeling a tissue bulge near the vaginal opening, pelvic pressure, lower back pain, urinary changes, and even difficulty keeping in a tampon. However, evidence about how common the problem is in the Sidama region is limited. This may hinder the need for efforts to be taken in identifying and treating the disorder. **What did the researchers do?** The research team assessed the symptoms of prolapse by asking women through house-to-house visits invited them to the nearby health facility and conducted pelvic examination to confirm the presence of prolapse. Women's characteristics that can be related to prolapse were also assessed through interview. **What did the researchers find?** A total of 815 women participated in interviews on prolapse symptoms, and 779 underwent pelvic examination. Among those examined, one in three women (241/779) has a physically confirmed prolapse. Among the confirmed prolapses, 189 women reported symptom of prolapse. Women who have birth many times, who work on prolonged heavy lifting activities, and who have a history of labor that lasted more than 24 h have a high chance to develop prolapse. Similarly, those who gave birth before the age of 18 years and those engaged in prolonged heavy lifting activities have higher chance of developing prolapse symptoms. **What do the findings mean?** The findings showed that prolapse is common in the Sidama region of Ethiopia and that it needs attention of stakeholders.

Keywords

anatomical prolapse, Ethiopia, pelvic organ prolapse, POP-Q, prolapse symptoms

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Introduction

Pelvic organ prolapse (POP) is one of the pelvic floor disorders in women characterized by the descent of one of the vaginal walls, cervix, uterus, bladder, or rectum into the vaginal lumen.^{1,2} It is a common condition for which women of all ages seek medical and surgical treatment.³ The prevalence varies based on the diagnosis method used. A recent (2022) review conducted by the International Urogynecology Consultation Committee shows that the prevalence of POP varies widely (1%–65%) based on whether it is assessed by symptoms (1%–31%), pelvic examination (10%–50%), or both (20%–65%).⁴ Even though there is no clear and universally agreed definition of POP,⁵ it is recommended to describe clinically significant prolapse by using both anatomical staging and patient-reported symptoms.⁶

The risk of POP is increased in low- and middle-income countries due to higher parity, early marriage, greater numbers of vaginal deliveries, and more frequent heavy manual work.^{7–9} The risk factors that have been identified so far are both non-modifiable (family history, ethnicity, and age) and modifiable (obesity, underweight, chronic malnutrition, heavy lifting, chronic medical problems, parity, and age at first birth).^{1,2,10–12}

POP causes a sensation of vaginal bulge, voiding and defecatory dysfunction, and sexual dysfunction which adversely affects the quality of life.^{13,14} Studies from both high- and low-income countries revealed that POP patients were struggling to handle their daily activities due to the symptoms of POP.^{15,16} POP has also a significant psychological impact on women.¹⁷

In Ethiopia, the prevalence of symptomatic POP varies from 1%–30% based on the population category, study setting, and diagnosis method used.^{18–21} This approach may underestimate the prevalence due to the asymptomatic

nature of POP. Objectively measured POP at the community level reaches up to 56.3%²⁰ based on the simplified pelvic organ prolapse (sPOP) assessment method. None of these studies have used the standard pelvic organ prolapse quantification (POP-Q) system. The POP-Q system is specific and objectively quantifies the prolapse by using a measuring instrument (centimeters), and nine points in the vagina and the tissues around it. The simplified version of the POP-Q (sPOP) system reduces the number of points to only four points (anterior, posterior, apex/cuff, and cervix) for measurement and does not necessarily use exact measurements.^{22,23} A review of POP anatomical assessments recommended the use of standardized POP-Q for effective communication between clinicians, reproducible evaluation, meaningful comparison of studies, and comparison of different populations.²⁴ Therefore, this study aimed to assess the prevalence of POP based on both standard POP-Q and subjective symptoms and assessed risk factors for POP among women in Dale and Wonsho districts, Sidama region, Ethiopia.

Conceptual framework

Based on the findings of different literature, the following conceptual framework was developed (Figure 1). The conceptual framework shows that different risk factors cause POP either through direct damage of pelvic muscles (levator ani muscle and its nerve supply) or by causing the collagen to weaken.^{25–31}

Methods and materials

Study setting

This study was conducted in the Dale and Wonsho districts of Sidama National Regional State, Ethiopia, over a period

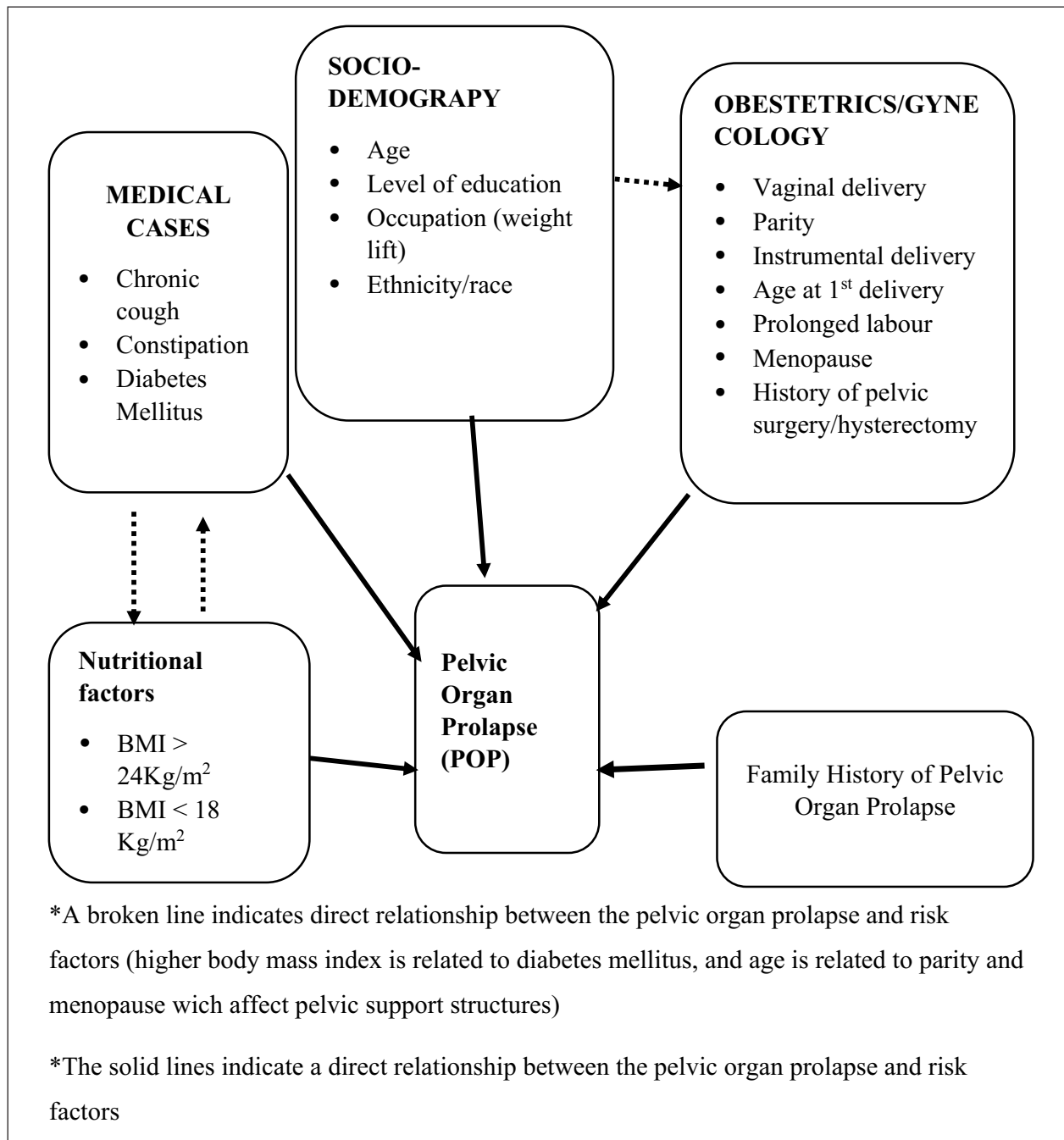


Figure 1. Conceptual framework of risk factors affecting pelvic organ prolapse.

of 8 months from 13 March to 28 October 2023. Both districts are known for their highly dense population and coffee production³² (Figure 2). Dale district has 10 health centers and 33 health posts. Hamlin Fistula Center, which provides care for fistula cases and POP, is located in Yirgalem town in Dale district. Wonsho district has five health centers and 17 health posts. According to the 2021 report of Sidama Regional Health Bureau, the total

population of Dale district is 254,653 and that of Wonsho district is 129,730.³³ According to the Ethiopian Central Statistical Agency, the female population accounts for 49.7% of the Dale district population and 49.2% of the Wonsho population.³⁴

In 2017, Hawassa University established its own Health and Demographic Surveillance System (HDSS) site in the Dale and Wonsho districts of the Sidama region.³² The

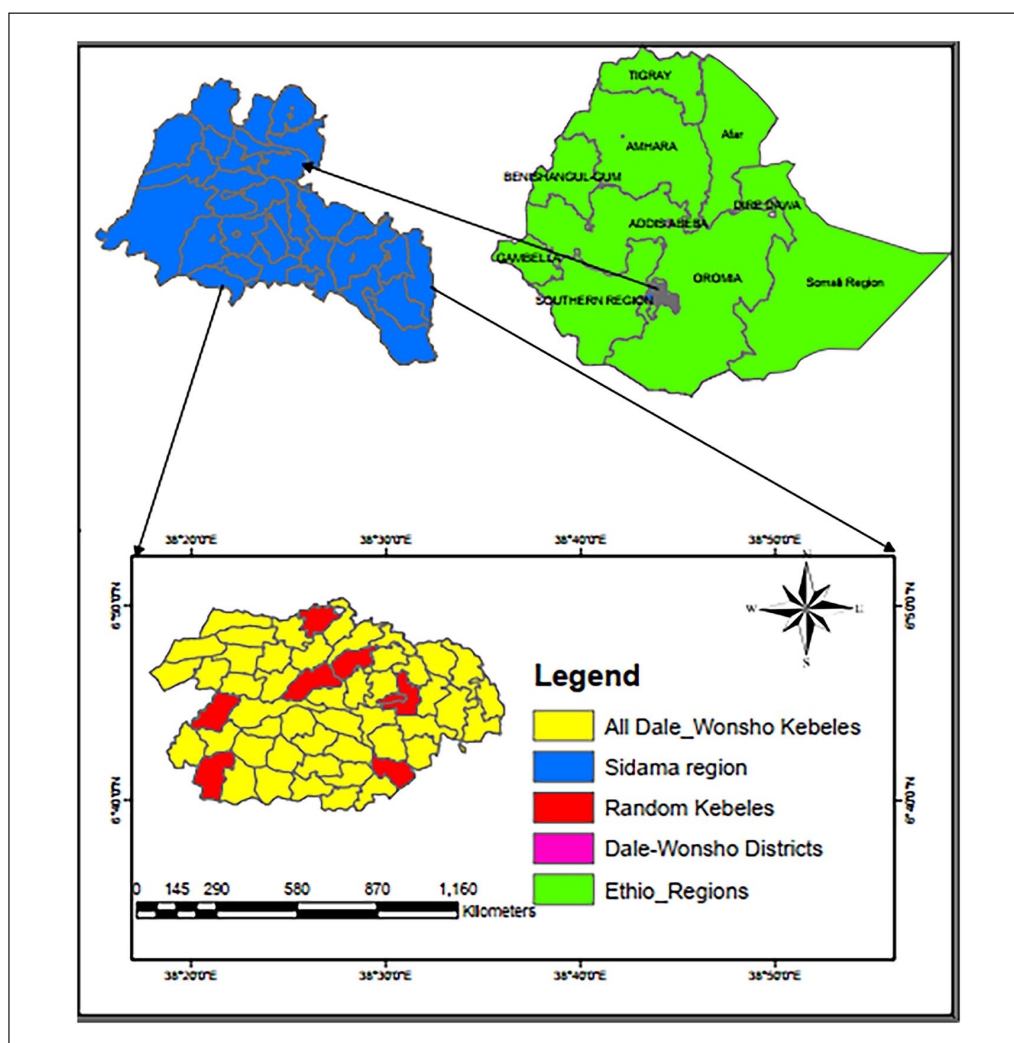


Figure 2. A map of study area in Dale and Wonsho districts, Sidama region, Ethiopia.

HDSS site includes 10 rural and two urban kebeles (small administrative units in Ethiopia). The surveillance site is referred to as the Dale–Wonsho Health and Demographic Surveillance Site (D–W HDSS). The main purpose of establishing the HDSS was to provide a background context for clinical trials and generate longitudinal epidemiological data.

Study design and population

A community-based cross-sectional study was conducted by using subjective and objective measure among women who have given birth (at least once) or are ≥ 18 years, and whose household information is found in the database of the Health and Demographic Survey of Hawassa University. Women who were pregnant (confirmed or suspected), in the immediate postpartum period (6 weeks), or unable to participate due to sickness were excluded.

Sample size and sampling technique

The sample size was calculated using Open-Epi version 3.1 both for the prevalence of the POP and its associated risk factors. The sample size for the prevalence study was calculated with the assumptions of 56.3% prevalence of POP and a non-response rate of 7%,²⁰ 95% confidence interval, and a design effect of 2. The calculated sample size was 813. The sample size for associated risk factors was also estimated for variables that were significantly associated with anatomical prolapse in a previous study conducted in northern Ethiopia.²⁰ The variable names, assumptions considered, and their respective results were summarized in a table (Supplemental File 1). A maximum sample size was obtained from the first objective which was 813. To select an equal number of participants, 101.6 women from each cluster, the size was approximated to 102 for each cluster, and the final sample size was adjusted

to 816. This was considered maximum and adequate to address the remaining objectives.

Hawassa University HDSS site was initially stratified into two districts (Dale and Wonsho). Then, representative *kebeles* (small administrative units in Ethiopia) were considered as “a cluster” for this study and selected from both districts (six *kebeles* from Dale district and two *kebeles* from Wonsho district) randomly. The number of households in each kebele ranges from 640 to 2200. Based on complex sample survey assumption, an equal number of eligible women from each *kebele*/cluster were selected using computer-generated random numbers (based on the list of their house numbers). Therefore, this study included two strata: Dale and Wonsho districts; eight clusters (*kebeles*), and 816 eligible women. The interview was conducted with the female head of the selected households.

Study variables and measurements

The outcome variables of this study were anatomical POP and symptomatic POP hereafter called “anatomical prolapse” and “symptomatic prolapse,” respectively. The anatomical prolapse is a POP of Stage $\geq$ II on the POP-Q system. There are nine measurement points in the POP-Q system. All are measured at maximumValsalva, except total vaginal length (TVL) which is measured at rest. Measurements are expressed in centimeters to the nearest 0.5 cm. The nine measurement points in and around the vagina are as follows: Genital hiatus (GH) measured from the middle of the external urethral meatus to the posterior aspect of the hymenal remnant, perineal body (PB) measured from the posterior aspect of the hymenal remnant to the middle of the anal opening, point C is the lowest part of cervix (or vaginal cuff), and point D is the topmost part of the posterior vaginal wall (posterior vaginal pouch). Both points are measured relative to the plane of hymenal remnants. A hymenal remnant is chosen as it is a clearly defined and easily identifiable structure. TVL is measured from hymenal remnant to point D. Point Aa is an arbitrary fixed point on the anterior vaginal wall, which is 3 cm back from the middle of the external urethral meatus in normal cases. Point Ba is the lowest part of the upper anterior vagina. This point is not a fixed point like Aa. It can be anywhere along the vaginal wall above the first 3 cm (Aa). Points Ap and Bp are similar to points Aa and Ba but found on the posterior vaginal wall. These measures are translated into a staging system as follows: Stage 0: Points Aa, Ba, Ap, and Bp are all at -3 cm and C and D are at greater than/equal to TVL—2 cm; Stage I: the criteria for stage zero are not met, and the leading edge of the prolapse is greater than 1 cm above the hymen; Stage II: the leading edge of the prolapse is between 1 cm above or below the hymen; Stage III: the leading edge is greater than 1 cm beyond the

hymen but less than TVL—2 cm from the hymen; and Stage IV: the leading edge of the prolapse is greater than TVL—2 cm beyond the hymenal remnant.^{22,35,36}

Symptomatic prolapse is considered when anatomical prolapse (Stage $\geq$ II) and prolapse symptom are reported. Symptoms of POP were collected by using the Sidaamu Afoo version of the pelvic organ prolapse symptom score (POP-SS) questionnaire,³⁷ which has seven questions with a 5-point Likert-type scale that ranges from 0 to 4 (0=never felt symptom, 1=occasionally, 2=sometimes, 3=most of the time, and 4=all of the time), a higher score indicating severe symptoms.³⁸ A response score different from zero indicates the presence of symptoms. Women were also asked which symptom they felt for a long time and how long she has the symptom.

The independent variables include sociodemographic characteristics (level of education, residence, occupation, ethnicity, age in years, and marital status), lifestyle variables (smoking habit and average hours of heavy lifting per day/carrying big baby, water, sand, and others), obstetrics and reproductive characteristics (mode of delivery, number of childbirth, place of delivery, history of a length of labor more than 24 h, age at first marriage, and age at first childbirth), medical and surgical history (chronic cough/more than 3 weeks, constipation/infrequent stooling and difficulty passing stool, diabetes mellitus, body mass index, history of pelvic surgery, trauma, and family history of POP).

Data collection tools and procedures

The data collection tool has six parts (sections). Part I is about the sociodemographic characteristics of the participants which has eight items; part II focuses on the POP-related lifestyle of the participants, which has six items; part III contains 14 items that ask about the obstetrics and gynecologic history of the participants; part IV is about the wealth index of the study participants' household, which has 28 items; part V is about POP-SS; and part VI is about objectively measured POP and related measures, which have 14 measurements. The questionnaires used to collect data about sociodemographic characteristics, lifestyle, obstetrics, and gynecologic history were developed from a review of related literature.^{39–43} It was initially developed in the English version and translated into the local language (Sidaamu Afoo) (Supplemental File 2). The POP-SS tool was used to assess prolapse symptoms by asking the participants how often they have had the following symptoms in the past 4 weeks: (1) A feeling of something coming down from the vagina? (2) a feeling of discomfort/pain in the vagina? (3) a heaviness/dragging feeling in the lower abdomen? (4) a dragging feeling in the lower back? (5) a difficulty in emptying the bladder? (6) a feeling of incomplete bladder emptying? and (7) a feeling of incomplete

bowel emptying? The total score was calculated by summing up all responses to the seven-question test. The questionnaire was previously translated to a local language and validated in the same study area among women with POP who were admitted to Yirgalem Hamlin Fistula Center.³⁷ The tool was valid and took 15–20 min to complete.

The data were collected using a Kobo Toolbox. Subjective data were collected by eight nurses through home-to-home visits. All study participants were invited for a pelvic examination at a nearby health facility and given an appointment (date and time) irrespective of their symptoms. The collected data were uploaded to the European Union Kobo Toolbox Server daily and monitored by the principal investigator.

POP quantification was done by two staff members of Yirgalem Hamlin Fistula Center. They are para-medical professionals (called “*Health Officers*” in Ethiopia) who have special training in fistula and POP management. Women empty their bladders and lie in a lithotomy position. The prolapse degree was measured by a ruler (spatula marked with a centimeter) used to measure the prolapse of nine points in and around the vagina.

Data collectors and field supervisors were trained for 3 days on the purpose of the study, the use of the Kobo tool, and each item in the questionnaire. Similarly, pelvic floor examiners were trained by a urogynaecologist at the Hamlin Fistula Center to minimize discrepancies across examiners. As part of the pre-test, they performed 10 POP-Qs under the supervision of the urogynaecologist on patients admitted to Hamlin Fistula Center for POP. At the data collection time, they were kept blinded about participant's background information including symptom status.

This article was prepared according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline, and the checklist was submitted as an additional file (Supplemental File 3).

Statistical analysis

The data set was downloaded from the Kobo Toolbox server and exported to Microsoft Excel 2013. This was imported to Stata version 17 software (StataCorp LLC, College Station, Texas, USA) for data cleaning, recode, and analysis. All forms of data analysis were done taking the nature of complex sampling design into account. The design variables used to declare the complex sample were comprised of the stratum, cluster, and weighting variables. In this study, the stratum variable was the districts (Dale and Wonsho) and the cluster variable was kebele. The weighting variable was created from the product of cluster selection weight and household selection weights. Then to normalize the weights, the survey weight of each unit is divided by the unweighted average of the survey weights. Complex sample summary measures for categorical variables were presented in terms of frequency and percentages. For continuous variables, mean and standard deviation or

median and interquartile range (IQR) were presented. The wealth index was determined using principal component analysis^{44,45} based on 28 items.

Complex sample modified-Poisson regression was used to investigate the association between the outcome variables (anatomical prolapse and symptomatic prolapse) and potential risk factors. In cross-sectional studies, the measure of choice is the prevalence ratio which can be either directly estimated by statistical models^{46,47} or transformed from odds ratios obtained from logistic regression.⁴⁸ However, when the prevalence of outcome of interest is common, the odds ratio overestimates the prevalence ratio.^{46,47} The prevalence ratio is easier to interpret and understand than the odds ratio by non-epidemiologists. In addition, the model-based estimation is more appropriate for controlling confounders.^{46,49} The Poisson regression equation is as follows: $\log(\pi/t) = \beta_0 + \beta_1 X_1 + \dots + \beta_k X_k$ ⁴⁶ where π is the event, t is the time followed up, and x s are the covariates. When a constant time is assigned to everyone in the study (modified Poisson regression), the estimated episode of interest is equal to prevalence ratio. The relative risk estimate of a given covariate is e^{β} .^{46,50} In complex sample analysis, even though the application of robust standard error is not allowed with the *svy* prefix, the inherent robustness in the *svy* estimation ensures that Poisson regression accounts for the survey design characteristics.⁵¹

Variables with p values less than or equal to 0.25 on bivariable analysis and other important variables (supported by literature)⁵² were included in the multivariable model. The model was refined repeatedly by excluding variables which does not significantly impact the overall model fit or the parameters of the remaining individual variables. This process was continued until model significance and goodness of fit were achieved. Adjusted Wald test was used to assess the overall significance of a model by comparing the full model against the reduced (null) model.⁵³ The test result showed that the full model is significantly different from the reduced model (anatomical prolapse $p=0.005$ and symptomatic prolapse $p=0.034$), suggesting that the variables included in the full model are important in explaining the outcome variable. The association of outcome variables and risk factors was expressed in terms of adjusted prevalence ratio (APR) with a 95% confidence interval. A multivariable linear regression model was used to assess multicollinearity among independent variables. A variance inflation factor (VIF) of less than 5 was taken as suggestive of less multicollinearity.⁵⁴ The data set on which this study is based is provided as an additional file (Supplemental File 4).

Results

Sociodemographic characteristics

A total of 816 women were selected, and 815 (99.9%) participated in the interview and were invited for pelvic examination at a nearby health center. One woman did not

wish to participate in the study. Among women who were invited, 779 (95.6%) underwent examination to assess for POP. The age of the participants ranged from 18 to 85 years with a mean age of 41.5 years and a standard deviation of 12.75 years. Seven hundred and fifteen (87.7%) of the participants were rural residents.

All participants experienced vaginal birth (100%). The median number of childbirths was 4 (IQR=3–5) with a minimum of one and maximum of nine frequencies of childbirth. The minimum age at first childbirth was 14 years, and the maximum age was 35 years. Table 1 depicts the sociodemographic and reproductive health characteristics of study participants.

Anatomical pelvic organ prolapse (POP-Q)

Based on the result of the POP-Q, among the 779 women who received pelvic examination, 324 (41.5%; 95% CI=31.9–51.9) had some degree of prolapse (Stages I–IV). Among these, Stage I prolapse was found in 83 (10.7%), Stage II in 169 (21.7%), Stage III in 46 (5.5%) and Stage IV in 26 (3.3%). Anatomical prolapse (Stages II–IV) were observed in 241 (30.9%; 95% CI=24–38.7) of the women (Table 2).

Symptomatic POP

The prevalence of symptomatic POP (in women with anatomical prolapse of Stages II and above) was 78.5% (189/241) (95% CI=69.1–85.7). This prevalence fell to 24.27% (95% CI=19.98–29.16) for the total population who underwent pelvic examination (Table 2). Among the symptomatic prolapse cases ($n=189$), the most commonly reported symptoms were a feeling of discomfort/pain in the vagina (98.4%) and a feeling of something passing through the vagina (96.8%) (Figure 3). The most chronic symptom was a feeling of something passing through the vagina (46.7%). The remaining symptoms were as follows: a feeling of discomfort/pain in the vagina (14.6%), dragging pain in the lower back 12%, a feeling of unemptied bowel (8.4%), a need to strain/push to urinate (7.9%), a feeling of unemptied bladder (5.9%), and a dragging/heaviness feeling in the lower abdomen (4.6%). The duration of symptoms ranges from 5 months to 20 years with a median of 48 months (IQR=42.1–53.9 months). Pelvic organ prolapse symptom (POP-S) was reported by 213 (27.4%; 95% CI=22–33.5) of participants who underwent pelvic examination (779).

Factors associated with anatomical prolapse (Stage $\geq$ II)

In a modified Poisson regression, average heavy lifting hours per day, number of childbirths, and experience of prolonged labor (>24 h) were significantly associated

Table 1. Sociodemographic and reproductive health characteristics of study participants involved in the prevalence of pelvic organ prolapse in Sidama region, Ethiopia, 2024 (weighted $n=815$).

Variables	Category	Frequency	%
Districts	Dale	590	72.4
	Wonsho	225	27.6
Residence	Urban	101	12.4
	Rural	714	87.6
Marital status	Married	739	90.6
	Others	77	9.4
Level of education	No formal education	572	70.2
	Primary school	161	19.7
	Secondary school and above	82	10.1
Religion	Protestant	715	87.7
	Orthodox	79	9.7
	Others	21	2.6
Occupation	Employed	35	4.3
	Non-employed	780	95.7
Ethnicity	Sidama	809	99.3
	Others $\neq$	6	0.7
Wealth index	Poorest	166	20.34
	Poorer	170	20.8
	Middle	163	20.1
	Rich	156	19.2
	Richest	160	19.6
Chronic cough (>3 weeks)	No	567	69.6
	Yes	248	30.4
Constipation	No	607	74.5
	Yes	208	25.5
Family history of POP	No	582	71.4
	Yes	233	28.6
History of pelvic surgery	No	665	81.5
	Yes	150	18.5
Body mass index (kg/m ²)	<18.5	248	30.5
	-24.9	481	59
	≥ 25	86	10.5
Abortion experience	No	745	92
	Yes	70	8
History of homebirth	No	197	24.2
	Yes	618	75.8
A place for the last childbirth	Home	528	64.8
	Health facility	287	35.2
Prolonged labor	No	472	58
	Yes	343	42
Menopause	No	545	66.8
	Yes	270	33.2

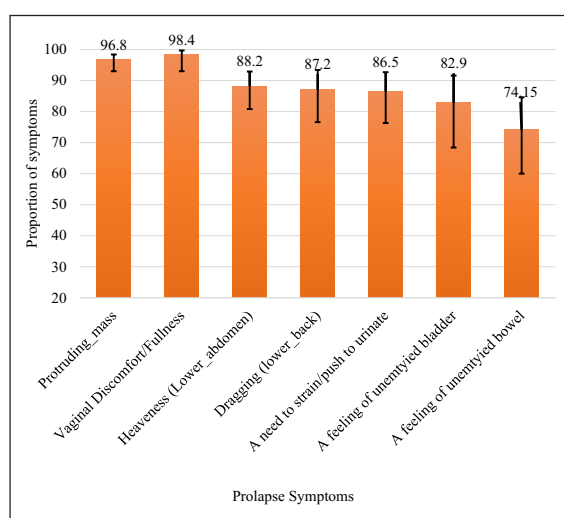
Note. Others: never married, widowed, and divorced; Others: Muslim and Catholic; Others $\neq$: Amhara and Gurage Oromo. POP: pelvic organ prolapse.

with anatomical prolapse. An one-unit increase in the average daily heavy lifting hours led to a 26% increase in the prevalence of anatomical prolapse (APR=1.26; 95%

Table 2. Pelvic organ prolapse characteristics among women in Sidama region, Ethiopia, 2024.

Variables	Categories	Anatomical prolapse (Stage $\geq$ II, $n = 241$)	Symptomatic prolapse ($n = 189$)
		Number (%)	Number (%)
Stage of prolapse	Stage II	169 (70.2)	119 (70.2)
	Stage III	46 (19.1)	44 (95)
	Stage IV	26 (10.7)	26 (100)
Prolapsed site	Anterior prolapse	211 (87.7)	167 (88.5)
	Posterior prolapse	148 (61.3)	126 (66.4)
	Apical prolapse	56 (23.4)	54 (28.7)
	Multiple sites ^a	127 (52.5)	110 (58.2)

^aMultiple sites prolapse: at least two of the following: anterior, posterior, and apical prolapses.

**Figure 3.** Proportion of prolapse symptoms reported by women in Sidama region, Ethiopia, 2024.

CI=1.1–11.4). The risk of developing anatomical prolapse increased by 17% for each unit increase in the number of childbirth (APR=1.7; 95% CI=1.1–1.24). Women who experienced prolonged labor (labor lasting more than 24 h) had a 32% higher likelihood of developing anatomical prolapse (APR=1.32; 95% CI=1.1–1.56) (Table 3).

Factors associated with symptomatic prolapse

An one-unit increase in the average daily heavy lifting hours increased the likelihood of developing symptomatic prolapse by 16% (APR=1.16; 95% CI=1.1–1.28). Women who gave birth before the age of 18 years had a 29% higher likelihood of developing symptomatic prolapse (APR=1.29; 95% CI=1.1–1.52) (Table 4).

Discussion

This survey showed that almost one-third (30.9%) of the women in the study area had anatomical POP as confirmed

clinically. The majority of the prolapse cases were Stage II (70.2%), while Stage III was observed in 19.1% and Stage IV in 10.7%. Among those with anatomical prolapse, 78.4% had symptomatic prolapse which accounts for 24.3% of the total sample. The likelihood of developing anatomical prolapse increased by 17% for one-unit increase in the frequency of childbirth, 26% with one-unit increase in average heavy lifting hours per day, and 32% with experiencing prolonged labor (≥ 24 h). Similarly, the likelihood of developing symptomatic prolapse was increased by 16% with prolonged heavy lifting hours and 29% with early childbirth (less than 18 years).

The prevalence of anatomical prolapse (30.9%) in this study is similar to a previous study conducted in Referral Hospitals of Amhara region, Ethiopia (31.8%),⁶⁸ tertiary hospitals in Uganda (27.5%),⁵⁵ and a community-based study in Turkey (27.1%).²⁷ However, this prevalence is higher than the prevalence reported from Pakistan (10.3%),⁵⁶ and the pooled prevalences reported from Ethiopia (22.7%–23.5%).^{57,58} The discrepancy could be the result of the difference in prevalence calculation and prolapse measurement and population studied. The prevalence from Pakistan was calculated for the source population (5064) but only 551 participants were clinically examined (among whom 521 had a prolapse). Since POP is usually asymptomatic,^{59–61} those who were not examined may have some degree of prolapse. The two systematic reviews and meta-analyses from Ethiopia included POP prevalences that were estimated by symptomatic approach which can underestimate the prevalence. In addition, the prevalence estimates were based on primary studies involving different populations such as facility-based and community-based studies. The reviews also encompassed studies that specifically focused on reproductive-age females. Furthermore, where the primary studies did not report the prevalence (such as case-control studies), manual calculation was used to estimate the prevalence.⁵⁷

On the contrary, the prevalence of anatomical prolapse in this study is much lower than the prevalence reported in earlier studies from northern Ethiopia (55.1%–56.3%)^{20,62} and Tanzania (64.6%).⁶³ This discrepancy could be due to

Table 3. Risk factors for anatomical pelvic organ prolapse in Sidama region, Ethiopia, 2024 (weighted $n = 779$).

Variables	Anatomical prolapse ($n = 779$)		CPR (95% CI)	APR (95% CI)
	Yes (%)	No (%)		
Average heavy lifting hours/day			1.34 (1.9–1.5)*	1.26 (1.14–1.4)**
Childbirth frequency			1.31 (1.2–1.4)*	1.17 (1.1–1.24)**
Chronic cough (>3 weeks)				
No	138 (25)	405 (75)	Ref	Ref
Yes	103 (44)	134 (56)	1.72 (1–2.8)*	1.28 (0.85–1.9)
Prolonged labor (>24 h)				
No	110 (24)	342 (76)	Ref	Ref
Yes	131 (40)	196 (60)	1.65 (1.2–2.3)*	1.32 (1.1–1.56)**
Constipation (>3 months)				
No	163 (28)	410 (72)	Ref	Ref
Yes	78 (38)	129 (62)	1.3 (1.1–1.7)*	1.04 (0.86–1.27)
Age at first delivery (years)				
<18	115 (49.7)	117 (50.3)	2.17 (1.38–3.4)*	1.57 (0.97–2.56)
≥18	125 (23)	421 (77)	Ref	Ref

*Significant at $p < 0.25$; **Highly significant at $p < 0.01$; Ref: reference category; CPR: crude prevalence ratio; APR: adjusted prevalence ratio; CI: confidence interval.

Table 4. Risk factors associated with symptomatic pelvic organ prolapse in Sidama region, Ethiopia, 2024 (weighted $n = 241$).

Variables	Symptomatic prolapse ($n = 241$)		CPR (95% CI)	APR (95% CI)
	Yes (%)	No (%)		
Average daily heavy lifting			1.18 (1.03–1.33)*	1.16 (1.1–1.28)**
Childbirth frequency			1.01 (1–1.14)*	1.01 (0.97–1.1)
Chronic cough (>3 weeks)				
No	100 (73)	38 (27)	Ref	Ref
Yes	89 (86.3)	14 (13.7)	1.19 (0.98–1.43)*	1.13 (0.99–1.3)
Prolonged labor (>24 h)				
No	85 (78)	25 (22)	Ref	Ref
Yes	104 (79)	27 (21)	1.02 (0.84–1.2)*	0.94 (0.8–1.1)
Family history of POP				
No	126 (75)	42 (25)	Ref	Ref
Yes	64 (86.5)	10 (13.5)	1.15 (1.02–1.3)*	1.1 (0.86–1.41)
Age at first delivery (years)				
<18	105 (91)	11 (9)	1.35 (1.13–1.6)*	1.29 (1.1–1.52)**
≥18	84 (67)	41 (33)	Ref	Ref

*Significant at $p < 0.25$; **Highly significant at $p < 0.01$; Ref: reference category; CPR: crude prevalence ratio; APR: adjusted prevalence ratio; CI: confidence interval.

the difference in measurement techniques, study subjects, and prevalence estimation methods. Previous reports from Ethiopia used the sPOP quantification method but this study used the standardized POP-Q method. This difference in measurement method and interobserver differences may have caused the discrepancy. In Tanzania, the study subjects were of higher parity (median=5, and IQR=0–14), but in this study, the median number of childbirths was 4 (IQR=3–5). In addition, the current prevalence was estimated based on complex survey analysis which takes into account the effect of complex design but the previous studies did not. This may affect both the prevalence estimation

and their respective standard errors.^{64,65} The discrepancy could be also secondary to the difference in genetic background even though the evidence is limited. A systematic review and meta-analysis showed that individual studies were of small sample size and often of poor quality.⁶⁶ It was stated that the genetic contributions to POP remain poorly understood, and much work was required to establish the role of genes in the pathogenesis of POP.⁶⁷

The most common stage of prolapse in this study was Stage II prolapse (70.2%). This is similar to previous reports from Tanzania (63.6%)⁶³ and Uganda (63.4%).⁵⁵ This indicates that POP is very common in the community.

We found a lower prevalence of symptomatic prolapse (24.3%) as compared to the anatomical prolapse (30.9%). It is expected to see lower correlation between anatomical prolapse and self-reported prolapse symptoms.^{27,55,63,68} The discrepancy is likely because most women will only experience symptoms when the leading edge of the prolapse approaches the hymen. As a result, prolapse above the hymen may be asymptomatic.⁶⁹ In addition, there may be under-reporting as the issue is sensitive and women may be reluctant to acknowledge this problem. Compared with previous studies, this study revealed a higher prevalence of reported symptomatic prolapse (78.4%) among women with anatomical prolapse. This might be due to the utilization of a locally validated tool that is more appropriate for participants to understand and respond. Indeed, a previous study from northern Ethiopia revealed that symptomatic prolapse was reported only in 46% of anatomical prolapse cases in a population where 56.4% were thought to have anatomical prolapsed.²⁰ This difference may also be related to the difference in measuring anatomical prolapse.

We observed that POP-Ss were more common in higher degrees of prolapse which is expected. In this study, prolapse symptoms were experienced by all women with Stage IV prolapse and 95% of women with Stage III prolapse. This is similar to previous reports where self-report for genital prolapse was 95% from Nepal,⁷⁰ 94% of women undergoing surgery for POP in Uganda,⁷¹ and 97.9% of women with Stage III or more in Ethiopia.²⁰ Prolapse symptoms were reported by 70% of Stage II patients in this study and 40.1% of previous studies from Ethiopia. This indicates that at least 30% of women with Stage II prolapse may remain asymptomatic.

In this study, the most commonly reported prolapse symptoms were a feeling of discomfort/pain in the vagina (98.4%) and a feeling of something passing through the vagina (96.8%). It was evidenced that women with POP beyond the hymen have increased symptoms that help to define symptomatic prolapsed.⁵⁹ A sense of bulging or protrusion in the vagina was considered as the most specific symptom.^{72,73} This finding highlights the importance of clinicians' and researchers' awareness of the significance of population specific symptoms for prolapse identification.

This study showed a significant association between anatomical prolapse and the frequency of childbirth. This is supported by findings from China,⁷⁴ Turkey,²⁷ Pakistan,⁵⁶ Tanzania,⁶³ Uganda,⁵⁵ and Ethiopia.^{20,57,75} POP is caused by injury to its supportive structures (levator ani muscle or its nerve supply and connective tissue). Vaginal delivery directly disrupts this structure due to overstretching, comprehension, and avulsion during childbirth.⁷⁶ Similarly, additional vaginal birth causes repeated trauma to these structures causing organ prolapsed.⁷⁷ In this study, all participants experienced vaginal birth and majority of them

gave birth more than one time. This result has both clinical and public health significance. It informs health care providers to counsel women on the impact of multiple childbirth and the importance of preventive measures and to individualize management plans.

In this study, an one-unit increase in the average daily heavy lifting hours leads to a higher likelihood of both anatomical and symptomatic prolapses. Similar findings were reported previously from Ethiopia,^{57,68,75} Nepal,⁷⁸ and Tanzania.⁶³ It was evidenced that lifting larger weights and strenuous physical activities affect pelvic ligaments and supporting structures.^{63,69,79} Thus, this study shows the need for education on handling heavy weight/load, workplace adjustment, and early interventions.

Women who faced prolonged labor (more than 24 h) had a higher likelihood of developing anatomical prolapse. Similar findings were reported from India,⁸⁰ Uganda,⁵⁵ Tanzania,⁶³ and Ethiopia.^{57,75} In addition to the possibility of pelvic floor damage in the case of prolonged labor, pudendal nerve damage was seen in women who labor ≥ 20 h.⁸¹ In this study area, women are still prone to prolonged labor due to a higher prevalence of home delivery (64%), early age childbirth, and lack of transportation (87.6% living in rural areas).

This study showed that early age childbirth (at less than 18 years) was significantly associated with symptomatic prolapse. Similar results were reported from India⁸² and Ethiopia where childbirth before the age of 20 years was associated with POP.⁶⁸ This could be related to the immaturity of the birth canal and supportive ligaments. Prolapse risk is also increased with multiple deliveries. This study indicates the importance of delaying early childbirth, family planning, birth spacing, and proactive management of pregnancy and childbirth.

This study has many strengths. The study employed a complex survey analysis, which accounted for the effect of a complex sampling design. In addition, the large sample size and high response rate enhance the likelihood that the results can be generalized to the target population in the Sidama region, Ethiopia. To our knowledge, this study is the first to utilize a standardized POP-Q method of anatomical assessment of prolapse for a community-based study in Ethiopia. Furthermore, the assessment of POP-Ss was conducted using a locally validated questionnaire.

This study also had some limitations. The study relied on an interviewer-administered questionnaire to assess risk factors for prolapse. However, the way this questionnaire was administered could have influenced participants' responses. Participants may have misreported their prolapse symptoms, wealth index items, and age due to social desirability bias. Most patients may also not know their exact age. Consequently, age was not found to be associated with prolapse in this study. Similarly, they may not be sure about their family history of prolapse. Most participants had no formal education and were rural residents.

Risk factors for prolapse were assessed through interviews. These factors may lead to overestimation or underestimation of the effects of risk factors. Therefore, when interpreting the study results, these issues should be taken into consideration.

Conclusion

The prevalence of both anatomical and symptomatic prolapses is high in the Sidama region of Ethiopia. Prolonged labor, increased parity, and prolonged duration of heavy lifting were risk factors significantly associated with anatomical prolapse. Early age childbirth and prolonged duration of heavy lifting were risk factors strongly associated with symptomatic POP. All risk factors identified in this study are preventable or at least modifiable. Thus, we recommend community-based interventions that focus on health education on risk factors, intrapartum care that prevents prolonged labor, and family planning services.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from Hawassa University, College of Medicine and Health Sciences, Institutional Review Board (Ref. No. IRB/157/14). Support letter was also obtained from Sidama Region Public Health Institute and the respective health facilities of the study area. A written voluntarily informed consent was obtained from study participants. Considering the sensitive nature of the condition, data about self-reported prolapse symptoms were collected in a private place at the home of the participants. A pelvic examination was performed in the delivery room where physical privacy and information confidentiality were ensured. The pelvic examination has some physical discomfort and psychological distress in exposing the private part. Travel cost to a health facility for pelvic examination was compensated with 200 Ethiopian Birr which was approximately 4 US Dollars. Participants with advanced prolapse (Stage IV) were linked to Yirgalem Hamline Fistula Center for treatment, and symptomatic prolapse Stage I–III cases were enrolled in an interventional study, which is a consecutive part of this project.

Consent for publication

Not applicable.

Author contribution(s)

Melese Siyoum: Conceptualization; Formal analysis; Funding acquisition; Methodology; Validation; Writing—original draft; Writing – review & editing.

Rahel Nardos: Fund acquisition; Methodology; Validation; Writing – review & editing.

Wondwosen Teklesilasie: Methodology; Validation; Writing – review & editing.

Ayalew Astatkie: Conceptualization; Formal analysis; Methodology; Validation; Writing – review & editing.

All authors read and approved the final article.

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Competing interests

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Availability of data and materials

The data set used for this study is available within the article and also as a supplementary file.

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Supplemental material

Supplemental material for this article is available online.

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PAPER III

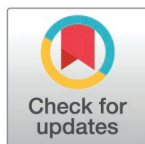
RESEARCH ARTICLE

Effect of midwife-led pelvic floor muscle training on prolapse symptoms and quality of life in women with pelvic organ prolapse in Ethiopia: A Cluster-randomized controlled trial

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Abstract

Background

Pelvic organ prolapse (POP) is a common condition that can significantly impact a woman's quality of life. Pelvic floor muscle training (PFMT) is recommended as a first-line conservative treatment for prolapse, but evidence on its effectiveness from low-resource settings is limited. This study aimed to assess the effect of midwife-led PFMT on prolapse symptoms and health-related quality of life (HRQoL) among women with mild-to-moderate POP in Ethiopia.

Methods and findings

A community-based, parallel-groups, two-arm cluster-randomized controlled trial was conducted in Dale and Wonsho districts of Sidama Region, Ethiopia. Women with symptomatic POP stages I–III were randomized by cluster to receive either midwife-led PFMT plus lifestyle counseling (intervention group) or lifestyle counseling alone (control group). The participants and counselors knew what the women were receiving, but they were not aware of the other group. The outcome assessors, who collected data at the end of intervention, were blinded to the participants' treatment allocation. The primary outcomes were changes in prolapse symptom score (POP-SS) and prolapse quality of life (P-QoL). Mixed-effects generalized linear model was used to determine the effect of PFMT on prolapse symptoms and P-QoL at 99% confidence level. Adjusted β coefficients were used as effect measures. The level of significance was adjusted for multiple comparisons.

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Data availability statement: All relevant data are within the manuscript and its [Supporting information](#) files.

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Competing interests: The authors have declared that no competing interests exist.

Abbreviations : CONSORT, Consolidated Standards of Reporting Trials; cRCTs, cluster-randomized controlled trials; HRQoL, health-related quality of life; ICC, intra-cluster correlation; MEGLM, mixed-effects generalized linear model; PFMT, pelvic floor muscle training; POP, pelvic organ prolapse; POP-Q, Pelvic Organ Prolapse Quantification; POP-SS, prolapse symptom score; P-QoL, prolapse-quality of life; PT, physical therapy training; RCT, randomized controlled trial.

A total of 187 women were randomized to intervention ($n=86$) from four clusters and control ($n=101$) arms from another four clusters. At sixth months, the intervention group showed significantly greater improvements both in prolapse symptoms and P-QoL. The mean change difference in POP-SS was -4.11 (99% CI $[-5.38, -2.83]$; $p < 0.001$). Similarly, the mean change difference was: -8.86 (99% CI $[-13.84, -3.89]$; $p < 0.001$) in physical domain of P-QoL; -11.18 (99% CI $[-15.03, -7.32]$; $p < 0.001$) in psychological domain of P-QoL, and -9.01 (99% CI $[-10.49, -5.54]$; $p < 0.001$) in personal relationship domain of P-QoL. A significantly higher proportion (83.72%) of women in the intervention group perceived their condition as “better” after the intervention as compared to 41.58% in the control group. Women with earlier stages of prolapse (stages I and II) experienced higher benefits compared to those in stage III.

Conclusions

A midwife-led PFMT combined with lifestyle counseling significantly improves prolapse symptoms and quality of life in mild-to-moderate POP. This strategy can be integrated into the existing maternal and reproductive health programs to address POP in low-income settings where access to trained specialist is limited.

Trial registration

The trial was registered at the Pan African Clinical Trial Registry (<https://pactr.samrc.ac.za>) database, with the registration number PACTR202302505126575 (<https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=24311>).

Author summary

Why was this study done?

- Pelvic organ prolapse (POP) is a prevalent condition that can severely impact women's quality of life, particularly in low-resource settings where access to specialized care is limited.
- Prior to this research, there was limited evidence regarding the effectiveness of pelvic floor muscle training (PFMT) as a conservative treatment option for POP in such contexts, highlighting the need for effective interventions.

What did the researchers do and find?

- The study utilized a cluster-randomized controlled trial design involving eight clusters (four clusters in each arm) and a total of 187 women, all drawn from these clusters, with mild-to-moderate POP in Sidama region, Ethiopia. The intervention group received midwife-led PFMT combined with lifestyle counseling, while the other group received only lifestyle counseling.
- The key findings from the study showed that women who participated in the midwife-led PFMT combined with lifestyle counseling experienced a significant reduction in their POP symptoms. Specifically, there was an average decrease of 4.11 points in their symptom scores, which indicates a notable improvement in how they felt. Additionally,

the women reported substantial enhancements in various aspects of their quality of life, meaning they felt better overall and were able to engage more fully in daily activities.

What do these findings mean?

- The research demonstrates that midwife-led PFMT can serve as an effective first-line treatment for POP, improving symptoms and quality of life in low-resource settings.
- However, limitations include reliance on self-reported data, and a relatively short follow-up period may limit generalizability of the findings.

Introduction

Symptomatic pelvic organ prolapse (POP) is the descent of one or more of the uterus, cervix, anterior or posterior vaginal wall, or the vaginal apex from its normal position. This descent can be caused by deficient pelvic fascia, or weakness in the ligaments or muscles that support the pelvic organs [1]. These structures can be affected by several risk factors including aging, vaginal childbirth, chronic constipation, hereditary connective tissue weakness, persistent elevated intra-abdominal pressure, menopause, and heavy lifting [2].

POP is a prevalent condition affecting many women globally, with estimated prevalence rates varying widely from 1% to 65% [3,4]. This broad range can be attributed to the challenges in accurately estimating prevalence, largely due to the differing methodologies employed in various studies. For instance, researchers may utilize a variety of symptom questionnaires and clinical examination techniques, leading to inconsistencies in the reported prevalence [3,5].

Women with symptomatic POP present with a range of prolapse-related symptoms that are associated with the urinary, sexual, and anorectal symptoms [6]. It is evidenced that depressive symptoms and sexual function disorders are frequently associated with POP [7,8]. In addition to disrupting daily functioning, these multifaceted symptoms of POP have significant negative impact on patients overall quality of life, body image and sexual function [8]. The severity of symptoms is directly related to the degree of prolapse. As the prolapse descends closer to or beyond the hymen, the symptoms become more frequent and bothersome [9,10].

The current POP treatment options are either surgery or conservative management approaches [11]. The conservative management options include pelvic floor muscle training (PFMT), pessary, life-style modification, or watchful waiting, which are recommended as first-line options if the prolapse is not the indication for corrective surgery [2]. Conservative management has the advantage of causing fewer adverse effects and complications [12]. The existing evidence shows that PFMT has a positive effect on prolapse symptoms and severity [13]. Due to its effectiveness and safety, PFMT is indicated as a first-line treatment for women with mild-to-moderate POP [13]. PFMT improves prolapse symptoms by improving pelvic muscle strength, endurance, power, relaxation and combination of these parameters [1].

Awareness of POP and conservative treatment option is very poor among women [14] and healthcare professionals [15] even in high-income countries. To enhance the accessibility and variety of services for women, it is essential to understand various models of service delivery [16]. In low- and middle-income countries, evidence about the feasibility and effect of PFMT on prolapse symptoms and health-related quality of life (HRQoL) is limited.

In Ethiopia, there is a scarcity of evidence on the effectiveness of PFMT, and women often seek healthcare only at advanced stages of prolapse [17] when impact of PFMT may be

limited. Additionally, the number of trained specialists such as urogynecologists or physical therapists are limited in Ethiopia. There are only 450 gynecologists registered in the Ethiopian Society of Obstetricians and Gynecologists out of which only 15 are urogynecologists and 13 are urogynecology fellows in 2021 [18]. In areas of the world with developed physical therapy training (PT) programs, PT management of POP is the gold standard for administering the service [19]. However, it is considered a sub-specialty within the profession and currently, the Ethiopian Ministry of Health does not support specialty practice for the profession of Physical Therapy [20]. Fortunately, midwives, who are generally more accessible than specialists [21], are capable of learning how to deliver PFMT services and are well-positioned to provide this support to women in their communities. To address these challenges and improve access to the conservative management options, research into different models of PFMT service delivery is critical particularly in low-resource settings.

The aim of this study was to assess the effect of PFMT provided by trained midwives on prolapse symptoms and HRQoL among women with mild-to-moderate POP (stages I–III) in Sidama region, Ethiopia. Our hypothesis was that providing midwife-led PFMT approximately monthly alongside three times per-day home-based exercise by participants for 6 months will improve prolapse symptoms and prolapse-quality of life (P-QoL).

Methodology

The Consolidated Standards of Reporting Trials (CONSORT) checklist

The Consolidated Standards of Reporting Trials (CONSORT) 2010 statement [22] was used to guide the reporting of this cluster-randomized controlled trial (cRCT). The CONSORT checklist consists of a 25-item checklist that focuses on the key elements for reporting the design, conduct, analysis, and interpretation of RCTs. An extension to the CONSORT statement for reporting cRCTs [23] was also consulted. We have addressed all applicable items from the CONSORT checklist in the reporting of this cRCT (S1 File).

Study design and participants

A community-based, parallel-groups, two-arm, cRCT was conducted among women with symptomatic POP stages I–III in D-W HDSS. First, a baseline survey was conducted to determine the burden and risk factors of POP and to identify eligible cases [24]. Women aged over 18 years with at least one symptom of POP, confirmed as stages I–III using the standard POP-Q measure [25], were included in the study. The identified cases were then randomized by community clusters into intervention and control arms. Cluster randomization was preferred to minimize spillover of the intervention to the control arm and due to the feasibility of providing the intervention at group level (nearby health facility). The clusters were *kebeles* which are the smallest administrative units in Ethiopia, similar to neighborhoods or wards. They have a wide range of population sizes, from 500 to several thousand residents [26]. The surface area of *kebeles* varies depending on their location and population density, with those in densely populated urban areas being smaller compared to rural *kebeles*. Each *kebele* is further divided into smaller units called *gots* or *villages*. *Kebele* administrations are responsible for providing basic services, such as health, education, and infrastructure, to their residents. They also play a crucial role in population-based surveys and research studies in Ethiopia, often serving as the primary sampling units [27,28]. *Kebeles* are organized into larger administrative divisions known as *woredas* (Districts).

Sample size calculations were performed using Open-Epi version 3.1, based on the following assumptions: a 99% confidence level, 80% power, an exposed-to-unexposed ratio of 1, a pelvic organ prolapse symptom score (POP-SS) mean difference of 3.16 with a standard

deviation of 4.78 in the intervention group, and a mean difference of 0.12 with a standard deviation of 3.86 in the control group over six months [15]. This calculation yielded a required sample size of 96, adjusted for an anticipated 16% refusal and loss to follow-up [15], resulting in an individual-based total sample size of 111.34. This sample size was utilized for all outcomes since we were unable to determine the effect of PFMT on quality of life as measured by the Prolapse Quality of Life Questionnaire. The decision to adjust the confidence level to 99% was based on the adjusted level of significance to 0.0125 than the usual *P*-value of 0.05 to account for multiple comparisons across various outcomes (POP-SS and three distinct domains of P-QoL).

To determine the minimum number of clusters required, the individual-based sample size was multiplied by the intra-cluster correlation (ICC) coefficient. Since there was no reported ICC from earlier studies, we used an ICC of 0.03, which was suggested as an estimated fairly typical value of the ICC [29,30]. This calculation indicated a need for 1.67 clusters per arm. To ensure adequate power [31,32], a total of eight clusters were selected randomly from the 12 available clusters in the D-W HDSS.

After adjusting for cluster effects with a variance inflation factor of 1.39, the total effective sample size increased to 155, resulting in an expected average of 19.4 participants per cluster. However, during enrollment, a slightly varying number of eligible cases was identified in each cluster. Excluding additional participants was deemed unethical, and alternative treatment options could not be provided due to the cRCT design. Furthermore, it was believed that including all eligible cases would be manageable and enhance the study's power [29,30]. Consequently, all eligible cases were included, raising the total sample size from 155 to 187 participants. The exclusion criteria were: women who were diagnosed to have symptomatic POP stages I–III, but planned to leave the study area within 6 months (study period), severely ill women, women with psychiatry disorders, women with delivered myoma, or women who want to have prolapse surgery within 6 months.

Randomization and masking

The study site, D-W HDSS, comprises eight kebeles from Dale district and four kebeles from Wonsho district. These were stratified into two strata based on their geographical location (Dale and Wonsho districts). Stratifying on location reduces stratum variability and helps to ensure that they are balanced across study arms [31,32]. To improve similarity across treatment and control groups, a balanced number of clusters from each stratum were assigned to each arm. First, all eligible clusters in each district were listed and assigned a unique identifier number. Then, a lottery method was used to select two of four clusters from the Wonsho district and randomly assigned to each arm. Similarly, six of eight clusters from Dale districts were selected and three clusters were assigned to each arm randomly by lottery method. Then, 102 households were selected from each cluster using computer-generated random numbers (based on the list of their house numbers) to identify eligible women. One woman (usually the head of the household) was recruited for the study.

To reduce the risk of spillover-effect of the intervention, the interventional and control clusters were separated by a buffer zone [31], and when it is impossible due to the limited number of clusters in the D-W HDSS, adjacent clusters were assigned to the same arm. Finally, all eligible study participants from each cluster identified during the baseline survey were included in the study (Fig 1).

The enrollment period was open for 8 months from 13 March to 28 October 2023. Each participant was followed for 6 months after enrollment. The last participants were enrolled on October 28, 2023 so the final follow-up visit was on April 27, 2024. Allocation concealment was conducted by staff of D-W HDSS at Hawassa University. To ensure unbiased allocation,

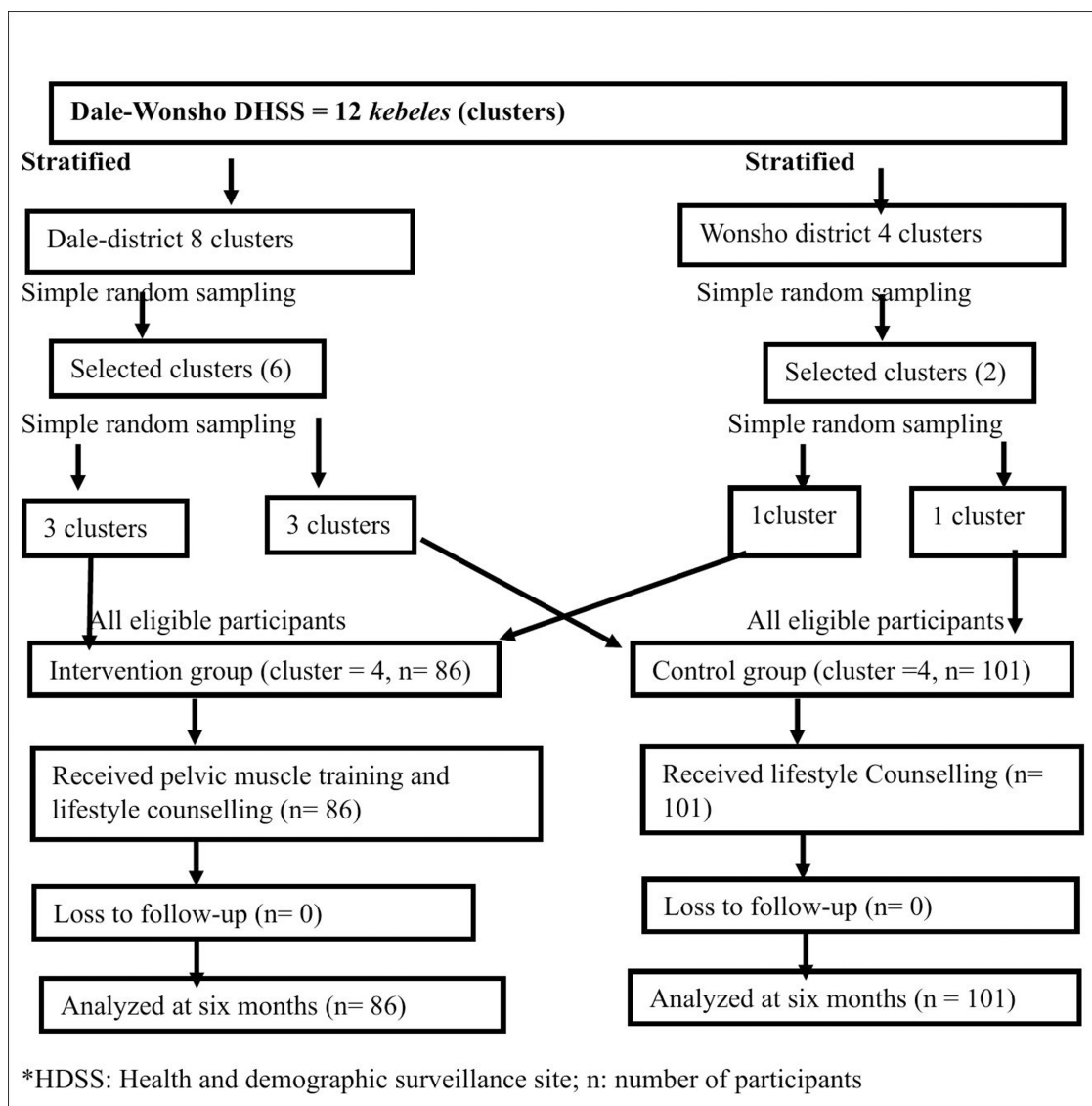


Fig 1. Randomization and Sampling procedure used to assess the effect of pelvic floor muscle training on prolapse symptoms and quality of life in Sidama Region, Ethiopia, August 2024.

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the lottery method was performed by an independent researcher who was not involved in the recruitment, intervention, or outcome assessment processes. Two staff members of Yirgalem Hamline Fistula Center, who performed pelvic examination to determine the POP stage, recruited eligible participants for intervention.

The participants in the intervention group were aware that they were receiving the PFMT program, but they were not aware of the control group. Similarly, the control group knew that they are receiving lifestyle counselling, but they are not aware of the intervention group. The same is true for the healthcare providers delivering the counselling. Moreover, the outcome assessors, who collected data at the end of intervention, were blinded to the participants' treatment allocation.

Procedure

In Ethiopia, each kebele/cluster is served by its own health post, staffed by health extension workers. Additionally, groups of five or more kebeles are supported by a single health center, staffed by formally trained healthcare professionals, including midwives. For this study, the intervention was implemented at eight distinct health centers. The intervention was implemented at health centers due to their capacity to deliver the training and their geographical accessibility to participants, especially when compared to hospitals. In this study area, all health centers have at least three degree-holding midwives responsible for providing antenatal, delivery, and postnatal care. Each health center is equipped with various rooms, including delivery rooms, cervical cancer screening rooms, and outpatient rooms, which are suitable for conducting the Pelvic Organ Prolapse Quantification (POP-Q) [25] assessments and ensuring confidentiality during individual counseling sessions.

From each selected health facility, two female midwives were trained either on PFMT and how to counsel patients, or only on how to counsel for life style modification based on their pre-allocated health facility. The training that included education on theory, simulation, and video aids was given by a fellowship trained urogynaecologist. Then, the trained midwives administered the intervention to the women assigned in the intervention arms.

Women who were assigned to intervention received PFMT and prolapse lifestyle advice focusing on risk factors for POP such as constipation, chronic coughing, heavy lifting, and other medical conditions. The control group received only lifestyle modification. In the intervention group, the pelvic examiners link eligible women to the assigned midwife with the POP-Q findings. Then, at the initial visit, women were informed by midwives about the stage of POP they had and type of prolapse (anterior, posterior, or central) which was explained in a private room. Then, the advantage of pelvic floor muscle exercise, and how it works, the detail of the exercise and follow-up schedule were explained in detail at the group level in a private room for 40–60 min.

They were trained to sit or lie comfortably, train pelvic muscles with 10 times 10-s maximum holds, and 10 fast contractions [15,33]. They were instructed to repeat this at least three times per day (morning, afternoon, and night) [15,34]. Women were taught how to precontract the pelvic floor muscles against increases in intra-abdominal pressure (Knack exercise). They were trained to exercise 10 long squeezes and lift contractions, each held for 10 s, allowing time between the squeeze to relax and lower the muscle for up to 5 s. The long squeezes were followed by 10 short squeezes. Women were advised to try to feel the releasing and relaxing of the squeeze after 10 short squeezes, and finally, to do a squeeze with a light cough for 10 times. The long squeezes were for 10 s each and the 10 quick squeezes for 1–2 s each.

To help participants correctly identify and contract their pelvic floor muscles, the participants in the intervention group received PFMT with internal digital biofeedback administered by the trained midwives. During the individual training sessions, midwives used various verbal cues and analogies. For example, participants were instructed to “imagine you are trying to stop the flow of urine or hold back gas. Squeeze as though you are trying to slow down or stop your urine mid-stream” [35]. This relevant analogy helped participants visualize the specific action they needed to perform. Throughout the exercises, midwives provided descriptive feedback to guide participants. They would say things like, “As you squeeze, focus on lifting the muscles around your vagina and anus upwards. You should feel a tightening and lifting sensation” [33,35,36]. This encouraged participants to be aware of the specific muscles being engaged during the contractions. We translated the Lifestyle Advice Leaflet from the POPPY trial [15] into Sidaamu Afoo, the local language, to enhance understanding and effectiveness during counseling sessions.

They were appointed to attend five visits (at weeks 0, 2, 6, 10, and 15) at a nearby health facility. The appointment frequency was adapted from the United Kingdom National Health Service (NHS) [37]. Initial appointments were scheduled closely together to reinforce correct exercise techniques and ensure participants fully understood all the advice provided. Subsequently, appointments were spaced further apart to promote independent home exercise. A 15-week intensive training was recommended to get adequate muscle strength [38]. The change in prolapse symptoms and HRQoL were analyzed at 6 months.

A lifestyle counseling was given for both arms focusing on the following points [15,36].

Bowel health. To avoid constipation, which increases strain on pelvic floor muscles and can exacerbate prolapse symptoms, it's important to consume a balanced diet rich in fruits, vegetables, and adequate fiber. Aim for 1.5–2 l of water daily to maintain bowel regularity. When using the toilet, sit fully rather than hovering, as this promotes muscle relaxation. Position yourself comfortably with your feet apart and hands resting on your thighs or supported. Keep your abdominal muscles relaxed; if you need to bear down, take a deep breath to ease tension. Light pressure on the vaginal bulge towards the back passage may assist with complete bowel emptying.

Bladder health. It's crucial to urinate only when the bladder signals the need, rather than going "just in case." Sitting fully on the toilet aids in muscle relaxation, and leaning forward slightly after urination can help ensure complete bladder emptying. Avoid straining, as this can worsen prolapse symptoms. Maintaining the recommended fluid intake of 1.5–2 l per day is essential; reducing fluids does not necessarily decrease urinary frequency and may lead to bladder issues.

Weight management. Maintaining a healthy weight is vital, as excess weight can place additional pressure on the pelvic floor. Weight loss may improve prolapse symptoms.

Reducing intra-abdominal pressure. For those with a chronic cough, follow prescribed treatments and stay hydrated to prevent strain from coughing. Proper lifting techniques are also important; adopt good habits even for lighter items, tightening pelvic floor muscles before lifting. When lifting heavy loads, divide the weight and lift from low positions to minimize strain.

Exercise and physical activity. It is advisable to avoid activities that worsen symptoms, such as prolonged standing. Try to alternate standing tasks with sitting breaks. Additionally, high-impact exercises, like jumping, jogging, or aerobics that involve both feet leaving the ground simultaneously, should be avoided. Instead, opt for low-impact activities like modified aerobics, cycling, using an elliptical trainer, or brisk walking.

Outcomes

Our primary outcomes were POP symptoms and HRQoL. The POP-SS was measured by the *Sidaamu Afoo* version of the POP-SS questionnaire [39]. The psychometric properties of the questionnaire have been evaluated in the same setting and found to have acceptable reliability and validity. It is a patient-reported-outcome measure that contains seven items with five Likert-scale ranging from 0 to 4, with a possible total score of 0–28 (the higher score representing worse symptom) [40]. HRQoL was measured by using the prolapse quality of life (P-QoL) questionnaire translated from the Amharic version [41]. While the original version has 20 items with nine domains [42], in a previous work designed to adapt the P-QoL locally (*to Amharic version*), the dimensions have been condensed into three: physical function (including General health perception, prolapse impact, role, physical and social limitation, and severity measures); psychological function (including emotional disturbances and sleep/energy disturbances); and personal relationships. Each domain is related to a particular aspect of QoL, and scores in each domain range from 0 to 100, the higher score indicating poor quality of life. This tool has previously been validated in a similar context (northern Ethiopia).

The secondary outcome, women's perceived change in prolapse, was evaluated using the patient global impression of change index (PGI-I), a seven-point Likert scale (1 = very much better to 7 = very much worse) [43]. In this study, patients were classified as improved if they scored 1, 2, or 3 on the PGI-I scale, no change if they scored 4, and worse if they scored 5, 6 or 7.

Intervention adherence was measured in terms of attendance at appointments [15] and the amount of exercise women reported at follow-up time. Women's adherence to training protocol is considered adequate when they complete at least 80% of the training sessions given by midwives [44].

The details of the baseline data collection procedures and tools have been published elsewhere [24]. All tools were translated from English and Amharic into the local language (*Sidaamu Afoo*).

The baseline data about sociodemographic characteristics and prolapse symptoms were collected through face-to-face interviews with women at their homes by eight first-degree nurses using electronic data collection forms prepared using Kobo tool box. The women were subsequently invited for pelvic examination in a nearby health center to confirm their prolapse status and degree of prolapse by using the POP-Q [25]. The POP-Q was performed by staff members of Yirgalem Hamlin Fistula Center who have special training on Fistula and POP identification. Then, women with symptomatic POP stages I–III were interviewed about how much the prolapse had affected their quality of life using P-QoL tool. The detailed POP-Q procedures and data quality assurance method were published elsewhere [24].

At 3 and 6 months of intervention, four first-degree nurses went to the house of the study participants and collected the data through face-to-face interviews. The data collection tool included the POP-SS and P-QoL questionnaires used at baseline, PGI-I change, and questions used to assess their adherence to training protocol [44].

Statistical analysis

All data analyses accounted for the complex sampling design, which included stratification by district (Dale and Wonsho), clustering by kebele, and weighting for unequal probability of selection. The weighting variable was the product of cluster and household selection weights, normalized by dividing each unit's survey weight by the unweighted average of the survey weights. Categorical variables were summarized as frequencies and percentages, while continuous variables were summarized using means and standard deviations or medians and interquartile ranges.

The analysis was based on the intention-to-treat principle. In practice, all participants adhered to their allocated treatment and completed the follow-up as scheduled. Although the intervention was randomly assigned at the cluster level, outcomes were evaluated at the individual level. An Individual-level analysis was performed using a mixed-effects generalized linear model (MEGLM), incorporating random effects to account for clustering by health centers and survey weights to adjust for unequal selection probabilities.

To complement the primary analysis, a cluster-level analysis was conducted following Hayes and Moulton's framework. Cluster-level means were calculated for key outcomes (mean change in POP-SS, physical domain, psychological domain, and personal relationship) and analyzed using Mann–Whitney U test to compare intervention and control clusters (S5 File).

To compare the primary outcomes at 6 months, we fitted a multilevel MEGLM to the change from baseline in POP-SS and each domain of HRQoL at three and 6 months. The model included fixed effects for treatment group, time, and other relevant covariates (stage of prolapse, duration of prolapse symptoms, residence, parity, age, level of education, history of prolonged labor, wealth index, constipation, and chronic cough), as well as a random intercept for patients within centers and a random slope for time within patients. The relevance of the

covariates was determined based on prior research, clinical aspect, and their potential impact on the intervention and outcomes (prolapse symptoms and quality of life). MEGLM was chosen for its flexibility and robustness needed to accurately model the complex and varied data structures often found in cRCT leading to more reliable and interpretable results [45].

The difference between intervention and control group was estimated by the mean change from baseline at 6 months. Bonferroni correction for multiple measurements [46] was used to adjust the level of significance to 0.0125 as we measured the effect of PFMT on four outcomes (POP-SS and three domains of HRQoL). Then a mean change difference between the intervention and control arms was presented with 99% confidence interval and *P*-values. This adjustment is crucial for maintaining statistical rigor and minimizing the risk of Type I errors in the analysis [46].

To evaluate model fit, we initially fitted a null model for each outcome variable (POP-SS and the three domains of Prolapse Quality of Life (P-QoL)), incorporating random effects for both cluster and participant ID. We calculated the intra-cluster correlation coefficient (ICC) to determine the proportion of variance in the outcome attributable to the clustering structure, which was found to be 4% and less in this study. Subsequently, we fitted models that included the intervention variable to the outcome variables individually. This step allowed us to assess the impact of the intervention on each outcome. We evaluated model fitness using the Pseudo Log-Likelihood values for model fitness and Adjusted Wald Test for significance of predictors. Higher (less negative) Pseudo Log-Likelihood values indicate better model fit and significant Wald test indicates the importance of the predictors [47]. This approach allowed us to identify the most appropriate models for each outcome. Residual analysis was done to assess homoscedasticity and normality of residuals by using the histogram. To check for effect modifiers, we employed statistical tests to assess interactions between PFMT and potential effect modifiers. This approach allowed us to determine whether the effect of PFMT varies across different subgroups. The data set on which the analysis based was provided as a [S2 File](#).

Results

Trial profile

A total of 187 eligible women were randomized to the intervention group ($n = 86$) or the control group (101). All of them completed the follow-up and completed the questionnaire at 3 and 6 months. The age of participants ranged from 19 to 80 years with a median of 36 years (IQR: 31–50). All were parous, with a median of 4 childbirths (IQR: 4–6). The median hours of daily heavy lifting work were 4 h (IQR: 3–5). The most common stage of prolapse was stage II 120/187 (64.17%). The median duration of feeling prolapse symptom was 48 (30–60) months with the minimum of 5 months and maximum of 20 years. At baseline, a slightly higher number of women in menopause, family history of prolapse, and history of home birth were observed in the intervention group. The mean baseline POP-SS and quality of life domain scores were almost similar across the groups. Almost half 92 (49.2%) of the participants had prolapse of multiple vaginal compartments; whereby 161 (86.1%) had anterior prolapse, 113 (60.43%) had posterior prolapse and 28/187 (14.97%) had apical prolapse. Overall, while the intervention and control arms were balanced in terms of most characteristics at baseline, there were some important characteristics that showed significant imbalances. Detailed sociodemographic characteristics are presented in [Table 1](#).

Adherence and follow-up

All study participants adhered strictly to their allocated treatment and completed the follow-up as scheduled. No participants changed their allocation, missed follow-up

Table 1. Sociodemographic and clinical characteristics of trial participants at Baseline in Sidama Region, Ethiopia (August 2024) (*n* = 187).

Variables	Category	Control (<i>n</i> = 101)	Intervention (<i>n</i> = 86)
Districts			
Number of clusters	Dale	3	3
	Wonsho	1	1
Number of participants	Dale	64	70
	Wonsho	37	16
Clusters	Aposto	21	–
	Megara	–	26
	Dagia	–	16
	Shoye	–	27
	Wayicho	26	–
	Dansha sire	17	–
	Mamana	37	–
	Bokaso	–	16
Age at baseline	Median (IQR)	34 (30–37)	50 (35–60)
Age at first birth	Median (IQR)	18 (17–19)	17 (16–20)
Number of childbirths	(Median (IQR)	4 (4–5)	5 (4–7)
Age at last delivery	Median (IQR)	30 (26–32)	36 (29–42)
Level of education	No formal education	67 (66.82%)	60 (69.47%)
	Primary school	18 (17.94%)	20 (23.16%)
	Secondary and above	15 (15.25%)	6 (7.38%)
Occupation	Employed	5 (5.38)	5 (5.79%)
	Un-employed	96 (94.62%)	81 (94.21%)
Menopause	Yes	24 (24.22%)	53 (61%)
	No	77 (75.78%)	34 (39%)
Experience of prolonged labor	Yes	62 (61%)	46 (53.16%)
	No	39 (39%)	40 (46.84%)
History of home birth	Yes	66 (65.47%)	63 (73.16%)
	No	35 (34.53%)	23 (26.84%)
Family history of prolapse	Yes	53 (52.47%)	8 (9%)
	No	48 (47.53%)	78 (91%)
Stage of prolapse	Stage 1	11 (11.21%)	11 (13.16%)
	Stage 2	65 (64.57%)	55 (64.21%)
	Stage 3	24 (24.22%)	19 (22.63%)
Body mass index	<18.5	43 (42.15%)	38 (44.74%)
	18.5–24.9	55 (54.26%)	43 (49.47%)
	≥25	4 (3.59%)	5 (5.79%)
Type (site) of prolapse	Anterior only	34 (33.66%)	37 (43.02%)
	Posterior only	15 (14.85%)	10 (11.63%)
	More than one site	52 (51.49%)	39 (45.35%)
Mean Base-line POP-SS	Mean, SD	12.17 ± (4)	13.86 ± (4.4)
Baseline Symptoms			
Protruding mass per vagina		97 (96.04%)	82 (95.35)
Vaginal Discomfort/pain		97 (96.04%)	83 (96.51%)
Heaviness in the lower abdomen		96 (95.05%)	77 (89.53%)
Lower back dragging		97 (96.04%)	79 (91.86%)
Strain to urinate		85 (84.16%)	81 (94.19%)
Difficulty to empty bladder		77 (76.24%)	81 (94.19%)

(Continued)

Table 1. (Continued)

Variables	Category	Control (n = 101)	Intervention (n = 86)
Difficulty to empty bowel		73 (72.28%)	67 (77.91%)
Prolapse quality of life (baseline)			
Physical function	Median (IQR)	40.5 (29.7–51)	43 (35–56.7)
Personal relation	Median (IQR)	44.44 (33–55)	44.44 (33–55)
Psychological function	Median (IQR)	46.69 (33–53)	40 (33–53)

IQR, inter-quartile range; SD, standard deviation; POP-SS, pelvic organ prolapse symptoms score.

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appointments, or failed to complete the treatment regimen. Consequently, while our analysis framework was based on the intention-to-treat principle, the actual adherence and follow-up were perfect, ensuring that all participants were analyzed according to their initial allocation.

Prolapse symptoms and quality of life at 6 months

A summary at the cluster level reveals that all clusters experienced at least a minimum mean change of 1 point in the POP-SS score. Notably, a larger change was observed in the intervention clusters compared to the control clusters, suggesting a more significant impact of the PFMT intervention on participants in those areas (Table 2).

Women in the intervention group reported significant improvements in prolapse symptoms and across all domains of P-QoL at six months. In the unadjusted model, the most substantial improvement was observed in the psychological function component of the P-QoL, with a mean change difference of −11.18 (99% CI [−15.03, −7.32]; $p < 0.001$), indicating a large effect size. Moreover, a significantly higher number of women in the intervention

Table 2. Change in Pelvic Organ Prolapse Symptom Scores (POP-SS) and prolapse-quality of life domains by cluster after intervention, Sidama Region, Ethiopia, August 2024.

Clusters	Group	Post-intervention	Outcome variables			
			POP-SS	Physical function	Psychological function	Personal relation
Aposto (n = 21)	Control	Mean ± SD	11.65 (±3.79)	41.20 (±19)	36.25 (±12)	38.64 (±15)
		Mean difference	−1.13 (±2.39)	−3.64 (±8.78)	−8.12 (±12.08)	−3.86 (±8.18)
Bokaso (n = 16)	Intervention	Mean ± SD	8.83 (±4.99)	35.33 (±14.3)	38.35 (±12.86)	29.63 (±11.92)
		Mean difference	−3.17 (±2.32)	−11.93 (±14.24)	−10.00 (±18.22)	−13.89 (±16.61)
Dagia (n = 16)	Intervention	Mean ± SD	8.67 (±5.07)	23.55 (±15.92)	26.68 (±14.63)	29.63 (±16.08)
		Mean difference	−6.06 (±3.54)	−19.50 (±11.60)	−11.49 (±18.71)	−16.05 (±15.22)
Dansha Sire (n = 17)	Control	Mean ± SD	12.42 (±5.40)	37.37 (±16.57)	35.10 (±16.42)	38 (±19.48)
		Mean difference	−1.16 (±1.82)	−1.42 (±4.56)	−3.16 (±8.02)	−2.92 (±7.44)
Mamana (n = 37)	Control	Mean ± SD	9.93 (±4.12)	39 (±14.97)	35.33 (±13.78)	39.09 (±13.61)
		Mean difference	−1.26 (±2.13)	−14.99 (±2.56)	−5.43 (±56)	−3.70 (±6.88)
Megara (n = 26)	Intervention	Mean ± SD	7.62 (±5.14)	23.46 (±14.28)	29.21 (±13.23)	32.18 (±18.28)
		Mean difference	−6.0 (±4)	−14.99 (±12.11)	−12.88 (±15.98)	−11.88 (±16.53)
Shoye (n = 27)	Intervention	Mean ± SD	8.8 (±5.01)	33.39 (±13.77)	30.24 (±14.49)	28.89 (±12.68)
		Mean difference	−5.90 (±4.77)	−11.61 (±17.69)	−12.45 (±13.67)	−11.11 (±13.52)
Wayicho (n = 26)	Control	Mean ± SD	10.41 (±4.26)	33.24 (±21)	35.42 (±14.43)	37.93 (±16.98)
		Mean difference	−1.72 (±3.20)	−3.72 (±6.86)	−8.97 (±12.00)	−4.60 (±11.30)

SD, standard deviation; POP-SS, Pelvic organ prolapse symptoms score.

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group reported their condition as “better” after the intervention compared to the control group. In the control group, more than 27/101 (26%) of women became worse in 6 months (Table 3).

Effect of covariates on pelvic organ prolapses and quality of life

We observed that women in the stages I and II prolapses experienced more marked improvements compared to stage III prolapse both in prolapse symptom and quality of life. Women with higher POP-SS scores, indicating more severe symptoms, experienced less improvement in the physical domain of quality of life compared to those with lower scores. The analysis showed that as the severity of prolapse symptoms increased, the associated improvements in the physical domain of the Prolapse Quality of Life (P-QoL) questionnaire were diminished. Moreover, after adjusting for the severity of prolapse symptoms and the stage of prolapse, the effect of PFMT on the physical domain of quality of life was slightly diminished but showed increased effects in the personal relationship and psychological domains (Table 4).

Table 3. Effect of pelvic floor muscle training on prolapse symptom and prolapse quality of life, Sidama Region, Ethiopia, August 2024.

Outcome	After 6months		Change difference from baseline (mean, 99% CI, P-value)
	Intervention (n = 86)	Control (n = 101)	
POP-SS (mean ± SD)	8.4 (±5.15)	10.8 (±4.48)	
Change from baseline (mean ± SD)	−5.44 (±4.03)	−1.34 (±2.47)	− 4.11 (−5.08 −3.14)
	P < 0.001	P < 0.001 ^t	P < 0.001 ^m
Prolapse-Quality of life			
Physical function (mean ± SD)	28.89 ± (15.6)	38.1 ± (18.1)	
Change from baseline physical function (mean ± SD)	−14.2 ± (14.85)	−2.44 ± (5.68)	− 11.48 (−15.9, −7.1)
	P<0.001 ^t	P = 0.0076 ^t	P<0.001 ^m
Psychological function (mean, ± SD)	24.96 ± (10.95)	35.5 ± (14.33)	
Change from baseline psychological function (mean, ± SD)	−17.76 ± (17.46)	−6.52 ± (10.39)	−11.24 (−16.8, −5.7)
	P < 0.001 ^t	P < 0.001 ^t	P = 0.01 ^m
Personal relation (mean, ± SD)	30.17 ± (15.13)	38.5 ± (15.89)	
Change from baseline personal relation (mean, ± SD)	−12.81 ± (15.80)	−3.84 ± (8.51)	−8.97 (−13.9, −4.02)
	P < 0.001 ^t	P < 0.001 ^t	P < 0.001 ^m
Perceived improvement after intervention			
Better	72 (83.72%)	42 (41.57%)	0.0049 ^x
No change	10 (11.63%)	32 (31.68%)	
Worse	4 (4.65%)	27 (26.73%)	
POP-SS at 6th months			
Protruding mass per vagina	71 (82.56%)	100 (99.01%)	0.009 ^x
Vaginal discomfort/pain	69 (80.23%)	100 (99.01%)	0.005 ^x
Heaviness in the lower abdomen	58 (67.44%)	93 (92.08%)	0.06 ^x
Lower back dragging	64 (74.42%)	95 (94.06%)	0.048 ^x
Strain to urinate	58 (67.44%)	81 (80.20%)	0.2 ^x
Difficulty to empty bladder	58 (67.44%)	70 (69.31%)	0.46 ^x
Difficulty to empty bowel	46 (53.49%)	67 (66.34%)	0.19 ^x

CI, confidence interval; SD, standard deviation; POP-SS, pelvic organ prolapse symptoms score; n, sample size.

P-values presented with ^t indicate paired t test, ^m was based on mixed-effects generalized linear model, and ^x indicate chi-square test.

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Table 4. Adjusted effect of pelvic floor muscle training on prolapse symptoms and quality of life in Sidama Region, Ethiopia, August 2024.

Predictors	Category	β (crude)	β (adjusted)	99%CI	P-value
POP-SS					
Intervention	Mean change	-4.11	-4.11	-5.38, -2.83	<0.001
Stage	Stage I	-5.22	-4.94	-7.38, -2.49	<0.001
	Stage II	-3.03	-2.99	-4.83, -1.13	<0.001
	Stage III	Ref	Ref		
Symptom duration		0.0	0.03	0.005, 0.06	=0.002
prolong labor		1.22	0.80	-0.704, 2.30	=0.17
Education	Not educated	Ref	Ref		
	Primary school	-0.5	-0.15	-1.77, 1.46	=0.81
	Secondary and above	0.04	-0.04	-2.11, 2.03	=0.96
Physical Function					
Intervention effect	Mean change	-11.47	-8.86	-13.84, -3.89	<0.001
Stage	Stage I	-39	-34.9	-42.16, -27.62	<0.001
	Stage II	-18.37	-16	-22.52, -10.79	<0.001
	Stage III	Ref	Ref		
Baseline POP-SS		1.45	0.64	0.21, 1.06	<0.001
Personal relationship					
Intervention effect	Mean change	-8.97	-9.01	(-10.49, -5.54)	<0.001
Stage of prolapse	Stage I	-24.3	-23.9	(-29.65, -18.23)	<0.001
	Stage II	-15.12	-15.20	(-20.69, -9.71)	<0.001
	Stage III	Ref	Ref		
Baseline POP-SS		0.83	0.23	(-0.08, 0.55)	0.06
Psychological function					
Intervention effect	Mean change	-11.24	-11.18	(-15.03, -7.32)	<0.001
Stage of prolapse	Stage I	-18.57	-16.80	(-24.34, -9.26)	<0.001
	Stage II	-5.53	-5.13	(-9.93, 0.32)	0.006
	Stage III	Ref	Ref		
Baseline POP-SS		0.33	0.02	(-0.43, 0.46)	0.9

POP-SS, pelvic organ prolapses symptom score; CI, confidence interval; Ref, reference category.

The regression table shows a combination of four different regression tables (POP-SS and three domains of Prolapse quality of life).

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Adverse events

No adverse events were observed.

Discussion

This study showed that midwife-led PFMT combined with lifestyle counseling significantly improves prolapse symptoms with a mean change difference of -4.11 (99% CI [-5.38, -2.83]; $p < 0.001$) in POP-SS and each domain of prolapse quality of life with a mean change difference of -8.86 (99% CI [-13.84, -3.89]; $p < 0.001$) in the physical domain, -9.01 (99% CI [-10.49, -5.54]; $p < 0.001$) in the personal relationship domain, and -11.18 (99% CI [-15.03, -7.32]; $p < 0.001$) in the psychological domain. A significantly higher number of women in the intervention group perceived their condition as “better” since the intervention compared to the control group, highlighting the subjective benefit of PFMT. The change in POP-SS was more noticeable in women with prolapse stage I with a mean change difference of -4.94 (99% CI [-7.38, -2.49]; $p < 0.001$) and stage II with a mean change difference of -2.99 (99%

CI $[-4.83, -1.13]$; $p < 0.001$) as compared to stage III in reducing POP-SS. Similar effect was observed on each domain of P-QoL. In addition, severity of baseline prolapse symptoms was associated with physical function of the P-QoL domain with a mean change difference of 0.64 (99% CI 0.21, 1.01; $p < 0.001$) compared to minor prolapse symptoms indicating that more severe symptoms were linked to less improvement.

The results of the present study align with existing literature from developed countries indicating the benefit of PFMT for the treatment of POP symptoms and quality of life. A multicenter randomized controlled trial (RCT) study from 25 centers (United Kingdom, Dunedin, New Zealand, and Australia) conducted by Hagen et al. [15] showed that PFMT led to a significant reduction in POP symptoms and improved quality of life. A single-center RCT and systematic review of RCT findings also show that PFMT is effective in reducing POP-symptoms, prolapse stage, and quality of life in women with POP-Q stages I–III [4]. Based on the findings of those studies, the Cochrane reviews [48,49] and national institute for health and care excellence (NICE) guidelines [50] recommended PFMT as a first line of treatment for incontinence and POP, to be provided at primary care facilities [51]. Our finding extends these findings and recommendations to a low-income setting which is of a different cultural and health care context, highlighting the universal applicability of PFMT across diverse settings. Moreover, the observed difference in mean change is statistically significant and clinically important as it exceeded the minimally important change of 1.5 for POP-SS [52]. Again, a remarkable improvement was reported on “a feeling of vaginal discomfort/pain and protruding mass through vagina” which are the major indicators for prolapse surgery and are regarded as the most crucial treatment target [53]. The significant reduction in these key symptoms underscores the importance of PFMT. These two symptoms are closely linked to the physical support provided by the pelvic floor muscles. Strengthening these muscles through PFMT may lead to a more noticeable reduction in these specific symptoms compared to others that may be less directly influenced by muscle strength or may involve more complex physiological changes.

The existing evidence shows that the improvement in POP-SS and P-QoL after PFMT can be attributable to several mechanisms. Overall, PFMT strengthens the pelvic floor muscle, providing better support for pelvic organs which can reduce/stop degree of prolapse and alleviate associated symptoms like vaginal bulging, discomfort, and lower back pain [44,54]. Enhanced muscle strength also improves urinary and bowel control, reducing symptoms like straining to urinate and difficulty emptying the bowel [54,55]. The contraction and relaxation of pelvic floor muscles during PFMT promote blood flow to the pelvic region and stimulate the nerves in the area, improving nerve function [56].

The study indicates that women with stages I and II prolapse experience a greater mean change difference in symptom scores compared to those with stage III, after adjusting for other factors. Borello-France and colleagues reported that women with stage II prolapse were better able to elevate their pelvic floor than those with stage III or IV [57]. Severity of prolapse symptoms was associated with physical function suggesting that more severe POP-SS causes less improvement. After adjusting for prolapse stage and symptom severity, the effect of PFMT remained significant with slightly reduced effect on physical function but slightly increased effects on personal relationship and psychological domains.

The findings of this study have important implications for clinical practice and public health policy in low-resource settings. The first implication is that the result suggests that midwife-led PFMT can be considered as a first-line conservative treatment for mild-to-moderate stage of prolapse in all settings especially in resource-limited settings where access to specialized care is limited. This can be integrated into the existing maternal and reproductive health programs. The second implication is that in settings where the number of urogynecologists/

pelvic physiotherapy experts is limited, like the current Ethiopian context, training midwives to deliver PFMT and lifestyle counseling is feasible and effective to address prolapse symptoms and improve quality of life among women with POP. We recognize that the most recommended form of PFMT is supervised training given by a physiotherapist or urogynecologists who have greater in-depth knowledge [1]. However, this is not feasible in low-resource settings due to shortage of trained specialists (only less than 28 urogynecologists in Ethiopia). It was evidenced that nurse-delivered PFMT have comparable effect with those delivered by specialists when implemented properly [58,59]. In the present study, the observed mean change difference was relatively larger and the compliance/adherence to training was better compared to previous studies. This adherence might be because midwives working in the nearby health facility and the women in the intervention know each other, and that may create trust and acceptability. This is a nice model that can be scaled up in other settings including high-income countries.

This study has its own strengths and limitations. Among others, the key strength of the study includes the rigorous cluster-randomized controlled design which enhances the internal validity of the finding, high adherence rate, and complete follow-up which ensure the reliability of the results. The use of validated and culturally adapted measurement tools ensures the relevance and accuracy of the collected data, and also the use of a complex survey design, which accounts for the clustered nature of the data, enhances the potential generalizability of the results to the target population. Above all, to our knowledge, this study is the first to evaluate the effect of PFMT on prolapse symptoms in Ethiopia.

However, some limitations should be considered. The reliance on self-reported adherence to PFMT and symptom improvement may introduce performance bias since the participants were not blinded to the intervention. These participants' knowledge of their treatment allocation may influence their reported outcomes that could lead to higher treatment effect and reported adherence rate. In addition, the follow-up period was relatively short, which prevents us from determining whether the observed effects are likely to be sustained over time. During randomization, we aimed to balance the two groups by allocating similar clusters using stratified cluster sampling. However, this method cannot account for individual-level variables, which is an inherent limitation of cluster sampling. As a result, the age of the participant, parity, and family history of the participants were not balanced in this study. The age discrepancy may stem from inaccuracies in measuring age, as many individuals in rural Ethiopia have no birth certificates.

Conclusions

Midwife-led PFMT combined with lifestyle counseling significantly improves prolapse symptoms and quality of life across all domains in women with POP. The observed treatment effects were significant and clinically important. The effects of PFMT were higher in women with earlier stage of prolapse. Moving over, in settings with a shortage of urogynecologists, training midwives to deliver PFMT and lifestyle counseling is a feasible and effective approach to improve prolapse symptoms and quality of life. Future studies should incorporate objective measures of adherence and explore long-term effects. Healthcare organizations should advocate and endorse the training of midwives and other healthcare providers to deliver PFMT. This study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from Institutional Review Board of Hawassa University, College of Medicine and Health Sciences (Ref. No. IRB/157/14). Written informed consent was obtained with provisions for participants unable to read and write to sign with their index fingers, confirming that the consent had been read to them. Given the sensitive nature of the condition, data regarding self-reported prolapse symptoms were collected in a private location within the participants' homes. Pelvic examinations were conducted in delivery rooms to

ensure participants' physical privacy, while lifestyle counseling and pelvic floor muscle training took place in private rooms. All study information was kept confidential, with participants assigned codes to replace their names and personally identifying information. Access to the key linking these codes to individual identities was restricted to the principal investigator. The risks to participants were minimal. While there was potential for psychological distress related to the pelvic examination, as well as temporary discomfort during physical exams and inconvenience from follow-up visits, these risks were mitigated by allowing participants to withdraw from the study at any time during the consent process. The research team provided travel costs and time compensation, equivalent to approximately four dollars (200 Ethiopian Birr), to the participants. During baseline data collection, around 26 participants with stage IV prolapse were referred to the Yirgalem Hamlin Fistula Center for further management. After the study's completion, women with symptomatic stage III prolapse in the control group were linked with the Yirgalem Hamlin Fistula Center for additional care.

Supporting information

S1 File. CONSORT 2010 checklist of information to include when reporting a Randomized trial.

(DOCX)

S2 File. The data set on which the analysis based.

(DTA)

S3 File. Study protocol.

(DOCX)

S4 File. CONSORT for Abstract.

(DOCX)

S5 File. Cluster-level analysis of the effects of midwife-led pelvic floor muscle training on prolapse symptoms and prolapse -related quality of life.

(DOCX)

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ANNEX I: Information Sheet

Hawassa University
College of Medicine and Health Science
School of Public Health

Title of the research: Epidemiology of Pelvic Organ Prolapse in Sidama National Regional State, Ethiopia, 2022.

Principal investigator: Melese Siyoum

Greetings! My name is _____. I am here on behalf of Mr. **Melese Siyoum** a PhD student at Hawassa University. He is conducting a research for the partial fulfilment of PhD degree in Public Health on the title mentioned above. You are chosen to participate in this study because you are resident of this kebele. The choice is made randomly. Before you decide whether or not to participate, I would like to explain about the study and what is expected from you.

The Objective of the study: The study will assess prevalence of and risk factors for Pelvic Organ Prolapse in Sidama National Regional State, Ethiopia. In addition, volunteer women who have a symptom of pelvic organ prolapse will be threatened either conservatively or referred to Hospital for further management.

Procedure: The data collection procedure involves interviewer-administered questionnaire and Pelvic examination to quantify the degree of pelvic organ prolapse. Now, I will ask you a set of questions using a structured questionnaire. After signing the consent form, I will then ask you the relevant questions and your responses will be written on the questionnaire. The interview will take about 40-50 minutes. The content of the questionnaire includes sociodemographic characteristics, wealth index, obstetric history, issues related to symptoms of the prolapse, and how it affected your quality of life. Finally, you will be given an appointment and will be examined by trained health care providers at a nearby health facility. A trained health care provider will confirm whether you have a prolapse or not. If you have a prolapse, you will be included in the trial study of two different treatment categories. In the trial study, there will be a five time visit at weeks 0, 2, 6, 10 and 15. The transportation cost will be covered by the research team.

The Benefit of the study: This study has direct and indirect benefits for women and the health care system. All women who participate in this study will be screened for the prolapse free of charge (without payment). In addition, the transportation cost and time compensation will be covered by the research team. Women who have mild to moderate prolapse (stage I-III) will be managed according to the trial protocol. Advanced cases will be referred to Yirgalem Hamline fistula center for treatment if you are volunteer. Beyond direct individual benefit, the finding of this study will identify the burden of the disease and help the regional health bureau to plan appropriate intervention. The result of the trial will be used by the concerned health offices and organization concerned to improve women health.

The Risk of the study: The intervention (procedure) going to be provided has no identified risks except the dedication of certain minutes for responding and repeated appointment to health facility (five times visit). In addition, you may face some discomfort from pelvic examination and some distress while exposing your private organ (genitalia). The interview and pelvic examination will be conducted at a private room and all information will be kept confidential.

The Rights of participants: You have a right to refuse participation totally or partially and even you can withdraw at any time. There is no risk you will face if you decline to participate.

Confidentiality: All information you give will be strictly confidential and will be kept safe and secure. Your role in the success of the research is important and I appreciate your contribution to the research.

Do you agree to participate in the research?

1- No (say thank you)

2- Yes (take informed consent)

Informed consent

The objective, benefits, harms, procedures and confidentiality of the study has been explained to me in the language I comprehend. I further understand that, taking part in this study and withdraw from participating at any time without having reason is purely voluntary. I agree to participate in this study.

Participant:

Sign..... Date.....

Data collector:

Sign..... Date.....

ANNEX II: English Version Questionnaire

Hawassa University
College of Medicine and Health Sciences
School of Public Health

Part One: Respondent's socio-demographic characteristics

Directions

Ask the following questions one at a time and write the response on the space provided or encircle the appropriate response from the options listed. Allow the participant to take time to remember the correct answer when needed.

Woreda_____ **kebele**_____ **Enumeration Area**_____ **Code**_____

Mobile_____

Sr. No.	Questions	Response category	Skip to
101.	What is your current Age?	_____years completed	
102.	Where is your permanent place of residence?	1. Urban 2. Rural	
103.	What is your current marital status?	1. Never married 2. Married 3. Widowed 4. Divorced 5. Separated	
104.	What is your Religion?	1. Ethiopian Orthodox 2. Protestant 3. Muslim 4. Catholic	

		5. Adventist 6. Other(specify)_____	
105.	What is your main Occupation?	1. Housewife 2. Farmer 3. Government employee 4. Nongovernmental employee 5. Private Business 6. Student 7. Others Specify)_____	
106.	What is your Ethnicity?	1. Sidama 2. Wolayta 3. Amhara 4. Gurage 5. Oromo 6. Other(specify)_____	
107.	What is your level of education?	1. Unable to read and write 2. Able to read and write without formal education 3. Primary Education 4. Secondary Education 5. Above secondary	
108.	What is your Husbands' level of education? Ask only if she is married (refer back to Q-103).	1. Unable to read and write 2. Able to read and write without formal education 3. Primary Education 4. Secondary Education 5. Above secondary	

Part-II: Lifestyle Questions

Ask the following questions one at a time and write the response on the space provided or encircle the appropriate response from the options listed.

201.	On average, for how long do you carry heavy objects/day (water, big baby, wood, stone, cereal, or grain)	----- hrs	
202.	Have you ever smoked cigarettes?	0. No 1. Yes	
203.	Do you have a family member who had Pelvic organ prolapse?	0. No 1. Yes	
204.	Did you ever have a chronic cough (>3weeks)	0. No 1. Yes	
205.	Did you ever have constipation (difficulty of defecation?)	0. No 1. Yes	
206.	Did you ever have a confirmed diabetes mellitus?	0. No 1. Yes	

Part III: Respondents' Obstetrics and Gynecologic related factors

Sr. No .	Questions	Choices of response	Skip to
301.	What was your age when you married for the first time?	----- years completed	
302.	Did you have a history of pregnancy terminated before seven months?	0. No 1. Yes	
303.	Did you give childbirth after seven months of pregnancy?	0. No 1. Yes	If no, go to Q312
304.	If yes, what was your age at first delivery?	----- in years 999..... don't know	

305.	How many children you delivered?	_____ no. of delivery	
306.	What was your age at last delivery?	----- years	
307.	Which mode of delivery have you ever faced? More than one option is possible	1. Spontaneous vaginal delivery 2. Cesarean delivery 3. Assisted instrumental delivery	
308.	Have you ever experienced labor that lasted more than one day and night (>24hrs)?	0. No 1. Yes	
309.	Have you ever given birth at home (previously)?	0. No 1. Yes	
310.	Where did you deliver your last child?	1. At home 2. Health facility	
311.	When did you start household work after delivery of your last baby?	----- days weeks after delivery	
312.	Do you have a history of pelvic surgery (episiotomy, hysterectomy, trauma, tumor removal)	0. No 1. Yes	
313.	Is your menstrual cycle stopped permanently (more than 3 cycles)? Without contraceptive use?	0. No 1. Yes	
314.	If yes for Q-313, for how long?	-----	

Part-IV: Study participants wealth Index

Ask (and observe when possible) the following questions one at a time and write the response on the space provided or encircle the appropriate response from the options listed.

401.	What is the main source of drinking water for members of your household?	Piped water: 1. Piped into dwelling 2. Piped to yard/plot 3. Public tap/standpipe 4. Borehole	
		Dug well: 1. Protected well 2. Unprotected well	
		Water from spring: 1. Protected spring 2. Unprotected spring	
		Surface water: 1. River/lake/pond/stream/dam	
402.	What is the main source of water used by your household for other purposes such as cooking and handwashing?	Piped water: 1. Piped into dwelling 2. Piped to yard/plot 3. Public tap/standpipe 4. Borehole	
		Dug well: 1. Protected well 2. Unprotected well	
		Water from spring: 1. Protected spring 2. Unprotected spring	
		Surface water: 1. River/lake/pond/stream/dam	
403.	Where is that water source located?	1. In own dwelling 2. In own yard/plot 3. Elsewhere	

404.	How long does it take to go there, get water, and come back?	1. Minutes _____ 2. Don't know	
405.	In the past two weeks, was the water from this source not available for at least one full day?	0. NO 1. Yes 2. Don't know	
406.	Do you do anything to the water to make it safer to drink?	0. No ----- 1. Yes	4.8
407.	What do you usually do to make the water safer to Drink? Record all mentioned	1. Boil 2. Add bleach/chlorine 3. Strain through a cloth 4. Use water filter (Sand/composite/etc.) 5. Solar disinfection 6. Let it stand and settle	
408.	What kind of toilet facility do members of your household usually use?	FLUSH OR POUR-FLUSH TOILET 1. Flush to a piped sewer system 2. Flush to septic tank 3. flush to a pit latrine 4. Flush to somewhere else 5. Flush, don't know where PIT LATRINE 1. Ventilated improved pit latrine 2. Pit latrine with slab 3. Pit latrine without slab/open pit 4. composting toilet 5. bucket toilet 6. Hanging toilet/hanging latrine 7. No facility/bush/field	
409.	Do you share this toilet facility with other households?	0. No 1. Yes	
410.	Including your own household, how many households use this toilet facility?	1. Less than 10 2. 10 or more 3. Don't know	
411.	Where is this toilet facility located?	1. In own dwelling 2. In own yard/plot 3. Elsewhere	

412.	What type of fuel does your household mainly use for cooking?	1. Electricity 2. Liquid petroleum gas 3. Natural gas 4. Biogas 5. Kerosene 6. Charcoal 7. Wood 8. Straw/grass 9. Agricultural crop 10. Animal dung 11. No food cooked in house	
413.	Is the cooking usually done in the house, in a separate building, or outdoors?	1. In the house 2. In separate building 3. Outdoors 4. Other	
414.	Do you have a separate room which is used as a kitchen?	1. Yes 2. No	
415.	Who is the owner of the house?	1. Me 2. Rental 3. Family 4. Relative 5. Others (specify)_____	
416.	How many rooms in this household are used for sleeping?	-----Rooms	
417.	Main material of the roof of the house?	1. Natural roofing (no roof, mud, and sod) 2. Rudimentary roofing (rustic mat/plastic sheet, reed/bamboo, wood planks, and cardboard) 3. Finished roofing (metal/corrugated iron, wood, calamine/cement, ceramic tiles, roofing shingles)	
418.	Main material of the floor of the house?	1. Natural floor (Earth/sand, dung)	

		2. Rudimentary floor (wood planks, and palm/bamboo) 3. Finished floor (parquet or polished wood, vinyl or asphalt strips/ plastic tiles, cement, ceramic tiles, carpet)																																		
419.	Does this household own any livestock, herds, other farm animals, or poultry?	0. No 1. Yes																																		
420.	How many of the following animals does this household own? IF NONE, RECORD '00'. IF 95 OR MORE, RECORD '95'. IF UNKNOWN, RECORD '98'.	1. Cows bulls _____ 2. Other cattle _____ 3. Horses/Donkeys/Mules _____ 4. Camels _____ 5. Goats _____ 6. Sheep _____ 7. Chickens/poultry _____ 8. Beehives _____																																		
421.	Do you have separate rooms for cattle?	1. Yes 2. No																																		
422.	Does any member of this household own any agricultural land?	0. No ----- 1. Yes	4.24																																	
423.	How many hectares of agricultural land do members of this household own?	_____ hectares																																		
424.	Which of the following does your household have? (Multiple answers possible)	<table border="1"> <thead> <tr> <th></th> <th>Yes (1)</th> <th>No (0)</th> </tr> </thead> <tbody> <tr> <td>1. Electricity-----</td> <td></td> <td></td> </tr> <tr> <td>2. Radio-----</td> <td></td> <td></td> </tr> <tr> <td>3. Television -----</td> <td></td> <td></td> </tr> <tr> <td>4. Non-mobile telephone-----</td> <td></td> <td></td> </tr> <tr> <td>5. Computer -----</td> <td></td> <td></td> </tr> <tr> <td>6. Refrigerator -----</td> <td></td> <td></td> </tr> <tr> <td>7. Table-----</td> <td></td> <td></td> </tr> <tr> <td>8. Chair -----</td> <td></td> <td></td> </tr> <tr> <td>9. Bed with spring matters---</td> <td></td> <td></td> </tr> <tr> <td>10. Electric mitad -----</td> <td></td> <td></td> </tr> </tbody> </table>		Yes (1)	No (0)	1. Electricity-----			2. Radio-----			3. Television -----			4. Non-mobile telephone-----			5. Computer -----			6. Refrigerator -----			7. Table-----			8. Chair -----			9. Bed with spring matters---			10. Electric mitad -----			
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7. Table-----																																				
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9. Bed with spring matters---																																				
10. Electric mitad -----																																				

		11. Kerosene lamp/pressure-- ---- 12. Lamp-----			
425.	Does any member of this household own:		Yes (1)	No(0)	
		1. Watch ----- 2. Mobile phone----- 3. Bicycle----- 4. Motorcycle/scooter- 5. Animal-drawn cart- 6. Car/truck ----- 7. Boat with motor----- 8. Baggage -----			
426.	Does any member of this household have a bank account?	0. No 1. Yes			
427.	Does any member of this household have a micro finance account?	0. No 1. Yes			
428.	How often does anyone smoke inside your house? Would you say daily, weekly, monthly, less often than once a month, or never?	1. Daily 2. Weekly 3. Monthly 4. Less often than once a month 5. Never			

PART-V: POP-SS

Direction

The following seven questionnaires are standard tools used to measure prolapse symptoms. Each item/question has 0 to 4 possible response scales. Inform the participant how to give a rate for each item based on how often she felt the prolapse symptom in the last four weeks (Put 'X' in the right box under each response scale).

Dear participant, please tell me how often did you feel the following POP symptoms in the last four weeks? (Please give the rating scale as follows: 0= never felt symptom in the last four weeks, 1= occasionally, 2= sometimes, 3= most of the time and 4= all of the time)

S.no	POP-Symptoms	0 never felt symptom in the last four weeks	1 occasionally	2 some times	3 most of the time	4 all of the time
501.	A feeling of something coming down from or in your vagina?					
502.	An uncomfortable feeling or pain in your vagina which is worse when standing?					
503.	A heaviness or dragging feeling in your lower abdomen/tummy?					
504.	A heaviness or dragging feeling in your lower back?					
505.	A need to strain (push) to empty your bladder?					
506.	A feeling that your bladder has not emptied completely?					
507.	A feeling that your bowel has not emptied completely?					

508.	Which of the symptoms above (questions 1–7) causes you most bother?	
509.	For how long have you felt one of the most chronic symptoms?	
Patient Global Impression of Change questionnaire Ask the following questions only at end-line assessment (after intervention). Both the control and interventional group participants will be asked at the end of six months.		
510.	How do you Perceive the change in prolapse since the start of the intervention?	1= Very much improved 2= Much improved 3= Minimally improved 4 = No change 5= Minimally worse 6= Much worse 7= Very much worse

Part-VI: Pelvic Floor Disability Index (PFDI-20)

Instructions: Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder, or pelvic symptoms and, if you do, **how much they bother you**. While answering these questions, please consider your symptoms over the last 3 months.

Pelvic Organ prolapse Distress Inventory 6 (POPDI-6)

S. N o	Do You...	NO	Yes			
		0 not presen t	1 not at all	2 some what	3 moder ately	4 quite a bit
601.	Usually experience pressure in the lower abdomen?					
602.	Usually experience heaviness or dullness in the pelvic area?					
603.	Usually have a bulge or something falling out that you can see or feel in your vaginal area?					
604.	Ever have to push on the vagina or around the rectum to have or complete a bowel movement?					
605.	Usually experience a feeling of incomplete bladder emptying?					
606.	Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?					

Colorectal-Anal distress Inventory 8 (CRAD-8)

	Do You...					
607.	Feel you need to strain too hard to have a bowel movement?					

608.	Feel you have not completely emptied your bowels at the end of a bowel movement?					
609.	Usually lose stool beyond your control if your stool is well-formed?					
610.	Usually lose stool beyond your control if your stool is loose?					
611.	Usually lose gas from the rectum beyond your control?					
612.	Usually have pain when you pass your stool?					
613.	Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?					
614.	Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?					

Urinary distress Inventory 6 (UDI-6)

	<i>Do You...</i>					
615.	Usually experience frequent urination?					
616.	Usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?					
617.	Usually experience urine leakage related to coughing, sneezing, or laughing?					
618.	Usually experience small amounts of urine leakage (that is, drops)?					
619.	Usually experience difficulty emptying your bladder?					
620.	Usually experience pain or discomfort in the lower abdomen or genital region?					

Part-VII: The International Consultation on Incontinence Questionnaire

Instructions:

Many people leak urine some of the time. This study is aimed to find out how many people leak urine and how much this bothers them. Please answer the following question, thinking about how you have been, on average, in the last four weeks.

S.No	Questions	Responses
701.	How often do you leak urine?	0. = never 1. = once a week 2. = 2-3 times a week 3. = once a day 4. = several times a day 5. = all the time
702.	How much urine do you usually leak?	0= none 2 = a small amount 4 = a moderate amount 6 = a large amount
703.	Overall, how much does leaking urine interfere with your everyday life? (give a value between 0 (not at all) and 10 (a great deal))	0 1 2 3 4 5 6 7 8 9 10 (encircle the appropriate number)
704.	When does urine leak? Select all that apply to you	0 = never leak 1 = before getting to the toilet 2 = leaks when coughing or sneezing 3 = leaks when sleeping 4 = leaks when exercising 5 = leaks when finished urinating and dressing 6 = leaks for no reason

		7 = leaks all the time
--	--	------------------------

Part VIII: Obstetric Fistula Screening Tool

Sr. No	Questions	Responses
801.	Have you ever given birth vaginally?	0 = No 1= YES
802.	Have you faced labor that lasted more than one day and night?	0 =No 1= Yes
803.	Do you have continuous leakage of urine?	0 =No 1 =Yes

Part-IX: Pelvic Organ Prolapse Quantification (POP-Q) (to be used by pelvic examiners)

Instructions: Measure the descent of all the nine measurement points in the POP-Q system. Measure all points at a maximum Valsalva, except Total Vaginal Length (TVL) which is measured at rest. Record measurements in centimeters to the nearest 0.5cm. TVL= is measured from Hymenal remnant to point D, Aa is an arbitrary fixed point on the anterior vaginal wall, which is 3cm back from the middle of the external urethral meatus in normal cases. Point Ba is the lowest part of the upper anterior vagina. This point is not a fixed point like Aa. It can be anywhere along the vaginal wall above the first 3cm (Aa). Point Ap and Bp are similar points to Aa and Ba but found on the posterior vaginal wall. GH is measured from external urethral meatus to hymenal remnant, PB from the hymenal remnant to the anal opening, C is the lowest part of cervix and point D is the insertion of uterosacral ligaments to the cervix. Both points are measured relative to the plane of hymenal remnants.

Height: _____ cm

Weight: _____ kg

Abdominal Striae: ☐ yes ☐ No

POP-Q:

Aa =	Ba =	C =
Gh =	Pb =	TVL =
Ap =	Bp =	D =

...

Circumference of prolapse (cm): _____

Standing Cough Stress Test: ☐ positive ☐ negative Volume (mL): _____

PART-X: PROLAPSE RELATED QUALITY OF LIFE (FOR CONFIRMED POP-PATIENTS ONLY)

Instruction: Below are some daily activities affected by prolapse. Please tell me how much your prolapse problem affected you (tick the correct column).

Domain	Items	0 Very good	1 Good	2 Fair	3 Poor	4 Very poor
Present general health (GHP)	How do you describe your health at present					
		0 Not at all	1 Slightly	2 Moderately	3 A lot	
	Prolapse impact on life (PI)					
Role limitations	To what extent does your prolapse affect your household task?					
	Does your prolapse affect your job/daily activity outside the home?					
Physical/social limitations	Does your prolapse affect your physical activities?					
	Does your prolapse affect your ability to travel?					
	Does your prolapse affect your social life?					

	Does your prolapse affect your ability to see/visit friends?					
Personal relationship	Does your prolapse affect your relationship with your partner?					
	Does your prolapse affect your sex life?					
	Does your prolapse affect your family life?					
Emotions	Does your prolapse make you feel depressed?					
	Does your prolapse make you nervous/anxious?					
	Does your prolapse make you feel bad about yourself?					
Sleep/Enrgy	Does your prolapse affect your sleep?					
	Does your prolapse make you tired?					
Actions	Use pad to protect prolapse					
	Do you push up the prolapse					
Severity measures	Pain/discomfort due to the prolapse?					
	Does the prolapse Prevent you from standing?					
Patient Global Impression of Improvement Ask the following questions only for end-line assessment (after intervention). Both the control and interventional group participants will be asked at the end of six months						

Patient Global Impression of Change	How do you feel about your health after this intervention?	1= Very much improved 2= Much improved 3= Minimally improved 4 = No change 5= Minimally worse 6= Much worse 7= Very much worse
--	---	--

Thank you for your participation

ANNEX-III: Sidaamu Afoo Version Questionnaire

QA'MISO I: MASHALAQQETE QOOLA

HAWAASI YUNIVERSITE

HIKKIMINNUNNA FAYYIMMATE SAYINSE KOLLEEJE

Dagoomu Fayyimmate Rosi Mine

Xiinxallote Umo: Otootto Gobba Higge Fultino Amuwi Mitiimma Sidaamu Dagoomu Qoqqowi Mootimma, Itophiya, 2014 M.D

Xiinxallote Anni: Melese Siyumihho

AYIIDDE KEEREHO!! Su'ma'ya _____ yinannie; ani xiinxallote taje gamba asseemmohu Kalaa Melese Siyumihu qara xiinxallote aana ikkana, iso riqiwe shiqoommo. Atera kaayyo iilliteennae atewa shiqoommo. Xiinxallote umi otootto gobba higge fultino amuwi aana xiinxallinanni. Doorroonnihehuno kaayyoteeti.

Xiinxallote Goofimarchu Mixonke

Xiinxallo illachishshannohuno: Amuwaho otootto gobba higge fultanno gede assannorichi maatiro bade afatenna noo mitiimma tirranni gedeeti, Sidaamu qoqqowi mootimmaraati. Ledoteno, ottootto gobba higge fultino amuwi sumuu yiha ikkiro, woyyaabbino hospitaalla sonkanni hattono qarra anfe agadhinanni gedeeti.

Xiinxallote Amuraati: Borri-xa'motenninna Fayyimmate ogeessinniiti mixote garinni hattono qara badateeti. Borri-xa'mote dawarokki borresseemmo. Tenne borri-xa'mo dawarate 40-50 xiqqeessaati. Tini borri-xa'mo amaddinohu ayimma, akata, miinja hattono ilate gadenna hattonno sirote bisi kifilla gobba higge fulturo leeltanno malaatta heeshshote aana abbitanno mitiimmaati. Goofimarchohono, dinye uyneennahe qajeeltino ogeeyyenni buuxo assinannihe mulekki no fayyimmate uurrinshara. Buuxote yannara mitiimma nooha ikkiro, lame gaamora beenkanni xaginsanni baycho keeshshatta. Tenne gaamora 5(onte) hinga buuxisiisi'nanni kaimunni (lamalate

(0) layinki lamalanni leyikkitera(6) tonnikkitera(10) tonaa-ontikki lamalara(15), hodhishshu baatooshshe xiinxallasine baattanno.

Xiinxallote Horo

Xiinxallo amuwaho uytanno horo umikkihunni otooito gobba higge fultino amuwira baatooshshiweelo fayyimmate ogeeyyenni bunxanni. Ledoteno, hodhishshahono hatto yannakkira xiinxallote gaamonni baantannihe.

Xiinxallote Beeqqo Lainohunni Baatooshshu Dino

Xiinxallo abbitanno qarra lainohunni: onte (5) hinge buuxote ha'rate gobbaanni mittu qarri illishannohu dino. Ledoteno, buuxo assinanni yannara teeda diwa hoogatenni injo macciishshama hoogate gobbaanni mittu qarri dino. Baxxitino kifilera teeda lowo geeshsha daheessine buuxo assinannita duu'ne kulleemmo; hattono fojo wolu mannira mittoreno dikullanni!

Fojo Lainohunni

Wo'manti taje kulattaeti, lowo geeshsha fojo wolu mannira dikuleemmo. Qole ate su'ma horontanni diborreeseemmo. Horontanni dawarootta dawaro ayeno diafanno.

Xiinxallote Beeqqo Assattohu Sumuu Yiittaronna Mereeroho Xa'mo Xa'me Gudummokkino Agurate Qoossokki Agarantinote!

Xiinxallote beeqqo assa hoogakki mittoreno amuwu afi'ranno owaante hooltanno hetano di'ikitino/mereeroho dawarte gudittakinni agurte ha'ra dandaatta.

Xa'mo heedhuhero woy xawinnohekkiri nooro, Melese Siyyumiho. Hawaasi yuniversitera loosaasincho xa tenne yannara xiinxallote aana xa'ma dandiitinanni

Bilbilu Kiirosi: 0912780577

Mashalaqqete Qoola

**Xinxxaloote horonna fojjo hitoonni agaraniro lowo geeshsha xawinsoonie dafira nna
hattonno wodanchoomma .konni dafira ane summudinni sumuu yooma gede
malaatiseemma!**

Sumuu Yaattae Ballo!

Dawaraancho/beeqaanchu:

Malaate..... Barra.....

Taje gamba assanohu:

Malaate..... Barra.....

QA'MISO II: SIDAAMU AFII GAANO

HAWAASI YUNIVERISITE HIKKIMINNUNNA FAYYIMMATE KOLEEJE

Dagoomu Fayyimmate Rosi Mine

Gafa Mite: Dawaraanchote Dagoomittete Haja Xa'mi'nanni Borri-xa'mo

Worada_____ Ollaa_____ Dargu Kiirro_____ Koodde_____

Mobayle_____

A.K.	Xa'mo	Dawaro	Sai
101.	Dirikki me''eho ?	_____wo'mu dirinni wori	
102.	Teessokki hiikkooti?	1. Quchumaho 2. Baadiyye	
103.	Adhammete Gara	1. Leexa 2. Adhantinota 3. shiidhinota 4. tidhantinota 5. baxxitinote	
104.	Ammanokki hiitteeti? (dawarokki qoqqowi?)	1. Ortodokise 2. Pirotestaante 3. Musiliime 4. Kaatolike 5. Wole xawisi_____	
105.	Loosu Qeecha?	1.. Minaama (mini ama) 2. Baatto loossi're galinoha 3 Mootimmate Loosaasincho 4 Mootimmannita ikkitinokki uurinshara	

		5 Halanyaho 6 Rosaanchoho 7 Wole xawisi_____	
106.	Hiikko ayiddeeti?/ Hiitte gosaati?	1. Sidaama 2. Wolayitta 3. Amaara 4. Guraage 5. Oromo 6. Wole xawisi_____	
107.	Rosikki deerri hiikkonneeti??	1. Nabbawanna borreessa didandeemma 2. Nabbawanna borreessa calla dandeemma 3. Umi dirimi rosaanchooti 4. 2 ^{ki} dirimi rosaanchooti 5. 2 ^{ki} dirimi aleenni rosinote	
108.	Gashshaniki rosi deerri hikkonneeti? Adhantinota ikkituro,(xa'mo 103 buuxxi)	1. Nabbawanna borreessa didandaanno 2. Nabbawanna borreessa calla dandaanno 3. Umi dirimi rosaanchooti 4. 2 ^{ki} dirimi rosaanchooti 5. 2 ^{ki} dirimi aleenni rosinoho	
Gaamo-II: Heeshshote Gade Xa'minanni Borri-xa'mo Konni woroonni noo borri-xa'mo , xa'mitto/a gedensaanni taaltino dawaro qoqqowi			
201.	Mereerimunni, ayyirrinore me'e saate bayiratta barrunni (waa, lowo qaqqo , haqqe, kinchonna gide	----- sate	
202.	Sigaara wiliishshite egennootta?	0. Dee'ni 1. Ee	

203.	Maatekki giddo otoottote ayyara gobbara higge fultinohu no ?	0. Dee'ni 1. Ee	
204.	Keeshshitino busano buuse egennota sase lamallara aleenni ?	0. Dee'ni 1. Ee	
205.	Jawa shumara ofolata woyte Fula giwanohenni? (fulate qarrissanno)	0. Dee'ni 1. Ee	
206.	Mundeekki giddo sukkaare noohero buuxi'rootta?	0. Dee'ni 1. Ee	

**Gaamo III: Amuwu Ilaranna Otoottote Fayyimma Ledo Xaadinohunni Xa'minanni Borri-
xa'mo**

A.k.	Xa'muuwa	Dawaaro	Sa'i
301.	Umikki yannara mine assi'roottahu meyikki dirikkiraati?	----- dirooti	
302.	Lamala agana ikkinokkiha, umo ka'e egennootanni?	0. Dee'ni 1. Ee	
303.	Lamalu aganni gedensanni ilite eggenotanni?	0. Dee'ni _____ 1. Ee	sa'i 312
304.	Xa'mo303, ee. ikkiro umo ilitta woyite meyikki deerikkiraati?	----- dirooti 999..... diafoomma	
305.	Me''e qaaquulle ilitta?	_____hige iloomma	
306.	Gedeniidi qaaqqo ilitta yannara meyikki dirikkiraati?	----- dirooti	
307.	Hitoonni ilte egennootta?	1. Qarru noyikkiha iloomma 2. Godowa dadhatenni	

	(Mittu aleenni doora dandiinanni)	3. Udiinnichu kaa'lonni iloomma	
308.	Mitto barra sae/(24) saate sae gamaa'mite egennoottanni?	0. Dee'ni 1. Ee	
309.	Sa'u yanna giddo mine ilte egennoottanni?	0. Dee'ni 1. Ee	
310.	Gedensiidikki qaaqqo hiikko ilootta?	1. Mine 2. fayyimmate uurinshara.	
311.	Gedensiidi qaaqqo ilittahu gedensaanni, meykkita mini looso loosa hanafootta?	----- barrinni lamalate gedensaanni	
312.	Godowa dadhite egennoottanni? (qaaqqu fula giweennae shiima darga darroonnie, otoottote darroonnie ,danotenni darroonnie, godowi giddo darshinore holaara darroonnie)	0. Dee'ni 1. Ee	
313.	Aganu mundeekki horontanni uurritinoni? (sas aganni aleenni)? Maatete damboowishsha horoonsi'rittakkinni	0. Dee'ni 1. Ee	
314.	Xa'mo 313, 'ee' yiittaro, mageeshshi yanna?	-----	

Gaamo -IV: Jajju woy Jirote Amadooshshe

Konni worooninoo xa'mubba xa'mateni (dandaamiro la'atenni) gara ikkitino dawaro dooni.

401.	Maatekki agganno waa afidhannohu hiikkiinniiti?	Baambu waa : 1. Mini giddo baambu waa 2. Hoowete afamanno baambu waa 3. Dagoomu tuqi horoonsi'ranno baambu waa	
------	---	---	--

		4. Umme fushshinoonni waa	
		Agarooshshe: 1. Garunni agaraminoha 2. Garunni agaraminokkiha	
		Buete waa: 1. Garunni agarroonnita 2. Garunni agarroonnikkita	
		Daadanno Waa: 1.Lagu/garbu/kofaminoha/xashshuwa/ waa	
402.	Maatekki sagale loosi'ratenna anga hayishshi'rate horoonsidhanno waa maminni afidhanno?	Baambu waa: 1. Mini giddo baambu waa 2. Hoowete afamanno baambu waa 3. Dagoomu tuqi horoonsi'ranno baambu waa 4. Umme fushshinoonni waa	
		Agarooshshe: 1. Garunni agaraminoha 2. Garunni agaraminokkiha	
		Buete waa: 1. Garunni agarroonnita 2. Garunni agarroonnikkita	
		Daadanno Waa: 2. 1.Lagu/garbu/kofaminoha/xashshu/ waa	

403.	Way afamanno dargi hiikkooti?	1. Meessi mini giddo 2.Meessi hoowe giddo 3. Wolu darginni	
404.	Waa dirri'ne hinganni yanna mageeshsha adhanno ?	1. Daqiiqa/xu'eessa _____ 2. Dibuu xoommo/a	
405.	Sa'uta lame lamala giddo way bae barra wo'ma keeshshino?	0. Dee'ni 1. Eewa 2. Diqaagamannoe	
406.	Way co'ichimma agarsiisate atewayinni agarrannire assoottori/tari no yite hedatta/o?	0. Dee'ni ----- 1. Eewa	4.8
407.	Anganni way co'ichimma agara maa assa noohe? Wo'manta hedo maareekki	1. Gafe agatenni 2. Xagga woratenni 3. Hocootunni ximbiiwaetnni 4. Waa ximbiimbanni meemonni (shaafa/shiimmaadda lubbuwa/etc.) 5. Arrishshote xawaabbinni xagisatenni 6. Mittowa kofatenni/ kuusatenni	
408.	Maatekki duucha yannara hiittooha shumate mine horoonsidhanno?	WAYINNI XAADINSOONNITA/ XAADINSOONNIKKITA 1. Baamba fanne horoonsi'nannita 2. Baambaho xaaddino way maashine 3. Ummooni balera waa horoonsi'ra 4. Base baalate waa horoonsi'ratenni 5. Shumate mini waa hiissine horoonsi'nanniro diafoommo/a?	

		BALE UMME QIXXEESSINOONNI SHUMATE MINE 1. Ayyare e'anno shumate mine 2. Bale umme suudinsoonni kinchinni 3. Bale umme afoo tu'noonnikkita 4. Mu'roote horonsi'nanni shumate mine. 5. Waa baaldete worreenna 6. Gottiima shumate mine 7. Injiinowi dino/dubbu giddo/xawoho	
409.	Tenne owaante woloota maate ledo horoonsidhinanni?	0. Dee'ni 1. Eewa	
410.	Ate maate ledo mageeshshi mannaati konne shumate mine horoonsidhinannihu?	1. 10 nni ajanno 2. 10 woy hakkuy ali 3. Afoommori/mari dino	
411.	Hakku shumate mini afmannohu hiikkooti?	1. Mini giddo 2. Meessi hoowe giddo 3. Wole dargaati	
412.	Maatekki sagale loosi'rate hiittee gaaze horoonsidhanno?	1. Korreentete wolqa 2. Du'nantanno gaaze 3. Kalaqamu gaaze 4. Addi addi keemikaalla 5. Laamba 6. Qitiissinoonni haqqe (kasale) 7. Haqqe 8. Kashee/hayissotenni 9. Gidu damatenni 10. Saadate obbinni	

		11. Sagale diloosi'neemmo	
413.	Sagale loosi'nannihu gallaniwaati, baxxitino kifileeti/ mini gobbaanniti?	1. Mini giddooti 2. Baxxino mineeti 3. Barandahooti 4. Wolewaati	
414.	Sagale loosi'rate horoonsidhinanni baxxino mini noo'ne?	0. Dinonke 1. Eewa	
415.	Minu galtinannihu ayeho?	1. Ko meessiho 2. Baante gallanniho 3. Fiixunniho 4. Elunniho 5. Wole hee'riro xawisi_____	
416.	Konni mini giddo gonxanni kifilla me''e no?	-----Kifilla no	
417.	Minu giddoydo iimiidi raga(korniise) mayinni biifinsoonniho?	1. Kalaqamu haqqinni (biinfori dino, sabbunni, nna kandoonni sabbinni) 2. Calla anfi gede assinnooniha (xu'minsoonnikki saattinni/plastic shara,	

		shomboqqotenni/leemmichunni, haqqu xaawulinni, and komborsaatunni) 3. Xu'minsoonnikorniise (siwiilunni/culku siwiilinni, haqqunni,alumineemetnni/simintotenni	
418.	Mini uulliidi loosaminohu mayinniiti?	1. Kalaqamunni noo gedeenni nooho (baatto/ bushshaho) 2. Safo tunge doogo hunnoonniho (haqqu xaawula, nna shomboqqotenni/ leemmichunni) 3. Xu'minsoonni mine (shakilunni) (haqqu xaawulinni xu'minsoonniha, uullano iimano shakila, simintotenni, alumineemetenni, uulla karranni shara(minxaafe)	
419.	Minu anni / ati saadate hoshsho, baatto hawuurranni saadanna lukkuwa ceo noosiho?	0. Dee'ni 1. Eewa	
420.	Aliidi saada giddonni minu annihi mageeshshaati? Mitturi nokki ikkiro(00) wori. 95 tu woroonna aleenni ikkiro (95) wori. Kiirro anfonikkiha ikkiro(98) wori	1. Saadanna bootta_____ 2. Wole saada_____ 3. Farado/harre/gaangootta ____ 4. Gaala_____ 5. Me''e _____ 6. Ge'reewo _____ 7. Caacurre/ lukkuwa _____ 8. Diishshote koshsha	

421.	Saada galtannowi baxxino dargi noo'ne?	0. Dee'ni 1. Eewa			
422.	Maate'ne giddo loosi'nanni baatto afi'nohu no?	0. Dee'ni ----- 1. Eewa		4.24	
423.	Minu annira me''e hekitaare ikkitannoti loossi'nanni baatto noosi?	_____Hekitaare			
424.	Konni worooni noori giddo mini'ne giddo afamanohu hiiko neeti? (mittete aleeni doora dandiinanni)	Eewa(1) 1. Korreente----- 2. Raadoone ----- 3. Telewishiine ----- 4. Mine silke----- 5. Kompiitere ----- 6. Mitore qiissanno udiinnichi --- 7. Xarapheezzu ----- 8. Barcimu ----- 9. Shiwote daallasi---- 10. Korreentete wolqanni sagale raisi'nanni mixashsho ----- 11. Laambunni/shaamu/ ----- 12. Faanoose-----		Dino (0)	
425.	Maatekki giddo togoo udiinni no:		Ee (1)	Dino (0)	

		1. Tolobishiine ----- 2. Bilbilu----- 3. Shalleette----- 4. Xexxerrisu----- 5. Saadate gaare- 6. Kaameelu/ hogowi kaameeli ----- 7. Yowolo motor nooti----- 8. Sasu goommi baajaaje ----- -----			
426.	Maatekkira baankete akkowaante kiir noonsa?	0. Dinonsa 1. Eewa			
427.	Maatekki giddo shiimmaadda daddalu uurinsha akkowaante kiir noonsa?	0. Dee'ni 1. Eewa			
428.	Maate'ne giddo sigaara wiliishshaahu barrunni me''e higeeti? Barrunni/lamalatenni/ aganunni/ dirunni / takkonta?	1. Barrunni 2. Lamalatenni 3. Aganunni 4. Aganunni mitteege 5. Takkonta			

Gaamo-V: Otootto Gobbara Higge Fulturo Leellanno Malaatta Buunxanni Borri-Xa'mo

Hajajo: Konni woroonni shiqqino lamala borri-xa'mo illachishshannohu otootto gobbara higge fultino amuwira xa'minanninna bikkinanni xa'muuwaati. Doorshu noohu (0) kayse 4 geeshshaati. Muxxe tenne xiinxallo beeqqaancho, sa'u shoole lamallara me''e higge malaatu macciishshamihero ballo eeggatena kulie? (keennanni gari : 0= horontanni dileellinoe malaatu sa'u shoole lamallara,, 1= keeshshe, 2= sae sae 3=roore yannanna 4= wo'ma woyte)

A.k	Leeltanno malaatta	0 Horon tanni dileell anno	1 Keesh she keeshs he	2 Sae sae	3 Roore yanna	4 Wo'm a yanna
511.	Ikkinorichi otoottote widoonni higge daynoha lawe macciishshaminoheni?					
512.	Otootto xissitannohenni roorenkanni uurrutta yannara ?					
513.	Mudukku woroonni ayirrannoherichi macciishshamannoheni?					
514.	Hallikkira wori adda duunaminori woy ayirrinori macciishshame egenninoheni?					
515.	Way shuma daggukkinni niixissannoheni?					

516.	Way shuma gooffinokkiha lawe macciishshamannoheni?					
517.	Jawiidi shuma gooffinokkiha lawe macciishshamannoheni?					
518.	Aleenni xawinsiri giddo roorenkanni mittinsino qarri hiikkonneeti? (xa'mo 1–7) geeshsha					
519.	Mageshshi yanna mittu malaati macciishshamihe roorenkanni seeda yannara?					
Kalqete Dhiwamaasinetenni Afi'nanni Babbaxxitino Borri-Xa'mo Konni woroonni no borri-xa'mo xa'minannihu goofimarchohooti. Xa'minannihu dhibbu malaati nooriranna nookkihuraati. Xa'minanni yanna lewu(6) agani gedensaanniiti						
520.	Xagisi'ra hanafittankunni may soorro leeltinoha lawannohe?	1= lowo geeshsha huroomma 2= woyyate 3= dhibbu ajanni ha'rinoe 4 = mitte soorro dino 5= shiima geeshsha xissanni nooe 6= xissanni nooe 7= lowo geeshsha xissanni nooe				

Gaamo-VI: mudukkunna sirote bisi qarqari bisu xe'ne daafira xa'manni borri-xa'mo (PFDI-20)

Hajajo: Konni woroonni noo xa'mora dawaro dawari; ha'runsote/buuxote xa'mo gedensaanni. Xa'minannihu helleete ,ufuuffaate, sirote bisi qarqari malaattanna mageeshshi geeshshi mittimmansa, buunxanni borri-xa'mo. Dawarratta woyte sasu(3) agani aleenni ikkinoheri qaagi!. **0 = dino malaatu, 1= wo'manka woyte dikkino, 2=shiima yanna 3 =mereerimunni nna 4 = horontanni shiima yanna**

Mudukkunna sirote bisi qarqari bisu xe'ne daafira xa'minanni borri-xa'mo (PFDI-20)

A. K		Dee'ni	Ee			
		0 dino malaatu	1 wo'manka woyte dikkino	2 shiima a woyte	3 mereerimunni	4 horontanni shish woyte
621.	Godowikkira woriidi qarqarira woroo qole xiwannori hee'ranno?					
622.	Siimu qarqarira ayirre macciishshame egenninohe?					
623.	Otoottote widoonni ikkinorichi fulanni nooha lawannohe gede ikkannohe?					
624.	Otoote woy jawa shuma fultanno qoxxeessa xiwannori no gede macciishshamannohe?					

625.	Way shuma gooffinokkiha lawe macciishshamannohe?					
626.	Shumaa'ratta yannara xiwannoheri nooha lawannohe otoottokkira/qubbichikinni kisse egennoottanni?					

Helleetenna Xuuxxote Xiwani Daafira Xa'minanni Borri-Xa'mo (CRAD-8)

627.	Jawa shumara ofolatta woyte niixisannoheni?					
628.	Jawa shumara ofolte ka'eennano gooffinokkiha lawe macciishshamannoheni?					
629.	Jawa shuma ate hajajo gobbaanni fultannoheni?					
630.	Deeo ikkiro, ate hajajo gobbaanni fulannohe?					
631.	Fooleessu /fuuto ate hajajo gobbaanni fultannoheni?					
632.	Jawa shumara ofollatta woyte xissannoheni?					
633.	Jawa shuma mudditannoheni lowo geeshsha ?					
634.	Hellee gobbara higge fultannoheni deeu gedensaanni?					

Way Shuma Mitiimma Daafira(UDI-6)

635.	Wayi shuma shumaa'ratta yannara macciishshamannoheri nooni?					
636.	Shuma ciphi-ciphi yitannohe muddite?					

637.	Shuma cippi-cippi yitanno, buusatta, hanxishshi'rattanna woy oso'litanna?					
638.	Shiima shuma cippi-cippi yitanno)?					
639.	Way shuma shumaadhe kaittarono gooffinokkiti macciishshantannohe?					
640.	Mudukku woridinna siimu qarqarira fayyimma dimacciishshantannohe?					

Gaamo-VII: Kalqete Shuma Cippi Yitanno Gara Xiinxallinanni Gade Borri-xa'mo

Hajajo:

Lowo manni way shuma cippi-cippi assanno. Tenne xiinxallo umi mageeshshi manni shumansa cippi- cippi assannonna mittii'manno yaateeti. Ballo, sa'u shoole lamallara me''e hige cippi - cippi assittaro hedi mereerimunni?

A.K	Xa'mo	Dawaro
705.	Me''e higge way shuma cippi yaatta?	6. =horontanni 7. = mitte hige lamalate gido. 8. = 2-3 geeshsha mitte lamela gido. 9. = mitte hige barrunni. 10. = Duucha hige mittu barri giddo 11. =wo'ma woyte.
706.	Mageeshshi shuma cippi assatta?	0 = horontanni 2 = shiima 4 = Mereerima. 6 = lowota

707.	Xaphoomunni, mageeshshi shuma barrunni cipi assatta? (0 nna 10 mereero qoqqowi)	0 1 2 3 4 5 6 7 8 9 10 (taltino dawaaro qoqqowi.)
708.	Mamoote way shuma cipi yitannohehu? (taltino dawaaro dori)	0 =horontanni diyitanno 1 = shumate minira ha'rammara albaanni. 2=buuseemma/hanxishshi'reemma yannara 3 = goxe he'reenna. 4 = looso looseemma woyte. 5 Shumaa're kaeemma woytenna uddi're kaeemma woyte 6 =Korkaatiweello. 7 = Wo'ma woyte.

GaamoVIII: Fesitullu Qarri Noo Amuwira Xa'minanni Borri Xa'mo

A.K	Xa'mo	Dawaro
109	Keeraancho ila ilte egennootta?	0 = Dee'ni 1= Ee
110	Mitto barranna hashsha sa'e gama'mite egennootanni?	0 =Dee'ni 1= Ee
111	Duucha woyte cipi yitannohenni?	0 =Dee'ni 1 =Ee

Gafa-IX: Otootto Gobba Higge Fultinotta Bikkinanni Gade (POP-Q) (horoonsi'nannihu hikkimannaahooti)

Hajajo::Honsu gari bikkote gade noose (POP-Q). mannimmate guunte/biso milli assinanni loossinsanni bikkinanni. Bikkinannihu seentimetiretanniiti

Hojja: _____ cm

Qelpheepho/ayirrinye: _____ kg

Godowaho malaatu leella: ☐ Ee ☐ Dee'ni

POP-Q:

Aa =	Ba =	C =
Gh =	Pb =	TVL =
Ap =	Bp =	D =

Otoottote doycho sentimetirenni wori! _____

Uurrite bussanni hedhenanni bikkinonni bikko: ☐ nose ☐ dinose

qelpheepho(mL): _____

**Gafa-X: Otootto Gobbara Futuro Hiittoo Heshshote Gade Nooro Bunxanni Borri- Xa'mo
(Otootto Gobbara Fultino Amuwira Calla)**

Hajajo: Konni woroonni noo malaati leellannohu otootto gobbara higge fultino amuwira
leellanno malaateeti. Taaltino dawarora malaatisi.

Ama do	Xa'muwa	0 Lowo geeshsha danchaho	1 dancha ho	2 duushs hanno	3 diduu shsha nno	4 lowo geeshsha didushsh anno
XAPHOOMU FAYYIMMA(G)	Fayyimmakki hiittoonni xawisatta?					
		0 wo'ma woyte dikkino	1 shiima yanna	2 mereer imunni	3 lowo	

					geesh sha	
	Otootto gobbara higge fulate mitiimma heeshshokkira.					
MINI LOOSO LOOSA HOOGA	Otootto gobba higge fultinohe dafira, mini loosi hittoo mitiimma abbinohe?					
	Otootto gobba higge fula ,mini gobbayidi loosikkira mitiimma abbinohe?					
Mannu noowa ha'ra hoogate qarra	Otootto gobba higge fulte milli yaattata mitiinsinoheni?					
	Otootto gobbara higge fultannohe baychunni baycho hodhate mitii'mitanni?					
	Otootto gobba higge fultino daafira,dagoomu ledó xaadate mitii'mitta?					
	Otootto gobba higge fultinohe daafira miillaki ledó xaadate mitii'mitta?					
Mannu ledó gade ledó	Otootto gobba higge fultinohe daafira,maatekkira mitiimma abbinoheni?					
	Otootto gobba higge fultino daafira siimu xaadooshshira mitiimma abbinohe?					

	Otootto gobba higge fultino daafira,maatekkira mitiimma abbinohe?				
Akata	Otootto gobba higge fultino daafira,dadillu macciishshamannoheni?				
	Otootto gobbara higge fultino daafira caaccawaatani?				
	Otootto gobba higge fultino daafira ate bunshe macciishshantannoheni?				
Goxichu/wolqa	Otootto gobba higge fultino daafira goxatta woyte mitii'mitta?				
	Otootto gobba higge fultinohe daafira bunshe calla macciishshantannohe?				
Marichi qaafo	Hocoota/pade horonsiraata.				
	Otootto gobba higge fultanno yannara xiibbe egennootta?				
	Otootto gobba higge fultino daafira xisso/injaa hooga maciishshantanoheni?				
	Otootto gobba higge fultinohe daafira uurrate mitii'mattani?				

Kalqete Dhiwamaasinetenni Afi'nanni Babbaxxitino Borri-Xa'mo

Konni woroonni no borri-xa'mo xa'minannihu goofimarchohooti. Xa'minannihu dhibbu malaati nooriranna nookkihuraati. Xa'minanni yanna lewu(6) agani gedensaanniiti

Kalqete Dhiwamaasinetenni Afi'nanni Babbaxxitino Borri-Xa'mo	Mamoote way shuma cipi yitannohehu? (taltino dawaaro dori)	1= lowo geeshsha huroomma 2= woyyate 3= dhibbu ajanni ha'rinoe 4 = mitte soorro dino 5= shiima geeshsha xissanni nooe 6= xissanni nooe 7= lowo geeshsha xissanni nooe	
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ANNEX-IV: Lifestyle Counselling and Pelvic Floor Muscle Training Protocol

What is a pelvic organ prolapse and what are the symptoms?

Pelvic organ prolapse, often known as 'prolapse,' is a vaginal alteration in which a pelvic organ, such as the bladder, bowel, rectum, or uterus, slips downwards in the vagina, creating the sensation of "something coming down" or "vaginal heaviness." The protrusion might be felt on either the inside or outside of the vaginal wall. Bladder, bowel, and sexual issues can all be caused by prolapse. The pelvic organs - the bladder, vagina, uterus, and rectum - are held and maintained inside the bony pelvis by ligaments and muscles, which are collectively known as the "pelvic floor."

To prevent incontinence, the pelvic floor muscles support the pelvic organs and manage the bladder and bowel. The pelvic organs can bulge into the vagina, forcing the vaginal walls to slip downwards, resulting in a prolapse, if either the pelvic floor muscles or the supporting structures fail. A prolapse might be minor, providing little or no discomfort, or severe, causing several issues and negatively impacting your quality of life. Whether the downward bulge is felt or visible within the vagina or can be felt or seen outside the vaginal entrance may affect how much the prolapse interferes with your life. Prolapse might vary from day to day and even within a single day. On some days, you may be completely unaware of your symptoms, while on others, you may be acutely conscious of them; it may be alright in the morning but very uncomfortable later in the day. The sensation of 'something coming down' or of vaginal heaviness/bulge is the most typical symptom. Other common bladder and bowel symptoms can be caused by a prolapse, but they may also be unrelated.

What causes pelvic organ prolapse?

Prolapse is caused by a number of events that disrupt the vaginal support system. The factors linked to pelvic organ prolapse are mentioned below, along with a brief explanation of why they are linked.

Pregnancy and childbirth:

This is the leading cause of pelvic organ prolapse, particularly following a vaginal delivery. As the baby grows, it exerts pressure on the pelvic organs and pelvic floor muscles. Additionally,

hormonal changes during pregnancy cause the supporting ligaments to relax in preparation for childbirth. Procedures such as episiotomies, vaginal tears, or forceps-assisted deliveries can compromise the pelvic support system, potentially leading to complications during delivery or later in life. Engaging in pelvic floor muscle exercises during pregnancy can help maintain the strength of these muscles.

Obesity and Overweight: Excess body weight increases the pressure on pelvic organs and the pelvic floor. Significant weight gain can further strain the supporting structures, heightening the risk of prolapse.

Heavy Lifting: Engaging in heavy lifting or frequent bending as part of your daily routine can elevate abdominal pressure downwards, which may increase the likelihood of prolapse, particularly if the pelvic floor supports are already compromised.

Family history: A strong family history of pelvic organ prolapse, such as your mother or sister, may enhance your chances of developing a prolapse. This is assumed to be owing to a weak collagen type.

Age: As you get older, you're more likely to get a prolapse. Muscle strength may deteriorate as a result of aging, along with other changes.

Menopausal changes: As your levels of vaginal estrogen drop, some of the hormonal change that accompany menopause might exacerbate prolapse symptoms. The reduced amount of vaginal estrogen after menopause may impact prolapse symptoms.

Constipation: constipation and straining to empty your bowels might increase the risk of prolapse or worsen the existing prolapse. Increased intra-abdominal pressure is directed down onto the pelvic floor, causing strain and tension.

Chronic cough: If you have asthma or other illnesses that cause you to cough frequently, you may be at risk for a prolapse. This is caused by the pelvic floor being strained by recurrent increases in intra-abdominal pressure.

Previous pelvic surgery: If you've already had a prolapse repair or a hysterectomy, your chance of getting another prolapse are higher.

What can you do to help a pelvic organ prolapse?

Pelvic organ prolapse is not a life-threatening disorder, and not all prolapses deteriorate; in fact, some may improve. If you have been told you have a pelvic organ prolapse, you might want to consider the following options:

- Do nothing and wait for your symptoms to improve.
- Develop healthy bladder and bowel habits
- Change your lifestyle to lessen downward pressures in your pelvis, especially if any of your current activities aggravate your symptoms, such as weight reduction or avoiding or reducing the amount of lifting you do.
- Increase the vaginal support by strengthening your pelvic floor muscles.
- Consult a gynecologist about surgery as a possibility (or choice).

If your prolapse is not bothersome, you may decide to do nothing. However, research suggests that completing pelvic floor muscle exercises and following the recommendations below can help prevent your prolapse from worsening.

Bowels

- It's critical to avoid constipation since it puts additional strain on the pelvic floor muscles, which can exacerbate prolapse symptoms.
- Eating a healthy diet rich in fruits, vegetables, and fiber can assist.
- Make sure you're getting enough water as well (between 1.5 to 2 liters of fluid per day).

When it's time to leave, try to adopt appropriate toilet habits:

- Don't overwork yourself
- Sit fully on the toilet, rather than hovering; this will aid in the relaxation of the correct muscles.
- Stand with your feet apart and your arms comfortably resting on your legs, supported by a seat or support.
- Don't tighten your abdominals; maintain your tummy relaxed.
- Avoid holding your breath; instead, aim to maintain a calm breathing pattern.
- Sit fully on the toilet, rather than hovering; this will aid in the relaxation of the correct muscles.

- Applying mild pressure vaginally on the bulging wall toward the rear canal may assist in more thoroughly and successfully emptying the bowels.

Bladder:

- ✓ Instead of going to the bathroom 'just in case,' go when your bladder needs to be emptied
- ✓ Sit fully on the toilet, rather than hovering; this will aid in the relaxation of the correct muscles.
- ✓ You might find it beneficial to lean forward and back numerous times after passing urine to help make sure that all the urine comes out
- ✓ do not push or strain to empty your bladder; you might increase the prolapse
- ✓ Try not to lower your daily fluids (1.5 – 2 liters per day is recommended); you may aggravate the prolapse if you push or strain to empty your bladder.
- ✓ The number of times you need to empty your bladder may not always be reduced by drinking less.

Intercourse

- ✓ Having sex with a prolapse is perfectly safe and will not harm or exacerbate the bulge.
- ✓ To aid with vaginal dryness or discomfort with penetration, consider alternative positions for sexual intercourse and use a suitable lubricant.

Weight:

- ✓ Being overweight causes the pelvic floor muscles to be overworked.
- ✓ If you reduce weight, your symptoms may improve.

Taking steps to lower your intra-abdominal pressure

Reduce your cough: If you have a chronic cough, make sure you take medications as directed and drinking plenty of water.

Lifting: It is not just the weight of the object you are lifting that can aggravate your symptoms. Bending and lifting on a regular or recurrent basis might also be a concern.

- Develop a good lifting habit for all chores, including light ones. Before each lift, tighten your pelvic floor muscles.

- Splitting weights for carrying, making more frequent journeys, and lifting correctly when taking something from low down are all good ideas.

Exercise and activities: Avoid activities that aggravate symptoms, like prolonged standing.

Whenever feasible, try to divide your day into shorter intervals of standing with moments of sitting in between. Jumping, jogging, or aerobics (any activity that requires both feet to be off the ground at the same time) might aggravate your symptoms, especially if your pelvic muscles are weak. Weight-bearing activities might sometimes put too much downward pressure on the body. Low-impact exercise like modified aerobics, cycling, a cross trainer, quick walking can be substituted.

INSTRUCTIONS: THIS COUNSELING IS INTENDED EXCLUSIVELY FOR WOMEN IN THE INTERVENTIONAL CLUSTERS.

Strengthening Your Pelvic Floor Muscles

The pelvic floor muscles serve as a supportive hammock for the pelvic organs. Engaging in pelvic floor muscle (PFM) exercises will enhance the strength and effectiveness of these muscles, helping to alleviate symptoms of prolapse.

Exercise Guidelines:

- Include both long-held squeezes and quick, rapid squeezes, ensuring that each squeeze is followed by complete relaxation of the muscles.
- Work the muscles until they are fatigued and repeat the exercises regularly to improve strength.
- These exercises can be performed in various positions. If your prolapse extends beyond the vaginal opening, you may find it easier to do them while lying down. If your prolapse is less severe, you can also perform them while sitting.
- You should feel a squeeze and lift internally. Avoid holding your breath or engaging other muscles, such as those in your legs or buttocks.

Pelvic Floor Muscle Exercises

1. Aim for 10 long squeezes, each held for 10 seconds, followed by 10 short squeezes.
 - If you find it challenging to hold a squeeze for long, start with shorter durations and gradually increase.
2. Perform these exercises at least three times a day.

3. Begin your routine while seated or lying down, and gradually increase the complexity over time.
4. After 3 to 5 months, you should notice improvements; continue practicing your pelvic floor exercises daily to maintain progress.
5. As your strength increases, try performing the exercises in different positions, including standing.
6. Eventually, incorporate these exercises into activities like walking and bending.
7. Ensure correct technique throughout all exercises for maximum benefit.

ANNEX-IV: Sidaamu Afii Version of Lifestyle Counselling and Pelvic Floor Muscle Training Protocol

HALLU WORU BISI KIFILERA UYNANNI QAJEELSHINNA HEESHSHOTE GADE AMADO

Otootto gobbara higge fultanno yaa mayyaate? Leellishshanno malaatta hiikkuriiti?

Otootto gobbara higge fula yaa: Amuwaho sirote bisi kifilera ufuuffa, otootto, hellee gobbaanni leelturo, gobba higge fultino yine woshshinanni. Hattono sirote bisi kifilera ayirrino gede macciishshamirooti. Aleenni xawinsiri bisu kifillanni gobba higge woy giddoonni hee'renni malaate leellishsha/macciishshamme heedhurooti.

Marichooti otootto, helleenna ufuuffa sirote bisi kifilla widoonni gobba higge fultanno gede assannori?

Lowo korkaati no kuriuu abbannori, Sirote bisi kifilera lowo maali (xunchi) biso irkise amadannohu mimmituwiinni baxxa hanafirooti roorenkanni togoori ikkannohu.

Godowa (godowu gata) nna qaaqqo ila: Roorenkanni godowanna qaaqqo sirote kifile widoonni ila abbitanno, qaaqqu godowamiro godowu giddo lophanni ha'ranno. Lophanni ha'ranno yannara sirote bissa aana lowo xiiwo kalaqanno. Hattono muje (hormone) godowu gatanno yannara cingiitanno gari soorramannohuraati ilate bisu kifilla qixxeessate kalaqamu ortenni. .

Danna saino maqee lexxanna du'ma: danna saino du'milli halli wori bisu kifilla irkisanno maalira xiiwo ledirooti. .

Ayirrinoricho bayi'ra/duha: Ayirrinoricho barru barrunni bayi'ra bisinke aana qoldissanno (godowu maalira) xiiwo leddanno daafira konne qarra abbanno.

Fiixaho kuni qarri hee'riha ikkiro: lawishshaho muli fiixira (amakkira/rodookkira) tini mitiimma heedhuha ikkiro heedhara dandaanno.

Diro: diru lexxanni ha'ri kiiri tini mitiimma lexxitanno..

Ilate yanna sa'a : ilate yanna sa'a tenne mitiimmarano qarra abbitanno.

Godowu moolle: jawa shumara ofollinanni yannara godowu mooleenna niixa konni qarrira xaadisanno..

Keeshshitino buusano : Asimete dhibbi woy buusiisanno dhibbi konni qarrira tuganno.

Mudukku woroonni godowa dadhiniro:mudukku woroonni godowa dadhinirono konne qarra abbitanno(otootto dadha qarra leddanno.):

Maricho assa hasiissanno bisu kifilla gobba higge sirote bisi kifilenni fultuha ikkiro?.

:

- Godowu moolannokki gede assi'ra.
- Haanxe afidhino sagale saga'la,gummanna laalo ita.
- Xalala waa aga (1.5-2) litire aga..

Jawa shuma ofollinanni yannara qoropho assa.:

- Umikki fajjo assittoti shumatta ofolatta yanna:
- Shumate ofolatta yanna ofolla hasiisanno,qupphi ya gawajjo abba danditanno.
- Ofollatanna uurrata yanna ragunni ofolla hasiissanno..
- Godowakki usudha dihasiissanno.
- Foolatta woyte foolekki giddo qolte amada hooga

UFUUFFATE KEERAANCHIMMA AGADHA:

- ✓ Way shuma daganno yannara calla ha'ra.
- ✓ Shumaa'ratta woyte ofolte shumaa'ra.
- ✓ Shumaa'ratta yanna niixa hooga.
- ✓ Ikkado waa barrunni aga (1.5 – 2) litire aga
- ✓ Keeraanchimma agadhate ikkado/ajishate waa aga.

SIIMU XAADOOSHSHI YANNARA.

- ✓ Otootto fultanno yannarano siimu xaadooshshi assa qarra diabbitanno woy qarra diledanno.
- ✓ Bisu moolannokki gede qufisannoricho horoonsi'ra(sirote bisi kifilera)

MAQEE LEXXA HOOGA

- ✓ Danna sa'ino du'ma hooga.
- ✓ Maqee lexxa hooga konni qarrira ditugganno..

Godowikkira xiiwo ledannore agura.

Buusano ajisha: buusanote hikkiminna assi'ranna buunsanni yannara co'icha waa aga..

AYIRRINORE BAYI'RA HOOGA: shotare calla kaysa qarraho ditugganno.

- Bayi'rattote yannara umo sekke agadha hasiissanno.

Mannimate guuntenna loosu yannara umo agadha:lowo yannna uurra hooga hattono loonsanni looso saatetenni beenke loosa.

HAJAJO: konni woroonni noo amaale uyinannihu mitiimma leeltino amuwira xaginsanni gaamoraati

Halli wori mannimaate guunte loosa.

Bisokki 10 higge seeda duu'ra, xaano harancho yanna 10 hige duu'ra.

- Bisokki harancho yanna calla duu'rattaha calla ikkiro,mule mule manninnaate guunte loosa hasiissanno.
- Halli wori mannimate guunte barrunni ajaanni ajeenna sase hige loosa hasiissanno.
- Ofolatta yannanna haawaatta yannara shotunni ka''a hasiissanno.
- Suutunni mannimate guunte jawaante leda hasiissanno(lamalatenni agannate giddo).
- Sasunni ontu agani geeshshi gedenssanni may badooshshi nooro bade afanna barrunni mitte hige loosa hasiissanno hurre lexxitanno gede.
- Mannimate guuntenni maalikki jawaatinoha ikkiro,mannimate guunte addi addi danita loosa lawishshu gede(uurra).
- Goofimarchohono,ha'ramatenninna bisokki qoldisatenni mannimate guunte loosa

Halli wori mannimate guunte ragunni loosa hasiissanno, maala(xuncha) kaajjishi'ratenni.



Meeting No: 9/2014

Ref. No: IRB/157/14

Date: 10/05/2022

Name of Researcher(s): **Melese Siyoum (MSc), Ayalew Astatkie (Ph.D), Wondwosen T/Selassie (Ph.D), Rahel Nardos (MD), Biniyam Sirak (MD)**

Topic of Proposal: *Epidemiology of pelvic organ prolapse in Sidama national regional state, Ethiopia*

Dear researcher(s),

The Institutional Review Board (IRB) at the College of Medicine and Health Sciences of Hawassa University has reviewed the aforementioned research protocol with special emphasis on the following points:

- | | | | | |
|--|-----|-------------------------------------|----|--------------------------|
| 1. Are all principles considered? | | | | |
| 1.1. Respect for persons: | Yes | ☒ | No | ☐ |
| 1.2. Beneficence: | Yes | ☒ | No | ☐ |
| 1.3. Justice: | Yes | ☒ | No | ☐ |
| 2. Are the objectives of the study ethically achievable? | Yes | ☒ | No | ☐ |
| 3. Are the proposed research methods ethically sound? | Yes | ☒ | No | ☐ |

Based on the aforementioned ethical assessment, the IRB has:

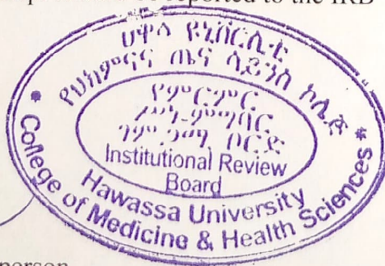
- | | | |
|---|-------------------------------------|--|
| A. Approved the proposal for implementation | ☒ | -Approval period from May.10/ 2022 to May. 9 /2023 |
| B. Conditionally Approved | ☐ | -Element Approved: Protocol Version No. 1 |
| C. Not Approved | ☐ | -Follow up report expected in 6 months |

Obligation of the PI:

1. Should comply with the standard international and national scientific and ethical guidelines
2. All amendment and changes made in protocol and consent form needs IRB approval
3. The PI should report SAE within 3 days of the event
4. End of study, including manuscript should be reported to the IRB

Yours faithfully,

Dawit Jember (Asst. Prof.)
Institutional Review Board Chairperson.





Ref. No: IRB/366/15

Date: 09/08/2023

Name of Researcher(s): **Melese Siyoum (MSc), Ayalew Astatkie (Ph.D), Wondosen T/Selassie (Ph.D), Rahel Nardos (MD), Biniyam Sirak (MD)**

Topic of Proposal: ***Epidemiology of pelvic organ prolapse in Sidama national regional state, Ethiopia***

Dear researcher(s),

The Institutional Review Board (IRB) at the College of Medicine and Health Sciences of Hawassa University has reviewed the aforementioned research protocol with special emphasis on the following points:

1. Are all principles considered?

1.1. Respect for persons:

Yes ☒ No ☐

1.2. Beneficence:

Yes ☒ No ☐

1.3. Justice:

Yes ☒ No ☐

2. Are the objectives of the study ethically achievable?

Yes ☒ No ☐

3. Are the proposed research methods ethically sound?

Yes ☒ No ☐

Based on the aforementioned ethical assessment, the IRB has:

A. Approved the proposal for implementation

☒ Approval period -**09 Aug 2023 to 08 Aug 2024**

B. Conditionally Approved

☐ Element Approved: **Protocol Version No. 1**

C. Not Approved

☐ Follow up report expected in **6 months**

Obligation of the PI:

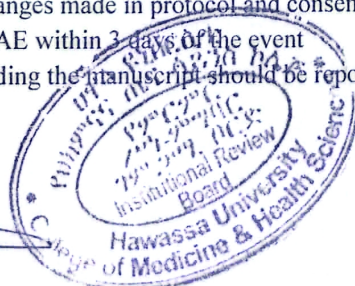
1. Should comply with the standard international and national scientific and ethical guidelines

2. All amendment and changes made in protocol and consent form needs IRB approval

3. The PI should report SAE within 3 days of the event

4. End of the study, including the manuscript should be reported to the IRB

Yours faithfully,



Dr. Embialle Mengistie (Ph.D. Associate Prof.)

Chairperson, Institutional Review Board



CERTIFICATE OF ATTENDANCE

This certificate is presented to

Melese Siyoum

for presenting his research work in Scientific Conference Organized by the School of Public Health in Collaboration with
the SENUPH II project
at the College of Medicine and Health Sciences, Hawassa, Sidama Region, Ethiopia
November 08 - 10, 2023

SENUPH II project

School of Public Health

Dr. Mihretu Belayneh Dinage
Chief Academic Affairs
Director



Certificate of Appreciation 3rd International Joint Research Conference



This is to certify that
Melese Siyoum

has successfully presented the abstract titled

**"Effect of Midwife-Led Pelvic Floor Muscle Training on Prolapse Symptoms and
Quality of Life in Women with Pelvic Organ Prolapse in Ethiopia: A
Cluster-Randomized Controlled Trial"**

during the 3rd International Joint Research Conference, held from
12th to 14th December 2024, at Bahir Dar, Ethiopia.

We extend our sincere appreciation for your valuable contribution to advancing research and
promoting scholarly collaboration in Amhara Public Health Institute and beyond.


Belay Bezabih Beyene (BMLS, MPH, gFETP)
Director General,
Amhara Public Health Institute (APHI)




Tafere Melaku (PhD)
Secretary, Forum for Higher Education
Institutions in the Amhara Region

