Effect of male partner involvement on maternity waiting home utilization in Hadiya Zone, Southern Ethiopia: a cluster-randomized controlled trial protocol

Teklemariam Yarinbab (teklemariam36@gmail.com)
Mizan Tepi University https://orcid.org/0000-0001-7652-3375
Mubarek Abera
Jimma University
Margo Harrison
University of Colorado
Tefera Belachew
Jimma University

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*Teklemariam Ergat Yarinbab[1,2], Mubarek Abera[3], Margo Harrison[4], Tefera Belachew Lema[5]

*Corresponding Author [teklemariam36@gmail.com]

Authors details

[1*]Department of Epidemiology and Biostatistics, College of Health & Medical Sciences, Mizan Tepi University, Ethiopia

[2*]Department of Population and Family Health, Institute of Health, Jimma University, Ethiopia

[3]Department of Psychiatry, Institute of Health, Jimma University, Ethiopia

[4]Department of Gynecology & Obstetrics, University of Colorado, Denver, USA

[5]Department of Human Nutrition & Dietetics, Institute of Health, Jimma University, Ethiopia

Email address/Institutional email address

Teklemariam Ergat Yarinbab teklemariam36@gmail.com / teklemariam@mtu.edu.et

Mubarek Abera Abmubarek@gmail.com

Margo Harrison MARGO.HARRISON@cuanschutz.edu

Tefera Belachew Lema teferabelachew2@gmail.com

Abstract

Background: The primary cause of adverse maternal health outcomes has been identified to be the delay in reaching care at health facility. This is often attributed to the long distances' women need to travel to gain access to health facilities. Literature show that maternity waiting homes (MWHs) contribute significantly to the reduction of maternal death and stillbirth among users. Despite its importance in improving maternal & neonatal health outcomes, the utilization of MWHs is very low in Ethiopia. So, it is important to investigate what strategies could be effective in improving MWH utilization in Ethiopia. The aim of this study is to assess if male partner involvement could be used as a solution to improve MWH utilization in Ethiopia.

Methods/design: This study will evaluate the effect of male partner involvement on MWH utilization in Hadiya Zone, Southern Ethiopia. A behavioral intervention will be performed using a cluster-randomized controlled trial design. The intervention will have two arms, i.e., experimental and control arms. The study participants will be pregnant women in their second trimesters with their male partners. The total trial sample size will be 388. That means 194 study participants in each arm. Randomization will be conducted at cluster level. Study participants and assessors will be masked. Data analysis will be performed by STATA version 14.0 using an Intention-To-Treat Approach.

Discussion: The content of the intervention will be group health education, home visits, and phone counseling. Health education will be delivered to "husband-expectant wife" pairs at the baseline. Then home visits will be conducted at the beginning of every month, and phone counseling will be conducted in the third week of every month for consecutive six months. The anticipated trial commencement time is November 2021.

Trial Registration: ClinicalTrials.gov Identifier: NCT05015023. Registered August 20, 2021. https://clinicaltrials.gov/ct2/show/NCT05015023

Key words: MWH utilization, male partner involvement, pregnancy outcomes, Ethiopia

Background

Maternal Health refers to the health of women before and during pregnancy, at childbirth and during the postpartum period. Sustainable Development Goal (SDG) target 3.1 aims to reduce the global maternal mortality ratio to less than 70 per 100 000 live births by 2030. Estimates for 2017 show that some 810 women die every day from pregnancy- or childbirth-related complications around the world. The estimate further declared that 295 000 women died during and following pregnancy and childbirth, globally. Accordingly, the global MMR in 2017 is estimated at 211 maternal deaths per 100 000 live births which is still far from the SDG target. The vast majority (94%) of this was reported to be occurred in low-resource settings (1,2).

Sub-Saharan Africa and Southern Asia accounted for approximately 86% (254 000) of the estimated global maternal deaths in 2017. Sub-Saharan Africa alone accounted for roughly two-thirds of maternal deaths and the MMR for Ethiopia is estimated to be 401 per 100 000 live births for the same year. This is more than four-fold higher than the global target. Most maternal and neonatal deaths are preventable. All women need access to high quality care in pregnancy, and during and after childbirth. It is particularly important that all births are attended by skilled health professionals, as timely management and treatment can make the difference between life and death for the mother as well as for the baby (2,3).

A primary cause of maternal mortality has been identified as delays in accessing health care. This is frequently attributed to the long distances that women must travel to reach health care facilities. In a recent *Lancet series*, MWHs were identified as a solution to improve outcomes by bringing women living in geographically isolated and undeserved areas closer to a healthcare facility that provides emergency obstetric care. Despite its importance in improving maternal and neonatal health services, the utilization of MWH is very low in Ethiopia. Though the country has more than three decades of experience in implementing maternity waiting homes, different studies have shown that MWHs are underutilized in the country. A recent study from Southwest Ethiopia showed that only 7% of the women reported utilization of MWHs (4–7).

The World Health Organization conditionally recommended that the quality of evidence on utilization of MWHs is poor and insufficiently documented. Further, WHO recommends additional research on “what strategies could be effective” in increasing utilization of MWHs and improving

other key maternal and neonatal health outcomes (8). Therefore, this study will evaluate the male partner involvement as a strategy for improving utilization of MWHs.

Research hypothesis

Null Hypothesis

- Promoting involvement of male partners will not increase utilization of MWH among pregnant women as compared to the routine care in the control group.
- Promoting involvement of male partners will not improve pregnancy outcomes as compared to the routine care among pregnant women in the control group.
- Promoting involvement of male partners will not improve maternal satisfaction as compared to the routine care among pregnant women in the control group.

Alternative Hypothesis

- Promoting involvement of male partners will increase utilization of MWHs among pregnant women as compared to the routine care in the control group.
- Promoting involvement of male partners will improve pregnancy outcomes as compared to the routine care among pregnant women in the control group.
- Promoting involvement of male partners will improve maternal satisfaction of health care services as compared to the routine care in the control group.

Aim of the study

This study will assess the effect of male partner involvement on MWH utilization in Hadiya Zone, Southern Ethiopia.

Objectives

- To evaluate the effect of male partner involvement on MWH utilization
- To assess the effect of male partner involvement on pregnancy outcomes
- To determine the effect of male partners involvement on maternal satisfaction

Methods/Design

Study design

A cluster-randomized controlled trial design will be used to evaluate the effect of male partner involvement on MWH utilization. Health Facilities (HFs) will be the clusters. There are thirty HFs with MWHs in Hadiya Zone. Ten non-adjacent HFs with functional MWHs will be randomly selected. This will minimize the risk of information contamination. Then those 10 selected HFs will be randomly allocated in to experimental and control groups. The intervention duration will be six months. The study findings will be reported in line with the CONSORT (Consolidated Standards of Reporting Trials) recommendations for cluster randomized trials (9). Pregnant women who are in their second trimesters and their male partners will be recruited and participate in the study.

The control group will continue to receive routine health education, which is a standard government health service for pregnant women visiting HFs for ANC services and is provided on a monthly basis by health care professionals at the facilities. Women receive routine health education at antenatal appointments throughout their pregnancy and at postnatal visits following delivery. The lessons are usually brief and cover topics such as self-care, nutrition, safe sex, rest, sleeping with ITN, birth, and an emergency plan (10).

In addition to the standard health education content, the intervention group will receive health education on the use of MWHs and the necessity of male partner support. The trial participants will also receive home visits and phone counseling as part of the intervention. At the start of the study, the pregnant women will receive health education along with their male partners/husbands. They will be provided brochures with information on self-care, nutrition, safe sex, rest, sleeping under ITN, delivery and emergency plans, the importance of MWHs, and paternal support. Throughout the intervention period, home visits will be made in the first week of each month. During home visits, family members will be advised and counseled. Similarly, throughout the intervention period, phone counseling will be provided in the third week of every month. The baseline assessment will take place at the start, and the final evaluation will take place six months later.

Study setting

The research will take place in the Hadiya Zone of southern Ethiopia. Hadiya Zone is a second-order administrative division in Southern Nations, Nationalities and Peoples Regional (SNNPR) State. It is located 250 kilometers southwest of Addis Ababa, Ethiopia's capital. Hadiya is divided in to one town administration and ten rural districts. The livelihood of the population mainly depends on agriculture. According to the CSA's 2007 Census, this Zone has a total population of 1,231,196 people, with 612,026 men and 619,170 women (11). Hadiya has a population density of 342.64 people per square kilometer, with a total area of 3,593.31 square kilometers. Out of total population 60,304 are estimated to be pregnant women. There are 317 Health Posts, 61 Health Centers, and 4 Hospitals in the Zone. Thirty of the health centers have maternity waiting homes.

Study participants

The study participants will be pregnant women in their second trimesters and their male partners. The pregnant women in their second trimesters (>12 weeks of gestation) with their male partners will be recruited to participate in the study.

Inclusion criteria

Pregnant women who are in their second trimesters (>12 weeks of gestational age), permanent residents of the area, currently live with their male partners/husbands, live in a place ≥30 minutes of walking-distance from the nearest health facility, whose husband has mobile phone, and who are voluntary to participate in the study with their husbands.

Exclusion criteria

Pregnant women who are not in their second trimesters (≤12 weeks of gestational age), do not live permanently in the area, currently not living with their male partners/husbands, live in < 30 minutes of walking distance from the nearest health facility, whose husband does not have mobile phone, or who are not voluntary to participate in the study with their husbands.

Sample size and power calculations

Hooper and Bourke's methods for parallel arm, cluster-randomized controlled trials with repeated cross-sections will be used to calculate sample size (12). To account for within-period intracluster correlation coefficient (ICC) and between-period ICC, the technique involves the measurement of

two design effects, with the product of the two being used to inflate the sample size under individual randomization. The within period ICC is the correlation between any two pregnant women in the same cluster and period, while the between period ICC is the correlation between any two pregnant women in different clusters and periods. The first design effect (dc) attributable to cluster randomization will be measured using a within-period ICC of 0.05 obtained from a community-based cluster randomized trial on encouraging pastoralist women in Ethiopia to use family planning (13). The design effect (d_c) will be calculated as:

$$\mathrm{dc} = 1 + (m-1)\rho$$

where m is the cluster-period size assumed to be 40 (i.e., the total number of pregnant women who will be questioned in each cluster) and ρ is the within-period ICC. Using the within-period ICC and a cluster autocorrelation coefficient (π) of 0.8, the second design effect (dr) attributable to repeated evaluations (baseline/endline) will be measured (12). The second design effect will be calculated as:

$$d_r = (1 - r^2)$$

Where $r = \left(\frac{m\rho\pi}{d_c}\right)$

The requisite sample size would then be calculated by multiplying the sample size assuming individual randomization by both design effects (dc & dr). It will be calculated as:

$$n = \left\lfloor \frac{(a+b)^2 * (p_1 q_1 + p_2 q_2)}{(|p_1 - p_2|)^2} \right\rfloor * d_c d_r$$

Where:

n represents the sample size in each of the groups i.e., intervention and control

a represents conventional multiplier (1.96) for alpha $(\alpha = 0.05)$ and b represents conventional multiplier (0.842) for power $(1 - \beta = 0.80)$

$p_1$represents proportion of utilization of MWH after intervention and q_1 represents proportion of non-users of MWH after intervention

p_2 represents proportion (5.8%) of users of MWH from a cluster randomized trial on upgraded MWHs and local leaders training in Jimma Zone, Ethiopia (14) and q_2 represents proportion of non-users of MWH (before intervention)

$|p_1 - p_2|$ - *an effect size*: is estimated to be 15%. It is an absolute change in the proportion of MWH utilization after intervention.

In addition to the above parameters, the necessary number of clusters and sample size will be calculated using the following parameters: 95 percent confidence interval, 80 percent power, 1:1 allocation ratio of intervention to control, 20% potential loss to follow up, and tabulated sample size ($n_0 = 199$) required to detect a difference in two proportions at 5% significance level with 80 percent power in literature (15). The number of clusters (k) for the sample will be determined using the formula $k = (n_0 d_c d_r)/m$ (12). The final sample size will be calculated by substituting the indicated values into the above formula. As a result, a total of 10 clusters will be needed with a total sample size of 388. There will be 194 pregnant woman-husband pairs in each arm.

Sampling techniques

There are thirty health facilities (HFs) with MWHs in Hadiya Zone. Among these, ten non-adjacent HFs with functional MWHs will be randomly selected. Then the selected ten HFs with functional MWHs will be randomly allocated to each arm (intervention and control arms). Pregnant women in their second trimesters with their male partners will be the study participants. The sampling frame will be list of pregnant women (>12 weeks of gestation) registered for ANC follow up at HFs. Then the study participants will be asked for their consent, enrolled in the study and will be followed up throughout the study period. Baseline assessment will be conducted at the beginning of the study. The intervention will be implemented. The intervention and control groups will be followed up for six months. Endline assessment will be conducted to evaluate the outcomes.

Randomization and masking

Health Facilities will be the trials randomization unit whereas the observation or analysis units will be the individual study participants. From the thirty HFs having MWHs, ten non-adjacent HFs with functional MWHs will be chosen at random. Then, alphabetically, these ten non-adjacent pre-selected HFs will be listed. To assign the HFs to the control or intervention groups, a simple randomization with a 1:1 allocation will be utilized. In Microsoft Excel 2010, a list of random

numbers will be created, and the generated values will be fixed by copying them as "values" next to the alphabetic list of pre-selected HFs. The first five will be chosen as intervention clusters, and the last five will be chosen as control clusters, in ascending order based on the produced random numbers. A statistician who is blind to the study groups and is not involved in the research will create the allocation sequence and randomize the clusters.

The HFs allocation will be hidden from the data collectors (assessors) and study participants. Cluster gatekeepers, particularly Woredas and Zonal Health Officials, will be instructed not to intervene in the control clusters until the study is finished.

Intervention protocol

Table 1: Summary of the intervention protocol

Content	Dose	Frequency	Duration	Compliance parameter
Health education Group Health Education will be delivered to the husband-wife pairs at community event. Both partners will attend the health education together. The health education will focus on the importance of ANC, danger signs during pregnancy, birth preparedness, advantages of using MWHs, institutional birth, and PNC services. Leaflets containing important messages on MWHs will be delivered to the participants.	Health education will be delivered to study participants for 120 minutes at baseline.	Once at baseline only	2 hours	Number of participants attended [Attendance sheet]
Home visits Home visits will be conducted in the first week of every month. Pregnant woman and/or her partner will be advised on ANC follow up, birth preparedness,MWH use, institutional birth and PNC.	Advice pregnant woman with her husband for 30 minutes. [30 min *6 = l80min/HH over six months]	Once a month	Six months	Number of participants obtain advice [Attendance sheet]
Phone counseling Phone counseling will be conducted in the third week of every month. It will focus on the male partners support and care to the expectant women. Male partners will be counseled to exercise shared decision making, couple communication, psychosocial support and instrumental support for maternal health service utilization.	Phone counseling will be conducted for 5 minutes. [5min*6 = 30min/HH over six months]	Once a month	Six months	Number participants reached on phone counseling [Attendance sheet]

CONSORT 2010 Flow Diagram

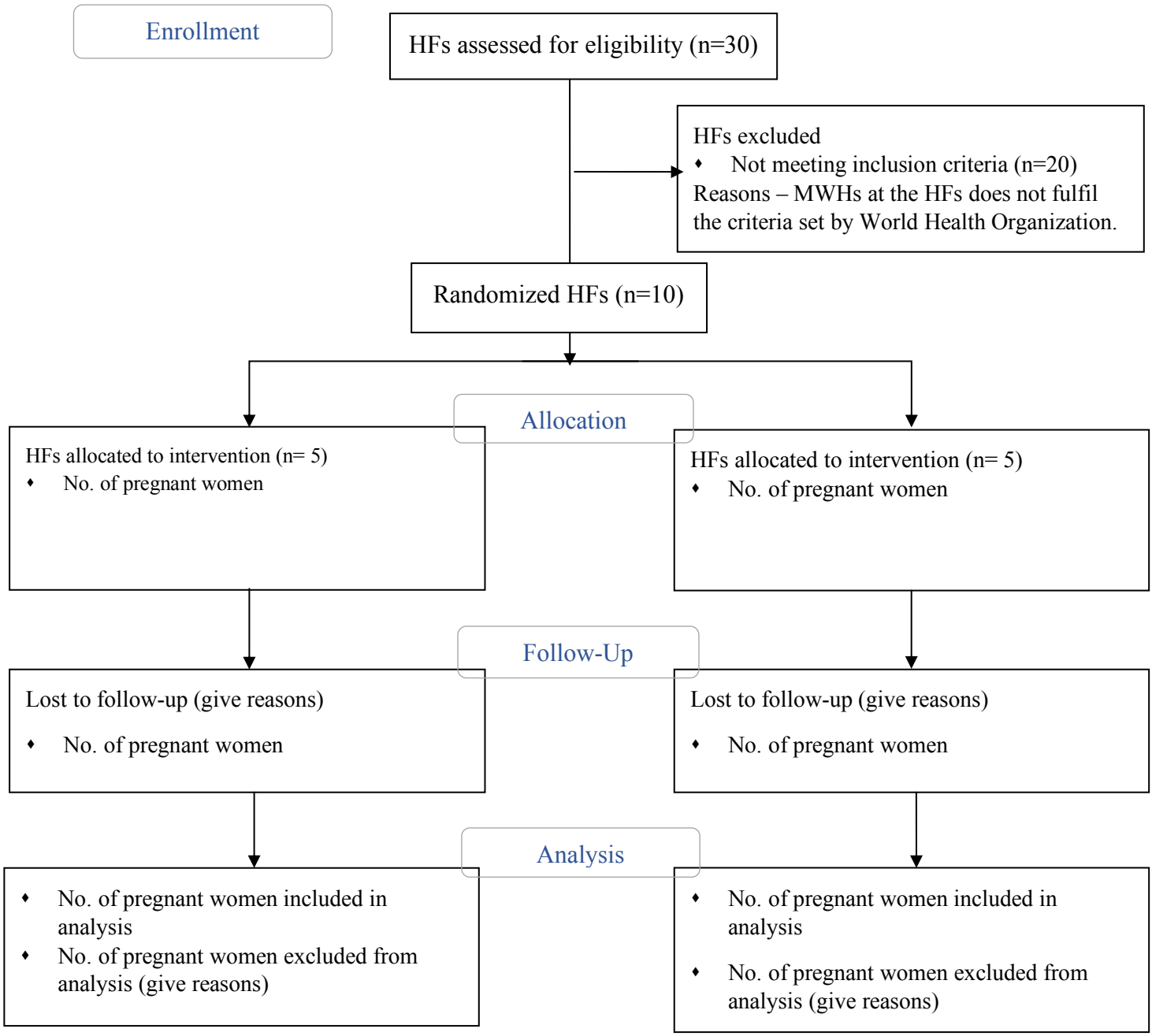

Figure 1: The trial flow diagram

Description of the intervention

The intervention activities will be designed and implemented to target both pregnant women and their male partners. The primary outcome of the intervention will be MWH utilization. The secondary outcomes will be pregnancy outcomes and maternal satisfaction. Two health professionals will be recruited from each HF and trained on the study protocol. The duration of the intervention will be six months. The study findings will be reported using CONSORT (Consolidated Standards of Reporting Trials) for cluster randomized trials criteria (9). The intervention will have three phases, i.e., baseline survey, implementation, and endline evaluation of the intervention.

Baseline survey/assessment: Baseline assessment will be conducted at the beginning of the study. It includes sociodemographic factors such as age, educational status, occupation, income, religion, residence, family size, and obstetric related factors such as birth order, parity, gravidity, maternal history, and paternal support in the most recent birth.

Implementation: The intervention will be commenced. The intervention packages will be health education, home visits, and phone counseling. At baseline, health education will be delivered to the participants in groups. The participants will be volunteer pregnant women with their male partners/husbands. Leaflets containing important health messages will be delivered to the participants. Home visits will be conducted in the first week of every month throughout the intervention period. Phone counseling will be conducted in the third week of every month throughout the intervention period. The study team will visit and monitor the progress of the intervention.

Final evaluation of the intervention: The final evaluation of the intervention will be conducted at the end of six months.

Control group: The control group will continue receiving the routine care delivered at HFs.

Plan of analysis

The data will be entered in to Epi Data Version 3.1 and then exported in to STATA version 14.0. The data analysis will be performed by Intention-To-Treat (ITT) approach. Generalized Estimating Equations (GEE) will be used. The primary outcome, MWH utilization, is a dichotomous variable and so will be analyzed with logistic regression. The other secondary outcome variables will be analyzed by per protocol approach as appropriate. Data will be reported as odds ratios and their corresponding confidence intervals. Tables, charts and graphs will be used to display the data.

Project time schedule

The trial duration is six months. The anticipated beginning month is November 2021.

Discussion

Maternity waiting homes were identified as a solution to improve maternal and neonatal health outcomes by bringing women living in remote areas closer to health institutions that provide emergency obstetric services. Literature have shown that the use of MWH is effective in improving maternal and neonatal health outcomes. In Ethiopia, the practice of MWHs spans more than three decades. But the practice of its utilization is still very low and the rates vary across regions in Ethiopia. World Health Organization (WHO) recommends further research to investigate what strategies could be effective at increasing the utilization of existing MWHs. Findings from several studies have shown that male partner involvement in maternal health services has a positive impact on its uptake (5,6,8,16). The investigators of this study have noticed that studies are lacking regarding the effect of male partners involvement on utilization of MWHs. Therefore, this trial aims to evaluate male partners involvement as a solution to improve MWH utilization.

Declarations

Ethics approval and consent to participate

Ethical clearance letter will be obtained from Jimma University before commencement of the actual study. Formal letter of permission will be obtained from respective administrative bodies of Hadiya Zone. Consents will be sought from cluster representatives. Study participants information will be kept confidential.

Availability of data and materials

The datasets are available from the corresponding author on reasonable request.

Competing interests

The authors declare they have no competing interests.

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This study is sponsored by Jimma University. Jimma University does not have any role in the design of the study, development of the protocol, and in writing the manuscript.

Authors contributions

TE conceived the research, designed the research methodology, developed the study protocol, and prepared the manuscript. MA, MH, and TB significantly contributed in designing the study methodology and reviewing the study protocol. All the authors read and approved the final manuscript.

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Authors information

[1*]Department of Epidemiology and Biostatistics, College of Health & Medical Sciences, Mizan Tepi University, Ethiopia

[2*]Department of Population and Family Health, Institute of Health, Jimma University, Ethiopia

[3]Department of Psychiatry, Institute of Health, Jimma University, Ethiopia

[4]Department of Gynecology & Obstetrics, University of Colorado, Denver, USA

[5]Department of Human Nutrition & Dietetics, Institute of Health, Jimma University, Ethiopia

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