

# Use of community-based interventions to promote Family Planning use among Pastoralist women in Ethiopia: Cluster randomized controlled trial

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## Research article

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# Abstract

**Background:** - Afar region is one of the pastoralists dominated regions in Ethiopia. The region is characterized by a low contraceptive prevalence rate (CPR) with 5.4%. Lack of awareness, husband objection, and religious influence was the reasons attributed to low CPR in the region. As objective we assessed the effect of a community-based interventions for promoting FP use among pastoralist communities of Afar region state, Ethiopia.

**Methods:** The design was parallel, cluster randomized controlled trial (CRT) recruiting married women. It had three arms: 1) women's education on FP, 2) male involvement in FP education and 3) control with one to one ratio. A total of 33 kebeles (lowest administrative structure) were randomized and allocated. Women's FP education and male involvement in FP education were the interventions. It was implemented using 1) health education on FP to married women and men by faema leaders (a traditional community-based structure that serves as a social support group) 2) Video-assisted message on FP, and 3) Assisting the faema leader using health workers. The intervention was given for a total of 9 months. FP use and intentions were measured as outcome variables based on woman's perspectives. Cluster level summaries considering a cluster effect analysis was performed. The result was presented with adjusted risks and 95% CI. A p-value <0.05 was used to declare statistically significant.

**Results:** There was a positive change in the proportion of married women who use FP in the women's FP education arm, absolute risk (AR) of 0.13(95% CI,0.08,0.17) and male involvement arm with AR of 0.29 (95% CI, 0.23,0.34) as compared to the control arm. In the control arm, the proportion of FP use was 4.3%, whereas it was 17.5% with women who receive FP education and 34% in the male involvement arm. Furthermore, the proportion of married women who had high intention to use FP was high in arms of women's FP education and male involvement with AR=3.4(95% CI: 2.48,4.91) and AR=2.1 (95% CI: 1.5,2.95), respectively as compared with the control arm.

**Conclusion:** The present study highlighted the effectiveness women's education on FP and male involvement in FP education brings a significant change in increasing the number of women who use FP and intention. Using the community-led support groups in the pastoralist community appears to be effective in increasing the number of women FP users and intention to use.

**Trial registration:** NCT03450564

## Background

In the developing world, including Ethiopia, maternal and child morbidity and mortality have remained high, despite the need for urgent action as declared by different international agreement (1). Such a burden can be averted by using effective family planning (FP) as a means to decrease unintended pregnancy and its consequences and thereby reduce maternal and newborn morbidity and mortality (1). Even though in 2016, there were 300 million women and girls from developing countries using FP -(2)- a considerable number (214 million) of women still had an unmet need for FP in the same year(1). Sub-

Saharan African (SSA) including Ethiopia accounts for the highest number of unmet needs for FP among women of reproductive age group with a value of 24.2 and 26%, respectively (3). Apart from this, there is a target to have access and use of FP for an additional 120 million women by the year 2020(2).

Ethiopia sets a goal to achieve a contraceptive prevalence rate (CPR) of 55% and total fertility rate (TFR) of 3 by the year 2020 -(4)- from the current CPR of 41%-(5)- and TFR of 4.6(6). However, FP use among pastoralist communities' is lower than the national average. Pastoralism is a way of life for 12 million Ethiopians and they are located in the most inaccessible areas and remotest part of the country. They are underserved in terms of health, social services, and economic infrastructures (7). Afar region is one of the pastoralist regions characterized by pastoralist/agro-pastoralist dominating population. The region's FP utilization was low characterized by CPR ranges from 5.4 –12.7% -(5, 6, 8)-, TFR of 5.5, and unmet need for FP of 17.2% (12.9 for spacing and 4.3% for limiting) (6). It should be noted that lack of awareness among women, religious rooted convictions, and norms against the use of FP and strong husbands' objection towards FP is likely to be the main cause of low FP use and large family size in the region (9, 10). Hence, such kind of negative norms on FP overshadows women's decision-making power in their families and limits their right to access the FP service

In Ethiopia from 2014-2018, the Reproductive, Maternal, and Newborn Health Innovation Fund (RIF) launched a project aimed to enhance the maternal and child health indicators (Antenatal care, institutional delivery and postnatal care) including FP of the pastoralist communities (9). As part of the project, we intend to increase the women who use FP by mitigating the barriers for not using FP in the Afar region, Ethiopia (11). Besides, based on our previous assessment on best practices for addressing socio-cultural barriers related to FP, educating women on FP and male involvement in FP education could be a good strategy to increase the FP use in the region (12). In addition to this, studies done elsewhere outside the pastoralist community shows an increment of FP use using different modalities. For instance, a study in different districts of India deploys an intervention like having group meetings, providing training to rural providers and community leaders -(13)- creating awareness and encouraging inter-spousal communication to enhance FP use(14). Importantly, previous studies in the pastoralist community had already brought a satisfactory change in promoting maternal, newborn, and child health (MNCH). For instance, male involvement, one health approach, having a migratory route of container clinic, mobile clinic and building maternity waiting home are some of the interventions that made a significant contribution in escalating MNCH (15-18). In addition, a study done in a pastoralist community of Kenya to promote male involvement in the MNCH service utilization and to share with other community members under their catchment had brought an improvement in the MNCH service utilization (17). Along with, evidence shows that as the women's decision-making capacity increases, the proportion of women who use FP increases (6, 19). Women's decision making regarding FP can be further enhanced through involving a male partner in FP service (20). Therefore, women's education on FP and male involvement in FP services can be done at the community level to increase the low FP use in the Pastoralist community. In Afar, there is "faema" which is a traditional community-based structure in the pastoralist community that serves as a social support group. It has a long history and high community acceptance and has a separate structure for males and females (21).

Furthermore, the Health Extension Program (HEP) which is believed to be one of Ethiopia's best programs in disease prevention, promoting good health and the use of FP service is less practiced in Afar(22, 23). Also, the women development army (WDA) that was established to strengthen the HEP in creating awareness, increase health-seeking behavior, and building a community sense of ownership has not been yet established despite its practice in the agrarian region of the country(22, 23). Moreover, we have a dearth of evidence on quantifying the effect of women's education on FP and male involvement in FP services for enhancing the number of FP users and intention among married women in the pastoralist community. Hence, using community-based interventions with a focus on approaching the community with the community could be a good strategy to educate the women and men. Along with using the Faema which has a separate structure for male and female, and high community acceptance could be a good strategy for enhancing FP use and intention among the pastoralist community. Also, as a rationale of the study assessing if structured health education provision about FP given by faema is more effective than the unstructured to increase FP use and intention. Therefore, we hypothesized that educating women on FP and having male involvement in FP education as part of community-based interventions could increase the number of married women who use FP and intention. To achieve our goal we employ a rigorous method (cluster randomized controlled trial(CRT)) which is practically feasible, and prevents contamination of the disseminated information at the ground (24). The main aim of the current study was to implement and evaluate the effect of community-based interventions (women's education on FP and male involvement in FP services) using CRT on FP use and intention among married women in Pastoralist community of Afar region, Ethiopia

## **Methods**

### **Study Design**

A cluster-randomized trial of parallel design with three arms (women's education on FP, male involvement in FP education, and control) was used. One to one ratio allocation of the intervention with a control arm was employed to assess the effect of community-based interventions to promote family planning (FP) use and intention among the pastoralist community. A repeated cross-sectional (cross-sections at baseline and end line) type of data was used to collect the intended information from married women. It contains baseline and end-line data collection with a nine-month duration.

### **Participants**

Cluster was created based on geographic boundaries. The clusters included in the study had at least 30 households with married women. Cluster are with natural borders and have enough distance (20-40km) from adjacent clusters to reduce risk for contamination. Inclusion criteria for woman's were: being married, and resides in a given cluster as usual place whereas those who declared infertile and seriously ill during data collection were excluded.

### **Study setting and period**

The cluster randomized controlled trial was conducted in the Afar region. Afar Region is one of nine regional states of Ethiopia. The region is composed of five 5 zones, 32 districts, five town administrations and 404 kebeles (lowest administrative unit), and having an estimated population of 1,816,304 out of those 799,174(44%) are females. The majority of the population reside in rural, and are pastoralists or agro-pastoralist in occupation and are Muslim religious followers (4). Three districts namely Mille, Afambo, and Kori were included in the intervention. The region is characterized by high early marriage which is mainly influenced by parental decision, and with a high prevalence of early pregnancy and delivery. It also expressed with high illiterate rate and high unmet need for FP (6, 22, 25). A clan-based system favoring large family size, being in a polygamous union of marriage, and a high burden of work among the women is a peculiar characteristic of the Afar women (21, 26, 27). Poor access to health care forces women to travel long distances and often demand the accompany of family members to seek health care including FP. The intervention was carried out for 9 months; from January to September 2018.

### **Study design, sample size determination, and sampling procedure**

The sample size was calculated using the literature of Richard and Lawrence-(28)- to determine the number of clusters required to detect a difference among different arms. Given a current FP utilization in Afar region of 11.6% -(6)-expected changes to be acquired following the intervention of 20%, 90% power, 95% confidence interval, considering the intracluster correlation of  $\rho=0.05$ , adjusting for non-response of the individual in a household of 20% and a design effect of 2.2. Taking an assumption of an equal number of clusters and the cluster sample size, the final sample size was 33 clusters and 891 married women. One cluster had 27 married women. Per arm, we include 11 clusters and 297 married women. A systematic sampling technique was used to select 27 married women from one cluster. A sampling fraction was calculated based on the total number of married women in the cluster. A random start number was selected to identify the first married woman in the clockwise direction. Hence, 9 clusters (5 male involvement and 4 women education) of Afambo, 7 clusters (5 male involvement and 2 women education) of Mille and 6 clusters (2 male involvement and 4 women education) of Kori were included in the intervention. We used the same sampling procedure to collect the follow-up data for the baseline and end line data.

### **Randomization**

We used a cluster randomized controlled trial parallel-group design with three arms. Using a computer-generated random number, the number of clusters was allocated into three arms (women's FP education, male involvement in FP education, and control) in simple randomization. To avoid bias during the process, the allocation of the clusters was done by another researcher and the result was communicated with the principal investigator. Clusters were randomized into two intervention arms and control conditions before the initiation of enrollment..Moreover, the study participants were not specifically informed in which intervention arm.

### **Community-Based Interventions**

The interventions targeted at the cluster level with community-based interventions. It includes 1) male involvement in FP education and 2) Educating women in FP. Each intervention (educating women in FP and male involvement in FP education) was compared with the control arm in terms of FP use and intention. The intervention targeted married women in educating women in FP arm and married women and men in the male involvement in FP education arm. The health education in male involvement in the FP education arm was given separately for married women and men. It was designed with the principle of approaching the community with their community member (faema leaders). Faema is a traditional community-based structure that serves as a social support group. It has a leader, good community acceptance with a separate structure for males and females. It has a long history and feasible to provide the intervention in an area where the health extension programs (HEP) did not strengthen as compare with the agrarian region of Ethiopia (12). HEWs are frontline health worker adopted by the government of Ethiopia (GOE) with a view to achieving universal coverage of primary health care among its rural population by 2009. They served as a major source of health information including FP message(23).

Moreover, the women development army (WDA) is a structure at the community level which was evident in the agrarian region to strengthen the HEP in creating awareness, increase health-seeking behavior, and building a community sense of ownership hasn't been yet established(22). Hence, to enhance FP use and intention among pastoralist community the following community-based interventions 1) health education on FP to married women and men by faema leader, 2) Video-assisted message on FP and 3) Assisting the faema leader using HEW and health workers. It should be noted that, before we provide the FP message to the community a tailored message which is highly acceptable in the community was discussed. Accordingly, the emphasis of the message was given on the purpose of FP for spacing than limiting the number of children. The intervention was guided using an integrated behavioral model (IBM) (29). A detailed description of these community-based interventions described based on the type of arm as illustrated below.

**1) Male involvement in FP education arm:** In this arm we provide the following community-based interventions 1) health education on FP to married women and men by female and male faema leader, respectively 2) Video-assisted message on FP and 3) Assisting the faema leader using HEW and health workers.

**A) The health education on FP by faema leader** targets married women and men in the cluster. We use male faema leaders to approach for the married men and female faema leader to the married women. In the beginning intensive training was given for the faema leader on a different aspect of FP by the research team. We trained 2 females and 2 males faema leader from each cluster for 03 days. The training for female faema leaders includes a detailed description of Muslim dominating countries' FP experience and its relation with reduction of TFR and maternal mortality -(30)- how to starts positively influencing the neighbors in their catchment to use FP and on different content of FP. The content includes information on the definition of FP, type of FP, the purpose of FP, effectiveness, and duration of prevention. It also included sessions that covered myths and misconception on FP and its side effects, how to overcome the pressure/ resistance comes from influential groups (husband, neighbors, clan and

religious leaders) on FP and being a role model by starting using of FP (Figure 1). After the training, with the mobilization of the faema leader, a regular meeting on FP was organized at the center of the cluster. The meeting was held twice a month with a 1-hour duration and it was done in the afternoon. Overall, the intervention was given for a total of 9-months. A constant schedule was prepared to keep the provision of health education message uniform across clusters in each session. Importantly, a logbook or registration book was prepared to follow the progress of the intervention. It contains the name of the participants, age, and type of topic discussed FP in each session of health education. The logbook was checked for its delivery by the research team once a month.

Furthermore, the training, organizing meeting, schedule, time allocated for health education and having and filing of a log book for the male faema leader was similar to the female faema leader, except, the content of the health education gives due focus on the active involvement of males in FP service. It includes promoting spousal communication, allowing his wife to use FP, accompanying her to the health facility, reminding her the schedule of taking FP, participating in choosing the type of FP, providing her financial support, and helping her in domestic activity.

**B) Video-assisted message on FP:** Video of married women who start to use FP, district's FP experts, male who actively involved in FP service and religious leader was recorded. The video recorded message from married women deals with the life experience related to FP (its process, benefit, possible challenges, and action taken). The video recorded message from the district's FP experts includes the benefit of FP, type of FP, possible side effect, management of side effect, and availability of FP in health facilities. Along with, the life experience of those men who actively involved in FP services such as; allowing his wife to use FP, accompanying her to the health facility, participating in choosing the type of FP, providing financial support and helping her in domestic activity was recorded and used to teach the male in the male involvement in FP services arm. In addition, a video recorded message from a religious leader were delivered for the male in the cluster. In the beginning, the importance of FP use for spacing the number of children was discussed with the religious leaders and a consensus was reached. After they agreed on the importance of FP, the message on FP vs Islamic religion with the focus of FP use did not contradict with their religion was recorded and disseminated. The recorded video message of (women who start to use FP, district's FP experts, male who actively involved in FP service and religious leader) on FP was uploaded to tablet smartphone. The tablet with its accessories was given for the faema leaders (male and female) to disseminate the FP message while they teach the community under their cluster. It was given for a total of 6 months. Training on how to operate, deliver, and teach the recorded video message was demonstrated and re-demonstrated by the faema leaders. All the FP message was prepared in the local language "Afarri".

**C) Assisting the faema leader using HEW and health workers.** In the beginning, the HEWs and health workers working at FP were trained. Along with the provision of health education at the cluster level by the faema leaders, the health care providers working in FP at the at the male involvement in FP education arm took orientation and training on making the health facility ready for FP service, availing method mix, managing side effect, and counseling married women on FP use based on informed consent.

Furthermore, the HEW at this arm were trained on how to assist faema leaders during FP related health education programs and provide house to house counseling to voluntary married women on how to use FP services. They also facilitate opportunities for using health centers when married women prefer to use FP including long-acting FP.

**2) Women's Education on FP use arm:** In this arm we provide the following community-based interventions 1) health education on FP to married women by female faema leader 2) Video-assisted message on FP and 3) Assisting the faema leader using HEW and health workers. The type of community-based interventions in this arm was similar with male involvement in FP Education arm except the following point 1) on the health education on FP by faema leader it targets only married women in the cluster 2) The video assisted message on FP recorded from married women and district's FP to teach the married women in the cluster and 3) On the assisting the faema leader using HEW and health workers, they support for female faema leaders to teach the married women in their clusters.

**3) Control arm:** In this arm we don't carried the provision of health education to the married women and men by faema leader, record video from (married women who start FP use, male who actively involved in FP service, religious leader and districts FP expert) and providing training to the HEW and health workers. In this arm the routine provision of FP by the government was maintained. It was cognizant that FP service was given at health facilities by health workers. Along with volunteer married women contacts HEW or health workers to use FP. In this arm we collect the baseline and end line data to compare with the intervention's arms (women's education on FP use and Male involvement in FP service).

### **Measurement of the outcome variables**

The purpose of this study was to evaluate the effect of community-based interventions (women's education on FP and male involvement in FP education) compared to the control group at the cluster level to increase the women's FP use and intention. It was measured based on the married woman's FP use and intention. The primary outcome was modern FP use with the question of "*Are you or your partner currently doing something or using any method to delay or prevent getting pregnant*". Moreover, a modern type of FP (pill, Depo-Provera, condom, Jadelle, Implanon, IUCD, etc) currently used by the women or her husband was collected. Intention to use of FP was used as a secondary outcome variable. A total of 8 items that range from the lowest level (*At this moment, I can list some benefits of FP use and I would gain if I use it*) to the highest level of intention to use FP (*It is expected that women in our community should use FP and so do I*) was used. The response ranges from 1(uncertain /Disagree) to 3(Certain/Agree). The response was summed up to form a continuous variable. It was categorized based on the response of married women mean value in to "*low intention to use FP*" and "*high intention to use FP*" for those married women who scored mean and below mean and above mean, respectively. In addition to the primary and secondary outcomes, the following variables were collected. The community responsibility was collected to describe the responsibility of her husband either as a clan, religious, and faema leader. In line with this, being a faema leader for the married women also included as community responsibility. Along with a positive/yes response for the current use of FP, the status of her husband to

know for the current use of FP, and the type of support obtained from her husband included in our study. To list the type of support; accompany the health facility, reminding the schedule for taking the FP, participating in choosing the type of FP, and either helping them in domestic activity or not.

### **Data collection tool and procedure**

We developed a questionnaire for the purpose of this study and attached as Additional File 1. The developed tool was piloted in 10% of the sample after it was developed by reviewing different literature on the previous finding that aims to explore barriers and facilitators to Reproductive Maternal Neonatal Health (RMNH) services including FP (6, 9, 10, 25). The collected piloted tool was exposed to a reliability test. It was done to assess the consistency of items in each construct (Cronbach's Alpha > 0.7). Besides, exploratory and confirmatory factor analysis was done (31). After all necessary modifications followed the piloted test, the tool was pretested in 5% of the sample to assure wording, skip pattern, and determine the time allotted to complete one interview. A repeated cross-sectional type of follow up data (baseline and end-line data) was used to collect the data as we fear high migration among the pastoralist community. For the secondary outcome variable intention to use of FP was constructed of 8 items had Cronbach alpha of 0.935, explained 87.7% of the variance with Kaiser-Meyer-Olkin (KMO) of 0.846 and Bartlett's Test of Sphericity of 0.00(31). Six clinical nurse data collectors and 2 supervisors were used to collecting the data after they got training on the items and how to use mobile-based applications. They were recruited outside the study/intervention areas and assigned to a different cluster of given districts. The baseline and end-line data were collected using an electronically smartphone-based application open data kit (ODK). Immediately after the data checked for its completeness, it was sent to the Mekelle University (MU) server where the data were accessed and utilized by the research team.

### **Data Quality Control**

The data collectors and supervisors were trained. Regular supervision and follow-up were made by supervisors. A reliable and valid tool was used. The data were collected using a mobile-based application (ODK) which ensures skip pattern; immediate scanning of the collected tool in the server, friendly to use, and avoids cost for paper duplication. Intensive training was given for faema leaders, HEW, health care providers, and religious leaders.

### **Data Monitoring and Safety**

A team from Mekelle University, Samara University, and the Afar regional health Bureau was established to monitor data safety. Hence, volunteer married women will go to a health facility and counseled to use contraceptives based on their informed consent at health facilities by the health care providers. The research team takes an effort to minimize the risk and maximize the benefit by following the provision of intervention using the protocol. And, there was no risk reported following the provision of the intervention.

### **Statistical Analyses**

The data collected using ODK was exported to R software version 3.4.2 for analysis. Intention to treat analysis was used as a framework of analysis. All the analysis was used with a 95% confidence interval (CI) and p-value < 0.05 used to declared statistically significant. Since the number of clusters per arm was 11 per arm, a cluster-level summary was used(28) to compare the women's FP education and male involvement in FP education arm with the control group. A separate cluster-level summary analysis was done the control arm with the women's FP education arm and the male involvement in FP education arm with the control arm by considering the cluster effect. It should be noted that, the interest of this study was to compare the control arm separately with the intervention arms. Hence, no analysis was made between male involvement in FP education and women's FP education arms. Finally, the result of FP use and the intention was described with t-test, degree of freedom(df), P-value, mean value of both groups (control and intervention), and adjusted risk with its 95% CI. Moreover, the prevalence ratio (the number of FP users at the end line divided to baseline) was done. Along with odds ratio were calculated for FP use and intention to use from the absolute risk value manually to make our interpretation more understandable and informative (32).

### **Any changes to the trial outcomes after trial commenced**

Even though, we strictly follow the protocol we have the following deviation from the original: First, in the beginning, we intend to provide the intervention for six months, however as the project life extended we provide the intervention for 9 months ; Second) we plan to analyze that data using Generalized estimating equation (GEE) which allows for baseline or covariate adjustment in the final model. However, we are unable to run the model with GEE due to the limited number of clusters per arm (<15). Hence, we use cluster-level summarizes to analyze the collected data and to report our result (32).

## **Results**

### **Participants and cluster flow**

A total of 43 clusters were eligible for the study, out of these 7 clusters did not fulfill the inclusion criteria (30 households, which contains married women and less) and 3 clusters were unable to reach due to the breaking of the bridge due to flood. Hence, 33 clusters were allocated to women's education, male involvement in FP education, and control arm. Hence, the 33 clusters were followed and analyzed. And there was no attrition from clusters. The variance of the cluster for FP use in the women's education on FP arm was 10.03 and 12.29, respectively before the intervention and after provision of the intervention (Figure 2). The trial stayed for a total of 9 months; start at Jan-2018 and the trial ends on Sep-2018.

### **Baseline and end-line data information of respondents on selected variable's**

A total of 891 respondents with 297 in each arm participated in the baseline data. In the male involvement in FP education arm, the mean age of the respondents was 25.9 ( $\pm 6.42$ ), heard of FP 269(90.6) and use of FP 17(5.72). Furthermore, in the end line data the mean age was 26.8 ( $\pm 6.10$ ), heard of FP 279(90.3) and use of FP 102(34.3) in the male involvement in FP education arm in FP education

arm. Hence, the prevalence ratio (end line FP users divided to baseline FP users) was 1.8 in control, 3.7 in women's FP education, and 6 in the male involvement in FP education arm (Table 1).

### **Estimation of FP use among married women per their arms**

The level of analysis in this trial was cluster-based. The number of respondents (proportion) reporting yes in use of FP was 13(0.48), 52 (1.93), and 102(3.78) among the control, women's FP education, and male involvement in FP education arm, respectively. Besides, the cluster mean (SD) for responding yes to FP use was 0.043(0.03) in control, 0.175(0.05) in women's FP education and 0.343(0.09) in the male involvement in FP education arm (Table 2).

### **Characteristics of FP users by study arms in the end-line data**

In the male involvement in FP education arm, 9(8.8%), 10(9.8%), and 17(5.7%) of the FP users accounted for the respondents or their husbands with community responsibility of religious, clan, and faema leaders, respectively. Depo-Provera was the most common 87(85.3) type of FP used in the male involvement in FP education arm. Eighty-eight (86.3%) and 86(97.7%) of the respondent in the male involvement in FP education arm, they disclose to their husband for using FP currently and they provide different types of support, respectively. These supports were accompanying to health facility 66(76.7%), reminding the schedule 81(94.2%), and participating in choosing the type of FP (Table 3).

### **Effect of community-based interventions (women's education on FP and Male involvement in FP education) on FP use**

The difference of FP use in women's education on FP and control arm is 0.13 and the 95% confidence interval is 0.08 to 0.17. And without the intervention (control arm) the proportion of FP use is about 4.3% and with the intervention of women's education on FP, it is 17.5%, an absolute risk increases of about 13%, but this might be as little as 8% or as much as 17%. Besides, to the male involvement in FP education versus the control arm in FP use, the difference is 0.29 and the 95% confidence interval is 0.23 to 0.34. And without the intervention (control arm) the proportion of FP use is about 4.3% and with the intervention of male involvement in FP education is 34.3%, an absolute risk increases of about 29%, but this might be as little as 23% or as much as 34%. Along with, the baseline characteristics of FP use were not significantly different from the control group with male involvement in FP education ( $t=1.82$ ,  $p$ -value=0.0895). Moreover, the FP use for control arm in the baseline data was not significantly different with women's education on FP arm ( $t=1.4$ ,  $p$ -value=0.1823). Furthermore, information on intention to use of FP shows that the difference of high intention to use of FP and its 95% CI among the women's education on FP and male involvement in FP education with control arm is 0.18(0.03,0.31) and 0.3(0.17,0.42), respectively. And without intervention, the proportion of women who has high intention to FP use is 12.9%, an absolute risk increase of about 1.8% among women's education on FP and 3% in male involvement in FP education arm (Table 4). Married women in the male involvement in FP education and women's education on FP have an approximate odds ratio of 11.4(6.23,20.93) and 4.6(2.46,8.71) more likely to use FP as compared with the control group, respectively. Similarly, married women in the

male involvement in FP education arm and women's education on FP arm have 3.4(2.48,4.91) and 2.1(1.50,2.95) high intention to use of FP, respectively as compared with the control arm.

### **Any potential harms of the trials**

The study report that there was no adverse event following the provision of the intervention due to the following reason;1) the decision for taking contraceptive mainly depends on the informed choice of the married women, 2) the provision of counseling was provided by a trained health professional at healthcare facilities and it includes management of potential side effect and action to be taken,3) there was a team which deals with data monitoring safety which was responsible for the provision of the intervention based on the protocol.

## **Discussion**

Our finding revealed that women's FP education and male involvement in FP education as a community-based intervention bring a significant change in increasing FP use and intention among the pastoralist community. Clustering effect was considered during data analysis. The difference of FP use in the male involvement in FP education and in women's education on FP arms as compared with the control arm is 0.29(0.23,0.34) and 0.13(0.08,0.17), respectively. Similarly, the proportion of FP use is 29% in the male involvement in FP education, 17.5% in the women's education on FP and 4.3% in the control arm. Along with, married women in the male involvement in FP education have high odds ratio of FP use 11.4(6.23,20.93) and high intention to use of FP 3.4(2.48,4.91) as compared with the control arm whereas it was 4.6(2.46,8.71) for FP use and 2.1(1.50,2.95) high intention to use of FP in the women's education on FP arm. It was cognizant that comparison on FP use and intention was made the two intervention arms (the male involvement in FP education and women's education on FP) separately with the control arm. It should be noted that the aims of this was to compare the control arm with the interventions arm and not between the two intervention arms. The study was done among 33 clusters with three arms: women's education on FP, male involvement in FP education and control arm. It was accompanied by applying different interventions; delivery of FP message by faema leaders, video-assisted message on FP and assisting the faema leader by HEW and health workers.

A quasi-experiment study in rural Vietnam reports a significant change in increasing the intrauterine device (IUD) utilization between the control and intervention groups. The intervention intended to provide tailored messages and counseling on IUCD for the male to make/allow his wife to use in the intervention group, while no intervention was done in the control group. The intervention was made two round contact in 6-months and it was guided by social cognitive theory(33). In line with this, our study revealed that a significant increment in FP uses for married women in the male involvement in FP education arm as compared with the control arm. Importantly, our study differs in the provision of health education message as compared with Vietnam study in which the delivery of the health education message on FP was on a group setting using the male faema leader to approach the male in a cluster/kebele. However, the Vietnam study uses a couple based for the provision of an FP message to ensure spouse

communication. Along with, approaching males via male in a group discussion on FP, a video assisted message on the importance of FP with their religion was delivered by religious leader to strengthen the FP message. In addition, we have a basic difference in the time of health education provision in which we give for a total of 9-months with twice a month whereas the Vietnam study made a two-round contact in a 6-months. It should be noted that male involvement in FP education helps not only in accepting a contraceptive but also in its effective use and continuation. One mechanism to improve male involvement in FP education could be achieved by the provision of health education messages to bring a positive attitude towards FP use (34). This implies involving male in FP service would help him to discuss freely with his wife, allow her to use, and accompanying her and provide financial support which in turn increase FP use and intention.

Furthermore, male involvement in the Maternal, Newborn and Child Health (MNCH) in the pastoralist community of Kenya brings an increment in the service utilization other than FP. Importantly, using the male structure (Boma model), they mobilize community, harmonization, and integration of different community structures, women empowerment and enhancing community participation in health service delivery (17). This illustrates male involvement is feasible and brings a remarkable change in the pastoralist context. It should be noted that, married women in our study embedded in strong religious and cultural perspectives which favors a large family size, high husband objection for not practicing of FP and poor decision-making for FP use (9, 10, 25). Moreover, all aspects of the health and wellbeing of the pastoralist women strongly affected by religious perspective and belief -(18)- and the community believed that all health problems are caused by supernatural forces (35). And, such strong resistance on FP can be resolved with a continuous discussion with the influential groups such as religious leader and male involvement in FP education on the importance of FP as it was evident in our study. For instance, a religious leader teaches the community on FP don't contradict with Islam religion. As a result, a considerable number of married women whose husband participating in community responsibility of either religious or clan leader start to use FP in our study. Hence, having male involvement in FP use would be crucial to increase the number of women who use FP and intention as it was evident in our study. Hereafter, this would create a golden opportunity for the women to use FP which help to improve the health status of the mother and her child by having optimal birth spacing, mitigate unwanted pregnancy and its consequence, improves the economy of the household and mental satisfaction.

A quasi-experimental study design in Military Barrack of Nigeria shows that a significant increment of contraceptive prevalence rate (CPR) in the intervention group than the control group. The CPR increase from 11.8% at baseline to 22.4% post-intervention (McNemar's  $\chi^2 = 125.41, p=0.0000$ ) whereas it was from 16% to 17.3% (McNemar's  $\chi^2 = 281.82, p = 0.09$ ) in the control group. In the study a total of 943 married women, 642 in the control and 321 in the intervention group were included. An interactive health education intervention on FP was carried out for 50 minutes followed by a question and answer session. The health talk was delivered by a health educator. Hence, the end line data was collected three months after the health education intervention started. The same individuals were interviewed in both the baseline and post-intervention phases(36).

A quasi-experimental nonequivalent control group design to evaluate the impact of community-based contraceptive distribution (CBD) in rural Mali revealed that an increment of FP use. The study employs three groups: community-based contraceptive distribution (CBD), education only and control arms. In the CBD, in assistance of the local chief, each village asked to select a FP promoter (male and women). They were responsible to provide FP education via group meetings, home visits and to sell contraceptives for the same sex. In addition to this, intensive training was given for community health agents and nurses to provide education only in the second arm whereas no intervention was done in the control arm. Overall, they found a large increment of any modern FP in the CBD(1 to 31%) following the control arm (2-14%) and education only (0 to 10%) (37). In line with the Mali study, our study uses a similar principle of approaching males via males and women via women in an area where the women had poor decision-making power in FP use and brings a significant change in FP use. We use a community-based structure (faema leader) which has high acceptance in the community. However, we have a difference in the strategies with the following points 1) use a faema leader to teach the community on the importance of using FP by providing health education not on selling the contraceptive, 2) the provision of health education about FP was given with a regular schedule(twice a month) despite of the interruption of the intervention delivery in the Mali's study 3) To strengthen the health education message on FP we add a video assisted message of influential groups(married women who start FP use, male who actively involved in FP service, religious leaders and district's FP experts) and 4) to monitor the progress of the intervention we use a log book which was monitor monthly by the research team whereas service statistics,activity report and interviews with trainers was used in a Mali study 5)time variation in the provision of the study which was 9-months in this study whereas it was 18 months in the Mali's study. Along with, the Mali study face the following challenges; contraceptive stockout, unable to give the education of FP by the promoters due to illness and not having a regular basis in the provision of education. Hence, our study was a novel in reducing the work burden on the faema leader by making them to focus on the provision of health education instead of selling contraceptive and collecting money. This implies that approaching the community via community and using a comprehensive community-based intervention would be vital to enhance FP use in area with low FP coverage and women influenced by multifaced factors.

A cluster-randomized controlled trial (CRT) with the Bandedereho couples' intervention in Rwanda engaged men and their partners in participatory, small group sessions of critical reflection and dialogue. From its 15 sessions on a different topic, FP included as one session with the aim of the description on the benefits of FP, provide information on different contraceptive methods and the value of couple communication. And they found a significant improvement of FP in the intervention as compared with the control group (38). A similar CRT in India with the focus of married men and couples brings a significant change in contraceptive use. It uses assessment, dialogue, education, FP goal setting & action plan, and provision of condoms and pill as well as contraceptives using trained village health care providers (39). The above findings support our study in which male involvement in FP education brings a significant change in FP use as compared with the control arm. This implies involving male in FP service

would be crucial to increase the uptake of contraceptive through encouraging inter-spousal communication, allowing his wife to use FP and provide support.

In line with our study, different study done elsewhere on community-based interventions using different approaches. To list some of these studies, a quasi-experimental with a control arm research design done in rural India. They carried out different intensive community mobilization at different level; women, spousal, family, community and health system level to enhance contraceptive uptake. On the women level they approach them via group meeting and individual counselling by frontline functionaries. On the spousal level they improve inter-spousal communication and decision making by encouraging partner involvement where as at family level they support daughter-in-law to have birth spacing. At the community and health system level they involve influential community members and strengthen the capacity of health care providers and frontline functionaries to develop better understanding of FP, respectively. Along with different behavioral change communication strategies including wall writings, IEC materials, community sensitization, activation of village health committees and folk and print media to promote FP use among married women. The intervention was carried out for 18-months. Accordingly, the increased CPR from 32 to 59% (27% point of change) in the intervention area where as it was only 5% point of change from 35 to 40% in the control area. (14). In line with the above study, a two-armed cluster randomized controlled trial in rural district of India on CHARM [Counseling Husbands to Achieve Reproductive health and Marital equity] with a three-session gender equity and FP counseling intervention delivered by male health care providers to married men, and with their wives to improve contraceptive uptake for the total of 18 months (baseline, 9 and 18 months follow-ups). After the baseline survey male village health system trained and approach husband in the intervention arm to implement CHARM. Counselling sessions delivered by trained male health care providers to married men (sessions 1 and 2) and couples (sessions 3). They use pictorial information on FP, barriers to FP and the importance of healthy and shared FP decision making. In addition, they offered condom and oral contraceptive pills. It uses social cognitive theory (SCT) to guide the intervention. Along with the health care providers in the intervention were trained to implement the CHARM intervention (FP counselling). Accordingly, women from the CHARM intervention more likely to use contraceptive at 9 and 18-months follow-ups than the control arm(40).

Furthermore,, in the Kinshasa study, they recruited community-based distributors (CBDs) to increase FP uptake through a group discussion, individual counseling, distribution of contraceptive (condom, pills, and CycleBeads) and arranging referral (41). Also, a study in Bahir district of India reports that an increment of FP following provision of training to the rural provider and community leaders, group meeting, and disseminating message using street theatre and wall painting for a total 21–27 months. A male and female agent was used to approach the men and women group, respectively in providing information and arranging referral as part of the intervention (13). Along with, a retrospective pre-post study in Pakistan on a community-based integrated approach to change women's FP behavior for the past 24 months and they found that an increment of 10.7% contraceptive prevalence rate with Sukh's initiative: create awareness, encourages intra-spousal communication, distribution of contraceptive and arrange a referral for better service (42).

The above-mentioned study done elsewhere (Rural India, Bahir district of India Kinshasa and Pakistan) they bring a significant change in the uptake of contraceptive. It should be noted that using different intervention (Group meeting and individual counselling, improve inter-spousal communication and decision making, supporting daughter-in-law to have birth spacing, involving influential community members and strengthen the capacity of health care providers, wall writings, IEC materials, community sensitization, activation of village health committees and folk and print media to promote FP use among married women, use pictorial information on FP, provide training to rural provider, disseminating message using street theatre and wall painting, creative awareness, distribution of contraceptive and arrange a referral for better service). Hence, our study was in line with the above interventions like involving influential person, group meeting, creating awareness, arranging referral to health facilities, and capacitating health professionals) and using a behavioral model to guide the intervention. However, it was different in terms of supporting daughter-in-law and using wall writing instead of we use audio-visual (video recorded message of influential person) to express their experience on FP, perspective FP vs religion and the benefit, type and effectiveness of FP. Also, we have a difference in the time provision of the intervention, we provide the intervention for 9-months whereas the above studies give the intervention for long period of time (18-21 months). This implies health education including women's education on FP is a good intervention to improve FP use by empowering the married women to have good knowledge, positive attitude and high intention to use of FP. The overall married women capacitating through FP health education could be positively strengthen their ability to convince the influential group (husband, clan and religious leader), positively influence their neighbored women and her child, increase access to information, easily absorb health education messages, critically think and take corrective action like using FP.

Our study deploys different interventions to bring a significant change in FP use. One of the strategies is to train faema leader-(21)- to teach the community member in their catchment. The teaching community is a novel strategy to bring a behavior change, however, such novel strategy would be effective if the change comes from the change agent as it was evident in our study where a considerable faema leader uses FP. However, when we see the method mix, most of the married women use short-acting contraceptives. Hence, further effort is needed to shift the short-acting FP users to long-acting FP which is effective, cheap, reduce work burden and needs less visit of the married women to the health facility(43).

Our study account that there was a significant change in intention to use FP in male involvement and women's education on FP arm following the provision of FP education by faema leaders as compared with control arm. This also supported by other studies conducted elsewhere (37, 44-47). The effect could be explained by the fact that having good/high intention is an important factor for women to use FP by considering the effect of having comprehensive knowledge and a positive attitude towards FP use

A study in rural Mali identifies the following challenges; community reluctance to accept FP message and use, insufficient funds to purchase contraceptive, unable to cover all the segment of the community in the provision of health education, religious influence with the concept of contraceptive use is prohibited by Islam fear of the community member to included their name in the promoter notebook. To overcome such

challenges, increasing the number of the education sessions, arranging a group talk in a break and reassured the community names and personal information would be kept confidential by the promoters (37). Similarly, a study in Kinshasa, DRC identify weak Interaction with clinical services, having weak support and supervision of community-based distributors and recurring stock-outs of contraceptive as main challenges (41). In line with these studies, our study deploys the following mechanism to minimize the challenges in the provision of the interventions. First, a tailored message which has high acceptance by the community was discussed. Accordingly, the emphasis was given to FP for spacing than limiting. Second, influential groups like religious leaders were approached and reach in consensus to disseminate information on FP using recorded video in the male involvement in FP education arm. Along with this, we use a video recorded message of (married women who start to use FP, male who actively involved in FP service and district's FP expert) on FP to educate and positively influence the community on FP use and to enhance the health education on FP given by the faema leaders. Third, we provide an education message on FP to promote and to ensure spousal communication and male support to enhance FP use of married women. Fourth, adequate preparation on the mobilization of the community member to attend the group FP education was done continuously by the faema leader in assistance with the HEW. Fifth we engage the important stakeholder from the beginning to avail contraceptive, method mix, counseling based on the informed consent and to provide the FP service without a fee.

Our study is a novel study on pastoralist communities in the area where married women embedded with strong cultural and religious perspectives promotes a high number of children and low FP coverage. As an approach, we use the existing community-based structure like faema which has a high acceptance in the community to enhance the number of FP users and intention. Also, we employ a cluster randomized controlled trial study design, which is methodologically strong and an integrated behavioral model (IBM). The IBM is suitable in areas where the use and decision to use FP service affected by different multifaced factors (relatives, neighbors, husband, religious, and clan leader). The model is more comprehensive than earlier behavioral models (such as Theory of reasoned action and theory of planned behavior). And it is capable of explaining a higher portion of the variance of the behavior (FP use and intention) under investigation. To enhance the predicting power of the model, we also adapted women's knowledge and male involvement in FP use. Moreover, approaching the community with the community's existing structure like faema which has a separate structure for both sexes, high acceptability, and long history would be vital for its feasibility and scale-up the future FP programs. Finally, our study uses a reliable and valid tool on family planning with the pastoralist context(31).

As a limitation of our trial, the evaluator of the outcome measures was not blinded to the type of intervention. Since the number of clusters allocated here are small, we employ a cluster-level summary analysis that did not account for covariate or baseline data adjustment in the final model. However, the proportion of women who use FP in the control arm vs male involvement in FP education and control arm vs women's education on FP is not significantly different at the baseline data. Moreover, the intervention period (9 months with the provision of education twice a month) may be a short time to bring a huge change in FP use and intention. Finally, our study will be generalizability intends to similar pastoralist community. Furthermore, even though CRT prefers to prevent contamination of information, we did not

employ a buffer zone. However, the intervention cluster was separated from the control cluster by a distance of 20-40 km.

## Conclusion

The present study highlighted the effectiveness of women's education on FP and male involvement in FP education brings a significant change in increasing the number of women who use FP and intention. Using the community-led support groups in the pastoralist community appears to be effective in increasing the number of women FP users and intention to use. Health education on FP using different intervention; educating community led-support, use of video assisted message and involving religious leaders are absolutely needed. There is an urgent need to plan interventions through women's education about FP and actively involved male in FP education for better FP use.

## Abbreviations

AOR, Adjusted Odds Ratio; AMREF, Africa Medical Research Fund; CPR, Contraceptive Prevalence Rate; CRT, Cluster-Randomized Controlled Trial; DFID, Development for International Fund; RIF, Reproductive Innovative Fund; EDHS, Ethiopian Demographic Health Survey; FMOH, Federal Ministry of Health; FP- Family Planning; HSTP- Health Sector Transformation Plan; TFR- Total Fertility Rate; WHO, World Health Organization

## Declarations

### Ethics approval and consent to participate

The study protocol was approved by the Institutional Review Board (IRB) of Mekelle University College of Health Sciences with a reference number of ERC 1435/2018. Permission was obtained from all relevant authorities in the Afar regional health bureau and participating district health offices. In the beginning, community consent was secured from the influential group (religious and clan leader). Verbal consent was secured before conducting the interviews. A one-page consent letter was attached to the cover page of each questionnaire as an information sheet which includes a detail description about the purpose of the study, benefit, and risk of participating in the study, participation is voluntary, the right to withdraw from the study, identification of informant was possible only through specific identification numbers and the privacy and confidentiality of collected information. The trial was registered in a ClinicalTrials.gov with a reference number of NCT03450564. And it can be accessed using <https://clinicaltrials.gov/ct2/show/NCT03450564>.

### Consent for publication

Not applicable.

### Availability of Data and Materials

Our data will be available upon a reasonable request and researchers would access an anonymized version of the data set either from the BMC Women Health Journal or through a direct request to the corresponding author via email ([mossalex75@gmail.com](mailto:mossalex75@gmail.com)).

### **Competing interests**

The authors declare that they don't have competing interests.

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### **Authors' contributions**

MA contributed to the initiation of the study, design, data collection, data analysis, and write up. AAM and AM contributed to the initiation of the study, design, and write up. ER contributed to the interpretation of the findings and write up of the manuscript. All authors read and approved the final manuscript.

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## Tables

Table 1:- Before and after the provision of the intervention information per women's education on FP, and male involvement in FP education, and control arm among Pastoralist married women Afar, 2019

Variables	Arms					
	Control		Women's education in FP		Male involvement in FP education	
	Baseline data n (%)	End line data n (%)	Baseline data n (%)	End line data n (%)	Baseline data n (%)	End line data n (%)
No of women	297	297	297	297	297	297
Mean (SD) age (years)	25.3(6.49)	26.9(6.72)	26.3(6.84)	26.4(6.75)	25.9(6.42)	26.8(6.10)
Heard of FP	252(84.8)	240(80.8)	265(89.2)	265(89)	269(90.6)	279(93.9)
Use of FP	7(2.35)	13(4.3)	14(4.71)	52(17.5)	17(5.72)	102(34.3)
Prevalence ratio (end line/baseline data) on FP use	1.8		3.7		6	

Table-2: - Cluster level numbers and proportions of pastoralist mothers reporting yes to overall FP use in women's FP education, male involvement in FP education and control arms following the intervention, Afar, Ethiopia, 2019

Clusters	Arms								
		Control (m=11 clusters)		Women education on FP education (m=11 clusters)			Male involvement in FP education (m=11 clusters)		
	Cluster size	# in clusters reporting yes	Cluster proportion reporting yes	Cluster size	# in clusters reporting yes	Cluster proportion reporting yes	Cluster size	# in clusters reporting yes	Cluster proportion reporting yes
1	27	1	0.04						
2	27	1	0.04						
3	27	2	0.07						
4	27	2	0.07						
5	27	0	0.00						
6	27	2	0.07						
7	27	1	0.04						
8	27	2	0.07						
9	27	2	0.07						
10	27	0	0.00						
11	27	0	0.00						
12				27	6	0.22			
13				27	4	0.15			
14				27	5	0.19			
15				27	7	0.26			
16				27	5	0.19			
17				27	7	0.26			
18				27	2	0.07			
19				27	5	0.19			
20				27	4	0.15			
21				27	4	0.15			
22				27	3	0.11			
23							27	10	0.37
24							27	11	0.41
25							27	13	0.48
26							27	9	0.33
27							27	14	0.52
28							27	9	0.33
29							27	7	0.26
30							27	8	0.30
31							27	6	0.22
32							27	7	0.26
33							27	8	0.30
Totals	297	13	0.48	297	52	1.93	297	102	3.78
Mean (SD)			0.043(0.03)			0.175(0.05)			0.343(0.09)

Table 3: -Description of FP users by selected variables per arms in Afar, Ethiopia,2019

Variables	Category	Arms		
		Control	Women's education on FP	Male involvement in FP education
		Use of FP	Use of FP	Use of FP
		n (%)	n (%)	n (%)
Community responsibility of respondent's husband	Religious leader	0(0.0)	3(5.8)	9(8.8)
	Clan leader	3(23.1)	5(9.6)	10(9.8)
	Faema leader*	1(7.7)	5(9.6)	17(5.7)
Type of current FP use	Pill	1(7.7)	4(7.7)	6(5.9)
	Depo-Provera	8(61.5)	45(86.5)	87(85.3)
	Implanon	2(15.4)	2(3.8)	8(7.8)
	Others **	2(14.4)	1(1.9)	1(1)
Disclose to their husband for using FP currently	Yes	5(38.4)	39(75)	88(86.3)
Get support from husband for use of FP	Yes	4(80)	39(100)	86(97.7)
Type of support from husband on FP use	Accompany to a health facility	2(50)	26(66.7)	66(76.7)
	Reminding the schedule	1(25)	33(84.6)	81(94.2)
	Participate in choosing the type of FP	1(25)	21(53.8)	62(72.1)
	Helping in domestic activity	2(50)	26(66.7)	64(74.4)

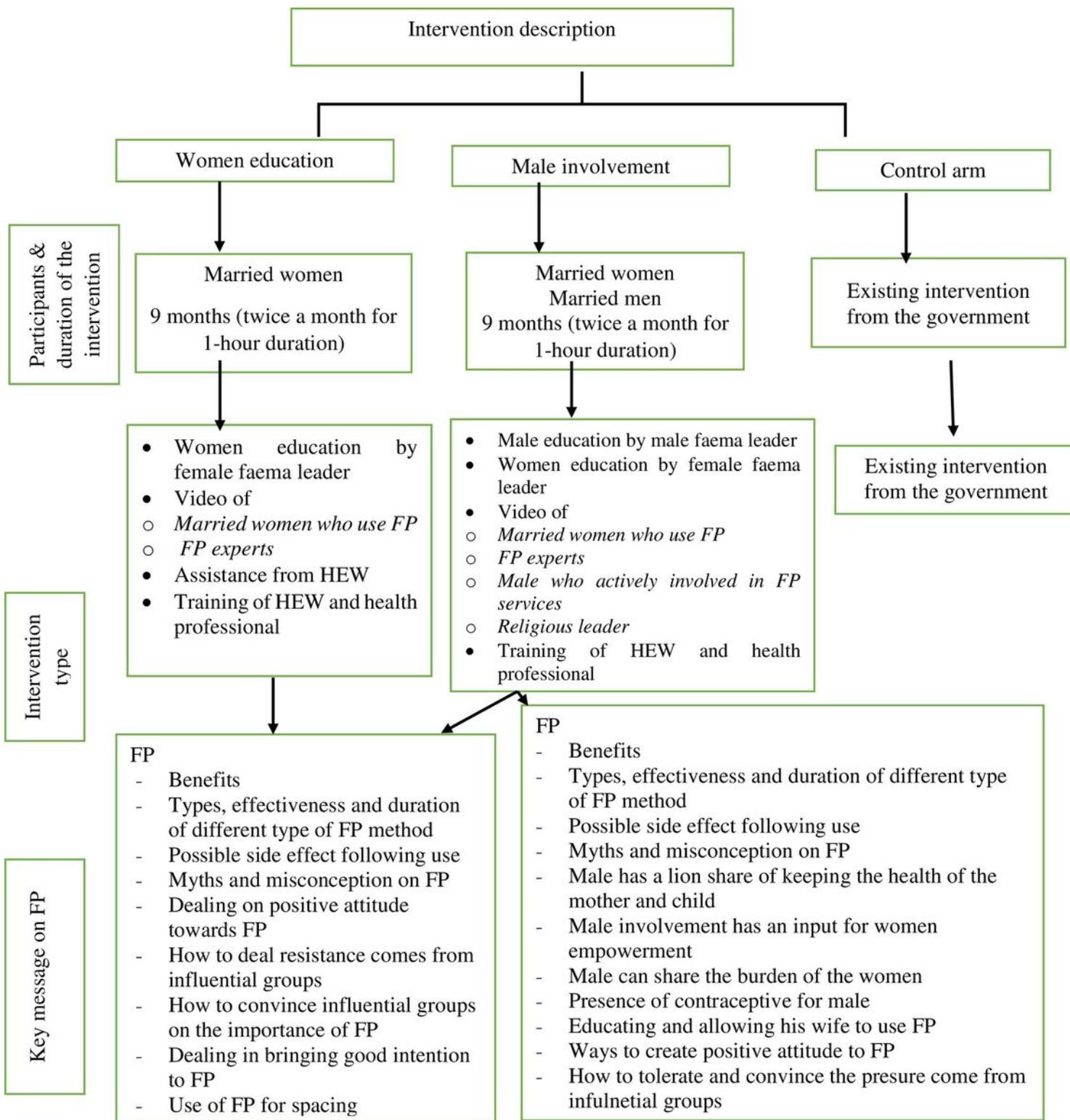
\*Applicable for both married women and men; \*\*Condom, Jadelle.

Table 4: Estimated independent t-test coefficients to show the effect of male involvement in FP education, women's education on FP versus control arm on FP use, Afar 2019.

Outcome	Mean Value		t-test	df	P-value	Absolute Risk	95% CI	
	Intervention	Control					Lower	Upper
<b>FP use</b>								
Male involvement in FP education	0.34	0.043	10.01	12.3	0.0000002*	0.29	0.23	0.34
Women's education on FP	0.17	0.043	6.59	15.7	0.000006*	0.13	0.08	0.17
<b>Intention to use of FP</b>								
Male involvement in FP education	1.59	1.29	5.14	19.7	0.00005*	0.3	0.17	0.42
Women's education on FP	1.47	1.29	2.52	19.1	0.02*	0.18	0.03	0.31

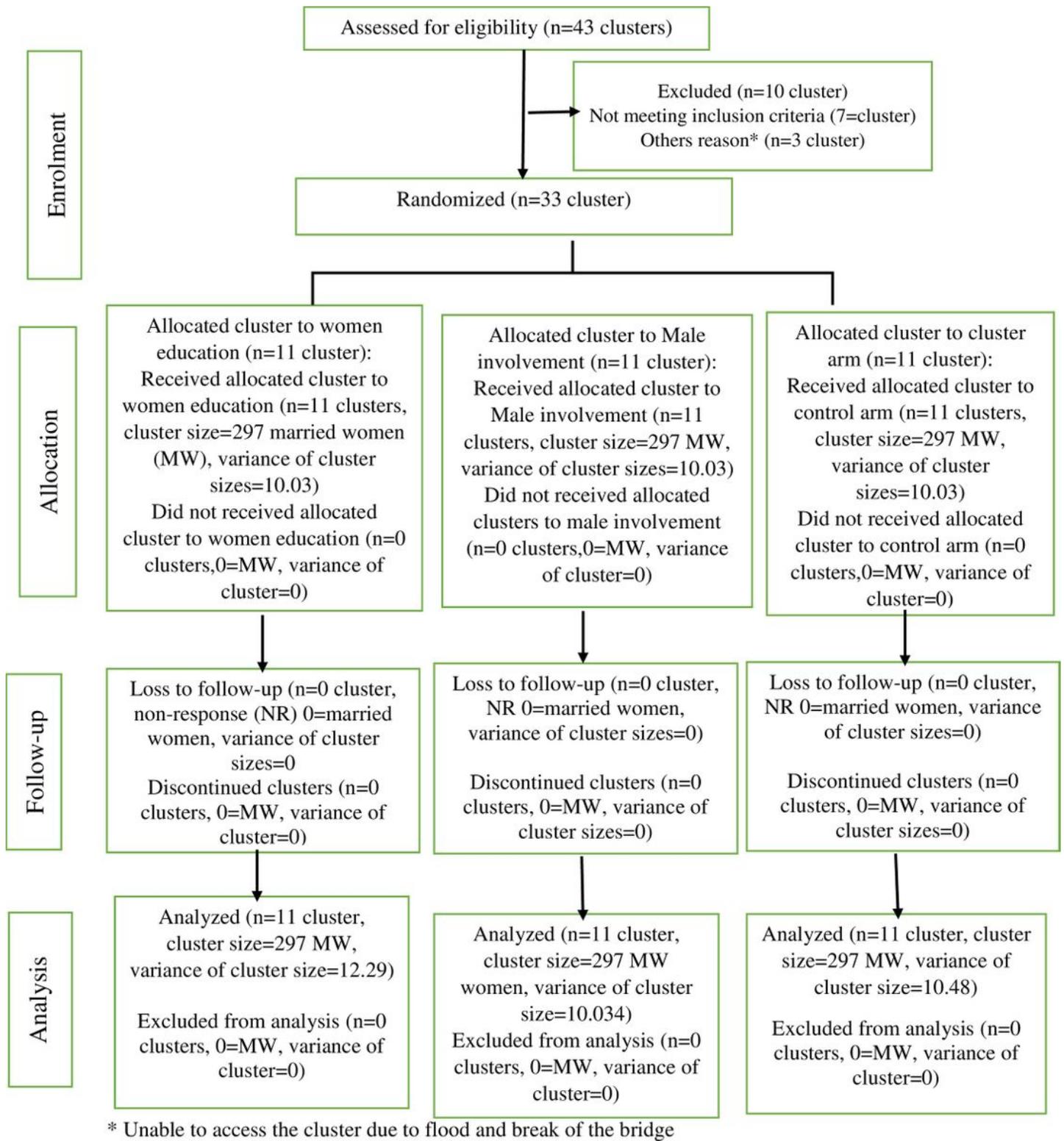
\*significant at p-value <0.05

## Figures



**Figure 1**

Type of family planning education per arms among pastoralist community Afar region, Ethiopia, 2019



**Figure 2**

Participants and cluster flow of the trial among pastoralist community Afar region, Ethiopia, 2019

## Supplementary Files

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