

The Effect of Community-Based Interventions on Increasing Family Planning Utilization in Pastoralist Community of Afar Region Ethiopia: A Cluster Randomized Controlled Trial

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## Summary

**Introduction:** Pastoralism, practiced on a quarter of the globe's surface. An estimated 50 million pastoralists live in sub-Saharan Africa. In Ethiopia, pastoralist community contributes to 12-15% of the total population and 60% of the surface area. Based on the report of Ethiopian Demographic Health Survey 2016 (EDHS) report, Ethiopia shows an impressive gain in family planning utilization. However, such gain is not uniformly distributed across the agrarian and pastoralist region. The Afar region was one of the regions with low performance of family planning utilization (11.6%). Therefore, this study aims at quantifying the effect of the community-based intervention which includes male involvement and women education on increasing family planning service utilization in pastoralist community from Afar region.

**Methods:** A cluster randomized controlled trial with three arm studies will be employed in 33 clusters of pastoralist community from Afar region. The intervention includes women education and male involvement in family planning utilization and this will be compared with the control group. A total of three data at pre-intervention, midline (follow-up) and post-intervention data will be collected with a four and half months time gap. The data structure will be restructured following collecting the baseline data to enable for follow up of the mother. Open data kit (ODK) will be used to collect the data and data will be analyzed by using R software version 3.4.2. Intention to treat analysis will be used as a framework for analysis. Generalized estimated equation analysis will be carried out to quantify the effect of the community-based intervention on family planning service utilization.

**Work plan:** A total of 9 months will be required to accomplish the goal of the research.

## Introduction

Pastoralism is the finely-honed symbiotic relationship between people, domesticated livestock and local rangelands in fragile and highly variable ecosystems, often existing at the threshold of human survival[1]. Pastoralism practiced on a quarter of the globe's surface[1]. An estimated 50 million pastoralists live in sub-Saharan Africa[2]. Pastoralism is one of the predominant livelihoods of East Africa. In Ethiopia, pastoralist community contributes to 12-15% of the total population and 60% of the surface area[3]. It contributes significantly to national economies and can conserve fragile natural resources. Yet, pastoralists remain socially and economically marginalized and have a little or no representation in local and national government[4]. Moreover, these mobile pastoralists are politically and economically marginalized and do not receive adequate support through governmental structures and technical cooperation[1]. Furthermore, the governments in the region continue to hold that Pastoralism is unsustainable and a barrier to development[4]. However, the community in pastoralist community can be benefited and improves their health by different intervention. Improving women health would be a central pillar. Family planning would be a cost-effective, simple and has many advantages for improving the health of the mother in general and pastoralist women in particular.

Family planning has been identified by the World Health Organization (WHO) as one of the six essential health interventions needed to achieve safe motherhood by reducing maternal and child mortality[5, 6]. Family planning saves [the] lives of women and children, improves the quality of life, prevents STI /HIV/AIDS and provides special nutritional benefits to the infant and protects the infant from infections. Use of FP prevents the depletion of maternal nutritional reserves and reduces the risk of anemia from repeated pregnancies and births. Women and couples who want safe and effective protection against pregnancy would benefit from access to more contraceptive choices[6, 7].

Globally, use of modern contraception has risen slightly, from 54% in 1990 to 57.4% in 2015. However, it was raised from 23.6% to 28.5% in Africa. 214 million women of reproductive age in developing countries have an unmet need for family planning. One-in-four women in Africa have an unmet need for family planning. The reason for high unmet need attributed to the limited

choice of methods, limited access to contraception, fear or experience of side-effects, cultural or religious opposition, poor quality of available services, users and providers bias and gender-based barriers. In addition, the involvement of men in family planning was very low which is manifested by the low use of contraception[6].

Based on the report of Ethiopian Demographic Health Survey (EDHS) report, Ethiopia shows an impressive gain in Reproductive maternal and neonatal health (RMNH). However, such gain is not uniformly distributed across the agrarian and pastoralist region. The changes for basic RMNH service in Ethiopia from EDHS 2000 to 2016 show that; Antenatal care (ANC) increase from 27 to 62%, institutional delivery from 6 to 28% and postnatal care within 2 days from 8% to 16.5%. Besides, the total fertility rate decreases from 5.5 to 4.8, even though the modern contraceptive increase from 6 to 36% [8-12]. Even though such changes are remarkable for the country, there is a big difference across the region particularly with the pastoralist community. Afar region is one of the pastoralist regions in the country. The Afar region is one of the regions with low performance of RMNH coverage. Accordingly, based on the report of EDHS, 2016 ANC fourth visit (20.6%), institutional delivery (14.7%), PNC visit within 2 days (11.6%) and family planning utilization (11.6%) [12]. Besides, such changes in the past 16 years were not noteworthy and based on the EDHS 2000 report the coverage modern family planning utilization was (7.4%)[9]. This low coverage of Family planning service in Afar region in particular and the pastoralist community, in general, could be attributed to the high influence of clan and religious leader and male dominance [13].

Furthermore, the life of pastoralist community depends on their livelihoods. Livelihoods of pastoral communities are vulnerable to sudden or gradual changes in social or ecological conditions (shocks and stresses). Mobility remains a highly effective coping strategy in such an environment [1]. However, evidence shows that the degree of pastoral mobility is going down [2]. This could be a nice opportunity for the government to strengthen the resettlement of these people by equipping the needs of their cattle's. Thus, will create a golden an opportunity to build infrastructure at nearby and increase the enrollment of girls to school which would have a long-term effect on empowering women.

Women's empowerment involves social change; even though, there are some resistances to the social change by traditionalist as a means a loss of power, status, and privilege for men. Many women work and earn incomes, but simply hand these over to their husbands [2]. But, women's empowerment is not necessarily a threat to men – it can bring better, more mutually supportive relations between men and women [2]. A context-based intervention could be a possible solution to bring a sustainable change for a pastoralist community. Besides, the strategies and intervention which are effective in the agrarian society may not work in the pastoralist community.

A previous study described the increase in RMNH service utilization among pastoralist community in the different area. These are male involvement through Boma model of AMREF Health in Kenya [14], having migratory routes of container clinic in the Turkana pastoralists [15] and addressing the need of pastoralist community through Mobile clinics which have been observed to be more cost-effective than fixed facilities and building maternity waiting for home [16], and one health approach, with the aim of joint training and interventions for vaccination for children and women and livestock [17]. However, there is a lack of information on the effect of the community-based intervention in increasing family planning service utilization. Our study hypothesizing that addressing intervention like women education and men involvement in family planning utilization would be a practical way to achieve family planning use in Pastoralist community of Afar region. Therefore, this study aims at quantifying the effect of community-based intervention namely education women on family planning and enhancing male involvement towards family planning use in pastoralist community of Afar region.

## Methods and Materials

### Study area

The intervention study will be done in Afar region. Afar Region is one of nine regional states of Ethiopia and has a total surface area of 97, 256 sq km. It extends all the way from Eritrea and Tigray in the North to Oromia regional state in the South and bounded on the East by Republic of Djibouti and Amhara regional state in the West. It is classified under the desert and semi-desert agro-ecological zone[18].

The region is divided into five zones, 32 districts, five town administrations and 404 kebeles (sub-districts) having an estimated population of 1,816,304 consisting of 799,174 (44%) females. Eighty-seven percent of the population is estimated to be rural and about 85% of the populations are pastoralist or agro-pastoralist and the majority of them are Muslim [18]. According to the Afar regional health Bureau report, the region has 1 regional hospital, 6 zonal hospitals, 92 health centers and 379 health post[19].

### Study period

The study/intervention will be carried out for 9months; October 1, 2017, to June 1, 2018. There will be collecting information about the outcomes events; intention to use and family planning use three times at baseline, midline and end line.

### Source population

All married women of the reproductive age group in Afar region.

### Study population

All married women of the three highly pastoralist districts(Afambo, Kori, and Mille) in Zone 1 of Afar region.

### Sample population

Randomly selected married women of the reproductive age group in the selected clusters of the three districts of Zone 1.

### Inclusion and Exclusion Criteria

Clusters which have 30 and above household will be included in the intervention. From the selected cluster, married women with reproductive age group (15-49 years) will be included in

the study. Women who are seriously ill and unable to communicate and who declared infertile will be excluded from the study.

## Variable

### Dependent variable

- Family planning use (use or not use)
- Intention to use of family planning (Low, moderate and High)

### Independent variable

The independent variable includes the following

- Socio-demographic and determinant of health,
- Reproductive history
- Knowledge of family planning
- Attitude on contraceptive, subjective norm and perceived behavioral control
- Media exposure to family planning.
- Male involvement in family planning

## Study design

A total of five objectives will be answered from the intervention study. The objective of the study will be related to each other. The only difference in the objective of the study is related to the study design and time of data collection.

Objective One: the objective of this study will be to describe the role of male involvement in intention to use of family planning. Besides, the woman actual behavior (use or not use of family planning) would be also measured. A cross-sectional study was employed to answer the objective of the study.

Objective two: The objective of this study will be to explore the progress of the intervention on family planning use following the delivery of the intervention. This will be carried out in the middle of the intervention with a 4 month and halftime gap. The study design will be embedded experimental model with one phase (at the middle of the intervention).

Objective Three: the third objective of this study will be to identify the behavioral determinant (Attitude, normative belief and perceived behavioral control) of family planning utilization. A nested case-control would be employed and the data will be collected in the midline following the provision of intervention. The study participants will be followed for 4 and half months. The intervention would be women education about family planning and male involvement to encourage his wife to use a family planning. Hence, following the provision of the intervention at the ground, there will be a woman who starts to use or not use of family planning. Accordingly, a married woman who starts to use family planning will be considered as “case”, while “control” will be labeled for married women who don't start to use family planning.

Objective four: The main aim of this study will be to quantify the effect of male involvement in increasing FP use.

Objective five: To quantify the effect of women education in increasing FP use. For objective four and five, a three-arm with a fixed sample size cluster randomized controlled trial study will be used. The data will be collected at baseline and end line.

### **Sample size determination**

Objective 1: The minimum sample size determination for this objective was calculated based on a single proportion formula with the prevalence of family planning in Afar region based on the EDHS 2016 report was 11.6% -[12]-, 95% confidence interval, margin error of 4% and a design effect of 3. Then, considering a 10% of nonresponse, the total sample size will be 822. However, the sample size for the intervention was 891, so this sample size was used.

Objective 2: Sample size will be determined based on the effectiveness of the intervention. At the mid of the intervention, the proportion of married women who start to use or not use contraceptive will be determined. Then, those married women who start to use contraceptive will be labeled as “case” and those who don't start to use contraceptive will be label as “controls”. The minimum sample size for the third objective will be determined by using Epi-info version 7. Accordingly, 15.1% of a woman based on the study done in Afar region, they don't want future child [13], the odds ratio of 2, case to control ratio of 1:2, and 10% of non-response, the total sample will be 179 cases and 358 controls.

Objective 3: the sample size for the qualitative study will be determined based on the saturation of information. However, for a planned purpose, six focus group discussion (FGD) which is four in the male arm (two for women and two for men) and two from women arm will be considered. Moreover, a total of four in-depth interviews (IDI) by selecting men who have an involvement in family planning and women who start to use family planning following the provision of intervention.

Objective 4 and 5: The sample sizes of this objective will be calculated by using the literature of Richard and Lawrence-[20]-to determine the number of clusters required to detect a difference among different arm in family planning utilization. Given a current family planning utilization in Afar region of 11.6%, based on the report of EDHS, 2016 [12]. The expected changes to be acquired following the intervention of 20%, 90% power, 95% confidence interval, considering intra-cluster correlation coefficient (ICC) variation of 0.05, adjusting for the loss of follow up or not response of individual in a cluster of 20% and design effect of 2.2 from clustering will be used for calculation of the sample size. The final sample will be 33 clusters. For one cluster, there will be 27 married women and it gives a total of 891 married women of reproductive age group.

The sample size for objective four “*to quantify the effect of male involvement in increasing FP use*”, will be 11 cluster and 297 married women and it will be the same for objective five “*to quantify the effect of women education in increasing FP use*”. At the end comparison of both interventions (male involvement arm and women education) will be made with the control arm. Hence, the overall sample size will be 33 clusters and 891 married women of reproductive age group.

### Sampling Procedure

**Objective 1:** First, three district which represents highly pastoralist community in the region were selected. Then, the number of clusters in the given district was listed. From the listed cluster, the total sample size was allocated equally to the cluster which gives 27 married women. A sampling fraction was calculated based on the number of women in the clusters. Married women were selected by systematic sampling technique. And random start numbers were selected to identify the first married woman to be included in the study.

**Objective 2:** The sampling technique for this objective will be collected at midline of the intervention. The same sampling procedure as objective one will be used. In addition, the internal assignment will be done for those married women who start to use family planning as “cases” and those married women who don’t start following the intervention will be labeled as “control”.

**Objective 3:** A purposive sampling technique will be used to select the study participants for the FGD and IDI. For the FGD, the participants will be selected based on their active participation in the provision of health education message in the intervention area. Men who have involvement or allow his wife to use family planning and married women who start to use family planning will be included to see the main reason for male involvement and use of family planning, respectively.

**Objective 4 and 5:** The sampling procedure for this objective will be answered by cluster sampling technique. First three districts will be selected, from each district; a total of 11 clusters will be selected randomly. From a given district, a total of 27 married women will be selected by systematic sampling technique. A sampling fraction will be calculated based on the total number of women in the cluster. A random start number will be selected to identify the first married woman to be included in the study. Hence, for objective 4 and 5 comparisons will be made; the male involvement arm and women arm with the control group, respectively.

## **Participants flow**

### **Recruitment Details**

The clusters will be recruited from three districts namely Mille, Afambo and Kori in Afar region. Accordingly, male involvement intervention will be done in 5 clusters of Mille, 4 clusters of Afambo and 2 clusters of Kori. And to the women arm the intervention will be carried out in 2 clusters of Mille, 5 clusters of Afambo and 4 clusters of Kori. Furthermore, 4 clusters of Mille, 2 clusters of Afambo and 5 clusters of Kori will be assigned to the control group. Allocation of the cluster to the intervention arm was due starting from October 1, 2017.

### **Pre-assignment Details**

Before assignment of the clusters to the intervention arm, a dissemination workshop was held in the study area. The way forward was discussed with stakeholder's from Afar regional health bureau, Federal Ministry of Health and a community representative (clan, faema and religious leaders, women affairs representative) and staffs of Mekelle and Samara University. The study considers 20% of the loss to follow up in the 9 months of the intervention study. Married women who are volunteering to participate in the study will be considered. For this purpose, the informed and information sheet of will be described in a detailed manner.

#### Arm/Group Information

The arm/ group information in this community-based study will be three. These are male involvement, women education, and control group. Accordingly, clusters were assigned to the three arms. Then intensive health education message based on their arm type will be delivered based on the information from the baseline finding.

#### Type of Units Assigned

The type of unit in this study will be clustered, in a total, we have 33 clusters which are equally divided into three clusters. Insides, a cluster, there will be married women and married men who would be a potential to get intensive health education message. Therefore, for one arm there will be 11 clusters and 297 married women which will be followed by the intervention period.

#### Period(s)

There are three times of gathering information about the outcomes events; intention to use and family planning use with a time gap of 4 and half month. The enrollment of the study within a cluster was enrolled starting from October 1, 2017, and anticipated to complete after 9 months follow-up. Besides, every month there will be a provision of health education message to intervention arms.

The study teams believe that all the study participants within the cluster to be completed the follow-up study. However, there might be some married women unable to interview due to various reason. The effort will be made to minimize the reason for not complete the study by strictly follow up the protocol.

## Baseline Characteristics

From each arm, a total of 11 clusters and 297 married women were collected. One cluster contains 27 married women. Descriptive statistics on socio-demographic characteristics, reproductive history, media exposure to family planning, male involvement towards family planning use and knowledge, attitude and practice about family planning was assessed. The descriptive label of the three arms was women education, male involvement, and control group.

### Intervention description:

The study aims at providing community-based intervention to increase the number of family planning users. These community-based interventions are educating women to use family planning and male involvement for use of family planning. And these interventions will be compared with the control group. At the initial stage, with the help of regional health bureau, a district which represents highly pastoralist and with a catchment of the capital city of the region “Semera” was selected. Accordingly, three districts namely; Mille, Afambo, and Kori were selected. Hence, an equal number of married women will be selected from these districts.

Each participating married women in the selected household (intervention arm) will receive a package of health education messages about family planning based on the intervention type. The type of health education will be contextualized to the target group namely women and men arm based on the baseline finding. In general, the women group will receive a health education message on the importance of family planning for spacing and limit the number of children. Besides, health education will be given for the purpose of family planning to improve the health of the mother and child and decrease maternal and child morbidity and to have a positive attitude.

Furthermore, in the men intervention arm, the same health education message will be given for the married women in the male intervention arm. Besides, enhancing male involvement through creating a positive attitude in family planning utilization will be given to the men. The study intends to provide different modalities of intervention at the community level. These are using health extension worker (HEW), “faema leader” ( a leader of existing structure in the community which helps to discuss about social issue and different events), use of role model from both

sides; married women and married men, use of audiovisual materials, and enrollment of clan and religious leader. A detail description of the intervention is described below.

### **Involvement of Faema Leader**

Faema is a structure composed of different individuals in the community which has a separate group for male and female. The faema group enables the community to share a different experience which has a potential to discuss the different aspect of health. They also support each other at different events like marriage, mourn and conflict resolution. The number of faema leader would be different from district to district depending on the number of population. For example in the male intervention, there are six male leaders and six female leaders and for the women intervention, there are 12 women leaders and control arm (8). Every two week there is an existing meeting with the community members to discuss different events. The research team will try to use this opportunity to discuss the community about family planning through using the faema leader and to conduct the meeting on regular basis. Initially, intensive training will be given to family planning for the faema leaders. Hence, efforts will be done to start the change from them and able to provide health education about family planning in their catchment area.

### **Use of Health Extension Workers (HEW)**

HEW will be also another existing structure of the government which intends to provide health education message about 17 packages of health. The first training will be given to family planning to the HEW. Then, the HEW will be responsible for providing health education for the married women and men and counsel them to use family planning. Accordingly, the HEW will be responsible for providing counseling and provision of family planning as goes through the house to house. In case of referral, they will respond to link the married women with health professionals at the health center. All the Health education content will be designed based on the finding of the baseline finding and efforts will be made to fill the gap. Besides, a log book will be used to monitor the provision of the intervention. In addition, to the above activity, they also responsible to support the faema leader while they provide health education to the community.

### **Use of Audiovisual Materials of Role models person in the community**

The audiovisual material will be used to deliver family planning message to the two intervention arms. An expert will be recorded at the local setting from role model in the community; women who use contraceptive and husbands allow his wife to use a contraceptive to share their experience. It will be transmitted in a social gathering at the cluster level. In addition, to the transmission of a message through audiovisual materials, a supplement of about the experience of the role model person will be delivered to the community. A total of 3-6 audiovisual materials will be recorded from both arms.

### **Active enrollment of clan and religious leader**

Clan and religious leader also used as input to deliver a message about the importance of family planning at any occasion like a mosque and social gathering to men. First discussion and consensus will be made about the importance of family planning. Then, they will be used as a key person to deliver family planning message to the men in the male involvement arm.

The above activities are a target at the demand creation. Hence, the health care providers working at health center will receive training about family planning including its type, importance, and counseling.

Accordingly, the above community-based intervention will be provided to the two intervention arms; male involvement and women education. And the basic difference in the deliveries of the intervention is described below.

### **Male involvement arm**

In pastoralist community, the most reason mentioned for not using of FP are husband objection and religious influence. And most of the decisions are in the palm of the husband to seek care for reproductive, maternal and neonatal health in general and FP in particular. Accordingly, the above all described intervention will be given to this arm namely; use of HEW to teach married women and men in their cluster, use of clan and religious leader, use of both faema leaders (male and female) and disseminate information through audiovisual materials and sharing experience of real experience of role model person.

### Women education arm

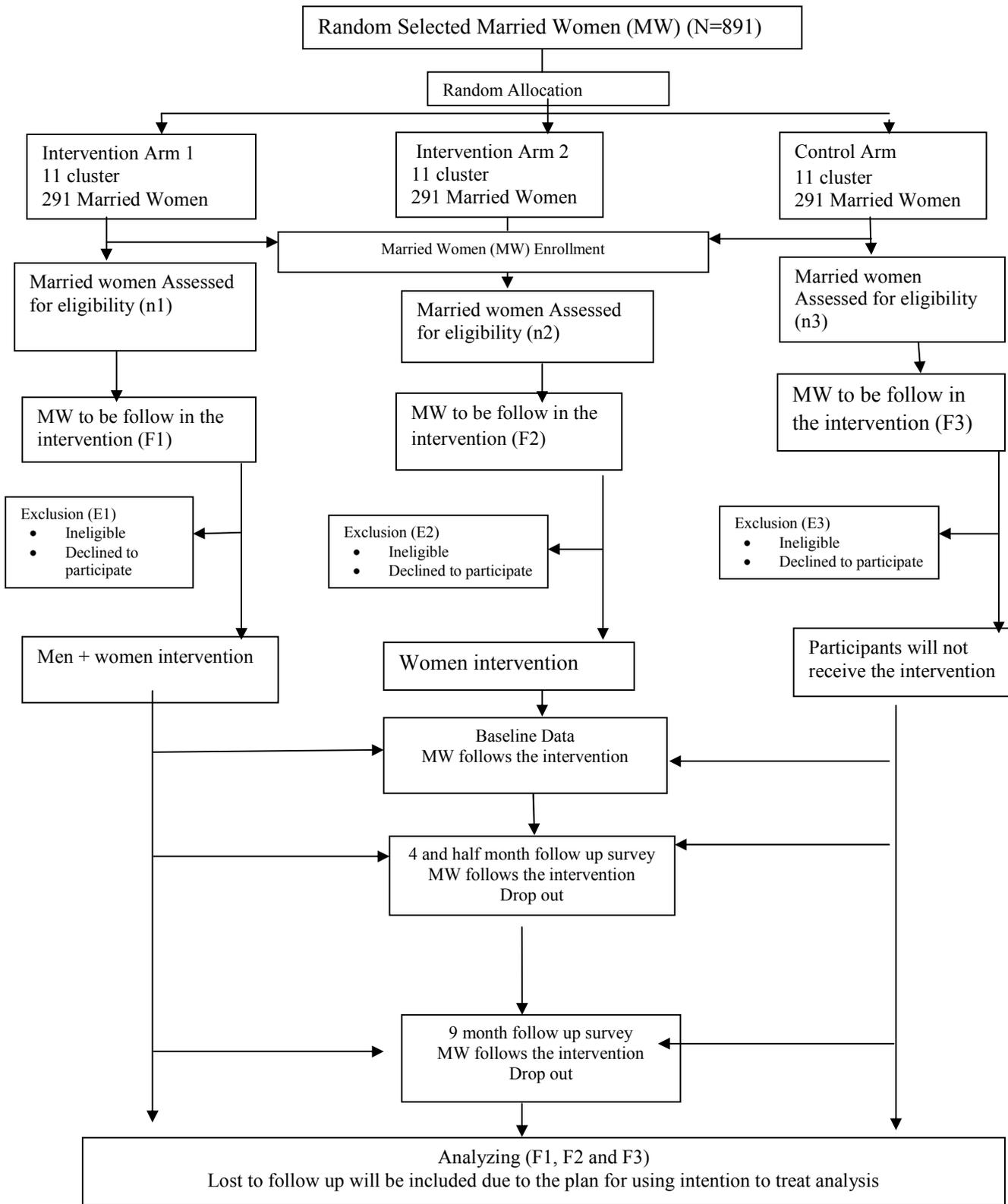
This intervention intends to provide health education message for married women to increase the utilization of family planning. In the married women arm, there will a similar community-based intervention with the male arm, except it lacks the use of clan and religious leader and male faema leader for the dissemination of information about family planning.

### Control group/arm

The third group in this community-based intervention will be following the community without a provision the above-listed community-based intervention. In this arm, there will be no intervention by the researchers, rather baseline and end line data will be collected.

### Consort Flow diagram

The detail description of the study protocol is described below using consort flow diagram. It includes information the type of intervention, the targeted person for the individual, inclusion and exclusion criteria of the protocol. Besides, it contains information on direction how to analyze the data.



**Figure 1: Consort Flow diagram**

### **Intervention of theoretical framework**

An integrated behavioral model will be used to answer the objective of the study. The model has attitude, normative belief and perceived behavioral control component with its effect on intention to use of family planning. The intention to family planning use will be affected by the skill of the woman [ability to remember and taking of pills, injectable and other contraceptive based on the schedule] and environment which are related to supply of the contraceptive at healthcare facility and influence from her husband, faema structure, clan and religious leader to affect the actual behavior (use or not use of family planning).

### **Data collection too and follow up**

The data collection tool contains socio-demographic and determinant of health, reproductive history, knowledge, Attitude, and practice of family planning. Besides, it has male involvement in contraceptive and mass media exposure to family planning. For the items of knowledge, attitude and male involvement reliability and validity test were done. The modification was made base on the finding of reliability and validity test of the pilot test. The test was done in 118 married women. The data was collected by using a mobile-based application called open data kit (ODK). Finally, the tool will be prepared based on the finding of the reliability and validity test. An experience data collector with health background and Afarri speaking will be recruited to collect the data. Besides, a master holder with health profession will be employed to supervise the whole data collection process.

In the initial step, a pre-intervention survey will be conducted after the randomization and allocation. And there will be three times data collection including the pre-intervention and post-intervention data. These are pre-intervention data; follow up data in 4 and half months and the post-intervention data. The data will be collected by 4 and half months interval to have a good longitudinal data. The type of data will be panel data with repeated cross-sectional.

The field worker will also arrange a meeting to discuss the importance of family planning with the intervention groups (women and men) by providing health education and discussion issue about the importance of using family planning and male involvement on contraceptive use.

Each participating household (intervention arm) will receive a package of health education about family planning messages based on the intervention type. The type of Health education will be contextualized to the target group namely women and men. The women group will receive a health education on the importance of family planning for spacing and limit the number of children. Besides, health education will be given for the purpose of family planning to improve the health of the mother and child and decrease maternal and child morbidity. Furthermore, in the men intervention arm, the same health education with the women plus male involvement in family planning utilization will be given. Besides, the married women in the male intervention, health education will be provided. The field work will be responsible for providing the health education to the intervention arm.

#### Data collection procedure

#### Reliability and validity test

The data collection tool contains socio-demographic, reproductive history, knowledge, Attitude, normative belief, perceived behavioral control, intention to use for family planning and practice of family planning. And it has male involvement in contraceptive use and mass media exposure to family planning. The principal investigator trained the data collectors and supervisors for two consecutive days on instruction; in the quantitative method, study guides, role-plays (demonstration), informed consent, how to approach participants, how to collect data using mobile health, ethical procedure and general information on contraceptives and the objective of the study. The data was collected by using a mobile-based application called open data kit (ODK).

Items of knowledge, attitude, normative belief, perceived behavioral control, intention to use for family planning and male involvement reliability and validity test was done. Initially, a tool was developed based on the RIF 1 finding. Hence, it was piloted on 10 %( 118) married women. After the pilot test the data was analyzed for reliability and analysis test. Then, by including the reliable and valid tool, it was pretested again in 5% (45) of the sample. Accordingly, modification was made based on the finding of reliability and validity test. A tool which has a Cronbach alpha of 0.7 and above was considered as assuming reliable item. Besides, constructive validity was done for the tool and those tools which have high validity score were included in the

final tool. Finally, the final tool was prepared based on the finding of the reliability and validity test.

### Baseline data collection

The reliable and valid data was used to collect the baseline data. Six clinical nurse data collectors and two supervisors with master holder in public health were used. Intensive training was given for data collector and supervisor on the item and how to use mobile based application for the data collection. The data collectors and the supervisor were assigned to a different cluster of a given district. The data were collected for a total of 1 month using ODK. Immediately after the data checked for its completeness it was sent to the Mekelle University Server. An information technology (IT) person at the Mekelle University (MU) server was assessing the whole data quality and information was provided for the data collector to take corrective action while they were in a field.

### Midline and Qualitative Data

Following the provision of intervention, there will be midline data collection after four and half month. It is similar to the baseline data with a difference in time of occasion data collection which will be collected at the middle of baseline and end line data. A reliable and valid data will be used to collect the data. Training will be given to data collectors and supervisors. ODK will be used to collect the data. In addition, to the midline data, there will be a qualitative data which will be collected at the middle to track the progress of the intervention.

FGD and IDI guide will be prepared with the English language and translated to local language Amharic. There will be 6 FGD and 4 IDIs sessions to assess the progress of the intervention and to explore the reason for male involvement and use of family planning. There will be 6 FGD sessions from the married women in the intervention arms (male involvement (4) and women arm (2)). For IDIs males who have an active involvement and allow his wife to use contraceptive and married women who start to use FP will be included. All sessions of FGD and IDI will be audio recorded with a digital recorder and field notes will be taken. And the purpose of FGD and IDI is mainly for identifying the main motivating factors for using family planning and active male involvement in the community. Hence, the input will be obtained to know the

progress of the intervention. This will be collected after 3 months following the delivery of the intervention.

### **End line Data collection**

End line data will be collected by using ODK mobile based application. The same procedure with the baseline data will be repeated to collect the end line data after the six-month duration of the intervention. Furthermore, fifteen data collector with health background will be used to collect the data. Three supervisors will be assigned to check for the daily activity, consistency, and completeness of the questionnaire and to give appropriate support during the data collection process. The data collectors and the supervisor will be assigned to a different cluster of a given district. The collected data will be sent to Mekelle University server. An information technology (IT) professional will be assigned to assess the quality of collected data and immediate feedback will be given to the data collectors and supervisors to take corrective action while they are in a field.

There will be a total of 2 episodes of data collection (pre and post intervention) for the intervention study in addition to the qualitative data which will be collected at the middle. In each visit, the field workers will collect information on different variables including the intention to use family planning and family planning use. The detail description of time event for measuring the outcome variable (intention to use and current use of family planning) and the intervention implementation (health education on family planning use and male involvement) schedule will be described in the table below.

**Table 1: Outcome measure and data collection points**

Outcomes and intervention Implementation	Participants Survey Measure points			Measures
	T1	T2	T3	
	Prior the intervention	4 and half months	9 months	
Primary outcome				
Family planning utilization	√	√	√	Current use of FP.
Secondary outcome				
Intention to use family planning	√	√	√	9 items which have a natural order.
Intervention Implementation				
Health education (HE) about FP to women	Once per month	Once per month	Once per month	A total of 9 HE session about FP
Male involvement in Family planning utilization	Once per month	Once per month	Once per month	A total of 9 HE on male involvement in FP utilization

#### Data supervision and monitoring

A total of 3 supervisors from Mekelle and Samara University will be enrolled for data and active supervision. The main task for the supervisor will be to supervise, monitor and evaluate the field workers. The supervisors will be selected according to criteria set including experience for data collection and supervision. And the role field worker and supervisor are described below.

#### Role of field workers

Field workers will:

- Attend the training for the data collection and participate all days
- Raise awareness every month for 9 months (health education messages)
- Provide information about the importance of birth spacing by using a modern contraceptive.
- Teach households how to get and handle side effect following using family planning
- Inform and support households to use family planning
- Inform household how to cope up with stigma and discrimination following using family planning.
- Teach men to enhance male involvement in family planning utilization.

- Collect follow up data on the proportion of women who start to use family planning. Besides, information will also collect on Knowledge, Attitude, and intention to use family planning.

### **Role of supervisor**

- To monitor the field workers
- To make sure health education is being given properly
- To assist field workers during health education sessions
- To make sure surveillance data is collected adequately and properly
- To help the field workers regarding any obstacle faced during the project
- To check the data and raise issues regarding the missed surveillance data
- To inform any concerned issues to the PI of the study

### **Message about Family planning**

The message about the provision of health education message for the intervention study will be derived from the baseline data to fill the gap. It will contain information on knowledge, attitude and male involvement. The table includes information on the content of the health education message, which provides the message or modality of provision and strategy to use for delivery of the health education message. Moreover, the degree of a message to be delivered will be increased its complexity through time. Here are the descriptions of the message with its corresponding arm. The health education will be given for a total of 1 hour in the afternoon where a large number of communities expected to be gathered.

**Table 2** Type of family planning message with its delivery mechanism by group of arm

Session	Contents of the message	Who provides the HE	Strategy of delivery
Session 1 <i>To both arm</i>	Overview about FP and knowledge on FP Types of FP <ul style="list-style-type: none"> <li>• Pills, Injectable, Implants, IUCD, and Condom</li> <li>• Provide the benefit of using FP (health, human right and demographic )</li> </ul>	HEW	Assessment Discussion
Session 2: <i>To both arm</i>	<ul style="list-style-type: none"> <li>• Barriers do not use for FP</li> <li>• Addressing the barriers to not use of family planning</li> <li>• Assess the joint decision of clients</li> </ul>	HEW, Faema leader	Discussion <ul style="list-style-type: none"> <li>• Use of role model person</li> </ul>
Session 3: <i>To both arm</i>	<ul style="list-style-type: none"> <li>• Assessing the attitudes, normative belief and perceived behavioral control towards family planning</li> <li>• Assessing the intention to use of FP</li> </ul>	HEW, Faema leader	Discussion <ul style="list-style-type: none"> <li>• Use of role model person</li> </ul>
Session 4: <i>To both arm</i>	<ul style="list-style-type: none"> <li>• Assessing the attitudes, normative belief and perceived behavioral control towards family planning</li> <li>• Assessing the intention to use of FP</li> </ul>	HEW, Faema leader	Discussion <ul style="list-style-type: none"> <li>• Use of role model person</li> </ul>
Session 5: <i>To both arm</i>	<ul style="list-style-type: none"> <li>• Assessing the attitudes of individuals towards family planning</li> <li>• Use of Role model person from both group to share the experience</li> </ul>	HEW, Faema leader, Role model person	Discussion <ul style="list-style-type: none"> <li>• Use of role model person</li> </ul>
Session 6: <i>To both arm</i>	<ul style="list-style-type: none"> <li>• Reassess the activity of session 1-5</li> </ul>	HEW, Faema leader	Assessment
To men group	<ul style="list-style-type: none"> <li>• Use Religious leaders to provide message about family planning</li> </ul>	Religious/clan leader	Discussion

## **Data handling and record keeping**

### **Content of the data**

#### **Eligible households data**

With the help of health extension workers, faema leaders and regional health bureau all households in the cluster of the pastoralist areas of the selected district were registered. This also helps to identify the potential cluster to the intervention.

#### **Baseline data**

A baseline data was collected for two purposes; to answer the objective “the role of male involvement in intention to use of family planning and family planning use”. Besides, it is also used for randomization and allocation of the clusters into male, women and control arm. The baseline data will be compared with the midline and end line data which is intended to collect after four and a half and nine months, respectively.

#### **Type of longitudinal data**

The type of data used in the longitudinal data will be a panel data or repeated cross-sectional. Hence, married women interviewed in the baseline data may or may not be included in the mid and end line data. This data will be collected by using ODK, entered into the MU server and exported to R software version 3.4.2 for follow up and analysis of the data. The data format will be changed from wide format to long format.

#### **Midline data**

The data will be collected after 4 and the half month following the baseline data. This will help to see the changes in the outcome variable with the baseline and end line data.

#### **Post-intervention/end line data**

After collecting the baseline and midline data, end-line data will be collected to compare the average changes of women who have an intention to use and use a modern contraceptive. In addition, the two outcomes variable like knowledge, attitude, and level of male involvement of the woman also used to compare the changes in the arms. This data will be collected after 9 months of the baseline data.

### Data Monitoring and Safety

The data monitoring and safety team composed of different individuals from Mekelle University, Semera University, and Afar regional health Bureau. In general, this study intends to provide health education message about family planning. Accordingly, married women will be counseled to use contraceptive after she got intensive counseling and all the decision will be based on the informed consent. The research team will take an effort to minimize the risk and maximize the benefit following the provision of intervention. And the study will be carried out based on the protocol and any conflicts which arise during the study will be solved as early as possible by discussing with the members of data monitoring and safety. Accordingly, action will be taken by counseling the mother. In addition, to the above activity, a log book or registration will be prepared to follow the progress of the intervention.

The registration book which contains detail information such as name, family size, number of married women with age group of 15-49 years, type of topic discussed family planning, the current status of family planning use and remarks to write important issue during the health education provision. The registration will be checked for its deliverability by the research team in addition to the HEW supervisor at the district. All the activities of the HEW will be controlled by the HEW supervisor of the district. The district health office will be also responsible for monitoring the progress of HEW supervisor at their district level.

### Measurement

**Family planning use:** the married women will be asked does her or her husband currently use family planning to delay a pregnancy. If the woman said yes she will be considered as “use of contraceptive” and “not use of contraceptive” if she said no. Hence, the family planning is depo, injectable, male or female condom, implants, IUCD and male and female sterilization.

**Intention:** A total of 9 items which have an ascending order will be used to measure the intention to use family planning. The responses for the items are three; agree, neutral and disagree. These items are, *I am not clear with the benefits of using family planning, At this moment, I can list some of the benefits of family planning use I would gain if I use it, I am happy if I could use family planning to space the number of children I would have in the future, I am happy if I could use family planning to limit the number of children I would have in the future, I am willing to use family planning to space/limit number of children, I have already decided that*

*I should use family planning in the near future, I have ever used family planning in the previous 6 months and I found it relevant to me, I have ever used FP in the past 6 months and I am quite sure I will continue using it in the future and It is expected that women in our community should use family planning and so do I.* All the response will be labeled to positive items with value of 3 to agree, two to neutral and one to disagree after changing the negative sentence to positive sentence. Accordingly, married women who score less than 50%, 50-74%, and 75% and above will be labeled as “*Low*”, “*Moderate*” and “*High*” intention to use for family planning.

**Unmet need:** This will be measured by Bradley et al. 2012 [21] new definition of unmet need for family planning. Accordingly women will be labeled as “*unmet need for spacing*” if the woman at risk of becoming pregnant, not using contraception, and either do not want to become pregnant within the next 2 years or are unsure if or when they want to become pregnant, or pregnant with a mistimed pregnancy or postpartum amenorrhea for up to 2 years following a mistimed birth and not using contraception. And “*unmet need for limiting*” if the women at risk of becoming pregnant, not using contraception, and want no (more) children or pregnant with an unwanted pregnancy or Postpartum amenorrhea for up to 2 years following an unwanted birth and not using contraception.

**Infertility:** A total of two items will be used to check the infertility status of women. These are asked verbally the woman either diagnosed with infertility or not and the result of the diagnosis of infertility. And if the woman said for the result of diagnosis infertile she will be considered as “infertile” and “fertile” is she said fertile.

**Male involvement:** - A total of 12 items based on the Guttman scale [22] with a response of one for disagree, two for not sure and 3 for agree. The statements are positive statements that show the degree of husband’s actual and potential involvement in family planning. Accordingly, it will be categorized as “high” - those who score 75 % and above, “moderate” with a score of 50-74% and “low” those score less than 50%.

**Knowledge:** Married women’s knowledge will be measured by the total number of correct answers to 21 items on knowledge with a minimum score of 21 and maximum of 63. To measure the knowledge it will be categorized based on the percent of knowledge of the distinct

characteristics of family planning as “high” - those who knew 80% and above, “moderate” those who know 60 - 79% and “low” those who knew less than 60%.

Attitude: This will be measured by a direct and indirect measurement. A total of 14 items of direct measurement and 26 of indirect measurement will be used. A multiplication of the expressional and instrumental altitude will be done and will be treated as a continuous variable with increasing order.

Normative belief: It is measured by two items namely injunctive and descriptive norm. A total of 17 items of direct measurement and 21 of indirect measurement will be used. A multiplication of the injunctive and descriptive will be done and will be treated as a continuous variable with increasing order.

Perceived behavioral control: It will be measured by two items; controllability and self-efficacy. A total of 9 items of direct measurement and 11 of indirect measurement will be used. A multiplication of the controllability and self-efficacy will be done and will be treated as a continuous variable with increasing order.

### **Data Quality Control**

To assure the quality of the data in the quantitative study, data collectors and supervisors will be trained and a regular supervision and follow-up will be made by supervisors and the principal investigator. In addition, a regular check-up for completeness and consistency of the data will be made on daily basis. The questionnaire will be translated into Amharic and back-translated into English by translators who are blind to the original questionnaire. To make the questionnaire standard, reliability and validity test was done for items of knowledge, male involvement, intention to use and attitude related questions.

Pilot test and Pre-test of the tool was carried out in the area which has similar characteristics with the study population in Assayta district was done before two weeks of the actual data collection to ensure clarity, wordings, logical sequence and skip patterns of the questions. The pre-tested sample was not included in the study and modification was made. Furthermore, the paper-based items will be transferred to the mobile based application which ensures skip pattern; immediate scanning of the quality of the tool in the server avoids cost for paper duplication and friendly

with the data collector. An IT professional will be assigned to the Mekelle University server to control the daily data collection process.

For the qualitative data collection (FGDs and IDIs), the research members will participate. Silent and comfortable places and convenient times will be selected and arranged to conduct, in-depth interview with key informants and focus group discussions so as to allow maximum concentration. Study participants will also be made to give a true answer through explaining the purpose and importance of the study and assuring the confidentiality of data they are going to provide.

### **Data management and Analysis**

Objective 1: The data for the paper will be analyzed for the intention to use and use of family planning. The intention will be analyzed by ordinal logistic regression since the composite measure has a natural order. The intention to use family planning will be treated as an ordinal variable with three outcomes; low, moderate and high intention to use family planning. The family planning use will be analyzed by logistic regression. The data will be analyzed using R software Version 3.4.

Objective 2: The nested case-control data will be analyzed by R software Version 3.4.2 after the collected data imported from ODK. Multivariable Logistic regression analysis will be used to analyze the data.

Objective 3: Data obtained from interviews and discussions will be familiarized through listening, reading and reviewing. Data generated by in-depth interviews and FGDs will be transcribed daily to Amharic versions and it will be exported to Atlasti.7 for analysis. Notes that will be taken during interviews and discussions will be summarized. Finally, key findings will be narrated and it will guide the future intervention.

Objective 4 and 5: Statistical analyses will be performed by using R software Version 3.4.2. Intention to treat analysis will be used as a framework for analysis. The follow-up data will be analyzed using generalized estimating equation (GEE). Before analysis, the data will be

restructured from a wide to a long format which allows the data to prepare for longitudinal data analysis.

All the analysis will be used with 95% confidence interval and p-value  $<0.05$  to declared statistically significant. At the initial bivariate analyses in the form of t-tests and chi-squares will be done to identify or appreciate differences on independent variable (knowledge male involvement, attitude, normative belief, perceived behavioral control and outcomes variable (family planning use and intention to use of family planning). Hence, the variable becomes significant at the bivariate analysis will be entered into the model of longitudinal data analysis; GEE. Variables will be entered into the final model based on two criteria. These criteria are a known confounder to bring a difference among the male, women and control arm and the second will be if there is a significant difference between the baseline and end line data observed. Advanced statistical analysis like GEE will be used to declare the effect of the community-based intervention on increasing family planning and intention to use for family planning.

Furthermore, prevalence ratio of the end line data to the baseline data will be computed for the two outcomes and knowledge, attitude, normative belief, perceived behavioral control and male involvement. The intention to treat analysis and dose analysis will be done by using R software version 3.4.2. Finally, a model with smallest diagnostic criteria (Deviance or -2 times log likelihood ratio, AIC (Akaike Information Criterion) or BIC (Bayesian Information Criterion)) will be used to select the best-fitted model.

**Table 3:** summary of the objective by study design, sample size, sampling procedure, and type of analysis

Objective	Study design	Sample size	Sampling procedure	Type of analysis	Remark
To describe the role of male involvement in intention to use of FP and FP use	Cross-sectional	891	Cluster sampling technique	Ordinary logistic regression for intention to use Logistic regression for FP use	A design effect of 3 will be used
To explore the progress of the intervention	Embedded experimental design	6 FGD 4 IDI	Purposive sampling technique	Thematic analysis	Atlasti 7 software
To identify behavioral determinant factor of family planning	Nested case-control study	179 use contraceptive and 358 do not use contraceptive	Cluster sampling technique	Originally logistic regression	
To identify the effect of male involvement in converting women with intention to use of family planning	Cluster randomized controlled trial	11 cluster for a male arm and 11 for the control arm	Cluster sampling technique	Generalized estimating equation(GEE)	
To identify the effect of male involvement in converting women with intention to use of family planning	Cluster randomized controlled trial	11 cluster for women arm and 11 for the control arm	Cluster sampling technique	Generalized estimating equation(GEE)	

### **Adverse Event Information**

The study believed that there will be no adverse event due to the intervention for the following reason 1) the decision for taking contraceptive mainly depend on the informed choice of the married women 2) the provision of counseling will be provided by a trained health professional at healthcare facilities. The counseling will include about the potential side effect and action to be taken following the side effect development 3) there is a team which deals with data monitoring safety which will be responsible for following the provision of the intervention based on the protocol. Furthermore, in case of violation of the protocol the study, the data monitoring safety will be responsible for providing corrective action.

### **Certain agreement**

The funding agencies have a contract agreement with Mekelle University, College of Health Sciences as a term of References (ToR). However, the sponsor organization does not have an influence on design, implementation, and analysis of the result. The principal investigator is currently working at Mekelle University with the RIF's project is responsible for handling and delivering the intervention based on the protocol. He is not is not an employee of the sponsor.

### **Results Point of Contact**

The point of contact for the intervention study will be Dr. Belete Assefa (Mekelle University College of Health Sciences, with the position of Academic and research Directorate director). His phone number is +251932344646 and email: [assefabelete@ymail.com](mailto:assefabelete@ymail.com)

### **Ethical consideration**

Permission to undertake the study was obtained from Mekelle University College of Health Sciences institutional review board and an official letter of cooperation was given to Afar Regional Health Bureau. Informed consent to participate in the study was secured before conducting the interview. For this, a one-page consent letter was attached to the cover page of each questionnaire and it was explained to study participants that participation is voluntary, confidential and private information would be protected. Information about the study was given

to the participants. The right of the respondent to withdraw from the interview or not to participate was respected. Identification of an informant was possible only through specific identification numbers. The detail information on the selection of the study participants, confidentiality, and participation, benefits, risks and contact person in case of any issue described below.

## **Information Sheet**

### **Selection of participant**

Clusters which have 30 and above households were the primary criteria for inclusion criteria in the intervention study. Married women in the pastoralist community were considered as eligible but to be part of the study, they should accept the informed consent. Selected married women in the study area were involved in the study.

### **Confidentiality**

All the information obtained from married women was used for the research purpose and reported collectively. Nothing was reported individually. In addition, the name of an individual was not appearing in anywhere in the research paper and even on the data collection form. To differentiate one from another the data collector, the research team used code. No one will have access to not-coded data except the data collector.

### **Participation**

Participation of married women was on a voluntary basis. They are free to refuse part or the entire questionnaire even after they have agreed to participate or provide information. Nothing happened to the participant activity in the institution. Besides, the married women had an opportunity to withdraw from the intervention or the longitudinal follow-up of the study participants.

### **Benefits**

This research is aimed to assess the effect of the community-based interventions on increasing family planning utilization in Pastoralist community from Afar region, Ethiopia. The findings of the study will be used to improve the family planning utilization through male involvement and women education to formulate policy, delivery of services and to bring change in family planning service provision in pastoralist community. Besides, it will have a great opportunity for

reduction of maternal and child morbidity and mortality in the country in general and in the region in particular.

### **Risks**

Since the research attempts to gather information from married women about family planning utilization in addition to the intention to use family planning and other related variables, it does not bring any problem to the married women. All the collected data and information related issues do not bring more than minimal risk to the participant. If anything happens the researcher will take a full responsibility and it will link to the near health facility. Besides, there is a team which deals with the data monitoring mechanism which ensures the process of the intervention and will be responsible to take corrective action in case of any violation of the study protocol.

### **Contact**

If study participant want to ask more question or if they face any problem with the data collection procedure or during follow up, they can communicate or call to the principal investigator Mr.Mussie Alemayehu through Cell Phone: +251914749082, email: [mossiaex75@gmail.com](mailto:mossiaex75@gmail.com), Dr.Alemayehu Bayray, Head of the institutional review board of Mekelle University through Cell Phone:+251914703261, email: [alemayehub35@gmail.com](mailto:alemayehub35@gmail.com). Besides, the contact person of data monitoring safety, Mr.Yassin Habib representative of Afar regional health Bureau through Cell Phone: +251911936340, email: [yashabel@gmail.com](mailto:yashabel@gmail.com) or Dr.Belete Assefa (Academic and research Directorate director of Mekelle University, College of Health Sciences ). His phone number is +251932344646 and email: [assefabelete@ymail.com](mailto:assefabelete@ymail.com)

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