

# Effectiveness of Checklist based Box system Interventions (CBBSI) versus routine care on improving utilization of Maternal Health Service in North West, Ethiopia: Study protocol for a Cluster Randomized Controlled Trial

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## Study protocol

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# Abstract

**Background** - Maternal mortality is still high in Ethiopia. Antenatal care, use of skilled delivery and postnatal care are key maternal health care services that can significantly reduce maternal mortality. However, in low and middle income countries including Ethiopia, utilization of these key services are not enough to deliver the recommended preventive, promotive and curative services. The aim of this study is to examine the effectiveness of checklist based box system interventions on improving maternal health service utilization. **Methods** - A community level cluster-randomized controlled trial will be conducted to compare the effectiveness of checklist based box system interventions over the routine standard of care. The intervention will use health extension program and provided by health extension workers and midwives, using a special type of health education scheduling and service utilization monitoring boxes, placed at health posts and health centers respectively. For this, 1,200 pregnant mothers, below 16 weeks of gestation, will be recruited from 30 clusters. Suspected pregnant mothers will be identified through a community survey and linked to the nearby health center. In a two weeks base, review of dropouts will be conducted at each intervention health center. Then intervention health posts (supervised by intervention health center) will be communicated for each dropout. Then, health extension workers will provide health education, using a person-centered manual prepared for this purpose. Data will be collected using ODK-Collect and analyzed using STATA version 13.0. Data will be analyzed by intention to treat analysis. Risk ratio will be computed at cluster level and the summary will be compared using t-test. Outcomes between intervention and control groups will be compared with random effects logistic regression models. **Discussion** - The authors of this study expect that, the study will generate evidence on the effectiveness of checklist based box system interventions on improving utilization of maternal health care service, that are strong enough to inform policies in the country.

## Background

Antenatal care (ANC), use of skilled delivery attendants and postnatal care (PNC) services are key maternal health care services (MHCS) that can significantly reduce maternal mortality [1]. Despite proven interventions that could prevent death or disability during pregnancy and childbirth, maternal mortality remains a major burden in many developing countries [2]. Although significant declines observed, progress in reducing maternal mortality in developing countries was insufficient to meet MDG 5a targets. Looking beyond 2015, the sustainable development goals offer a renewed opportunity to see improvements in maternal health [3].

Within the continuum of reproductive health care, ANC provides a platform for important health-care functions, including health promotion, screening and diagnosis, and disease prevention [4]. So, all pregnant women should have at least four ANC assessments by/under the supervision of skilled attendant [5]. Antenatal care, entry point for other MHCS, may play an indirect role in reducing maternal mortality by encouraging women to deliver in a health facility [6]. It has been argued that efforts should be based on a continuum of care perspectives and, thus, joint strengthening of antenatal, delivery and post-partum care is relevant [7,8].

Many authors agreed that, factors influencing MHCS utilization operate at various levels: individual, household, community and state level, but the role of individual, household and other factors and determinants differ from one culture, geographic and social setting to another [9-11].

Globally, an estimated 289,000 women died during pregnancy and childbirth in 2013, a 45% decline from 1990. Most of them died because they had no access to skilled routine and emergency care [12].

Even though effective health interventions are available, most studies in developing countries like Ethiopia indicate that the potential to deliver health information and services using MHCS still remains underutilized [13]. In Ethiopia, one explanation for poor health outcomes among women is the nonuse of modern health care service by a great proportion of women in the country [14].

Comparison of findings from studies investigating utilization of MHCS in low and middle-income countries indicates that women are more likely to attend ANC than to deliver in health facilities. For instance, in Ethiopia, overall MHCS utilization is low, 2016 EDHS showed that 62% and 32% of pregnant women made at least one and four ANC visits; SBA and PNC are reported as 27.7% and 16.5% respectively [15]. In addition 34% dropout rate of mothers starting ANC 1 but not reach at least four visits, was observed in 2017 [16]. In addition, mothers attending ANC service are receiving the key service packages with different level of completeness. In Ethiopia, 65% of pregnant women among those reached by 2012 EPI survey received tetanus toxoid vaccination, and long-lasting insecticidal nets utilization was reported to be 42% in 2011 Malaria Indicator Survey [17-20].

The analysis of 2011 EDHS showed that only 26.2% of those attending ANC started their ANC visit during the recommended timing (first trimester), majority (56.4%) started during the second trimester and 16.7% started during the third trimester [1]. Similarly 2014 EMDHS showed that the average time the women start the first ANC was five month [17].

A study in southwest shoa, Ethiopia showed, the coverage of at least four ANC visits and SBA were 45.5% and 28.6% respectively [21]. A similar study conducted in rural haramaya, Ethiopia showed that 74.3%, 28.7% and 22% of mothers got the first ANC, SBA and PNC respectively [22]. Ethiopia is following focused antenatal care (FANC), where mothers are recommended to have at least four visits throughout their pregnancy. This trial is designed to fit this FANC for antenatal care service delivery.

In general, utilization of MHCS is not initiated as per the recommendation, and the proportion of mothers utilizing the service decreases as one go from the first ANC to the third PNC. Thus, the aim of this trial is to use the rigor of Cluster Randomized Controlled Trial for the evaluation of checklist based box system interventions on improving MHCS utilizations. The evidence from this trial is believed to contribute for programs and policies aimed to improve MHCS utilization.

## **Methods/design**

### **Design**

Cluster Randomized Controlled Trial study design, double-blind masking, parallel group and two arm intervention was employed to assess the effectiveness of checklist based box system interventions on improving utilization of maternal health care service in East Gojjam Zone, Northwest, Ethiopia. Participant flow detail (Fig 1)

## **Setting**

The study will be conducted in East Gojjam Zone, one of the administrative zones of Amhara Region, Northwest Ethiopia. According to EDHS 2016, the region's maternal health service utilization is: first and fourth ANC was found to be 67.1% and 31.5% respectively, health facility delivery was 27.1% and postnatal care was 18.4% [15]. Debre-markos, the capital city of East gojjam zone is located in the northwest direction 299 km far from the national capital Addis Ababa. According to the USAID estimate, the population of east gojjam zone was estimated to be 2,613,835 with male population 1,292,042 (49.4%) and female population 1,321,788 (50.6%) [23].

## **The Context: Primary Health Care Unit**

The Ethiopian health service is restructured into a three tier system; primary, secondary and tertiary level of care. The primary level of care includes primary hospital, health center and health post. The Primary Health care unit is composed of a health center (HC) and five satellite health posts (HPs). These provide both preventive and curative services to approximately 25,000 people altogether. HCs served as a referral center and practical training institution for HEWs. In turn, primary hospitals serve as a referral center for HCs under its catchment areas, a practical training center for nurses and other paramedical health professionals [20].

Ethiopia's Health Extension Program (HEP) is a community based strategy to deliver health promotion, disease prevention and selected curative health services at the community level. It is a mechanism to provide health service free of charge to all segment of population in the country by payed health extension workers (HEWs). HEWs are drawn from the community they are going to serve, and are trained for one year. Two HEWs per health post are deployed to provide services under the 16 packages by making house-to-house visits. Improving access and utilization of latrines, increasing contraceptive acceptance rate, antenatal care and post natal care, improved health seeking behavior, expanded vaccination services, malaria control and prevention and reduction of new HIV infection are some of the major package that are expected to be delivered by HEWs. HEWs spend 75% of their time on home-to-home visits providing promotional and preventive interventions and 25% of their time at health posts [20,24]. Even though MHS is delivered in different levels of the health tire system, this trial is focusing on improving service delivery in the primary health care units. Using the existing referral linkages between primary health care units, all the three contact points are expected to happen at health center level (recommended), where the monitoring box is placed. If the mother took one of the visits including delivery by her preference, in facilities other than the intervention health center, it will be tracked by HEWs and if it is confirmed her individual folder will be transferred to the next compartment. But in this process if the

mother is permanently shifted to other facility/residence, she will be excluded from the study. Since the set of services are similar for primary hospitals and above, the trial can be applied for hospitals as well.

### **Participant Eligibility Criteria**

The participants for this trial will be pregnant mothers residing in three of the selected districts of East Gojjam zone (Debre-Markos, Gozamin and Machakel districts). Their recruitment will pass a two stage screening process: using a preset criteria the initial screening will be done at community level using Stanback et al, 1999 pregnancy screening checklist and mothers having a suspected pregnancy will have a laboratory confirmation at health center. Then those having gestational age of 16 weeks will be recruited for the study. Mothers who fulfill the above listed criteria but, who have severe psychological illness, which could interfere with, consent and study participation, those who have severe clinical complications that need hospitalization and mothers who need special type of ANC follow-up, other than the recommended focused ANC will be excluded from the study.

### **Sample Size Determination**

The sample size was calculated based on the recommendations of sample size calculations for cluster randomized controlled trials with fixed number of clusters [25], by using the following assumptions: utilization of the third postnatal care in the control group is 16% based on previous study [26], number of clusters available-30 (15 clusters per arm), with 95% confidence interval and 80% power, intra-cluster correlation coefficient of 0.04849 [27]. The sample size was calculated to determine number of observations required per cluster, for two-sample comparison of proportions (using normal approximation), using STATA. Assuming individual randomization, sample size per arm is 194. Then allowing for cluster randomization, average cluster size required is 40. A total of 1200 pregnant mothers (600 in intervention, and 600 in control) will be recruited to detect 12% increase in the utilization of ANC visit 4 and skilled birth attendance and postnatal care. The outcome is treated as a binary measure.

### **Randomization and Sampling Procedures**

Among the 16 districts in East Gojjam Zone, Debre-Markos, gozamin and Machakel were selected purposefully, confirming that each of them didn't have projects aiming to increase utilization of maternal health services. Health posts (with their catchments), under selected districts are the unit of randomization for this trial. Since a component of the planned intervention will be delivered at community, individual randomization is not appropriate in this situation, as it would result in contamination; so 30 non-adjacent health posts (clusters) were selected. Once cluster recruitment has been completed, participating clusters were allocated to one of the two trial arms (in 1:1 allocation), on an equal basis (a total of 30 clusters, fifteen clusters in each arm) by using SPSS-generated random number sequence. This trial is aimed to increase service utilization, and took previously delivered mothers as a baseline to compare the status of service utilization in selected areas, as well as to compare the status of maternal health service utilization after the intervention. For this, all mothers delivered in the last one year,

regardless of their place of delivery, who are living in the catchment area of selected health posts were entered in to SPSS and 'random case selection' of the required sample size was done.

## **Screening and Enrollment**

In Ethiopia the linkage between primary health care units is defined, each health post has its own catchment population to serve. This linkage works primarily by proximity of health facilities to the catchment population. Community level referral of this trial works following this defined primary health care units linkage. Based on this, health extension workers will use family folder (a detail record of households), to identify women of reproductive age (WRA). Then, the first level screening takes place at community level using Stanback et al, 1999 pregnancy screening checklist. Mothers having suspected pregnancy, will receive community level referral slip to be received by the near by health center. Then the second screening will take place at Health center using beta-human chorionic gonadotropin (HCG) urine test, laboratory confirmation of pregnancy. Mothers who have known pregnancy but not initiated the first ANC will also be referred for the service. If a mother has a positive HCG result, she will be recruited for the study and on the same day she will receive the First ANC service.

## **Intervention Description:**

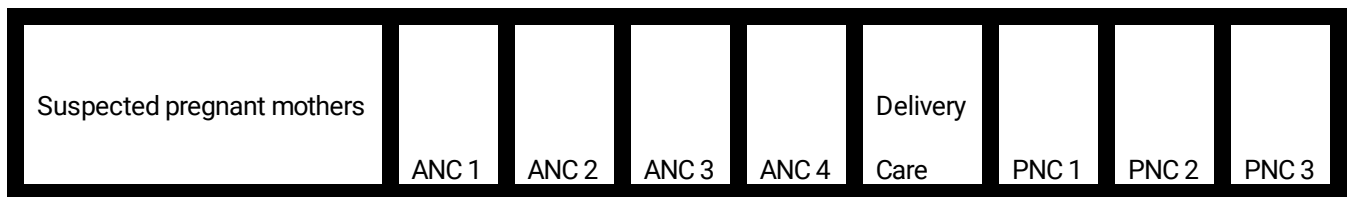
### **Trial Arm I/Intervention**

The intervention has two main focus areas: the first is demand creation at community level done by HEWs and the second is service utilization monitoring through dropout tracing mechanisms. Two separately designed boxes were introduced to help facilitate the above interventions. Health posts received 'Health education scheduling boxes'; the main purpose of these 12 compartment boxes is to prioritize the most common reasons raised by mothers for not utilizing each of the maternal health services, and to provide focused health educations. As the Ethiopian health system encourages mothers to receive maternal health services at health center and above, in these interventions HEWs have done more of demand creation activities.

**Health post.** HEWs use family folders to locate women of reproductive age and do home-to-home pregnancy screening using Stanback et al, 1999 checklist. Mothers having suspected pregnancy will be referred to the nearby health center for laboratory confirmation, and if they are pregnant they will receive the first ANC at the receiving health center. In this process HEWs link mothers with the receiving health center through a referral slip.

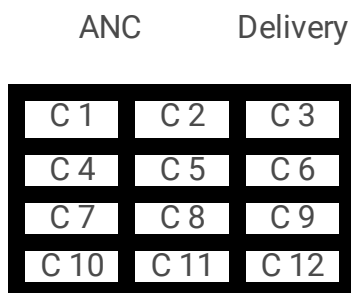
While conducting home-to-home visit HEWs identify reasons raised by women for not utilizing maternal health services (ANC, skilled birth attendance and PNC), the list of reasons will be kept in health education scheduling boxes. Reasons raised by most mothers will be the topic for HEWs health education. Upon missed service, HEWs will be communicated and they identify the reason and discuss with the mother and made her to resume the service.

**Health center:** Once the mothers are linked to the nearby health center, they will be followed for their subsequent attendance of consecutive maternal health care services (ANC (2-4<sup>th</sup> visits), skilled birth attendance, and post-natal care (1-3)). This will be checked using special designed service utilization monitoring box. This box is a nine-compartment box: the first compartment is for mothers suspected for having pregnancy using the pregnancy-screening checklist from HEWs. If the mothers came and confirm their pregnancy (HCG test) they will get the first ANC and their card will be transferred to the next compartment, the same procedure will be followed for the coming consecutive MHCS visits. The visits for ANC service will follow the 4-visit WHO ANC model (i.e. First ANC (before 16 weeks of gestation), second ANC (24-28 weeks), Third ANC (30-32 weeks), fourth ANC (36-40 weeks), and facility delivery assisted by skilled health care providers (health center and above) and PNC 1 at 6 hours, PNC 2 at 6 days and PNC 3 at 6 weeks of delivery). This service utilization-monitoring box will help Midwives to identify mothers who fail to follow the above smooth transition. If a mother is identified as a 'dropout', Midwives at health centers will communicate HEWs in which the mother is belonging. Again these mothers will be approached for person-centered health education to resume their service within the recommended time interval.



***Service Utilization Monitoring Box – Health Center***

In each compartment Individual folder for the mother with a list of services for that specific visit will be placed, and when the mother come and took the service her folder will be transferred to the next compartment, but when a mother didn't come and took the service her folder will remain there. In this process the dropouts for each visits will be traced.



Individual  
Knowledge  
Facility  
Others

### *Health Education scheduling box – Health Post (C-compartment)*

If a mother missed antenatal care following knowledge gap, the reason-picking card will be placed at compartment 4. Similarly compartments containing more cards will be focus for discussion.

### **Trial Arm II/Control**

Participants in the control arm will receive the existing routine care: mass health education by health extension workers and receive MHCS at health centers through giving appointments for subsequent follow-ups. Unlike the intervention arm, this group will not receive community level pregnancy screening, will not be given health education scheduling box, person centered health education manual and service utilization monitoring box.

### **Intervention Process**

Before the study team introduced the intervention, a detail intervention package was developed, with a focus of narrating what steps to follow while implementing this intervention. In addition, other pre-introduction activities, like development of training manual and person-centered manual for health extension workers (Amharic version) and for health care providers was developed, specification for health education scheduling boxes and service utilization monitoring boxes was developed and 15 boxes for health posts and 05 boxes for health centers were procured. Sensitization workshop for local health administrators, training of all health extension workers coming from 15-selected health posts and training of 2 midwives from each selected health center (one delivery case team lead and one midwives) was conducted. Boxes, printed checklists referral slips, registers and manuals were distributed accordingly and onsite orientation was made. Then community survey and enrollment was started. Follow-up visits were made based on the previously developed compliance parameters.

### **Data Collection Tools and Techniques**

Data will be collected using a semi-structured and pre-tested questionnaire. The questionnaire used to collect data was designed by reviewing relevant literatures and related national and international standards, and the focus is on educational and ecological assessment, mother experience related to pregnancy, delivery and postnatal care, social and epidemiological assessment, behavioral and



environmental assessment, general social support and social capital and health service quality components. This will be translated to Amharic version (Local Language of the study area).

Then the translated version was uploaded to kobo toolbox, and open data kit (ODK) will be used to collect data. The study will use face-to-face interview and the data will be collected using mobile devices in front of each selected mother's home. Filled questionnaires will be saved in the mobile devices, and will be sent to the central server immediately after completing the interview. In cases where the data collectors can't complete the questionnaires' and when an internet connection can't be accessed the filled questionnaires' will be sent when there is internet connection available. The data collection will be managed directly from Jimma university server. Each data collector and supervisor has got a code; this made data management easily done. For both of the arms if the study participants move from the study area before the study is completed, they will be registered as dropouts to lost to follow-up. This trial will have two phases of data collection: baseline study (before the intervention is introduced) and end line study (after the intervention is introduced).

Table 1: Representation of CBBSI using Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)

Time Point	Allocation	Enrolment	Study Period				Close-out
			Post allocation				
			Intervention (12 Months)				
-t1	Baseline Study (t <sub>0</sub> )	16 weeks of pregnancy	36-40 weeks of pregnancy	After 40 weeks of pregnancy	42 days after delivery	End line Study (t <sub>1</sub> )	
ENROLMENT							
Allocation	x						
Eligibility Screening		x					
Informed Consent			x				
INTERVENTION							
CBBS Intervention							
Routine Care							
ASSESSMENT							
Socio-demographic Characteristics			x			x	
Educational and ecological			x			x	
Knowledge related to Pregnancy, delivery and postnatal care			x			x	
Early initiation of ANC			x			x	
Four antenatal care			x			x	
Skilled birth care			x			x	
Postnatal care three			x			x	
Pregnancy, delivery and			x			x	
Postnatal care related							
Social and epidemiological			x			x	
Behavioral and environmental			x			x	
General social support			x			x	
and social capital							
Health service quality			x			x	

## Data Quality Control

Training for selected data collectors and supervisors will be conducted, with the focus of making common understanding for each and every question. In addition to this a manual explaining each and every question with its response categories was prepared, this manual also include sections explaining on 'how to use ODK to collect data' with examples demonstrating the features of the application. The data collection will be conducted by BSC holder Midwives; and supervised by two MPH holder professionals. In addition to this, a close follow-up by the principal investigator will be done. The field data collection will be supported by ODK in which each and every question is settled to be required; help to avoid missing data. Also range checks were setted for selected data values accordingly. This ODK will also allow editing the responses in front of each interviewee. Similarly GPS coordinates of each and every interview place will be recorded at the end of each interview, which will allow graphical representation of the study site.

## Analysis Plan

Data from the trial will be analyzed by intention to treat analysis at both cluster and participant levels. Participants will be assigned to the cluster they were resident in at the time the trial began. Data analysis will take place in two levels, in cluster level and in individual level. Risk ratio will be computed at cluster level, and the results of this cluster summary will be compared using t-test. Primary and secondary outcomes will be compared between intervention and control groups with random effects logistic regression models, taking account of clustering/correlation. All estimates will be presented with 95% confidence intervals. STATA version 13.0 will be used to run the analysis.

## Outcome Measures

**Primary outcome** – continued utilization of maternal health care service (ANC – PNC)

- Mothers attending the fourth antenatal care
- Mothers delivering at health facilities assisted by skilled care providers
- Mothers attending the third postnatal care at 6 weeks of delivery

**Secondary outcome** – secondary outcome measures will assess whether the trial has an effect on the following maternal health service utilization; early initiation of antenatal care (before 16 weeks of gestation) and utilization of the first antenatal care.

## Dissemination Plan

Detailed study protocol will be published on open access journal. Any modifications that will be made to the protocol will be communicated to relevant parties such as trial registry and both of the ethics committees. After the result is produced, it will be submitted to the Jimma University, Amhara Region public health institute, East Gojjam zone health department and governmental and non-governmental organizations working in maternal health programs. The findings of this study will also be presented in scientific conferences. Also, manuscript will be prepared and submitted to a peer-reviewed scientific journal for possible publication.

## Discussion

This trial is designed to improve continued utilization of maternal health care service and will be applied both in urban and rural settings. Unlike the routine care, pregnancy identification will take place at community level. As this trial is designed to be implemented by combining both demand creation and service utilization monitoring components the investigators believe that, the evidences generated will contribute for maternal health programs in the regional and national level.

## Trial Status

Thirty clusters were selected and the preparatory activities like: development of training manuals, referral slips and registers were completed. Sensitization workshop for local health administrators and training for intervention implementers (health extension workers and Midwives) was conducted. Specification for specially designed boxes for health posts and health centers was developed and procurement and distribution was made accordingly. Baseline study was collected in both the intervention and control clusters, and enrollment of mother as per the prespecified criterion is being conducted. Protocol version 1 dated 26 March 2019, Recruitment began 22 November 2018, and the approximate date that the recruitment completed will be by October 2019.

## **Abbreviations**

ANC: Antenatal Care; CBBSI: Checklist based box system interventions; EDHS: Ethiopian Demographic and Health Survey; EMDHS: Ethiopian Mini Demographic and Health Survey; EPI: Expanded Program on Immunization; GPS: Global Positioning System; HC: Health Center; HCG: Human Chorionic Gonadotropin; HP: Health Post; HIV: Human Immunodeficiency Virus; MDG: Millennium Development Goal; MHCS: Maternal Health Care Service; ODK: Open Data Kit; PNC: Postnatal Care; SBA: Skilled Birth Attendance; USAID: United States Agency for International Development; WHO: World Health Organization

## **Declaration**

### **Ethics approval and Consent to participation**

Ethical clearance for the study was obtained from Jimma University Institutional review board (IHRPGD/841/17) and Amhara Public Health institute. A formal letter with the detailed implementation plan for the intervention was submitted to the federal ministry of health and Amhara regional health bureau and a letter of support was obtained from both of the organizations. In communication with east gojjam zone health department, district health offices and selected health centers were communicated through formal letter. Then, a one-day formal orientation on the implementation plan was provided to local health administrators. Participant information sheet and consent form was developed and before data collection mothers were told about the objective of the study and oral informed consent was obtained.

### **Consent for Publication**

Not applicable.

### **Availability of data and materials**

Not applicable.

### **Competing Interest**

The authors declare that they have no competing interests.

## Funding

The study team is grateful for the support provided by Armauer Hansen Research Institute (AHRI) as an innovative maternal health care improvement trial. AHRI has no role in the design of the study, development of data collection tools and the development of protocol for the trial.

## Authors' Contribution

NB, the principal investigator of this study, initiated the trial idea, wrote initial draft of the proposal, developed the protocol and supervises the implementation of the intervention. NB, MG and GT are participating in maturing the implementation plan, study design and statistical design of the trial. All authors critically reviewed and approved the final study protocol.

## Acknowledgment

We would like to thank Grand Challenges Ethiopia Coordinating office of Armauer Hansen Research Institute for the financial support provided to implement this trial.

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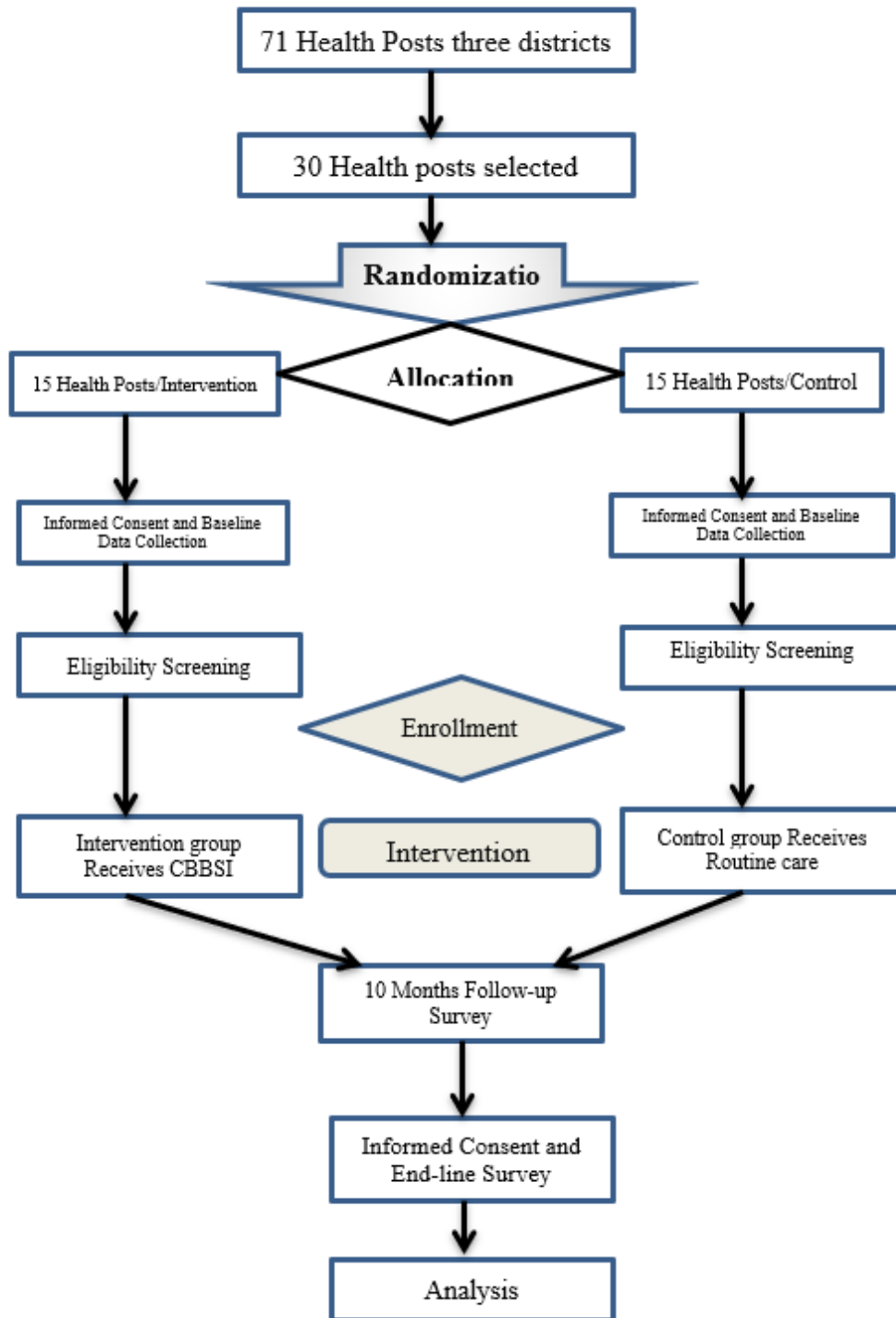
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## Additional File Legend

**Additional File I:** SPIRIT 2013 Checklist: recommended items to address in clinical trial protocol

## Figures



*Fig. 1 Participant Flow*

**Figure 1**

Participant Flow

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [ItemsfromWHOTRDSCBBSI.docx](#)
- [PictorialRepresentation.pdf](#)
- [CBBSISPIRITChecklist.pdf](#)