

“Combined Interventional Approach vs. Conventional utilization of full antenatal care services and pregnancy outcome in district Dehradun: A Cluster Randomized Controlled Trial” A study protocol.

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DOI: <http://doi.org/10.1729/Journal.23211>

Abstract

Introduction:- MMR of Uttarakhand state is very high as comparison to national index and it is on 27th position in India out of 35 states and union territories to provide full ANC services. In Dehradun district, full ANC of urban and rural are quite low 15.3% and 23.2% respectively, even in urban region half than the national index 31.1%.

Aim:- To determine the effect of Combined Interventional Approach (CIA) to achieve full ANC among pregnant women and its impact on pregnancy outcome.

Material and methods:- A cluster randomized controlled trial will be conducted in Dehradun district, Uttarakhand among all pregnant women registered in first trimester, will be selected by multi stage cluster sampling. Sample size will be calculated after pilot study. A precise inclusion and exclusion criteria will be followed. Study duration will be 10 months 15 days.

Combined Interventional Approach (CIA):- It includes multiple interventions (control room, mobile application, community participation, identification and utilization of alternative referral transport at community level and sensitization of community for high risk pregnancy) with conventional/routine ANC services.

Tools:- Subject data sheet, Mother and Child Protection Card, Reproductive and Child Health Register and Delivery register.

Statistical analysis:- Data will be collected and analyzed using descriptive and inferential statistics ($p < 0.5$).

Discussion :- This study, if proven effective, then without any extra cost and burden, ANC services can be strengthened with these interventions and full ANC coverage can be improved which ultimately improve pregnancy outcome as well as maternal and neonatal health that is a big need of time, especially in low resource countries like India.

Keywords:- *Combined Interventional Approach, Conventional utilization of full antenatal care, pregnancy outcome and full antenatal care.*

Introduction

Antenatal care is a fundamental right of a pregnant woman. Antenatal care is the care of women during pregnancy to achieve a healthy mother and a healthy baby at the end of pregnancy. Antenatal care provided by LHV, ANM, SN in peripheral areas of urban and rural settings of public health system. Antenatal care should be started as soon as pregnancy confirms and first visit and registration should be before 12 weeks of conception¹.

For better utilization of ANC services, at least four contacts during pregnancy and at least one contact/visit in perinatal period is necessary. Antenatal care services aims to early identification and timely management of pregnancy related complications, to prevent

and reduce the maternal and perinatal mortality and morbidity. Better antenatal care can improve pregnancy outcome and neonatal outcome as well².

Main challenges to provide antenatal care to all pregnant women are first identification of gap and then provision for evidence based interventions³. In India, maternal and neonatal mortality are quite high 130/100,000 live births and 28 per 1000 birth in 2016 respectively. In Uttarakhand state, maternal mortality is 201 maternal deaths per 1, 00,000 live birth and NMR of Uttarakhand in rural is 38/1000 live births. In Dehradun, NMR was quite high 30 per 1000 live births in rural areas^{4,5}.

Evidence based studies suggests most common three causes of maternal deaths are underutilization of antenatal care services, timely unrecognized high risk pregnancies and lastly lack of transport facility, all these three causes are mostly preventable⁶.

Maternal and neonatal health indicators are not satisfactory in Dehradun district as nearly 81% do not receive full ANC, nearly 69% children do not receive a health check up by skilled health personal within 2 days of delivery, nearly 70% of pregnant women do not receive iron folic acid for recommended period of 100 or more days, only 49.5% of total birth conducted in public institution of Dehradun, Uttarakhand⁷.

A study on WHO model, in Mozambique conducted in 2011 for "implementation of evidence-based antenatal care in Mozambique: a RCT, that suggested that developing countries need to increase their support for beneficial interventions at all three levels:- policy, organizational and health delivery level need intervention³.

WHO guidelines, 2016 clearly suggested more contacts gives more time and opportunity to assess pregnant women's ill health, timely identification and management of high risk pregnancies for better outcomes².

In India Incidence of anemia during pregnancy ranges between 65-75%⁸. About 16-40% maternal deaths occur due to anemia that is also a major cause of maternal morbidity. Pregnancy is the physiological state when pregnant women need various nutrients and iron and folic acid supplements to reduce incidence of Anemia⁹.

The interventions for successful elimination of neonatal tetanus are increased coverage of maternal tetanus immunization through antenatal care services, promotion of institutional deliveries through JSY scheme, availability of safe delivery kits training and promotion of safe delivery practices under the National Health Mission¹⁰.

To improve utilization of antenatal care in developing countries, focus should be on full antenatal care as it includes most important components of ANC, four visits means more contacts, two tetanus toxoid and at least 100 days iron folic acid supplementation to pregnant women to reduce maternal and neonatal mortality and morbidity¹¹.

Even after provision of 108 and 102 ambulance services, referral transport for pregnant women is still a major problem to achieve safe delivery and healthy mother and baby. For maximum utilization of antenatal care services early referral and well equipped transfer facilities are necessary⁶.

Community participation is necessary intervention to reach each and every pregnant woman therefore all public health programs targets community participation for maximum utilization of antenatal care services. Community participation should be encouraged and intervention like SMS services among women seeking antenatal care, health care providers and community are very effective^{12,13}.

Routine antenatal care is not as effective as expected but it requires interventions with routine care, only one intervention is not as effective as combination of interventions and integrated, controlled monitoring and implementation is required¹⁴.

In district Dehradun, full ANC of urban and rural region are quite low 15.3% and 23.2% respectively¹⁵, that needs study along with immediate interventions to improve full ANC coverage for better pregnancy outcome.

Another study in Jabalpur district of Madhya Pradesh shows that even after all physical facilities was present in urban areas in comparison to rural areas, there was poor utilization of antenatal care services which needs detailed study and immediate intervention¹⁶.

Policy, programs and special interventions should be initiated to remove the inequality in utilization of health services in district Dehradun, Uttarakhand¹⁷. Utilization of JSY services was found to be low in rural areas of Uttarakhand i.e. 38.7%. Thus, IEC activities and ASHA's work need to be strengthened and properly monitored. Awareness of full ANC as part of JSY scheme with community participation is also necessary to improve utilization of ANC services¹⁸. So this study aims to determine the effect of Combined

Intervention Approach (CIA) to achieve full antenatal care among pregnant women and its impact on pregnancy outcome in district Dehradun.

Need of the study: -

There is a need of combination of evidence based interventions with current routine ANC services, for better pregnancy outcome as well as maternal and neonatal health. There are lack of evidence based interventional studies to identify the gap and bridge the gap of utilization of full antenatal care services in India.

As this study has very good feasibility, so interventions can be carried out with routine ANC services by peripheral health care providers without any extra outsourcing and harmful effects on study participants.

Scope of the study:

If this study proven to be effective, then without any extra cost and burden, ANC services can be strengthened with these interventions and full ANC coverage can be improved that ultimately improve pregnancy outcome as well as maternal and neonatal health. It can be continued as added approach by health care providers in the conventional system after the study. Presently there are lack of interventions to achieve full ANC and for maximum utilization of antenatal services. This study will help to identify the gap between intervention and control group. If the study outcome will prove the significant difference between these groups, then this study project will be helpful for low resource countries to achieve the maximum utilization of full ANC and better pregnancy outcome.

Hypothesis (H₀)- There will be no difference in utilization of full ANC services and pregnancy outcome between Combined Intervention Approach (CIA) and conventional utilization of ANC services.

Operational definitions:-

Combined Intervention Approach (CIA):- It includes multiple intervention (set up of control room, mobile application, community participation with identification and utilization of alternative referral transport at community level and sensitization for high risk pregnancy with conventional ANC services).

Conventional utilization of ANC services:- Routine health services given by health care providers

Full ANC:- Four ANC visits, two tetanus toxoid injections and IFA tablets for 180 or more days.

Assumptions:-

complete utilization of antenatal care services in Uttarakhand will affect the pregnancy outcome as well as maternal and neonatal health.

All the documented data (Mother and Child Protection Card, RCH Register and delivery register) will show that health care providers have done the work honestly.

All health care providers and pregnant women will co-coordinate honestly for the completion of interventional study at Uttarakhand.

Delimitation: -This study is delimited to the pregnant women registered in first trimester of pregnancy in district Dehradun including rural and urban area both.

Aims and objectives: -

Primary Objective:

- To determine the effect of Combined Intervention Approach (CIA) to achieve full antenatal care among pregnant women and its impact on pregnancy outcome.

Secondary objectives:

- To measure the utilisation of ANC services and their pregnancy outcome.
- To compare and identify the gap in control and intervention group among pregnant women, utilising ANC services and their pregnancy outcome.
- To measure the maternal and neonatal health indicators in both control and intervention group.

Material and methods: -

Research approach: A quantitative research approach, **Research Design:** it will be a post-test only, cluster randomized controlled trial.

Sample: -Sample of the study will be pregnant women registered in first trimester at Dehradun district, Uttarakhand, India.

Sampling technique:- Multistage cluster sampling will be used. There are 13 district in Uttarakhand state, due to high rate of NMR and low utilization of full ANC, Dehradun district was selected. There are six blocks in Dehradun, so each block will be selected as a cluster, but there are some blocks have only 10 functional Sub-center and some have 42, so from each block 10 Sub-center will be randomly selected by computer generated randomization method. Each Sub-centre will be final cluster for registration of the pregnant women for study. Finally randomization will be done among six blocks and three blocks will be in intervention group and three will be in control group with 30 sub- centres in each arm. Clusters of UPHC'S will be made for both arm by simple randomization method at urban region.

Sample size: -Sample size will be calculated after pilot study.

Inclusion criteria:

Pregnant woman aged 18-49 years, residents living in Dehradun, registered in Eligible Couple register and registering during first trimester of pregnancy will be eligible for enrollment.

Exclusion criteria:-Those who are not willing to participate/ providing informed written consent in the study and registered after first trimester.

Study Duration: -Total duration of study will be 10 months 15 days. Recruitment will be done for first 03 months of study then Follow-up will be continuing during 9 months pregnancy and 42 days after delivery.

Data Collection Procedure:-

1. Data for ANC will be collected at peripheral ANC clinic working as sub-centre and UPHC in district Dehradun and from JSY room by RCH register, MCP card and delivery register that are currently in use in government system along with semi structured Performa.
2. Data collection monitoring and verification will be done randomly on each session of ANC days at peripheral ANC clinic.
3. Consent of the pregnant women will be taken after requesting at the time of exit from ANC clinic and data obtained by health providers will be cross checked.
4. If difference found in collected data and information provided by beneficiary, then health care providers will be asked to resolve the problem accordingly.
5. MCP card, RCH register and delivery register will be used for primary data collection.
 - At ANC clinic for registration and subsequent follow ups for measurements of full ANC coverage and demographic variables.
 - At delivery/ JSY room for the measurements of pregnancy, maternal and neonatal health outcome and also demographic variables.

Intervention group:

1. **“Janani Kendra”**- A control room will be set up at District level for monitoring, reporting, communication and coordination with pregnant mothers, peripheral health workers and community volunteers. For pregnant mother it will work as a call center for missed ANC, various queries and help regarding ANC services and delivery facilities and for availability of alternative transport facilities if needed.
2. **Mobile application** will be developed for time bound follow up by SMS to all registered pregnant mothers, concerned ASHA and ANM for due dates of next ANC visits and due date of delivery. Janani Kendra(control room) will make telephonic call for only missed antenatal care visits and drop out mothers to concerned pregnant mothers, ASHA, ANM and community volunteers to ensure all minimum four visits to avail them full antenatal care and to ensure institutional delivery.
3. **Meri saheli** - Female local community volunteer "Meri saheli" 5 in numbers in each Sub-center and UPHC area and 5 male community volunteers also, to ensure and facilitate antenatal visits in case of missed ANC visit and dropout cases and for identification of local alternative referral transport.

4. **Identification of alternative referral transport at community level-** Identification of 5 local private vehicles in each Sub-center and UPHC area, to be identified by ASHA, ANM, Meri saheli and male community volunteers. The contact number of drivers and vehicle number will be kept in control room and will be provided to health providers on ANC days to mention on each MCP card of every pregnant mother in her area, along with 108 and 102 ambulance services.
5. **Due list** – Due list will be prepared as book in two copy format which will be made at the time of every ANC visits at ANC clinic for next visit and one copy will be given to ASHA to ensure all due pregnant will attend ANC clinic on that due date to ensure timely subsequent visit pregnant women.
6. **God bharai rasam** -In eighth month of pregnancy of all high risk pregnancies "GOD BHARAI RASM" will be arranged at home of that pregnant women with the help of ICDS department (Anganwadi workers), ASHA and community volunteers for sensitization of pregnant mother, her family and community about high risk pregnancy and review of micro plan made previously for planning of delivery at the time of registration as now she needs especial care and management of her pregnancy.

Control group: -

Routine service by ASHA, ANM, LHV and SN and local health care delivery system in control group.

Study tools: -

- **Subject datasheet**
- **Tool no.1- Mother and Child Protection Card.**
- **Tool no.2- Reproductive and Child Health Register**
- **Tool no.3- Delivery register**
- **Tool no.4-Informational guideline for pregnant women**

Subject data sheet includes demographic details about pregnant women for female occupation, husband education and occupation, family income, per capita income and clinical variables includes ,choice of delivery point (private or government), distance of delivery point from residence which will be pasted on Reproductive and child health register.

Tool no.1- Mother and Child Protection Card. (currently used by health care providers in government system to record the information of pregnant women for ANC checkup),**tool no.2-Reproductive and Child Health Register**(section -2 tracking of pregnant women will be used to collect data for the study) [it is issued by ministry of health and family welfare, Govt. of India and maintained by lady health visitor at govt. sector],**tool no.3-Delivery register** at JSY room/ delivery point to collect data.[it is issued by ministry of health and family welfare, Govt. of India and maintained by health care providers at govt. sector],**tool no.4-Informational guideline for pregnant women** includes Janani Kendra contact number, MCTS number, due list, alternate referral services, and contact number of health care providers and nearest delivery point which will be pasted on MCP card of pregnant women at the time of first visit.

Outcome variables: -

Pregnancy outcome :- Live birth (full term or preterm birth), stillbirth, spontaneous abortion, and induced abortion.

Maternal health care indicator: -Maternal mortality rate, number of ANC visits, Hb level at birth, institutional birth by skilled birth attendant, two tetanus toxoid injection, consumption of IFA for 100 days or more.

Neonatal health care indicator: -Thermal care, early initiation of breast feeding within1 hours, at least one postnatal care visit within two days of birth and birth weight.

Confounding variable:-

Age, husband education, socioeconomic status (caste, income, education, occupation), height of mother, BMI and gravida.

Plan of data analysis: -

Analysis will be done using descriptive and inferential statistics. Calculations will be carried out using Microsoft excel and Statistical package for social sciences (SPSS). Data will be analyzed using descriptive (measures of central tendency & measures of dispersion) and inferential statistics.

Ethical clearance:-

Ethical approval will be taken from institutional ethics committee of AIIMS, Rishikesh. Written informed consent will be taken from each study subject. They will be assured of anonymity and confidentiality of the information provided during the study. The consent will also give the right to the subject to withdraw from the study at any time.

Pilot study:-

Pilot study will be conducted at district Haridwar to assess feasibility of the study and decide a plan on statistical analysis.

Potential benefits to the participants:- Interventions will improve the health status of pregnant women such as Hb level, immunization for tetanus etc which will ultimately improve the pregnancy outcome as well as maternal and neonatal health. Pregnant women will gain the benefits of better ANC services, management of high risk pregnancy, early identification, and timely availability of alternative referral transport services.

Potential risk of harms to the participants:- No harm to participants.

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