

Group Antenatal Care to Promote a Healthy Pregnancy and Optimize Maternal and Newborn Outcomes: A Cluster Randomized Controlled Trial

Principal Investigators: Jody Lori, PhD, University of Michigan and Dr. John Williams, Dodowa Health Research Centre

Co-investigators: Cheryl Moyer, PhD, University of Michigan

Study Sponsor: National Institutes of Health; Eunice Kennedy Shriver National Institute of Child Health & Human Development. Grant#: RO1HD096277

ClinicalTrials.gov: ID#: NCT04033003

Part 1: Informed Consent (for women participating in Group ANC)

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Invitation to be Part of a Research Study

The Dodowa Health Research Centre and University of Michigan in the United States are leading a research study. We want to find out how to help women in Ghana have safer births and healthier babies. You are being asked to be in this study because you are a pregnant woman over the age of 15 and speak Dangme, Ga, Akan, Ewe, or English. Taking part in this research project is voluntary. You can choose to be in the study or not be in the study, it is up to you. If you choose not to be in the study, it will not affect your care at the health facility or hospital. You can leave the study at any time and it will not affect your care at the health facility or hospital now or in the future.

Important Information about the Research Study

The purpose of this study is to learn about the best way to provide antenatal care (ANC) to ensure that all women are prepared for childbirth, can recognize problem, and know what to do if problems arise. In this study some health centers will be offering antenatal care (ANC) the regular way, and others will be offering ANC in small groups. The type of ANC care (group or individual) was decided randomly, by a computer, and not by anyone involved in the study or delivering care. Either way, we need to ask women the same questions throughout their pregnancies and beyond to know which way worked better. At this health facility, we are offering ANC in small groups of about 10 – 14 women.

What will happen if you take part in this study?

There will be a total of nine (9) ANC visits during the study. The first visit (today) will be an individual meeting with the midwife during which you will receive all your regular antenatal care - labs, blood pressure checks, urine tests, weight, medications, etc. For ANC visits 2 – 9 you will meet with the midwife and with a group of other pregnant women. Each group ANC visit will last about 2 hours. You will also receive all your regular antenatal care - labs, blood pressure checks, urine tests, weight, medications, etc during

If you take part in this study, you will be asked to complete five (5) surveys. The 1st survey will be today and will take about 60 minute. We will ask some general questions about you, some questions about your health and caring for yourself and your baby during and after pregnancy, about family planning, and your relationships.

You will be asked to meet again to complete a survey during your 3rd trimester, and after the birth of your baby. During these visits you will complete a survey and we will collect information from your ANC card about your blood pressure checks, labs, weight, urine test, medications, etc. Your survey responses and medical information will be kept strictly confidential. These meetings will take about 45 to 60 minutes.

The last two surveys will be done by phone. We will call 6 month and 1 year after you deliver. Each survey will last about 20 - 30 minutes.

How could you benefit from this study?

You will not get special treatment or rewards for being in the group, but we do hope that being in the group and sharing your ideas might help other women and their babies in the future.

Sometimes people tell us they feel good about helping make things better for others. Your participation will also benefit the health system of Ghana with program implementation and improved quality of care for pregnant women and their unborn babies.

What risks might result from being in this study?

Being in the group is not likely to cause you any harm, however there is a small risk of breach of confidentiality. We will ask everyone in the group not to talk outside of the group about anything that we discuss in the group. This way whatever you say will be confidential. We don't think anything we talk about will upset you, but if it does you can leave at any time with no problem to you. If this does happen, you can privately talk to the midwife or other health facility staff who can help you get over being upset.

How will we protect your information?

The information you give us will be kept strictly confidential. We will ask everyone in the group not to talk outside of the group about anything that we discuss in the group. This way whatever you say will be confidential. Researchers will not discuss what happens in the group outside the research team. We will not talk about you being in the group outside the research team. We will store and use your information for future research. We may share it with other researchers but we will not share any information that could identify you. If you do not want your data to be stored and shared you may choose to not be in the study. You will be identified in research records only by a code number that will be stored on a computer that is encrypted and password protected. We will keep your name, phone number, and study ID so we can contact you for follow-up visits. Information that identifies you personally will be kept in a separate locked file cabinet and encrypted on a password protected computer. No one will be able to see it except the research team.

We will use the camera on the tablet to take a shot of your signature or thumbprint on this form. You will be given the original copy and the image will be stored in a password protected file on an encrypted computer or secure server.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

You will not be named in any reports (including www.clinicaltrials.gov) and at no time will a link between you and the answers you give be released.

How will we compensate you for being part of the study?

You will not be paid to be in the study. Each time you complete a survey that is part of the study you will receive a small token of appreciation such as a baby hat, baby blanket, baby socks, or a tote bag.

Your Participation in this Study is Voluntary

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. The investigator may stop your participation in the study without your consent if they believe your health requires a different level of care.

Contact Information for Study Team and Question about the Research

If you any questions concerning this study, you can ask me now or contact the study coordinator Ms Vida Kukula on 0208451202 at the Dodowa Health Research Centre or call her on 0208451202/0244167999.

If you have questions or concerns about the research, please contact the Principal Investigators, **Dr John Williams at Dodowa Health Research Centre on telephone number 0244755358 or Prof. Jody Lori. For international calls from Ghana to the US, +1734-763-0097 or email: jrlori@umich.edu.** Please note the time in Michigan is 5 hours earlier than in Ghana.

Contact Information for Questions about Your Rights as a Research Participant

This research has been reviewed and approved by the Ghana Health Service Ethics Review Committee, the Institutional Review Boards of Dodowa Research Health Centre, and the University of Michigan Health Sciences and Behavioral Sciences Institutional Review Board.

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For international calls from Ghana to the US, +1734-936-0933 or email: irbhsbs@umich.edu.

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If you have any questions about your rights as a research participant, or wish to obtain information, ask questions, or discuss concerns about this study with someone other than the researchers, please contact the following:

Administrator of Ghana Health Service Ethical Review Committee, Ms. Hannah Frimpong on 0302681109/0507041223.

If you wish to find out more about the Dodowa Institutional Review Board, you may contact Ms. Irene Honam Tsey on 0208420640.

Part 2: Informed Consent Form

I have been adequately been informed of (or I have read and understood) the purpose, benefits, risks and procedures for the research title *Group Antenatal Care to Promote a Healthy Pregnancy and Optimize Maternal and Newborn Outcomes: A Cluster Randomized Controlled Trial* . I have been given an opportunity to ask any questions about the research and any questions that I have asked have been answered to my satisfaction. I know that I can refuse to participate in this study and understand that if I agree to participate I can withdraw my consent at any time without any problem. I also understand that any information collected will be treated confidentially. I hereby freely agree to participate in this study.

Date

Name and signature or mark of participant

If participants cannot read the form themselves, a witness must sign here:

I was present while the benefits, risks and procedures were read to the participant. All questions were answered and the participant has agreed to take part in the research.

Date

Name and signature of witness

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in this research have been explained to the above individual.

Date

Name and signature of person who obtained consent