

Study: A Feasibility Study of Integrating Maternal Nutrition Interventions into Antenatal Care Services in Ethiopia: A Cluster-Randomized Evaluation

Clinicaltrials.gov: NCT04125368

Document date: June 2, 2021

CONSENT OF PROVIDER (NURSE-MIDWIFE)

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We will be observing two ANC consultations today. The information collected during this observation will be used to improve maternal nutrition through antenatal care services in this community and across Ethiopia.

There will be no cost to you other than your time. Your participation in the observation is voluntary. You have the right to not participate if you do not want to. Not participating will not affect you or your work at the health center.

During the antenatal care consultations, we will be present in the room only to observe. You can do the antenatal care consultation as normal, without worrying about our presence. We will ask for the consent of the pregnant woman before the start of each consultation. You and the pregnant woman can ask us to stop observing at any time during the consultation. With your permission, we will take notes during the observation and no one will have access to the notes of our observations except the research team.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the observation, or you can talk with:

Dr. Hanna Y. Berhane
Deputy Director for Research and Community Services, Addis Continental Institute of Public Health
Address: Yeka Sub City, Woreda 13, House No. B227
Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts
Research Fellow and IRB Chair
International Food Policy Research Institute
Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA
Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study?	No	0
	Yes	1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF PROVIDER (HEALTH EXTENSION WORKER)

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We will be observing one ANC consultation today. The information collected during this observation will be used to improve maternal nutrition through antenatal care services in this community and across Ethiopia.

There will be no cost to you other than your time. Your participation in the observation is voluntary. You have the right to not participate if you do not want to. Not participating will not affect you or your work at the health post.

During the antenatal care consultation, we will be present in the room only to observe. You can do the antenatal care consultation as normal, without worrying about our presence. We will ask for the consent of the pregnant woman before the start of the consultation. You and the pregnant woman can ask us to stop observing at any time during the consultation. With your permission, we will take notes during the observation and no one will have access to the notes of our observations except the research team.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the observation, or you can talk with:

Dr. Hanna Y. Berhane
Assistant Professor, Addis Continental Institute of Public Health
Address: Yeka Sub City, Woreda 13, House No. B227
Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts
Research Fellow and IRB Chair
International Food Policy Research Institute
Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA
Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study?	No	0
	Yes	1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF CLIENT (PREGNANT WOMAN)

If the pregnant woman is not married and is less than 18 years of age, one of her parents/guardians must give consent.

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We came to you today because you are visiting a health facility in this area. Our work today will be conducted in two stages: First, we would like to observe the antenatal care consultation you receive. Then, at the end, we would like to ask you some questions. The interview may last for about 10-15 minutes.

There will be no cost to you other than your time. Your participation in the observation is voluntary. You have the right to not participate if you do not want to. Not participating will not affect the services that you receive at the health facility.

During the antenatal care consultation, we will be present in the room only to observe. You can do the antenatal care consultation as normal, without worrying about our presence. The health care provider and you can ask us to stop observing at any time during the consultation. The same is true for the interview that we will conduct with you. You do not have to respond to questions to which you do not wish to respond. You can decide to stop the interview at any time. With your permission, we will take notes during the observation and no one will have access to the notes of our observations except the research team.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the observation, or you can talk with:

Dr. Hanna Y. Berhane
Assistant Professor, Addis Continental Institute of Public Health
Address: Yeka Sub City, Woreda 13, House No. B227
Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts
Research Fellow and IRB Chair
International Food Policy Research Institute
Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA
Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study?	No	0
	Yes	1
<i>If woman is not married and <18 years of age:</i>		
Does the parent/guardian give consent for the woman to participate in this study?	No.....	0
	Yes	1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF RESPONDENT (HUSBAND)

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We want to talk with you about health and nutrition during pregnancy. We will also be asking you questions about your household. The information that you provide us will be used to improve maternal nutrition through antenatal care services in this community and across Ethiopia.

The interview may last for about 30 minutes.

The information you will give us will not be disclosed to anyone. It will be kept strictly confidential. No matter how you answer our questions, you will continue to receive all services that you normally receive through health facilities and from Health Extension Workers.

There will be no cost to you other than your time. Your participation in the interview is voluntary. You have the right to not participate if you do not want to. You also have the right to refuse to answer specific questions or to stop this interview at any point during the interview. Not participating will not affect you or your family.

Your participation will be highly appreciated. The answers you give will help provide better information to policymakers and practitioners so that they can plan for better services that will respond to your needs.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the interview, or you can talk with:

Dr. Hanna Y. Berhane

Deputy Director for Research and Community Services, Addis Continental Institute of Public Health

Address: Yeka Sub City, Woreda 13, House No. B227

Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts

Research Fellow and IRB Chair

International Food Policy Research Institute

Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA

Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study?	No	0
	Yes	1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF RESPONDENT (HEALTH EXTENSION WORKER)

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We want to talk with you about the services that you provide at this health post. We will also be asking you questions about training and supervision that you received. The information that you provide us will be used to improve maternal nutrition through antenatal care services in this area and across Ethiopia.

The interview may last for about one hour.

The information you will give us will not be disclosed to anyone. It will be kept strictly confidential.

There will be no cost to you other than your time. Your participation in the interview is voluntary. You have the right to not participate if you do not want to. You also have the right to refuse to answer specific questions or to stop this interview at any point during the interview. Not participating will not affect you or your work.

Your participation will be highly appreciated. The answers you give will help provide better information to policymakers and practitioners so that they can plan for better services that will respond to your needs.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the interview, or you can talk with:

Dr. Hanna Y. Berhane
Deputy Director for Research and Community Services, Addis Continental Institute of Public Health
Address: Yeka Sub City, Woreda 13, House No. B227
Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts
Research Fellow and IRB Chair
International Food Policy Research Institute
Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA
Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study? No 0
--

Yes 1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF RESPONDENT (NURSE-MIDWIFE)

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We want to talk with you about the services that you provide at this health center. We will also be asking you questions about training and supervision that you received. The information that you provide us will be used to improve maternal nutrition through antenatal care services in this area and across Ethiopia.

The interview may last for about one hour.

The information you will give us will not be disclosed to anyone. It will be kept strictly confidential.

There will be no cost to you other than your time. Your participation in the interview is voluntary. You have the right to not participate if you do not want to. You also have the right to refuse to answer specific questions or to stop this interview at any point during the interview. Not participating will not affect you or your work.

Your participation will be highly appreciated. The answers you give will help provide better information to policymakers and practitioners so that they can plan for better services that will respond to your needs.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the interview, or you can talk with:

Dr. Hanna Y. Berhane
Deputy Director for Research and Community Services, Addis Continental Institute of Public Health
Address: Yeka Sub City, Woreda 13, House No. B227
Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts
Research Fellow and IRB Chair
International Food Policy Research Institute
Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA
Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study? No 0

Yes 1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF RESPONDENT (PREGNANT WOMAN)

If the pregnant woman is not married and is less than 18 years of age, one of her parents/guardians must give consent.

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We want to talk with you about your health and nutrition during pregnancy. We will also be asking you questions about your household. The information that you provide us will be used to improve maternal nutrition through antenatal care services in this community and across Ethiopia.

The interview may last for about two hours.

The information you will give us will not be disclosed to anyone. It will be kept strictly confidential. No matter how you answer our questions, you will continue to receive all services that you normally receive through health facilities and from Health Extension Workers.

There will be no cost to you other than your time. Your participation in the interview is voluntary. You have the right to not participate if you do not want to. You also have the right to refuse to answer specific questions or to stop this interview at any point during the interview. Not participating will not affect you or your family.

Your participation will be highly appreciated. The answers you give will help provide better information to policymakers and practitioners so that they can plan for better services that will respond to your needs.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the interview, or you can talk with:

Dr. Hanna Y. Berhane

Deputy Director for Research and Community Services, Addis Continental Institute of Public Health

Address: Yeka Sub City, Woreda 13, House No. B227

Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts

Research Fellow and IRB Chair

International Food Policy Research Institute

Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA

Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study?	No	0
	Yes	1
<i>If woman is not married and <18 years of age:</i>		
Does the parent/guardian give consent for the woman to participate in this study?	No.....	0
	Yes	1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR

CONSENT OF RESPONDENT (RECENTLY DELIVERED WOMAN)

If the recently delivered woman is not married and is less than 18 years of age, a parent/guardian must give consent.

Thank you for speaking with us today.

This interview will be held in accordance with COVID-19 prevention guidelines.

My name is [NAME OF INTERVIEWER]. I am a member of a survey team from Addis Continental Institute of Public Health (ACIPH), a research organization based in Addis Ababa. Together with the International Food Policy Research Institute (IFPRI), we are studying the Alive and Thrive program on maternal nutrition in this area.

We want to talk with you about your health and nutrition during your most recent pregnancy. We will also be asking you questions about your household. The information that you provide us will be used to improve maternal nutrition through antenatal care services in this community and across Ethiopia.

The interview may last for about two hours.

The information you will give us will not be disclosed to anyone. It will be kept strictly confidential. No matter how you answer our questions, you will continue to receive all services that you normally receive through health facilities and from Health Extension Workers.

There will be no cost to you other than your time. Your participation in the interview is voluntary. You have the right to not participate if you do not want to. You also have the right to refuse to answer specific questions or to stop this interview at any point during the interview. Not participating will not affect you or your family.

Your participation will be highly appreciated. The answers you give will help provide better information to policymakers and practitioners so that they can plan for better services that will respond to your needs.

Contact with our survey team presents a risk of spreading COVID-19, an illness that can spread from person to person. To protect you, our survey team members will maintain two meters of distance, wear a mask, and wash or sanitize hands before and after the interview. We will also provide you with a mask. Each member of our survey team was checked for any symptoms of COVID-19 before starting work today. We ask that you let us know whether you have experienced any COVID-19 related symptoms today, so that additional safety measures can be applied if needed.

If you have any questions concerning the study, you may ask questions at any time before agreeing to participate or during the interview, or you can talk with:

Dr. Hanna Y. Berhane
Deputy Director for Research and Community Services, Addis Continental Institute of Public Health
Address: Yeka Sub City, Woreda 13, House No. B227
Tel: +251 116 390034 | Email: hannayaciph@gmail.com

Dr. Lieven Huybregts
Research Fellow and IRB Chair
International Food Policy Research Institute
Address: 1201 Eye St. NW, Washington, DC 20005-3915 USA
Tel: +1 202-862-6481 | Email: l.huybregts@cgiar.org

The researcher read to me orally and explained the consent form. I understand that I am free to discontinue participation at any time if I so choose, and that the investigator will gladly answer any questions that arise.

Do you agree to participate in this study?	No	0
	Yes	1
<i>If woman is not married and <18 years of age:</i>		
Does the parent/guardian give consent for the woman to participate in this study?	No.....	0
	Yes	1

Interviewer's signature: _____ Date: _____ / _____ / _____
DAY MONTH YEAR