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It Takes a Village: a pilot randomized trial to enhance pregnancy care and support in northern Ghana

Submission date
20/05/2024

Recruitment status
No longer recruiting

Registration date
15/07/2024

Overall study status
Completed

Last Edited
28/10/2024

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Maternal mortality remains a significant challenge in the Global South, particularly in sub-Saharan Africa. Many maternal deaths result from causes that could be prevented with simple and low-cost interventions. The World Health Organization (WHO) recommends several practices to ensure a healthy pregnancy, including initiating antenatal care (ANC) in the first trimester, having at least eight contacts with healthcare providers, delivering in a health facility, and starting postnatal care within 24 hours of birth.

In Ghana, the maternal mortality rate stands at 263 women per 100,000 live births, which far exceeds the Sustainable Development Goal 3.1 target of fewer than 70 women per 100,000. Although access to healthcare has improved over time, many pregnant women still do not receive the recommended services. Facilitating contact between providers and patients, especially in rural and impoverished communities, is crucial to ensuring healthy pregnancies. Interventions to improve women's access to care must also consider sociocultural factors such as the lack of autonomy in making health decisions, particularly when payment is required for services. This underscores the need for maternal interventions that are tailored to the context in which they are implemented and that do not exacerbate existing inequalities.

Although maternal service fees were officially waived in Ghana in 2004, many pregnant women still incur out-of-pocket expenses. Indirect costs of attending ANC are also substantial; it often requires an entire day, including transportation and food expenses, as well as finding coverage for childcare and household chores. Since men typically control household finances, their minimal involvement in ANC and low regard for the value of maternal care contribute to the underutilization of these services. Therefore, providing a structured way for men to become involved in pregnancy could improve women's access to care.

Birth preparedness, which involves planning for normal delivery and understanding how to identify and address complications, offers an opportunity for household engagement. Incorporating intra-household dynamics and communicating directly with other household members may strengthen birth planning and enhance both financial and moral support for

women. In Ghana, male involvement during pregnancy is not a current social norm. Changing perceptions about traditional gender roles may require endorsement from trusted authority figures to promote messages around this topic. It is crucial to involve other stakeholders in women's healthcare carefully to avoid potentially curtailing the limited autonomy women have in patriarchal societies.

Our study aimed to strengthen support for pregnant women and ease the burden of antenatal care. We worked directly with communities to emphasize the importance of antenatal care services and supporting women during pregnancy. We also enhanced standard antenatal care by adding home-based services, including monthly phone calls and a home visit to develop a birth plan together with other household members.

Who can participate?
Pregnant women who are registering for the first antenatal care visit at one of the study centres. Registration is restricted to women who live in the catchment area of the study facility, are 18+ years old, registering for first ANC visit in their first or second trimester of pregnancy.

What does the study involve?
Community meetings at randomly selected villages from the catchment area and enhanced model of antenatal care that includes monthly phone calls and a home visit in the 7th month of pregnancy that includes the woman's husband and mother in law to develop a birth plan.

What are the possible benefits and risks of participating?
Community engagement about pregnancy and antenatal care, encouraging community support for pregnant women, maintaining contact throughout pregnancy via phone, and developing a birth plan with important family members at the woman's home.
Risk include discomfort from study questions.

Where is the study run from?
Navrongo Health Research Centre in the Upper East Region of Ghana.

When is the study starting and how long is it expected to run for?
July 2020 to November 2022

Who is funding the study?
Development Impact West Africa (DIWA)

Who is the main contact?
Aaron Abuosi, AAbuosi@ug.edu.gh
Aleksandra Jakubowski, PhD, a.jakubowski@northeastern.edu

Contact information

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Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
AEARCTR-0010360

Study information

Scientific Title
A pilot randomized trial to enhance antenatal care for women in northern Ghana

Study objectives
Providing enhanced model of antenatal care (that includes phone calls and home visit) as well as community outreach will improve pregnancy care, strengthen support during pregnancy, improve knowledge of danger signs and birth preparedness.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 16/07/2021, Navrongo Health Research Centre Institutional Review Board (P.O. Box 114, Navrongo, -, Ghana; +233-382122310; irb@navrongo-hrc.org), ref: App/UofMCtCE/7/2021

2. approved 29/07/2021, Committee for Protection of Human Subjects (1608 Fourth Street, Berkeley, 94710, United States of America; +1 5106427461; ophs@berkeley.edu), ref: FWA# 00006252

Study design
Multi centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Antenatal care for pregnant women

Interventions
Randomized controlled trial testing the impact of 1) community meetings to improve knowledge about antenatal care and support for women during pregnancy and 2) enhanced model of antenatal care that included monthly phone calls and a home visit. The control communities did not receive community meetings about antenatal care and control pregnant women received standard antenatal care (women encouraged to come back to facilities for routine checkups during pregnancy).

To implement the community-level intervention, our study leveraged durbars: traditional village meetings in northern Ghana where local authority figures discuss important matters with community members. Durbars are mobilized by the village chief and elders and the messages aired through these meetings are generally respected because they are sanctioned by the authority figures. We asked for permission to organize pregnancy-themed durbars in which the midwife from a local clinic met with men and women from the villages they serve to discuss the barriers women face to ANC attendance and provided education about pregnancy, antenatal care, and supporting women during pregnancy. We then randomized half of the communities in the study catchment area to receive an ANC-focused durbar. Themes that were stressed to communities included the importance of starting ANC in the first trimester, the significance of various services included in ANC (such as hemoglobin test, ultrasound, iron supplements), and male partner involvement. Randomization to the Durbars intervention was allocated by investigators using random number generator, with 50% chance of village selection. Each randomly selected community received one ANC-themed durbar during the study period.

Following the Durbars intervention, research staff were stationed at five clinics to recruit pregnant women for the study. Eligible women were 18 years or older, new registrants for ANC, and in the first or second trimester of pregnancy. Once recruited, research staff randomly pulled a sealed envelope that allocated an ID number and treatment assignment to the participant. Control women received standard care that encouraged them to return to health facilities for in-person ANC services and deliver the baby at the health facility. Recruited women had 40% chance of being randomly allocated for the Enhanced ANC intervention, that added monthly phone calls and a home visit to the standard care. Midwives made monthly phone calls based on a schedule developed by the research staff to check on the woman’s health and pregnancy, remind her of pregnancy danger signs, and encourage her to return for in-person checkups. Community health officers (CHOs) added home visits to their community outreach trips. The

home visit was scheduled to occur in the seventh month of pregnancy to ensure the plans were already tangible but left enough time for making the arrangements. The CHO scheduled the home visit ahead of time to ensure that the pregnant woman's husbands and mothers-in-law were available to take part in birth planning in birth planning.

Intervention Type
Behavioural

Primary outcome(s)
Community intervention: ANC initiated in first trimester measured by recording month at first round of survey collected when woman is registering for ANC.
Enhanced ANC intervention: Woman developed a birth plan measured by survey response after birth (yes/no)

Key secondary outcome(s))
1. Husband/partner accompanied woman to first ANC appointment measured by survey response after first ANC visit.
2. Woman received at least 8 ANC visits during pregnancy measured by survey response after birth.
3. Woman received all recommended ANC services measured by survey response after birth.
4. Woman used birth plan measured by survey response after birth.
5. Woman developed birth plan with husband measured by survey response after birth.
6. Woman had money saved for delivery measured by survey response after birth.
7. Woman made arrangements for blood donor prior to delivery measured by survey response after birth.

Completion date
07/11/2022

Eligibility

Key inclusion criteria
1. Pregnant woman at least 18 years old
2. In first of second trimester of pregnancy at ANC registration
3. Enrolling in ANC at one of the study clinics
4. Woman lives in one of the villages in the catchment area

Participant type(s)
Patient, Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

Female

Total final enrolment
283

Key exclusion criteria
1. Younger than 18 years
2. registering for first ANC appointment in third trimester of pregnancy

Date of first enrolment
12/08/2021

Date of final enrolment
13/01/2022

Locations

Countries of recruitment
Ghana

Study participating centre
Presbyterian Health Centre, Garu
Garu Township, Upper East Region of Ghana
Garu
Ghana
-

Study participating centre
Presbyterian Health Centre, Bolgatanga
Bolgatanga Township, Upper East Region of Ghana
Bolgatanga
Ghana
-

Study participating centre
Presbyterian Health Centre, Nomalgo
Nomalgo Township, Upper East Region of Ghana
Nomalgo
Ghana
-

Study participating centre

Presbyterian Health Centre, Woriyanga
Woriyanga Township, Upper East Region of Ghana
Woriyanga
Ghana
-

Study participating centre
Presbyterian Health Centre, Sumaduri
Sumaduri Township, Upper East Region of Ghana
Sumaduri
Ghana
-

Sponsor information

Organisation
Development Impact West Africa

Funder(s)

Funder type
Research organisation

Funder Name
Development Impact West Africa

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request from Aleksandra Jakubowski, a.jakubowski@northeastern.edu. Data will be anonymized prior to sharing the dataset.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/10/2024	28/10/2024	Yes	No