ISRCTN53107672 https://doi.org/10.1186/ISRCTN53107672

PANDA e-health for antenatal care

Submission date
05/02/2024

Recruitment status
No longer recruiting

Registration date
16/02/2024

Overall study status
Completed

Last Edited
06/11/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Globally, 2 million babies were stillborn and 2.4 million died within 28 days after birth in 2019. Ninety-eight percent of these perinatal deaths occur in LMICs, with Sub-Saharan Africa and South Asia bearing the greatest burden. Studies have demonstrated an increased risk of perinatal death among women who did not attend antenatal care, had less than four ANC visits or a later initiation. Antenatal care has been associated with improved pregnancy outcomes, for instance, during ANC women are offered testing and diagnosed for infections, including syphilis and HIV, blood pressure is monitored as well as prevention and treatment of mother-to-child transmission of HIV. Antenatal care also offers the opportunity to educate women about pregnancy, birth and newborn care and to develop an individualised birth plan which consider personal needs and wishes, resulting in a positive experience of care for the woman, the baby and her companion. Attending four or more ANC contacts is one of the targets of the Every Newborn Collaboration for 2025. Since 2016, WHO has moved from the Focused Antenatal Care Model (minimum of 4 visits) to recommending at least eight ANC contacts throughout pregnancy. The new model focuses on the provision of respectful, individualised and woman-centred care. In Tanzania, most women attend one antenatal visit but only half attend four or more. Women value the importance of antenatal care but their choice to attend subsequent visits is highly influenced by the visit's contents and how providers approached and treat them during the visit. In recent years, applications and software have developed to support provision of healthcare services and newborn care. Through these e-health solutions health professionals can be facilitated in the diagnosis and treatment of complications early in pregnancy and are supported in providing health education. The interactive nature of some mobile solutions facilitates provision of respectful care and better communication between the woman and the health professional, encouraging continuous attendance to visits. One mobile solution is the Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system, which enables practitioners, allied healthcare professionals and Community Health Workers (CHW) to provide antenatal care to vulnerable populations and people living in LMICs. The aim of this trial is to test the hypothesis that implementation of a PANDA package will increase the number of antenatal contacts between woman and health-provider and reduce episodes of severe neonatal morbidity and mortality in Tanzania.

Who can participate?
Pregnant women (aged 18 and above) booked at a study site in the first and second trimester (estimated <28 weeks gestation), regardless of parity.

Partners of women (aged 18 and above) recruited into the study, who also attended at least one ANC visit with their female partner.
Nurse-midwives delivering routine ANC in control sites.
Nurse-midwives using PANDA to deliver ANC to pregnant women in intervention sites.
Obstetricians / Senior Medical Officers from the Haydom Referral Hospital, in charge of validating the ANC visit data received in the Medical Unit from the intervention facilities.
District health officers, Regional Health officers, representative of Ministry of Health and other key stakeholders involved in prenatal care in Manyara Region and Tanzania.

What does the study involve?
Pregnant women recruited to the usual care arm of the trial will have details of their antenatal care collected from records each time they attend for routine care, whilst pregnant women recruited to the intervention arm will have their antenatal care data entered into the PANDA system app. Women in the intervention arm may also be asked if they are willing to have their antenatal visit observed by a researcher. After the birth all women will be invited to complete an exit questionnaire asking about aspects of their pregnancy and birth care and will be asked if willing to take part in a follow up interview 2-6 weeks postbirth. Partners of participating women, healthcare workers and key informants will be invited to take part in one-to-one interviews.

What are the possible benefits and risks of participating?
There is no direct benefit intended to you of taking part in this research. However, this study may assist health workers to improve the antenatal care provided to women in the future.

Where is the study run from?
The PANDA trial is run by the NIHR Stillbirth & Neonatal Death Unit at the Liverpool School of Tropical Medicine with Catholic University of Health and Allied Sciences, Mwanza (Tanzania) and Haydom Lutheran Hospital is the coordinating centre in Manyara, Tanzania. The Sponsor, Liverpool School of Tropical Medicine, is ultimately responsible for the safe conduct of the study and the well-being of participants.

When is the study starting and how long is it expected to run for?
July 2023 to December 2025

Who is funding the study?
This study is funded by UK National Institute for Health Research Global Health Research Unit on the Prevention and Management of Stillbirth and Neonatal Death in sub-Saharan Africa and South Asia [132027].

Who is the main contact?
Prof Dame Tina Lavender (CI), tina.lavender@lstmed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Tina Lavender

ORCID ID

https://orcid.org/0000-0003-1473-4956

Contact details
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA
+44 151 832 1689
tina.lavender@lstmed.ac.uk

Additional identifiers

Protocol serial number
LSTM 23-060

Study information

Scientific Title
Evaluation of the PANDA e-health system as a tool to increase antenatal contacts and improve perinatal outcomes in Tanzania: A pragmatic cluster randomised controlled trial

Acronym
PANDA

Study objectives
The PANDA trial will test the hypothesis that implementation of the adapted Pregnancy and Newborn Diagnostic Assessment (PANDA), incorporating respectful care prompts, increases the number of ANC contacts between women and health providers and reduces episodes of severe perinatal morbidity and mortality in Tanzania, when compared to usual care.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Submitted 18/09/2023, Liverpool School of Tropical Medicine (Pembroke Place, Liverpool, L3 5QA, United Kingdom; +44 1517029396; lstmrec@lstmed.ac.uk), ref: 23-060

2. Approved 15/12/2023, National Institute for Medical Research Tanzania (3 Barack Obama Drive, Dar Es Salaam, PO Box 9653, Tanzania; +25522212400; nimrethics@gmail.com), ref: NIMR /HQ/R.8A/Vol.IX/4087

Primary study design
Observational

Study design
Pragmatic multicentre cluster randomized controlled trial with embedded economic evaluation and alongside process evaluation

Study type(s)

Other

Health condition(s) or problem(s) studied
PANDA will include pregnant women attending antenatal care to collect data on maternal and newborn care outcomes

Interventions
The Pregnancy and Newborn Diagnostic Assessment (PANDA) e-health system will be used in intervention sites. The intervention comprises of three key components, making up the PANDA Care Package
1. The PANDA app – icon-based Android application
2. Point of Care testing diagnostic tools
3. The Medical Unit– java web-based database hosted inside the referral hospital.

The intervention will be compared with 'usual care' for pregnant women attending the control facilities for antenatal care. This will include history taking and screening using an antenatal card, which the health worker completes.

Intervention Type
Mixed

Primary outcome(s)
1. Number of women who have >4 antenatal visits measured using number of antenatal visits attended prior to birth
2. Rate of severe perinatal morbidity and mortality measured using NICU admission >24hours, Apgar Score < 7 at 5 min, stillbirth, early neonatal death

Key secondary outcome(s)
1. Maternal antenatal experience measured using semi-structured qualitative interviews conducted with women during their antenatal care period on the trial and up to 2-6 weeks post-birth
2. Maternal perceptions of respectful care measured using the Person-Centred Prenatal Care Scale Exit questionnaire administered at study exit visit post-birth
3. Number of antenatal referrals to central facility measured using total number of external referrals for high risk pregnancy collected on site and central unit referral logs at study exit
4. Intrapartum transfer rates central facility measured using referrals data collected on the post-birth form at study exit
5. Maternal clinical outcomes including mode of birth, transfusion, anaemia, severe pre-eclampsia, postpartum haemorrhage, sepsis, breastfeeding, WHO severe morbidity scale and maternal mortality (up to 6 weeks PN) measured using post-birth, Adverse Events and Serious Adverse Events forms collected during antenatal care visits up to study exit post-birth
6. Neonatal clinical outcomes including components of the severe perinatal morbidity outcome measured using Adverse and Serious Adverse event forms collected during antenatal care visits up to study exit post-birth

Cost-effectiveness outcomes:
7. Cost to implement PANDA (including training and device provision) measured using a bespoke resource utilisation questionnaire, which will be completed once by each participating site. The questionnaire captures the resources used by each site to implement the PANDA intervention.

Process evaluation outcomes:
8. PANDA implementation in terms of fidelity, 'dose', reach and adaptation made in the study context is measured using the baseline and monthly site logs; participant recruitment logs; observation grid and checklists and semi structured qualitative interviews conducted with women, partners, health workers and key informants during the course of the trial
9. Why the use of PANDA e-health system has increased / not increased the number of antenatal contacts between woman and providers from the perspectives of women, partners and healthcare workers measured using semi structured qualitative interviews during the course of the trial.
10. Implementation strategy/ies for scale-up and dissemination of PANDA e-health system in other districts and region in Tanzania measured using baseline and monthly site logs; observation grid and checklists and semi structured qualitative interviews health workers and key informants during the course of the trial

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Main trial inclusion: Pregnant women (aged 18 and above) booked or planning to start their ANC at the study sites in the first and second trimester, regardless of parity.

Process Evaluation inclusion:
Pregnant women (age 18 and above) recruited into the study (both control and intervention arms) who:
1. Have actively engaged in antenatal care (>4 more visits)
2. Have not actively engaged in antenatal care (< 4 visits)
3. Partners of women (aged 18 and above) recruited into the study, who also attended at least one ANC visit with their partner.
4. Midwives delivering routine ANC in control sites.
5. Midwives using PANDA to deliver ANC to pregnant women in intervention sites.
6. Obstetricians / Senior Medical Officers from the Haydom Referral Hospital, in charge of validating the ANC visits received in the Medical Unit from the intervention facilities.
7. District health officers, Regional Health officers, representative of Ministry of Health and other key stakeholders involved in prenatal care in Manyara Region and Tanzania

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit

60 Years

Sex
Female

Key exclusion criteria
1. Women on ‘high risk’ pathway
2. Women unable/declining consent

Date of first enrolment
19/02/2024

Date of final enrolment
28/02/2025

Locations

Countries of recruitment
Tanzania

Study participating centre
Haydom Lutheran Hospital
Mbulu District
Manyara
Tanzania
PO Box 9000

Study participating centre
Bassodesh Dispensary
Hanang District
Manyara Region
Tanzania
-

Study participating centre
Bassotu Dispensary
Bassotu Ziwani
Manyara Region
Tanzania
-

Study participating centre

Getanuwas Dispensary
Hanang District
Manyara Region
Tanzania
-

Study participating centre
Murjanda Dispensary
Hanang District
Manyara Region
Tanzania
-

Study participating centre
Laghanga Dispensary
Hanang District
Manyara Region
Tanzania
-

Study participating centre
Gendabi Health Centre
Hanang District
Manyara Region
Tanzania
-

Study participating centre
Endahargadat Dispensary
Mbulu District
Manyara Region
Tanzania
-

Study participating centre
Kidarafa Dispensary
Mkalama District
Singida Region
Tanzania
-

Study participating centre
St Agnes Mwanga
Mkalama District
Singida Region
Tanzania
-

Study participating centre
Mewadan Dispensary
Mbulu District
Manyara Region
Tanzania
-

Study participating centre
Haydarer Dispensary
Mbulu District
Manyara Region
Tanzania
-

Study participating centre
Maretadu Dispensary
Mbulu District
Manyara Region
Tanzania
-

Study participating centre
Labay Pentecostal Dispensary
Mbulu District
Manyara Region
Tanzania
-

Study participating centre
Bashay Dispensary
Mbulu District
Manyara Region

Tanzania
-

Study participating centre
Masqaroda Dispensary
Mbulu District
Manyara Region
Tanzania
-

Study participating centre
St Alois Health Center
Mbulu District
Manyara Region
Tanzania
-

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Datasets generated and/or analysed during the trial will be available on request from the sponsor, Liverpool School of Tropical Medicine. The Chief Investigator will make the decision to supply research data to potential new users tina.lavender@lstmed.ac.uk)

IPD sharing plan summary
Available on request