ISRCTN94429427 https://doi.org/10.1186/ISRCTN94429427

CRADLE 5: Evaluating the national scale-up of the CRADLE vital signs alert device in Sierra Leone. Helping pregnant women get to the right place at the right time.

Submission date
12/04/2022

Recruitment status
No longer recruiting

Registration date
20/04/2022

Overall study status
Completed

Last Edited
30/06/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Sierra Leone (SL) has one of the highest death rates among pregnant women and their infants in the world. Sadly, 1 in 17 women will die during their lifetime in childbirth. More than three-quarters of these unnecessary deaths are caused by diseases of high blood pressure, bleeding and infection, all of which are preventable. If treated at the right time, the life-saving interventions are not expensive and are currently available in Sierra Leone. Unfortunately, almost 1 in 5 healthcare facilities do not have a functioning blood pressure device, and staff are often not adequately equipped to respond, meaning these women are not identified until they are very sick.
The CRADLE device is an accurate, portable and easy-to-use blood pressure and heart rate monitoring that has a built-in traffic light alert system. This warning system alerts even untrained users when a woman has abnormal heart rate and/or blood pressure, and therefore when they need to act. In 2017, the CRADLE device and training package were trialed across eight countries. The trial data from Sierra Leone was promising; introducing CRADLE into one hospital and the surrounding community facilities reduced the number of women dying by 60%. The aim of this study is to scale up the device and training across the whole country to determine whether nationwide use is feasible and can improve outcomes for mothers and their infants by 20%.

Who can participate?
Women who are pregnant within the time period of the trial from a participating district in Sierra Leone

What does the study involve?
Eight districts in Sierra Leone will each be randomly allocated, one after the other, step by step, to receive the CRADLE device and training. By the end of the trial, all of the districts will be included. This means that all hospitals and community clinics providing care to pregnant women will have received CRADLE devices and all their staff will be trained to use the device, and how

to respond when a woman is sick. All pregnant women will receive care using the CRADLE device during their antenatal visits, labour and post-delivery care.

What are the possible benefits and risks of participating?
The CRADLE device is a safe and validated blood pressure machine. Blood pressure and heart rate measurement are both recommended by the WHO as standard care for pregnant women. The study will provide additional blood pressure devices to all government healthcare facilities; currently 20% of facilities do not have even one functioning blood pressure device. The aim of the traffic light and training package is to help the healthcare worker to recognise and respond to abnormal vital signs when a woman has either low (bleeding or infection) or high (pre-eclampsia/eclampsia) blood pressure. There are no additional risks to participants.

Where is the study run from?
This study is running in eight of the sixteen districts in Sierra Leone and is being sponsored by King's College London (UK)

When is the study starting and how long is it expected to run for?
September 2021 to January 2024

Who is funding the study?
National Institute for Health Research (NIHR) Global Health Research Group (CRIBS) (UK)

Who is the main contact?
1. Dr Alexandra Ridout, Alexandra.ridout@kcl.ac.uk
2. Dr Francis Moses, franqoline@gmail.com
3. Prof. Andrew Shennan, Andrew.shennan@kcl.ac.uk

Study website
https://cribs-i.org

Contact information

Type(s)
Scientific

Contact name
Dr Alexandra Ridout

ORCID ID
https://orcid.org/0000-0003-0988-7229

Contact details
King's College London
London
United Kingdom
SE1 7EH
+44 (0)20 7188 7188
Alexandra.ridout@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HR/DP-21/22-27014

Study information

Scientific Title
Scale up of the CRADLE Vital Signs Alert (VSA) in Sierra Leone: a stepped-wedged type 2 hybrid implementation-effectiveness randomised controlled trial

Acronym
CRADLE 5

Study objectives
Real-world scale-up of the CRADLE semi-automated Vital Sign Alert device and simple education package used by healthcare providers across community and facility levels will reduce maternal and perinatal mortality and major maternal morbidity from the three leading causes of maternal death in Sierra Leone (obstetric haemorrhage, sepsis and pre-eclampsia).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 27/01/2022, King's College London Ethics Committee (Franklin Wilkins Building, 5.9 Waterloo Bridge Wing, Waterloo Road, London, SE1 9NH, UK; +44 (0)20 7848 4020/4077; rec@kcl.ac.uk), ref: HR/DP-21/22-27014
2. Approved 24/01/2022, Sierra Leone Ethics and Scientific Review Committee (Government of Sierra Leone. Office for the Sierra Leone Ethics and Scientific Review Committee, Directorate of Training and Research, 5th floor, Youyi Building Brookfields, Freetown, Ministry of Health and Sanitation, Sierra Leone; +232 (0)78 36 64 93; efoday@mohs.gov.sl), ref: not applicable

Study design
Hybrid 2 implementation-effectiveness cluster stepped-wedge randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Reduction of maternal and perinatal morbidity and mortality from obstetric haemorrhage, sepsis and pre-eclampsia in pregnant or postpartum women in Sierra Leone

Interventions
The researchers will undertake a implementation-effectiveness cluster randomised controlled trial in a stepped wedge design, rolling out the intervention and prospectively evaluating both the implementation of this complex intervention and its impact on significant maternal and neonatal morbidity and maternal mortality. They will use mixed methods to explore implementation outcomes.

Eight districts in Sierra Leone have been identified to take part in the stepped wedge randomised control trial and will be randomised to the eight randomisation clusters. Randomisation will be managed via a secure web-based randomisation facility.

Each randomisation cluster crosses over from control to the CRADLE intervention at six-weekly intervals. Each district comprises a secondary or tertiary health centre with multiple satellite government primary and community peripheral health units. Prior to transitioning to the CRADLE intervention, all women will be managed according to local guidelines. None of the districts will receive the intervention at timepoint 0. District 1 is randomly allocated to receive the intervention at timepoint 1, while all the remaining areas contribute to the control at this timepoint. District 2 is randomly allocated to the intervention at timepoint 2 and so on.

Component 1 - Microlife CRADLE Vital Sign Alert (VSA) device:
The Microlife CRADLE VSA is one of the few blood pressure devices to have been validated in pregnancy (including pre-eclampsia) and the only one validated for women with low BP. It is cost-effective (<$20) and can be used effectively by unskilled personnel after minimal training. The device fulfils the World Health Organisation requirements for low-resource settings. Other unique developments suited to low-income countries include a micro-USB charging ability and a “traffic light” early warning system for hypertension and shock (secondary to either obstetric haemorrhage or sepsis).

Component 2 - Training programme:
The training programme consists of a short, animated film, interactive session, booklet, poster and aide memoire card attached to the CRADLE device. The animated film is in English and has also been translated into Krio.
The content of this training material covers:
1. Use of the Microlife CRADLE device
2. Basic clinical assessment of pregnant women
3. Understanding pre-eclampsia/eclampsia, obstetric haemorrhage and sepsis and review of local management guidelines and protocols
4. Triggers for treatment/referral and familiarisation with local referral pathways
5. CRADLE VSA troubleshooting
6. CRADLE maintenance manual

The trial will run for 12 months. None of the eight districts will have the intervention during the first six weeks. Every six weeks thereafter, each district, one at a time, will receive the intervention. By the end of the 12 months all districts will have received the intervention. Outcome data from all districts will be collected continuously throughout the 12 month trial, with each district having a different amount of before and after data.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Microlife CRADLE Vital Sign Alert (VSA) device

Primary outcome measure
Current primary outcome measures as of 09/06/2023:
The primary outcome is the rate of a composite of maternal (per 10,000 deliveries) and neonatal (per 1000 deliveries) mortality or major maternal morbidity (with no double counting) occurring during pregnancy, labour or within 42 days of delivery including at least one of:
1. Maternal death (all-cause mortality) - measured using routinely collected data at baseline and monthly throughout the 12-month trial
2. Stillbirth (born without signs of life at or after 28 weeks of gestation) - measured using routinely collected data at baseline and monthly throughout the 12-month trial
3. Eclampsia (occurrence of generalised convulsions with increased blood pressure in the absence of epilepsy or another condition predisposing to convulsions) - measured using routinely collected data at baseline and monthly throughout the 12-month trial
4. Emergency hysterectomy (surgical removal of all or part of the uterus) - measured using routinely collected data at baseline and monthly throughout the 12-month trial

Previous primary outcome measures:
The primary outcome is the rate of a composite of maternal (per 10,000 deliveries) and neonatal (per 1000 deliveries) mortality or major maternal morbidity (with no double counting) occurring during pregnancy, labour or within 42 days of delivery including at least one of:
1. Maternal death (all-cause mortality) - measured using routinely collected data at baseline and monthly throughout the 12-month trial
2. Stillbirth (born without signs of life at or after 24 weeks of gestation) - measured using routinely collected data at baseline and monthly throughout the 12-month trial
3. Eclampsia (occurrence of generalised convulsions with increased blood pressure in the absence of epilepsy or another condition predisposing to convulsions) - measured using routinely collected data at baseline and monthly throughout the 12-month trial
4. Emergency hysterectomy (surgical removal of all or part of the uterus) - measured using routinely collected data at baseline and monthly throughout the 12-month trial

Secondary outcome measures
1. Cause and place of maternal death - measured using routinely collected data at baseline and monthly throughout the trial

2. Number and cause of fresh and macerated stillbirths - measured using routinely collected data at baseline and monthly throughout the trial
3. Number and cause of early and late neonatal deaths - measured using routinely collected data at baseline and monthly throughout the trial
4. Place of eclamptic fit - measured using routinely collected data at baseline and monthly throughout the trial
5. Cause of emergency hysterectomy - measured using routinely collected data at baseline and monthly throughout the trial

Routinely collected markers of poor maternal and neonatal outcomes will also be collected from the District Health Information Software 2 (DHIS2) and the National Emergency Medical Service (NEMS) routine database as additional secondary outcomes for each district:
6. Number of obstetric complications related to pregnancy-induced hypertension - measured from routinely collected data from DHIS2 at baseline and monthly throughout the trial
7. Number of obstetric complications related to haemorrhage - measured from routinely collected data from DHIS2 at baseline and monthly throughout the trial
8. Number of obstetric complications related to pregnancy-related infection - measured from routinely collected data from DHIS2 at baseline and monthly throughout the trial
9. Number of obstetric complications related to anaemia - measured from routinely collected data from DHIS2 at baseline and monthly throughout the trial
10. Total number of maternity referrals - measured from routinely collected data from the National Emergency Medical Service (NEMs) at baseline and monthly throughout the trial
11. Number of NEMS maternity referrals related to:
11.1. Hypertension - measured from routinely collected data from the National Emergency Medical Service (NEMs) at baseline and monthly throughout the trial
11.2. Eclampsia - measured from routinely collected data from the National Emergency Medical Service (NEMs) at baseline and monthly throughout the trial
11.3. Bleeding in pregnancy - measured from routinely collected data from the National Emergency Medical Service (NEMs) at baseline and monthly throughout the trial
11.4. Pregnancy-related infection - measured from routinely collected data from the National Emergency Medical Service (NEMs) at baseline and monthly throughout the trial
12. Number of NEMS maternity referrals with blood transfusion requested - measured from routinely collected data from the National Emergency Medical Service (NEMs) at baseline and monthly throughout the trial

Process and implementation outcomes measures include:
13.1. Fidelity/intervention implemented as intended i.e. number of facilities receiving CRADLE devices, number and proportion of healthcare staff trained in CRADLE, number and proportion of blood pressures taken and documented as per CRADLE training, fidelity of CRADLE training. Measured using routinely collected data, reporting forms and direct observations at baseline and monthly throughout the trial
13.2. Adoption/engagement and uptake of CRADLE i.e. timeliness and appropriateness of referrals before and after use of CRADLE, number of proportion of timely and accurate escalation of care when compared to before the introduction of CRADLE, measured using routinely collected data, direct observations, interviews, and focus groups monthly, at baseline, 6, 9-12 months
13.3. Acceptability/satisfaction with the CRADLE intervention among healthcare staff and women and local stakeholders, measured using routinely collected data, interviews and focus groups at baseline, 3, 6, 9-12 months
13.4 Womens' experiences by exploring their views and perspectives on the CRADLE intervention, referral, maternity care and exploring potential mechanisms of change, measured using interviews and focus groups at baseline, 3, 6, 9-12 months.

Baseline and monthly thereafter contextual measures across all districts using routinely collected DHIS2 data will include:
1.1. Number of deliveries completed by: doctor, midwife, SACHO (surgical assistant community health officers), SECHN midwife (state enrolled community health nurse midwife)
1.2. Number of deliveries completed by: CHO (community health officer), CHA (community health assistant), SECHN (state enrolled community health nurse), MCH Aide (maternal and child health aide)
1.3. Number of deliveries completed by: TBAs (traditional birth attendants) and others
2.1. Number of normal vaginal deliveries
2.2. Number of assisted vaginal deliveries
2.3. Number of caesarean sections
3.1. Number of women who had antenatal care 1st visit
3.2. Number of women who had antenatal care 1st visit under 12 weeks
3.3. Number of women who had antenatal care 4th visit (booked)
3.4. Number of women who had antenatal 8th visit (booked):
4.1. Stockout of magnesium sulphate (MgSO4)
4.2. Stockout of ampicillin
4.3. Stockout of gentamycin
4.4. Stockout of metronidazole
4.5. Stockout of oxytocin
4.6. Stockout of misoprostol

Overall study start date
01/09/2021

Completion date
01/01/2024

Eligibility

Key inclusion criteria
All pregnant/postpartum women living in the Trial District within the trial timeframe accessing government maternity healthcare

Participant type(s)
Patient

Age group
All

Sex
Female

Target number of participants
8 clusters. Participants will be all pregnant women within the time period (total trial runs across 12 months).

Key exclusion criteria

No women will be excluded from this trial criteria, as, from an ethical and logistical standpoint, all pregnant women (including those below the age of 16 years) should have access to blood pressure measurement during the antenatal care

Date of first enrolment
29/04/2022

Date of final enrolment
05/06/2023

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Bonthe, Falaba, Karene, Kailahun, Koinadugu, Kono, Moyamba and Tonkolili districts
Sierra Leone
-

Sponsor information

Organisation
King's College London

Sponsor details
8th Floor
Melbourne House
44-46 Aldwych
London
England
United Kingdom
WC2B 4LL
+44 (0)20 7848 3224
EA-VPResearch@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Global Health Research Group (GHRG)

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

Publication and dissemination plan
Planned publications in high-impact peer-reviewed journals and presentations at conferences and seminars.

Intention to publish date
15/02/2025

Individual participant data (IPD) sharing plan
Fully anonymised participant-level quantitative data may be available upon reasonable request and approval. Participants in the qualitative interviews and focus groups discussions are not consenting for their data to be shared publicly or be released to anyone other than the research team and regulatory bodies auditing research practice. For inquiries regarding or requests for the data, please contact Dr Alex Ridout (Alexandra.ridout@kcl.ac.uk) or Dr Francis Moses (franqoline@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		15/09/2023	19/09/2023	Yes	No
Protocol article	Abstract O57 CRADLE 5	13/06/2023	30/06/2025	Yes	No