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Heat adaptation for pregnant women and infants

Submission date
24/04/2025

Recruitment status
No longer recruiting

Registration date
10/06/2025

Overall study status
Completed

Last Edited
02/06/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Extreme heat poses an increasingly serious risk to maternal and newborn health, particularly in low-resource settings where access to cooling infrastructure, safe water, and quality healthcare is limited. Pregnant women are especially vulnerable to heat-related stress due to physiological changes that increase fluid requirements and impair the body's ability to regulate temperature. This study investigates whether a co-designed, multi-level heat adaptation intervention can reduce the incidence of maternal dehydration and improve maternal and newborn health outcomes in rural Zimbabwe.
The study will evaluate both the effectiveness and the implementation of the intervention. The primary focus is to determine whether the intervention reduces the prevalence of mild-to-moderate dehydration during labour, as measured by urine specific gravity. Secondary outcomes include maternal mental health, adverse birth outcomes, and thermal exposure at the household level. The research will also assess how well the intervention was delivered and received, providing critical insights into its feasibility, acceptability, and scalability.

Who can participate?
The study will enrol pregnant women aged 16 years or older who are between 26 and 30 weeks of gestation, reside within the Mt Darwin District, and intend to give birth at one of the designated study facilities. Women experiencing serious pregnancy complications requiring hospitalisation will be excluded.

What does the study involve?
A total of 800 participants will be recruited and assigned to one of two cohorts: a pre-intervention group (400 women enrolled between November 2024 and May 2025) and a post-intervention group (400 women enrolled between November 2025 and May 2026). Both cohorts will be followed prospectively through routine antenatal care, delivery, and up to 72 hours postpartum (or 10 days if necessary).
Women in the second cohort will receive a comprehensive heat adaptation package, which includes personal cooling kits (containing a hat, fan, umbrella, and water bottle), early warning heat alerts delivered by trained Village Health Workers, promotion of traditional water-cooling methods, and behavioural messaging through radio and community groups. The intervention also engages family members, community leaders, and facility staff to create supportive

environments that facilitate the management of heat stress. Facility-level measures include shade tree planting, solar energy systems, ceiling installations, hydration stations, and structural modifications to reduce indoor temperatures.
Data will be collected at four key points: enrolment, antenatal follow-up, delivery, and postpartum. Urine samples, skin temperature, and mental well-being scores will be assessed alongside clinical records and household temperature monitoring. In-depth interviews and process tracking tools will capture fidelity and participant experiences.

What are the possible benefits and risks of participating?
Participants may gain improved access to heat protection resources and greater support in managing heat-related risks during pregnancy. The study offers no direct therapeutic benefit, but participants may benefit from improved comfort and health education. The risk profile is minimal; no invasive treatments are involved. All urine and temperature measurements are non-invasive, and participation is voluntary. To compensate for time and transport costs, participants will receive a modest reimbursement of $10 USD per study visit.
Findings from this study will inform the integration of heat adaptation interventions into maternal health systems in climate-vulnerable regions. Results will support evidence-based policy decisions and may guide future scale-up across Zimbabwe and other heat-affected countries.

Where is the study run from?
CeSHHAR Zimbabwe leads the study in collaboration with Mt Darwin District Hospital, Chitse Rural Clinic, and Dotito Rural Clinic (Zimbabwe)

When is the study starting and how long is it expected to run for?
The study will run from December 2024 to July 2026, with enrolment occurring in two seasonal cycles to align with peak heat periods.

Who is funding the study?
Wellcome Trust, grant agreement number 226758/Z/22/Z (UK)

Who is the primary contact?
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Contact information

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Additional identifiers

Study information

Scientific Title
Co-produced, complex heat adaptation interventions to reduce heat impacts on pregnant women and newborns in Southern Africa: an intervention development and feasibility evaluation study

Acronym
HAPI

Study objectives
It is hypothesised that the co-produced, complex heat adaptation intervention will reduce the prevalence of mild to moderate hypovolemic maternal dehydration during labour, defined as urine specific gravity >1.015, as measured by a handheld optical refractometer, among pregnant women in Zimbabwe.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/12/2024, Medical Research Council of Zimbabwe (20 Cambridge Road, Avondale, Harare, -, Zimbabwe; +263 (0)8644 073772; mrcz@mrcz.org.zw), ref: MRCZ A/3111

Primary study design
Interventional

Study design

Multi-centre non-randomized quasi-experimental pre-post interventional study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Maternal dehydration and heat-related health complications

Interventions
This is a non-randomised, quasi-experimental pre-post interventional study designed to evaluate the feasibility, acceptability, scalability, and pilot effectiveness of a multi-level, multi-component heat adaptation intervention aimed at reducing maternal dehydration and improving maternal and newborn birth outcomes in rural Zimbabwe. The study will be conducted in the catchment areas of Mt Darwin District Hospital, Chitse Rural Clinic, and Dotito Rural Clinic. A total of 800 pregnant women will be enrolled at 26–30 weeks of gestation: 400 in a pre-intervention cohort (November 2024–May 2025) and 400 in a post-intervention cohort (November 2025–May 2026). All participants must intend to deliver at one of the study facilities or nearby clinics. Each cohort will be followed prospectively through routine antenatal care (ANC) contacts scheduled at 4-week intervals - specifically targeting visits at approximately 26, 30, 34 and 38 weeks of gestation - aligned with national ANC guidelines. While actual follow-up will depend on the gestational age at enrolment, the study team will aim to conduct at least one pre-delivery follow-up visit for all participants, in addition to assessments at enrolment, delivery, and postpartum. The window for postpartum visits is up to 10 days. Urine samples for hydration assessment will be collected at four key timepoints: enrolment, follow-up visit, delivery, and postpartum. The intervention comprises a co-designed package of behavioural, structural, nature and policy-level actions, delivered across five implementation levels: individual, household, community, facility, and policy. Participants in the post-intervention cohort will receive the full intervention package, while the pre-intervention cohort serves as the control group. No individual-level randomisation is used. This quasi-experimental, non-randomised design allows for cohort-level comparison of outcome measures pre- and post-intervention exposure. The package includes:
1. Individual-level interventions such as provision of Personal Cooling Kits (wide-brimmed hat, fan, umbrella, water bottle) with structured demonstrations, promotion of traditional water-cooling technologies (chirongo and josaka), and delivery of Mother Heat Alert messages by trained Village Health Workers (VHWs), based on localised heat index thresholds adapted from the U.S. National Oceanic and Atmospheric Administration (NOAA) and the US National Weather Service (NWS).
2. Household-level interventions involving partner and family engagement through structured home visits by Village Health Workers (VHWs) to promote rest, hydration, and labour redistribution, and Cool Roofs to reduce indoor temperatures through the application of reflective paint to household roofs.
3. Community-level interventions will combine behavioural, built environment, and nature-based strategies to strengthen heat resilience for pregnant and postpartum women. Heat Champions - trained community health workers - will deliver tailored risk communication on hydration, rest, and cooling during community visits and events. Boreholes will be transformed into resilience hubs with educational displays and microenterprises. Women's self-help groups and men’s behaviour change interventions will promote peer support and shared caregiving. Traditional leaders will lead participatory adaptation dialogues rooted in ancestral stewardship. Community tree planting will provide shade, reduce ambient temperatures, and reinforce environmental responsibility as a visible, shared adaptation response.
4. Facility-level interventions will enhance thermal comfort and heat resilience across maternity and postpartum wards. Behavioural and structural strategies include the integration of ANC

Heat Health Talks into weekly antenatal care sessions, focusing on heat risks and protective behaviours. Hydration stations will be established within wards to provide immediate, accessible, and potable water to both patients and the health workforce, reducing the physical and psychological barriers to adequate intake during extreme heat. In parallel, the Water Buddie System introduces a behaviourally anchored model of health workforce peer accountability and emotional support, pairing staff to remind, motivate, and normalise hydration as a collective health practice. Drawing on the psychology of buddy systems, this intervention engages trust, routine reinforcement, and social modelling to improve consistent fluid intake among health workers. Built environment upgrades include ceiling installation or repair, energy-efficient LED lighting, solar power systems, and large-volume water storage tanks to ensure cooling and sanitation continuity. Visual messaging displays will rotate guidance on hydration and heat stress, reinforcing protective action. As a nature-based intervention, indigenous shade trees will be planted around facilities to reduce ambient temperatures and contribute to carbon sequestration.
5. Policy-level measures including co-developed Guidelines for Climate-Resilient Vernacular Dwellings, Facility Retrofitting Guidance for thermally safer health infrastructure, and the establishment of a National Interdisciplinary, Multisectoral Climate Health Cluster to function as a governance infrastructure to deliberate on policy, financing, political engagement, and multisectoral coordination.

Participants will be assessed using a mix of quantitative and qualitative methods. The primary outcome is the incidence of mild-to-moderate hypovolemic maternal dehydration during labour, defined as urine specific gravity >1.015, measured via a handheld optical refractometer. Hydration status will be monitored every four weeks from enrolment through postpartum. Secondary outcomes include maternal and newborn composite clinical endpoints (e.g., emergency Caesarean, preterm birth, low birthweight), physiological and behavioural heat strain indicators, adherence to and acceptability of intervention components, mental wellbeing (measured by WHO-5, EQ-5D, and PSS), and household thermal exposure. Fidelity and process metrics will be captured through structured logs, attendance registers, observations, context diaries, qualitative interviews, and community-level feedback mechanisms.

Data will be collected electronically using tablet-based tools in participants' preferred languages. All study staff and Village Health Workers will be trained in consent procedures, study protocols, and standardised measurement techniques. Participants will receive a modest reimbursement of USD 10 per study visit to offset time and transport costs. Findings from the study will inform intervention optimisation, scalability, and policy uptake of heat adaptation interventions targeting heat-vulnerable pregnant and postpartum populations in low-resource settings.

Intervention Type
Behavioural

Primary outcome(s)
Mild-to-moderate hypovolemic maternal dehydration is measured using urine specific gravity (USG >1.015), assessed using validated digital handheld refractometers, including the ATAGO PAL-10S (Cat. No. 4410), at enrolment (26–30 weeks' gestation), at a 4-week antenatal care follow-up visit, during labour, and within 72 hours postpartum (with follow-up window extended to a maximum of 10 days postpartum for participants not seen within 72 hours).

Key secondary outcome(s)

1. Heat strain (physiological) is measured using skin temperature, assessed with validated non-contact infrared thermometers at enrolment (26–30 weeks' gestation), at least one 4-weekly antenatal care follow-up visit, during labour, and within 72 hours postpartum (with follow-up window extended to a maximum of 10 days postpartum for participants not seen within 72 hours). Mean values will be analysed to compare physiological heat stress between the pre- and post-intervention cohorts.
2. Maternal psychological wellbeing is measured using three validated instruments: the Women's Wellbeing and Capability Index (WWCI), the EQ-5D-5L (including the EQ-VAS and overall health state score), and the Perceived Stress Scale (PSS-10). The WWCI is a multidimensional, culturally adapted questionnaire assessing domains such as physical strength, time autonomy, emotional wellbeing, rest, future optimism, caregiving capacity, safety, social support, financial resilience, and housing adequacy. All three instruments are administered at enrolment (26–30 weeks' gestation), at least one antenatal care follow-up visit, and at the postpartum visit (within 72 hours postpartum, with follow-up window extended to a maximum of 10 days postpartum for participants not seen within 72 hours). Scores from each instrument will be analysed independently and compared between pre- and post-intervention cohorts.
3. Maternal composite clinical outcome is measured as the occurrence of one or more obstetric complications — obstetric emergencies, emergency Caesarean section, pre-eclampsia /eclampsia, antepartum haemorrhage, postpartum haemorrhage, or maternal sepsis — as diagnosed by the attending clinician and recorded in routine maternal case records at the time of delivery and/or at the postpartum visit (within 72 hours postpartum, with follow-up window extended to 10 days postpartum for participants not seen within 72 hours). The proportion of participants experiencing at least one complication will be compared between pre- and post-intervention cohorts
4. Neonatal composite clinical outcome is measured as the occurrence of one or more adverse neonatal events, including stillbirth, preterm birth (defined as gestational age <37 weeks and 0 days), low birth weight (defined as birth weight <2500g), APGAR score ≤6 at 5 minutes, or neonatal unit admission. Data are extracted from facility-based delivery records and patient-held maternal health cards within 72 hours postpartum (with follow-up extended to a maximum of 10 days postpartum for participants not seen within 72 hours). The proportion of newborns experiencing at least one event will be compared between pre- and post-intervention cohorts.
5. Household thermal exposure is measured using digital indoor environmental sensors (Onset HOBO MX1101 and MX1104), which continuously monitor dry bulb temperature, globe temperature, and relative humidity at 15-minute intervals. Sensors are battery-powered, with an accuracy of ±0.21°C for temperature (0–50°C) and ±2% for relative humidity (20–80%). In a subsample of households, sensors are securely placed in the primary sleeping or living area at the time of enrolment (26–30 weeks' gestation) and remain in place to collect indoor environmental data continuously until 10 days postpartum. Mean household temperature trends and variability will be compared between pre- and post-intervention cohorts.
6. Implementation outcomes—including intervention fidelity, feasibility, participant engagement, context, and mechanisms of impact—are measured using a mixed-methods approach guided by the United Kingdom Medical Research Council (MRC) Framework for Process Evaluation of Complex Public Health Interventions. Fidelity is measured using structured activity logs, intervention delivery records, and direct observation checklists collected continuously during implementation. Feasibility is assessed through implementer debriefs, key informant interviews, and structured process documentation at midline (5–6 months) and endline (10–12 months). Participant engagement is measured using attendance registers, in-depth interviews, and focus group discussions conducted at midline and endline. Mechanisms of impact are assessed using structured participant feedback forms, acceptability ratings, and narrative data collected through interviews and group discussions. Contextual factors are monitored using researcher field journals, community dialogue reports, and the HAPI Context Tracker, applied longitudinally across the full implementation timeline.

Completion date
15/07/2026

Eligibility

Key inclusion criteria
1. Pregnant, with a gestational age between 26 and 30 weeks at the time of enrolment
2. Aged 16 years or older at the time of providing consent
3. Intending to give birth at a participating health facility within Mt Darwin District (Mt Darwin District Hospital, Chitse Rural Clinic, or Dotito Rural Clinic)
4. Not currently experiencing serious complications of pregnancy that have required hospitalisation
5. Residing within the catchment area of one of the participating facilities
6. Willing and able to provide written informed consent to participate in the study

Participant type(s)
Patient, Population, Service user, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
49 Years

Sex
Female

Total final enrolment
765

Key exclusion criteria
1. Women who are not pregnant at the time of screening
2. Pregnant women with a gestational age below 26 weeks or above 30 weeks at enrolment
3 . Pregnant girls under the age of 16 at the time of consent
4. Women not intending to give birth at any health facility within Mt Darwin District
5. Women with serious pregnancy-related complications requiring current or prior hospitalisation (e.g., severe pre-eclampsia, antepartum haemorrhage)
6. Individuals unable or unwilling to provide written informed consent

Date of first enrolment
19/12/2024

Date of final enrolment
25/04/2026

Locations

Countries of recruitment
Zimbabwe

Study participating centre
Mt Darwin Rural District Hospital
Post Office Box 97
Mt Darwin
Zimbabwe
263

Study participating centre
Chitse Rural Health Center
Post Office Box 97
Mt Darwin
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263

Study participating centre
Dotito Rural Health Centre
Post Office Box 90
Mt Darwin
Zimbabwe
263

Sponsor information

Organisation
Centre for Sexual Health and HIV/AIDS Research Zimbabwe (CeSHHAR Zimbabwe)

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
• Data custodian contact: Dr Fortunate Machingura (fortunate.machingura@ceshhar.org)
• Data available: Anonymised individual-level clinical data related to primary and secondary outcomes
• Availability timeframe: From June 2027, upon reasonable request
• Consent for data sharing: Explicitly included in informed consent forms and approved by the Medical Research Council of Zimbabwe (MRCZ A/3111)
• Anonymisation: All shared datasets will be fully anonymised, with identifying variables removed or masked in accordance with international data protection standards
• Restrictions: Data access requests will be subject to ethical review and data use agreements to ensure participant confidentiality and appropriate use

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			13/05/2025	No	Yes
Participant information sheet			13/05/2025	No	Yes
Protocol file	version 1.4	08/01/2024	13/05/2025	No	No
Statistical Analysis Plan			02/06/2026	No	No