

STUDY PROTOCOL

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Keywords Climate change, Adaptation, Heat exposure, Health impacts, Passive cooling, Controlled trial, Sub-Saharan Africa, South Africa, Ghana

Introduction

Background and rationale

to adapt to climate variability and weather extremes
[34]

researchers will not be blinded to the intervention allocation. There are no pre-defined specific criteria for discontinuing the allocated interventions, but reasons for withdrawal will be tracked and reported in subsequent publications and taken into consideration for analysis.

Setting

The trial will take place in four locations across Ghana and SA: (i) Ga-Mashie (Ghana), a coastal fishing community in Accra; (ii) Nkwantakese (Ghana), a rural village about 25 km outside of Kumasi; (iii) Site B in Khayelitsha (SA), a mixed formal-informal township in the greater

Sample size calculation

Due to the limited available literature on heat adaptation interventions and objective measures of sleep, sample size was calculated based previous findings around

Table 1 Health and environmental outcomes

Outcome	Definition	Functional form	Device/tool	Timing of collection
Clinical measures				
Anthropometrics	Weight (kg), height (m), waist circumference (cm)	Continuous	Seca 813 digital scale; stadiometer; measuring tape	Start of measurement week
Body composition	Body fat mass, body fat %, and fat free mass measured using BIA	Continuous	Quantum Legacy BIA Analyzer	Once per hot season
Blood pressure	Systolic and diastolic resting blood pressure (mmHg) measured in triplicate on two occasions	Continuous	Omron Automatic Digital Blood Pressure Monitor	Start of measurement week
Core body temperature	Internal body temperature (°C) estimated using thermal energy transfer	Continuous	CORE sensor	Continuous over 7-day period
Glucose	Fasting capillary blood glucose (mmol/L)	Continuous	AccuChek Instant Device	Start of measurement week
Physical activity	Acceleration counts per minute	Continuous	Actical accelerometer	Continuous over 7-day period
Sleep behaviour	Actigraphy-derived sleep behaviour (various parameters)	Continuous	Actiwatch Spectrum Plus	Continuous over 7-day period
Hydration status	Urine specific gravity, measure of number of solutes dissolved in urine as compared to water (1,000)	Continuous	Siemens Clinitek Status Analyzer	Start of measurement week
Kidney function	Albumin-to-creatinine ratios (mg/mmol categories)	Categorical	Siemens Clinitek Status Analyzer	Start of measurement week
Questionnaires				
Depression	Responses to 20-item questionnaire rating depression symptom (0 to 3 for each item); scores ranging 0–60, higher scores indicate greater depressive symptoms	Categorical	Center for Epidemiologic Studies Depression Scale (CES-D)	Once per hot season
Drinking behaviour	Self-reported average amount and frequency of liquid consumption	Count	Adapted food frequency questionnaire	Start of measurement week
Mood	Self-reported questionnaire containing 210-item scales (positive and negative affect scores between 10–50).	Categorical	Positive and Negative Affect Scale (PANAS)	End of measurement week
Physical activity	Self-reported physical activity participation in three settings and sedentary behaviour in the past week (MET-minutes)	Categorical	Global Physical Activity Questionnaire (GPAQ)	Once per hot season
Sleep quality	Self-reported sleep quality during the past month; Global PSQI score ranging from 0 to 21. Higher scores indicate poorer sleep quality	Categorical	Pittsburgh Sleep Quality Index (PSQI)	End of measurement week
Excess daytime sleepiness	Responses to 8 items rated on 4-point Likert scale, total score 0–24 with higher number indicating a higher daytime sleepiness	Categorical	Epworth Sleepiness Scale (ESS)	End of measurement week
Thermal comfort	Rating of nocturnal thermal comfort on a 7-point Likert scale	Categorical	ASHRAE 7-point thermal sensation scale	During each night of the measurement week

Table 1 (continued)

Outcome	Definition	Functional form	Device/tool	Timing of collection
Indoor thermal conditions				
Air temperature	Ambient indoor air temperature (°C)	Continuous	DS1923 iButton Hygrochron heat and humidity measurement device	Continuous during the study period
Relative humidity	Water vapor present in the air compared with the total that can be held at a given temperature (%)	Continuous	DS1923 iButton Hygrochron heat and humidity measurement device	Continuous during the study period
External meteorological conditions				
Air temperature	Ambient outdoor air temperature (°C)	Continuous	Automatic Weather Station	Continuous during the study period
Relative humidity	Water vapor present in the air compared with the total that can be held at a given temperature (%)	Continuous	Automatic Weather Station	Continuous during the study period
Wind speed	Hourly average air speed (m/s)	Continuous	Automatic Weather Station	Continuous during the study period
Sunshine	Hourly and total sunshine hours per day	Continuous	Automatic Weather Station	Continuous during the study period
Rainfall	Hourly amount of rainfall (mm)	Continuous	Automatic Weather Station	Continuous during the study period
Cloud cover	Portion of the sky (octas) covered by all types of cloud at the time of observation	Count	Observation	Daily during the study period

Participants self-report average amount and frequency of liquid consumption.

Physical activity Physical activity will be assessed objectively using the Actical accelerometer (Philips Respironics, Bend, OR, USA). The monitor will be worn

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intervention exposure and sleep, our primary outcome as well as secondary physical and mental health outcomes. The mediating effect of night-time indoor temperature on this association will be investigated, while adjusting for the covariates described under Objective 1). In addition to this, structural equation modelling (SEM) will be used to produce a pictographic representation of a-priori determined relationships between the variables of interest. It does this by estimating path equations simultaneously allowing for the calculation of direct, indirect and total effects. For missing data, we will explore different imputation methods and run sensitivity analyses to explore whether participants lost to follow-up differ when compared to those who completed the study measurement periods.

Objective 3. Qualitative data analysis will be done in parallel with the community engagement workshops and Focus Group Discussions, allowing emerging analysis to shape subsequent implementation and data collection procedures. The analysis will answer process evaluation questions and draw on various qualitative methods including but not limited to reflexive thematic analysis and codebook analysis. A qualitative analysis software (such as MAXQDA) will be used by the investigators to facilitate coding, data management, and data interpretation.

Monitoring

An independent advisory committee has been appointed to provide project oversight. The committee is comprised of experts in human physiology, climate science, biostatistics, and investigators with expertise in clinical trials

group differences at both the cross-sectional and longitudinal endpoints.

As global warming progresses so will the need to build local capacity to respond and adapt to heat-related health issues in Africa. HABVIA aims to contribute to this by providing a multidisciplinary platform for climate-health research, education, and policy. In addition, the study's commitment to community engagement for the design and implementation of the intervention, and the resulting mixed-methods approach, will allow for in-depth interpretation of the intervention outcomes and improve relevance and acceptability. Ultimately, the impact of these interventions will depend on uptake, by using locally sourced materials and generating site specific climate and social data that considers baseline health profiles, where pre-existing conditions may make people more vulnerable to heat stress, HABVIA is working towards tailored solutions for multi-vulnerable communities. It can also provide a framework for intervention development in future climate-related studies.

Trial status

This clinical trial is registered with the Pan African Clinical Trials Registry (PACTR), trial ID PACTR202401521630856, version 1. Retrospectively registered on January 12, 2024. The research activities commenced in November 2023, with participant recruitment starting in December 2023 and concluding in September 2024. Research activities are planned to continue until March 2027. This version refers to version 1 (12th January 2024) of the approved protocol.

Abbreviations

AWS	Automatic Weather Station
BIA	Bioelectrical Impedance Analysis
CPM	Counts Per Minute
HABVIA	Heat Adaptation Benefits for Vulnerable groups In Africa
PACTR	Pan African Clinical Trials Registry
SSA	Sub-Saharan Africa
SA	South Africa
SAWS	South African Weather Services
UKRMRC	United Kingdom Medical Research Council

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12889-025-22757-6>.

Supplementary Material 1.

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Authors' contributions

MN and LD conceptualised this study. TK, ADG, KBA, GH, EVL, DEA, MS, and CG contributed to the study conceptualisation and defining study procedures.

MD, CA, and LMS wrote the first draft of the protocol. MD finalised the manuscript.

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