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Study protocol

Community-based Investigation of the Risk Factors for Cardiovascular Diseases in Ibadan and suburbs (COMBAT-CVDs)- Design and Methods

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ABSTRACT

Africa is gradually becoming the epicentre for the burden of cardiovascular diseases (CVDs) worldwide, and community-based data alluding to the pattern and dynamics of escalating epidemiological thresholds of CVDs among indigenous Africans are limited. This manuscript focuses on the design and methods of Community-based Investigation of the Risk Factors for Cardiovascular Diseases in Ibadan and suburbs (COMBAT-CVDs), an ongoing community-based door-to-door study assessing the profile, burden and dynamics of CVDs risk factors among residents of Ibadan and suburbs. COMBAT-CVDs is a cohort of community-dwelling indigenous Africans, males and females, ≥18years from ten communities in Ibadan, Nigeria. The recruitment of participants for the first wave (W_0) started in 2020, covering; questionnaire administration and physical examination. The World Health Organization's STEPS Instrument for Chronic Disease Risk Factor Surveillance was used for data collection. Data were collected on sociodemographic, socioeconomic and lifestyle-related characteristics, history of CVDs, stress, depression and sleep quality. Also, anthropometric and blood pressure measures were conducted by trained personnel using standard operating procedures and instruments. Data collection for the second wave is underway, and the collection of blood and other biological samples for genetic epidemiology is planned, subject to availability of funds. For the W_0 recruitment, a total of 3638 community-dwelling adults (males – 54.6% and females – 45.4%) participated with a ≥99.7% response rate. The COMBAT-CVDs will likely provide novel data, insightful characterization of CVDs risk factors and evidence for context-specific and culturally relevant interventions for the community-based prevention and management of CVDs among Africans in this setting.

Keywords: *COMBAT-CVDs; Cardiovascular diseases; Genetic epidemiology; Ibadan; Nigeria; Africa*

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INTRODUCTION

Cardiovascular diseases (CVDs) remain the leading cause of morbidity and mortality worldwide (Roth et al., 2018; Roth et al., 2020), with significantly rising thresholds in sub-Saharan Africa (Akpa et al., 2020; Yuyun et al., 2020). It accounts for an increased disability life-adjusted years of 12.1 million in 1990 to 18.6 million in 2019 (Roth et al., 2020). While CVDs pose a health problem worldwide, they are often typically discounted as a matter of public health importance among African populations due to the overwhelming burden of infectious diseases (Keates et al., 2017). There is a crucial need to ascertain the burden of CVDs and identify the significance of lifestyle, environmental, and genetic factors on this epidemic in Sub-Saharan Africa (SSA).

Even though a surge in several traditional risk factors such as; physical inactivity and poor dietary habits have been speculated among indigenous SSA populations (Amegah, 2018), these factors' unique and comparative contributions to CVDs occurrence is yet to be characterized. Furthermore, most findings on the burden of CVDs in SSA were primarily from hospital-based settings (Owolabi et al., 2018; Feris and Naicker, 2020), making it tedious to discern the natural history of occurrence. Although some traditional risk factors of CVDs have been identified, the dynamics of these factors are still emerging. The impetus of discerning novel risk factors resulting from lifestyle transitions cannot be underestimated

in discerning cost-effective interventions for the primordial prevention and management of CVDs among African populations. Therefore, understanding the risk factors for CVDs at the community level is crucial for primary prevention.

CVDs manifestations are complex and can involve a constellation of factors in a multifaceted interaction of environment, lifestyle and genetic predisposition. Therefore, any effort(s) towards reducing the burden and designing culturally relevant effective prevention strategies will necessitate a holistic understanding of the relative contributions of CVDs risk factors in SSA. The underlying prevalence, incidence, and risk factors of CVDs in SSA, particularly Nigeria, have not been sufficiently characterized in a community-based setting. This is further aggravated by the dearth of expertise and facilities for sustainable, cutting-edge community-based and longitudinal CVDs research in SSA.

Therefore, the Community-based Investigation of the Risk Factors for Cardiovascular Diseases in Ibadan and suburbs (COMBAT-CVDs) is an indigenous initiative designed to adopt multicultural and ethnically diverse indigenous Africans in Nigeria to adequately characterize or quantify risk factors of CVDs in this setting. The COMBAT-CVDs is likely to unravel novel risk factors of CVDs and provide evidence for community-based and culturally relevant interventions to address the escalating burden of CVDs in this setting.

MATERIALS AND METHODS

Project organization: Study investigators for the COMBAT-CVDs are professionals with vast experience in epidemiology, biostatistics, medicine, rehabilitation science, nutrition and genetic epidemiology. Also, the study employed research assistants, volunteer interviewers and data clerks that could communicate with the respondents without any language barrier. There are also technical staff working at the back-end of the Research Electronic Data Capture (REDCap). The REDCap was an electronic platform used for data capturing. All staff are responsible to their supervisors, who are responsible to the Principal Investigator.

Study Design: The COMBAT-CVDs study is an ongoing study with data collected based on planned waves of data collection using predefined inclusion and exclusion criteria. The design is grounded on a risk-set sampling stratagem of indigenous black populations in a community-based setting that meets the baseline inclusion criteria. The Research Ethics Review Committee of the Department of Planning, Research and Statistics Division of the Ministry of Health, Oyo State Government, Nigeria, approved the study (Approval number AD13/479/2029A). All interviews, assessments and sample collection for the just concluded (and planned waves) were carried out within the community after permission from the community leaders and signed informed consent from intending respondents after community advocacy.

Specific Aims and Hypotheses: COMBAT-CVDs has three broad objectives and underlying hypotheses: our first objective is to evaluate the qualitative and quantitative contributions of traditional sociodemographic, lifestyle and psychosocial risk factors to CVDs among an indigenous black population in a community-based setting. First, we have started cross-sectional recruitment of males and females in Ibadan, Nigeria, and a follow-up in a planned cohort study (Fig. 1). The fundamental premise for this objective is that the distribution of the risk factors is likely to manipulate the dynamics and burden of CVDs among indigenous populations in a community-based setting. Second, we plan to compare sociodemographic, lifestyle, and psychosocial risk factors (at the first wave – W_0) and follow-up for CVDs onset. We hypothesize that differences in the pattern of traditional sociodemographic, lifestyle and psychosocial risk factors may explain variances in CVDs occurrence, type, and outcome among indigenous populations in a community-based setting. The fundamental premise for this objective is to secure reliable phenotypic data to evaluate CVDs risk factors among indigenous populations. Also, the long-term exposure to the risk factors mentioned above could manipulate the dynamics and burden of CVDs outcomes among indigenous populations in a community-based setting. Third, we plan to survey and explicate the beliefs, knowledge, attitude, and practices of indigenous black populations about voluntary involvement in research studies, CVDs and their traditional risk factors. The premise for these objectives stems from the need to secure evidenced-based information for public health and community-based interventions in the form of community education for CVDs prevention, control and management.

Study Location: Ibadan is the third-largest city in Nigeria, located on longitude 3°5′ East of the Greenwich Meridian and latitude 7°2′ North of the equator, at about 530 kilometres Southwest of Abuja, the Federal capital territory of Abuja, Nigeria (National Population Commission - NPC/Nigeria and ICF Macro, 2009). It is made up of eleven local government areas comprising five urban and six peri-urban or rural local governments (Olanrewaju, 2018). Ibadan is heterogeneous by nature and unique for its cultural aggregation of indigenous tribes with a mixed agglomeration of different socio-economic stratum in Nigeria (Fabiyi, 2004).

Sample size estimation and power validation: With a two-sided 95% confidence level, 80% power, 39.2% prevalence of hypertension in Nigeria (Wahab et al., 2021), a 50% R^2 and a 20% non-response rate, a minimum sample size of n=2,840 (approximated to 3,000) was needed to detect odds ratio ≥1.40 for CVDs risk factors in the study. The sample size was proportionally allocated to the selected communities based on their estimated adult population.

Sampling Stratagem: The eligible participants were being selected through multistage sampling techniques. As a result of the door-to-door nature of the data collection, communities in Ibadan (and suburbs) where potential respondents could be assessed during working hours of the day were purposively selected from two semi-urban and three urban LGAs in

Ibadan. A door-to-door approach is being used to recruit every consenting adult in a household visited until the sample size proportionally allocated to the community is reached. A total of ten communities were included in the first wave of recruitment for the study, and subsequent waves are being planned.

Inclusion and Exclusion criteria: All consenting adults (aged >18years) who were permanent resident members of the selected household at the time of the study will be/were recruited. To participate in the study, respondents must be at least 18 years at the last birthday, permanent residents of the selected household/community or have been living continuously in the community in the last six months preceding the survey and apparently healthy. Adults who were not permanent residents of the visited household/community and sick individuals were exempted from recruitment. Also, pregnant and lactating women were excluded from the study.

Enrolment: The enrolment of respondents starts with a detailed presentation of the study objectives to eligible respondents, followed by a consent offering (asserted through the signing of the consent form) by respondents. Trained research assistants conducted in-person interviews in private (and respondents could withdraw from the enrolment at any time without suffering any harm or consequences), followed by physical examination: anthropometric and blood pressure measurements. Fasting blood sample collection is planned and will be collected (in the subsequent waves of recruitment) by a trained phlebotomist after contacting respondents for blood sample collection with detailed instructions on fasting at a prescheduled date.

Data Collection: The data collection comprises three parts: answering the questionnaire, physical (anthropometric and blood pressure) measurements and biochemical assessments (Table 1).

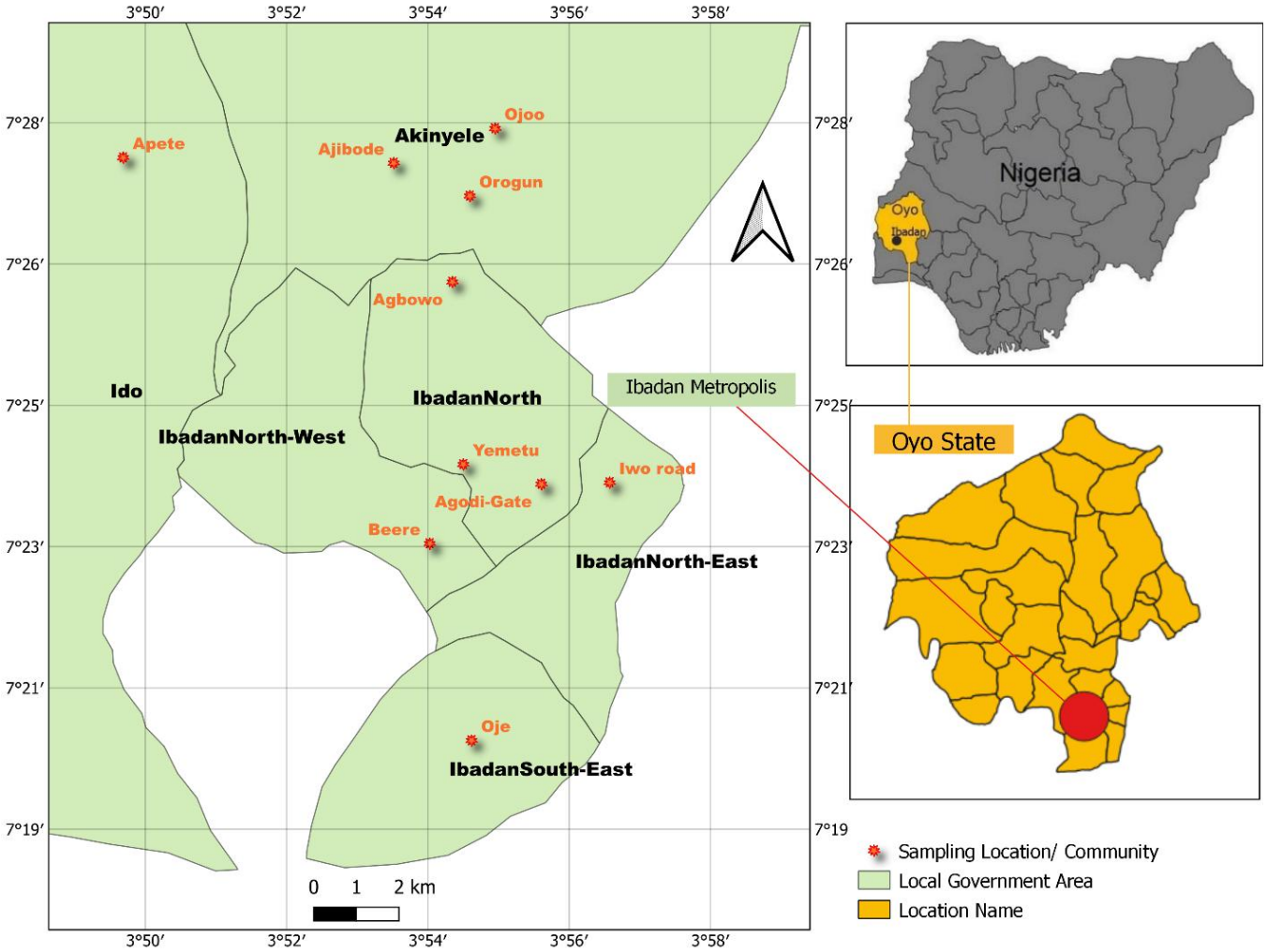

Figure 1:
Sampling locations for COMBAT-CVDs study in Ibadan Nigeria

Table 1:
Overview Variables and Measurements in the COMBAT-CVDs study

Data	Variables	Wave*	
COMBAT-CVDs protocol		W_0	W_N
Socio-demographic and Socio-economic characteristics	Age (years)	√	√[a]
	Sex	√	√[a]
	Formal education	√	√[a]
	Years of education	√	√[a]
	Occupation	√	√[a]
	Marital status	√	√[a]
	Household size	√	√[a]
	Religion	√	√[a]
	Average monthly income	√	√[a]
	Ethnicity	√	√[a]
	Ethnicity of father	√	√[a]
	Ethnicity of mother	√	√[a]
	State of origin	√	√[a]
	Place of residence	√	√[a]
	Household assets & characteristics etc.	√	√[a]
Lifestyle characteristics	Tobacco smoking	√	√[a]
	Alcohol use	√	√[a]
	Consumption of fruits and vegetable	√	√[a]
Alcohol disorders	Alcohol use disorders identification test	√	√[a]
Physical activities	At work, travel and leisure	√	√[a]
History of CVDs	Raise blood pressure	√	√[a]
	Diabetes	√	√[a]
	Stroke	√	√[a]
	Family history of chronic diseases	√	√[a]
	Medical condition(s) etc.	√	√[a]
Psychosocial factors	Anxiety disorders and perceived stress	√	√[a]
	Depression	√	√[a]
Sleep Quality	Sleep quality scale	√	√[a]
Anthropometric measurements	Weight (kg)	√	√[a]
	Height (cm)	√	√[a]
	Waist circumference (cm)	√	√[a]
	Hip circumference (cm)	√	√[a]
Blood pressure reading	Systolic blood pressure (mmHg)	√	√[a]
	Diastolic blood pressure (mmHg)	√	√[a]
	Pulse rate (per minute)	√	√[a]
Biological samples	Glucose, Insulin, Lipid profile, etc.	√[b]	√[b]

COMBAT-CVDs: Community-based Investigation of the Risk Factors for Cardiovascular Diseases in Ibadan and suburbs.
** Timepoint of recruitment and it is planned triennially.*
W_0: First wave recruitment.
W_N: a new wave of recruitment and follow-up and will be planned two years after the baseline recruitment.
a: data would be updated at the next wave of data collection (W_N) for respondents recruited at W_0.
b: planned but subject to availability of funds.
CVDs: cardiovascular diseases.

Questionnaire: The questionnaire was administered via face-to-face interview, asking about sociodemographic, socioeconomic, household and lifestyle characteristics. The lifestyle-related questions included tobacco smoking, alcohol use and consumption of fruit and vegetables. For W_0 (and subsequent waves), information on personal and family history of CVDs in first- and second-degree relatives and parents' ethnicity was provided. We applied the Alcohol Use Disorders Identification Test (Saunders *et al.*, 1993) to screen for alcohol use disorders, and the Global Physical Activity Questionnaire (Bull *et al.*, 2009) was used to profile respondents' physical activity. The Perceived Stress Scale was applied to evaluate respondents' perception of stress (Cohen *et al.*, 1983), and the Zung Self-Rating Depression Scale was applied to assess the level of depression (Zung, 1965). Also, the Sleep Quality Scale was used to comprehensively assess the sleep quality of respondents (Yi *et al.*, 2006).

Anthropometric measurements: Body weight was measured to the nearest 0.1kg using validated weight scales. Non-stretchable tape rule was used to measure height and circumferences of waist and hip to the nearest 0.1cm in a standing position. Waist circumference was measured at the midpoint, between the lower border of the rib cage and the

iliac crest, and hip circumference was measured at the largest circumference. All anthropometric measurements were carried out using the World Health Organization STEPwise Approach to NCD Risk Factor Surveillance manual (WHO, 2020)

Blood pressure measurements: Using the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (Chobanian *et al.*, 2003), blood pressure measurements were taken thrice while respondents were seated using standard operating procedures. The average of the last two of the baseline measurements was used for analysis to assess blood pressure and define hypertension in this study.

Fasting blood sample collection: For the fasting blood sample, respondents would be invited and requested to undertake an overnight fast (refrain food or beverage consumption) for at least 8 hours before the blood sample collection. Blood samples (≤ 20 millilitres) would be drawn through venipuncture by a trained phlebotomist (World Health Organisation, 2010). Blood samples would be processed within 24hours of the collection, centrifuged, and aliquots of serum and plasma would be stored at ≤ - 20°C (Steinberg *et al.*, 1997; Wong and Luban, 2016). Biochemical analysis of the following biomarkers would be carried out using standard operating procedure; fasting blood glucose, glycated haemoglobin, insulin, c-peptide, lipid profile (total cholesterol, triglyceride, high-density lipoprotein), creatinine, aspartate transaminase/serum glutamic oxaloacetic transaminase, alanine transaminase/serum glutamic-pyruvic transaminase, 25-OH-Vitamin D and high-sensitivity C-reactive protein (Myers *et al.*, 2004; Sacks *et al.*, 2011; da Silva *et al.*, 2018).

Respondent feedback and referral: Respondents was or would be offered health education on living a healthy lifestyle, and respondents with poor serum biomarkers would be advised to consult with a physician or schedule an appointment with a trained physician in the COMBAT-CVDs team.

Quality control and data management: First, research assistants, support staff, data clerks, and the entire research team underwent a two-day training on the aims and objectives of the COMBAT-CVDs. All research assistants recruited could speak at least one prominent local language (Yoruba, Igbo and Hausa) fluently. To lessen the fortuitous misunderstandings among respondents, all personal interviews were conducted with research assistants who could fluently speak and understand the English language and at least one of the major local languages (Yoruba, Igbo and Hausa). Also, all questionnaires and measurements were reviewed and checked (for consistency and clarification of missing/unclear responses) by a research team supervisor at the community within 24 hours of recruitment. Study data were collected electronically and managed using REDCap electronic data capture tools hosted at the University of Ibadan, Nigeria (Harris *et al.*, 2009; Harris *et al.*, 2019). Technical staff at the back-end of the database monitored and managed recruitment, data upload and quality in real-time throughout the period of recruitment in the W_0 of the study. The same stratagem will be deployed for subsequent recruitment waves for the study.

A total of 3638 community-dwelling adults (males – 54.6% and female – 45.4%) participated in the W_0 recruitment with a ≥99.7% response rate; sociodemographic characteristics (100%), lifestyle characteristics (100%), dietary factors (100%), psychosocial factors (100%), sleep quality (99.9%), anthropometric measurements (99.8%) and blood pressure readings (99.7%). Details of the response rate in the W_0 of recruitment is presented in Table 2. Also, recruitment and data collection for the second wave (W_1) recruitment is planned and underway.

Table 2:
Response rate (%) to each item in the COMBAT-CVDs study

Variable	Frequency (n)	% Response rate
Sociodemographic characteristics		
Age	3638	100.0
Sex	3638	100.0
Education	3638	100.0
Religion	3638	100.0
Residence	3638	100.0
Occupation	3638	100.0
Marital status	3638	100.0
Socio-economic characteristics	3635	99.9
Lifestyle characteristics		
Smoking	3638	100.0
Alcohol use	3638	100.0
Physical activity	3638	100.0
Family History of CVDs	3638	100.0
Dietary Factor		
Fruit consumption	3638	100.0
Vegetable consumption	3638	100.0
Psychosocial factors		
Depression	3638	100.0
Stress	3638	100.0
Sleep quality	3635	99.9
Anthropometric measurements		
Weight	3630	99.8
Height	3632	99.8
Waist circumference	3630	99.8
Hip circumference	3632	99.8
Blood pressure readings		
Pulse rate	3628	99.7
Systolic blood pressure	3628	99.7
Diastolic blood pressure	3628	99.7

COMBAT-CVDs: Community-based Investigation of the Risk Factors for Cardiovascular Diseases in Ibadan and suburbs
CVDs: cardiovascular diseases

Statistical analysis: Rigorous data cleaning strategies will be implemented to ensure that high-quality data are analyzed to enhance the reporting of appropriate information. Also, multiple imputations techniques will be used to handle missing data (Gebregziabher and DeSantis, 2010) as

appropriate, taking into account missing data apparatus, functionality, and confounder selection according to principles reported elsewhere (VanderWeele, 2019). Data analysis will commence with appropriate descriptive statistical methods and apply appropriate bivariate and multivariate statistical methods depending on the outcome variable in the hypothesis being tested. All statistical analyses will be performed using R statistical program (version 3.6.2) and IBM SPSS Statistics for Windows, version 25 (IBM Corporation, Armonk, NY USA) at a two-sided P-value < 0.05.

DISCUSSION

The COMBAT-CVDs is an ongoing study among indigenous black populations in a community-based setting using a door-to-door approach. First recruitment and data collection for the W_0 is complete with an over 99.7% response rate. Second, there is currently planned recruitment and data collection for the W_1 stage of the study. There are numerous ground-breaking aspects to the COMBAT-CVDs that is worth mentioning. First, it is one of the first studies (with a plan to follow-up participants) to assess the constellation of sociodemographic, lifestyle, psychosocial, and environmental factors of CVDs in this challenging setting. The risk factors of CVDs to be explored by the COMBAT-CVDs include; traditional (such as smoking, obesity, hyperlipidemia, hypertension, etc.), evolving (sleep quality, psychosocial, inflammation, etc.), and environmental factors already reported in industrialized societies but with limited data in the current setting.

Second, COMBAT-CVDs will incorporate strategic plans for outreach targeted at key community leaders at all strata to assess perceptions about CVDs and design suitable and culturally relevant public health education as an intervention to address those perceptions. Third, COMBAT-CVDs aims to encourage community sensitization to promote the early presentation and regular or routine medical check-ups to identify populations at risk of CVDs among black populations in indigenous settings, thereby significantly minimizing late presentations at end-stage CVDs and for prompt treatment. Furthermore, aside from providing relevant statistics to quantify the burden of CVDs in research publications for uptake and impact, our study hopes to simplify the dissemination of critical findings for easy assimilation by the general public using social media platforms and presentation in religious/worship centres. On a final note, the COMBAT-CVDs is designed for skills and capacity-building in a multidisciplinary team of researchers/health workers using a team-building approach to deliver on the impetus of sustainable CVDs prevention and good quality of care in a community-based setting of indigenous black populations.

Some challenges are likely while executing this phenomenal study, and they are worth mentioning. First, the recruitment of respondents within a community-based setting would imply that potentially eligible respondents would provide identifiable information for a planned follow-up. To this effect, all recruitment data will be securely stored in a vault to which only the principal investigator shall have access. Also, respondents' information would be de-identified before data analysis. Second, the funding available for this study is quite limited, which affected data collection on biological samples during the W_0 of recruitment. We also plan to seek additional funding during the subsequent waves. Third, the storing of bio-samples in freezers may be threatened by erratic power supply, subject to adequate funding, and we hope to resolve this by securing alternate power source(s), including solar-powered inverters for the freezers.

The COMBAT-CVDs is an ongoing phenomenal study that will likely provide novel data and insightful characterization of CVDs risk factors and ultimately provide evidence for context-specific and culturally relevant interventions for the community prevention and management of CVDs among community-dwelling indigenous Africans in this setting.

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Authors' contributions: *OMA is the principal investigator and conceptualized the study; OJA, RO, AEA, BJO and OOA were study supervisors and APO supervised the data acquisition; OJAs is the data manager and responsible for data curation; APO drafted the manuscript; all authors contributed to the interpretation, APO and OMA critically revised the manuscript for important intellectual content. All authors read and approved the final version to be published and agreed to be accountable for the work.*

Data sharing: *Individual, de-identified participant data from the COMBAT-CVDs can be shared upon request from any qualified investigator, following approval of a protocol and signed data release agreement. All data requests should be addressed to the corresponding author.*

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