


# BMJ Open Sustainable dietary weight loss intervention and its effects on cardiometabolic parameters and greenhouse gas emissions: study protocol of a randomised controlled trial with overweight and obese adults in Ouagadougou, Burkina Faso

Alina Herrmann <sup>1</sup>, Anais Gonnet,<sup>1</sup> Roche Modeste Millogo,<sup>2</sup> Wendmintiri Jeanne d'Arc Kabré,<sup>2</sup> Tenin Rosine Beremwidougou,<sup>2</sup> Issa Coulibaly,<sup>2</sup> Idrissa Ouili,<sup>2</sup> Souleymane Zoromé,<sup>2</sup> Konstantin Weil,<sup>1</sup> Hannah Fuelbert,<sup>1</sup> Abdramane Soura,<sup>2</sup> Ina Danquah<sup>1</sup>

**To cite:** Herrmann A, Gonnet A, Millogo RM, *et al*. Sustainable dietary weight loss intervention and its effects on cardiometabolic parameters and greenhouse gas emissions: study protocol of a randomised controlled trial with overweight and obese adults in Ouagadougou, Burkina Faso. *BMJ Open* 2023;**13**:e070524. doi:10.1136/bmjopen-2022-070524

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-070524>).

Received 25 November 2022  
Accepted 02 March 2023



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For numbered affiliations see end of article.

## Correspondence to

Dr Ina Danquah;  
[ina.danquah@uni-heidelberg.de](mailto:ina.danquah@uni-heidelberg.de)

## ABSTRACT

**Introduction** The global obesity epidemic and its adverse health effects have reached sub-Saharan Africa. In some urban settings, like Burkina Faso's capital Ouagadougou, up to 43% of the adult population are overweight or obese. At the same time, modernised food systems are responsible for 26% of global greenhouse gas emissions, 50% of land use and 70% of freshwater use. International guidelines on the treatment of overweight and obesity recommend dietary intervention programmes that promote reduced calorie intake and increased physical activity. So far, weight loss interventions rarely consider sustainable dietary concepts, including healthfulness, affordability, cultural appropriateness and environmental friendliness. Therefore, we present a study protocol of a novel randomised controlled trial that aims to establish the effects of a sustainable weight loss intervention on cardiometabolic and environmental outcomes in urban Burkina Faso.

**Methods and analysis** We conduct a non-blinded randomised controlled trial, comparing a 6-month sustainable diet weight loss intervention programme (n=125) with a standard weight loss information material and 5 min oral counselling at baseline (n=125). Primary outcome is a reduction in fasting plasma glucose of  $\geq 0.1$  mmol/L. Outcome measures are assessed at baseline, after 6 months and after 12 months.

**Ethics and dissemination** Ethical approval for the study has been obtained from the Medical Faculty of Heidelberg University (S-376/2019) and from the Ministry of Health and the Ministry of Higher Education, Scientific Research and Innovation in Ouagadougou, Burkina Faso (No 2021-01-001). The results of the study will be disseminated to local stakeholders at a final project meeting and to the wider research community through peer-reviewed publications and conferences.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The weight loss intervention is framed around the four dimensions of sustainable diets, which are healthfulness, affordability, cultural appropriateness and environmental friendliness.
- ⇒ This weight loss trial also evaluates changes in greenhouse gas emissions from dietary intake as secondary outcome.
- ⇒ During a consolidation phase of 6 months after the intensive intervention phase, we will establish the long-term intervention effects.
- ⇒ For the secondary cardiometabolic outcomes, type II error may occur owing to the moderate sample size.

**Trial registration number** DRKS00025991.

## INTRODUCTION

Overweight and obesity are increasingly threatening population health in low and middle-income settings, such as in sub-Saharan Africa. In Ouagadougou, Burkina Faso, the prevalence of overweight and obesity (defined as body mass index (BMI)  $\geq 25.0$  kg/m<sup>2</sup>) increased from 18% in 1993 to 43% in some urban settings like Ouagadougou in 2012.<sup>1 2</sup> The proportion of deaths attributable to non-communicable diseases has reached up to 74% in the capital Ouagadougou, particularly in higher socioeconomic classes.<sup>3 4</sup> While the double burden of malnutrition, namely the coexistence of undernutrition and overnutrition, partly results from the natural epidemiological transition due

to increased life expectancy and population growth, the accelerated urbanisation, economic development and associated lifestyle changes contribute to this alarming situation.<sup>2 5 6</sup>

At the same time the global food production system is responsible for 26% of greenhouse gas (GHG) emissions, 50% of land use, >70% of global freshwater use and 80% of deforestation.<sup>7 8</sup> Clearly, these natural resources will be continuously strained and might even be lost to future generations if they are not managed and conserved responsibly. While the environmental footprints of low-income settings are still low compared with high-income settings,<sup>9</sup> urban Burkina Faso and other cities in sub-Saharan Africa are experiencing a nutrition transition from a cereal-based, low-fat, high-fibre diet to a modernised diet with increased fat and sugar intakes as well as processed foods.<sup>10 11</sup> This trend will contribute to the pressure on planetary boundaries and deteriorates food and nutrient security for low-income populations.<sup>12</sup>

Lifestyle interventions aiming at dietary modifications constitute the first option to prevent obesity-related cardiometabolic conditions because of relatively low costs and minimal risk of complications.<sup>13–15</sup> While there has been a wide range of randomised controlled trials (RCT) testing the most effective dietary weight loss interventions in high-income settings,<sup>16</sup> there are only few studies with limited quality, which evaluated weight loss interventions in resource-poor contexts, especially in sub-Saharan Africa.<sup>17 18</sup> Weight loss trials rarely explicitly address the concept of sustainable diets with the four components of healthfulness, cultural appropriateness, affordability and environmental friendliness in the development and implementation of the intervention.

Therefore, the present study aims at establishing the effects of a family-based, culturally adapted, dietary weight loss intervention on health and environmental outcomes. The specific objectives are (1) to rigorously design a sustainable dietary weight loss intervention for adults with overweight or obesity living in Ouagadougou, addressing the four attributes of sustainable diets, and (2) to determine the effects of this sustainable dietary weight loss intervention on cardiometabolic traits and GHG emissions among 2×125 adults in Ouagadougou.

This study is a monocentric, non-blinded RCT with an intervention group and a control group to compare the effects of a family-based, 6-month sustainable diet weight loss intervention programme versus the provision of printed material and a 5 min oral counselling as the standard treatment group. Table 1 summarises the trial registration data.

## METHODS AND ANALYSIS

In the following we will describe the methods of the study protocol in Version 7.0, dated 29 September 2021.

## Study setting

This RCT will be conducted within the framework of the Ouagadougou Health and Demographic Surveillance System (HDSS), which is the only urban HDSS in West Africa. It has been established in 2008 and is located in five neighbourhoods at the northern periphery of the capital. The Ouagadougou HDSS covers a contiguous population of around 89 700 inhabitants (informal: 41 100; formal: 48 600) living in 20 000 households. The RCT will be conducted in two distinct districts, Tanghin, a formal settlement, and Polesgo, an informal settlement to cover households with different socioeconomic characteristics.

## Recruitment

Recruitment was conducted by the project partner *Institut Supérieur des Sciences de la Population* (ISSP) from March 2022 until May 2022. Six fieldworkers have actively visited HDSS households and contacted potential participants, who were then screened for the inclusion criteria by taking anthropometric measurements. The purpose and procedures, as well as the inclusion and exclusion criteria, were thoroughly explained to all potential participants before informed consents were signed (see online supplemental appendices A and B). Furthermore, potential participants were informed early on, that they will be randomly assigned to either the intervention group or the control group and that they are not able to choose. All potential study participants were informed, that overweight and obesity can lead to diabetes mellitus, and that the study aims at evaluating an intervention programme for weight loss preventing diabetes and other adverse health outcomes. Participants receive a small fee for each visit at the assessment centre at baseline, midline and endline to reimburse their transportation costs and possible missed working time (1000 CFA francs).

## Eligibility criteria

The inclusion and exclusion criteria for the study are displayed in table 2.

We refrain from excluding forms of secondary obesity other than those based on long-term oral corticosteroid use due to limited diagnostic capacities in the participating health centres.

## Intervention

The intervention comprises a 6-month intensive dietary and lifestyle intervention. The contents are based on the ‘Guidelines for the management of overweight and obesity’<sup>15</sup> developed by the American Heart Association Task Force on Practice Guidelines, the American College of Cardiology and The Obesity Society, and a pilot study with Ghanaian adults in Berlin.<sup>19</sup> However, the intervention was intensely adapted to meet local needs and possibilities of the participants in Ouagadougou and the criteria of a sustainable diet. To account for the dimensions of environmentally friendliness and healthfulness, recommendations for a planetary health diet as proposed

**Table 1** Trial registration data according to WHO Trial Registration Data Set (Version 1.3.1)

Primary registry and trial identifying number	<i>Deutsches Register für Klinische Studien</i> (DRKS, German Clinical Trials Register); DRKS00025991
Date of registration in primary registry	29 September 2021
Secondary identifying numbers	U1111-1282-7889
Source(s) of monetary or material support	See primary sponsor. No additional monetary or material support.
Primary sponsor	Robert Bosch Foundation
Secondary sponsor(s)	None
Contact for public queries	Elke.braun@uni-heidelberg.de
Contact for scientific queries	Ina.danquah@uni-heidelberg.de
Public title	Sustainable diet weight loss intervention for adults in urban Burkina Faso
Scientific title	Sustainable diet weight loss intervention and its effects on cardiometabolic parameters and greenhouse gas emissions: a randomised controlled trial with overweight and obese adults in Ouagadougou, Burkina Faso
Countries of recruitment	Burkina Faso
Health condition(s) or problem(s) studied	Overweight/obesity
Intervention(s)	Weight loss intervention directed at behavioural changes in diet and physical activity: <ul style="list-style-type: none"> <li>▶ Intervention group: 6-month intensive dietary and physical activity programme.</li> <li>▶ Control group: standard dietary counselling with information material.</li> </ul>
Key inclusion and exclusion criteria	Inclusion criteria: <ul style="list-style-type: none"> <li>▶ Age ≥25 years.</li> <li>▶ Sex: all sexes.</li> <li>▶ BMI: ≥25 kg/m<sup>2</sup> or abdominal circumference &gt;80 cm for women or &gt;94 cm for men.</li> <li>▶ The cooperation of the family cook.</li> </ul> Exclusion criteria: <ul style="list-style-type: none"> <li>▶ Age ≥56 years (retirement age).</li> <li>▶ Receiving long-term oral corticosteroids or weight loss medication.</li> <li>▶ Health conditions that interfere with adherence.</li> <li>▶ Current pregnancy.</li> </ul>
Study type	<ul style="list-style-type: none"> <li>▶ Intervention study.</li> <li>▶ Randomised controlled trial (RCT).</li> <li>▶ Parallel assignments into intervention and control groups.</li> <li>▶ Behavioural intervention does not allow blinding.</li> <li>▶ Primary purpose: prevention.</li> </ul>
Date of first enrolment	23 March 2022
Target sample size	2×125 individuals
Recruitment status	Completed on 16 May 2022
Primary outcome	Reduction in fasting plasma glucose (FPG) of ≥0.1 mmol/L (difference between baseline and after 6 months)
Key secondary outcomes	<ul style="list-style-type: none"> <li>▶ Improvements in biomarkers of glucose metabolism based on OGTT and HbA1c.</li> <li>▶ Reductions in systolic and diastolic blood pressure.</li> <li>▶ Improvements in fasting blood lipids.</li> <li>▶ Changes in dietary behaviour according to repeated 24-hour dietary recall.</li> <li>▶ Changes in greenhouse gas emissions from dietary intake.</li> </ul>

BMI, body mass index; OGTT, oral glucose tolerance test.

by the EAT-Lancet Commission<sup>20</sup> were incorporated. Cultural appropriateness and affordability were incorporated through formative research. This comprised a diet survey using a locally adapted, semiquantitative African

Food Propensity Questionnaire<sup>21</sup> among 1000 adults in Ouagadougou, and a qualitative study with 38 participants in Ouagadougou, mapping current dietary behaviour and exploring participants' perceptions of a sustainable

**Table 2** Eligibility criteria

Inclusion criteria	Exclusion criteria
Age $\geq 25$ years.	Age over 56 (official retirement age in Burkina Faso).
General overweight or obesity (BMI $\geq 25.0$ kg/m <sup>2</sup> ) or abdominal overweight or obesity (waist circumference for women: $>80$ cm, for men: $>94$ cm).	Receiving long-term oral corticosteroids or weight loss medication.
Cooperation of the family cook.	Having health disorders that interfere with adherence.
Residing permanently in the study areas.	Residing temporarily in the study areas.
Ability to give informed written consent.	Currently being pregnant.
Informed written consent.	
BMI, body mass index.	

diet as well as their preferences for the intervention. The results of these formative studies will be reported in detail elsewhere.

Table 3 displays the official recommendations, the adaptations in this study and the reasons for the adaptation.

Concretely, the intervention consisted of four elements: group counselling, market visits, cooking sessions and physical exercise courses:

#### A. Group counselling

Three group counselling sessions are delivered throughout the 6 months of the intervention phase. Trained nurses cover the basic knowledge about health risks of overweight and obesity, the health benefits of weight loss, the aims of the weight loss programme, the food pyramid and other basics about a healthy and sustainable diet, including concrete recommendations for food groups and portion sizes to reduce body weight. The second and third group counselling sessions will additionally give room for participants to share problems and get feedback for improved adherence to the weight loss recommendations.

#### B. Individualised market visits and cooking sessions

Each participant takes part in one intensive and individual training session comprising a market visit and a cooking session, lasting 3–4 hours. A trained nurse observes how the participant/household cook buys products and prepares meals in order to give advice on improving the choice of products and their preparation with regard to weight loss and sustainability aspects. Furthermore, the nurse eats the prepared meal together with the family and motivates the family to support the weight loss aim of the participant.

#### C. Physical exercise

During the intensive intervention phase, participants will be invited to take part in physical exercise sessions once a week. The sessions will be offered in a public space and be accessible to all. They will comprise culture-appropriate and gender-appropriate exercises based on the preferences of the participants. It is permitted for participants to intensify physical activity at their own accord and adjust their diet within the frame of recommendations provided in the group counselling.

The control group will receive standard nutrition counselling with established printed information material (food pyramid), which is being used by nutritionists in the region, and a 5 min oral counselling during or after the baseline examination. The use of weight loss medication is prohibited in both groups.

#### Adherence

All intervention elements will be delivered in the communities of the study participants by trained nurses (elements A and B) of the local health centres (Centre de Santé et de Promotion Sociale, CSPS) or fieldworkers (element C) to ease access and increase acceptability. Participation in all activities will be documented for each study participant by the study personnel. Each fieldworker will be responsible for 20 participants, organising appointments and reminders on the intervention elements A and B to reinforce participation. The fieldworkers will also call participants if they have not taken part in any of the intervention elements or assessments to ask how they can make up for a missed session or assessment and support further participation. Individual adherence to recommendations for diet and physical activity will be monitored through interview-based questionnaires. This includes physical activity assessments at baseline, after 6 months and after 12 months. Furthermore, 24-hour dietary recall (24-HDR) protocols will be conducted on 2 days/week at baseline, and after 3, 6 and 12 months.

#### Patient and public involvement

The intervention programme has been designed in close collaboration with social and biomedical scientists at the University of Ouagadougou (ISSP) and the Centre de Recherche en Santé de Nouna. As indicated above, formative research with the local population was conducted to get to know their needs and preferences for this intervention study. The findings of this RCT will be disseminated to local, regional and national policy makers as well as to the international scientific audience.

#### Sample size calculation

The sample size calculation was based on the primary outcome fasting plasma glucose (FPG) reduction (minimum 0.1 mmol/L) and accounts for different FPG variances. For a statistical power of 80% and  $\alpha$  level of 0.05, sample sizes were calculated for baseline mean FPG of 5.5 mmol/L. For a difference in mean FPG reduction of 0.1 mmol/L, the sample size of 100 controls and 100



**Table 3** Adaptations of the guidelines for the management of overweight and obesity by the American Heart Association Task Force on Practice Guidelines (AHA), the American College of Cardiology (ACC) and The Obesity Society (TOS)

Variable	AHA, ACC and TOS guidelines	Intervention adapted to Ouagadougou	Reasons for adaptation
Participants	Individuals with adiposity.	Burkinabe adults with either general overweight/obesity or abdominal overweight/obesity and one adult family volunteer. Main cook agrees to cooperate.	Recruit adults in Ouagadougou with high prevalence of adiposity; encourage support from family members, particularly from those who are responsible for the family meals; encourage healthier lifestyle in the entire family.
Inclusion criteria	Body mass index (BMI) $\geq 30.0$ kg/m <sup>2</sup> or waist circumference $\geq 88$ cm for women and $\geq 102$ cm for men, if BMI $25.0 < 30.0$ kg/m <sup>2</sup> .	BMI $\geq 25.0$ kg/m <sup>2</sup> or waist circumference $\geq 80$ cm for women and $\geq 94$ cm for men.	Potential recruits may have central obesity but have a low BMI; acknowledge the important role of central body fat accumulation.
Setting	General practitioner.	Community for recruitment; community, trusted local health centres and home for intervention.	Encourage community and family involvement; increase compliance; reduce attrition.
Duration of the intervention	3 months.	6-month intensive intervention period with 3 group counsellings, 1 individual home-based contact and weekly sport sessions in groups.	Facilitate motivation, compliance, self-efficacy, family involvement and sustainability.
Weight loss goal	$\geq 5\%$ of initial body weight if BMI $25.0 < 30.0$ kg/m <sup>2</sup> ; $\geq 10\%$ of initial body weight if BMI $\geq 30.0$ kg/m <sup>2</sup> .	$\geq 2.5$ kg in the intervention group.	Realistic for adults in Ouagadougou and still relevant to improve the cardiometabolic profile.
Physical activity (PA)	$>30$ min/day ( $\approx 1200$ – $1800$ kcal/week); mainly endurance sports; for individuals with BMI $\geq 30.0$ kg/m <sup>2</sup> , increase PA in daily routine (eg, walking, taking stairs); PA counselling: health-beneficial effects of physical activity beyond weight loss and PA goal setting.	$>30$ min/day ( $\approx 1200$ – $1800$ kcal/week); increase PA in daily routine (eg, brisk walking); group counselling: health-beneficial effects of physical activity beyond weight loss; PA goal setting: GPAQ; PA groups sessions.	Most relevant; achievable recommendations, accounting for workload and family time; encouragement of self-chosen activity in a group or alone; incorporates goal setting, behavioural contracting and tailored health communication.
Dietary intervention and targets	Dietary advice by general practitioner: daily energy deficit of 500 kcal; reduction of total fat and/or reduction of carbohydrates.	3 group counsellings with a dietician in the language of choice (French, Morré); 1 home-based cooking session focusing on cooking methods, portion sizes, food choices and fat amount for cooking; diet goal setting: 24-hour dietary recall protocols.	Bilingual dietary counselling available; achievable and comprehensible approach, given the low level of formal education and health literacy in the study population; engage the available family in a domestic setting especially those who prepare the family meals; incorporates goal setting, behavioural contracting and tailored health communication.

GPAQ, Global Physical Activity Questionnaire.

participants in the intervention group will be sufficient. To account for potential loss to follow-up (25%), we aim at a total sample size of  $2 \times 125$  individuals. Assumptions of this calculation are based on results of large systematic reviews and meta-analyses of weight loss and diabetes prevention trials.<sup>22 23</sup>

### Outcomes and data collection

Outcome measurements are taken from all participants at baseline, after 6 months (midline) and after 12 months

(endline). All outcome measurements are taken at the local health centres in Tanghin or Polesgo (CSPS). The measurements are taken using standardised procedures, as detailed in table 4, and will be conducted by thoroughly trained staff.

### Primary outcome

The weight loss goal in this intervention is to reduce  $\geq 2.5$  kg in body weight during the intensive intervention period (6 months). This will approximately translate into

**Table 4** Data collection and individual participant timeline

Steps for participant and data collection	Month of the study							
	0	1	2	3	4	5	6	12
<b>Recruitment</b>	x							
Check for eligibility criteria, including anthropometric measurements.	x							
Oral and written study information and informed consent taking.	x							
<b>Sociodemographic and physical assessments</b>	x						x	x
Sociodemographic questionnaire.	x							
Global Physical Activity Questionnaire (GPAQ).	x						x	x
Anthropometric measurements: ▶ Height. ▶ Weight. ▶ Waist circumference.	x						x	x
Cardiometabolic measurements: ▶ Blood pressure. ▶ Resting heart rate. ▶ Fasting blood glucose. ▶ Oral glucose tolerance test. ▶ HbA1c. ▶ Blood lipids: TG, total cholesterol, HDL.	x						x	x
<b>Dietary assessments</b>	x			x			x	x
24-hour dietary recall.	xx			xx			xx	xx
<b>Sustainable diet weight loss intervention</b>		x	x	x	x	x	x	
Standard counselling material (control group).		x						
Group counselling (intervention group).		x		x		x		
Guided market visit+cooking session (intervention group).					x			
Guided physical activity session (intervention group).		xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	
HDL, high-density lipoprotein; TG, triglyceride.								

reductions in BMI of  $\geq 0.5 \text{ kg/m}^2$  and waist circumference of  $\geq 1.5 \text{ cm}$ . The primary outcome is a reduction in FPG of  $\geq 0.1 \text{ mmol/L}$ , measured as a difference between the baseline assessment and the assessment after 6 months. This is because higher FPG levels are associated with a higher risk of developing type 2 diabetes.<sup>24</sup> Body weight is measured without shoes and in light clothing on a digital scale (SECA 874). Weight will be measured twice with an acceptable difference being 0.5 kg. If the difference is greater than 0.5 kg, a third measurement will be taken. Height will be measured with a transportable stadiometer (SECA 213). It will be measured twice with an acceptable difference being  $< 0.5 \text{ cm}$ . If the difference is  $\geq 0.5 \text{ cm}$ , a third measurement will be taken. BMI will be calculated by the standard formula of (weight in kg)/(height in m).<sup>2</sup> Waist circumference will be measured with a measuring tape (SECA 201) at the height of the umbilicus or at the largest circumference between the lower ribcage and the umbilicus. Two measures are taken and their difference should not exceed 1 cm. Otherwise, a third measurement will be taken. Glucose concentrations will be measured at the point of care with a HemoCue Glucose 201+ PE Analyzer in mmol/L.

### Secondary outcomes

Secondary outcomes will also be assessed based on the measurements at baseline, after 6 months and after 12 months:

- Improvements in biomarkers of glucose metabolism based on an oral glucose tolerance test and HbA1c (%). HbA1c will be measured using a HemoCue 501 HbA1c Analyzer.
- Reductions in systolic and diastolic blood pressure: Blood pressure will be measured by seating the participant at least 5 min before measurement. Then, three measurements will be taken every 2 min with the semi-automated OMRON M400 device. If one of the three measurements differs by more than 10 mm Hg from the other values, a third measurement will be taken. The mean of the two closest systolic measurements and the mean of the two corresponding diastolic measurements will be reported.
- Reductions in resting heart rate: Resting heart rate will be measured three times using the same semiautomated device. The mean of the two lowest measurements will be recorded.
- Improvements in fasting blood lipids: Triglycerides (mg/dL), total cholesterol (mg/dL) and high-density lipoprotein cholesterol (mg/dL) concentrations will be measured based on fasting venous blood samples using Selectra Pro S (ELITech Clinical Chemistry). An approximate measure of low-density lipoprotein cholesterol (mg/dL) will be calculated via Friedewald formula.
- Changes in dietary behaviour according to repeated 24-HDR: Two 24-HDR with a 1-week interval on a different day will be recorded in person at baseline, and after 3, 6 and 12 months. This quantitative dietary

assessment tool captures the timing of meals, portion sizes, modes of preparation and recipes.

- Changes of estimated GHG emissions of the food intake: The estimates will be derived by multiplication of food intakes as documented in 24-HDR with regionally specific emission factors.

### Assessment of covariates

At the baseline assessment, a basic questionnaire on socio-demographic characteristics will be administered.

### Assignment to intervention and control groups

The allocation to the intervention groups will be conducted using a list-based randomisation, stratified by the type of settlement (formal and informal settlements) and sex. Allocation sequence, enrolment and assignment to interventions will be performed by the HDSS data manager at ISSP. Due to the nature of the intervention, participants and examiners are not blinded to the intervention allocation at baseline. Moreover, the field team is not blinded to the intervention groups at midline and endline examinations.

### Data management

All data collected are entered and stored digitally on tablets, except for the 24-HDR, which will be digitalised after paper-and-pencil documentation. The data entry platform (Survey CTO) allows supporting settings, such as plausible ranges of data values and default settings for measurement units. A consistency check is conducted after each fieldwork day. Following the first 3 days of the baseline examination, a debriefing is conducted, specifically aiming at receiving input for improvements or concerns from the data collection. Weekly meetings are held with the field supervisors and study coordinators in Germany and Burkina Faso during data collection to coordinate the work. Furthermore, the whole study team has formed a social media group to provide continuous support and real-time exchange. While the participants and the study team in Ouagadougou are not blinded to intervention status, the data analysis will be performed by an independent biostatistician, who will be blinded to the intervention status.

### Data analysis

For the impact evaluation, we will use an intention-to-treat approach, comparing the differences in primary and secondary outcome measures between the control group and the intervention group. This will be done after the intensive intervention period (6 months) and after the consolidation phase (12 months), while the primary timepoint is at 6 months after baseline. We will use linear regression models treating the differences in outcome measures as continuous variables. Relevant confounders, such as age, sex and socioeconomic variables, as well as the settlement type will be taken into account.

As an additional analysis the costs for implementing and maintaining the proposed dietary intervention will be calculated. Mean costs of the intervention will be

compared between the intervention group and the control group using linear models. Combining this information with economic models that relate surrogate markers of the RCT to disease incidence, we will calculate an (incremental) cost-effectiveness ratio that shows if and to what extent the investigated intervention is cost-effective.

In order to deal with non-adherence to the protocol intention-to-treat and per-protocol analysis will be performed and compared. Moreover, missing data will be handled by performing multiple imputation for covariables using the multiple imputation by chained equations approach.

### Data monitoring

The sponsor will not appoint a data monitoring committee and will have no role in the interpretation of the data. The reasons are that this trial has no foreseen substantial safety issues,<sup>15 25 26</sup> is not double blinded and is not expected to have a major impact on clinical practice.

There will be a midline evaluation after 6 months and an endline evaluation after 12 months. The termination guidelines are based on the criteria of safety, benefit and futility: safety issues could arise when the study unexpectedly causes serious illness or death. This is not anticipated based on experiences from previous dietary interventions.<sup>19</sup> Benefit issues could apply when the study hypothesis is unexpectedly proven early within the predesignated criteria. Continuing to expose subjects in the inferior arm and keeping them away from the benefit would no longer be ethical. This criterion will apply when the participants report to have achieved the weight loss goal after 3 months instead of 6 months. Futility issues would emerge when the study hypothesis is unexpectedly shown to be unprovable within the constraints of the trial, based on statistical analysis of early study data. This will be the case when the dropout rate of participants in both study arms will exceed 10%.

In order to detect any issues related to safety, benefit or futility, the study nurses will document the participants' experiences with the intervention programme during the market visits and cooking sessions using a participant logbook. Furthermore, participants are encouraged to share their experiences at any other visit/contact with study staff. This will facilitate the monitoring of any unforeseen adverse events or unintended effects of the trial. As this is a single-centred trial with close contact between the two investigating institutions, no auditing is planned.

The Heidelberg Institute of Global Health acts as the coordinating centre for the study. The steering committee consists of a multiethnic team of partners in Heidelberg, Germany and Ouagadougou, Burkina Faso. It consists of the principal investigators (PIs) (AS and ID) and the study coordinators in Burkina Faso (RMM) and Germany (AG and formerly AH). Furthermore, RMM acts as study coordinator and SZ as supervisor in Ouagadougou. PIs ID and AS oversee the conduct of the study. Study coordinator AG (and formerly AH) organises the steering

committee meetings and coordinates the trial conduct in Ouagadougou. RMM and his team in Ouagadougou see the implementation of the study. The PIs are the guarantors and decision makers for the project.

### ETHICS AND DISSEMINATION

The present study protocol and all study-related materials were reviewed and approved by the Ethics Committee of the Medical Faculty of Heidelberg University (S-376/2019) in Version 4.0 and by the Ethics Committee for Health Research from the Ministry of Health and the Ministry of Higher Education, Scientific Research and Innovation in Ouagadougou, Burkina Faso (No 2021-01-001) in Version 4.0. Relevant protocol amendments with regard to changes in eligibility criteria, outcomes or analysis steps will be communicated to the research team, the ethical committees and the Deutsches Register für Klinische Studien (DRKS) trial registry. The research team and ethical committees will be informed via email. The changes to the protocol will be reported at the DRKS web template. Furthermore, changes relevant to participants will be communicated by staff at ISSP, University of Ouagadougou during the baseline, midline or endline assessments.

### Consent or assent

Participation in the study is completely voluntary. Study participants were given written study information and the informed consent form (see online supplemental appendices A and B). A well-trained fieldworker explained the aims and the detailed procedures of the study to each potential participant orally and gave sufficient time to ask and respond to all questions. All fieldworkers have a high school diploma, have worked for the HDSS for more than 5 years and have received a special training for this study. All participants gave written informed consent. When participants were illiterate, a witness was involved to confirm that oral explanations matched the written information, and the participants consented by thumb print. The witness' signature was taken to document consent. Consent can be withdrawn at any point in time, including the destruction of biological samples and deletion of collected data, without bearing any negative effects in terms of healthcare or otherwise. The participants will be informed about their results of the anthropometrical examinations.

Up to date, no ancillary studies are planned. If any ancillary study is planned, which needs data or specimen, which are not covered by the current study information and informed consent, participants will be asked to sign a separate consent form.

### Confidentiality

Complete confidentiality of data will apply, and the data collection will conform to the requirements of the German national and federal legislations on data protection (Datenschutz-Grundverordnung, general data protection



regulation (DSGVO), Landesdatenschutzgesetz, state data protection law (LDSG) or Bundesdatenschutzgesetz, federal data protection law (BDSG). Particularly, digital data will be stored on password-protected files. Data will be available exclusively to members of the study team instructed for complete confidentiality. Participant-related information on results will be provided to the families, and exclusively by the clinical officer in charge or the PI. Third parties will not have access to personal data. Informed consent forms, laboratory books and other participant-related documents will be safely stored during study conduct and, subsequently, at the co-PI's office premises.

### Access to data

Data will be available exclusively to members of the study team instructed for complete confidentiality. Third parties can apply to the PIs for access to the study data (eg, full protocol, pseudonymised data for research purposes only, statistical code) on submission of a data analysis proposal.

### Unexpected results and ancillary care

Data from the baseline, midline and endline examinations might reveal hints to a pathological diagnosis of a cardiometabolic disease, such as type 2 diabetes or hypertension. If we find pathological values of FPG, HbA1c, blood lipids, blood pressure or other pathological results, the study staff is obliged to inform the PIs. In that case, participants are referred to a medical centre for further diagnosis and receive a fixed sum as financial support, which should cover the transportation costs and limited treatment costs for the first visit (2500 CFA francs).

### Dissemination policy

Results will be published in peer-reviewed, international, scientific journals to be communicated to the scientific community. For authorship eligibility, we will draw on the International Committee of Medical Journal Editors guidelines in their current form. No professional writers will be included.

Furthermore, this study is embedded in a larger research project on sustainable nutrition in sub-Saharan Africa. Stakeholder meetings in Ouagadougou will be used to inform local policy makers and other stakeholders such as non-governmental organisations working in the nutrition sector. After final analysis, all study participants will be invited to a dissemination event, at which the major results of the study will be communicated to all interested inhabitants of the recruitment areas in Ouagadougou.

### Author affiliations

<sup>1</sup>Heidelberg Institute of Global Health (HIGH), Heidelberg University Hospital and Medical Faculty, Heidelberg University, Heidelberg, Germany

<sup>2</sup>Institut Supérieur des Sciences de la Population (ISSP), University of Ouagadougou, Ouagadougou, Burkina Faso

**Acknowledgements** For the publication fee we acknowledge financial support by Deutsche Forschungsgemeinschaft within the funding programme „Open Access Publikationskosten“ as well as by Heidelberg University.

**Contributors** AS and ID conceptualised the study. AH, AG, RMM, WJd'AK, TRB, IO, IC, SZ, KW, HF, AS and ID adapted the intervention design to the local context. AG, RMM, WJd'AK, TRB, IC and IO are implementing the intervention and coordinating the data acquisition and management. ID and RMM will lead the data analysis. AH and ID wrote the study protocol, which was reviewed and commented by all authors.

**Funding** This work was supported by the Robert Bosch Foundation within the framework of the Robert Bosch Junior Professorship 2019 (grant number: 01000035-002).

**Disclaimer** The Robert Bosch Foundation has not had any role in designing or implementing the study and will not be involved in analysis, interpretation or decisions on where to submit the data.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

**Ethics approval** Ethical approval for the study has been obtained from the Medical Faculty of Heidelberg University (S-376/2019) and from the Ministry of Health and the Ministry of Higher Education, Scientific Research and Innovation in Ouagadougou, Burkina Faso (No 2021-01-001).

**Provenance and peer review** Not commissioned; externally peer reviewed.

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### ORCID iD

Alina Herrmann <http://orcid.org/0000-0002-6502-106X>

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