**Protocol title**: Effect of a nutrition education and physical activity intervention on Metabolic Syndrome among females of reproductive age in Wakiso district, central Uganda: an individually randomized parallel-group trial

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**LIST OF ABBREVIATIONS AND ACRONYMS**

| | |
|---|---|
| ATP III | National Cholesterol Education Program Adult Treatment Panel III |
| BMI | Body Mass Index |
| CHD | Coronary Heart Disease |
| CVD | Cardiovascular disease |
| DBP | Diastolic blood pressure |
| FBG | Fasting blood glucose |
| HDL | High-Density Lipoprotein Cholesterol |
| IPAQ | Physical Activity Questionnaire |
| LDL | Low-Density Lipoprotein Cholesterol |
| MetS | Metabolic syndrome |
| SBP | Systolic blood pressure |
| T2DM | Type 2 Diabetes Mellitus |
| TG | Triglycerides |
| WHO | World Health Organization |

## OPERATIONAL DEFINITIONS

**Cardiovascular diseases:** These diseases include coronary heart disease, cerebro-vascular disease, raised blood pressure, peripheral artery disease, rheumatic heart disease and congenital heart disease.

**Metabolic:** This refers to biochemical processes involved in the body's normal functioning

**Metabolic Health:** This refers to an individual's possession of optimal levels of blood sugar, triglycerides, high-density lipoprotein (HDL) cholesterol, blood pressure, and waist circumference, without using medications

**Metabolic Syndrome:** Metabolic syndrome (MetS) is a cluster of risk factors for type 2 diabetes (T2DM) and cardiovascular disease (CVD). It is defined by five components [raised waist circumference (WC), raised triglycerides, reduced high density lipoprotein (HDL) Cholesterol, raised fasting glucose and raised blood pressure (BP)].

**Motivational interviewing:** "Motivational interviewing is a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence"[1]

**Physical activity:** Is defined as "any bodily movement produced by skeletal muscles that results in caloric expenditure"[2].

**Prevalence of metabolic health:** This refers to the proportion of people who have optimal levels of all the risk factor variables without any medication.

**Reproductive age:** This refers to the female in the age group 15-49 years.

**Reproductive factors:** This refers to factors of reproductive history including early menarche, parity, miscarriages, and menopause.

**Risk factor:** This refers to an 'aspect of personal behavior or lifestyle, an environmental exposure, or a hereditary characteristic that is associated with an increase in the occurrence of a particular disease, injury, or other health condition'.

**Modifiable risk factor:** A behavioral risk factor that can be reduced or controlled by intervention, thereby reducing the probability of disease for instance obesity, dietary habits, psychosocial factors, alcohol abuse and cigarette smoking.

**Non-modifiable risk factor:** A risk factor that cannot be reduced or controlled by intervention for instance age, sex, race, genetics/family history

## PROJECT SUMMARY

Metabolic Syndrome (MetS) has seen a significant rise in prevalence worldwide, including regions such as sub-Saharan Africa and low-income countries like Uganda, where females are more affected than males. Despite the availability of effective interventions, the effectiveness of lifestyle modification interventions in low-income countries such as Uganda is not well-established, unlike in high-income countries.

### General objective

To evaluate the effect of a 12-week community-based nutrition education, physical activity and motivational interviewing intervention on MetS among females of reproductive age in central Uganda.

### Methods

This design is an individual randomized parallel-group study conducted among 120 participants (intervention (n=60) or control (n=60) groups) aged 15-49 in Wakiso district, central Uganda. The intervention will include an information leaflet, group nutrition education sessions, group physical activity sessions and group motivation interviewing sessions. The control group will receive the usual standard of care and referrals to the nearest health facilities.

Data will be collected at baseline and end line on sociodemographic factors, selected cardiovascular outcomes, biochemical outcomes, anthropometric measures, behavioural outcomes, and knowledge on MetS, using a household survey including a modified STEPS questionnaire.

Analyses will be conducted using Stata (SE/14.0). Descriptive analysis (means and SD) and Chi-square tests for categorical outcomes will compare baseline characteristics and metabolic risk factors between the intervention and the control groups. Student T-tests will be applied to continuous variables to assess cardio-metabolic parameters and their variations. Statistical significance will be at $p < 0.05$. A multilevel generalized linear mixed model (GLMM) will analyze the impact of time and study group on metabolic outcomes independent of other factors. The study will be conducted for 12 weeks following recruitment of the participants.

### Ethics and dissemination

The study received ethical approval from the Higher Degrees, Research, and Ethics Committee of Makerere University School of Public Health and from the Uganda National Council for Science and Technology.

The results of the study will be disseminated through peer-reviewed publications and scientific meetings.

## 1.0 INTRODUCTION/ BACKGROUND

### 1.1 Background

Metabolic Syndrome (MetS) is defined by a clustering of risk factors for cardiovascular disease (CVD) and type 2 diabetes mellitus (T2DM). The risk factors consists of five components [raised waist circumference (WC), raised triglycerides(TG), reduced high density lipoprotein (HDL) Cholesterol, raised fasting glucose and raised blood pressure(BP)[3], that occur together more often than by chance alone [3].

Globally, metabolic syndrome (MetS) is a problem of public health concern (K. Alberti et al., 2009; Kaur, 2014). Prevalence of MetS ranges from < 10% to 84% [4, 5], In Africa it ranges between 0-50% [6-8]. In Uganda, studies on the prevalence of MetS in the general population are currently lacking However, a study conducted among HIV individuals on first line antiretroviral therapy in south Western Uganda revealed a high MetS prevalence of (58%)[9], while one among patients with severe mental illness in a regional tertiary hospital in western Uganda indicated a prevalence of 23.5%. The consequences of MetS include an increased risk for type II diabetes mellitus, cardiovascular diseases and stroke[10, 11] and their associated morbidity and mortality. It is noteworthy, that the prevalence of MetS in most populations is higher in females as compared to males [9, 12-14]. Additionally, the effects of MetS in females of reproductive age and their off springs leading to poor maternal health, obstetric and perinatal outcomes[15, 16] and contribute to pregnancy induced hypertension, pre-eclampsia, gestational diabetes and infertility as well as prematurity, abortions, macrosomia and neural tube defects may occur. However, the prevalence of MetS in the female population in Uganda and its associated factors is currently unknown.

Currently, the Ministry of Health has carried out some interventions to control cardiovascular diseases in general, with attention focused largely on identification of individual risk factors for CVDs like hypertension and diabetes. However, there are limited interventions for Metabolic Syndrome. Probably due to a paucity of research on effective interventions and lack of guidelines for management of Metabolic Syndrome. Nutrition education and counselling interventions are known to influence dietary and lifestyle behavioral change. Lifestyle/dietary change is essential in the prevention and management of MetS. Nutrition promotion and lifestyle modification interventions including nutrition education and counselling interventions have been effectively used to address MetS or its components in other settings [17-21]. However, the effectiveness of such interventions among women of

reproductive age in Uganda have little been studied. Thus there is limited information on effectiveness of such interventions in Uganda..

Thus, there are gaps on an effective community nutrition education intervention that can promote dietary/lifestyle behavioral change for management of MetS among females of reproductive age in Uganda.

This research will therefore investigate the effect of a nutrition education and physical activity intervention among females of reproductive age with MetS in Central Uganda in order to contribute to inform the design of appropriate interventions for management of MetS in Uganda.

### 1.2 RATIONALE FOR PROPOSED TRIAL

This study will determine the effect of a nutrition education, physical activity and motivation interviewing on metabolic syndrome indicators (WC, BP, HDL, TGS, blood sugar). Women in Uganda generally are instrumental in making key decisions in food selection (buying), processing and preparation for their families, it is necessary to provide them with essential education/knowledge to make appropriate decisions to prepare and provide food which is healthy, nutritious and adequate, in addition to encouraging them to adopt physical activity. These lifestyles changes may help women with MetS and their families to have improved outcomes. The intervention will therefore be designed to educate women with MetS on how to effectively utilize locally available foods and adopt physical activity in order to improve their metabolic profile.

The primary objective of the study is to assess the effect of interventions for preventing and managing Metabolic Syndrome, for informing policy.

## 2.0 OBJECTIVES

### 2.1 GENERAL OBJECTIVE

The overall objective of the trial is to determine the effect of a community-based group nutrition education, physical activity, and group motivational interviewing intervention regarding dietary intake and physical activity on Metabolic Syndrome among females of reproductive age in Wakiso district, Central Uganda.

### 2.2 SPECIFIC OBJECTIVES

#### 2.2.1 Primary objective

The primary objectives of the trial are as follows:

- To determine the effect of nutrition education, physical activity and motivational interviewing intervention on Metabolic Syndrome among females aged 15-49 years in Wakiso district.

#### 2.2.2 Secondary objective

- To determine the effect of nutrition education, physical activity and motivational interviewing intervention on metabolic syndrome outcomes (blood pressure, high-density lipoprotein cholesterol, triglycerides, fasting blood sugar, waist circumference) and dietary intake, physical activity among females aged 15-49 years with metabolic syndrome in Wakiso district.

## 3.0 DESIGN AND METHODS

### 3.1 Study Design:

The study design is an Individual Randomized Parallel-Group Trial study with both an intervention group and a control group in Wakiso district, Central Uganda. All women with Metabolic Syndrome identified in our baseline study will be randomized to either intervention and control groups. The intervention will be administered in 5 groups of 12 participants.

### 3.2 Study Arms:

The study will employ two study arms; an intervention group and a control group.

### 3.3 The interventions

**Intervention: Nutrition/dietary education and motivational interviewing**

The nutritional promotion intervention will consist of two components: group motivational interviewing and group nutrition education sessions. These will be provided by a team consisting of the principle investigator, nutritionists, health workers (nurses/clinical officers) and community psychologist.

**Dosage of the intervention**

The nutrition intervention will consist of one hour of weekly group seminar sessions for 12 sessions and one hour of monthly individual motivational interviewing sessions for 3 sessions undertaken for 3 months. The choice of the group sessions in our study was determined to be sufficient intervention duration based on studies with similar methodologies [22]. In our study, group sessions will be held in a safe and convenient community location such as a community center, health facility or place for religious gathering with a hall for community activities.

For group nutrition education, written and oral instruction will be used including lectures, power point and poster presentations. Individual counselling will employ motivational counselling techniques. The intervention group will have 60 participants. This will form about 12 participants per group, with a total of 5 groups. Each group will be under the direct supervision of one trained nutritionist. The nutritionist will be located in 5 enumeration areas and will provide the intervention package to the participants as stated above. The nutritionists will undergo 18 hours of training on the delivery of the curriculum designed for the study.

**Package of the group nutrition education sessions**

The package will be guided by the curriculum and will mainly focus on the importance of health diet in MetS, healthy food choices, adequate daily distribution of meals, daily fat consumption targets, eating habits, serving sizes and portion sizes, goals for weight loss, techniques for diet compliance for weight loss, shopping tips for healthy food choices, food preparation and modification, meal planning, health eating (increasing intake of fruits, vegetables, fish and water and reducing consumption of sugar, fat, sodium, and fried foods) to reduce the components of metabolic syndrome and using photo books with examples of health meals. Additionally, participants will be encouraged to do moderate-intensity physical activity like brisk walking, climbing stairs and housework for at least 45 minutes.

**Package of the group physical activity intervention sessions**

Group physical activity sessions will cover a range of topics, including the different physical activity types, the importance of physical activity, and ways to incorporate physical activity into daily life, the WHO recommendations for physical activity and simple physical activity routines, the levels of physical activity and strategies to increase it, the risks associated with physical activity, exercise safety, and injury prevention, overcoming common barriers to exercise, staying motivated, nutrition for physical activity, and monitoring progress with exercise logs. Participants will receive encouragement to perform a minimum of 150 minutes of moderate-intensity or 75 minutes of vigorous-intensity aerobic physical activity per week, which includes activities like running, climbing stairs, and participating in sports. Additionally, participants will be encouraged to actively participate in muscle-strengthening activities, such as going to the gym, lifting heavy objects, or practicing yoga, for a minimum of two days per week, at a moderate level of intensity. Participants will receive guidance to decrease sedentary behavior by substituting it with any level of physical activity. Participants will receive leaflets containing key messages for their reference.

**Package of the group motivation interviewing sessions**

3 sessions of group motivation interviewing (MI) will be held monthly over 3 months in groups of approximately 12 participants covering various topics, including goal setting, factors that motivate lifestyle and behavioural change, relapse and its management, coping strategies and support, eating habits at various settings. Discussions will be held on relevant topics using MI techniques.

**Comparison:** In the comparison group, participants with MetS will be subjected to only usual standard of care with no specific individualized interventions. This will include referral of the participants to the usual health care facilities for management of their conditions as per the existing routine health facilities protocols. This is for purposes of controlling for possible changes in outcome variable due to other influences or behaviours.

Effort will be undertaken to reduce non-adherence in intervention group through evaluating questionnaires and meeting attendance, use of paper and phone reminders, provision of information about study objectives and planned meeting schedules, and reinforcement of the need for compliance during follow up meetings.

**Table 2: Summary table for the intervention and non-intervention arms**

| No. | **Intervention arm** | **Control arm** |
|---|---|---|
| 1. | **Participants** =60 women of reproductive age with MetS divided into 6 groups at baseline | **Participants** =60 women of reproductive age with MetS ( no groups) at base line |
| 2. | **Intervention and duration:**<br>One hour of weekly group nutrition education seminar sessions offered for 12 sessions in 3 months and<br>One hour of monthly group motivational interviewing sessions offered for 3 sessions undertaken for 3 months. | **Duration of follow up:**<br>Usual standard of care in nutrition education varies depending on either inpatient or outpatient setting |
| | **Behavioral change for dietary intake and physical activity enhanced by, motivation interviewing** | Usual standard of care in nutrition education and counselling. There is limited or no focus on Motivational Interviewing for behavioural cchange |
| | **Delivered by:**<br>Nutritionists and health workers using a tailor made curricular guide and materials for MetS | Delivered by:<br>Nutritionists and health workers using nutrition guides and materials for management of malnutrition (under and over nutrition) |
| | **Intervention topics and content :**<br>Focus on health dietary practices to manage MetS and prevent chronic non communicable diseases; over nutrition and associated risk of developing chronic non communicable diseases.<br>Specifically:<br>Types of nutrients and food sources: carbohydrates, protein, fats and cholesterol.<br>Intake of sugar, salt, saturated and non-saturated fats and daily fat consumption targets<br>Diary intake<br>Fruit and vegetable intake<br>Portion sizes and serving sizes<br>Making health food choices<br>Menu planning and food preparation<br>Physical activity<br>Goal setting<br>Lifestyle modification | Usual standard of care in nutrition education target prevention and management of malnutrition |
| | | |
| | **Assessment of fidelity of implementation:** supervision of trainers and frequent meetings by principle investigator with the trainers | None |
| | | |

### 3.4 Study Participants:

Female aged 15-49 years with Metabolic Syndrome in Wakiso district.

The intervention group participants will be women identified in Wakiso district during our baseline study. The intervention group will receive group nutritional education, group physical activity, and motivational interviewing. The control group also with Metabolic Syndrome identified in Wakiso district in the baseline study will receive usual standard of care.

**Inclusion Criteria:** Being a female aged 15-49 years in Wakiso district, Central Uganda with metabolic syndrome (defined by the 2009 Joint Interim Statement (JIS)), living in the community for at least one year, able to provide informed consent (oral or written), including consent for a follow-up interview 3 months after the start of the study. Participants under 18 years, should be able to provide assent and get informed consent from their parent /guardian or legal representative.

**Exclusion Criteria:** Females with chronic diseases such as liver, kidney, heart diseases or any diseases that could be worsened or affected by intervention sessions, participants on a prescribed diet plan, and those with the potential to undergo any surgical procedure during the intervention period.

### 3.5 Recruitment and enrollment of participants

We will use the database of a baseline study conducted to determine the prevalence of Metabolic Syndrome in Wakiso district (Manuscript under peer review) as our source of participants. Those participants who were diagnosed with MetS will be recruited into the study.

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### 3.6 Outcomes of interest:

**Primary outcome**

The primary outcome will be the between–group change in MetS prevalence after 3 months from start of intervention.

The 2009 Joint Interim Statement (JIS) will be used to diagnose MetS, defined as the presence of ≥ 3 of the following 5 factors: increased WC (women: ≥ 80 cm), low HDL-C ( women: <50 mg/dl (1.3 mmol/l) or treatment of low HDL-C), Hypertriglyceridemia ≥150 mg/dl (1.7 mmol/l) or treatment, elevated BP (systolic BP ≥ 130 mmHg and/ or diastolic ≥85

mmHg or treatment for hypertension) and elevated fasting blood sugar (FPG ≥ 100 mg/dl (5.6 mmol/l) or diabetes mellitus or treatment[3]

The European cutoffs for waist circumference will be used as recommended by WHO because of the unavailability of population/country specific WC cutoffs for sub-Saharan Africans [3] or Uganda.

**Secondary outcomes**

The secondary outcome will be the within - and between group variations in each of the following variable measured.

- dietary habits and behaviors (salt intake, fruits and vegetables intake, fat intake,
- anthropometric (weight, WC and BMI)
- cardio-metabolic (hypertension, blood glucose, triglycerides, HDL)
- nutrition knowledge
- lifestyle (physical activity, alcohol intake, cigarette smoking)

Mean change in parameters across the comparison and intervention groups will be determined. The measurement of the outcomes will be conducted before and at the end of the activities to determine the effect of the intervention**.**

### 3.7 Sample size Determination

**Sample size for participants with Metabolic Syndrome (Primary outcome variable)**

Using Power analysis computation of sample size with G.Power 3.1.9.4 software. The estimates will be based on a significance level of 5% and power of 80% to detect a difference between-group of 0.20 in MetS prevalence after 3 months intervention. A sample size of 98 is obtained. After accounting for design effect the sample size is 104. Assuming a dropout rate and failure to consent rate of 10%, 120 participants will be needed in total. 60 participants in the intervention and 60 in the non- intervention groups.

### Sample selection

**Sampling Procedure:** A purposive sample of females with Metabolic Syndrome in Wakiso from the baseline study undertaken in Wakiso district will be followed up in the community, screened and invited for participation in the study at baseline.

**Randomization: Sequence generation**

The randomization procedure will be automatically performed by a biostatistician to minimize the differences between the two groups for all stratifying variables. Using a computer random number generator a randomisation list of permuted blocks of size 8 with an allocation ratio of 1:1 will be generated.Then the participants will be randomly allocated to either the intervention arm (60) or the control group (60) and followed up for 3 months.

**Randomization: Allocation Concealment**

Random allocation will be conducted with minimization algorithm centrally in a single step to obtain two lists of nominative data. The allocation concealment will be by sealed opaque envelop to preserve allocation concealment. The biostatistician will assign numbers to the envelopes from 1 to 120. This will help prevent the possibility for researchers to predict or influence the allocation of participants. Due to practical reasons, we shall obtain informed consent after the randomization process.

The study coordinator who will be blinded to the randomisation allocation list will enrol the participants. The numbered envelopes will be distributed in sequence from 1 to 120 to a list of names from the baseline survey diagnosed with Metabolic Syndrome. This list of names will be generated after randomisation of those names.

All the individuals belonging to the intervention group will be separated from the individuals belonging to the control group and two allocation lists will be generated with control and intervention groups. The principal investigator will then follow up and identify the study participants in their respective villages, with the assistance of the village chairpersons.

**Blinding**

Given the nature of the intervention, it may not be possible to blind the participants and the health care workers. However, the laboratory technicians and research assistants who will collect the data will be blinded to the group assignment.

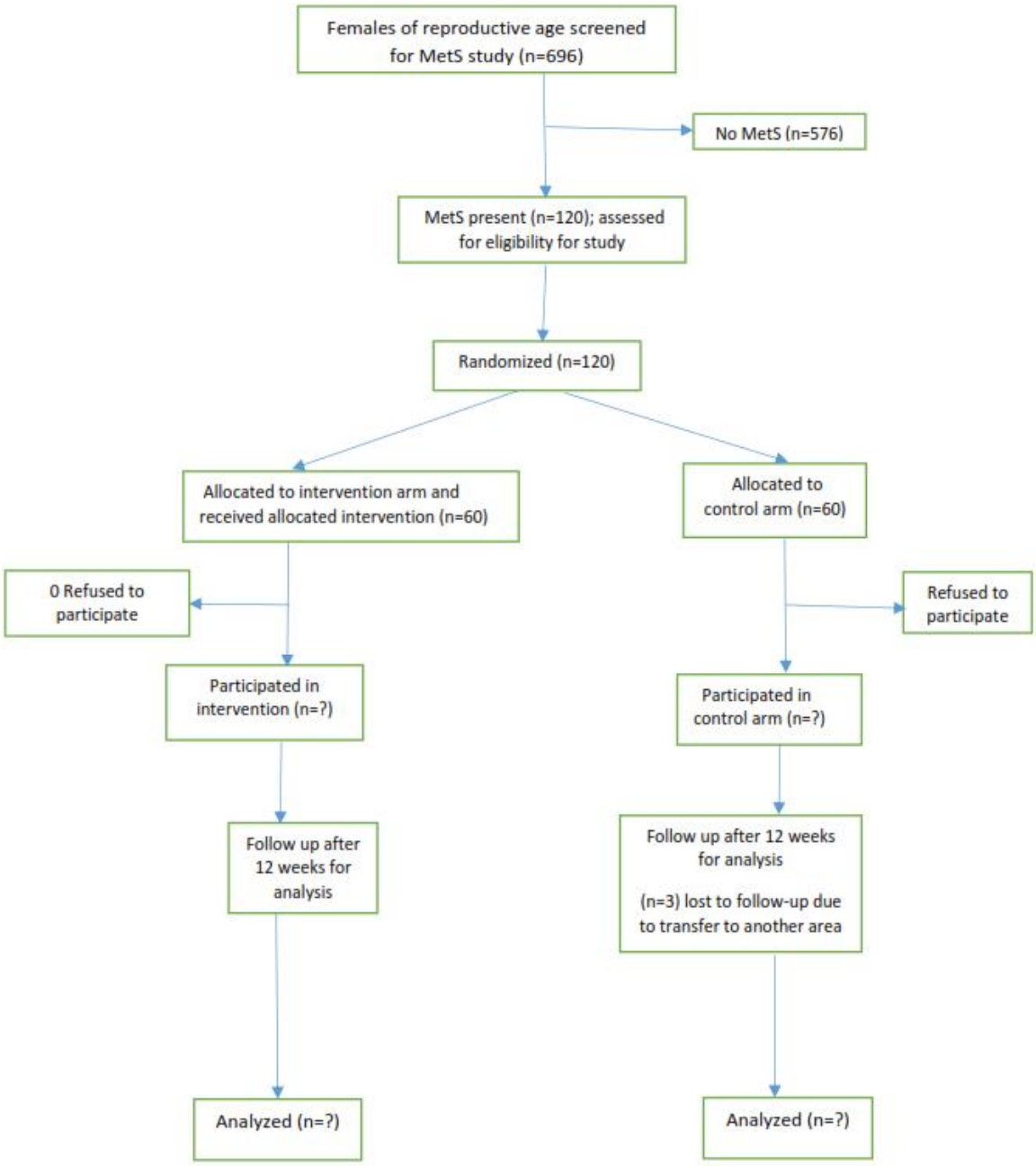
**Design and development of the training curriculum for the Intervention**

Step 1: The principle investigator will conduct the design and development of the curriculum. Initially a desk review/literature review will be conducted in which materials on dietary intake and lifestyle behavioral change for management of Metabolic Syndrome among females of reproductive will be reviewed. Materials and documents from Ministry of Health, academic research institutions doing work related to MetS and nutrition and relevant articles will be reviewed. Key information and finding from study one (On factors associated with MetS) will also be incorporated in the desk review. This will generate information on good

practices, training needs and competence gaps in delivery of nutrition education and counselling which will be used to draft a curriculum framework (outlining main nutrition education topics on appropriate dietary intake and lifestyle behavioral change for Metabolic syndrome to be undertaken and when offered during the 12 weeks of the intervention) and then an initial draft curriculum developed.

Step 2: The initial draft curriculum will be shared with the content experts (nutritionists and public health experts) from Makerere University School of Public Health, in the Ministry of Health, Uganda for input. Following their feedback, revisions and amendments to the curriculum will be made. The investigator will then review and refine the curriculum based on the feedback to develop the draft curriculum which will be field tested in a sub-county in Kampala and necessary corrections made based on feedback from the pre-test. After corrections have been made, the final curriculum document will then be used to train the healthcare workers and nutritionists for 18 hours (3 days), in preparation for the intervention.

**Figure 1: Flow diagram of study participants**



### 3.8 Quality Control Measures

Training of study team members: The study team members will undergo 18 hours of training on the study curriculum. This will be additional training to the initial 3 days of training on Metabolic syndrome that the study team underwent.The goal of this training will be for the study team to provide standardized intervention.

**Adherence to Study Intervention:**

Adherence to the intervention will be monitored through evaluating questionnaires and meeting attendance registration, use of paper reminders provision of information about study objectives and planned meeting schedules, and reinforcement of the need for compliance during follow-up meetings.

**Minimizing Loss to Follow-Up:**

We will try to minimize loss to follow-up. Participants will be given verbal reminders after each training session. The

As part of an incentive for continued participation, participants will participate in the supervised group sessions only during the weekends so that their usual working routines are not disrupted.

Motivation counselling will be provided by skilled community psychologists to motivate participants to attend the weekly sessions.

**Data collection**: The study will employ 2 laboratory technicians to draw off blood and 6 trained data collectors/research assistants (female nurses and graduate nutritionists), who will be trained for 3 days on the study protocol and how to use ODK to collect data and sending data to the servers at base line and end line of the study. The data collection tools will be field tested from a nearby district to the study districts.

**Intervention implementation:** The study will use 5 masters of public health nutrition trainees with a nutrition background at undergraduate to conduct the group nutrition education training for the study participants. 5 sports scientists will provide physical activity sessions For the group motivation interviewing sessions, 5 qualified health workers with training in motivation interviewing and nutrition will undertake the group motivation interviewing sessions.

### 3.9 Data Collection and Management:

#### 3.9.1 Data collection tool

To ensure consistency and minimization of errors in the data collected, standardized methods of data management will be used by the study team.

**Data Collection Procedures:** Base line data will be collected from study participants in the intervention and control group. This will be before the introduction of the intervention. At baseline data collection, informed consent, questionnaires on comprehensive medical history, dietary intake, smoking and alcohol intake, medication use, physical activity, anthropometry, BP, FBS and lipid profile tests will be undertaken for all participants.

After the introduction of the intervention, data will be collected serially from study participants in the intervention arm on selected variables before the group sessions to monitor adherence of participants to the intervention. Final end-line data similar to data collected at baseline will be collected in both the intervention and non-intervention arms. In control group, the participants who have baseline data will be considered in analysis for comparison purposes.

**Socio-demographic characteristics**

A standardized interviewer-administered questionnaire will be adopted to obtain data on socio-demographic factors, behavioral factors (smoking status, alcohol intake, physically active or not) and history of NCDs like Diabetes, hypertension, obesity and dyslipidemia. A questionnaire will be administered for analysis of the daily consumption and type of foods eaten at breakfast, or as snacks, at lunch and super.

**Dietary measurements**

Initial and follow-up visits will include anthropometrical data, biochemical parameters, and assessment of current diet.

The 24 h recall questionnaire will be used before and after nutritional counseling and evaluated for the presence or absence of changes in eating habits. The food frequency questionnaire (FFQ) will be used at baseline and end line.

Nutritional analysis will be carried out with software ENA for Smart. Table of Food Composition will be used to determine the macro and micronutrients content of foods.

**Biochemical measurements**

Respondents will be advised not to have any meals before the measures. A blood sample of approximately 5 milliliters will be collected in the morning after a 12-hour overnight fast

from each participant and analyzed using the COBAS 6000 Analyser Series at Mulago National Referral Hospital Department of Clinical Chemistry Laboratory to assess fasting blood glucose, total cholesterol, HDL-cholesterol and triglycerides.

**Physical measurements:**

Anthropometry: Body weight will be measured to the nearest 0.01 kg with a portable electronic scale (Seca). Height will be measured to the nearest 0.5 cm without shoes while standing on a level, hard surface using a calibrated stadiometer. Body mass index (BMI) will be computed from body weight and height measurements.

Waist circumference will be measured to the nearest 0.1 cm using a non-stretchable standard tape measure. The measurements will be taken with individuals in light clothing. The tape will be placed just above the uppermost lateral border of the right ilium, at the end of a normal expiration. WC will be taken by female nurses and female medical students.

Blood pressure will be taken using Omron digital blood pressure monitor at rest.

**Data management**

All the data collected in the field will be entered in ODK tool embedded with skip patterns and constraints to ensure data quality and reduce bias. The investigator will cross-check all data at the end of each day and any errors discovered will be corrected immediately or by the research assistants the following day as appropriate. Quantitative data (ODK data) will be downloaded from server and exported to stata version 14 for cleaning.

**Data Analysis**

The data for participants who attend less than 60 % of their respective intervention sessions will be excluded from analyses.

Participants with attendance rates below 60% in the intervention sessions will not be included in the analyses.

The analyses will be conducted using Stata statistical software (SE/ 14.0, StataCorp, College Station, TX, USA. Variables will be expressed using descriptive analysis (means and SD). The baseline information for both comparison and intervention groups will be statistically compared regarding all influencing factors at baseline and end line (12 weeks). The chi-square test will analyse for differences in categorical outcomes, including baseline study characteristics, metabolic risk factors (waist circumference (WC), blood pressure (BP), triglycerides, fasting blood sugar(FBS), and high-density lipoprotein (HDL) Cholesterol),

and other factors including dietary habits such as fruits and vegetable intake, and food groups consumed. Behaviours, including smoking, alcohol intake, and physical activity, will also be analysed.

The Student T test for independent samples and variance analysis (ANOVA) will compare cardio-metabolic parameters (and their variations - to find any differences between findings) between the intervention group and the comparison group at the baseline and end of the intervention (after-before).

A 2 factor (2 x 2; group x time) repeated measures analysis of variance (ANOVA) will be performed for each dependent variable and a 1-way ANOVA will be used to assess the significance of differences between groups on the dependent variables assessed. Tukey's post hoc analysis will be performed if there is a significant finding. The T test for paired data will be applied to investigate within –group variable variations (after-before). Statistical significance will be set at $p < 0.05$.

Linear relationships will be estimated using Pearson correlation (crude model) to examine the associations between changes in variables, expressed as percentage of change ((endpoint - baseline value)/baseline value × 100). A multilevel generalized linear mixed model (GLMM) will be performed to identify the contribution of changes in time /round (baseline, end-line) and group (control, intervention) to changes in metabolic parameters (BP, WC, HDLC, FBS and Triglycerides) independent of other factors (education level, age, occupation etc). The model allows for the analysis of data with repeated measures, particularly baseline and end-line measurements for each individual. It also assesses the effects of the intervention and accounts for the correlation between observations within individuals due to repeated measures, as well as the clustering of individuals within the control and intervention groups.

### 3.10 Ethical Considerations

Approval will be sought from by the MakSPH Higher Degree's Research and Ethical Committee (HDREC) and Uganda National Council of Science and Technology (UNCST).

All participants will be informed about the purpose of the study and the use of resulting data. Consent will be obtained from all respondents. All participants will sign a voluntary informed consent form for being included study. Assigned copy of the informed consent will be given to each participant after the interview. For participants under 18 years, we will seek consent of their legal guardians and assent of the participants.

Confidentiality will be always observed by only allowing investigators to access the data. Electronic or hard copies of data will be stored securely. Anonymity of respondents will be ensured by using codes as identifiers.

Participants in intervention group will be informed about the risks associated with intervention including discomfort of finger prick and venepunctures, possible discomfort and dizziness following physical activity. The study team will ensure that participant safety, privacy and confidentiality are ensured during the intervention sessions.

The participants in the control group will be given information about the principles of a healthy lifestyle from study team.

Female nurses and female graduate medical students will conduct waist circumference measurements. Qualified laboratory technicians will conduct finger pricks and venipunctures.

All newly detected NCD patients will be given a referral form to attend the nearest health center for further management.

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