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Effect of nutrition education, motivational interviewing and exercise intervention on women with metabolic syndrome in Wakiso district

Submission date
01/06/2024

Recruitment status
No longer recruiting

Registration date
06/06/2024

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Metabolic syndrome (MetS) is becoming more common worldwide and in sub-Saharan African countries like Uganda. MetS means having several risk factors for heart disease and type 2 diabetes. A person has MetS if they have three of five risk factors: raised waist circumference, high triglycerides, low high-density lipoprotein cholesterol, high fasting blood glucose, and high blood pressure. Research shows that MetS is more common among females than males in sub-Saharan Africa, especially in urban areas. This trend is partly due to higher rates of obesity and physical inactivity among women. Other factors include diets high in carbohydrates and fats, sedentary lifestyles, and increasing smoking and alcohol intake. In developed countries, community-based interventions like nutrition education and physical activity have effectively managed MetS. However, such research is lacking in sub-Saharan Africa, making it difficult to make evidence-based decisions to manage the condition. Therefore, this study aims to determine the impact of a community-based intervention of group nutrition education, physical activity, and group counselling on MetS and its associated indicators among females of reproductive age (15-49 years).

Who can participate?
Participants in this study include females aged 15-49 years diagnosed with MetS in Wakiso district

What does the study involve?
The Interventions to be compared will include providing nutrition education, physical activity, and motivational counselling to one group for 12 weeks and providing standard care to the control group for 12 weeks. A study team comprising the principal investigator, public health nutritionists, sports scientists, community psychologists, and nurses/clinical officers will implement the intervention. The study team will undergo 18 hours of training on the study curriculum delivery.

Participants will be divided into five groups of 12 and will attend one-hour weekly seminar sessions for 12 weeks. These sessions will include lectures, PowerPoint presentations, and poster presentations. Additionally, participants will receive one hour of group motivational counselling each month for three months to facilitate behaviour change.

The intervention group will consist of 60 participants divided into 5 groups, with each group supervised by one trained nutritionist. Each of the 5 nutritionists will work with participants from 5 designated areas to provide the intervention package, as described above.

Group Nutrition Education: The group nutrition education sessions will cover various topics aimed at helping participants adopt healthy dietary habits for a healthy weight for their bone structure and well-being. These topics include:
1. The importance of a healthy diet in managing MetS
2. Opting for healthier alternatives and making wise decisions in terms of food consumption
3. Distribution of meals adequately throughout the day
4. Setting targets for daily fat consumption
5. Developing healthy eating habits including serving sizes and portion control
6. Setting weight loss goals and techniques for sticking to a diet plan
7. Tips for shopping for healthy food
8. Food preparation and modification strategies
9. Meal planning
10. Promoting healthy eating by increasing intake of fruits, vegetables, fish and water while reducing consumption of sugar, fat, sodium, and fried foods.
11. Using photo books with examples of healthy meals to aid meal selection.
Participants will be encouraged to do moderate-intensity physical activity such as brisk walking, climbing stairs, and housework for at least 45 minutes.

Group Physical Activity: The sessions will focus on teaching participants how to perform moderate and vigorous-intensity aerobic physical activities, muscle-strengthening exercises, and avoiding sedentary behaviour.
Topics covered in these sessions will include:
1. The different physical activity types
2. The importance of physical activity for health
3. Ways to incorporate physical activity into daily life
4. WHO recommendations for physical activity
5. Simple physical activity routines
6. Levels of physical activity and associated risks
7. Exercise safety and injury prevention
8. Overcoming common barriers to physical activity
9. Strategies for staying motivated
10. Nutrition for physical activity
11. Monitoring progress with exercise logs

Participants will receive leaflets with key messages for reference. They will be encouraged to continue with the exercises at home so that they aim for at least 150 moderate-intensity aerobic activity per week or 75 minutes of vigorous-intensity aerobic activity per week, or a combination of both, in addition to engaging in muscle-strengthening activities (such as gym workouts, or lifting heavy items) of at least moderate intensity for a minimum of two days a week. They will be provided with exercise logs to document the exercises they engage in each week.

Group Motivational Counselling: Group counselling sessions will take place monthly and cover various topics, such as goal setting, factors motivating lifestyle and behavioural change,

managing relapses, coping strategies, and support systems. Discussions will focus on relevant nutrition and physical activity topics using motivational counselling techniques to facilitate behavioural change and adherence to the intervention

The group sessions will be conducted in a safe and convenient community location, such as community centres, health facilities, or places for religious gatherings.

Control: In the control group, participants diagnosed with MetS will receive only the usual standard of care. This includes referral of the participants to regular health care facilities for the management of their conditions according to established protocols. To reduce noncompliance in the intervention group, the study will evaluate questionnaires and meeting attendance, use reminders, provide information, and reinforce adherence during follow-up meetings.

Assessments on the outcomes will be conducted at baseline and end line after 12 weeks.

What are the possible benefits and risks of participating?
Potential benefits:
1. Improvement in overall health including better metabolic markers, weight management and increased physical fitness
2. Participants may gain knowledge about nutrition, physical activity and lifestyle factors that can positively influence their health outcomes
3. By participating, one contributes to advancing scientific knowledge about the prevention and management of MetS

Risks:
1. Engaging in physical activity and diet modification may cause temporary discomfort to participants
2. Participants may need to commit time to attend nutrition education and physical activity sessions, which could be a burden for some people

Where is the study run from?
Makerere University College of Health Sciences, School of Public Health, Department of Community Health, and Behavioural Sciences

When is the study starting and how long is it expected to run for?
November 2020 to June 2024

Who is funding the study?
1. The Government of Uganda through the Makerere University Research and Innovation Fund (MakRIF)
2. Strengthening Education and Training Capacity in Sexual and Reproductive Health and Rights in Uganda (SET-SRHR) Project

Who is the main contact?
Dr David Lubogo, ludavid.lubogo@mak.ac.ug

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
Protocol (071)

Study information

Scientific Title
Effect of nutrition education, motivational interviewing and physical activity intervention on metabolic syndrome among females of reproductive age in Wakiso district, central Uganda: an individually randomised parallel-group trial

Study objectives
A 12-week intervention of nutrition education, physical activity, and 3-monthly motivational interviewing improves metabolic syndrome outcomes [behavioral (dietary intake, physical activity), educational (knowledge) outcomes, cardiovascular outcomes (BP), biochemical outcomes (HDL, TGS, blood sugar) and anthropometric measures (WC, weight)] among women of reproductive age in the intervention group compared to the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 15/12/2020, Makerere University School of Public Health, Higher Degrees, Research and Ethics Committee (Makerere University School of Public Health, Kampala, P.O.Box 7072, Uganda; +256 414532207; hdrecadmin@musph.ac.ug), ref: IRB00011353

2. Approved 28/12/2021, Uganda National Council for Science and Technology (Uganda National Council for Science and Technology, Plot 6 Kimera Road, Ntinda, Kampala, P.O.Box 6884, Uganda; +256 414 705500; info@uncst.go.ug), ref: HS1281ES

Primary study design
Interventional

Study design

Single blind single centre interventional individually randomized parallel-group trial design with a one-to-one allocation ratio to either intervention or control group.

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Interventions: Nutrition education, physical activity, and motivational interviewing
The initial stage for the intervention will involve designing and developing materials/curricula for the intervention. The materials to be developed will consider some findings from a baseline study (factors associated with MetS). The principal investigator will design and develop materials with technical input from experts in Makerere University School of Public Health and the Ministry of Health and outline the main nutrition education and physical activity topics to be undertaken and when offered during the 12 weeks of the intervention.

The intervention will comprise group nutrition education, physical activity, and motivational interviewing sessions. These will be provided by a team consisting of the principal investigator, public health nutritionists, sports scientists, community psychologists, and nurses/clinical officers.

Dosage of the intervention
The nutrition education and physical activity intervention will consist of one hour of weekly group seminar sessions for 12 sessions and one hour of monthly group motivational interviewing sessions for 3 sessions undertaken for 3 months. Group education sessions will employ written and oral instruction (lectures, PowerPoint, and poster presentations). During the physical activity sessions, participants will be instructed on how to conduct moderate-intensity aerobic activity, vigorous-intensity aerobic activity, and muscle-strengthening activities of at least moderate intensity, as well as advice on avoiding sedentary behavior. Leaflets containing key messages will be provided to participants for reference.

The choice of group sessions in the study will be determined to be of a sufficient intervention duration based on studies with similar methodologies. Group sessions will be held in a safe and convenient community location such as a community center, health facility, or place for religious gatherings with a hall for community activities. The intervention group will have 60 participants. This will form about 12 participants per group, comprising 5 groups. Each group will be under the direct supervision of one trained nutritionist. The nutritionist will be located in 5 enumeration areas and 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 curriculum will guide the package and will mainly focus on the importance of healthy 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 motivation interviewing sessions
3 sessions of group motivation interviewing (MI) will be held monthly over 3 months in 5 groups of approximately 12 participants covering various topics, including goal setting, factors that motivate lifestyle and behavioral change, relapse and its management, coping strategies, and support, eating habits at various settings. Discussions will be held on relevant topics using MI techniques.

Package of the group physical activity sessions
Group physical activity sessions will cover topics related to physical activity including the different physical activity types, the importance of physical activity, and ways to incorporate physical activity into daily life. WHO recommendations for physical activity, simple physical activity routines, the levels of physical activity, the risks associated with physical activity, exercise safety, and injury prevention, overcoming common barriers to physical activity, staying motivated, nutrition for physical activity, and monitoring progress with exercise logs

Control: In the control group, 60 participants with MetS will be subjected to only the usual standard of care with no specific individualized interventions. This will include referral of the participants to the usual health care facilities to manage their conditions as per the existing routine health facilities protocols. This is to control for possible changes in outcome variables due to other influences or behaviors. An effort will be undertaken to reduce noncompliance in the intervention group by evaluating questionnaires and meeting attendance, using paper and phone reminders, providing information about study objectives and planned meeting schedules, and reinforcing the need for compliance during follow-up meetings.

Sample selection
Sampling Procedure: A purposive sample of females with MetS in Wakiso from sub-study 1 will be followed up in the community, screened, and invited for participation in the study at baseline.

Randomization: Sequence generation and allocation Concealment
After baseline data on participants has been collected, the randomization procedure will be automatically performed by a biostatistician to minimize the differences between the two groups for all stratifying variables. Then the participants will be randomly allocated to either the intervention arm or the non-intervention arm and followed up for 3 months. Random allocation will be conducted with a minimization algorithm centrally in a single step to obtain two lists of nominative data. 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 randomization.

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

Outcome measures
Metabolic Syndrome will be defined according to the 2009 Joint Interim Statement (JIS) as the presence of ≥ 3 of the following 5 factors: increased waist circumference (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. Baseline data will be collected from participants in both the intervention and control groups before the intervention is introduced. The baseline data collection will include measurements of blood pressure (BP), fasting blood sugar (FBS), high-density lipoprotein cholesterol (HDL cholesterol), triglycerides, and waist circumference for all participants. Final End-line data similar to data collected at baseline will be collected in both the intervention and control arms. In the control arm, the participants who have baseline data will be considered in the analysis for comparison purposes.

Intervention Type
Behavioural

Primary outcome(s)
Prevalence of Metabolic Syndrome measured using data collected on blood pressure (BP), fasting blood sugar (FBS), high-density lipoprotein cholesterol (HDL cholesterol), triglycerides, and waist circumference using standard methods at baseline and 12 weeks

Key secondary outcome(s)
The following secondary outcome variables will be assessed within and between group variations at baseline and end-line (12 weeks after baseline):
1. Dietary habits and behaviors (salt intake, fruits, and vegetable intake, fat intake) measured using a 24-hour recall and food frequency questionnaire
2. Anthropometric outcomes (weight, waist circumference, and BMI) measured using the WHO step-wise approach tools
3. Cardio-metabolic outcomes (blood pressure, fasting blood glucose, triglycerides, HDL cholesterol) measured using the WHO step-wise approach tools
4. Nutrition knowledge measured using a questionnaire
5. Lifestyle (physical activity, alcohol intake, cigarette smoking) measured using the WHO STEP-wise approach tools

Completion date
24/06/2024

Eligibility

Key inclusion criteria
1. Females aged 15-49 years who were diagnosed with MetS in Wakiso district
2. Metabolic Syndrome diagnosis based on the 2009 Joint Interim Statement (JIS)
3. One year of community residence in Wakiso district
4. Able to provide informed consent (oral or written)
5. Able to provide assent (for those under 18 years) and obtain informed consent of their parent /guardian or legal representative

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
15 Years

Upper age limit
49 Years

Sex
Female

Total final enrolment
120

Key exclusion criteria
1. Females with chronic diseases such as liver, kidney, heart diseases, or any diseases that could be worsened or affected by intervention sessions
2. Participants on an already prescribed diet plan
3. Participants who are scheduled to undergo any surgical procedure during the intervention period

Date of first enrolment
01/03/2023

Date of final enrolment
24/06/2023

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University
College of Health Sciences, School of Public Health
Kampala
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P.O.Box 7072

Sponsor information

Organisation
Makerere University

ROR

https://ror.org/03dmz0111

Funder(s)

Funder type
Government

Funder Name
Government of Uganda through the Makerere Research and Innovation Fund (MakRIF)

Funder Name
Strengthening Education and Training Capacity in Sexual and Reproductive Health and Rights in Uganda (SET-SRHR) Project

Results and Publications

Individual participant data (IPD) sharing plan
The individual participant data (IPD) will be available upon request. The data shared will include individual participant data used for the reported results, following de-identification. This includes text, tables, figures, appendices, the study protocol, and the statistical analysis plan. Access to the data will be granted to researchers who provide a methodologically sound proposal, starting three months after the publication of the article, and will be available for five years. Proposals should be directed to ludavid.lubogo@mak.ac.ug. Data requestors must sign a data access agreement to gain access.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/02/2025	22/07/2025	Yes	No
Protocol file			05/06/2024	No	No
Statistical Analysis Plan			05/06/2024	No	No