

Participant Information Leaflet and Consent Form

This leaflet must be given to all prospective participants to enable them to know enough about the research before deciding to or not to participate

Title of Research: Impact of Dietary Counseling on Nutritional Status, Antioxidant Nutrient Intake, and Metabolic Syndrome Parameters in People with Metabolic Syndrome Attending Diet Therapy Clinic at a Municipal Hospital in Kumasi, Ghana

Name(s) and affiliation(s) of the researcher(s): This research is being conducted by Aminu Suleman Baba of the Department of Biochemistry and Biotechnology of KNUST, Kumasi.

Background (Please explain simply and briefly what the study is about): Research suggests that metabolic syndrome (MetS) has been associated with increased oxidative stress and its related complications. Studies suggest dietary approaches to increase antioxidant intake may help limit MetS-associated oxidative stress. Also, it has been suggested that nutritional status and MetS parameters can be improved by dietary Counseling. In Ghana, people with MetS are routinely referred for dietary counselling intervention for the management of MetS in hospital facilities with a dietitian. However, there are limited data on the effect of dietetic intervention on the antioxidant and oxidative stress status of people living with MetS in Ghana.

Purpose(s) of research: The main objective of this is to assess the impact of dietary counseling on nutritional status, antioxidant nutrient intake, and metabolic syndrome parameters in people with metabolic syndrome attending diet therapy clinic at a municipal hospital in Kumasi, Ghana

Procedure of the research, what shall be required of the each participant and approximate total number of participants that would be involved in the research: A total of 82 participants will be recruited into this research. A semi-structured questionnaire would be used to assess respondents' demographic characteristics and medical histories. Anthropometric parameters i.e., height, waist circumference, weight, BMI of the participants will also be measured. Five milliliters (5ml) of venous blood will be collected for analyses of lipid profile and fasting plasma glucose levels. All participants must adhere to the Covid-19 protocols.

Risk(s): There is no intended risk to participant in this study, however, a little discomfort and pain would be felt by participants during venipuncture to obtain 5ml of blood for the analyses

Benefit(s): Participants will benefit by knowing their nutritional status and know what to eat through the nutritional counseling to improve their antioxidant status.

Confidentiality: All information collected in this study will be given code numbers. Names will be coded promptly and codes will be recorded to enable the research team trace when giving feedback to study subjects about their laboratory test results and nutritional status. Abnormal result will be communicated to participants through the medical officer in charge of the wellness clinic, who the research team is closely working with. The research team will adopt the highest form of confidentiality. No name or identifier will be used in any publication or reports from this study.

Voluntariness: Taking part in this study should be out of your own free will. You are not under any obligation to. Participation is entirely voluntary

Alternatives to participation: If you choose not to participate, this will not affect your treatment in this hospital. You will not be discriminated against in any way should you decide not to partake in this study and the researchers will bear no grudge against you.

Withdrawal from the research: You may decide to withdraw from the research at any time without having to explain yourself. You may also choose not to answer any question you find uncomfortable or private.

Consequence of Withdrawal: There will be no consequence, loss of benefit or care to you if you choose to withdraw from the study. Please note however, that some of the information that may have been obtained from you without identifiers, before you chose to withdraw, may have been modified or used in analysis reports and publications. These cannot be removed anymore. We do however promise to comply with the terms to which you signed to earlier on.

Costs/Compensation: for their time and inconvenience, participants will be given snacks.

Contacts: If you have any questions and contributions concerning this study, please do not hesitate to contact **Mr. Aminu Suleman Baba on 0548043492.**

Further, if you have any concern about the conduct of this study, your welfare or your rights as a research participant, you may contact:

**The Office of the Chairman
Committee on Human Research and Publication Ethics
Kumasi
Tel: 03220 63248 or 020 5453785**

CONSENT FORM

Statement of person obtaining informed consent:

I have fully explained this research to _____ and have given sufficient information about the study, including that on procedures, risks and benefits, to enable the prospective participant make an informed decision to or not to participate.

DATE: _____ NAME: _____

Statement of person giving consent:

I have read the information on this study/research or have had it translated into a language I understand. I have also talked it over with the interviewer to my satisfaction.

I understand that my participation is voluntary (not compulsory).

I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it.

I understand that I may freely stop being part of this study at any time without having to explain myself.

I have received a copy of this information leaflet and consent form to keep for myself.

NAME: _____

DATE: _____ SIGNATURE/THUMB PRINT: _____

Statement of person witnessing consent (Process for Non-Literate Participants):

I _____ (Name of Witness) certify that information given to _____ (Name of Participant), in the local language, is a true reflection of what I have read from the study Participant Information Leaflet, attached.

WITNESS' SIGNATURE (maintain if participant is non-literate): _____