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# The effect of traditional diets on immune regulation in obese adults in Tanzania

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|---|---|---|
| **Submission date** | **Recruitment status** | [X] Prospectively registered |
| 08/12/2023 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [X] Statistical analysis plan |
| 10/01/2024 | Completed | [_] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 25/07/2025 | Other | [_] Record updated in last year |

**Plain English summary of protocol**

Background and study aims

Obesity rates are rapidly rising in the developing world and with them a surge of non-communicable diseases (NCDs). This change in disease patterns is attributed to urbanization and the gradual shift to Westernized diets and a more sedentary lifestyle. Traditional diets such as the Mediterranean and Japanese diets have been shown to offer a wide diversity of nutrient sources and reduce the risk for obesity and nutrition-related NCDs. However, to date, the health benefits of traditional African diets remain mainly unexplored and these diets are at risk of disappearing due to their poor documentation. This study aims to investigate the effects of consuming traditional Tanzania diets (plant-based and fermented) in regulating aberrant immune response in obese adults in Tanzania.

Who can participate?

The study will recruit adults aged 30-60 years of both genders. We will exclude participants with chronic diseases such as chronic infections, cardiovascular diseases, inflammatory diseases, and metabolic diseases. Participants in the healthy control arm will have a BMI between 18.5-24.9 Kg /M2 while those in the overweight/obese arm will have a BMI between 25.0-40.0 Kg/M2. We will also exclude participants with a recent history of fever, antibiotic use, and those who have recently used other medications that could interfere with immune function.

What does the study involve?

Participants in the overweight/obese group will be randomized into one of the three intervention arms for 6 weeks; the first group will receive a traditional plant-based diet, the second group will receive a fermented banana beverage (mbege), and the third group will be a control group. Participants in all three arms will also receive a single dose of Pneumococcal conjugate and tetanus toxoid vaccines at week 4 of the dietary intervention. From each participant, blood and stool samples will be collected at the start of the diet intervention, after 4 weeks, and lastly after 8 weeks.

What are the possible benefits and risks of participating?

The benefits of participating in this study include free health screening and nutritional counseling. The study also aims to impart lasting behavioral changes that would promote healthier eating habits and improve the quality of life of the participants and their families who

will then serve as ambassadors within the community. Risks of participating are minimal as the diets to be investigated are common traditional diets from the same community and they will be prepared under strict hygienic conditions by an experienced and trained cook. The vaccines that will be used have a well-described safety profile and each participant will be screened for a history of allergy and other risk factors that could predict adverse responses to the vaccines before being enrolled in the study.

Where is the study run from?
The study will be managed by the Kilimanjaro Christian Medical University College (KCMUCo) in Moshi, Tanzania.

When is the study starting and how long is it expected to run for?
March 2023 to May 2026

Who is funding the study?
The study is funded by the Joint Programming Initiative A healthy diet for a healthy life (JPI) (The Netherlands)

Who is the main contact?
Dr Quirijn de Mast
Quirijn.deMast@radboudumc.nl

# Contact information

### Type(s)
Scientific

### Contact name
Dr Quirijn de Mast

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### Type(s)
Public, Principal investigator

### Contact name
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### ORCID ID
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# Additional identifiers

# Study information

### Scientific Title
The effect of diet on immune and vaccine responses in people living with obesity in transitioning communities.

### Acronym
TransInf

### Study objectives
Traditional plant-based diets and traditional fermented foods have immunomodulatory effects that can reduce immunometabolic dysregulation and improve vaccine response in people living with overweight/obesity.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
1. Approved 29/09/2023, National Institute for Medical Research (P.O.Box 9653, Dar es Salaam, -, Tanzania; +255-22-2121400; hq@nimr.or.tz), ref: NIMR/HQ/R.8a/Vol.IX/4432

2. Approved 30/06/2023, CRERC (P.O. Box 2240, Moshi, -, Tanzania; +255 272753616; info@kcmcu.ac.tz), ref: 2638

### Primary study design
Interventional

### Study design
Cross-sectional design with a randomized open-label proof-of-concept nutritional intervention study

### Study type(s)
Other

### Health condition(s) or problem(s) studied
Immune dysregulation and improvement of vaccine responses in overweight/obese adults

### Interventions

Participants will be randomized into one of three intervention arms
1. Traditional plant-based, high fiber and polyphenol diet
2. Traditional fermented banana beverage
3. No treatment (control group).

Each intervention arm will contain (n = 30 participants with BMI ≥ 27 < 40 kg/m²) matched for age and sex. They will receive the dietary intervention for a total of 6 weeks, for at least 5 days each week. Additionally, the participants will receive one dose of each of two vaccines at week 4 of the diet intervention, Pneumococcal conjugate vaccine (0.5 ml intramuscularly) and tetanus toxoid vaccine (0.5 ml intramuscularly).

### Intervention Type
Behavioural

### Primary outcome(s)
1. Cytokines will be measured using enzyme-linked immunosorbent assays (ELISA) at baseline, 4 and 8 weeks.
2. Antibody responses to Pneumococcal conjugate and tetanus toxoid vaccines will be measured at baseline and 4 weeks after receiving the vaccines.

### Key secondary outcome(s)
1. Plasma proteome will be measured using the OLINK platform at baseline, 4 and 8 weeks.
2. Plasma metabolome will be measured using untargeted mass spectrometry at baseline, 4 and 8 weeks.
3. Whole blood transcriptome will be measured using RNA sequencing at baseline, 4 and 8 weeks.
4. Gut microbiome will be assessed by sequencing of the V3–V4 region of 16S rRNA gene as well as the internal transcribed spacer (ITS) region of stool samples at baseline, 4 and 8 weeks.
5. Telomere length of peripheral blood mononuclear cells (PBMCs) will be measured using PCR at baseline, 4 and 8 weeks.
6. DNA methylation will be measured using an assay for transposase-accessible chromatin with sequencing (ATAC-seq) at baseline, 4 and 8 weeks.

### Completion date
31/05/2026

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 27/02/2024:
1. Age between 30 and 60 years·
2. BMI > 25 kg/m² at screening (‘overweight/obesity group) or 18.5–24.9 kg/m² at screening (‘normal weight controls)
3. Westernized-style diet as a regular diet, as assessed one week prior to recruitment while participants were taking their usual diets (using a 24-hour dietary recall on three non-consecutive days, including one weekend)·
4. Taking alcoholic drinks but not fermented banana beverage (Consuming a fermented banana beverage less than twice a week).
5. For female: practising highly effective birth control method: this means one of the two:
5.1. Currently using hormonal contraceptive, or
5.2. Providing a consent to oblige to a “double-barrier method” (i.e. 1 physical barrier method plus the use of a chemical barrier, for example, male condom plus spermicide, Types of barrier

methods include condoms, diaphragms, cervical caps, and the contraceptive sponge) to prevent conception during the time of the study.

Previous inclusion criteria:
1. Age between 35 and 60 years·
2. BMI > 27 kg/m² at screening (‘overweight/obesity group) or 18.5–24.9 kg/m² at screening (‘normal weight controls)
3. Westernized-style diet as a regular diet, as assessed one week prior to recruitment while participants were taking their usual diets (using a 24-hour dietary recall on three non-consecutive days, including one weekend)·
4. Taking alcoholic drinks but not fermented banana beverage (Consuming a fermented banana beverage less than twice a week).
5. For female: practising highly effective birth control method: this means one of the two:
5.1. Currently using hormonal contraceptive, or
5.2. Providing a consent to oblige to a “double-barrier method” (i.e. 1 physical barrier method plus the use of a chemical barrier, for example, male condom plus spermicide, Types of barrier methods include condoms, diaphragms, cervical caps, and the contraceptive sponge) to prevent conception during the time of the study.

## Participant type(s)
Employee

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
30 Years

## Upper age limit
60 Years

## Sex
All

## Key exclusion criteria
Current exclusion criteria as 27/02/2024:
1. A Positive HIV test.
2. A Positive malaria test.
3. A Positive urinary pregnancy test.
4. Abnormal blood pressure (Systolic <90 but >140 mmHg, Diastolic < 60 but >100 mmHg).
5. Diabetic patients (RBG > 11.1 mmol/L).
6. History of fever at least 30 days prior to enrolment.
7. Past medical history of a chronic illness.
8. History of antibiotic therapy or any immune modulatory drugs 3 weeks prior to enrolment.
9. Currently breastfeeding
10. Positive history of mental illness.
11. Positive history of alcohol or illicit drug use.
12. Currently enrolled in a weight loss program or partaking in another clinical trial.

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6. History of fever at least 30 days prior to enrolment.
7. Past medical history of a chronic illness.
8. History of antibiotic therapy or any immune modulatory drugs 3 weeks prior to enrolment.
9. Currently breastfeeding or in menopause.
10. Positive history of mental illness.
11. Positive history of alcohol or illicit drug use.
12. Currently enrolled in a weight loss program or partaking in another clinical trial.

### Date of first enrolment
06/02/2024

### Date of final enrolment
05/06/2024

## Locations

### Countries of recruitment
Tanzania

### Study participating centre
**Kilimanjaro Christian Medical Centre University (KCMCU)**
Box 2240 Moshi, Tanzania
Moshi
Tanzania
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## Sponsor information

### Organisation
Radboud University Nijmegen Medical Centre

### ROR
https://ror.org/05wg1m734

## Funder(s)

### Funder type

Charity

### Funder Name
Joint Programming Initiative A healthy diet for a healthy life

### Alternative Name(s)
JPI A Healthy Diet for a Healthy Life, Healthy Diet for a Healthy Life, JPI HDHL

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Associations and societies (private and public)

### Location
Netherlands

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored online in Castor EDC as well as in a cloud based digital research environment (DRE) at Radboudumc. The datasets will be made available upon request from the study PIs: Dr Godfrey Temba at gtemba@kcmuco.ac.tz and/or Dr Quirijn de Mast at Quirijn.deMast@radboudumc.nl.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | | 12/12/2023 | No | Yes |
| Protocol file | | | 12/12/2023 | No | No |
| Statistical Analysis Plan | version 1 | 29/05/2024 | 29/05/2024 | No | No |