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The effect of food change between traditional Tanzanian and western-type foods on inflammation and metabolism

Submission date
01/03/2021

Recruitment status
No longer recruiting

Registration date
26/03/2021

Overall study status
Completed

Last Edited
04/04/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
The current wave of urbanization and dietary transition that takes place in many African regions has profound effects on the function of the immune system. This coincides with changes in disease epidemiology with a sharp increase in non-communicable diseases (NCDs), along with the ongoing high burden of infectious diseases. Important gaps remain in our insight into the mechanisms underlying this epidemiologic transition. Recent studies, including data in healthy Tanzanian individuals, suggest that a switch from unprocessed or locally processed traditional low-calorie, high-fiber diet to a high-caloric, high-fat more industrialized processed food 'western-type' diet increases inflammation. Therefore, this study aims to assess the inflammatory and metabolic effects and changes in gut microbial profiles of a 2-week food change.

Who can participate?
Healthy Tanzanian male individuals aged 20-40 and living in a rural or urban area in the Moshi district in the Kilimanjaro region.

What does the study involve?
Recruited rural living individuals will be fed a high-fat, high simple-sugar, high-calorie intake and low-fiber more industrialized processed food 'western-type' diet and urban living individuals a low-fat, low simple sugar, high-fiber unprocessed or locally processed traditionally rural-type diet. Participants will be provided with meals three times daily for 2 weeks under the cost of the project. Food will be prepared by an experienced cook using stringent hygienic measures and served at the place of preparation.

What are the possible benefits and risks of participating?
Risks associated with short dietary intervention are minimal. This may include mild gastrointestinal symptoms that are easy to resolve in a few days, such as diarrhea, bloating or constipation, due to sudden dietary changes. Regarding sample collection, procedures used have only minimal risk such as local hematoma related to blood sampling. Volunteers will also have no direct benefit from the intervention. However, volunteers who consent to participate will

receive free health check-ups for HIV, malaria, blood sugar and blood pressure. The cost of transport to the KCRI research center situated in Moshi municipal in the Kilimanjaro region, Tanzania for blood and stool sampling will be reimbursed to the participants. The only burden overseen for participation in this study is that participants will be required to visit the cooking facility to take meals three times a day for 2 weeks and to visit the KCRI Clinical Trial Unit for sampling at the beginning and the end of the intervention. However, the cooking facility for the rural participants will be placed close to the sampling area so that participants can access it easily.

Where is the study run from?
Kilimanjaro Clinical Research Institute (Tanzania)

When is the study starting and how long is it expected to run for?
September 2020 to August 2021

Who is funding the study?
The Joint Programming Initiative a Healthy Diet for a Healthy Life (JPI HDHL)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
DIET-study version 1.1

Study information

Scientific Title
The inflammatory and metabolic effects of a 2-week food change between traditional Tanzanian and western-type foods in healthy Tanzanian male individuals

Acronym
DIET

Study objectives
The hypothesis underlying the current study proposal is that the change from unprocessed or locally processed traditional Tanzanian food to an industrially processed, energy-dense, high-fat, high-calorie food, increases inflammation and leads to significant modulation in food-derived and endogenous plasma metabolites, lipids, and gut microbiome changes.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Approved 30/09/2020, Kilimanjaro Christian Medical College Research Ethics and Review Committee (CRERC) (PO Box 2240, Moshi, Tanzania; +255 (0)2753616; beatrice.temba@kcmuco.ac.tz), ref: 2483
2. Approved 03/12/2020, National Institute for Medical Research (NIMR), Tanzania (3 Barack Obama Drive, PO Box 9653, 11101 Dar es Salaam, Tanzania; +255 (0)22 2121400; hq@nimr.or.tz, info@nimr.or.tz), ref: NIMR/HQ/R.8a/Vol. IX 3570

Primary study design
Interventional

Study design
Single-center prospective intervention study, self-controlled randomized design

Study type(s)
Other

Health condition(s) or problem(s) studied
Inflammatory and metabolic effect of food change between traditional and western-type foods in healthy male individuals

Interventions
This dietary intervention will focus on the effect of food change between traditional Tanzanian and western-type foods on inflammatory, metabolic changes and changes in the gut microbiome composition. A total of 76 healthy male individuals aged 20-40 years living in either urban area (n=48) or a rural area in Moshi districts (n=28) will be enrolled.

In part one: Participants consuming a traditional high-fiber, low-simple sugar, low-fat traditional Tanzanian type diet (rural area) or a low-fiber, high-simple sugar, high-fat western-type diet (urban area) will be selected using a dietary recall history of the previous week. First, dietary habits in the home environment will be studied for 1 week with participants taking their usual diet. Blood and stool samples will be taken after this week. Per group (rural/urban), participants will be randomized for the dietary intervention for 2 weeks (n=23 per group) or remain on their usual diet (n=5 per group).

In part two: Banana brew (mbege) is commonly consumed in rural areas. Mbege is made from fermented banana to which millet is added. Mbege contains yeast (Saccharomyces cerevisiae) and is a rich source of fibers, flavonoids (millet), and the disaccharide trehalose. Both flavonoids and trehalose exhibit anti-inflammatory properties. To test the immune-modulatory effect of consuming banana brew, 20 volunteers from the urban area who consume alcohol, but not banana beer will be randomized for a banana beer intervention for 1 week. Participants will receive 1 l of a local brew ‘Mbege’ daily while consuming their usual diet. The effect of other factors will be controlled by taking measurements from the same participants before and after the intervention. Blood and stool samples will be taken before and after the intervention period of 1 week.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measures as of 29/03/2021:
1. Circulating inflammation-related human protein biomarkers measured using enzyme-linked

immunosorbent assay (ELISA) or comparable techniques at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
2. The capacity of the circulating immune cells to produce inflammatory cytokines in ex vivo whole blood stimulation to different stimuli, measured using ELISA on the culture supernatant at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
3. Blood transcriptome measured using RNAseq technology with NovaSeq™ Sequencing System at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
4. Plasma metabolome assessed using high-throughput mass spectrometry (untargeted metabolomics) at baseline (day 0), post intervention (day 14) and optionally at day 30 post intervention (day 44)
5. Coagulation parameters (thrombin and plasmin generation) measured using modified calibrated automated thrombography (MidiCAT; Synapse Research Institute, Maastricht, the Netherlands) at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
6. Gut microbiome composition measured using metagenomic sequencing of stool samples collected at baseline (day 0), post intervention (day 14) and optionally at 30 days post intervention (day 44)

Previous primary outcome measures:
Measured at baseline and after 2 weeks of the dietary intervention:
1. Circulating inflammation-related human protein biomarkers measured using enzyme-linked immunosorbent assay (ELISA) or comparable techniques at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
2. The capacity of the circulating immune cells to produce inflammatory cytokines in ex vivo whole blood stimulation to different stimuli, measured using ELISA on the culture supernatant at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
3. Blood transcriptome measured using RNAseq technology with NovaSeq™ Sequencing System at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
4. Plasma metabolome assessed using high-throughput mass spectrometry (untargeted metabolomics) at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
5. Plasma lipids (lipidome) measured using mass spectrometry analysis (LC-MS) at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)
6. Coagulation parameters (thrombin and plasmin generation) measured using modified calibrated automated thrombography (MidiCAT; Synapse Research Institute, Maastricht, the Netherlands) at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)

Key secondary outcome(s)
Current secondary outcome measure as of 29/03/2021:
Plasma lipids (lipidome) measured using mass spectrometry analysis (LC-MS) at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44)

Previous secondary outcome measure:
Gut microbiome composition measured using metagenomic sequencing of stool samples collected at baseline (day 0), post intervention (day 14) and 30 days post intervention (day 44).

Completion date
09/08/2021

Eligibility

Key inclusion criteria
1. Tanzanian healthy male individuals aged 20-40 years and BMI 18-25 kg/m²
2. Living either in rural or in urban areas in the Moshi district for more than a month before participation and consuming either a traditional Tanzanian or a western-type diet
3. Use alcohol, either local brew 'Mbege' or commercially available beer
4. Can stay in the study area throughout the intervention period

Justification: Age, gender, and BMI are known to influence immune responses including inflammation, and they also affect the composition of gut microbiota. Elderly individuals have declined immune function, a phenomenon referred to as immunosenescence, while higher BMI is associated with increased inflammation. On the other hand, females have varying hormonal levels linked to the menstrual cycle and the use of contraceptives. The choice of age categories, BMI range, and sex are done to limit the well know confounding effects of these factors on inflammation and on gut microbiota composition among individuals.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
40 Years

Sex
Male

Total final enrolment
76

Key exclusion criteria
1. HIV seropositive
2. Malaria seropositive - updated 29/03/2021: positive malaria rapid diagnostic test
3. Blood pressure outside the defined range (≤60 mmHg diastolic or ≥140 mmHg systolic)
4. Fasting blood sugar (>6.0 mmol/l)
5. BMI outside the defined range (18-25 kg/m²)
6. Food allergies
7. Acute (febrile) illness in the previous month
8. Use of any medication as well as the use of antibiotics in the past three months or vaccination
9. hospital admission in the past year
10. A known chronic condition such as active malignancy, liver or kidney disease, tuberculosis infection, chronic hepatitis B or C infection
11. History of hypertension, diabetes, cardiovascular diseases
12. Failure to consent

13. Female sex
14. None alcohol users or reported alcoholism
15. Participation in another clinical trial at the same time or within the last 30 days

Date of first enrolment
12/04/2021

Date of final enrolment
05/07/2021

Locations

Countries of recruitment
Tanzania

Study participating centre
Kilimanjaro Clinical Research Institute (KCRI)
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Sponsor information

Organisation
Radboud University Nijmegen Medical Centre

ROR
https://ror.org/05wg1m734

Organisation
Kilimanjaro Clinical Research Institute (KCRI)

Funder(s)

Funder type
Research organisation

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
Sequence data will be deposited at the European Genome–phenome Archive, which is hosted by the EBI and the CRG, and the accession number will be made available after publication. Metabolomics data will be deposited to the EMBL-EBI MetaboLights database the study identifier will be available after publication. Other datasets such as metadata circulating inflammatory proteins and ex vivo cytokines will be stored in the Data Archiving and Networked Services (DANS) repository (https://dans.knaw.nl).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/04/2025	04/04/2025	Yes	No
Protocol file		01/05/2020	10/10/2022	No	No