ISRCTN16542275 https://doi.org/10.1186/ISRCTN16542275

The effects of fruit before meals on regulating fullness and changing body measurements

Submission date
20/02/2024

Recruitment status
No longer recruiting

Registration date
28/02/2024

Overall study status
Completed

Last Edited
26/02/2024

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Overweight and obesity are impending major public health concerns. It is estimated that around 2.6 billion people were overweight or obese (body mass index [BMI] 25 kg/m² and over) in 2020, representing 38% of the world population. Currently, no definitive treatments are available and clinically recommended, even though overweight and obesity are the risk factors for multiple diseases. Here, the researchers aimed to conduct a study of the effects of fruit before meals and walking after meals in overweight and obese individuals.

Who can participate?
Healthy adults aged 20-29 years old with a BMI over 23 kg/m².

What does the study involve?
Participants are randomly allocated into four groups. The first group is a placebo group that does not receive any treatment. The second group consumed fruit before meals (breakfast, lunch and dinner) whilst the third group performed a 10-minute walk after meals. The fourth group is the combination of fruit before a meal and a 10-minute walk after a meal. Before the intervention, laboratory assistants took blood samples to measure fasting blood glucose levels and DPP4 enzyme activity.

What are the possible benefits and risks of participating?
All participants received free diet education and BMI, waist circumference, fasting blood glucose, and DPP4 enzyme activity measurements. The possible risks were allergy to fresh fruits and stomach and foot muscle cramps during walking after meals.

Where is the study run from?
Universitas Sebelas Maret (Indonesia)

When is the study starting, and how long is it expected to run for?
April 2020 to November 2021

Who is funding the study?
Ministry of Education, Culture, Research, and Technology (Indonesia)

Who is the main contact?
Dono Indarto, MD PhD, dono@staff.uns.ac.id

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Dono Indarto

ORCID ID
https://orcid.org/0000-0001-7420-5816

Contact details
Biomedical Laboratory
Faculty of Medicine
Universitas Sebelas Maret
Jl. Ir. Sutami 36A Kentingan
Jebres
Surakarta
Indonesia
57126
+62 (0)85601579139
dono@staff.uns.ac.id

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
01/02/05/65/ID.33720112P211142020020600002

Study information

Scientific Title
Fruit before meals preserves satiety and affects anthropometric measurements in overweight and obese individuals: a randomized controlled trial of fruits before meals and physical exercise after meals

Acronym
FBM

Study objectives

Fruit meal sequence with or without combination of postprandial exercise (PE) preserve satiety and reduce anthropometric measurements in the overweight and obese individuals.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 08/04/2020, Research Ethical Committee, Faculty of Medicine, Universitas Sebelas Maret (Jl. Ir. Sutami 36A Kentingan, Jebres, Surakarta, 57126, Indonesia; +62 (0)271664178; kepk@fk.uns.ac.id), ref: 042/UN27.06.6.1/KEPK/EC/2020

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obese and overweight

Interventions
Participants were randomly allocated into four groups using folded paper. The first group is a placebo group that does not receive any treatment. The second group consumed fruit before meals (breakfast, lunch and dinner) whilst the third group performed a 10-minute walk after meals. The fourth group is the combination of fruit before a meal and a 10-minute walk after a meal.

A total of 500 g of mixed fruits per day were consumed by participants in groups two and four which consisted of orange, banana, fuji apple (Cripps Pink), green apple (Granny Smith), snakefruit, papaya, pear, apple guava, water guava, and dragon fruit.

The duration of the intervention was 30 days.

Intervention Type
Mixed

Primary outcome(s)
1. Nutritional intake: The daily food intake of all selected participants was assessed using the 24-hour food recall questionnaire on days 0, 15, and 30 and converted into daily intake values of nutrients using the free NutriSurvey software (https://www.nutrisurvey.de), translated into Indonesian.
2. Anthropometric measurements: body weight (kg) was measured after the participants emptied the bladder and was done without shoes. Height (cm) was measured using a stadiometer to calculate the distance between the top of the head (vertex) and the bottom of the foot. Body mass index (BMI) was calculated by dividing the weight in kilograms by the square of the height in meters with the cut-off points from the World Health Organization (WHO) classification for the Asian population. The anthropometric measurements were assessed on

days 0, 15, and 30.
3. Waist circumference: Participants stood up straight and breathed normally. The waist circumference of all selected participants was measured midway between the top of the hip bone and the bottom rib bone using a metline on days 0, 15, and 30.
4. Fasting blood glucose levels: All selected participants were fasting for 8 hours before taking venous blood samples in the morning on days 0, 15, and 30. Labelled blood samples were collected into coagulant tubes and then sent to the clinical laboratory to measure fasting blood glucose levels using a routine hexokinase method.
5. Food satiety (fullness) indexes: food satiety indexes were measured using Satiety Labelled Intensity Magnitude (SLIM). The SLIM was a 100-mm bidirectional hunger-fullness scale for assessing food satiety in individuals after a meal. The measurement was performed 30, 60, 90, 120, and 150 minutes after meals on days 0 and 30.

Key secondary outcome(s))
Dipeptidyl peptidase (DPP4) activity assay: Serum blood samples were diluted with phosphate-buffered (PBS) pH 7.4. A DPP4 substrate, H-Gly-Prop-nitroanilide (Sigma-Aldrich, St. Louis, MO, USA) was dissolved with the PBS to achieve a 2 mM final concentration. Blood samples were mixed and homogenized with the substrate working solution in a 1:1 ratio. The DPP4 activity was read using a spectrophotometer at λ = 405 nm at 25°C every 10 min for 60 min. The Beer-Lambert formula was used to calculate the DPP4 activity.

Completion date
24/11/2021

Eligibility

Key inclusion criteria
1. Aged 20-29 years
2. Body mass index (BMI) >23 kg/cm2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 years

Upper age limit
29 years

Sex
All

Total final enrolment
45

Key exclusion criteria
Individuals with chronic diseases such as heart, renal, and hepatic diseases

Date of first enrolment
01/12/2020

Date of final enrolment
10/02/2021

Locations

Countries of recruitment
Indonesia

Study participating centre
Physiology Laboratory
Level 2 Building C Faculty of Medicine, universitas Sebelas Maret
Jl. Ir. Sutami 36A Kentingan, Jebres
Surakarta
Indonesia
57126

Sponsor information

Organisation
Sebelas Maret University

ROR
https://ror.org/021hq5q33

Funder(s)

Funder type
Government

Funder Name
Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi

Alternative Name(s)
Ministry of Education, Culture, Research, and Technology, Ministry of Education, Culture, Research, and Technology, Republic of Indonesia, Kemdikbudristek, Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi, Republik Indonesia, Indonesia Ministry of Education, Culture,

Research, and Technology, Indonesian Ministry of Education, Culture, Research, and Technology, Kementerian Pendidikan, Kebudayaan, Riset, dan Teknologi, MECRT, Kemdikbudristek

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dono Indarto, MD PhD, dono@staff.uns.ac.id.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes