ISRCTN13920339 https://doi.org/10.1186/ISRCTN13920339

The effect of breakfast fruit meal sequence and physical exercise on glucose level and DPP4 activity among patients with diabetes

Submission date
05/05/2022

Recruitment status
No longer recruiting

Registration date
13/05/2022

Overall study status
Completed

Last Edited
20/12/2022

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) remains a major public health concern of which the management includes lifestyle modification and pharmacotherapy. Lifestyle modification can be done by increasing fiber intake from fruits and vegetables and physical exercise. The aim of this study was to compare the short term effects of breakfast fruits meal sequence and postprandial exercise on blood glucose level and DPP4 activity among type 2 diabetes mellitus patients

Who can participate?
Patients aged 45–65 years old with type 2 diabetes

What does the study involve?
Participants were randomly allocated to four groups that consumed the breakfast for 7 days. Groups differed on the amount of exercise they were required to do each day after breakfast. To provide an adequate macro and micro-nutrient intake, the daily food composition was based on the Indonesian diabetes diet and contained 55% carbohydrates (mixed brown and white rice), 25% protein and 20% fat from tofu, egg, meat and mixed vegetables.

What are the possible benefits and risks of participating?
The benefits to participants include:
1. Free blood tests
2. Free whole fruits
3. Knowing their daily energy and nutrition intake
4. Knowing their nutrition status and pancreas function
5. Reduced FBG level
6. Decreased DPP4 activity
The risks include:
1. Mild or moderate pain when giving blood samples
2. Food allergy
3. Discomfort in the stomach

Where is the study run from?
This study was performed at two primary health clinics in Tasikmadu District, Karanganyar Regency and Kartasura District, Sukoharjo Regency, Central Java, Indonesia.

When is the study starting and how long is it expected to run for?
April 2017 to November 2017

Who is funding the study?
Institute of Research and Community Services, Universitas Sebelas Maret, Surakarta (Indonesia)

Who is the main contact?
1. Dono Indarto, dono@staff.uns.ac.id
2. Dwipajati, dwipajati@poltekkes-malang.ac.id

Contact information

Additional identifiers

Study information

Scientific Title
Acute effects of breakfast fruits meal sequence and postprandial exercise on blood glucose level and DPP4 activity among type 2 diabetes mellitus patients: a pilot study

Acronym
Nil known

Study objectives
Different fruit meal sequence with or without combination of postprandial exercise (PE) has different effetcs on blood glucose levels and DPP4 activity in Indonesian patients with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2017, Research Ethical Committee, Faculty of Medicine, Universitas Sebelas Maret (Public Hospital Dr. Moewardi, No. 132, Jebres, Surakarta 57126, Indonesia; +62 8121500630; wdatmo@gmail.com), ref: 502/VI/HREC/2017

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Type 2 diabetes mellitus

Interventions
Initially, we distributed our research plan to all Health Clinics for Management Program of Chronic Diseases in Surakarta and nearby cities. However, only two Health Clinics at Taksikmadu District, Karanganyar Regency and Kartasura District, Sukoharjo Regency respectively participated in this study. To calculate the sample size in this study, we used a numerical analytics formula (Dahlan, 2010) and used the existing study from Trico et al. (2016) which provided the mean differences in blood glucose levels between control and treatment groups.

Patients were randomly divided into four groups using sealed envelopes.
The first (control) group consisted of 10 patients who usually ate their meals, based on the Indonesian diabetes diet.
The treatment (T1-3) groups consisted of 9 patients/group who consumed 50g banana before having their breakfast (T1), consumed 50g banana after having their breakfast and followed by performing 2 min jumping jacks (T2) and consumed 50g banana before having their breakfast and followed by performing 2 min jumping jacks (T3) in the day 1 and 7 interventions in front of investigators.
The food composition of each meal during a 7 day-intervention was equally restricted to a specific food composition on day 1 and day 7 interventions of breakfast and closely monitored by the investigators every day. In addition, research participants could consume other fruits with a similar composition to bananas from day 2 to day 6 intervention. The daily food proportion in this study is based on the Indonesian diabetes diet, contained 55% carbohydrates (mixed brown and white rice), 25% protein and 20% fat from tofu, egg, meat and mixed vegetables. The source of fresh fruits (papaya and orange) was based on their availability in the local market and they were consumed with a similar amount to bananas. The amount of vegetable consumption was based on the American Diabetes Recommendation.

Intervention Type
Behavioural

Primary outcome(s)
Measured on days 1 and 7:
1. Fasting blood glucose level was measured using the hexokinase method
2. One hour postprandial blood glucose level was measured using the same method
3. Fasting DPP4 activity was determined using a colorimetric assay with a synthetic Gly-Pro-p nitroanilide substrate
4. One hour postprandial DPP4 activity was determined using the same assay with a synthetic Gly-Pro-p nitroanilide substrate

Key secondary outcome(s)
1. Basic characteristics including age, gender, marital status, education, job, food allergy, duration of type 2 diabetes illness, and type of oral antidiabetic drugs. These data were collected using open questionnaires consisting of short questions and performed one week before the research commenced.
2. Nutritional Intake (macro- and micronutrients) was collected using a 24-hour food recall questionnaire on days 1 and 7 and converted into daily intake values of macro- and micronutrients using the free nutrisurvey software (https://www.nutrisurvey.de), which has been translated into the Indonesian language

Completion date

14/11/2017

Eligibility

Key inclusion criteria
1. Diagnosed with T2DM
2. Aged 45–65 years old
3. Able to ingest fresh fruits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Taking DPP4 inhibitors (sitagliptin, vildagliptin, and similar drugs)
2. Patients with comorbidities such as heart, renal, and hepatic diseases

Date of first enrolment
23/07/2017

Date of final enrolment
01/10/2017

Locations

Countries of recruitment
Indonesia

Study participating centre
Health Clinics Griya Husada 2
Suruh Kalong RT 01/RW 07
Pandeyan
Tasikmadu District
Karanganyar Regency
Indonesia
57722

Study participating centre
Health Clinics Amal Sehat
Wirorejan RT 02/RW 07
Ngadirejo
Kartasura District
Sukoharjo Regency
Indonesia
57163

Sponsor information

Organisation
Sebelas Maret University

ROR
https://ror.org/021hq5q33

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Culture, Research, and Technology (Kementrian Pendidikan, Kebudayaan, Riset dan Teknologi (Kemendikbudristek), Republik Indonesia

Results and Publications

Individual participant data (IPD) sharing plan
Patient data are kept confidential. Therefore, data requests need to be sent to Dono Indarto (dono@staff.uns.ac.id) and the Research Ethical Committee, Faculty of Medicine, Universitas Sebelas Maret/Public Hospital Dr Moewardi, Surakarta.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/09/2022	20/12/2022	Yes	No