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Comparative effects of consuming various whole fruits before meals on fasting blood glucose and insulin levels among patients with type 2 diabetes mellitus in Indonesia

Submission date
30/12/2021

Recruitment status
No longer recruiting

Registration date
20/01/2022

Overall study status
Completed

Last Edited
18/01/2022

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
Type 2 diabetes is a common condition that causes the level of sugar (glucose) in the blood to become too high. The majority of patients with type 2 diabetes have low fibre intake especially from whole fruits. Previous studies have indicated that consumption of 50 g of Ambon banana before having breakfast reduces fasting blood glucose (FBG) in patients with type 2 diabetes and waist circumference in overweight adults. The aim of this study is to analyze the effects of eating whole fruits with low, medium and high glycemic indexes before meals on FBG and insulin levels in patients with type 2 diabetes.

Who can participate?
Patients aged 30–75 years old with type 2 diabetes

What does the study involve?
The participants are randomly divided into four groups. The first (control) group receive education on diabetes and diet on the first day of intervention and the day after 7 days wash out. The treatment (T) groups consisted of the T1, T2 and T3 groups. The T1 group receive the same diet education on the first day of the intervention and consume 250 g/day whole fruits with a low glycaemic index (Ambon banana, red apple, Asia pear, Malang orange or khalas date) after having breakfast, lunch and dinner with steamed rice, animal meats and or plant proteins, and mixed vegetables for 7 days. The T2 and T3 groups receive the same as the T1 group but the T2 group consume 250 g/day whole fruits with a moderate glycaemic index (California papaya, golek mango, honey pineapple, lady's finger banana or longan) and the patients in the T3 group consume 250 g/day whole fruits with a high glycaemic index (ripe Ambon banana, red watermelon, melon or sapodilla). After that, all patients in the T1-3 groups go back to their normal eating habits for the next 7 days and the following day they begin to consume 250g/day whole fruits with a low, moderate or high glycaemic index before having breakfast, lunch and dinner with steamed rice, animal meats and or plant proteins, and mixed vegetables for 7 days.

What are the possible benefits and risks of participating?
The benefits to participants include:
1. Free tests
2. Free whole fruits
3. Knowing their daily energy and nutrition intake
4. Knowing their nutrition status and pancreas function
5. Reduced FBG
6. Increased insulin levels
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?
The four Health Clinics for the Management Program of Chronic Diseases (MTA, Mitra Sehat, Dr. Nurfanda and Persadia) in Surakarta city, Central Java Province (Indonesia)

When is the study starting and how long is it expected to run for?
October 2018 to March 2019

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

Who is the main contact?
1. Dono Indarto, dono@staff.uns.ac.id
2. Nuraini Fitri

Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Low-, medium and high glycaemic index fruits meal sequence randomized controlled trial among type 2 diabetes mellitus (T2DM) in Indonesia

Study objectives
1. Meal sequence modification leads to improvement of the patients' diabetic profile
2. Meal sequence modification by fruits with different glycemic indexes results in different diabetic responses

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/10/2018, Health Research Ethics Committee, Faculty of Medicine, Universitas Sebelas Maret (2nd Floor, Gedung Pendidikan Dokter, Jl. Ir. Sutami 36A, Kentingan, Surakarta 57126, Central Java, Indonesia; +62 (0)271 664178 ext. 125; kepk@fk.uns.ac.id), ref: 316/UN27.6 /KEPK/2018

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

Interventions
The researchers randomly chose four from 12 Health Clinics for Management Program of Chronic Diseases in Surakarta city, Central Java province which had sufficient patients with type 2 diabetes. To recruit the diabetes patients, they used a formula from Dahlan (2010) and the results of a previous study performed by Trico et al. (2016) to obtain 9 patients/group and added 30% patients/group to avoid loss of follow up. The patients were randomly divided into four groups.

The first (control) group consisted of 12 patients who received education on diabetes and diet on the first day of intervention and the day after 7 days wash out. The treatment (T) groups consisted of the T1, T2 and T3 groups, which had 12, 12 and 11 patients with type 2 diabetes, respectively. The T1 group received the same diet education on the first day of the intervention and consumed 250 g/day whole fruits with low glycaemic index (Ambon banana, red apple, Asia pear, Malang orange or khalas date) after having breakfast, lunch and dinner with steamed rice, animal meats and or plant proteins, and mixed vegetables for 7 days. The T2 and T3 groups received the same as the T1 group did but the patients in the T2 group consumed 250 g/day whole fruits with moderate glycaemic index (California papaya, golek mango, honey pineapple, lady's finger banana or longan) and the patients in the T3 group consumed 250 g/day whole

fruits with high glycaemic index (ripe Ambon banana, red watermelon, melon or sapodilla). After that, all patients in the T1-3 groups were back to their eating habits for the next 7 days and the following day they began to consume 250g/day whole fruits with a low, moderate or high glycaemic index before having breakfast, lunch and dinner with steamed rice, animal meats and or plant proteins, and mixed vegetables for 7 days.

Intervention Type
Behavioural

Primary outcome(s)
1. Fasting blood glucose (FBG) levels measured using the enzymatic method (glucose oxidase – peroxidase aminoantypirin) at 1, 7, 14 and 21 days
2. Insulin levels measured using an enzyme-linked immunosorbent assay (ELISA) kit at 1, 7, 14 and 21 days
3. HOMA-β ratio calculated using the FBG and insulin levels with the formula: (HOMA-β = 20 X insulin level) / (FBG level – 3.5) at 1, 7, 14 and 21 days.
4. Acetic acid levels determined using gas chromatography-mass spectrometry at 14 and 21 days

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, collected using open questionnaires consisting of short questions 1 week before the research commenced.
2. Physical activity collected using a global physical activity questionnaire from the World Health Organization (2016), which asked how long the patients performed vigorous or moderate physical activity during active and recreational times, what kind of transportation the patients went to their work or a specific place, and how long the patients performed mild physical activities/day such as sitting, lying and watching television, 1 week before the research commenced.
2. Daily food intake collected using a 24-hour food recall questionnaire at 1, 7, 14 and 21 days and converted into daily intake values of macro- and micronutrients using the free nutrisurvey software (https://www.nutrisurvey.de), which has been translated into Indonesian
3. Anthropometric data such as body weight, height and waist circumference measured using a scale and a tape measure at 1, 7, 14 and 21 days
4. Nutrition status presented as body mass index with the formula: body weight (kg)/ height^2 (m^2), based on the Indonesian Ministry of Health (2013), at 1, 7, 14 and 21 days
5. Waist circumference/height ratio in cm determined at 1, 7, 14 and 21 days
6. DPP4 enzyme activity determined using a colorimetric assay with a synthetic Gly-Pro-p nitroanilide substrate at 1, 7, 14 and 21 days
7. HOMA-IR ratio calculated using the FBG and insulin levels with the formula: (HOMA-IR = FBG X insulin levels) / 22.5 at 1, 7, 14 and 21 days

Completion date
20/03/2019

Eligibility

Key inclusion criteria
1. Aged 30–75 years old
2. Routinely treated by anti-diabetic drugs except for DPP4 inhibitor
3. Able to ingest fresh fruits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
47

Key exclusion criteria
1. Pregnant
2. Smoking
3. Chronic disease (e.g. heart, kidney, liver disease)
4. Insulin and DPP4 inhibitor therapy
5. Not routinely visiting the clinics

Date of first enrolment
01/11/2018

Date of final enrolment
15/12/2018

Locations

Countries of recruitment
Indonesia

Study participating centre
Klinik Pratama MTA
Semanggi, Pasar Kliwon
Surakarta
Indonesia
57191

Study participating centre
Klinik Mitra Sehat
Jl. Brigjend Katamso No.121B, Mojosongo
Surakarta
Indonesia
57127

Study participating centre
Klinik Dr. Nurfanda
Wirocanan RT 02 RW 04, Kertonatan, Kartasura
Sukoharjo
Indonesia
57166

Study participating centre
Persadia Cabang Surakarta
Jalan Kolonel Sutarto No. 132, Jebres
Surakarta
Indonesia
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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