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Impact of date-based nutritional bar intake on metabolic health

Submission date	Recruitment status
08/04/2024	No longer recruiting
Registration date	**Overall study status**
15/04/2024	Completed
Last Edited	**Condition category**
19/06/2024	Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Most available nutritional energy bars in the food markets comprise dried fruit mixes as the main carbohydrate source. Date palm fruits provide superior nutritional and health benefits, compared to other fruits. They are rich sources of many essential nutrients including carbohydrates, dietary fiber, vitamins, minerals, phytochemicals, and antioxidants. The date palm fruits are produced in many countries around the world and about 10-15% of the total production is lost or sold at extremely low prices. Despite this, date fruits have been rarely used as an ingredient in commercially available energy bars or supplements. This study aims to investigate the impact of a newly formulated date-based energy bar (DBNB) on appetite, postprandial metabolism, antioxidant levels, and thermic effect of feeding, and compare to weight and macronutrient-matched mixed fruits-based bar (FBNB), as a control arm. Participants will be asked to conduct two experimental trials in random order in which they are asked to consume a DBNB in one day and an FBNB on the other day.

Who can participate?
Healthy adult volunteers aged 18 – 45 years old

What does the study involve?
Each potential participant will undergo a health screening check, measuring their body weight and height. Participants will be randomly assigned to conduct two experimental trials, consuming a DBNB in one day and a FBNB in the other day and separated for 5 to 7 days in between. On the trial day, a nurse specialist will insert a venous cannula and a 6-ml fasting blood sample will be collected along with a measurement of metabolic rate and subjective appetite ratings. Following this, and according to the assigned trial type, participants will be asked to consume a-140 g (containing about 510 kcal) of either DBNB or FBNB. After ingesting the trial bars, metabolic rate will be measured and subjective appetite ratings and blood samples will be collected at 30, 60, 90, 120, and 180 minutes. During the experimental trials, food intake will be prohibited, but water will still be provided at any time the participant asks for it.

What are the possible benefits and risks of participating?
The results of this study will help to understand if the DBNB provide more or the same health benefits as the widely available FBNB. This includes revealing their impact on appetite,

postprandial responses of glucose, triglycerides, insulin, antioxidants, and energy expenditure. All participants will receive a detailed report about their general health status including body weight, blood glucose and triglyceride levels and current energy needs. The participants will also get dietary and physical activity advice according to their current body weight status. There are no major risks involved in this study. Cannulation and blood sampling will be done by professional nursing staff from the University Medical City, and other research activities will be run by experienced research staff. Therefore, the risks associated with the procedures involved in this study are extremely small. However, all participants will have the right to withdraw from the study at any time point.

Where is the study run from?
Qassim University, Saudi Arabia

When is the study starting and how long is it expected to run for?
January 2023 to May 2024

Who is funding the study?
Deputyship for Research and Innovation, Ministry of Education, Saudi Arabia (project number: QU-IF-1-1-3)

Who is the main contact:
Dr. Hani A. Alfheeaid, h.alfheeaid@qu.edu.sa

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
23-24-15

Study information

Scientific Title
Health effects of consuming formulated date-based nutritional bar in comparison to mixed fruit nutritional bar

Study objectives
Although the energy and macronutrient composition of the formulated Date-Based Nutritional Bar (DBNB) and Mixed Fruit Nutritional Bar (FBNB) are identical, the types of sugars, fiber and micronutrients they contain are different. Thus, the health effects (including postprandial glucose, triglycerides and insulin responses, and energy substrate oxidation) of DBNB consumption could be different from the FBNB.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 09/02/2023, Committee of Research Ethics, Deanship of Scientific Research at Qassim University (Deanship of Scientific Research, Qassim University, Buraidah, 51452, Saudi Arabia; +966163010355; bioethics@qu.edu.sa), ref: 23-24-15

2. Approved 25/01/2024, Committee of Research Ethics, Deanship of Scientific Research at Qassim University (Deanship of Scientific Research, Qassim University, Buraidah, 51452, Saudi Arabia; 00966163010355; bioethics@qu.edu.sa), ref: 24-74-04

Primary study design
Interventional

Study design
Single-blind cross-over randomized controlled trial with a single-centre

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Health (effects on metabolic health)

Interventions
Thirty (30) healthy male adults will be recruited to participate in a single-blind cross-over randomized controlled trial (single-centre). Participants will be asked to conduct two experimental trials in which they will have to consume a date-based nutritional bar (DBNB) in one day and a mixed fruit-based nutritional bar (FBNB) in the other day, separated by 5 to 7 days in between for washout. The participants will be randomly assigned to start either trial (each lasting for 3.5 hours in total) using an online randomization tool. Both trial bars (DBNB and FBNB) are matched for weight and macronutrient composition, containing about 510 kcal in total for each. All measurements and blood sampling are performed in the fasted state and repeated at 30, 60, 90, 120 and 180 minutes after ingestion of the date-based (DBNB) or the mixed fruit-based nutritional bar (FBNB).

Intervention Type
Supplement

Primary outcome(s)

Postprandial serum glucose, insulin and triglyceride responses are evaluated in the fasted state and at 30, 60, 90, 120 and 180 minutes after ingestion of date-based or mixed fruit-based nutritional bars. The serum glucose and triglyceride concentrations are assessed using colorimetric reagents, while serum insulin concentrations are assessed using enzyme-linked immunosorbent assay (ELISA) kits.

Key secondary outcome(s)
1. Thermic effect of feeding and energy substrate oxidation (carbohydrate and fat oxidation rates) are measured using canopy hood indirect calorimetry (Quark RMR, COSMED) in the fasted state and at 30, 60, 90, 120 and 180 minutes after ingestion of date-based or mixed fruit-based nutritional bar.
2. Antioxidative activity is determined using plasma concentrations of total phenolic content, total antioxidative capacity, malondialdehyde and superoxide dismutase in the fasted state and at 60, 120 and 180 minutes after ingestion of date-based or mixed fruit-based nutritional bar. The plasma concentrations of total phenolic content are assessed using colorimetric reagents, while plasma concentrations of total antioxidative capacity, malondialdehyde and superoxide dismutase are assessed using enzyme-linked immunosorbent assay (ELISA) kits.
3. Appetite is measured subjectively using visual analogue scale (VAS) questionnaires in the fasted state and at 30, 60, 90, 120 and 180 minutes after ingestion of date-based or mixed fruit-based nutritional bars

Completion date
30/05/2024

Eligibility

Key inclusion criteria
1. Healthy male adults
2. Normal body weight with body mass index (BMI)= 18 to ≤ 25 kg m-2
3. Body weight stable for previous 4 months

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Male

Total final enrolment

27

Key exclusion criteria
1. History of eating disorder
2. History of gastrointestinal problems or surgery
3. History of allergy
4. History of chronic illness
5. On any medication
6. Smoking
7. On nutritional supplements
8. Following specific diet
9. Currently taking part in other research
10. Being overweight (> 25 BMI kg/m2) or underweight (BMI < 18 kg/m2)

Date of first enrolment
04/06/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
Nutrition and Metabolic Investigation Unit (NMIU) at Qassim University
College of Agriculture and Food, Building (A2), Ground Floor (Entrance #2243)
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Sponsor information

Organisation
Qassim University

ROR
https://ror.org/01wsfe280

Funder(s)

Funder type

Government

Funder Name
Deputyship for Research and Innovation (DRI) at the Ministry of Education (MOE)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during this study will be available upon request from Dr Hani Alfheeaid (Research PI), h.alfheeaid@qu.edu.sa.
The study is conducted in compliance with the Declaration of Helsinki and Ethical Guidelines. All participants will be asked to provide their written consent with the option to withdraw from participation at any point. Collected data will be anonymized and safely stored at Qasim University's internal research database.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/06/2024	19/06/2024	Yes	No