Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of honey plus Habbatus sauda (Nigella sativa) supplementation (Afiyah) on body composition, metabolic parameters and gut microbiome of healthy adults: A double-blind, randomized controlled trial

Protocol summary

Study aim

1. To measure the effects of AF on plasma glucose, HbA1c and insulin levels, lipid profile, liver and kidney functions, resting blood pressure, body weight, fat percentage and waist to hip ratio, lung volume, capacity and cognitive function 2. To observe the effect of AF on an oxidative stress marker (Malondialdehyde), antioxidative enzymes (Superoxide dismutase and catalase), pro-inflammatory cytokines (IL-6 and IL-1β)

Design

Randomized controlled study

Settings and conduct

A multiple centre, double-blind, placebo-controlled, randomised controlled trial will be conducted at several colleagues UiTM Selangor, Puncak Alam Campus During recruitment, all participants will receive advice regarding physical activity along with assessment of their level of PA. Participants are advised to conform to 150 mins of PA per week to standardized their level of PA.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Men and women. 2. 25 to 45 years old and available to participate in the study for 12 weeks. Exclusion criteria: 1. Co-morbidities - diabetes, pre-diabetes, hypertension, cardiovascular conditions. 2. Hypothyroidism. 3. Renal disease or malignancy or on thiazide diuretics, beta-blockers or corticosteroids. 4. Severe illness in the past three months. 5. Pregnant or breastfeeding in the past 12 months. 6. Mental health issues. 7. Smokers. 8. On other regular dietary oral supplements or medications containing antioxidants and caffeine.

Intervention groups

Treatment Group (AF) - Oral supplementation with AF gummy for 12 weeks.

Main outcome variables

plasma glucose, HbA1c and insulin levels, lipid profile, liver and kidney functions, resting blood pressure, body weight, fat percentage and waist to hip ratio cognitive function, oxidative stress marker, antioxidative enzymes, pro-inflammatory cytokines (IL-6 and IL-1β), lung volume and capacity

General information

Reason for update

to clarify that the investigational product tested is "Afiyah" which is a proprietary formulation of honey and habbatus sauda made into a gummy form

Acronym

AF (Afiyah)

IRCT registration information

IRCT registration number: **IRCT20220317054316N3**
Registration date: **2022-07-31, 1401/05/09**
Registration timing: **prospective**

Last update: **2022-08-27, 1401/06/05**
Update count: **1**

Registration date

2022-07-31, 1401/05/09

Registrant information

Name
ISA MOHAMAD-RODI
Name of organization / entity
Universiti Teknologi MARA
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01
Expected recruitment end date
2022-12-23, 1401/10/02
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of honey plus Habbatus sauda (Nigella sativa) supplementation (Afiyah) on body composition, metabolic parameters and gut microbiome of healthy adults: A double-blind, randomized controlled trial

Public title
The effect of "Afiyah" on body composition, metabolic parameters and gut microbiome of healthy adults: A double-blind, randomized controlled trial
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 25 to 45 years old available to participate in the study for 12 weeks.
Exclusion criteria:
Co-morbidities (known diabetes, pre-diabetes (impaired fasting glucose), hypertension, cardiovascular conditions (ischemic heart disease, peripheral arterial disease, abdominal aortic aneurysm, carotid artery disease, morbid obesity) Hypothyroidism Renal disease or malignancy or on thiazide diuretics, beta-blockers or corticosteroids. Prior hospital admission for severe illness in the past three months. Pregnant or breastfeeding in the past 12 months. Mental health issues. Smokers On other regular dietary oral supplements or medications containing antioxidants and caffeine.
Age
From **25 years** old to **45 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **35**
Treatment Group (AF) - Oral supplementation with AF gummy for 12 weeks. Control group - Oral supplementation with placebo gummy for 12 weeks
Randomization (investigator's opinion)
Randomized
Randomization description
The participants will be randomized into intervention and control groups using stratified permuted two by two blocks. The stratification will be on gender to obtain an equal number of gender in both groups. The third-party will assign the random allocation sequence to the participants. The concealment of allocation sequence will be conducted using random.org
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blinding will be applied in this study. The investigator, participants evaluators, monitors and data analysts will be blinded. Only the manufacturer (third party) will have information on the type of treatment received by participants (whether intervention and placebo). The third party will be providing the gummies (AF and placebo). The placebo gummies will be made to resemble the AF gummies in appearance and colour.
Placebo
Used
Assignment
Parallel
Other design features
no

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee, Universiti Teknologi MARA
Street address
Research Management Centre, Universiti Teknologi MARA
City
Shah Alam
Postal code
40450
Approval date
2022-07-27, 1401/05/05
Ethics committee reference number
REC/07/2022 (ST/CT/4)

Health conditions studied

1

Description of health condition studied
Healthy adult
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
To measure the effects of AF on plasma glucose, HbA1c and insulin levels, lipid profile, liver and kidney functions of healthy adults.

Timepoint
baseline, after 6-week, after 12-weeks
Method of measurement
blood

2

Description
To measure the effects of AF on resting blood pressure, body weight, fat percentage and waist to hip ratio in healthy adults
Timepoint
baseline, after 6-weeks, after 12- weeks
Method of measurement
anthropometric measurement

3

Description
To assess the effect of AF on cognitive function in healthy adults,
Timepoint
baseline, after 6-weeks, after 12-weeks
Method of measurement
mini mental state examination

4

Description
To observe the effect of AF on an oxidative stress marker (Malondialdehyde), antioxidative enzymes (Superoxide dismutase and catalase), as well as pro-inflammatory cytokines (IL-6 and IL-1β) in healthy adults.
Timepoint
baseline, after 12-weeks
Method of measurement
serum blood

5

Description
To measure the effects of AF on lung volume and capacity in healthy adults
Timepoint
baseline, after 6-weeks, after 12-weeks
Method of measurement
spirometry

6

Description
To observe the effect of AF on an oxidative enzymes in healthy adults
Timepoint
Baseline, 6-week and after 12-week
Method of measurement
serum blood

7

Description
To observe the effect of AF on diet (24 hours recall) in healthy adults
Timepoint
baseline, 6- week and after 12-week
Method of measurement
ButriPro assessment on 24 hour diet recall

8

Description
To observe the effect of AF on IL-6 and IL-1beta in healthy adults.
Timepoint
after 12-week
Method of measurement
serum blood

Secondary outcomes

1

Description
To profile the composition of the gut microbiome following a 12-week AF supplementation in healthy adults using 16s metagenomics sequencing.
Timepoint
after 12-weeks
Method of measurement
feces

2

Description
To identify key bacterial genera that can be potentially involved in mediating effect of AF on biochemistry and clinical parameter in healthy adults
Timepoint
after 12-week
Method of measurement
serum blood

Intervention groups

1

Description
Intervention group: The participants will be given oral supplementation with AF gummy 1 tablet (10mg) daily for 12 weeks. They will receive dietary advice from dietician on standard diet recall and to conform to 150 minutes of physical activity per week to standardize their physical activity level.
Category
Treatment - Other

2

Description
Control group: The participants will be given oral placebo gummy 1 tablet (10 mg) daily for 12 weeks. They will receive dietary advice from dietician on standard diet recall and to conform to 150 minutes of physical activity per week to standardize their physical activity level.
Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Health Sciences, Universiti Teknologi MARA

Full name of responsible person
Nabila Najwa Mohd Yusof

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Universiti Teknologi MARA

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Grant name
Industrial Grant - As Sunnah Global Ventures Sdn. Bhd. [1430503-U]

Grant code / Reference number
100-TNCPI/PRI 16/6/2 (014/2022)

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Universiti Teknologi MARA

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Universiti Teknologi MARA

Full name of responsible person
Nor Ashikin Bt Mohamed Noor Khan

Position
Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
"Affiyah" data will be kept for the use of research only
When the data will become available and for how long
data will be available when the data collection finish and will be kept for 7 years
To whom data/document is available
only for the group members of this research
Under which criteria data/document could be used
for research only
From where data/document is obtainable
from the Principal Investigator
What processes are involved for a request to access data/document
An official letter will be needed and the reason(s) for the request
Comments
No