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Effects of combined exercise with and without Nigella sativa on glycemic and lipidemic control, musculoskeletal functions and biomarkers in patients with type 2 diabetes

Submission date
11/09/2023

Recruitment status
No longer recruiting

Registration date
27/10/2023

Overall study status
Completed

Last Edited
27/10/2023

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
There is a high prevalence of multimorbidity (the presence of two or more long-term health conditions) in patients with type 2 diabetes mellitus (T2DM), which could lead to premature death, reduced quality of life, increased healthcare use, high burden of treatment, loss of physical functioning, increased mental health problems, polypharmacy (use of multiple medicines), and fragmentation of care. Therefore, the aim of this study is to examine the effects of Nigella sativa (NS) and combined exercise (CE) on body measurements, musculoskeletal functions, inflammatory and oxidative stress (OS) plus metabolic profile (blood sugar and lipids) of participants with T2DM.

Who can participate?
Men with T2DM aged 40 to 60 years

What does the study involve?
Participants are divided into three groups:
The EX group: different exercise workouts at least 3 days per week under supervision for 4 weeks.
The EX + NS group: different exercise workouts at least 3 days per week under supervision for 4 weeks accompanied plus NS intervention.
The CON group: patients in this group did not receive any intervention (neither EX nor NS).
NS was given orally twice a day in the morning and evening. Each dose contained two capsules (500 mg each capsule).
Body measurements, musculoskeletal functions, inflammatory and OS status and metabolic profile are measured at the start of the study and at the end of the 4-week interval.

What are the possible benefits and risks of participating?
The intervention used in this study presented several risks associated with physical activity. The rigid eligibility criteria helped to reduce the risks, but a few risks

secondary to peripheral neuropathy still had to be considered. The main risks related to physical activity are foot issues and events of low blood sugar. The risk of foot issues was mitigated by prioritizing non-impact exercises over weight-bearing exercises. Participants were instructed to undertake a thorough examination of their feet following every exercise session to avoid sores, and they also had to wear comfortable shoes. Meanwhile, the risk of low blood sugar was mitigated by measuring participants' glucose levels before and after the session. A carbohydrate snack was given to the participants if their glucose levels were lower than 100 mg/ dL, whereas the participants were asked to pause for 10 minutes if their sugar levels exceeded 200 mg/dL, and if the levels remained high after that interval, participants were scheduled for another session. The possible intervention-related risks were outlined in the information sheet and participants were encouraged to pose questions before deciding whether to be involved in the study or not.

Where is the study run from?
Imam Abdulrahman bin Faisal University and General of Health Affairs in Najran Region (Saudi Arabia)

When is the study starting and how long is it expected to run for?
January 2017 to September 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Hiedar Hussain Khursan Alyami, 2160700002@iau.edu.sa

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
IRB-PGS-21018-01-313

Study information

Scientific Title
Comparison of the effects of combined exercise with and without Nigella sativa on glycemic and lipidemic control, musculoskeletal functions and biomarkers (inflammatory and oxidative) in patients with type 2 diabetes mellitus: a randomized controlled trial

Study objectives
1. A significant difference in anthropometric and blood pressure measurements as a result of EX with and without nigella sativa (NS) will be found
2. A significant difference in musculoskeletal functions as a result of EX with and without NS will be found
3. A significant difference in oxidative agent as a result of EX with and without NS will be found
4. A significant difference in inflammatory mediator profile as a result of EX with and without NS will be found
5. A significant difference in metabolic profile as a result of EX with and without NS will be found

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/12/2018, Ethics committee of Immam Abdulrahman Bin Faisal University and General of Health Affairs in Najran Region (PO Box 1982, Dammam, 3144, Saudi Arabia; +966 (0) 133332412; irb@iau.edu.sa), ref: IRB-PGS-2018-01-313

Study design
Experimental interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Type 2 diabetes mellitus (T2DM)

Interventions
Patients were divided into three groups: exercise-only (EX) group, exercise with NS (EN) group, and control (CON) group. Each group before and after the interventions underwent anthropometric and hemodynamic measurements, blood tests to identify the glycaemic profile, metabolic profile, oxidative stress markers, inflammatory markers, and musculoskeletal function evaluation. After that, the patients were subject to treatment for 4 weeks.

The (EX) group: different exercise workouts at least 3 days per week under supervision for 4 weeks

The (EX + NS) group: different exercise workouts at least 3 days per week under supervision for 4 weeks accompanied plus NS intervention.

The (CON) group: patients in this group did not receive any intervention (neither EX nor NS).

NS was obtained from the physiology department of Imam Abdulrahman Bin Faisal University. NS was given orally twice a day in the morning and evening. Each dose contained two capsules (500 mg each capsule).

Intervention Type
Mixed

Primary outcome(s)
Measured before the intervention and 4 weeks after the intervention:
1. Anthropometric measurements including weight in kilograms (kg) and height in centimetres (cm) measured using a Digital Physician Scale (MDW-250L, Adam Equipment Co. Ltd., UK)
2. Metabolic profile (glycaemic and lipidemic profiles): FBG and lipid profile assays (cholesterol, triglyceride, LDL, HDL) carried out on chemistry analyzer DxC 700 AU (Beckman Coulter US, Inc., USA) by colorimetric techniques
3. Systolic blood pressure and diastolic blood pressure measured using GE Healthcare CARESCAPE Vital Signs V100 monitors
4. Oxidative stress markers measured using the Thiobarbituric Acid Reactive Substances (TBARS) test and the Catalase Activity (CAT) test
5. Inflammatory markers measured using the Human Tissue Necrotic Factor - α (TNF-α) test, the Human Interleukin 4 (IL-4) test and the Human Adiponectin (ADP) test

Key secondary outcome(s))
Measured before the intervention and 4 weeks after the intervention:
1. Endurance and functional exercise capacity measured using the 6-minute walk test (6MWT)
2. Functional mobility measured using the timed up-and-go test (TUGT)
3. Grip strength measured using a calibrated Jamar dynamometer
4. Functional strength of the lower body was evaluated by the sit-to-stand test (STS)

Completion date
01/09/2020

Eligibility

Key inclusion criteria
1. Male sex
2. Age range 40 to 60 years
3. Non-active or sedentary lifestyle
4. Non-smoker
5. ADA-based T2DM that has been diagnosed for more than 2 years
6. Without medication modifications during the past 6 months
7. 6.5-9% baseline HbA1c
8. Ready for participation in a monitored exercise programme
9. BMI >30 kg/m²
10. Taking only oral hypoglycaemic medications
11. Free of any serious complications

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
60 years

Sex
Male

Total final enrolment
90

Key exclusion criteria
1. Foot deformities
2. Heart or lung conditions
3. Uncontrolled blood pressure
4. Current ulcers
5. Additional neuropathic complications

Date of first enrolment
01/10/2019

Date of final enrolment
01/12/2019

Locations

Countries of recruitment
Saudi Arabia

Study participating centre
King Khalid Hospital
Najran
Saudi Arabia
66241

Sponsor information

Organisation
Imam Abdulrahman Bin Faisal University

ROR
https://ror.org/038cy8j79

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The dataset generated during and analysed during the current study will be available upon request from Hiedar Hussain Khursan Alyami (hiedaralyami@gmail.com)

IPD sharing plan summary
Available on request