

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

<b>Submission date</b> 11/09/2023	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 27/10/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 27/10/2023	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

### Contact name

Dr Hiedar Alyami

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## Additional identifiers

### EudraCT/CTIS number

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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**

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**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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Community, Home

**Study type(s)**

Efficacy

**Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

## **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 measure**

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 -  $\alpha$  (TNF- $\alpha$ ) test, the Human Interleukin 4 (IL-4) test and the Human Adiponectin (ADP) test

## **Secondary outcome measures**

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)

## **Overall study start date**

01/01/2017

**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/m<sup>2</sup>
10. Taking only oral hypoglycaemic medications
11. Free of any serious complications

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

40 Years

**Upper age limit**

60 Years

**Sex**

Male

**Target number of participants**

90

**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

### Sponsor details

Najran

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### Sponsor type

University/education

### Website

<https://www.iau.edu.sa/en>

### ROR

<https://ror.org/038cy8j79>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

# Results and Publications

## **Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

## **Intention to publish date**

01/12/2023

## **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