

Effects of supervised structured aerobic exercise training (SSAET) on patients with type 2 diabetes mellitus compared with routine medical management

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| Submission date 13/04/2015 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 12/12/2016 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 24/01/2019 | Condition category Nutritional, Metabolic, Endocrine | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Diabetes is a condition that causes a person's blood sugar level to become too high. Insulin is the hormone made by beta-cells in the pancreas and controls the amount of glucose in the blood. In type 2 diabetes, the body does not produce enough insulin for it to work properly or the body cells do not react properly to insulin (insulin resistance). People are more likely to develop diabetes if they are overweight, do not exercise, eat an unhealthy diet or are of an older age. People with type 2 diabetes are usually treated by oral medication, insulin therapy and lifestyle interventions, such as doing more exercise and eating healthily. Unfortunately, over time many patients will develop insulin resistance and stop responding to oral medicine or insulin therapy. There is a lot of evidence which supports the importance and effectiveness of exercise and physical activity in patients with type 2 diabetes. Exercise helps to stabilise blood glucose levels, maintain a healthy weight and reduce insulin resistance in patients. However, there is no 'gold standard' exercise plan for patients with type 2 diabetes. This is because there is not enough evidence to determine the best type, intensity, duration or frequency of exercise for patients. The aim of this study is to see what effect a structured, long-term exercise plan has on patients with type 2 diabetes.

Who can participate?

Patients aged 30-70 with type 2 diabetes

What does the study involve?

Participants are randomly allocated into one of two groups. One group receives routine medication and a diet plan. The other group receives routine medication, a diet plan, and participates in 25 weeks of supervised and structured aerobic exercise (treadmill exercise). Both groups are assessed for their blood sugar and insulin levels, cholesterol, weight, breathlessness, blood pressure and complications, if any.

What are the possible benefits and risks of participating?

The results of this study will help patients manage their diabetes and reduce symptoms. There are no risks associated with participating in this study.

Where is the study run from?

Riphah Rehabilitation Centre (Pakistan)

When is the study starting and how long is it expected to run for?

January 2015 to June 2016

Who is funding the study?

Riphah International University (Pakistan)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

Study information

Scientific Title

Effects of supervised structured aerobic exercise training (SSAET) on patients with type 2 diabetes mellitus compared with routine medical management: a randomised controlled trial

Study objectives

SSAET enhances treatment, affects biomarkers and improves the overall health status of patients with type 2 diabetes mellitus compared to routine medical management alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee University of Lahore, Pakistan, 10/03/2015, ref: IRB-UOL/00314/0A35

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Diabetes mellitus type 2

Interventions

1. The control group received routine medication and dietary plan (non-exercised group)
2. The experimental group received the SSAET program, routine medication and dietary plan (exercise group).

Patients in the experimental group will be subjected to long-term (25 weeks) supervised and structured aerobic exercise (SSAE) training (treadmill activity). The effect of supervised, and structured aerobic exercises training (treadmill activity) will be studied on glycaemic control, insulin in blood, aerobic capacity, cholesterol, proteins and enzymes in muscles, waist, weight, body mass index, level of exertion, breathlessness during physical activity, blood pressure and complications if any in such patients.

Intervention Type

Behavioural

Primary outcome measure

1. Insulin resistance, measured using the HOMA Method
2. Glycemic control (HbA1c), measured using a kit
3. Plasma insulin level, measured using a kit
4. Fasting blood glucose level, estimated by glucometer

Measured at baseline and at the completion of 6 month (25 weeks) intervention.

Secondary outcome measures

1. LDL and HDL cholesterol, measured from blood by using kits
2. Aerobic capacity (VO2 peak), measured by resting heart rate based method
3. Body weight
4. Body mass index (BMI)
5. Level of exertion, measured using the Borge scale
6. Dyspnea, measured by dyspnea index
7. Blood pressure, measured by BP apparatus
8. Post diabetic complications, measured by physical examination
9. Inflammatory markers, measured by Human ELISA Kits

Measured at baseline and at the completion of 6 month (25 weeks) intervention.

Overall study start date

01/01/2015

Completion date

30/06/2016

Eligibility**Key inclusion criteria**

1. Patients with type 2 diabetes mellitus diagnosed as per WHO criteria
2. Established diagnosis of type 2 diabetes mellitus with 1 year history
3. Age 30-70
4. No other post-diabetic complications or comorbidity
5. No prior history of regular physical exercise

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100

Key exclusion criteria

1. Patients with type 1 diabetes mellitus or pregnancy induced diabetes
2. Aged less than 30/more than 70
3. Patients with any other post-diabetic complications or comorbidity

4. Musculoskeletal, cardiopulmonary or neurological problems.
5. Smokers
6. Patients with type 2 diabetes mellitus with a history of regular exercise

Date of first enrolment

01/01/2015

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

Pakistan

Study participating centre**Riphah Rehabilitation Centre**

IIMCT Pakistan Railways General Hospital
Rawalpindi
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Sponsor information

Organisation

Riphah International University

Sponsor details

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Sponsor type

University/education

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ROR

<https://ror.org/02kdm5630>

Funder(s)

Funder type

University/education

Funder Name

Riphah International University

Results and Publications

Publication and dissemination plan

Findings will be published in four research papers.

Intention to publish date

30/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | results | 11/01/2017 | 24/01/2019 | Yes | No |
| Results article | results | 18/05/2016 | 24/01/2019 | Yes | No |
| Results article | results | 01/11/2017 | 24/01/2019 | Yes | No |
| Results article | results | 01/06/2017 | 24/01/2019 | Yes | No |
| Results article | results | 01/10/2018 | 24/01/2019 | Yes | No |