ISRCTN16466697 https://doi.org/10.1186/ISRCTN16466697

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

Submission date
13/04/2015

Recruitment status
No longer recruiting

Registration date
12/12/2016

Overall study status
Completed

Last Edited
24/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Mr S Shakil-ur-Rehman
shakil.urrehman@riphah.edu.pk

Contact information

Type(s)
Scientific

Contact name
Mr Syed Shakil-ur-Rehman

ORCID ID
https://orcid.org/0000-0002-6682-9896

Contact details
Riphah College of Rehabilitation Sciences,
274 main Peshawar Road
Rawalpindi
Pakistan
46000
+92 320 7866611
shakil.urrehman@riphah.edu.pk

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
Pakistan
46000

Sponsor information

Organisation
Riphah International University

ROR
https://ror.org/02kdm5630

Funder(s)

Funder type
University/education

Funder Name
Riphah International University

Results and Publications

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

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes