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Effects of a combined exercise therapy on physical condition, muscle strength, quality of life and serum profiles in type 2 diabetes mellitus

Submission date 11/03/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/04/2010	**Overall study status** Completed	
Last Edited 29/04/2010	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A randomised controlled trial investigating the effects of 12 weeks of combined aerobic and resistance exercise program on serum profiles, functional capacity, isokinetic muscle strength and quality of life type 2 diabetes mellitus

Study objectives
Type 2 diabetes is associated with obesity and physical inactivity and this impairment prevalence is increasing in occidental countries due to the growing predominance of obesity and sedentary life styles. The aim of this study is to analyse the adaptations induced by combined exercise on serum profiles, muscle strength and fatigue, physical fitness, corporal composition and quality of life related with health on type 2 diabetes mellitus patients.

Hypotheses:
1. The combined exercise therapy may lead to improvements in the neuromuscular function, physical fitness, metabolic parameters and health related-quality of life of type 2 diabetes patients.
2. Gains in neuromuscular function are related to improvements in metabolic parameters in patients with type 2 diabetes.
3. Gains in physical fitness are related to changes in health related-quality of life of type 2 diabetes patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of health and well being of the University of Évora approved on the 10th of June of 2008 (ref: 08050)

Study design
Single centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type II diabetes mellitus

Interventions
The supervised exercise therapy consisted of 1 hour-session for 3-times/week and for 12-weeks. Each session included
1. 10 minutes of warming up with slow walks and easy movements of progressive intensity
2. 25 minutes of aerobic exercises at 6065% of maximal heart rate
3. 15 minutes of strength exercises with lower and upper limb using patient's own weight resistance, light
loads (e.g. 2-4 sets of 10 repetitions of unilateral knee flexion-extension at a slow pace with the body in a vertical position or of raising the arms over the head holding a stick)
4. 10 minutes of overall mobility and cooling down.
Patients heart rate was monitored using a pulse-meter.
During this 3-month period, participants in the control group (CG) continued their daily activities, with no physical exercise similar to those in the therapy. There was no follow-up beyond the end of the 3 month intervention period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary endpoint with respect to efficacy of the combined exercise therapy in type-2 diabetes patient was to produce a moderate decrease in serum glycated hemoglobine (HbA1c) levels. Therefore, this parameter was measured from fasting blood samples along others, such as fasting glucose, HDL and LDL cholesterol, triglycerides, alanino aminotransferase (ALT) and aspartate aminotrasnferase (AST) in a standardized manner at laboratories of the hospital of the city of Évora (Portugal).

Measurements were made at baseline and post-intervention at 12 weeks.

Secondary outcome measures
1. Muscle condition: maximal peak force of the knee extensors and flexors was recorded by using the Biodex System-3 Isokinetic Dynamometer (Biodex Corp., Shirley, NY, USA). Each subset performed biolateral tests of maximal isokinetic leg strength and leg muscle fatigue.
2. Health-related quality of life (HRQOL), measured using the Portuguese language version of the Short Form 36 Health Survey (SF-36)
3. Body composition: percentage fat, total and abdominal, were assessed using dual-energy X-ray absorptiometry (DXA, Norland Excell Plus, Norland Inc, Fort Atkinson, USA)
4. Functional capacity of the patients, assessed by several tests, performed in a standardized manner:
4.1. Maximal walking speed test over 10 metres
4.2. 10-stairs climbing test
4.3. 10-stairs climbing test carrying a bag weighing 5 kg in each hand
4.4. Timed up and go test
4.5. 30 seconds chair stand test
4.6. 6-minutes walking test
Measurements were made at baseline and post-intervention at 12 weeks.

Overall study start date
10/09/2008

Completion date
21/12/2008

Eligibility

Key inclusion criteria
1. Non-smokers and not consumers of alcohol
2. Either sex
3. Age between 30 and 70 years
4. At least 3 years with diagnosed type-2 diabetes mellitus

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50 potentially eligible, 43 gave consent (exercise group: 22; control group 21)

Key exclusion criteria
Presence of any disorders that might prevent physical training load and require other psychological, physical or nutritional therapy

Date of first enrolment
10/09/2008

Date of final enrolment
21/12/2008

Locations

Countries of recruitment
Portugal

Study participating centre
S/ Reguentos de Monsaraz, 44
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Sponsor information

Organisation
University of Évora (Portugal)

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Sponsor type
University/education

ROR
https://ror.org/02gyps716

Funder(s)

Funder type
University/education

Funder Name
University of Évora (Portugal)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration