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Italian diabetes exercise study: a 20-center randomised controlled clinical trial designed to evaluate the safety and efficacy of intensive lifestyle intervention on controllable cardiovascular risk factors in type 2 diabetic subjects with metabolic syndrome

Submission date
04/08/2005

Recruitment status
No longer recruiting

Registration date
19/09/2005

Overall study status
Completed

Last Edited
28/04/2015

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
Italian diabetes exercise study: a 20-center randomised controlled clinical trial designed to evaluate the safety and efficacy of intensive lifestyle intervention on controllable cardiovascular risk factors in type 2 diabetic subjects with metabolic syndrome

Acronym
IDES

Study objectives
This study is designed to determine whether an intensive lifestyle intervention of exercise training, prescribed and supervised, as well as standard care, improves the controllable cardiovascular risk factors in type 2 diabetic subjects with metabolic syndrome, as compared with simple counselling program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Diabetes and metabolic syndrome.

Interventions

Patients recruited to the study are assigned randomly to an exercise prescription (aerobic + strength) intervention
Control: Exercise counselling

Intervention Type
Behavioural

Primary outcome measure
The Primary Endpoint will be to determine the numbers of patients within two groups that after 12 months achieve a % rate reduction of the following parameters: Hba1c = ≥15%, Cholesterol - low density lipoprotein (LDL) = ≥15%, Triglyceride = ≥15%, Cholesterol - high density lipoprotein (HDL) = ≥+15%, Blood Pressure = ≥5 mmHg x diastolic and systolic, BMI = BMI reduction ≥7% for patients with BMI ≥27, Waist ≥-10%

Secondary outcome measures
Secondary endpoints are the numbers of patients within two groups that after 12 months, achieve set standards of
1. Well-being
2. Dose/response between volume and intensity of exercise training and controllable cardiovascular risk factors
3. Impact of Exercise training on: coagulation and inflammation markers, endothelial function
4. The frequency of medication for three classes of drugs (hypolipemic, hypoglycemic, and antihypertensive therapies)
5. 10-year coronary heart disease (CHD) risk (as calculated from Framingham risk tables)
6. Cost analysis: Direct medical costs and Direct and Indirect social costs

Overall study start date
30/09/2005

Completion date
31/01/2007

Eligibility

Key inclusion criteria
Type 2 diabetes patients with metabolic syndrome, age from 40 to 80 years, duration of diabetes >1 year, body mass index (BMI) ≥27, ≤40, sedentary for at least six months, able to walk without assistance and eligible after cardiovascular algorithm evaluation. Of these, only those who give written informed consent.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

500

Key exclusion criteria
Patients having at least one of the following conditions will be excluded from the study:
1. A history or evidence on physical examination of significant central nervous system dysfunction (i.e. hemiparesis, myelopathy, cerebellar ataxia)
2. Significant musculoskeletal deformity (i.e. amputation, scoliosis, abnormality of range of motion [ROM]) that would prevent participation (<90° of humeral abduction, inability to grip, <10° of combined ankle inversion/eversion)
3. Lower extremity arthritis or pain that limits exercise
4. History or clinical evidence of severe cardiovascular diseases that limit or contraindicate the exercise
5. A history or evidence on physical examination of vestibular dysfunction
6. A history of angina or angina equivalent symptoms (i.e. nausea, diaphoresis, shortness of breath with exercise)
7. Symptomatic postural hypotension defined as a fall in blood pressure (i.e. >20 mmHg for systolic or >10 mmHg for diastolic blood pressure) in response to postural change, from supine to standing
8. A history or evidence on physical examination of plantar skin pressure ulcer

Date of first enrolment
30/09/2005

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Italy

Study participating centre
Via Montesanto, snc
Monterotondo, Roma
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Sponsor information

Organisation
Metabolic Fitness Association (Italy)

Sponsor details
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Sponsor type
Not defined

Website
http://www.metabolicfitness.it

Funder(s)

Funder type
Industry

Funder Name
Metabolic Fitness Association (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2008		Yes	No
Results article	results	08/11/2010		Yes	No
Results article	results	28/11/2011		Yes	No
Results article	results	01/03/2012		Yes	No
Results article	results	01/06/2012		Yes	No
Results article	results	01/06/2012		Yes	No
	results				

Results article	01/08/2014	Yes	No