

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 19/09/2005	Overall study status Completed	
Last Edited 28/04/2015	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

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 = $\geq 15\%$, Cholesterol - low density lipoprotein (LDL) = $\geq 15\%$, Triglyceride = $\geq 15\%$, Cholesterol - high density lipoprotein (HDL) = $\geq +15\%$, Blood Pressure = ≥ 5 mmHg x diastolic and systolic, BMI = BMI reduction $\geq 7\%$ for patients with BMI ≥ 27 , Waist $\geq -10\%$

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

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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+39 (0)6 90080260
info@metabolicfitness.it

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