ISRCTN09240628 https://doi.org/10.1186/ISRCTN09240628

Diabetes em Movimento® - Community-based exercise program for people with type 2 diabetes

Submission date
16/12/2012

Recruitment status
No longer recruiting

Registration date
28/12/2012

Overall study status
Completed

Last Edited
31/10/2019

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Type 2 diabetes is a chronic disease that affects approximately 12.4% of Portuguese population and is associated with complications such as metabolic discontrol, diabetic foot, retinopathy (persistent or acute damage to the retina of the eye), nephropathy (damage to kidney), coronary artery disease and cerebrovascular disease. Exercise is widely recommended to control of type 2 diabetes and its complications.
This study aims to:
Determine the acute effects of different exercise types, intensities and durations in glycemic control and insulin resistance
Determine the effects of a long term supervised exercise program in glycemic control, cardiovascular risk factors and physical fitness.

Who can participate?
The Diabetes em Movimento® study aims to recruit about 60 individuals with diagnosed type 2 diabetes, from both genders, aged 55 or over, without major cardiovascular and orthopaedic disease and without gait and balance problems.

What does the study involve?
Before participation, individuals will be evaluated at all variables analyzed in this study and a treadmill cardiovascular stress test. In the first phase of this study, 30 individuals (intervention group) will be submitted to exercise sessions of different types, intensities and durations. After this phase of acute effects, this group will participate in a long term (9 months) supervise exercise program. The control group (30 individuals) will be advised to continue normal living and not to engage in supervised exercise. All variables will be analyzed every 3 months.

What are the possible benefits and risks of participating?
Participants can experience an immediate direct benefit from exercise sessions like reduced blood glucose levels and improved insulin sensitivity. Long term participation in a supervised exercise program can lead to a better glycemic control, reduced cardiovascular risk and improved physical fitness.

The main risks are exercise-related adverse acute events like hypoglycaemia (low blood sugar), hyperglycemia (high blood sugar), angina pectoris (temporary chest discomfort that occurs when the heart is not getting enough blood), musculoskeletal injuries and dehydration. Proper planning of exercise sessions, and their monitoring by exercise professionals are crucial aspects to guarantee the safety of participants and to prevent this adverse events.

Where is the study run from?
The Diabetes em Movimento® study has been set up by Research Center in Sports, Health Sciences and Human Development at the University of Trás-os-Montes and Alto Douro.

When is the study starting and how long is it expected to run for?
Recruitment will start in January 2013. Participants will be enrolled in the study for a period of one year; however, the study will extend beyond this as we intend to evaluate participant's health over many months.

Who is funding the study?
Funding has been provided by Portuguese Foundation for Science and Technology.

Who is the main contact?
Dr Romeu Mendes
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Study website
http://www.diabetesemmovimento.com

Contact information

Type(s)
Scientific

Contact name
Dr Romeu Mendes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Acute and chronic effects of exercise on type 2 diabetes management: influence on glycemic control, insulin resistance, cardiovascular risk factors and physical fitness

Study objectives
It is hypothesized that different exercise types, intensities and durations have different acute effects on blood glucose and insulin resistance of type 2 diabetic patients.

It is also hypothesized that type 2 diabetic patients who engage in a supervised exercise program improve their glycemic control, cardiovascular risk factors and physical fitness in comparison with a control group without supervised exercise.

Protocol of the exercise program that we will used in this study:
Mendes R, Sousa N, Reis VM, Themudo Barata JL. Programa de Exercício na Diabetes Tipo 2. Revista Portuguesa de Diabetes 2011;6(2):62-70.

http://www.academia.edu/865461
/Programa_de_Exercicio_na_Diabetes_Tipo_2_Exercise_program_for_type_2_diabetes_

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cova da Beira Hospital Centre Ethics Committee, Portugal, 15/05/2009, ref: 36/2009

Study design
Acute Effects: Randomized crossover trial
Chronic Effects: Longitudinal controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)

Quality of life

Participant information sheet
Patient information can be found at http://diabetesemmovimento.wordpress.com/inscricoes

Health condition(s) or problem(s) studied
Type 2 diabetes and cardiovascular risk

Interventions
In acute effects study, participants will be submitted to different exercise sessions (type, intensity and duration) in comparison to a control session of rest (crossover study).

In chronic effects study, participants will engage in a long term supervised exercise program (9 months), 3 sessions per week, 70 minutes duration. Exercise sessions will follow international recommendations for exercise in type 2 diabetes: aerobic, resistance, flexibility and agility exercise. Control group will continue normal living with no supervised exercise.

Intervention Type
Behavioural

Primary outcome measure
1. Glycemic control: blood fast glucose, ambulatory capillary glucose and glycated hemoglobin
2. Insulin resistance: Homeostasis Model Assessment (HOMA) and Quantitative Insulin-Sensitivity Check Index (QUICKI) methods
3. Cardiovascular risk factors: blood pressure; blood lipid profile; body mass index, waist circumference; body fat
4. Physical fitness: 6-min Walk Test; 30 Second Chair Stand Test; Timed Get Up and Go Test; Seat and Reach Test

Secondary outcome measures
1. Medication
2. Nutritional Habits
3. Levels of Physical Activity
4. Exercise adherence
5. Exercise frequency
6. Exercise-related acute adverse events
7. Detraining and deconditioning

Overall study start date
01/01/2013

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 08/04/2013:
1. Patients with diagnosed type 2 diabetes at least for three months
2. Both genders

3. Age ≥ 55 years
4. Non-smokers
5. Not engaged in supervised exercise
6. Community-dwelling
7. Medical recommendation for lifestyle intervention
8. Known medical history
9. Diabetes complications under medical control (metabolic discontrol, diabetic foot, diabetic retinopathy, diabetic nephropathy, diabetic autonomic neuropathy and cardiovascular risk)
10. No cardiovascular, respiratory and musculoskeletal contraindications to exercise
11. No gait and balance problems
12. Not taking insulin for less than 3 months
13. Volunteer participation with signed informed consent

Previous inclusion criteria until 08/04/2013:
1. Patients with diagnosed type 2 diabetes
2. Both genders
3. Age 17
4. Community-dwelling
5. Medical recommendation for lifestyle intervention
6. Known medical history

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Current exclusion criteria as of 08/04/2013:
1. Participation in another supervised exercise program
2. Changes in diabetes and cardiovascular medications
3. Exercise adherence less than 65%
4. Aggravation of diabetes complications or other major health problem

Previous exclusion criteria until 08/04/2013:
1. Already engaged in supervised exercise
2. Major cardiovascular and orthopedic disease
3. Gait and balance problems

Date of first enrolment
01/01/2013

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
Portugal

Study participating centre
Research Centre in Sports Sciences, Health Sciences and Human Development
University of Trás-os-Montes e Alto Douro
Vila Real
Portugal
5001-801

Study participating centre
University of Beira Interior
Cova da Beira Hospital Centre
Portugal
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Sponsor information

Organisation
University of Trás-os-Montes and Alto Douro (Portugal)

Sponsor details
Centro de Investigação em Desporto, Saúde e Desenvolvimento Humano
Universidade de Trás-os-Montes e Alto Douro
Edifício Ciências do Desporto
Apartado 1013
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cidesd.geral@utad.pt

Sponsor type
University/education

Website
http://www.utad.pt

ROR
https://ror.org/03qc8vh97

Funder(s)

Funder type
Government

Funder Name
Fundação para a Ciência e a Tecnologia (Portugal) Reference SFRH/BD/47733/2008

Alternative Name(s)
Foundation for Science and Technology, Portuguese Science and Technology Foundation, Fundacao para a Ciencia e a Tecnologia, FCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Portugal

Funder Name
European Social Fund Reference SFRH/BD/47733/2008

Alternative Name(s)
Европейският социален фонд, Evropský sociální fond, Den Europæiske Socialfond, Europäischer Sozialfonds, Euroopa Sotsiaalfond, Ευρωπαϊκό Κοινωνικό Ταμείο, Fondo Social Europeo, Fonds social européen, Europski socijalni fond, Fondo sociale europeO, Eiropas Sociālais fonds, Europos socialinis fondas, Európai Szociális Alap, Fond Soċjali Ewropew, Europees Sociaal FondS, Europejski Fundusz Społeczny, Fundo Social Europeu, Fondul Social European, Európsky sociálny fond, Evropski socialni sklad, Euroopan sosiaalirahasto, Europeiska socialfonden, European Social Fund, Fondo Social Europeo Plus, Европейски социален фонд плюс, Evropský sociální fond plus, Europæiske Socialfond Plus, Europäische Sozialfonds+, Euroopa Sotsiaalfond+, Ευρωπαϊκό Κοινωνικό Ταμείο+, Fonds social européen+, Europski socijalni fond plus, Fondo sociale europeo Plus, Eiropas Sociālais fonds Plus, Europos socialinis fondas +, Európai Szociális Alap Plusz, Europees Sociaal Fonds Plus, Europejski Fundusz Społeczny Plus, Fundo Social Europeu Mais, Fondul social european Plus, Európsky sociálny fond +, Evropski socialni sklad +, Euroopan sosiaalirahasto plus, Europeiska socialfonden+, ESF, ЕСФ, EKT, FSE, ESZA, EFS, ESS, ESR, ESF+, ESZA+, EFS+, FSE+, ESS+, ESR+

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan

1. To publish results from a pilot study and the final trial.
2. To disseminate the trial among Portuguese and European societies in the scope of Diabetology, Endocrinology, Sports Medicine, General Practice and Public Health.
3. To participate in national and international scientific events.

Intention to publish date

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?
Other publications		01/09/1977		Yes	No
Abstract results		25/04/2013		No	No
Abstract results		25/04/2013		No	No
Results article		01/06/2013		Yes	No
Other publications		01/12/2013		Yes	No
Abstract results		01/08/2015		No	No
Other publications		01/09/2015		Yes	No
Abstract results		05/10/2015		No	No
Other publications		01/11/2016		Yes	No
Other publications		20/06/2017		Yes	No
Other publications		13/09/2017		Yes	No
Other publications		28/10/2019		Yes	No