

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

<b>Submission date</b> 16/12/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/10/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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) supervised 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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## Contact information

### Type(s)

Scientific

### Contact name

Dr Romeu Mendes

### ORCID ID

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### Contact details

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## Additional identifiers

### Protocol serial number

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 use 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

## Study type(s)

Quality of life

## 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(s)

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

### Key secondary outcome(s)

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

### 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  $\geq$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

## 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)

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

### Funding Body Type

Government organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Portugal

### Funder Name

European Social Fund Reference SFRH/BD/47733/2008

### Alternative Name(s)

European Social Fund, Европейският социален фонд, Европейският социален фонд плюс, Fondo Social Europeo, Fondo Social Europeo Plus, Ευρωπαϊκό Κοινωνικό Ταμείο, Ευρωπαϊκό Κοινωνικό Ταμείο+, Ciste Sóisialta na hEorpa Plus, Ciste Sóisialta na hEorpa, ESF, ESF+, ЕСФ, ЕСФ+, FSE, FSE+, EKT, EKT+, CSE, CSE+

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

Location

## 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?
<a href="#">Results article</a>		01/06/2013		Yes	No
<a href="#">Abstract results</a>		25/04/2013		No	No
<a href="#">Abstract results</a>		25/04/2013		No	No
<a href="#">Abstract results</a>		01/08/2015		No	No
<a href="#">Abstract results</a>		05/10/2015		No	No
<a href="#">Other publications</a>		01/09/1977		Yes	No
<a href="#">Other publications</a>		01/12/2013		Yes	No
<a href="#">Other publications</a>		01/09/2015		Yes	No
<a href="#">Other publications</a>		01/11/2016		Yes	No
<a href="#">Other publications</a>		20/06/2017		Yes	No
<a href="#">Other publications</a>		13/09/2017		Yes	No
<a href="#">Other publications</a>		28/10/2019		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes