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A whole-body vibration program in type 2 diabetic patients

Submission date	Recruitment status	[ ] Prospectively registered
06/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/11/2013	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/11/2013	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Diabetes is one of the most prevalent non-communicable diseases worldwide. Treatment methods are usually focused to control blood glucose levels in order to prevent long-term diabetes complications such as retinopathy (damage to the retina of the eye), nephropathy (damage to the kidneys) or neuropathy. However, despite treatment, exercise and nutritional control, a large number of patients develop these complications. Neuropathy is considered an important complication in diabetic patients involving loss of sensitivity (especially at foot level). Diabetic neuropathy is considered a health priority because of the high risk to develop diabetic foot. Moreover, sensitivity loss has been identified as an important predictor of reduced postural control, imbalance and fall risk. Hence, to investigate the effects of treatments on structural and functional components of sensitivity loss could provide useful information for doctors to manage neuropathic problems in primary care, especially in populations with a high risk of developing neuropathy, such as diabetic patients.

On the other hand, despite traditional consideration about the harmfulness of mechanical vibration exposure, during the last decades research has shown positive effects of mechanical vibration on health. In those studies and reviews, the term whole-body vibration (WBV) has been used to refer to a type of training which consists of standing over vibratory devices which transmit mechanical vibrations to the body, producing several adaptation processes at different structural and functional levels. Most of these studies have been conducted to observe the effects of whole-body vibration on physical fitness parameters, important clinical outcomes for some health conditions or health-related quality of life
measures in several populations (adults, elderly, athletes, etc.). However, few studies have investigated the effect on sensitivity parameters.

The main aim of this study is to test the effect of a whole-body vibration program on HbA1c (the amount of glucose that is being carried by the red blood cells in the body) and vibration threshold in diabetic type 2 patients.

Who can participate?

Men and women diagnosed with type 2 diabetes aged from 40 to 85 years old.

What does the study involve?

Participants will be randomly allocated to either the experimental group or the placebo group.

The experimental group will undergo 24 sessions of whole-body vibration of 15 minutes per session , three times per week over two months.
The placebo group will undergo 24 sessions of false sub-threshold vibrations (hidden speakers) of 15 minutes per session, three times per week over two months.

What are the possible benefits and risks of participating?
The possible benefits are decreases in HbA1c and vibration threshold.
The possible risks of whole-body vibration include back pain, fatigue and soreness.

Where is the study run from?
Primary Care Center, Manuel Encinas, Spain.

When is the study starting and how long is it expected to run for?
The study started in April 2013 and ran until the start of October 2013.

Who is funding the study?
FundeSalud and Research Group on Physical Activity, Health and Quality of Life (Grupo de investigación en Actividad Fisica, salud y Calidad de Vida) (AFYCAV), Spain

Who is the main contact?
Prof. Narcis Gusi

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Cost-effectiveness of a whole-body vibration program in patients with type 2 diabetes

Study objectives
1. A whole-body vibration program is safe and effective to decrease glycosylated hemoglobin (HbA1c) and vibration threshold in diabetic type 2 patients.
2. A whole-body vibration program is effective to decrease body mass index, fat percentage, blood pressure and lipidic profile in diabetic type 2 patients.
3. A whole-body vibration program is effective to improve strength, balance and health related quality of life in diabetic type 2 patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Biomedical Ethical Committee of the University of Extremadura, 09 October 2012, ref: 44/2012

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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 type 2

Interventions
Two groups: Experimental group and placebo group.

Experimental group: 24 sessions of whole-body vibration of 15 minutes per sessions, three times per week during 2 months.

Placebo group: 24 sessions of a false sub-threshold vibrations (hidden speakers) of 15 minutes per sessions, three times per week during 2 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. HbA1c. Measured with laboratory blood analysis at baseline and two months.
2. Vibration threshold. Measured with biothensiometer (vibraton II) at baseline, acute effects, one month and two month.

Secondary outcome measures
1. Health related quality of life. Measured with EQ-5D-5L; SF-12; 15-D, Diabetes Quality of Life Measure (DQOL) and Foot Health Status Questionnaire (FHSQ). Measured at baseline and two months.
2. Balance. Measured with plate force (Romberg test open and closed eyes), Time and Go test (TUG). Measured at baseline and two months.
3. Strength. Measured with Chair and stand test, BMI, Tilts and stadiometer (Soehnle professional). Measured at baseline and two months.
4. Muscular and Fat percentage. Measured with impedance meter (Tanita) at baseline and two months.
5. Blood pressure. Measured with doppler at baseline and two months.
6. Lipidic profile. Measured with laboratory blood analysis at baseline and two months.
7. Diabetic neuropathy. Measured with Michigan Neuropathy Screening Instrument and monofilament at baseline and two months.
8. Body mass index (BMI). Measured at baseline and two months.

Overall study start date
08/04/2013

Completion date
04/10/2013

Eligibility

Key inclusion criteria
1. Male and female, 40 to 85 years old, diagnosed with type 2 diabetes
2. Agreement to volunteer for the study by giving a written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
90

Key exclusion criteria

1. Contraindications to high intensity exercise participation:
1.1. Retinopathy
1.2. Musculoskeletal limitations
1.3. Severe balance impairments
1.4. High risk of thrombosis
2. Psychotropic and neurotoxic drugs intake
3. Exposure to neurotoxins (industrial accidents, contact with toxic dumps)
4. Radiotherapy treatment
5. High risk of non-diabetic neuropathy (AIDS, uremia, alcoholism)
6. People who have or have had a job with high exposure to whole-body mechanical vibration
7. Individuals undergoing or have completed a whole-body vibration program

Date of first enrolment
08/04/2013

Date of final enrolment
04/10/2013

Locations

Countries of recruitment
Spain

Study participating centre
Av. de la Universidad s/n
Caceres
Spain
10003

Sponsor information

Organisation
University of Extremadura (Spain)

Sponsor details
Avda. de Elvas s/n
Badajoz
Spain
06071

Sponsor type
University/education

Website

http://www.unex.es

ROR
https://ror.org/0174shg90

Funder(s)

Funder type
Government

Funder Name
FundeSalud (Spain) (DIAB02/2012)

Alternative Name(s)
Foundation for Research and Training of Health Professionals of Extremadura, FundeSalud

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Funder Name
Research Group on Physical Activity, Health and Quality of Life (Grupo de investigación en Actividad Fisica, salud y Calidad de Vida) (AFYCAV) (Spain)

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