

# Cost-effectiveness of exercise programmes to prevent low back pain and falls (I): low-frequency vibratory exercise

**Submission date**  
12/08/2009

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
14/10/2009

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
21/08/2019

**Condition category**  
Musculoskeletal Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CEBP42/2006

# Study information

## Scientific Title

Cost-effectiveness of exercise programmes to prevent low back pain and falls (I): a blinded randomised controlled trial of low-frequency vibratory exercise

## Acronym

Vibrobackpain

## Study objectives

1. Low-frequency vibratory exercise will prevent moderate low-back pain
2. Low-frequency vibratory exercise will reduce the risk of falling in patients with low back pain
3. Low-frequency vibratory exercise is a cost-effective addition to usual care in patients with low back pain

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Biomedical Ethical Committee of the University of Extremadura approved on the 10th October 2006 (ref: 42/2006)

## Study design

Blinded randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Prevention

## 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

Chronic low back pain

## Interventions

The participants will be randomly assigned to intervention or control group by a random table built by computer:

1. Interventional group: Three-month progressive whole body vibration (WBV) programme set at 20 HZ , applied twice a week

2. Control group: Care as usual

The treatment will last three months and patients will be followed up for one year.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Measured at baseline, three months, and one year:

1. Socio-sanitary costs
2. Functional and psychological disability in CLBP (using Roland-Morris questionnaire and Fear-Avoidance Beliefs Questionnaire [FABQ])
3. Health-related quality of life (using the EuroQoL questionnaire [EQ-5D]) and their utilities to health economic analyses
4. Fitness and neuromuscular function (using the tests of Sorensen, Ito-Shirado, straight leg raising and balance with Biodex Balance Platform)

### **Secondary outcome measures**

Measured at baseline, three months, and one year:

1. Health related quality of life measured using the 36-item short form health survey (SF36) and the 15-D instrument
2. Grade of satisfaction with programme
3. The Start Back Tool (SBST) instrument to evaluate unspecified low back pain

### **Overall study start date**

01/09/2009

### **Completion date**

20/01/2010

## **Eligibility**

### **Key inclusion criteria**

1. Patients with chronic low-back pain (CLBP) without major neurological alterations
2. Patient assessed by Pain Unit in Extremadura
3. Diagnosis of chronic low back pain (CLBP) according to "International Classification of Diseases, Ninth Revision (ICD-9)"
4. CLBP episodes for more than six months
5. Informed consent
6. Aged 40 to 70 years, male and female

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

**Target number of participants**

60 patients

**Total final enrolment**

50

**Key exclusion criteria**

1. Other major disease
2. Regular physical activity more than one day a week in the last 5 years
3. Any drug intake that may affect balance significantly - to avoid external influences

**Date of first enrolment**

01/09/2009

**Date of final enrolment**

20/01/2010

## **Locations**

**Countries of recruitment**

Spain

**Study participating centre**

Faculty of Sport Sciences

Caceres

Spain

10071

## **Sponsor information**

**Organisation**

University of Extremadura (Spain)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<http://www.unex.es>

**ROR**

<https://ror.org/0174shg90>

## Funder(s)

**Funder type**

Government

**Funder Name**

Government of Extremadura and European Social Funds (Spain) (ref: PRI070B093)

**Funder Name**

Government of Spain (Spain) - grant for a university research-professor student (FPU) (ref: AP2008-02211)

## 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?
<a href="#">Results article</a>	results	01/07/2011	21/08/2019	Yes	No