

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

<b>Submission date</b> 12/08/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/08/2019	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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)

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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)

### 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

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