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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

Registration date
14/10/2009

Overall study status
Completed

Last Edited
21/08/2019

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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
Goverment 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?
Results article	results	01/07/2011	21/08/2019	Yes	No