

Cost-effectiveness of an individual on line real-life computer-tailored physical activity and educational intervention at work-site to secondary prevention of non-specific sub acute or recurrent low back pain on office workers: "Look after your back"

Submission date 29/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/07/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

N/A

Study information

Scientific Title

Cost-effectiveness of an individual on line real-life computer-tailored physical activity and educational intervention at work-site to secondary prevention of non-specific sub acute and recurrent low back pain in office workers: blinded randomised controlled trial

Acronym

CTE project

Study objectives

1. An individual on line real-life computer-tailored physical activity and educational intervention at work-site with e-mail reminder will prevent moderate low-back pain on office workers
2. An individual on line real-life computer-tailored physical activity and educational intervention at work-site with e-mail reminder will reduce the risk of disability in patients with low back pain
3. An individual on line real-life computer-tailored physical activity and educational intervention at work-site with e-mail reminder will improve the quality of life in patients with low back pain
4. An individual on line real-life computer-tailored physical activity and educational intervention at work-site with e-mail reminder 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 16th June 2010 (ref: 32/2010)

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

Non-specific 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: eight-month individual online real-life computer-tailored physical activity and educational intervention at work-site with an e-mail reminder
2. Control group: eight-month individual online real-life computer-tailored physical activity and educational intervention at work-site without a e-mail reminder

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured at baseline, three months and eight months:

1. Socio-sanitary costs (direct and indirects costs)
2. Functional and psychological disability in nonspecific low back pain (using Roland-Morris Questionnaire, the Oswestry Disability Index and the Start Back Tool [SBST])
3. Health-related quality of life (using the EuroQoL questionnaire [EQ-5D]) and their utilities to health economic analyses
4. Fitness and muscular function (using the handgrip strength test, Ito-Shirado and leg and back flexibility)

Secondary outcome measures

1. Grade of satisfaction with programme
2. International Physical Activity Questionnaire (IPAQ)
3. Stage of change

Overall study start date

16/06/2010

Completion date

17/02/2011

Eligibility**Key inclusion criteria**

1. Workers (aged 18 - 65 years, either sex) with subacute non-specific low back pain
2. Patient assessed by Preventive Medicine Services from University of Extremadura
3. Working with a computer and internet access at work
4. Informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

100

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 back pain significantly - to avoid external influences

Date of first enrolment

16/06/2010

Date of final enrolment

17/02/2011

Locations

Countries of recruitment

Spain

Study participating centre

Avda Universidad s/n

Caceres

Spain

10003

Sponsor information

Organisation

University of Extremadura (Spain)

Sponsor details

Avenida 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

University/education

Funder Name

University of Extremadura (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