The changes in walking performance during and after walking with coaching music for chronic low back pain patients and asymptomatic controls

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The main objective of this study is to explore the changes in the walkingperformance, while walking with the Sports Coach set at 50-70% of the maximal heart rate for chronic low back pain patients and asymptomatic controls.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON29729

Source
ToetsingOnline

Brief title
The changes in walking performance for walking with music

Condition

- Other condition

Synonym
backpain, chronic pain

Health condition

Chronische klachten aan het houdings- en bewegingsapparaat (lage rugklachten)

Research involving

Human

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: Ministerie van Economische Zaken / Bsik Zaken

Intervention

Keyword: Chronic low back pain, Physical activity, Walking performance

Outcome measures

Primary outcome

The primary outcome parameter is walking performance assessed with the 6 minute walk test before and after the intervention.

Secondary outcome

- Disability in the CLBP patients, assessed with the Roland Morris Disability Questionnaire. The intensity of pain in CLBP patients will be measured with the Visual Analog Scale.

- Perceived exertion, assessed with the Borg scale.

- Step frequency, assessed with accelerometer values from the Sports Coach device.

- Energy expenditure in kcal/minute assessed with the accelerometer values from the Sports Coach.

- Heart frequency will be measured by means of a dedicated chest belt (PR Aken,

ADSL Leuven), which is part of the Sports Coach.

- Intrinsic Motivation assessed with the Intrinsic Motivation Inventory.

Study description

Background summary

Pain in the musculoskeletal system is an important public health problem due to high impact on disability, sickness absence, work disability and health care costs. In recent years, physical disuse has been presented as one of the factors for chronicity in theoretical research models on pain. Physical reconditioning forms the basis for intensive physical rehabilitation of patients with CLBP. Reconditioning however does not only form the basis for rehabilitation for people with chronic pain and illnesses, but also healthy subjects want to improve their well-being via upgrading their physical activity level.

Philips developed a device (Sports Coach) to assist people while running or walking. The Sports Coach consists of a music player and a chest belt. In the present study the Sports Coach will be used during walking, it will measure step frequency, as well as heart rate as a measure of effort of the subject. The Sports Coach will generate an advised walking pace based on the heart rate. In the current study, patients with low back pain and asymptomatic controls will walk with a heart beat between 50% and 70% of their maximum heart rate. When the heart rate is below or above the set range, the music will respectively speed up or slow down to coach the persons to walk in the right pace.

Study objective

The main objective of this study is to explore the changes in the walkingperformance, while walking with the Sports Coach set at 50-70% of the maximal heart rate for chronic low back pain patients and asymptomatic controls.

Study design

To investigate the changes after walking with the Sports Coach prototype, a prognostic cohort study will be used. After inclusion, the baseline measurement (T0) will take place, followed by a 4 weeks intervention with the Sports Coach. After these 4 weeks of intervention a second measurement (T1) will be

performed.

Intervention

The intervention includes 12 walking sessions for the CLBP patients and the asymptomatic controls with the Sports Coach. The participants are instructed to walk three times a week, 30 minutes each for 4 weeks. In each session the subjects is requested to walk in such a way that his/her heart rate remains between 50% and 70% of his/her maximum heart rate (HRmax = 220 - subject*s age).

Study burden and risks

As far as known, the participants are not exposed to any risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Inclusion criteria CLBP patients
- Age between 18 and 65 years
- Primary complaint non-specific chronic low back pain
- No structural pathology
- They are willing to walk with music
- Informed consent to participate in the study;Inclusion criteria healthy participants
- Age between 18 and 65 years
- Reported normal health
- No history of back pain in the last 6 months
- They are willing to walk with music
- Informed consent to participate in the study

Exclusion criteria

- Wheelchair- bound participants
- Specific causes of chronic pain
- Surgery on the back in the last 6 months
- Terminal or progressive disease
- Insufficient knowledge of the Dutch language
- Insufficient cognitive skills
- Cardiovasculair disorders
- Use of medication, which influences the heart rate

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start

Start date (anticipated):	01-08-2006
Enrollment:	36
Type:	Anticipated

Ethics review

Approved WMO Date:	01-08-2006
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL12112.080.06