Chronic low back pain and gaming.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29085

Source
Nationaal Trial Register

Health condition

chronic low back pain (chronische lage rugpijn)

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: subsidie Wetenschappelijk Onderzoek Roessingh
(Scientific Research Roessingh)

Intervention

Outcome measures

Primary outcome

Motor performance expressed in the amount of time needed to complete a series of predefined reaching movements (i.e. reaching to and pressing the buttons corresponding with the required movement of Pacman in the game).

Secondary outcome

1. Attention to task performance and attention to back sensation both measured by a numerical rating scale (NRS) ranging from 0 (“no attention at all”) to 10 (“full attention”);

2. Expected and experienced pain rating both measured by a NRS ranging from 0 (“no pain at all”) to 10 (“worst pain imaginable”).

Study description

Background summary

Rationale:

Previous studies proved that chronic low back pain (CLBP) patients’ motor performance is deviated compared to healthy subjects. Recent research has shown that giving knowledge of performance (KP) feedback on a simple motor task cannot dissolve the difference between patients’ and healthy subjects’ performance in a back challenging condition which provokes pain-related cognitions. This may be related to an increased attention towards back sensations, known as hypervigilance, which simple KP feedback, apparently is not capable to counterbalance. Therefore, a more enriched feedback strategy should be applied. Gaming feedback might be such an enriched feedback strategy.

Objective:

Can feedback by means of motivating gaming counterbalance the deteriorations in motor performance due to provoking pain-related cognitions in CLBP patients?

Study design:

Prospective intervention study.

Study population:

A group of 30 adult (18-70 yrs) chronic low back pain patients and a age- and sex-matched group of 15 control subjects without a history of back complaint. All subjects will be recruited in the Netherlands.

Intervention:

All subjects perform a PacMan game, in which PacMan is controlled by arrow buttons at

maximal reach distance. The goal is to perform (and, thus move) as fast as possible. The experiment consists of a practice condition and three experimental conditions: 1) condition without motivation in which baseline performance level is determined, 2) motivating condition in which the influence of motivation (by playing pacman) is determined and 3) motivating feedback condition in which ghosts will be introduced that represent a performance norm. All three conditions will be performed in a neutral and back challenging (provoking) condition. Both patients and healthy subjects will participate in all conditions in order to facilitate correction for any condition effects.

Main study parameters/endpoints:

Motor performance, expressed in time to finish a sequence of reaching movements in order to control PacMan's movement in the game.

Study objective

Previous studies proved that chronic low back pain (CLBP) patients' motor performance is deviated compared to healthy subjects. This applies for performance of low back motor task, but also tasks that do not involve the back. In addition, the deterioration further increases when tasks have to be performed in a back challenging condition, a condition that provokes pain-related cognitions.

Recent research has shown that giving knowledge of performance (KP) feedback on a simple motor task can dissolve the difference between patients' and healthy subjects' performance in a neutral sitting condition. However, in a back challenging condition which provokes pain-related cognitions there remained differences between patients and healthy subjects.

Some studies have related pain-related cognitions (especially catastrophizing) to an increased attention towards back sensations, known as hypervigilance. It is plausible that hypervigilance distracts attention from performance in a back challenging condition. Apparently, simple KP feedback is not capable to counterbalance this. Therefore, a more enriched feedback strategy should be applied.

Gaming might be such a feedback strategy. It has proven to have a positive effect on attention towards performance (probably via motivation) and has proven to even be able to distract attention from pain in burn patients. In sum, gaming feedback seems to be a promising manner to compensate for the deviations in motor performance as seen is back challenging conditions.

Therefore, the goal in the present study is to determine whether feedback by means of motivating gaming can counterbalance the deteriorations in motor performance cause by provocation of pain-related cognitions in CLBP patients.

Study design

The study comprises a once-only visit of 30-45min in which the following procedures are applied:

1. General introduction and informed consent;

2. Baseline questionnaire assessment:

A. All subjects: Socio-demographics (age, length, gender etc.);

B. Patients only:

i. VAS pain (100mm lines indicating minimal, maximal and present pain intensity);

ii. TAMPA scale of kinesiophobia;

iii. PCS (catastrophizing).
3. Practice trials: Subjects are asked to lay prone on the examining table. They will see a sequence of arrows displayed on a screen and are asked to reproduce this sequence by reaching to and pressing the corresponding arrow buttons as fast as possible. The task will be repeated until the subject has been equally fast (<500ms difference) across three subsequent trials. The maximal amount of practice trials is set at 10 repetitions;

4. Condition without motivation: Same task as practice tirals. Before task performance subjects have to indicate their current and expected pain level on a 0-10 NRS (integrated in the game) with 0 representing “no pain” and 10 “worst pain imaginable”.

Subsequently, the subject performs three trials with feedback on performance time.

After finishing the last trial subjects have to score (NRS) experienced pain, level of attention to the game and attention to the back (0 = “no attention”; 10 = “continuous attention”).

Additionally the same protocol (i.e. questionnaires, task performance, questionnaires) is done in a provoking position;

5. Motivating condition: At the screen in front of the subjects a PacMan figure is displayed at the beginning of a labyrinth. Subjects are instructed that they can move PacMan trough the labyrinth by reaching for and subsequently pressing on the arrow buttons corresponding to the direction PacMan has to move.

A block of 3 neutral and a subsequent block of 3 provoking trials are done; each block preceeded and followed by questionnaire assessment as described earlier. Subjects receive feedback on performance time after each trial;

6. Motivating/learning feedback condition: At the screen in front of the subjects PacMan is displayed at the beginning of a labyrinth along with some ghosts. Subjects are instructed that this time they will be competing with one or more ghosts in the game that represent a performance norm. It is explained that the end of an attempt a highscore will be shown:

winning the race increases the score, losing decreases the score.

A block of 6 neutral and a subsequent block of 6 provoking trials are done; each block preceeded and followed by questionnaire assessment as described earlier. Subjects receive feedback on both highscore and performance time after each trial.

The order of 4-6 is randomized.

Intervention

Provoking position (i.e. lying prone without trunk support, a posture that is assumed to provoke pain-related cognitions in patients).

Effect of the provoking position will be compared to patients' performance in a neutral position (i.e. lying prone with trunk support) and performance of healthy controls.

Contacts

Public
Roessingh Research and Development
Roessinghsbleekweg 33b
D. Kusters
Enschede 7522 AH
The Netherlands
+31 (0)53 4875766
Scientific
Roessingh Research and Development
Roessinghsbleekweg 33b
D. Kusters
Enschede 7522 AH
The Netherlands
+31 (0)53 4875766

Eligibility criteria

Inclusion criteria

All subjects must:

1. Be aged between 18 and 70 years;

2. Have a length between 1m50 and 2m00 (task layout requirement);

3. Be able to perform the experiments in this study (according to the therapist’s judgement for patients).

Patients additionally must:

1. Have low back pain without specific pathological causes present for at least 12 weeks;

2. Be free of other pain problems.

Exclusion criteria

1. Subjects will be excluded in case of:

1. Upper-extremity disorders;

2. Other pathologies compromising manual motor performance;

3. Insufficient mastering of the Dutch language.

In addition, control subjects will be excluded if they have had an episode of (back) pain complaints in the 6 months previous to study participation.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2010
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-02-2011
Application type:	First submission

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
NTR-new	NL2657
NTR-old	NTR2785
Other	METC Medisch Spectrum Twente (Enschede) : P10-20
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A