BackActive: Exposure in vivo in chronic low back pain patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24939

Source
NTR

Brief title
BackActive

Health condition

Chronic low back pain

Sponsors and support

Primary sponsor: University of Maastricht, Department of Medical Clinical and Experimental Psychology
Source(s) of monetary or material Support: ZON-MW, The Netherlands Organization for Health Research and Development (Projectnr 1436.0002)

Intervention

Outcome measures

Primary outcome

To evaluate the (cost-)effectiveness of a graded exposure in vivo treatment as compared to behavioural graded activity in patients with chronic low back pain who report substantial pain-related fear.

Primary outcome measures: functional disability, generic functional status.

Secondary outcome

Physical activity level.

Study description

Background summary

Fear of movement/(re)injury is an important determinant in the development and maintenance of chronic low back pain (CLBP). CLBP patients with substantial fear of movement/(re)injury might benefit from exposure in vivo treatment that aims to increase physical activity level by means of decreasing fear of movement/(re)injury. During exposure in vivo patients have to perform activities that are considered harmful to the back. Both through the use of exposure in vivo and behavioural experiments fear is reduced, while beliefs about the harmful consequences of activities are disconfirmed.
Patients are randomly assigned to either exposure in vivo or graded activity. Measurements take place twice before treatment, directly after treatment, and 6 and 12 months after treatment. During treatment daily measurements are gathered.

Study objective

It is hypothesized that in chronic low back pain patients with fear of movement/(re)injury, exposure in vivo will be more effective in reducing functional disability levels than the usual graded activity treatment.

Study design

N/A

Intervention

Participants are randomly assigned to either exposure in vivo or behavioural graded activity. Through exposure in vivo participants are motivated to perform activities, through which fear of movement/(re)injury and functional disability are decreased. Graded activity gradually increase physical activity levels by means of positive reinforcement and time contingency principles.

Contacts

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Eligibility criteria

Inclusion criteria

Criteria for acceptance in the study are:

1. Non-specific low back pain;

2. Duration of pain disability 3 months or more;

3. Age between 18-65 years;

4. Substantial pain-related fear (Tampa Scale for Kinesiophobia > 33).

Exclusion criteria

Exclusion criteria are:

1. No consent;

2. Illiteracy;

3. Pregnancy;

4. Substance abuse;

5. Involvement in any litigation concerning disability income;

6. Specific medical disorders and cardiovascular diseases, preventing participation at physical exercise;

7. Low back pain attributable to recognizable pathology (e.g. infection, tumor, osteoporosis, rheumatoid arthritis, fracture, or inflammatory process, prolapsed intervertebral disc);

8. Psychopathology: pretest criteria applied to a standardized test, the SCL-90 and Beck Depression Inventory;

9. Patients with restricted disability due to their back pain (Roland Disability Questionnaire score < 4).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2003
Enrollment:	110
Type:	Actual

Ethics review

Positive opinion

Date:	21-09-2005
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	NL377
NTR-old	NTR417
Other	Projectnummer ZonMw : 1436.0002
ISRCTN	ISRCTN88087718

Study results

Summary results
N/A