

BackActive: exposure in vivo in chronic low back pain patients

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/12/2015	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
NTR417; Project number ZonMw 1436.0002

Study information

Scientific Title

BackActive: exposure in vivo in chronic low back pain patients

Acronym

BackActive

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised single-blind active-controlled parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Not specified

Study type(s)

Treatment

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

Low back pain

Interventions

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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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 measures

Physical activity level

Overall study start date

01/09/2003

Completion date

01/09/2007

Eligibility**Key inclusion criteria**

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)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

110

Key exclusion criteria

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)

Date of first enrolment

01/09/2003

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

University Maastricht

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

University Maastricht (UM) (Netherlands)

Sponsor details

Department of Medical Clinical and Experimental Psychology

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Sponsor type

University/education

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Netherlands

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	15/08/2008		Yes	No
Results article	results	14/12/2015		Yes	No