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BackActive: exposure in vivo in chronic low back pain patients

Submission date	Recruitment status	[_] Prospectively registered
27/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/12/2015	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
Physical activity level

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

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)

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes