

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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24939

Bron

NTR

Verkorte titel

BackActive

Aandoening

Chronic low back pain

Ondersteuning

Primaire sponsor: University of Maastricht, Department of Medical Clinical and Experimental Psychology

Overige ondersteuning: ZON-MW, The Netherlands Organization for Health Research and Development (Projectnr 1436.0002)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2003
Aantal proefpersonen:	110
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 21-09-2005
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL377
NTR-old	NTR417
Ander register	Projectnummer ZonMw : 1436.0002
ISRCTN	ISRCTN88087718

Resultaten

Samenvatting resultaten

N/A