An investigation into the treatment of chronic low back pain

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38191

Source
ToetsingOnline

Brief title
Treatment of chronic low back pain

Condition

- Other condition

Synonym
chronic low back pain, lumbago, non specific low back pain

Health condition

musculoskeletale pijnaandoening: aspecifieke chronisch lage rugpijn

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic low back pain, psychological factors, safety behaviour, treatment

Outcome measures

Primary outcome

I. On a daily basis:

a. Manipulation check: measures of fearful cognitions with a questionnaire

consisting of items from the TSK, PASS, PCS and IUS (also used in 4, 5)

b. Self-reported achievement of therapy goals and valued life goals in general

(reported by patient as well as spouse/partner)

c. Pain intensity

d. Self-reported use of safety behaviour (reported by the patient as well as by

the spouse/partner)

II. At 7 different assessment moments (see flowchart of the study, section C,

p. 18):

a. Pain disability (QBPDQ)

b. Pain-related fear (TSK, PHODA and PHODA-SeV)

c. Pain catastrophizing (PCS)

d. Need to control questionnaire

e. Safety behaviour questionnaire

f. Pain Solutions Questionnaire (PaSol)

g. Two behavioural performance tasks (BAT): A standardized bag carrying task

and a personalized task

h. Positive and Negative Affect Schedule (PANAS)

Secondary outcome

1. The amount of within-session fear reduction is measured. This will allow us to investigate how within-session fear reduction and between-session fear reduction are related to each other. For this purpose, patients are asked to rate the following items on a scale from 0 to 10 before and after each exposure exercise:

a) *If you had to do the exercise again, how much damage to your back do you expect to be done?* (0= no damage at all, 10= a lot of damage)

b) *If you had to do the exercise again, what are the odds you will not be able to do this?* (0= zero odds, 10= I am sure I can do this)

c) *How sure are you of this expectation?* (0= not sure at all, 10= very sure)

2. Furthermore, we will use *subjective units of distress* (SUDs) to measure the amount of distress that is experienced by the patient before, during and after the exposure exercise. Participants are asked to indicate their experienced level of distress on a scale from 0 (complete relaxation) to 10 (extreme distress).

3 . Other parameters:

a) Credibility check (CEQ)

b) Fidelity check (for researchers only)

c) Demographic information of patient: age, gender, educational level,

employment status, duration of complaints, previous treatment including

surgery, pain radiation

Study description

Background summary

Exposure in vivo therapy (EXP) aims to reduce pain-related fear - a key maintaining factor of chronic low back pain (CLBP) - while increasing level of daily functioning, despite the pain. This is done by exposing patients to their most feared activities/movements, while behavioural experiments are performed that serve to correct catastrophic (erroneous) beliefs about pain. Yet, performing exposure exercises might be very threatening for patients and might encourage them to build in subtle safety behaviour (SB) during EXP. Whether SB should be allowed or not during therapy is heavily debated. Whereas some argue that it will only interfere with therapeutic progress because it prevents the disconfirming experience EXP tries to offer, others argue that it will facilitate therapeutic progress, because it enhances one's sense of control, if used judiciously. So far (clinical-)experimental studies have provided mixed evidence nor have they lead to any clinical recommendation.

Study objective

The main aim of the current study is to investigate the influence of these SBs on therapeutic progress and outcome. We hypothesize that: 1) SB has a facilitating effect on fear reduction within a therapy session, but that it is also related to stronger fear increase in between sessions and in the long run compared to when SB is omitted from therapy, 2) patients using SB during therapy might benefit less in the long run compared to when SB is omitted from therapy.

A secondary aim of this study is to gain more insight into the concept of SB, since there is a lot of confusion with regard to what SB is.
Specifically, we aim to
- Further identify which SB*s are commonly used (active, passive, overt and covert) in CLBP patients
- Monitor the spontaneous use of SB during daily functioning
- Find out to what extent SB is related to level of pain-related fear and level of functional disability

Study design

The study entails a replicated single-case experimental design in 12 patients

with chronic low back pain. Participants are randomly assigned to one of three groups: 1) an Exposure-neutral group (SB-neu), 2) a group receiving EXP with a SB maintenance instruction (SB-main) 3) a group receiving EXP with a SB decrease instruction (SB-decr).

Intervention

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Phase 1: Preparation (week 1 - week 3)
1. Intake session with the (rehabilitation) physician
a. Patients are medically evaluated by the (rehabilitation) physician to exclude any serious medical pathology and make sure the patient is suited for entering in an exposure program (regular care).
b. The patient (and the spouse/partner) are informed about the possibility to participate in a study (additional).
c. If the patient is willing to participate, written consent to have the researcher contact the patient by telephone is obtained (see section E1.A, E2.A). Then, the patient (and partner) receive(s) patient and partner information as well as the *Algemene brochure medisch-wetenschappelijk onderzoek* (additional).
2. Contact by telephone by the researcher: when written consent to be contacted is obtained, this information is passed on to the researcher, who then contacts the patient by telephone to explain what study participation entails and address questions the patient or the partner may have.
3. Screening sessions (regular care)
a. The patient is screened by a behaviour therapist, a physical therapist and an occupational therapist.
The behavioural therapist checks for psycho-social counter-indications and explores the history of the complaints. This helps to identify the best treatment options for a specific patient The physical therapist check for any physical counter-indications; the occupational therapists explores the patients* motivation, expectation and personal goals.
4. Information & screening session with the researcher (additional)
a. The researcher explains the study, answers all questions related to study participation, and explains the use of the daily measures (additional).
b. Written informed consent for study participation is obtained with the patient and partner (see section E1.B, E1.C, E2.B., E2.C).
c. All of the inclusion and exclusion criteria are checked.

5. A cognitive-behavioural analysis of the patients* complaints is made by the therapist (team; psychologist and physical or occupational therapist) and based on this, treatment goals are formulated (regular care).
a. Daily measures are started from here on until 1-week post treatment (additional).
6. PHODA-session
a. A hierarchy of feared activities is set up with the Photograph Series of Daily Activities (PHODA). Based on the fear hierarchy, the exposure exercises are selected (regular care).
b. The SB*s that are used during those activities are identified. Because patients themselves are not always aware of the SB*s they are using, the partner is also asked to join in on the identification of SBs (additional).
c. A Safety Behavior Quesionnaire is administered to the patient and the partner (additional).
7. Explain treatment recommendation: the rehabilitation physician discusses the treatment recommendation of the therapist (team) with the patient (regular care).
Phase 2: Baseline 1 (week 4 - week 5)
8. Measurement occassion 1 (M1; additional)
a. This entails a baseline period in which no treatment sessions are planned of 7 to 14 days before of the first therapy session, thus creating a pseudo-randomization. Daily measures are further completed by the patient and the partner.
b. The patient visits the azM to fill out the battery of questionnaires.
c. During this visit, the patients performs a standard behavioural performance task, as well as a personalized behavioural task.
d. The presence of the partner is also requested during this measurement.
Phase 3: Education (week 6)
9. Education session by therapist (team):
a. This involves an explanation of the FA-model (regular care)
b. Additionally, the SB-neu group receives a treatment rationale that makes no explicit reference to the use of SB, while the SB-main group receives the rationale that SB may be used to make matters easier, and the SB-decr is told that SB is best omitted in order to reach the desired outcome (additional).
10. Education session by the rehabilitation physician: the rehabilitation physician explain the medical results that have been obtained with the patient (e.g., discussing X-rays, MRI imaging)
Phase 4: Baseline 2 (week 7 - week 8)
11. Measurement occasion 2 (M2; additional)
a. Daily measures are further completed by the patient and the partner.
b. The patient visits the azM to fill out the battery of questionnaires.
c. During this visit, the patients also performs a standard behavioural performance task, as well as a personalized behavioural task.
d. The presence of the partner is also requested during this measurement.
Phase 5: Exposure in vivo (week 9 - week 15)
12. Exposure in vivo sessions (about 12 sessions on average, 2 sessions/week). The therapist (team) proceeds with sessions consisting of exposure exercises

and behavioural experiments. During these sessions and depending on the condition, the previously explained treatment rationales are explained again: no explicit reference to SB (SB-neu), SB-maintenance instruction (SB-main) or SB-decrease instruction (SB-decr) (regular care with adjustments per condition).
13. Measurement occasion 3, halfway during treatment, i.e., after 6 exposure sessions (on average) (M3; additional).
14. Measurement occasion 4, 1 week post-end of treatment (M4; additional). (week 16)
Phase 6: Follow up (week 20 - week 56)
15. Measurement occasion 5: 3 months after end of treatment (M5; regular care).
16. Measurement occasion 6: 6 months after end of treatment (M6; additional) .
17. Measurement occasion 7: 12 months after end of treatment (M7; additional)

Study burden and risks

The current study does not expose patients to any risks that are not usually related to rehabilitation or movement in general. Patients are requested to spend some extra time on top of regular care for the purpose of the study. The extra burden includes:
- filling out daily computerized measures at home starting from 1 week before M1 until M4, as well as during 10 days at M5, M6 and M7 (about 10min/day for the patient).
- fill out questionnaires at the azM at 7 different measurement occasions (on average 30 minutes per measurement occasion).
- perform two behavioural performance tasks at the azM at 7 different measurement occasions (on average 1 hour per measurement occasion).
- involvement of the partner: help in identification of SB during the PHODA session and on M1 to M7;filling out daily computerized measures at home starting from 1 week before M1 until M4, as well as during 10 days at M5, M6 and M7 (about 5min/day for the partner).
Patients are reimbursed for transportation that is required for the information & screening sessions with the researcher and the 7 measurement sessions (¤ 0,19 per km/car and complete reimbursement for public transportation costs).
Partners are reimbursed for transportation as well, if this requires an extra transportation besides the one the patient has to make anyway.
Participants will also receive a gift in the form of a breakfast coupon for 2 (¤ 24,90) in return for their study participation.
Indirectly, the participant can help to gain more insight in factors that can hamper or facilitate therapeutic progress/outcome, and help to formulate treatment recommendations that may further improve EXP for CLBP in general.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Potential participants:
- suffer from chronic low back pain not caused by serious spinal injury, for at least 3 to 6 months
- are between 18 and 65 years of age
- report a sufficient level of disability and
- moderate to high levels of pain-related fear (total TSK score >= 37 or at least 4 TSk items with a rating >= 3)
- having a partner willing to participate as well

Exclusion criteria

Patients are excluded if one or more of the following criteria is applicable:
- Specific medical disorder or cardiovascular disease preventing participation in physical exercise

- Serious psychopathologic co-morbidity (checked during the intake session with the rehab. physician and during the general screening)
- Alcohol or drug abuse
- Illiteracy
- Pregnancy
- Involvement in litigation concerning the patient*s ability to work or disability income
- Non-Dutch speaking

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-08-2012
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2012
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	27-08-2012
Application type:	Amendment

Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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
CCMO	NL37708.068.11