ISRCTN35108886 https://doi.org/10.1186/ISRCTN35108886

Illness perceptions and activity limitations in chronic low back pain.

Submission date	Recruitment status
16/02/2010	No longer recruiting
Registration date	**Overall study status**
08/03/2010	Completed
Last Edited	**Condition category**
04/04/2013	Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Petra Siemonsma

Contact details
Dr. Jan van Breemen Institute
Clinimetric Laboratory
Dr. Jan van Breemenstraat 2
Amsterdam
Netherlands
1056 AB
+31 (0)20 5896285
p.siemonsma@janvanbreemen.nl

Additional identifiers

Protocol serial number
014-32-041; WC02-059

Study information

Scientific Title
Illness perceptions and activity limitations in chronic low back pain. A component approach to innovate rehabilitation programmes for patients with chronic low back pain.

Study objectives
The overall objective of this study is innovation of rehabilitation programmes by gaining a better understanding of the working mechanism and applicability of one component of chronic low back pain (CLBP) rehabilitation. This component is cognitive restructuring based on Leventhals Self Regulation model (SRM), and is labelled Cognitive Treatment of Illness Perceptions (CTIP). The SRM links illness perceptions (ideas about illness) to activity limitations. The aim of this study is to investigate the question: which patients, with what patient characteristics, will benefit most from cognitive treatment aimed at restructuring illness perceptions. The study comprises three phases. An explorative phase in which is focussed on the design and application of the rehabilitation programme and in which the research design is optimised. An experimental phase testing the rehabilitation programme (effectiveness study and predictor study). And a generalisation phase, researching the generalisability of the results to other settings by focussing on treatment delivery and implementation problems (treatment integrity study). Together these studies aim to provide a clinically relevant and broad evidence base for CTIP.

Conceptualisation of treatment content has finished and been published, and thereby the explorative phase has ended. Hypothesis about patient characteristics predictive of treatment effect were generated in this phase, and include
1. rational approach of problems
2. adequate discussion skills
3. adequate verbal skill
4. being problem focussed

The experimental phase consists of 3 group Randomised Clinical Trial (2x intervention, 1x waiting list). Randomisation followed a predetermined computer-generated block-randomisation schedule, generated before the screening (blocks size 12), and oblique sealed and numbered envelopes were prepared by an independent fellow researcher. The RCT is integrated with a predictor study and treatment integrity study. Both short-term (18 weeks) and longer-term (1 year) effects are studied. Therapists and assessors are blinded for group allocation. Therapists, assessors and patients are blinded for the hypothesized predictor variables.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Slotervaart Hospital, Amsterdam approved on the 16th of June 2003 (ref: protocol no 0514)

Study design
3 arm randomised controlled trial predictor and treatment integrity study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic non-specific low back pain (CLBP)

Interventions

Patients were randomised (2:1 ratio) to
1. Cognitive treatment of illness perceptions (CTIP):
14x one-hour sessions over a maximum period of 18 weeks
2. Waiting list control:
CTIP between weeks 18 and 36
The double size of the intervention group is to enable study of predictors of treatment success
Therapists: physiotherapists, occupational therapists and psychologists were trained to deliver the intervention according to the treatment protocol
The total duration of follow up was 52 weeks for the intervention group and 68 weeks for the control group.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Patient-specific activity limitations (PSFL). Clinically relevant change =18 mm, measured at 18, 36 and 52 weeks (also at 68 weeks for control group).
18 weeks is theorised to be the first time point where changes are expected.

Key secondary outcome(s))
1. Secondary outcome: General activity limitations (QBPDS), measured at 18, 36 and 52 weeks (also at 68 weeks for control group).
2. Tertiary outcome: Health care consumption (cost-diary), measured at 18, 36 and 52 weeks (also at 68 weeks for control group).
36 weeks is theorised to be the first time point where changes are expected.

3. Process measure: illness perceptions (IPQ-R), measured at timepoints 18, 36 and 52 weeks (also at 68 weeks for control group).
18 weeks is theorised to be the first time point where changes are expected.

Completion date
01/05/2010

Eligibility

Key inclusion criteria
1. Age 18 - 70 years
2. Non-specific low back pain with or without radiation to the leg(s) for at least 3 months
3. Current episode of back pain lasting less than 5 years
4. Activity limitations (Roland Disability Questionnaire > 3)
5. No previous multidisciplinary treatment for CLBP
6. No involvement in litigation concerning CLBP
7. Absence of serious psychological or psychiatric problems
8. No substance abuse interfering with treatment or assessment
9. Not pregnant
10. Able to fill in questionnaires without help
11. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/12/2004

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Dr. Jan van Breemen Institute
Amsterdam
Netherlands
1056 AB

Sponsor information

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

ROR
https://ror.org/01yaj9a77

Funder(s)

Funder type
Government

Funder Name
Netherlands Organization for Health Research and Development (ZonMw) (Netherlands) (ref: 014-32-041)

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	01/12/2008		Yes	No
Results article	results	01/02/2010		Yes	No
Results article	results	01/04/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes