ISRCTN22714229 https://doi.org/10.1186/ISRCTN22714229

(Cost-)effectiveness of a physical, a cognitive-behavioural and an integrated treatment in chronic low back pain disability

Submission date	Recruitment status	[ ] Prospectively registered
30/04/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/10/2017	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.lobadis.nl/lobadis/study3/default.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
014-32-007

Study information

Scientific Title
(Cost-)effectiveness of a physical, a cognitive-behavioural and an integrated treatment in chronic low back pain disability: a randomised controlled trial

Acronym
Lobadis 3

Study objectives
The treatment of non-specific chronic low back pain (CLBP) is often based on different models regarding the maintenance of pain and disability:
1. Loss of muscle strength and endurance including aerobic capacity (physical deconditioning model)
2. Avoidance of activity due to learning, cognitive processes and environmental influences (cognitive behavioral model)
3. The combination of both models (biopsychosocial model)

Four differing treatments were developed:
1. Active Physical Treatment (APT)
2. Cognitive-Behavioural Treatment (CBT)
3. Combination Treatment consisting of APT plus CBT (CT)
4. Waiting List control group (WL)

It is hypothesised that:
1. All three active treatments are more effective in reducing low back pain disability than a waiting list control treatment (short term analysis)
2. CT is more effective and cost-effective than APT and CBT

Additional research questions are:
1. Does deconditioning exist in CLBP-patients?
2. What factors mediate the decrease in outcome (especially the effect of pain catastrophising and internal control of pain will be investigated)
3. Can prognositic factors for each of the treatments be identified?
4. Do physiological and psychological factors that are often described as very important, influence the level of performance in CLBP-patients?
5. Psychometric research on the Roland Disability Questionnaire and Quebec Back Pain Disability Scale (stabilility and responsiveness)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non-specific chronic low back pain

Interventions
Active Physical Treatment (APT):
Cardiovascular and leg/back extending muscle strengthening (three sessions/week for ten weeks)

Cognitive-Behavioural Treatment (CBT):
Combination of graded activity of patient relevant activities and problem solving training (19 and ten sessions in ten weeks respectively)

Combination Treatment (CT):
Combination of APT and CBT in the same frequency

Waiting List (WL):
After ten weeks of no treatment regular rehabilitation treatment is offered

Post-treatment WL will be compared to APT, CBT and CT. Also, CT will be compared to APT and CT. Six and 12 months post-treatment CT will be compared to APT and CBT.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Roland Disability Questionnaire (RDQ)

Secondary outcome measures
1. Three patient specific main complaints by using the patient specific approach method (Tugwell et. al.)
2. Current pain by using the Visual Analogue Scale (VAS) for pain at this moment
3. Pain Rating Index (total score) of the McGill Pain Questionnaire
4. Beck Depression Inventory

5. Patients global assessment of overall result measured by a transitional seven-point ordinal scale (1 = vastly worsened, 7 = completely recovered)
6. Treatment satisfaction by using VAS for the overall treatment provided to the patient
7. Six performance tests:
a. five minutes walking (meters)
b. fifty foot walking (seconds)
c. five times sit to stand, performed twice and average time needed to perform a series of five times is calculated (seconds)
d. loaded forward reaching by holding a stick with a weight of 2.25 or 4.5 kg in front of the body at shoulder height and extend as far as possible (centimeters)
e. one minute stair climbing (number of stairs)
f. Progressive Isoinertial Lifting Evaluation (PILE)-test weight lifting from floor to waist

Overall study start date
01/04/2002

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Patients for the first time referred to three outdoor rehabilitation centers in the Netherlands
2. Age between 18 and 65 years
3. Non specific CLBP with or without irradiation to leg for more than three months resulting in disability (Roland Morris Disability score more than three)
4. Ability to walk at least 100 m without interruption

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
223

Key exclusion criteria
1. Vertebral fracture
2. Spinal inflammatory disease
3. Spinal infections or malignancy
4. Current nerve root pathology
5. Spondylolysis or -listhesis
6. Lumbar spondylodesis

7. Medical co-morbidity making intensive exercising impossible (e.g. cardiovascular or metabolic disease)
8. Ongoing diagnostic procedures or treatment for their CLBP at the time of referral
9. Not proficient in Dutch
10. Pregnancy
11. Substance abuse that could intervene with the rehabilitation treatment
12. Patients have to stop other therapies except pain medication for their back complaints
13. The Symptom Checklist (SCL-90) and the Dutch Personality Questionnaire (NPV) are used to check for psychopathology that would hamper individual or group processes

Date of first enrolment
01/04/2002

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
Rehabilitation Centre Blixembosch
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Sponsor information

Organisation
Netherlands Organisation for Health Research and Development (ZonMw)

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Sponsor type
Research organisation

ROR

https://ror.org/01yaj9a77

Funder(s)

Funder type
Research organisation

Funder Name
,950 Euro funded by Netherlands Organisation for Health Research and Development (ZonMw) (014-32-007)

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	20/01/2006		Yes	No