"Back on Track"; Chronic low back pain rehabilitation program in primary care

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Primary objective- To assess the differences in treatment effect (change of functional disability between pre- and post-treatment, and between pre-treatment and 3 months of follow up) between the new primary care intervention *Back on Track* and...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON40529

Source
ToetsingOnline

Brief title
Chronic low back pain rehabilitation program in primary care

Condition

- Other condition

Synonym
non-specific chronic low back pain, persistent low back complaints

Health condition

a-specifieke chronische lage rugklachten

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Provincie Limburg en CZfonds

Intervention

Keyword: Biopsychosocial intervention, Chronic low back pain, Functional disability, Primary care

Outcome measures

Primary outcome

Functional Disability: Quebec Back Pain Disability Scale (QBPDS)

Secondary outcome

Quality of Life: EuroQol (EQ-5D)

Anxiety & Depression: Hospital Anxiety and Depression Scale (HADS)

Catastrophizing: Pain Catastrophizing Scale (PCS)

Pain intensity: Numeric Rating Scale (NRS)

Kinesiophobia: Tampa Scale of Kinesiophobia (TSK)

Self-efficacy: Pain Self-Efficacy Questionnaire (PSEQ)

Credibility & Expectancy: Credibility Expectancy Questionnaire (CEQ)

Perceived effect: Global Perceived Effect (GPE)

Cost diary: Trimbos and iMTA questionnaire on Costs associated with Psychiatric

illness (TiC-P)

Social demographic characteristics of the patient: general questionnaire

including social demographic characteristics (age, gender, nationality, home

situation, educational level, employment status, health status)

Study description

Background summary

Chronic Low-back pain (CLBP) is one of the major health problems in Western countries and has high impact on medical and societal costs. For the majority of these cases (90%) medical specialists are not able to specifically find a cause for low-back symptoms and are therefore called non-specific low-back pain. Various therapeutic interventions have been developed to prevent or reduce CLBP and the accompanying high medical and societal costs. Interventions based on cognitive-behavioral concepts are assumed to be more effective as compared to exercise interventions since focusing on psychosocial factors might result in long-term effects as well. However, such interventions are primarily offered as a multidisciplinary rehabilitation programs and are very costly. Studies investigating whether it would be feasible and effective to substitute a multidisciplinary cognitive based program into primary care would therefore be of main importance. In addition, since previous studies suggested that the amount of improvement from an intervention based on psychosocial aspects might vary between subgroups of patients with CLBP (e.g. patients with complex psychosocial problems will respond differentially than patients with less psychosocial factors), it would therefore be interesting to evaluate the effect of such interventions in specific subgroups, especially in WPN2 and WPN3 since the contributing role of psychosocial factors in the maintenance of disability is only low to moderate.

The first part of this project will therefore focus on the effectiveness of a newly developed primary care intervention *Back on Track* in improving daily life functioning in patients with CLBP who are experiencing moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2-classification) as compared to regular physical therapy based on the Dutch guideline. It is expected that the new primary care intervention *Back on Track* will be more effective than primary care interventions without a cognitive behavioral approach (e.g. regular physical therapy). Subsequently it will be investigated whether the primary care intervention *Back on Track* will be more cost-effective than primary usual care.

In addition, patients experiencing moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is low to moderate (WPN3- classification) are hypothesized to benefit from this new intervention as well. Therefore, in the second part of this project it will be evaluated whether an intervention based on a cognitive behavioral approach is feasible and results in improved daily life functioning for this subgroup of patients.

Study objective

Primary objective
- To assess the differences in treatment effect (change of functional disability between pre- and post-treatment, and between pre-treatment and 3 months of follow up) between the new primary care intervention *Back on Track* and usual primary care in patients with CLBP experiencing moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

Hypothesis: It is hypothesized that the new primary care intervention *Back on Track* will be more effective in reducing functional disability at post-treatment and after 3 months follow-up than a usual primary care intervention in patients with CLBP experiencing moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

Secondary Objectives:
- To assess the difference in cost-effectiveness and cost-utility between the new primary care intervention *Back on Track* and usual primary care in patients with CLBP experiencing moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

Hypothesis: It is hypothesized that the new primary care intervention *Back on Track* will be more cost-effective in reducing functional disability than usual primary care in patients with CLBP experiencing moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

- To assess whether the primary care intervention *Back on Track* improves functional disability (QBPDS) directly after treatment and after 3 months of follow-up in patients with CLBP experiencing moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is low to moderate (WPN3-).

Hypothesis: It is hypothesized that the new primary care intervention *Back on Track* will improve functional disability directly after treatment and after 3 months of follow-up in patients with CLBP experiencing moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is low to moderate (WPN3-).

Study design

A *Back on Track* intervention study with a RCT-arm.

Patients with CLBP and classified as WPN2 and WPN3- will be recruited by consultants in rehabilitation medicine, working at Maastricht University Medical Center (MUMC+). Patients with a WPN2 classification will be randomized to either the new *Back on Track* primary care intervention or primary care as usual, both provided by physical therapists in primary care. Physiotherapy practices are located in Maastricht and surrounding villages. Both treatment periods will last for eight weeks maximally. Both patients and data-analysts will be blinded throughout the study. Patients classified as WPN3- will be informed about the study by their consultant in rehabilitation medicine and will be free to choose between the new intervention *Back on Track* and regular multidisciplinary pain rehabilitation care. Participation would automatically mean that they would receive the *Back on Track* intervention. Blinding is therefore not possible.

Intervention

The new primary care intervention *Back on Track* (intervention)
The *Back on Track* intervention comprises four individual sessions (30 minutes) and eight group sessions (60 minutes), provided by physical therapists in primary care. The intervention will include a combination of exercise therapy with cognitive behavioral elements. Using a biopsychosocial approach, patients will be stimulated to improve their perception and attitude about pain and functional status.
Physical therapists will receive a treatment manual with information about each session specifically and an education program (three evenings, four hours each). Patients will receive a book in which patients can make notes and homework.

Primary care as usual (control)
Content of consultations will not be protocolled, but therapists are requested to follow the guideline for low back pain of the Royal Dutch Society for Physical Therapy (KNGF Richtlijn, lage rugpijn). Patients will receive maximally 12 individual sessions for a maximum of 8 weeks.

Study burden and risks

Patients with CLBP and a WPN2 and WPN3- classification will be recruited by consultants in rehabilitation medicine, working at MUMC+ during a consultation (regular care). Patients who were found eligible for the study will receive both oral and written information (human subject information) about the study via the consultant in rehabilitation medicine. When patients are willing to participate in the study, the consultant in rehabilitation medicine asks for permission by a written consent to collect general contact information about the patient which will be send to the research team. The patient will be invited for an intake at Maastricht University (approximately 1 hour) to

receive additional information about the study, to ask remaining questions, to sign their informed consent and to perform baseline measurements (e.g. questionnaires; t=1). Finally, the patient will be randomized (WPN2) or allocated (WPN3-) to the specific treatment which will be both provided in Maastricht and surrounding villages. Treatment will last for 7/8 weeks in total. Directly after finishing the treatment (t=2) and after 3 months of follow up (t=3), questionnaires will be completed again (approximately 45 minutes). The questionnaires can be completed online at the individual*s home computer. In case patients are not able to fill in the questionnaires electronically, they will be offered paper questionnaires. Paper questionnaires will be send by post with a return envelope and stamp, what enables the patients to return the questionnaires after completing.

It is expected that the risks associated with participation to the study are negligible and that the burden will be minimal. Measurements that will be conducted during the study consist of questionnaires only and are not invasive or risk full. As discussed earlier, both treatments (intervention and control) are executed as regular care for several years already. All physical therapist will have basic knowledge about cognitive-behavioral principles since most curriculums of physical therapy academies include aspects of these principles (e.g. Graded Activity and Graded Exposure). In addition, physical therapists will follow an education program to ensure that they will be competent in providing the new intervention program and to ensure that the intervention will be delivered in a standardized manner as well.

We expect that patients with CLBP classified as WPN2 and WPN3- will directly benefit from the treatments. Furthermore, it is expected that the existing waiting list in multidisciplinary settings will shorten, due to the fact the study enables the patients to start the treatment in primary care almost directly. The *Back on Track* intervention will use open group sessions. In addition, the study enables the patients to receive treatments in physical therapy practices which will be located closely to the patient*s home. These physical therapy practices will probably be located more closely to the patient*s home than multidisciplinary rehabilitation centers. The *Back on Track* intervention might therefore minimize patient*s time for traveling.

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

- Chronic low back pain; defined as pain between scapulae and gluteal region, whether or not with radiation towards one or both legs, present for at least three months.
- Presence of contributing social and psychological factors, however not complex (WPN2 and WPN3-).
- Age between 18 and 65 year
- Sufficient knowledge of the Dutch language
- Acceptance towards the biopsychosocial approach instead of biomedical approach

Exclusion criteria

- Chronic low back pain attributable to e.g. infection, tumour, osteoporosis, fracture, structural deformation, inflammatory process, radicular syndrome or cauda equina syndrome
- Pregnancy
- Serious psychiatric disease that will interfere with rehabilitation treatment (according the expert opinion of the consultant in rehabilitation medicine).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	112
Type:	Anticipated

Ethics review

Not approved

Date:	24-02-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC 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	NL46421.068.13