The effectiveness of a biopsychosocial rehabilitation program in Primary care (Back on Track) versus primary care as usual in patients with chronic low back pain in which psychosocial factors minimally influence daily life functioning: A Randomized Controlled Trial

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Primary Objective: 1. To assess the difference in treatment effect (change in functional disability between pre-treatment and 12 months of follow-up post-treatment) between the new primary care intervention *Back on Track* and primary care as usual...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41907

Source
ToetsingOnline

Brief title
Chronic low back pain rehabilitation in primary care: an RCT

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: Adelante Zorgvernieuwing;Provincie Limburg & 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 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 multidisciplinary rehabilitation programs and are very costly. In addition, 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 may respond differentially than patients with less psychosocial factors). It would therefore be interesting to evaluate the effect of a biopsychosocial intervention provided in primary care in a specific subgroup, particularly in WPN2 since the contributing role of psychosocial factors in the maintenance of disability is at maximum low.

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). This new intervention will be compared with regular physical therapy in primary care settings. It is expected that the new primary care intervention *Back on Track* will be more effective than regular primary care physical therapy. Subsequently, it will be investigated whether the primary care intervention *Back on Track* will be more cost-effective than primary care as usual.

Study objective

Primary Objective:
1. To assess the difference in treatment effect (change in functional

disability between pre-treatment and 12 months of follow-up post-treatment) between the new primary care intervention *Back on Track* and primary care as usual in patients with CLBP experiencing moderate levels 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 12 months of follow-up post-treatment than a usual primary care intervention in patients with CLBP experiencing a moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

Secondary Objectives:
1. To assess the difference in treatment effect (change in functional disability between pre- and post-treatment) between the new primary care intervention *Back on Track* and usual primary care in patients with CLBP experiencing a 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 than a usual primary care intervention in patients with CLBP experiencing a moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

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

3. To assess the difference in cost-effectiveness and cost-utility over a one-year period between the new primary care intervention *Back on Track* and primary care as usual in patients with CLBP experiencing a 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 over a one-year period in reducing functional disability than primary care as usual in patients with CLBP

experiencing a moderate level of disability and the contributing role to this disability of psychosocial factors is at maximum low (WPN2).

Study design

A multicentre (n=8) double-blind Randomized Controlled Trial (RCT) will be conducted including a pragmatic design. Patients with CLBP and classified as WPN2 will be recruited by consultants in rehabilitation medicine, working at Maastricht University Medical Center (MUMC+). Patients will be randomized (central randomization) to either the new *Back on Track* primary care intervention or primary care as usual (ratio 1:1). Block-randomizations via a computerized random number generator including bloksizes of 4,6 and 8 will be used. No stratification. Both treatment conditions will be provided by physical therapists in primary care. Four physical therapy practices will provide the new *Back on Track* primary care intervention and four physical therapy practices will provide the primary care as usual intervention. The selected physical therapy practices in the study will be located in Maastricht and surrounding villages.

In total, both treatment conditions (the *Back on Track* intervention and primary care as usual) will last for 8 weeks maximally. Physical therapists who will provide the "Back on Track" intervention will receive a treatment manual and education program (three education meetings). Protocol adherence will be assessed using audio recordings. Patients will receive a workbook with explanations, illustrations and home assignments. Primary care as usual will comprise of regular physical therapy. Therapists will not receive a treatment protocol or educational program. It is expected that therapists will use the guideline for low back pain of the Royal Dutch Society for Physical Therapy (KNGF Richtlijn, lage rugpijn) during their consultations; however consultations will not be protocolled. Physical therapists are only advised to use maximally 12 individual sessions (30 minutes each) for a maximum of 8 weeks to preserve from endless treatments.

Overall, patients need to complete web-based questionnaires at four time points:
T1 = prior to the therapy
T2 = directly after completing the therapy
T3 = after three months follow-up
T4 = after twelve months follow-up

In addition, both therapists and patients will be asked to complete the CEQ-questionnaire directly after the first treatment.

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. 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 (for detailed information see protocol)

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). Physical therapists are only advised to use maximally 12 individual sessions (30 minutes each) for a maximum of 8 weeks to preserve from endless treatments.

Study burden and risks

It is expected that the risks associated with participation to the study are negligible and that the burden will be minimal. The measurements that will be conducted during the study consist of a set of questionnaires only and are not invasive or risk full. The patient will be invited for an intake at Maastricht University (±1 h) and need to complete the CEQ-questionnaire (±5 min.) and T2-, T3-, and T4-questionnaires at home (±45 min). In total, the burden for the patient to participate in this study will be approximately 3.5 hours. In addition, the *Back on Track* intervention will include approximately 10 hours divided over 7/8 weeks. Since care as usual is not protocolled, an accurate estimation about the required time for therapy cannot be provided. The study will restrict physical therapists providing care as usual only to provide maximal 12 individual sessions (30 minutes each) for a maximum of 8 weeks. No additional risks for *care as usual* are expected since therapists will provide primary physical therapy as usual which is regular care in primary care settings.
Overall, the *Back on Track* intervention is based on elements of cognitive behavioral interventions used in multidisciplinary pain rehabilitation settings (MUMC+ and Adelante, Hoensbroek, the Netherlands). Literature addresses the importance to implement these principles in the management of CLBP since these principles proved to be effective in reducing functional disability and pain. In addition, cognitive behavioral interventions seem effective in reducing fear-avoidance beliefs and anxiety/depression. The *Back on Track* will in part focus on elements of GA and GE. Advice, education about pain and potential influencing factors will be provided and patients will be stimulated to be physically active. The intervention will inspire confidence, attempts to reduce kinesiophobia and pain-related fear, and will stimulate patients to have pleasure in being active. All these elements are implemented in the MUMC+ and Adelante for more than 20 and 25 years

respectively, without any problems or negative effects. Also literature reported no adverse events when providing cognitive behavioral based therapies. Since most curriculums of physical therapy academies include cognitive-behavioral principles it is expected that general physical therapists in primary care already possess basic knowledge about cognitive-behavioral principles. It is therefore expected that the *Back on Track* intervention will be provided appropriately and without any additional risk. Physical therapists that will provide the *Back on Track* intervention will receive a treatment manual, an educational program and will make audio recordings in order to standardize the treatment and to assess protocol adherence.
As stated before, the *Back on Track* intervention focuses on exercise therapy as well. There is no evidence that exercise would increase the risk of future low back pain episodes. In contrast, literature showed that increased physical activity status would be beneficial and safe for people with low back pain. Increased physical status would prevent from future low back pain episodes.
Overall, it is important to keep in mind that this study will include only patients with a WPN2 classification. These patients are classified as not having extreme or complex psychosocial factors and high levels of disability. Therefore, it is expected that the *Back on Track* intervention will not be risk full. All patients with complex psychosocial factors and high levels of disability will not be included in the study.

We expect that patients will directly benefit from both interventions (*Back on Track* intervention and primary care as usual). Since the *Back on Track* intervention will focus on all biopsychosocial factors it is expected that this intervention will be more effective than primary care as usual and that these results will be maintained in long-term follow-up. Patients that will receive the *Back on Track* intervention will be stimulated to generalize aspects of the treatment to their daily life. Patients will receive a workbook as well. This will enable the patient to appropriately understand information provided in therapy and to reread this information. In addition, the *Back on Track* intervention will provide group sessions what might stimulate interaction between patients what might be beneficial for the rehabilitation process of the patient. A further aim of this study is to keep waiting lists to a minimum by using *open* group session in the *Back on Track* intervention. It is expected that an open group system will result in a continuous inflow of new patients and outflow of patients finishing the intervention. Patients do not need to wait for a new group but can continue their rehabilitation program. Furthermore, it is expected that patients might benefit from these open group sessions since patients on different levels might inspire each other. New patients might be stimulated and might learn from patients that were included earlier, while earlier included patients might recognize own improvements when comparing themselves with new patients. Another important benefit is the fact that the study will refund traveling expenses to Maastricht University and physical therapy costs. Refunding therapy costs will enable all patients to

receive physical therapy, irrespective of their health care insurance.

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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 classification)
- 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
- Any suspicion of an (underlying) psychiatric disease, for which psychiatric treatment is better suited, according to 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:	Recruitment stopped
Start date (anticipated):	27-08-2014
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO Date:	22-07-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-12-2014

Application type:	Amendment
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	NL48533.068.14

Study results

Date completed:	01-09-2017
Actual enrolment:	25

Summary results
Trial is onging in other countries