A primary care biopsychosocial intervention (Back on Track) for patients with chronic low back pain in which psychosocial factors moderately influence daily life functioning: A pilot study

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Primary Objective: 1. To assess whether the primary care intervention *Back on Track* significantly improves functional disability (QBPDS) between pre- and post-treatment in patients with CLBP experiencing a moderate to high level of disability and...

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

Summary

ID

NL-OMON41811

Source
ToetsingOnline

Brief title
Chronic low back pain rehabilitation in primary care: A pilot study

Condition

- Other condition

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

Health condition

aspecifieke chronische lage rugklachten

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiegeneeskunde
Source(s) of monetary or material Support: Adelante Zorgvernieuwing;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)

Social demographic characteristics of the patient: general questionnaire

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

situation, educational level, employment status, health status)

Treatment satisfaction: Treatment satisfaction questionnaire (TSQ)

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 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, it would therefore be interesting to evaluate the effect of such intervention in a specific subgroups, particularly in WPN3- since the contributing role of psychosocial factors in the maintenance of disability is mild to moderate.

This pilot study will therefore focus on the feasibility and effectiveness of a newly developed primary care intervention *Back on Track* which is based on multidisciplinary pain rehabilitation interventions in improving daily life functioning in patients with CLBP who experience moderate levels of disability and the contributing role to this disability of psychosocial factors is mild to moderate (WPN3- classification). It is expected that the new primary care intervention *Back on Track* will improve functional disability in this subgroup of patients with CLBP which normally receive multidisciplinary pain rehabilitation interventions.

Study objective

Primary Objective:
1. To assess whether the primary care intervention *Back on Track* significantly improves functional disability (QBPDS) between pre- and post-treatment in patients with CLBP experiencing a moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is mild to moderate (WPN3-).

Hypothesis: It is hypothesized that the new primary care intervention *Back on Track* will significantly improve functional disability between pre- and post-treatment in patients with CLBP experiencing a moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is mild to moderate (WPN3-).

Secondary Objective:
1. To assess whether the primary care intervention *Back on Track* significantly improves functional disability (QBPDS) between pre-treatment and 3 months of follow-up in patients with CLBP experiencing a moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is mild to moderate (WPN3-).

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

2. To assess whether the primary care intervention *Back on Track* significantly improves functional disability (QBPDS) between pre-treatment and 12 months of follow-up in patients with CLBP experiencing a moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is mild to moderate (WPN3-).

Hypothesis: It is hypothesized that the new primary care intervention *Back on Track* will significantly improve functional disability between pre-treatment and 12 months of follow-up in patients with CLBP experiencing a moderate to high level of disability and in which the contributing role of psychosocial factors to this disability is mild to moderate (WPN3-).

3. To assess the feasibility of the new primary care intervention *Back on Track* in terms of treatment expectations and credibility, treatment fidelity (quality), dose delivered (completeness), reach (participation rate), and dose received (exposure & satisfaction). (Process evaluation)

Hypothesis: It is hypothesized that the new primary care intervention *Back on Track* is feasible in terms of treatment expectations and credibility, treatment fidelity (quality), dose delivered (completeness), reach (participation rate), and dose received (exposure & satisfaction).

Study design

A pilot study with a pre-post test design will be conducted involving patients with CLBP and classified as WPN3-. Patient recruitment will be executed by consultants in rehabilitation medicine, working at Maastricht University Medical Center (MUMC+). Patients will have the opportunity to participate in

the study and to receive the *Back on Track* intervention or not to participate in the study and receive multidisciplinary care as usual. Since participation would automatically mean that they will receive the *Back on Track* intervention, randomization and blinding is not applicable.

In total, the new *Back on Track* primary care intervention will last for approximately 8 weeks. The *Back on Track* intervention will be provided by physical therapists in primary care and will comprise of four individual sessions (30 minutes) and eight group sessions (60 minutes) using a biopsychosocial approach. In order to standardize the new *Back on Track* primary care intervention, physical therapists who will provide this intervention will receive a treatment manual and education program which consist of three education meetings of 4 hours. Protocol adherence will be assessed using audio recordings.

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 and return it.

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 workbook with explanations, illustrations and home assignments.

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 questionnaires and are not invasive or risk full. The patient will be invited for an intake at the UM (±60 min) and need to complete the CEQ-questionnaire (±5 min.) and T2- (±50 min), 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.
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. 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 (for detailed information, see protocol § 5.1). 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 used in the *Back on Track* intervention. 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 WPN3- classification. These patients are classified as having no extreme or complex psychosocial factors and high levels of disability. Therefore, it is expected that the risks associated to the *Back on Track* intervention will be negligible. All patients with complex psychosocial factors and high levels of disability will not be included in the study. Furthermore, the consultant in rehabilitation medicine will keep responsibility for the treatment period and will be involved throughout the process. After the treatment period, all patients will receive a final evaluation with their consultant in rehabilitation medicine. The consultant in rehabilitation medicine will indicate the improvement of the patients, the patients* behaviors and the ability to generalize aspects from the intervention towards their home situation. This final evaluation with the consultant in rehabilitation medicine is comparable with regular care in multidisciplinary settings.

We expect that patients will directly benefit from the *Back on Track* intervention. The *Back on Track* intervention will focus on psychosocial factors and is assumed to have benefits on long-term. Patients will be stimulated to generalize aspects of the treatment to their daily life during the treatment. 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 which might stimulate interaction between patients and might be beneficial for the rehabilitation process of the patient. Another important benefit of the *Back on Track* intervention is the absence of waiting lists. Especially multidisciplinary cognitive behavioural treatments deal with large waiting lists. Since the *Back on Track* intervention uses open group sessions, it is expected that patients are able to start with the intervention almost directly. 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 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 who were included earlier, while earlier included patients might recognize own improvements when comparing themselves with new patients. Furthermore, the *Back on Track* intervention will be performed in physical therapy practices which will be located closely to the patient*s home. These physical therapy practices might be located more closely to the patient*s home than multidisciplinary rehabilitation centres. The *Back on Track* intervention might therefore minimize patient*s time for traveling. Another important benefit is the fact that the study will refund all traveling expenses to Maastricht University and physical therapy costs for the study. Refunding therapy costs will enable all patients to receive physical therapy, irrespective of their health care insurance.

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 (WPN3-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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-11-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	08-09-2014
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	NL48556.068.14