A classification algorithm for low back pain: matching patients to treatments that they are most likely to benefit from

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To evaluate the (cost)effectiveness of a classification algorithm, based on patient*s symptoms andclinical presentation, that directs patients with non specific LBP to the therapy (exercise therapy ormanual therapy) that they are most likely to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON31626

Source
ToetsingOnline

Brief title
CABP

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym
Low back pain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw Doelmatigheidsonderzoek

Intervention

Keyword: Exercise therapy, Low back pain, Manual therapy, Randomized controlled trial

Outcome measures

Primary outcome

General perceived recovery (7-point scale), functional status (ODI), pain

intensity (11-point NRS),

general health (SF-36) and quality of life (EuroQol). Assessments take place at

baseline, and 8, 26 and

52 weeks after randomization.

Secondary outcome

n a

Study description

Background summary

Low back pain (LBP) is common and has major consequences. Exercise therapy and manual therapy
are frequently applied and there is strong evidence that both are more effective than no treatment. But
effects are modest and it is still unclear what patients benefit most from what type of treatment.

Study objective

To evaluate the (cost)effectiveness of a classification algorithm, based on patient*s symptoms and
clinical presentation, that directs patients with non specific LBP to the therapy (exercise therapy or
manual therapy) that they are most likely to benefit from. In an US-based study, this algorithm has
proven to be effective. This is compared to the usual care.

Study design

A randomized controlled trial including cost-effectiveness and cost-utility analyses.

Intervention

Patients are randomized into the two groups. In the classification group patients receive treatment
(exercise therapy or manual therapy) as decided by the classification algorithm. Patients in the control
group receive usual care, that is without using the classification algorithm for treatment decision making.

Study burden and risks

The interventions as provided in this study are part of the daily routine in primary health care and therefore there are no risks in taking part in this study. The only extra burden is that some extra measurements will take place one before, and three afterwards in the course of one year. The physical measures (e.g. range of motion) are also part of daily routine in primary health care with no risks. The other measures include questionnaires only. This relative small burden is in proportion to the potential value as the results of this study can be used for improving the health care for patients with low back pain in the future.

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

patients with non-specific LBP for more than 6 weeks who attend a physiotherapist or manual therapist (with or without a GP referral). Non specific LBP is defined as pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without leg pain

Exclusion criteria

Pain caused by specific patho-physiological disorders (e.g. hernia nuclei pulposi, fracture or tumor).

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-05-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	02-04-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23039
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL20371.029.07
OMON	NL-OMON23039