Classification algorithm for low back pain.

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Is using the classification algorithm for matching LBP patients to treatments more effective and cost-effective as compared to usual care on the short and long term?

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23039

Bron
NTR

Verkorte titel
CABP

Aandoening

1. Low back pain;

2. classification algorithm;

3. clinical prediction rule.
(NLD: Lage rugklachten; classificatie algoritme; predictie regel).

Ondersteuning

Primaire sponsor: EMGO Institue, VU University Medical Centre
Overige ondersteuning: ZonMw (The Netherlands Organisation for Health Research and Development)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

An international expert panel recommended a core set for LBP (Bombardier 2000) using patient reported outcomes for pain, function, global recovery and return to work. In line with this the following validated outcome measures are used: global perceived recovery (7-point scale), functional status (Oswestry Disability Index (ODI)), and pain intensity (11-point NRS). All are measured by means of patient self report, that is, questionnaires.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Low back pain (LBP) is common and the associated costs are enormous. There is strong evidence that exercise therapy and manual therapy (both frequently applied in the Netherlands), are more effective than continued care by the GP or no treatment. But the effects are modest and no one is clearly superior. Matching LBP-patients to interventions that they are most likely to benefit from is a promising approach for improving the effectiveness of these treatments. There is evidence that a recently developed a classification algorithm improves clinical outcome for LBP patients.

Objective:

Is using the classification algorithm for matching LBP patients to treatments more effective and cost-effective as compared to usual care on the short and long term?

Study design:

A randomized controlled trial.

Study population:

We include patients with non-specific LBP (> 6 weeks) who attend a physiotherapist or manual therapist.

Intervention:

Group 1: Classification algorithm group. Here, based on the classification algorithm, patients receive exercise therapy (either a specific directional exercise program, or a specific trunk strengthening/stabilization exercise program) or manual therapy.
Group 2: Usual Care group. Here, patients receive treatment (exercise- or manual therapy) as customary in the current situation, that is, without using the classification algorithm.

Main study parameters/endpoints:

The following validated outcome measures are used: global perceived recovery (7-point scale), functional status (Oswestry Disability Index (ODI)), and pain intensity (11-point NRS). All are measured by means of patient self report (questionnaires). For the economic evaluation health care costs, patient and family costs, and production losses will be included. Relevant data is collected through cost diaries. The cost-effectiveness ratios will include the clinical effect measures of the trial (as described above) and work absenteeism. For the cost-utility the EuroQol and expressed in costs per QALY will be the primary end point.

Doel van het onderzoek

Is using the classification algorithm for matching LBP patients to treatments more effective and cost-effective as compared to usual care on the short and long term?

Onderzoeksopzet

Timing: baseline, 8 (post-treatment), 26 and 52 weeks after randomization.

Onderzoeksproduct en/of interventie

1. Classification algorithm group
In this group patients are classified according to the classification algorithm, taking into account: time since onset, age, location of symptoms, patients' response to repeated spinal movement, straight leg raise, prone lumbar instability test, lumbar range of motion (ROM) and aberrant movement during ROM (AROM), and the FABQ work subscale score. Based on this classification patients receive exercise therapy (either a specific directional exercise program, or a specific trunk
strengthening/stabilization exercise program) or manual therapy.

1.a. Specific directional exercise program
Based on movement testing and symptom response to positions of sitting, standing, or walking patients receive a repeated directional exercise program as described by Brennan (2006).

1.b. Trunk strengthening/stabilization exercise program

Here patients receive an exercise program focused on trunk strengthening and stabilization as described by Richardson (1995);

1.c. Manual therapy

Here patients receive treatment according to the Manual Therapy-guidelines of the Royal Association of Physiotherapy (KNGF) (Heijmans et al 2003), delivered by manual therapists, including thrust manipulation as described by Brennan (2006).

In all three protocols, if patients improve substantially (ODI score < 20, or a 30% reduction from baseline on the ODI), in line with Brennan(2006), they progress to a general exercise program following the KNGF LBP-guideline.

2. Usual Care group

In this group patients receive treatment (exercise- or manual therapy) as customary in the current situation, that is, without using the classification algorithm. Exercise therapy (delivered by physiotherapists) will be in line with the KNGF-guidelines for LBP and the latest evidence (Hayden et al 2005). It aims to optimize the mobility and stability of the lumbar spine, specifically focusing on stretching and strengthening. It will be a supervised, individually designed program. Patients are encouraged to perform exercises regularly and to incorporate them into daily routine. Modalities and passive 'hands-on' techniques are excluded.

Manual therapy (delivered by manual therapists) will follow the guidelines for manual therapists (Heijmans et al 2003) including 'hands-on' muscular mobilization techniques (aimed at improving soft tissue function) and specific articular mobilization techniques (i.e. to improve overall joint function). These techniques may be supported by exercises as described in the physiotherapy KNGF-guideline.
In both treatment groups frequency and maximum number of sessions are left, as in daily practice, to the discretion of the therapists (on average 7 to 9 sessions) Number of sessions and compliance to the treatment protocol will be evaluated through treatment registration forms.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are included if they suffer non-specific LBP for more than 6 weeks and 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, not caused by specific patho-physiological disorders (e.g. hernia nuclei pulposi, fracture or tumor).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Acute LBP less than 6 weeks, specific LBP (eg. osteoporosis, cauda equina syndrome, etc); pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2008
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-01-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 31626
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1134

Register	ID
NTR-old	NTR1176
CCMO	NL20371.029.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31626

Resultaten

Samenvatting resultaten

Apeldoorn AT, Ostelo RW, van Helvoirt H, Fritz JM, de Vet HC, van Tulder MW. The cost-effectiveness of a treatment-based classification system for low back pain: design of a randomised controlled trial and economic evaluation. BMC Musculoskelet Disord 2010;11:58.
Apeldoorn AT, Ostelo RW, van Helvoirt H, Fritz JM, Knol DL, van Tulder MW, de Vet HCW. A randomized controlled trial on the effectiveness of a classification-based system for sub-acute and chronic low back pain in primary care. Spine 2012;37:1347-56.
Apeldoorn AT, Bosmans JE, Ostelo RW, de Vet HCW, van Tulder MW. Cost-effectiveness of a classification-based treatment system for sub-acute and chronic low back pain in primary care. Eur Spine J 2012;21:1290-300.