Onderzoek naar het effect van orthomanuele behandeling bij rugklachten.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22432

Source
NTR

Brief title
OOG

Health condition

Chronic aspecific low back pain.

Sponsors and support

Primary sponsor: nil
Source(s) of monetary or material Support: Nederlandse Vereniging voor Orthomanuele Geneeskunde

Intervention

Outcome measures

Primary outcome

Intensity of low back pain on a 100 mm VAS
Global perceived recovery, measured on a seven point scale ranging from "completely

recovered"to "worse than ever.

Secondary outcome

1. Disability due to low back pain, measured by the Roland disability questionnaire;

2. Quality of life, measured by the Euroqol.

Study description

Background summary

Efficacy study of the additional value of orthomanual treatment in the painclinic treatment of chronic low back pain.

Study objective

Orthomanual treatment is of additional value in the painclinic treatment of chronic low back pain.

Study design

1. Baseline;

2. 3 months;

3. 6 months;

4. 12 months after start of treatment.

Intervention

1. Pain clinic treatment (usual care);

2. Pain clinic treatment + orthomanual treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Non-specific low back pain;

2. Duration at least 3 months;

3. Able to answer questionnaires in Dutch;

4. No previous orthomanual treatment.

Exclusion criteria

1. Specific low backpain, e.g.:

A. Spondylitis/ discitis;

B. Spondylolysis/ listhesis.

2. Contraindications for manipulation, e.g.:

A. Recent trauma;

B. Malignicy;

C. Osteoporosis;

D. Longstanding use of steroids;

E. Pregnancy.

3. Disorders hindering treatment, e.g.:

A. Anatomic anomalies ((hemi-)lumbalisation, (hemi-)sacralisation);

B. Low back surgery.

4. Disorders influencing the outcome, e.g.:

A. Lumbo-sacral radicular syndrome;

B. Systemic painsyndromes (fibromyalgia, RA);

C. Severe functional impairment of the lower extremity;

D. Severe scoliosis;

E. Muscular disease;

F. CVA.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-05-2009
Application type:	First submission

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
NTR-new	NL1708
NTR-old	NTR1818
Other	METc VU : 2008/24
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A