Efficacy of orthomanual treatment in addition to usual care in patients with low back pain in a painclinic population.

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

Summary

ID

NL-OMON38387

Source
ToetsingOnline

Brief title
Efficacy of orthomanual treatment

Condition

- Other condition

Synonym
low back pain/ lumbago

Health condition

standsafwijkingen van de wervelkolom

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Research is facillitated by the EMGO institute of the VU university;extra costs are paid for by the Dutch Association of Orthomanual Doctors (NVOMG)

Intervention

Keyword: Efficacy, low back pain, orthomanual treatment, painclinic

Outcome measures

Primary outcome

Outcome measures after 3, 6, and 12 months

Pain: VAS

Backspecific function: Roland Morris Disability Questionnaire

5 scale general measure of change

Secondary outcome

Outcome measures after 3, 6, and 12 months

Generic scale: Euroqol

Other treatments (out of protocol) and side effects will be recorded

Study description

Background summary

Orthomanual medicine is a manipulative treatment that has been developed in the Netherlands. The technique is frequently used in the treatment of chronic low back pain. A large observational study was conducted which had a short follow-up period and which used only limited measurement instruments. In this study about 3/4 of the patients reported an improvement of their complaints. This result is compatible with the experience of orthomanual physicians that the technique seems to be effective in the treatment of patients with long standing low back pain that has shown to be refractory to other types of

(manipulative) treatment.

Study objective

In the proposed study we wish to investigate whether orthomanual treatment is of additional value in the treatment of a population of patients with chronic low back pain. We aim to recruit a population that has been referred for evaluation to the painclinic, because these patients will generally have long standing complaints that have shown to be refractory to the usual first-line interventions.

Study design

Randomized controlled trial

Intervention

Intervention 1: usual care by painclinic
Intervention 2: usual care by painclinic + orthomanual treatment

Study burden and risks

Burden:
Next to the painclinic treatment patients in the interventiongroup will be referred to an orthomanual physician. The first consultation will be sceduled within three weeks after inclusion. A normal medical history and a normal medical examination will be conducted, together with the orthomanual examination, mainly to verify the possibility to treat the patient by orthomanual techniques, and to reconfirm in- and exclusioncriteria. Generally a series of 5-7 treatments is needed for a first correction. After three months the patient should be re-examined and in many cases a few corrections have to be repeated. If the treatment has been effective patients are advised to consult their physician only when complaits return. If the treatment has been uneffective it is possible that further treatment is advised. Generally 8-10 sessions of approximately 20 min. are needed in the first year.

Risk:
There is some literature about possible adverse effects of manipulative treatment in general. It shows that minor side effects, like temporary dizziness, are common after manipulation of the cervical spine, but that serious side effects are extremely rare. Reported side effects most frequently result from rotatory HVT techniques that are not used in orthomanual treatment. (savety reporting p. 8)

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

non specific low back pain
duration at least 3 months
able to answer questionnaires in Dutch
no previous orthomanual treatment

Exclusion criteria

contraindications for manipulation
specific low back pain
condition influencing treatment or outcome

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-11-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-02-2012
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL22636.029.08