Army Low Back Training Study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20205

Source
NTR

Brief title
ALBATROS

Health condition

Subacute and chronic nonspecific low back pain.

Sponsors and support

Primary sponsor: Pieter H. Helmhout and Chris C. Harts
address: see above
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

1. Global Perceived Effect;

2. Patient Specific Functional Status;

3. Low-back specific functional status (RDQ).

Secondary outcome

1. Tampa Scale for Kinesiophobia;

2. General Helath Qeuestionnaire;

3. Work and Social status;

4. Patient satisfaction;

5. Isometric strength of lumbar extensors.

Study description

Background summary

Although a substantial number of trials have been conducted that included lumbar extension training in low back pain patients, hardly any study has emphasized a minimal intervention approach comparable to ours.

Currently, a randomized controlled trial is carried out in six military health centers in The Netherlands and Germany, in which a 10-week program of not more than 2 training sessions (10-15 minutes) per week is studied in soldiers with nonspecific low back pain for more than 4 weeks. The purpose of the study is to investigate the efficacy of this 'minimal intervention program', compared to usual care. Moreover, attempts are made to identify subgroups of different responders to the intervention.

Besides, a baseline measurement, follow-up data are gathered at two short-term intervals (5 and 10 weeks after randomization) and two long-term intervals (6 months and one year after the end of the intervention), respectively.

Inclusion will end in July 2005.

Study objective

Efficacy of minimal intervention strategy (isolated training of the lumbar extensors) with the use of a control group receiving usual care.

Study design

N/A

Intervention

1. Isolated training of the lumbar extensors muscles on a training device in a 10-week progressive resistance training program;

2. Usual care including hands-on treatment (manual therapy) and/or hands-off treatment (excercise therapy without isolated lumbar extensor training and education).

Contacts

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Eligibility criteria

Inclusion criteria

1. Royal Netherlands Army militairy personnel aged between 18 and 55;

2. Non specific low back pain for at least 4 weeks;

3. Availabibity for treatment during (at least) 8 weeks.

Exclusion criteria

1. Specific LBP (fractures, tumors, herniated disc or other relevant neurologic diseases;

2. Treatment during the last month;

3. Spinal surgery in the past 2 years;

4. Disability to perform an isometric strength test of the lumbar extensor muscles.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2002
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	04-08-2005
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	NL71
NTR-old	NTR102
Other	: N/A
ISRCTN	ISRCTN19334317

Study results

Summary results

1. Arch Phys Med Rehabil. 2008 Sep;89(9):1675-85.
2. Comparison of a high-intensity and a low-intensity lumbar extensor training program as minimal intervention treatment in low back pain: a randomized trial. Helmhout et al. Eur Spine J. 2004 Oct;13(6):537-47.
3. Rationale and design of a multicenter randomized controlled trial on a 'minimal intervention' in Dutch army personnel with non-specific low back pain. Helmhout et al. BMC Musculoskelet Disord. 2004 Nov 9;5(1):40.