

Army Low Back Training Study

Submission date 02/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/10/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/06/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Army Low Back Training Study

Acronym

ALBATRoS

Study objectives

To evaluate the efficacy of progressive, isolated resistance training of the lumbar extensor muscles, compared to the usual care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethics Committee of the Netherlands Central Military Hospital.

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Aspecific low back pain

Interventions

Specific strengthening of the lumbar extensor muscles versus usual care for aspecific low back pain.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Global perceived effect, measured by self-assessment on a 7-point scale
2. Patient-specific functional status, measured by a questionnaire following a patient-specific approach

3. Low-back specific functional status, measured by the validated Dutch version of the Roland Disability Questionnaire

Beside a baseline measurement, follow-up data are gathered at two short-term intervals and two long-term intervals. Short-term follow-up measurements are at 5 and 10 weeks after randomisation. Long-term follow-up measurements are at 6 months and one year after the end of the intervention, respectively.

Secondary outcome measures

1. Fear of movement or re-injury, measured by the Tampa Scale for Kinesiophobia
2. Mental health, measured by the Dutch translation of the 12-item General Health Questionnaire
3. Social health, measured by a subscale of the Impact on Participation and Autonomy Questionnaire
4. Overall work status
5. Individual back extension strength progression
6. Patient satisfaction, measured at the end of the treatment program

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Overall study start date

01/04/2002

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. Military employees of the RNLA between the age of 18 and 54 years
2. At least 4 weeks of continuous or recurrent (at least three times a week) episodes of low back pain (LBP) pain localised
3. Between posterior iliac crests and angulus inferior scapulae
4. Availability to visit the local military health centre two times a week during 10 consecutive weeks
5. No more than two sessions of absence due to job-related activities (e.g. military exercise, course, leave)
6. Willingness to abandon other treatment interventions for the lower back during the intervention period
7. Signed informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

Not provided at time of registration

Total final enrolment

129

Key exclusion criteria

1. Spinal surgery in the last 2 years
2. Specific treatment for LBP in the last 4 weeks (e.g. physiotherapy, manual therapy)
3. Severe LBP which hinders in performing maximal isometric strength efforts
4. Specific LBP, defined as herniated disc, ankylosing spondylitis, spondylolisthesis
5. Neurological diseases

Date of first enrolment

01/04/2002

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

Germany

Netherlands

Study participating centre

P.O. Box 90004

Utrecht

Netherlands

3509 AA

Sponsor information

Organisation

Royal Netherlands Army (The Netherlands)

Sponsor details

Occupational Health and Safety Service

P.O. Box 90004

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Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Dutch Ministry of Defence (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/11/2004		Yes	No
Results article	results	01/09/2008	11/06/2019	Yes	No