

# Army Low Back Training Study

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Pieter Herman Helmhout

### Contact details

P.O. Box 90004

Utrecht

Netherlands

3509 AA

+31 (0)30 2366605

tgtf@army.dnet.mindef.nl

## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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.

**Key secondary outcome(s))**

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

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**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)

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Dutch Ministry of Defence (The Netherlands)

## **Results and Publications**

**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?
<a href="#">Results article</a>	results	01/09/2008	11/06/2019	Yes	No
<a href="#">Protocol article</a>	protocol	09/11/2004		Yes	No