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Army Low Back Training Study

Submission date	Recruitment status	[_] Prospectively registered
02/09/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/10/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2019	Musculoskeletal Diseases	

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

Utrecht
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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