

# Intensive back training protocol for low back pain

<b>Submission date</b> 26/05/2004	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/10/2021	<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**  
Prof Riekie de Vet

**Contact details**  
Van der Boechorststraat 7  
Amsterdam  
Netherlands  
1081 BT  
+31 (0)20 4448176  
hcw.dev@vumc.nl

## Additional identifiers

**Protocol serial number**  
945-03-2003

## Study information

**Scientific Title**  
Intensive back training protocol for low back pain

**Study objectives**

Low back pain is defined as pain and discomfort, localised below the costal margin and above the inferior gluteal folds, with or without leg pain. Non-specific low back pain is defined as low back pain not attributed to recognisable, specific pathology (e.g. infection, tumour, osteoporosis, rheumatoid arthritis, fracture, inflammatory process, radicular syndrome or cauda equina syndrome).

**Hypothesis:**

This trial will evaluate the cost-effectiveness and cost-utility of the intensive group training protocol compared with physiotherapy guideline care.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Quality of life

**Health condition(s) or problem(s) studied**

Non-specific low back pain.

**Interventions**

Intensive group training protocol (the protocol combines exercise therapy with principles of back school and behavioural therapy) versus physiotherapy guideline care.

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome(s)**

Not provided at time of registration

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/01/2006

**Eligibility**

**Key inclusion criteria**

Patients will be recruited by participating physiotherapists in Amsterdam and its environment.

Inclusion criteria are:

1. Patients with non-specific low back pain
2. Referred to physiotherapy by a general practitioner or medical specialist
3. Current episode of low back pain for more than 6 weeks
4. Age between 18 and 65 years
5. Health insurance with AGIS

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Total final enrolment**

114

**Key exclusion criteria**

1. Specific low back pain, attributable to e.g. infection, tumour, osteoporosis, rheumatoid arthritis, fracture, inflammatory process, radicular syndrome or cauda equina syndrome
2. Pregnancy
3. Pelvic pain or instability
4. Lawsuit
5. If their general practitioner or medical specialist advised them not to perform physically straining activities

**Date of first enrolment**

01/01/2005

**Date of final enrolment**

01/01/2006

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre**

Van der Boechorststraat 7

Amsterdam

Netherlands

1081 BT

# Sponsor information

## Organisation

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

## ROR

<https://ror.org/01yaj9a77>

# Funder(s)

## Funder type

Research organisation

## Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands) (ref: 945-03-2003).

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## 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>		29/07/2008	29/10/2021	Yes	No
<a href="#">Protocol article</a>	Protocol	01/11/2004		Yes	No