

Intensive back training protocol for low back pain

Submission date 26/05/2004	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 28/07/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 29/10/2021	Condition category Musculoskeletal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Riekke de Vet

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

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article		29/07/2008	29/10/2021	Yes	No
Protocol article	Protocol	01/11/2004		Yes	No