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Intensive back training protocol for low back pain

Submission date	Recruitment status	[X] Prospectively registered
26/05/2004	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
28/07/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2021	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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2005

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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)

Sponsor details
Laan van Nieuw Oost Indië 334
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Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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