Intensive back training protocol for low back pain.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27037

Source
Nationaal Trial Register

Brief title
N/A

Intervention

Outcome measures

Primary outcome

1. Functional status (Roland Morris Disability Questionnaire);

2. General improvement (6-point schale ranging from 'much worse' to 'completely recovered');

3. Pain intensity (11-point numerical rating scale);

4. Work absenteeism (number of days of sick leave);

5. General health, quality of life (Euroqol).

Secondary outcome

1. Fear avoidance (Tampa scale of kinesiophobia);

2. Catastrophising (Pain Coping Inventory);

3. Self-efficacy (Pain Self-efficacy Questionnaire);

4. Patient satisfaction (Hudak & Wright 2000);

5. Aerobic capacity (Chester Steptest);

6. Flexibility (Fingertip-to-floor distance);

7. Strength (Ito test).

Study description

Background summary

Background:

Low back pain is a major health and socio-economic problem in Western countries. It is one of the most frequent reasons for referral to physiotherapy in primary care. The variation in treatment of sub-acute and chronic low back pain is enormous. And the cost-effectiveness of these treatments has not been assessed.

Physiotherapist in the region of Amsterdam have developed a specific intensive group training protocol for the management of sub-acute and chronic low back pain. In this protocol the principles of exercise therapy, back school and behavioural treatment are combined.

Objective:

The objective of this study is to compare the cost-effectiveness of an intensive group training protocol including behavioural principles versus usual physiotherapy care for sub-acute and chronic low back pain.

Research question:

Is an intensive group training protocol including behavioural principles more (cost)effective than usual physiotherapy care for patients with low back pain?

Study design:

Randomised controlled trial (RCT) with an economic evaluation.

Study population:

Patients with non-specific low back pain referred to one of the participating physiotherapists by their general practitioner are eligible for participation in the trial.

Patients are included if the current episode of low back pain lasts more than 6 weeks and if the complaints show no tendency to decrease, meaning that the patient has not increased his activities in the last three weeks. Furthermore, patients have to be between the age of 18 and 65 years old, live or work in Amsterdam and have a health insurance with one insurance company (Agis). This health insurance company covers about 80 to 90 percent of the Amsterdam population and is the only company that reimburses the intensive group training protocol.

Patients are excluded from the study if:

1. they have specific low back pain, attributable to e.g. infection, tumour, osteoporosis, rheumatoid arthritis, fracture, inflammatory process, radicular syndrome or cauda equina syndrome;

2. their general practitioner or medical specialist advised them not to perform physically straining activities;

3. they are pregnant;

4. they have pelvic pain/instability;

5. they are dealing with a lawsuit related to either their low back pain or related to their disability for work. Patients are recruited by participating physiotherapists.

Interventions:

The protocol consists of exercise therapy, back school principles with adequate information about pain, ergonomics and advice on physical activity. Participants will be training in groups of 5-8 persons twice a week for an hour and a half during twelve weeks. Patients assigned tot usual physiotherapy care will receive individual physiotherapy according to the published Low Back Pain Guidelines of the Royal Dutch College for Physiotherapy.

Outcome measures:

All participants will be followed during one year; outcomes will be assessed at baseline, after 6, 13, 26 and 52 weeks. Primary outcome measures are functional status, general improvement, pain intensity, work absenteeism and general health. For the economic evaluation participants are asked to complete cost diaries; these include information on medical and non-medical costs.

Power/ data-analysis:

280 patients will be recruited, 140 patients with sub-acute and 140 patients with chronic low back pain. Intention-to-treat analyses will be conducted for all patients participating in both groups. Bootstrapping will be used for pair-wise comparison of the mean differences in direct health care, direct non-health care, total direct, indirect and total costs between the intervention groups.

Economic evaluation:

the cost effectiveness analysis will be conducted from a societal perspective. Direct health care costs, including the costs for physiotherapy, additional visits to other health care providers, prescription medication, professional home-care and hospitalisation and direct non-healthcare costs such as out-of-pocket expenses, costs for paid and unpaid help and travel expenses will be included. Also data on indirect costs of loss of production due to back pain will be estimated for both paid and unpaid labour.

Study objective

The intensive group training protocol is a new intervention that combines exercise therapy with principles of back schools and behavioural therapy. We expect this new intervention to be superior compared to usual physiotherapy care.

Study design

N/A

Intervention

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

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Eligibility criteria

Inclusion criteria

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

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.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2003
Enrollment:	280
Type:	Actual

Ethics review

Positive opinion

Date:	12-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL289
NTR-old	NTR327
Other	: 945-03-2003
ISRCTN	ISRCTN45641649

Study results

Summary results
BMC Musculoskelet Disord. 2004 Nov 23;5:45.