Lumbar supports for home care workers with low back pain, an efficacy study

Submission date	Recruitment status	Prospectively registered	
05/12/2005	No longer recruiting	☐ Protocol	
Registration date 05/12/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	Individual participant data	
06/04/2011	Musculoskeletal Diseases		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study objectives

Results of a systematic review showed that lumbar supports are not effective in the primary prevention of Low Back Pain (LBP), but there were positive indications for the secondary preventive use of lumbar supports in the reduction of low back pain. In this randomised controlled trial (RCT) we study the secondary preventive efficacy of these lumbar supports.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Low back pain (LBP)

Interventions

A lumbar support was provided to the intervention group in addition to usual care (primary and secondary care for the management of LBP, available as usual).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. Number of days low back pain per month
- 2. Number of days sick leave per year (calendar days)
- 3. Cost effectiveness

Key secondary outcome(s))

- 1. Severity of experienced low back pain (11 point NRS)
- 2. Functional status (Quebec Back Pain Disability Scale)
- 3. Compliance

Completion date

30/12/2004

Eligibility

Key inclusion criteria

- 1. Reporting LBP at the start of the study, or reporting two or more episodes of LBP in the 12 months prior to the start of the study
- 2. Performing medical care and/or domestic tasks as a home care worker

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Suffering from specific LBP e.g. rheumatoid arthritis or vertebral fractions
- 2. Pregnant at the start of the study
- 3. Receiving medical treatment for high blood pressure

Date of first enrolment

01/05/2003

Date of final enrolment

30/12/2004

Locations

Countries of recruitment

Netherlands

Study participating centre Erasmus Medical Center

Rotterdam Netherlands 3000 DR

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands) - Department of General Practice

ROR

https://ror.org/018906e22

Funder(s)

Funder type

Research organisation

Funder Name

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

Results and Publications

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?
Results article	results	01/09/2002		Yes	No
Results article	results	20/11/2007		Yes	No
Results article	results	15/12/2010		Yes	No