

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

Submission date 05/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 06/04/2011	Condition category 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 B.W. Koes

Contact details
Erasmus Medical Center
Department of General Practice
P.O. Box 1738
Rotterdam
Netherlands
3000 DR
+31 (0)10 4087620
b.koes@erasmusmc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/05/2003

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

Age group

Adult

Sex

Both

Target number of participants

360

Key exclusion criteria

1. Suffering from specific LBP e.g. rheumatoid arthritis or vertebral fractures
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

Sponsor details

P.O. Box 1738
Rotterdam
Netherlands
3000 DR

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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