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The Sherbrooke Model

Submission date	Recruitment status	[_] Prospectively registered
21/08/2003	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/08/2003	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/06/2009	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
3140.0001

Study information

Scientific Title

Acronym
ASE

Study objectives
A randomised controlled trial and cost-effectiveness evaluation in employees sick-listed for a period of 2 to 6 weeks due to low back pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study design, protocols, procedures and informed consent form were approved by the Medical Ethics Committee of VU University Medical Centre, and all participants provided written, informed consent.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non specific low back pain

Interventions
1. Participatory ergonomics
2. Graded activity
3. Usual care

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Return to work.

Outcome measures are assessed before randomisation (after 2 - 6 weeks on sick leave) and 12 weeks, 26 weeks and 52 weeks after first day of sick leave.

Secondary outcome measures
Secondary outcome measures:
1. Pain intensity
2. Functional status
3. General improvement

Intermediate variables:
1. Kinesiophobia
2. Pain coping

Cost-effectiveness analysis:
1. Direct and indirect costs due to low back pain

Outcome measures are assessed before randomisation (after 2 - 6 weeks on sick leave) and 12 weeks, 26 weeks and 52 weeks after first day of sick leave.

Overall study start date
01/01/1999

Completion date
01/10/2002

Eligibility

Key inclusion criteria
Workers on sick leave for 2 to 6 weeks due to non specific low back pain.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
1. Specific causes of low back pain:
1.1. Herniated discs with pareses
1.2. Paralysis
1.3. Spinal tumour
1.4. Spinal fracture
1.5. Ankylosing spondilitis
1.6. Spinal stenosis

1.7. Spondylolisthesis
1.8. Specific rheumatological diseases
1.9. Pregnancy
2. Serious psychiatric disorders
3. Legal conflict at work
4. Sick-listed due to low back pain less than one month prior to the current episode of sick leave

Date of first enrolment
01/01/1999

Date of final enrolment
01/10/2002

Locations

Countries of recruitment
Netherlands

Study participating centre
van der Boechorststraat 7
Amsterdam
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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: 3140.0001)

Funder Name
Dutch Ministries of Health, Welfare and Sports and of Social Affairs (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?
Protocol article	protocol	21/11/2003		Yes	No
Results article	results	01/02/2007		Yes	No
Results article	results	20/05/2009		Yes	No