

Transmural occupational care for low back pain, a randomised controlled trial and cost-effectiveness evaluation

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 18/03/2010	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR354

Study information

Scientific Title

Acronym

Bridge study

Study objectives

1. Is occupational transmural care for workers visiting outpatient clinics of a hospital more (cost-) effective on return-to-work than usual clinical medical care?
2. How is the program for transmural occupational care and its implementation (i.e. the applicability, compliance to, satisfaction, barriers) evaluated by patients with LBP, their employer and their health care professionals?

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Low back pain (LBP)

Interventions

1. Graded Activity protocol. Based on a cognitive behavioral program. It will be applied by a physical therapist.
2. Work(place) adaptations. Based on active participation and strong commitment of both the worker and the employer. It will be applied by a occupational therapist.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Sick leave duration until full return-to-work
2. Functional status
3. Pain
4. Direct and indirect costs

Key secondary outcome(s))

1. Pain coping
2. Quality of life
3. Patient satisfaction

Completion date

15/03/2009

Eligibility

Key inclusion criteria

1. Non-specific and specific low back pain, lasting more than 6 weeks
2. Sick listed due to low back pain (completely or partially)
3. Between 18 and 65 years of age
4. Employed in a company or organisation
5. Ability to complete questionnaires written in the Dutch language

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Specific low back pain due to spinal tumor; spinal fracture; or spinal inflammation
2. Cardiological diseases which hamper physical activity
3. Juridical conflict at work
4. Psychosis
5. Pregnancy; until 3 months after giving birth
6. Back surgery; until 6 weeks after

Date of first enrolment

15/03/2005

Date of final enrolment

15/03/2009

Locations

Countries of recruitment

Netherlands

Study participating centre
VU Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
TNO Quality of Life (Work & Employment) (Netherlands)

ROR
<https://ror.org/01bnjb948>

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Gak Institute Foundation (Stichting Instituut Gak [SIG])

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	20/09/2007		Yes	No
Results article	results	30/11/2009		Yes	No
Results article	results	16/03/2010		Yes	No