ISRCTN28478651 https://doi.org/10.1186/ISRCTN28478651

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

Registration date
19/12/2005

Overall study status
Completed

Last Edited
18/03/2010

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
1. Pain coping
2. Quality of life
3. Patient satisfaction

Overall study start date
15/03/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

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)

Sponsor details
P.O. Box 718
Hoofddorp
Netherlands
2130 AS

Sponsor type
Research organisation

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

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