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The Amsterdam Graded Activity Study

Submission date 30/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/05/2007	**Overall study status** Completed	
Last Edited 02/11/2022	**Condition category** 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
N/A

Study information

Scientific Title
The Amsterdam Graded Activity Study

Acronym
AGAS

Study objectives
A behaviour-oriented physical exercise program (graded activity) is more effective than usual care in sick-listed workers with low back pain with regard to return to work, disability, pain and pain-related fears.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, single blinded, active controlled, parallel group 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

Interventions
Graded activity:
The graded activity intervention consisted of two sessions of physical exercises a week until full return to regular work was achieved. The intervention was supervised by skilled physiotherapists. During the course of the intervention the load of the exercises was gradually increased towards a preset exercise goal, following a time-contingent exercise scheme. The exercise goals were connected with return-to-work goals. The intervention had a maximum duration of three months.

Usual care:
The workers who were allocated to the usual care group received the usual guidance by the occupational physician. There were no special requirements for other treatments except that the workers were not allowed to attend treatment sessions at the same physiotherapy practice where the workers of the graded activity group were treated.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Days of sick leave due to low back pain
2. Disability
3. Pain

Secondary outcome measures
Pain-related fears

Overall study start date
01/04/1999

Completion date
31/01/2002

Eligibility

Key inclusion criteria
1. Sick leave because of non-specific low back pain. This could be either full or partial sick leave
2. A minimum duration of the complaints of four weeks in succession

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
134

Total final enrolment
134

Key exclusion criteria
1. Radiation below the knee in combination with signs of nerve root compression
2. Cardiovascular contra-indications for physical activity, as checked by the Physical Activities Readiness Questionnaire
3. A conflict between worker and employer with legal involvement
4. Pregnancy

Date of first enrolment

01/04/1999

Date of final enrolment
31/01/2002

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije University Medical Centre (VUMC)
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details
Department of Public and Occupational Health
P.O. Box 7057
Amsterdam
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1007 MB

Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
The Dutch Health Care Insurance Board (CVZ) (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
Not provided at time of registration

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		20/01/2004		Yes	No
Results article		01/12/2005		Yes	No
Results article		01/07/2007		Yes	No
Results article		15/05/2008	02/11/2022	Yes	No