# The Amsterdam Graded Activity Study.

No registrations found.

Ethical review Positive opinion

**Status** Recruitment stopped

Health condition type -

Study type Interventional

## **Summary**

#### ID

NL-OMON26734

Source

NTR

**Brief title** 

**AGAS** 

#### **Health condition**

English: occupational health, low back pain, sick leave, behavioral, physical exercise, return to work, disability, pain.

(NLD: bedrijfsgezondheidszorg, lage rugpijn, ziekteverzuim, gedragsgeoriënteerd, lichamelijke oefeningen, werkhervatting, beperkingen, pijn).

### **Sponsors and support**

**Primary sponsor:** The study was initiated by the Department of Public and Occupational Health, VU University Medical Center

**Source(s) of monetary or material Support:** Grant Support: The Dutch Health Insurance Executive Council (CVZ), grant DPZ 169/0.

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

- 1. Days of sick leave due to low back pain;
- 2. Disability;
- 3. Pain.

#### **Secondary outcome**

Pain-related fears.

## **Study description**

### **Background summary**

Behavior-oriented graded activity interventions have been suggested for sick-listed workers with low back pain on return to work, but have not been extensively evaluated. One hundred and thirty-four workers were randomly assigned to either a graded activity intervention (n=67) or usual care (n=67) and followed-up for 12 months. The graded activity group returned back to work faster with a median of 54 days compared to 67 days in the usual care group. The graded activity intervention was more effective after approximately 50 days post-randomization (HRR = 1.9, CI = 1.2-3.1, p=0.01). Differences between the groups in number of recurrent episodes, total number of days of sick leave due to low back pain, and total number of days of sick leave due to all diagnoses, were in favor of the graded activity group, although not statistically significant. No effects of the graded activity intervention were found for functional status or pain.

Conclusion: Graded activity intervention is a valuable strategy to enhance short-term return to work outcomes.

#### Study objective

A behavior-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.

#### Study design

N/A

#### Intervention

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 3 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.

### **Contacts**

#### **Public**

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# **Eligibility criteria**

#### 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 4 weeks in succession.

### **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.

# Study design

### **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

#### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-04-1999

Enrollment: 134

Type: Actual

## **Ethics review**

Positive opinion

Date: 19-04-2007

Application type: First submission

# **Study registrations**

## Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

RegisterIDNTR-newNL928NTR-oldNTR952

Other :

ISRCTN ISRCTN46141261

## **Study results**

#### **Summary results**

- 1. Staal JB, Hlobil H, Twisk JW, Smid T, Koke AJ, van Mechelen W. Graded activity for low back pain in occupational health care: a randomized, controlled trial. Ann Intern Med 2004;140(2):77-84.<br/>
- 2. Hlobil H, Staal JB, Twisk J, Koke A, Ariens G, Smid T, van Mechelen W. The effects of a graded activity intervention for low back pain in occupational health on sick leave, functional status and pain: 12-month results of a randomized controlled trial. J Occup Rehabil 2005;15(4):569-80. <br/>
- 3. Hlobil H, Uegaki K, Staal JB, de Bruyne MC, Smid T, van Mechelen W. Substantial sick-leave costs savings due to a graded activity intervention for workers with non-specific sub-acute low back pain. Eur Spine J. 2006 Dec 21; [Epub ahead of print]. <br/>
- 4. Arthritis Rheum. 2008 May 15;59(5):642-9.<br