

# Ambulant feedback and monitoring program to influence the daily activity pattern of patients with chronic low back pain

Published: 23-04-2007

Last updated: 08-05-2024

The purpose of this study is to investigate whether ambulant feedback of measured activity pattern is able to change the daily activity pattern of patients with chronic low back pain.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON31222

### Source

ToetsingOnline

### Brief title

Ambulant feedback program for influencing daily activities

### Condition

- Other condition

### Synonym

chronic low back pain

### Health condition

ziekten van het bewegingsapparaat en het bindweefsel

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Revalidatiecentrum Het Roessingh

**Source(s) of monetary or material Support:** Senter

## Intervention

**Keyword:** daily activity pattern, feedback, individualized, low back pain

## Outcome measures

### Primary outcome

The main study parameter is physical activity pattern in daily life, expressed as mean absolute acceleration by means of a triaxial accelerometer.

### Secondary outcome

Physical fitness

Self- perceived activity level

Coping strategies

Disability level

Pain-intensity

Depression level

## Study description

### Background summary

Pain in the musculoskeletal system is an important public health problem due to high impact on disability, sickness absence, work disability and health care costs. Physical activity level is assumed to be an important determinant pain. Theoretical models together postulate that psychological aspects are important and that dependent on the cognitions of the patient, different behavior towards daily activities exist. Therefore it is important to make these patients aware of their inconsistent activity pattern by developing individually optimized treatment programs.

## **Study objective**

The purpose of this study is to investigate whether ambulant feedback of measured activity pattern is able to change the daily activity pattern of patients with chronic low back pain.

## **Study design**

A repeated measures design will be used to investigate the research questions. After the baseline measurement (pretest; T0), the four weeks of intervention (T1) will take place. After these weeks of intervention a second measurement period (post-test; T2) will be performed. After a month there will be a follow-up period (T3) where only questionnaires are taken.

## **Intervention**

Participants receive the accelerometer and PDA for a five-week period. On the PDA visible feedback is shown and during the intervention also individually tailored feedback is added. One group receives feedback every hour (group 1) and one group receives feedback 3 times a day (group 2). During this intervention both groups receive pop-ups of the VAS-scale three times a day to define how their pain intensity is at that moment.

## **Study burden and risks**

Patients can get an insight in their own activity pattern. They can become aware of their behavior and adjust this to their situation if necessary. Through regular feedback they learn how their complaints are related to his behavior in certain situations. This way, participants can keep their activity level balanced and this can influence their health.

As far as known, the participants are not exposed to any risks. The condition test is adjusted individually to each participant and controlled by heart rate. The functional test is assessed at normal, comfortable walking speed. During the intervention, daily activity is monitored with no hindrance of the ambulant activity device and the feedback is individual-tailored. The feedback tips are checked by specialists for harmfulness. The patient can ignore the feedback tips if he doesn't feel able to follow the tips.

## **Contacts**

### **Public**

Revalidatiecentrum Het Roessingh

roessingsbleekweg 33b  
7522 AH enschede  
Nederland  
**Scientific**  
Revalidatiecentrum Het Roessingh

roessingsbleekweg 33b  
7522 AH enschede  
Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

- age between 18 and 65 years
- primary complaint non-specific chronic low back pain
- no structural pathology

### **Exclusion criteria**

- wheelchair-bound patients
- specific causes of chronic pain
- surgery in the last 6 months
- terminal or progressive disease
- insufficient knowledge of Dutch language
- medication influencing daily activities (fatigue, dizziness)
- first generation non-western patients

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	42
Type:	Actual

## Ethics review

Approved WMO	
Date:	23-04-2007
Application type:	First submission
Review commission:	METC Twente (Enschede)

## 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.

5 - Ambulant feedback and monitoring program to influence the daily activity pattern ... 13-05-2025

## In other registers

### Register

CCMO

### ID

NL16462.080.07