# Testing a self-help intervention program for people with peripheral arterial disease: a pilot study among 10 patients

Published: 19-10-2009
Last updated: 04-05-2024

To examine whether a self-help psychological intervention program, based on relaxation, changing negative coping styles and finding new goals would be useful for people with PAD.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Arteriosclerosis, stenosis, vascular insufficiency and necrosis |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON33339

**Source**
ToetsingOnline

**Brief title**
Self-help intervention program for people with PAD

### Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

**Synonym**
Peripheral arterial disease, vasculair disease

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Universiteit Leiden
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** arterial disease, emotional problems, PAD, self-help intervention program

## Outcome measures

### Primary outcome

Only a short depression questionnaire of 7 items will be administered before

and after the self-help program.

### Secondary outcome

n.a.

# Study description

### Background summary

Given that PAD is a progressive disease with decreasing functioning and decreasing quality of life, and given the prevalence of depression among PAD patients and its assumed influence on the progression of a chronic disease, there is a need to examine what form of psychological support might help PAD patients to endure the course of the disease process. Therefore recent research has focused on the identification of risk factors and protective factors associated with the development of emotional problems in response to PAD. The results had two important outcomes: 1) that negative thinking styles (such as rumination, catastrophizing) are important risk factors for the development of emotional problems; and 2) that goal re-engagement strategies or putting effort towards new, meaningful goals are protective factors against the development of emotional problems in response to the PAD. On basis of these results, it has been suggested that self-help psychological intervention programs should be developed for people with PAD including both of these components. Studies in other illness populations already showed positive effects of self-help intervention programs in improving psychological health. The present study is a pilot study to examine whether such a self-help program would be useful for people with peripheral arterial disease as well.

### Study objective

To examine whether a self-help psychological intervention program, based on relaxation, changing negative coping styles and finding new goals would be

useful for people with PAD.

### Study design

In this pilot study, 10 PAD patients with mild depression scores (as assessed by the HADS) will be invited by their doctor in attendance to read and try-out the self-help program. People with cognitive impairments and people over 80 years will not be included. Approaching patients will occur according to a detailed schedule. People will receive information about the study and an informed consent form. Confidentiality is warranted. If a person is willing to participate, he or she receives the self-help program. After one week people are contacted by telephone by the doctor in attendance to ask about the progress. After four weeks, the participant will be contacted again by telephone to ask feedback about the program. They are also asked to answer the 7 items of the HADS depression scale again in order to be able to determine difference scores before and after the program.

### Intervention

The self-help program consists of a workbook and a work program. The content of the program is based on 3 themes: mindfulness-based relaxation, bringing about cognitive changes, and working on finding new goals. In the book, participants are suggested to work on the intervention 4 days a week (1 hour per day) for a period of 4 weeks. The first week focuses on relaxation exercises, the second and third week focuses on identifying and changing negative thoughts, and the fourth week focuses on finding new goals in life.

### Study burden and risks

n.a.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Male and female;
Age 80 years and younger;
Mild depression scores

## Exclusion criteria

older dan 80
cognitively impaired
mentally disabled

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Other |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 10-05-2010 |
| Enrollment: | 10 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 19-10-2009 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

## 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

| Register | ID |
|---|---|
| CCMO | NL28646.058.09 |