

# Effect-evaluation of the intervention “Being active without Worries”.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20588

### Source

NTR

### Brief title

N/A

## Intervention

## Outcome measures

### Primary outcome

Depressive and stress related symptomatology, as measured by the CES-D, perceived stress scale, daily hassles scale.

These measures will be administered two weeks before subjects start the course, 1 week after ending the course and next 6, 12 and 18 months after ending the course.

### Secondary outcome

Secondary outcomes are social support, mastery, self- esteem, self- efficacy, assertiveness and neighborhood perception

These will be measured two weeks before subjects start the course, 1 week after ending the course and next 6, 12 and 18 months after ending the course by means of questionnaires as the SSL, personal mastery scale, the NPV, ALCOS and the SIG.

Percentage of participating women will be determined by means of enrollment numbers for

the course, satisfaction with the course will be determined by means of a questionnaire.

## Study description

### Background summary

Social economic characteristics explain for an important part mental health problems. Individuals with a depression have often experienced one or more stressful life events in the year preceding their depression. The meaning attributed to these stressful experiences is an important explanatory factor in the onset of depression. Women with low social economic status (LSES) in disadvantaged neighborhoods are often charged with multiple stressors (low education, low income, poor labor conditions, unemployment) and are a vulnerable group for the onset of mental health problems such as depression and stress.

Nationally, the “coping with depression” course has been developed in different versions for different target groups. However, research shows that the course is not easily accessible for LSES groups. There is considerably more drop- out amongst LSES participants, the course level and homework are considered to be too difficult, and the enrollment method using ads is less suitable. The course has been adapted to the target population by, amongst others, adding an exercise component. Exercise has a beneficial anti- depressant effect.

The goal of the project is to carry out an effect evaluation of the course “being active without worries”, in order to investigate if the course can prevent depressive and stress related symptomatology in LSES women.

### Study objective

1. Can a larger percentage of Low SES women with depressive and/or stress related symptomatology be reached with an intervention when this contains an exercise component?
2. How effective is exercise only (B) compared to a control group (C) and does exercise plus psycho- education (BP) offer a surplus value above B?
3. How do LSES women appreciate this new intervention?

### Intervention

1. B-condition, the eight- week intervention is offered with only the exercise component;
2. BP-condition, the eight- week intervention is offered with the exercise and psycho- education components;
3. A C-condition, a control condition with postponed intervention for 3 months.  
(see also summary for explanation).

## Contacts

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## Eligibility criteria

### Inclusion criteria

The research population consists of adult women (20-55 yrs) with a low- SES background. Furthermore, the women must have mild to moderate (sub clinical) depressive symptomatology as measured with the CES- D, or suffer from stress related complaints.

### Exclusion criteria

Because of the design of the intervention, participants are not allowed to have severe hearing problems or severe physical handicaps.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)

Control: Active

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 30-08-2005  
Enrollment: 240  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 26-08-2005  
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

Register	ID
NTR-new	NL162
NTR-old	NTR197
Other	: ZonMw 4016.0004
ISRCTN	ISRCTN42389025

# Study results

## Summary results

N/A