

Effect-evaluation of the intervention "Being active without Worries"

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/11/2008	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
ZonMw 4016.0004; NTR197

Study information

Scientific Title

Effect-evaluation of the intervention "Being active without Worries": an intervention aimed at reducing depressive and stress symptomatology in adult low socioeconomic status (LSES) women from disfavoured communities

Study objectives

1. Can a larger percentage of low socioeconomic status (LSES) 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?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, single-blind, active controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Depressive and stress related symptomatology

Interventions

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. AC-condition: a control condition with postponed intervention for 3 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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 measures

1. Social support
2. Mastery
3. Self-esteem
4. Self-efficacy
5. Assertiveness
6. 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 such as the Social Support List (SSL), personal mastery scale, the NPV, ALCOS and the SIG. Percentage of participating women will be determined by means of enrolment numbers for the course, satisfaction with the course will be determined by means of a questionnaire.

Overall study start date

30/08/2005

Completion date

31/08/2009

Eligibility**Key inclusion criteria**

1. The research population consists of adult women (20 - 55 years) with a LSES background
2. Furthermore, the women must have mild to moderate (sub-clinical) depressive symptomatology as measured with the Centre for Epidemiologic Studies Depression Scale (CES-D), or suffer from stress related complaints

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

240

Key exclusion criteria

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

Date of first enrolment

30/08/2005

Date of final enrolment

31/08/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Maastricht University

Maastricht

Netherlands

6200 MD

Sponsor information

Organisation

University Maastricht (UM) (The Netherlands)

Sponsor details

P.O. Box 616

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Sponsor type

University/education

ROR

<https://ror.org/02jz4aj89>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (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

IPD sharing plan summary

Not provided at time of registration