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

Submission date	Recruitment status	[ ] Prospectively registered
20/12/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/12/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/11/2008	Mental and Behavioural Disorders	[ ] 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 disfavourised 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