Mindfulness as a preventive intervention: a randomized controlled trial.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24278

Bron
Nationaal Trial Register

Aandoening

Aandoeningen: Depressie en angststoornissen.
Depressie en angststoornissen komen veel voor en vormen een ernstig gezondheidsprobleem. Jaarlijks lijdt 1 op de 4 Nederlanders aan één van deze stoornissen (Meijer e.a., 2006). Ze behoren tot de top-10 van ziekten met de grootste ziektelast. Depressie heeft de hoogste prevalentie bij volwassenen. Jaarlijks hebben ongeveer 600.000 volwassenen in Nederland te kampen met een depressie (Bijl, Ravelli, & Van Zessen, 1998). Verreweg de belangrijkste risicofactor voor het krijgen van een psychische stoornis is het hebben van lichte tot matige psychische klachten (Smit e.a., 2004).

Disorders: Depression and anxiety disorders.
Depression and anxiety disorders are common health problems and are a serious health issue. Annually 1 out of 4 persons suffers one of these disorders in the Netherlands (Meijer e.a., 2006). They belong to the top-10 disorders with the largest disease burden. Depression has the highest prevalence for adults. In the Netherlands approximately 600.000 adults annually have a depression (axe, Ravelli, & Van Zessen, 1998). The main risk factor for developing a mental disorder is the presence of light to moderate mental symptoms (Smit e.a., 2004).

Ondersteuning

Primaire sponsor: Universiteit Twente
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Overige ondersteuning: Universiteit Twente
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Gebouw Citadel, kamer H401
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction of psychological symptoms (depression, anxiety).

Toelichting onderzoek

Achtergrond van het onderzoek

Depression and anxiety disorders are common health problems among adults in the Netherlands. These disorders have a major negative impact on the functioning and quality of life of the patient. Moreover, these disturbances lead to enormous health care costs annually and increased use of health services. The main risk factor for developing mental disorders is the presence of moderate depression and anxiety. Indicated prevention aims to reduce psychological symptoms and increase psychological flexibility thus decreasing the risk of mental disorders. GGNet has developed a preventive mindfulness training for adults with mild and moderate mental symptoms. This course is based on the principles of Mindfulness Based Cognitive Therapy (MBCT). The University of Twente will perform (in cooperation with GGNet, Dimence, Mediant and GGZ Leiden) an investigation into the effects of the course. The course is compared with a waiting list control group. Primary outcomes are anxiety and depression. Secondary outcomes are positive mental health, experiential avoidance and mindfulness.

Doel van het onderzoek

The purpose of the study is to conduct a randomised controlled trial with the training course 'Less stress through mindfulness' as an intervention to study the:

1. Effectiveness in terms of reduction of psychological symptoms (depressive symptoms and anxiety);

2. Effectiveness in terms of improvements in positive mental health, psychological flexibility and mindfulness.
The hypothesis is that the interventiongroup is superior to a comparison group, which offered no preventive intervention, in terms of clinical outcomes (reduction of psychological symptoms and improvement of positive mental health, psychological flexibility and mindfulness).

Onderzoeksopzet

The subjects have to work 1½ hours weekly for 11 weeks attending the course, with possibly a follow-up session after 4 to 6 weeks, and do exercises at home 30 minutes a day. At the beginning of the study there will be an introductory meeting of 30 minutes, plus a section of the M.I.N.I.-Plus of 15-30 minutes of duration. Furthermore, subjects are asked to fill in questionnaires at three times, with a load of approximately 1½-2 hours in total.

The following validated instruments will be used:

1. Depression and Anxiety: M.I.N.I-Plus;

2. Depression: Center for Epidemiologic Studies Depression Scale (CES-D);

3. Anxiety: HADS-A;

4. Psychological flexibility: Acceptance and action questionnaire II (AAQ-II);

5. Mindfulness: Five Facet Mindfulness Questionnaire (FFMQ);

6. Positive mental health: Mental Health Continuum – short form (MHC-SF);

7. Demografic variables: gender, age, education, marital status, cultural background, medication.

At the end of the course participant receive an evaluationform. The participants can indicate whether the course met their expectations, what they felt about the duration and content of the course, and what they felt about the contact with the teachers and the teaching material (degree of difficulty, amount of text, assignments, etc.). They can also give recommendations about the material.

Measurement points:

1. Baseline (T01) at the introductory meeting;

2. Pretest (T02) directly before the start of the course;

3. Posttest (T1) 3 months after the baseline;

4. Follow-up (T2) 3 months after the end of the course.

With exception of the demographic variables and the M.I.N.I.-Plus (only at baseline T01), all instruments will be administered at all three measurement points.

Onderzoeksproduct en/of interventie

TRAINING COURSE. The mindfulness training is a targeted intervention group of 11 meetings of 1½ hours and possibly a follow-up session after 4-6 weeks, which is conducted in groups of about 8 to 15 participants. This intervention is based on MBCT. The training consists of three elements: attention (session 1, 2 and 3), acceptance (5, 7, 9 and 10) and dealing differently with thoughts (session 4, 6 and 8). The last meeting has evaluation as a theme. In the first sessions participants learn how they can consciously focus their attention on the here and now. They also learn how to cope with periods of distraction from what they are doing and return to the present moment. Two basic exercises will be practised: the body scan and the focus of attention on breathing. The practice of mindfulness in daily life will be extensively dwelt on. In meetings about acceptance participants learn how they can be accept things as they are. The importance of the concepts are discussed and exercises are done to learn to accept negative emotions and thoughts. When dealing differently with thoughts, the emphasis is on learning that thoughts are not the basis of everyone's identity. One learns to observe thoughts as emerging and disappearing phenomena, take way from thoughts and not to respond to negative emotions and thoughts. For more information see the appendix (page 15 of the protocol).

CONTROLGROUP. The controlgroup is is offered the same intervention after 3 months. They will be placed in a waitinglist group, but are free to use other kinds of interventions.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults (male and female) of 18 years and older with mild tot moderate psychological distress.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Serious psychopathology requiring immediate treatment measured with the M.I.N.I.-Plus. When there is a serious depression or anxiety disorder, the clients will be referred to GGNet, Dimence, Mediant or GGZ Leiden for a treatment. There has been an agreement with the Health organisations that the clients will be seen shortly (within a week);

2. People recently started on pharmacological treatment, within three months (before the start of the research). If so, it is not well deductable if the effects are to be attributed to the intervention or the pharmacological treatment;

3. Currently undergoing psychological (self-help)treatment at a mental health institution;

4. Not enough time for following the training;

5. Inadequate control of the Dutch language (reading or learning difficulties).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-11-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1979
NTR-old	NTR2096
CCMO	NL29851.097.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A