'Living life to the fullest'. A randomized controlled trial.

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

Samenvatting

ID

NL-OMON20886

Bron
Nationaal Trial Register

Aandoening

(Symptomes of) depression and mood disorders
(Symptomen van) depressie en stemmingsstoornissen

Ondersteuning

Primaire sponsor: Universiteit van Twente
Overige ondersteuning: Universiteit van Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Reduction of mood symptoms and disorders.

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. Besides treatment, there is more evidence that prevention and early intervention is a cost-effective alternative to decrease the incidence of mental disorders. The main risk factor for developing mental disorders is the presence of moderate depression and anxiety. Indicated prevention en early intervention aims to reduce psychological symptoms and increase psychological flexibility, thus decreasing the risk of mental disorders.

The University of Twente therefore developed a online intervention, "VoluitLeven", for adults with symptoms of mood disorder and mild to moderate mood disorders in the Netherlands. This onlinecourse is based on the principles of Acceptance and Commitment Therapy (ACT) and mindfulness, and can be used as a indicated preventive and early intervention program. The onlinecourse can be worked through in the security of their own home and time, with help of a counselor.

This study there will be an investigation into the effects of the onlinecourse on psychological symptoms, mindfulness, psychological flexibility, positive mental health and cost-effectiveness. The intervention will be compared to a waitinlist controlgroup and a minimal intervention controlgroup.

Doel van het onderzoek

The purpose of the study is to conduct a randomised controlled trial with the onlinecourse 'Voluit Leven' as an intervention to study the:

1. Cost-effectiveness in terms of reduction of psychological symptoms (mood symptoms and disorders);

2. (Cost)effectiveness in terms of decrease in symptoms of anxiety;

3. Effectiveness in terms of improvements in mindfulness, psychological flexibility, agency and positive mental health.

The hypothesis is that:

1. The interventiongroup is superior to a waitinglist comparison group, with unrestricted access to usual care, in terms of cost-effectiveness;

2. The interventiongroup is superior to a minimal intervention comparison group, in terms of clinical outcomes (reduction of psychological symptoms disorders);

3. The interventiongroup is superior to a minimal intervention comparison group, in terms of reduction of symptoms of anxiety, and improvement of psychological flexibility, agency, positive mental health, and mindfulness.

Onderzoeksopzet

At the beginning of the study there will be an introductory meeting by phone of approximately 30 minutes, for exlusion of serious psychopathology using the M.I.N.I.-Plus and the SDS (Sheehan Disability Scale). Furthermore, subjects are asked to fill in questionnaires at fourtimes, before the randomisation, at 3 months, at 6 months, and at 12 months.

The following validated instruments will be used:

1. Diagnosis: M.I.N.I-Plus;

2. Severity: SDS;

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

4. Anxiety: HADS-A (Hospital Anxiety and Depression Scale - Anxiety);

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

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

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

8. Quality of Life: EQ (EuroQol);

9. Cost effectiviness: TIC-P (Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness);

10. Growth motivation: GMI (Grotwth Motivation Index);

11. Agency: Self defining memories;

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

13. Remaining: Alcohol (Weekly Recall), Mindfulnesspractice (open question).

Measurement points:

1. Baseline (T01) directly before the randomization;

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

3. Posttest (T2) 6 months after the baseline;

4. Follow-up (T3) 12 months after the baseline.

With exception of the demographic variables (only at baseline T01), the M.I.N.I.-Plus and the TIC-P (not at T1), all instruments will be administered at all four measurement points. Also the waitinglist condition will not have the measurement at follow-up (T3), because by then they have allready recieved the intervention.

Onderzoeksproduct en/of interventie

ONLINECOURSE 'VOLUITLEVEN':

Subjects receive the free onlinecourse "VoluitLeven", based on the book 'Voluit leven' (Bohlmeijer & Hulsbergen, 2009). The onlinecourse consists of nine modules that can be completed in 9 weeks. Because it is a onlinecourse, participants have a total of 12 weeks to complete the program. In module 1, the principles and objectives are introduced. In Module 2 and 3, participants will receive insight and experience that experiential avoidance does not work. In Module 4, 5 and 6 participants exercise with acceptance, mindfulness and cognitive defusion. In module 7 and 8 participants explicit their values and translate them into concrete behavior. Section 9 focuses on the maintaining of the health gains and relapse prevention.

WAITINGLIST CONDITION:

People who are on the waitinglist, do not receive an onlinecourse. They have unlimited access to standard care. So they can use all the care they want, something that is mentioned in the newsletter. The waitinglist group can get the onlinecourse they choose after 6 months (from baseline).

MINIMAL INTERVENTION CONDITION:

The people in the minimal intervention comparison group receive an onlinecourse Expressive

writing, where they are to write daily or regularly about negative emotions they have experienced during the day. It will require approximately 15-30 minutes each day to complete the assignments. In addition, they will spend 45 minutes a week on the feedback of the counselors. The diaries are private. The participants can send parts or conclusions of their diaries by mail in respond of the feedback and quetsions of the counselors at the end of the week. Participants can download and print their diaries for their own use.The coaching is identical to the intervention group.
The rationale of this intervention is that people are offered a meaningful but minimal intervention. We expect that mood symptoms will diminish, but to a lesser extent than participants in the onlinecourse "VoluitLeven." Also, we expect no effects on the assumed processes or mediators (psychological flexibility and mindfulness). Finally, we expect that in the long term effects will decrease while the effects of the onlinecourse ' VoluitLeven" will be retained. A similar design in which a comprehensive intervention was compared with a minimal intervention was successfully applied in a study on the effects of life-review (pot et al., 2008).

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Adults of 18 years and older with mild to moderate (symptoms of) mood disorder.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Serious psychopathology requiring immediate treatment measured by the M.I.N.I.-Plus and the SDS. The diagnostic interview will be performed by trained employees (under supervision of pdychologists with a BIG registration as a GZ-psychologist). When there is serious psychopathology, the clients will be referred to their general practitioner;

2. The presence of a moderate to high suicide risk in accordance with the M.I.N.I.-Plus;

3. Recently started on pharmacological treatment, before three months of the research. If so, it is not well deductable if the effects are to be attributed to the intervention or the pharmacological treatment;

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

5. Not enough time for following the training;

6. Inadequat control of the Dutch language (reading or learning problems).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	30-01-2011
Aantal proefpersonen:	195
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-02-2011
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	NL2608
NTR-old	NTR2736
Ander register	METiGG : 33619
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A