VoluitLeven.nl.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22631

Source
NTR

Health condition

Mood symptoms and -disorders.
Stemmingsklachten en - stoornissen.

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: University of Twente

Intervention

Outcome measures

Primary outcome

Reduction of mood symptoms and disorders.

Secondary outcome

Reduction of symptoms of anxiety and an improvement of mindfulness, positive mental health, psychological flexibility, agency and mindfulness. Reduction in costs of diseaese and health care use.

Study description

Background summary

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 mooddisorder and mild to moderate mood disorders. 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. In this study the onlinecourse there will be an investigation into the effects of the onlinecourse on psychological symptoms, mindfulness, psychological flexibility, positive mental health and cost-effectiveness.

Study objective

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; anxiety symptoms);

2. 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 mood symptoms and -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.

Study design

Participants of the experimental condition have to be willing to spend 2 to 4 hours a week during 9 weeks of the program. The time and place for practicing is free to decide. The participants in the minimal intervention condition have to be willing to spend 1 to 1½ hours during the 9 weeks program. They also are free to decide their own time and place for practicing.

Experimental condition and minimal intervention condition: From participation the subjects must complete a CES-D form. In addition, there will be a interview by phone, for use of the M.I.N.I.-Plus and the SDS. This gives a total burden of about 15-30 minutes. The additional questionnaire at T0 costs approximately 45 minutes to complete. The questionnaires at T1 are approximately 30 minutes to complete. At T2 and T3 the interview by phone is approximately 15-30 minutes to complete, and the questionnaire approximately 30 minutes. The total burden in the experimental and minimal intervention condition is 150-210 minutes.

Waiting list condition : From participation the subjects must complete a CES-D form. In addition, at T0 and T2 there will be an interview by phone, for use of the M.I.N.I.-Plus and the SDS. This gives a total burden of about 15-30 minutes. The questionnaire at T0 costs approximately 45 minutes to complete and the questionnaires at T1 and T2 are approximately 30 minutes to complete. The total burden in this waitinglist condition is 135-180 minutes.

The following validated instruments will be used:

1. Depression and Anxiety: M.I.N.I-Plus and Sheehan Disability Scale (SDS);

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

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

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

5. Mindfulness: Five Facet Mindfulness Questionnaire - Short form (FFMQ-SF);

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

7. Eusoqol (EQ);

8. Seldefining Memories (SDMS);

9. Growth Motivation index (GMI);

10. TRIMBOS/IMTA Questionnaire for Costs Associated with Psychiatric Illness, verkort (TIC-P);

11. Weekly Recall;

12. Demografic variables: gender, age, education, marital status, cultural background, daily activities.

Measurement points:

1. Baseline (T0) directly before the start of the intervention;

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

3. Follow-up (T2) 6 months after the end of the intervention;

4. Follow-up (T3) 12 months after the end of the intervention.

With exception of the demographic variables, the M.I.N.I.-Plus, SDS and TIC-P (interventiongroups not at T1; waitinglistgroup not at T1), all instruments will be administered at all three measurement points. The waitinglistgroup does not recieve the T3 measurement.

Intervention

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. For more information about the onlinecourse "VoluitLeven" see the Appendix in the research protocol.

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 etal., 2008).

Contacts

Public
Postbus 217
Wendy Pots
Enschede 7500 AE
The Netherlands
+31 (0)53 489 3913
Scientific
Postbus 217
Wendy Pots
Enschede 7500 AE
The Netherlands
+31 (0)53 489 3913

Eligibility criteria

Inclusion criteria

Participants are adults of 18 years and older, with no apparent psychopathology. However, they have mild to moderate mood symptoms and -disorders.

Exclusion criteria

1. Serious psychopathology requiring immediate treatment measured with the M.I.N.I.-Plus and the SDS. When there is serious psychoptahology, the clients will be referred to contact their general practitioner for treatment;

2. The presence of a mild to high suicide risk, measured by the M.I.N.I.-Plus;

3. People recently started on pharmacological treatment (for the mood symptoms or -disorders), within three months (before the start of the research);

4. Currently undergoing psychological (self-help) treatment;

5. Not enough time for following the onlinetraining;

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	01-03-2011
Enrollment:	195
Type:	Actual

Ethics review

Positive opinion Date:	28-07-2011
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	NL2864
NTR-old	NTR3007
CCMO	NL33619.097.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A