

Acceptance and Commitment Therapy as a self-help intervention for adults with mild to moderate psychological distress: a randomized controlled trial

Published: 04-09-2009

Last updated: 04-05-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON33448

Source

ToetsingOnline

Brief title

Acceptance and Commitment Therapy as a self-help intervention

Condition

- Mood disorders and disturbances NEC

Synonym

depression, sadness

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Fonds Psychische Gezondheid

Intervention

Keyword: Acceptance, Mindfulness, Prevention of psychological disorders, Self-help intervention

Outcome measures

Primary outcome

Decreased psychological distress (depression, anxiety)

Secondary outcome

Increased mental health.

Study description

Background summary

Many adults in the Netherlands suffer from mental disorders, such as depression and anxiety. These disorders have a high negative impact on the quality of life. They also cause high economic costs and increased use of health services. Besides treatment, there is more evidence that also prevention is a cost-effective alternative to decrease the incidence of mental disorders.

The University of Twente therefore developed the preventive group intervention *Voluit Leven*, based on Acceptance and Commitment Therapy for adults with mild to moderate psychological distress. The group intervention was evaluated in a randomized controlled trial with 93 adults with psychological distress. The results showed that the intervention group, compared with a wait list group, had decreased psychological distress (depression and anxiety), fatigue and had increased psychological flexibility and mental health.

This intervention is now developed as a self-help book based on Acceptance and Commitment Therapy and mindfulness, whereby people can work independently through the book with supportive counselor contact.

Study objective

The purpose of the study is to conduct a randomized controlled trial with the self-help intervention *Voluit leven* for adults with mild to moderate psychological distress.

The research question is: What are the effects of the preventive self-help

intervention *Voluit leven* for adults with mild to moderate psychological distress, based on Acceptance and Commitment Therapy, on psychological distress, fatigue, mindfulness, psychological flexibility and mental health as compared to a waitlist group?

Study design

A randomized controlled trial with three parallel groups:

1. Experimental condition: the self-help intervention *Voluit leven* with process monitoring by a counselor with e-mail contact.
2. Experimental condition: the self-help intervention with process monitoring and personal support by a counselor with e-mail contact.
3. Control condition: a waitlist group, the participants receive the self-help intervention after three months.

Intervention

Self-help intervention with process monitoring by a counselor : The self-help intervention *Voluit leven* is a book with 9 modules that can be followed in 9 weeks. The intervention is monitored by counselor e-mail contact.

Self-help intervention with process and personal support by a counselor: This is the same intervention described above, but the counselor provides also more personal support.

Waitlist group: The participants on the waitlist do not receive the intervention.

Study burden and risks

Participants have to work about 2 a 4 hours per week in the self-help book. Thereby, the participants are asked to fill out questionnaires at five moments. This gives a burden of about 4 hours. We expect not many risks for the participants, because there are relative healthy population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Adults of 18 years and older with mild to moderate psychological distress

Exclusion criteria

1. Serious psychopathology requiring immediate treatment measured with the M.I.N.I
2. Recently started on pharmacological treatment
3. Currently undergoing treatment at a mental health institution
4. Reporting no psychological complaints (a score of 9 or below on the CES-D or a score of 2 or below on the HADS-A) .
5. Not enough time for following the self-help intervention
6. Poor control of the Dutch language (reading or learning difficulties)
7. Not having e-mail address

Study design

Design

Study type: Interventional

Intervention model: Other

Allocation: Randomized controlled trial
Masking: Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-09-2009
Enrollment: 184
Type: Anticipated

Ethics review

Approved WMO
Date: 04-09-2009
Application type: First submission
Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL28042.097.09