

The stories we live by: A randomized controlled trial into the effects of a guided online self-help intervention based on integrative reminiscence for adults in the second half of life with mild to moderate depressive complaints.

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The University of Twente has developed an online preventive self-help course 'The stories we live by Online', with additional e-mail guidance of a counselor (The stories we live by + counselor) or online with peer contact (The stories we...

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

Summary

ID

NL-OMON39589

Source

ToetsingOnline

Brief title

Online course The stories we live by

Condition

- Mood disorders and disturbances NEC
- Lifestyle issues

Synonym

depressive complaints, gloom

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, guided online self-help, integrative reminiscence, mental health

Outcome measures

Primary outcome

The primary outcome measure is reduction of depressive symptoms, measured with the CES-D. Depressive symptoms are measured at baseline and 3, 6 and 12 months after baseline.

Secondary outcome

The secondary outcomes are improvements in health status (measured by the EQ-VAS, subjective health and functional limitations), positive mental health (measured by the MHC-SF), vitality (measured by the vitality subscale of the MOS SF-36), mastery (measured with the Pearlin Mastery Scale) and social support (measured by the SSL-12-I), and a reduction of loneliness (measured with the Loneliness Scale).

Study description

Background summary

Relevance

Within the preventive mental health care research on the effectiveness of interventions is highly valued. Randomized clinical trials are seen as the preferred method to demonstrate the effectiveness.

There is much interest in mental health care for courses aimed at the prevention of mental disorders. The group course "The stories we live by" is currently conducted by many mental health institutes in the Netherlands. If the effectiveness of online self-help course can also be demonstrated, mental health organizations can offer 'The stories we live by' in a cost-effective and fast way through the Internet. 'The stories we live by Online' can also be used by psychologists in primary mental health care. Within primary care, there is a great need for useful and affordable online interventions that can be used by psychologists independently. Counselors can guide participants of 'The stories we live by Online' in an easy and fast way, because of the relatively small time investment. In addition, it can shorten waiting times (Cuijpers & Schuurmans, 2007). Guidance via the Internet is accessible, effective and may reach hard-to-reach populations (Cuijpers & Schuurmans, 2007; Postel, de Jong & de Haan, 2005; Postel, de Haan, in Huurne, Becker & de Jong, 2011; Schalken, 2010). More and more institutions within the mental health extend the existing care with online and blended care courses. With this, organizations hope to reach more people: people who can not be achieved with regular face-to-face treatment.

Adults in the second half of life with depressive symptoms are currently insufficiently reached and a course focused on dealing with depression mainly achieves participants with severe depressive symptoms. Moreover, the threshold for participation in a group course is high, making it difficult to reach sufficient participants to start the course. The self-help course 'The stories we live by Online' is easily accessible, first because it is centered on memories of their own lives (reminiscence). This is a recognizable, daily activity of many adults in the second half of life. Second, participants are recruited from a positive framework, under the motto of enhancing the mental health instead of focusing on reducing psychological distress. In practice, adults with mild to moderate depression are well reached by an accessible course with such a positive approach (Fledderus, Bohlmeijer, Pieterse & Schreurs, 2012; Westerhof, Maessen, de Bruijn & Smets, 2008). Third, an online self-help course may reach other people, who do not want to go to a therapist or a face-to-face group course (Cuijpers & Schuurmans, 2007; Jorm & Griffiths, 2006). Mental health problems suffer from stigma and form a barrier to seek help from a professional (Jorm & Griffiths, 2006). In addition, people follow the course in their own time and at their own desired location, which provides benefits for people who work during the day and may not have time to take a course at preset times. Moreover, it saves people time because they do not have to travel to get to an intervention (Cuijpers & Schuurmans, 2007).

Study objective

The University of Twente has developed an online preventive self-help course 'The stories we live by Online', with additional e-mail guidance of a counselor (The stories we live by + counselor) or online with peer contact (The stories we live by + peer contact). The course can be followed by participants at home

in their own time. This study investigates the effects of the two variants of the course on depressive symptoms and well-being, compared with a waiting list control group, through a randomized controlled trial.

Primary Objective:

The primary objective of this study is to evaluate the effectiveness of The stories we live by Online with counselor or fellow participants as compared to a waitinglist control group in terms of reduction in depressive symptoms.

Secondary Objective (s):

The secondary objective of this study is to evaluate the effectiveness of The stories we live by Online with counselor or fellow participants as compared to a waitinglist control group in terms of reduction in terms of increase of (mental) health (positive mental health, vitality, mastery, social support) and decrease loneliness. Another secondary aim of this study is to determine whether ego-integrity and value-oriented living mediate the described effects.

Study design

A randomized, controlled intervention study with three parallel groups:

1. First experimental condition The stories we live by + counselor: the online self-help course 'The stories we live by' with support from a counselor by e-mail.
2. Second experimental condition The stories we live by + peer contact: the online self-help course 'The stories we live by' with support from peers (fellow participants).
3. Waiting list control condition: a waiting list group where the participants receive 'The stories we live by' after 6 months (choice in support from counselor or support from peers).

Intervention

The online self-help course is based on the self-help book "The stories we live by," and makes use of integrative reminiscence (life review). The intervention consists of six modules over 12 weeks. The experimental group The stories we live by + counselor receive 2-weekly feedback and support from the counselor via e-mail. Participants in the experimental group The stories we live by + peer contact individually follow the course, but react on each other 2-weekly. A peer group consists of 4 participants.

Study burden and risks

Participation in the study is expected to be without risks. The study is based on an earlier group course and self-help course on The stories we live by, which proved effective. In addition, participation is voluntary: the study participants can stop at any time and if necessary, seek an alternative

treatment. Participants with severe psychological problems are strongly advised to consult their general practitioner. The extra burden on the questionnaires is limited to approximately 200 minutes in the experimental conditions and 150 minutes for the waiting list control group, spread over 1 year.

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

- Age * 40
- The presence of mild to moderate depressive complaints (CES-D score * 10).

Exclusion criteria

- The presence of severe depressive complaints according to the M.I.N.I.
- A moderate or high risk of suicidality according to the M.I.N.I.
- Recently started with medication therapy for somberheids complaints (3 months ago).
- Receiving an ongoing psychological (self-help) treatment for depressive complaints.
- Not enough time to follow the course well.
- Poor mastery of the Dutch language (read or learning difficulties).
- No email address or no access to the internet.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-02-2013
Enrollment:	186
Type:	Actual

Ethics review

Approved WMO	
Date:	22-10-2012
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO	
Date:	25-02-2014
Application type:	Amendment

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	NL41224.044.12