

# De stories we live.

## A randomised controlled trial anex cost-effectiveness study.

Published: 04-02-2009

Last updated: 07-05-2024

Goals of the proposed study are to empirically test the course 'The stories we live by' on: 1. The effectiveness in reduction of depressive and anxiety symptoms; 2. The effectiveness in improvement of quality of life and psychological health;...

<b>Ethical review</b>	-
<b>Status</b>	Pending
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

### Summary

#### ID

NL-OMON32211

#### Source

ToetsingOnline

#### Brief title

The stories we live by.

#### Condition

- Other condition
- Mood disorders and disturbances NEC

#### Synonym

Depression, Generalized Anxiety Disorder, Major Depressive Disorder

#### Health condition

Ook nog bij psychische stoornissen: angststoornissen en -symptomen

#### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Twente

**Source(s) of monetary or material Support:** ZonMW

## Intervention

**Keyword:** 55 years and older, Depression and anxiety, Integrative reminiscence, RCT

## Outcome measures

### Primary outcome

Reduction of depressive and anxiety disorders.

### Secondary outcome

Promotion of quality of life and psychological health.

## Study description

### Background summary

Among elderly people, depression and anxiety are a significant health problem. By far the most important risk factor of late-life depression or anxiety disorder is the presence of depressive symptoms and/or anxiety symptoms. Prevention has to constitute a main objective, in order to reduce the risk of new onsets of anxiety and depression. International research indicates that integrative reminiscence leads to a reduction in depressive symptoms and may also be effective in reducing anxiety. Integrative reminiscence is a low threshold intervention specifically developed for the elderly and directed at an active re-evaluation of one's life. In this project the (cost-)effectiveness of the course 'The stories we live by', based on integrative reminiscence, is investigated. In this study the effects of the course on depression, anxiety, quality of life and mental health are investigated by means of a randomized controlled trial. In addition economic analyses will be conducted.

### Hypothesis:

The intervention is superior compared to the "no prevention" comparison condition in clinical outcome measures (reduction in anxiety and depressive symptoms and improvement in quality of life and psychological health) and cost-effectiveness.

### Study objective

Goals of the proposed study are to empirically test the course 'The stories we live by' on:

1. The effectiveness in reduction of depressive and anxiety symptoms;
2. The effectiveness in improvement of quality of life and psychological health;
3. The prognostic (moderating) factors that predict success or failure in symptom reduction (reminiscence style, personality, sex, initial symptom levels of depression and anxiety);
4. The presence or absence of mastery, sense of meaning, negative thinking as mediating factors;
5. The cost-effectiveness, or incremental costs, by avoided "possible cases";
6. The cost-utility, or incremental costs, by quality adjusted life year (QALY).

## **Study design**

The design of the study is a randomized controlled trial with two parallel groups. First there is the experimental condition, attending 'The stories we live by'. Second there is the "no-prevention" comparison condition with open access to care-as-usual, in which participants can use all care they wish. This is a pragmatic, non-blind multi-site trial.

## **Intervention**

The course 'The stories we live by' is offered twice by every participating mental health prevention department. This is a group specific intervention with a maximum of four participants, that consists of seven sessions of 2 hours and one follow-up session after eight weeks. In this intervention participants are invited to recall memories of their own life by means of different topics: youth and family, work and care, love and friendship, difficult times, life as a book with chapters, metaphors, meaning in life. Participants are given questions about these topics which they have to answer at home. Through specific questioning an active (re-)evaluation of one's own life story takes place.

The people that do not follow the course are compared to the comparison group. They do not receive a preventive course, but they do have an infinite access to care as usual. This means that they are allowed to use all care they wish, which is named with emphasis in the information letter they receive. After the study the comparison group is still invited to participate in the course.

## **Study burden and risks**

Burden associated with the intervention:

Participants of the course "The stories we live by" receive 1 intake-conversation (30 minutes), 7 course meetings and 1 follow-up meeting (all 2 hours). In being able to follow the course there is travelling involved.

De participants in the control group receive no intervention. After the research however, they are still offered to follow the course "the stories we live by".

Burden associated with the study:

Participants of this study have to fill out questionnaires at four different measure moments; before the intervention, 4 weeks after the start of the intervention, directly after the intervention and 6 months after the intervention. The first questionnaire is somewhat larger than the other questionnaires and will take approximately 60 minutes. Filling in the other questionnaires will take approximately 30-45 minutes by measure moment (for the questionnaires to use see pp. 7 and 8 of the protocol).

Additional estimation of the risks:

We do not expect any risks for the participants involved. After all:

1. Participants participate out of own movement because they suffer from light to moderate depressive complaints and/or anxiety complaints. The possibly positive result of diagnostic study into the possible presence of a depressive impairment cannot come as a complete surprise. In other words, the test person is not faced then with an incriminating fact new for him or and.
2. The intervention is consequently presented at any time as a possibility more of getting grip on one's life. In the course there is a focus on bringing forth memories and life-stories that empower the participant.

## 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

- An age of 55 years and over;
- The presence of clinical relevant depressive and/or anxiety symptoms;
- The willingness to autobiographical reflect oneself to find meaning and worth in life.

### Exclusion criteria

- The presence of a DSM-IV major depressive disorder
- The absence of depressive symptoms
- The presence of a DSM-IV generalized anxiety disorder
- The absence of anxiety symptoms
- Being actively treated elsewhere (with medication or psychotherapy) when registered
- Any condition that may prevent people from successful participation in the preventive group (like unable to function in a group or a crisis situation)

## 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:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	240
Type:	Anticipated

## Ethics review

Not available

## 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	NL22041.097.08