The stories we live by, a life-review method for people of 55 years and over with depressive and anxiety symptoms.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22643

Source
Nationaal Trial Register

Brief title
The stories we live by

Health condition

Depression, Anxiety

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Depressive symptoms, measured with the CES-D.

Secondary outcome

Secundary outcomes:

1. Current major depressive episode, measured with the MINI;

2. Anxiety symptoms, measured with the HADS-A;

3. Quality of life, measured with the EuroQol 5-D;

4. Positive mental health, measured with the MHC-SF.

Moderarting outcomes:

1. Demographics (age, gender and education level);

2. Personality, measured with the NEO-FFI;

3. Past major depressive episodes, measured with the MINI;

4. Important life events;

5. Chronic diseases.

Mediating outcomes:

1. Reminiscence functions, measured with the RFS;

2. Perceived control, measured with the Mastery scale;

3. Automatic positive thoughts, measured with the ATQ-P;

4. Meaning in life, measured with the MLQ-SF.

Measures for the economic evaluation:

1. Resource use, measured with the TIC-P;

2. Production losses, measured with the PRODISQ.

Study description

Background summary

A study evaluating “The stories we live by”, a preventive life-review group intervention, which was recently developed for adults of 55 years and over with depressive and anxiety symptoms. Both clinical and economic effectiveness will be evaluated in a pragmatic randomized controlled trial. The participants in the intervention condition will receive the 8-session preventive intervention. The participants in the control condition will have access to usual care.

Study objective

Our main hypothesis is that the life-review intervention leads to a significant reduction of depressive and anxiety symptoms, and in current major depression, and a significant improvement in quality of life and positive mental health, compared to the no-treatment control condition.

In addition, we explore if gender, age, education level, personality, past major depressive episodes, important life events and chronic diseases, in combination with the intervention, predict higher or lower effects on depressive and anxiety symptoms, quality of life and positive mental health.

Furthermore, we hypothesize that reminiscence functions, perceived control, automatic positive thoughts and meaning in life mediate the intervention’s effects on clinical endpoints.

Finally, we expect that the incremental costs per case of depression and anxiety avoided (cost-effectiveness) and per quality adjusted life year (QALY; cost-utility) are lower in the intervention condition, compared to the care-as-usual condition.

Study design

Participants will be asked to complete questionnaires at baseline (t0), directly after the end of the intervention (t1), 3 months after the end of the intervention (t2), and –only in the intervention condition– 6 months after the end of the intervention (t3). The primary and secondary outcome measures will be recorded at all measurements (except for current major depressive episode), moderators only once at t0, the mediators at t0, t1 and t2 and the measures for economic evaluation only at t0 and t2.

Intervention

Intervention:

The stories we live by integrates narrative therapy and life-review. The intervention is aimed

at four to six people and consists of eight similarly structured two-hour sessions. The essence of the intervention is to discover stories about one's life that help the individual to lead a contented life. The stories we live by consists of three main components. The first component is a focus on developing alternative, more positive, "thicker" life stories. Since the intervention is aimed at older adults with depressive and anxiety symptoms, we expect their stories to contain themes such as incapacity, disappointment and "being a victim".
The second important component of the intervention is the systematic evaluation of one's life course, with a special focus on integrating negative life events with positive life events within participants' life stories. The intervention places the problems and conflicts that participants experience in the context of their life course, which involves making explicit links between the past and the present. During the intervention meetings, participants have to review their lives. Each intervention meeting has a different life theme, namely "our origin", "youth", "work and care", "love and conflicts", "loss and difficult periods", "metaphor", "the course of
life" and "the future". Before each meeting, participants have to answer questions about different life themes. At home, they have to reflect upon these questions and write the responses down briefly. During the meetings, they have the opportunity to exchange and discuss the answers and experiences with the other participants. In the final meetings, attention is focused on the near future, to invite participants to convert their "new identity" into concrete actions.
The third important component of the intervention is the attention for specific positive memories, which are special and unique for a certain period in the participant's life. Participants have to write down exactly what they remember of this situation and describe it by means of the following questions: "Where was it?", "What did the environment look like?", "Which people where there and what did everyone look like?", "What happened exactly?".

Control condition:

Participants in the control condition receive no intervention. However, they have unrestricted access to care-as-usual and may receive all health care they desire. Moreover, participants are not withheld from any treatment (e.g. they may receive psychological treatment). In the context of the economic evaluation, health care uptake will be closely monitored. After conclusion of the RCT, the participants in the control condition will be invited to take part in the intervention.

Contacts

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Eligibility criteria

Inclusion criteria

1. An age of 55 years or over;

2. The presence of slight to moderate depressive and anxiety symptoms. The presence of these symptoms will be measured by a score of 10 and above on the Dutch version of the Center for Epidemiological Studies Depression Scale (CES-D) and a score of 3 and above on the Dutch version ofthe anxiety scale of the Hospital and Anxiety Scale (HADS-A).

Exclusion criteria

1. Diagnosed with full-blown depression or having a moderate to high suicide risk according the Dutch version of the Mini International Neuropsychiatric Interview (MINI);

2. Scoring below the inclusion criteria of depressive and anxiety symptoms, measured by a score of 9 and below on the CES-D and a score of 2
and below on the HADS-A;

2. Started taking anti-depressant medication or benzodiazepines recently (within the previous 2 months);

3. Currently receiving any psychological treatment;

4. Other serious psychopathology; then people are referred for psychological treatment.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	12-06-2009
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	NL1750
NTR-old	NTR1860
Other	ZonMw/METIGG : 120610003/ NL22041.097.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A