Effect of life review therapy in depressed palliative cancer patients.

No registrations found.

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

Summary

ID

NL-OMON28376

Source
Nationaal Trial Register

Brief title
SLRUAMRPIDPHANALCP

Health condition

depression, palliative care, quality of life, life review therapy

depressie, palliatieve zorg, kwaliteit van leven, life review therapie

Sponsors and support

Primary sponsor: VU university, VU medical center, Netherlands Cancer Instituut, Ingeborg Douwes Center
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Level of depressive symptoms (HADS)

Secondary outcome

1. Specificity of the autobiographical memory;

2. Ego-integrity;

3. Quality of life;

4. Quality of life of the spouse.

Study description

Background summary

Background of the study:

About 2500 Dutch individuals develop head and neck cancer (HNC) each year of who approximately 700 die from this disease. In about 50% of (HNC) patients in the palliative phase, comorbid symptoms of depression are present. Incurable ill cancer patients often experience feelings of sadness, depression, hopelessness and spiritual distress, such as an evaluation of one’s past and problems with finding a new meaning in life with a palliative disease. In the daily practice of psychosocial care there is an urgent need to evidence-based psychosocial intervention methods enhancing the quality of life and dying and relieving the emotional distress in palliative cancer patients. Structured life review therapy seems to be an intervention appropriate to this need.

Objective of the study:

The goal of this study is to investigate the effectiveness of a structured life review protocol named ‘’Dear Memories’’ on decreasing depressive symptoms and enhancing quality of life in palliative HNC and lung cancer patients. A second aim is to investigate whether the autobiographical memory is malleable. We would like to investigate possible determinants of efficacy of the intervention, such as age, gender and cultural background. If the protocol appears to be effective, it can be introduced in psychosocial care in other cancer patients as well.

Study design:

A multicenter prospective randomised control trial with two parallel groups. Patients are assigned to either an intervention group; receiving the life review protocol immediately after

premeasurement or to a waiting list condition, receiving care-as-usual and a follow-up measurement after one month to asses long-term effectiveness.

Study population:

A sample of 150 HNC and LC patients without curative treatment options with a prognosis of > 3 months and with depressive symptoms (HADS score>7) will be included. Exclusion criteria are very severe depressive symptoms, cognitive impairment, not able to communicate verbally, insufficient mastery Dutch language, psychotic symptoms or behaviour (delusions or hallucinations).

Intervention:

The intervention will be individually administered and consists of four weekly sessions, with every session focusing on a particular life period – childhood, adolescence, adulthood and summary. For each period, 14 questions are prepared that are designed to prompt specific positive memories. For example: ‘’What is the most pleasant situation that you remember from your childhood? The interviewer tries to get a specific view of the situation by asking for more information. Patients receive feedback on how well they are doing in retrieving specific memories.

Primary study parameters/outcome of the study:

Primary outcome is level of depressive symptoms (HADS).

Secundary study parameters/outcome of the study:

Secondary outcome measures of the respondents are clinical depression (MINI), quality of life (EORTC QLQ-PAL15, EORTC QLQ-HN35, EORTC-QLQ-LC13), ego integrity (NEIS) and specificity of Autobiographical Memory (AMT). Outcome measures of partners are: level of depressive symptoms (HADS), care givers reaction (CRA) and post traumatic growth (PTGI).

Study objective

The LRT is expected to have a positive effect on quality of life, decreasing level of depressive symptoms and improving specificity of autobiographical memory retrieval.

Study design

Pre-test, post-test (5 weeks) and follow-up test (9 weeks).

Intervention

Patients are assigned to either an intervention group; receiving the life review protocol immediately after premeasurement or to a waiting list condition, receiving care-as-usual and a follow-up measurement after one month to asses long-term effectiveness.

Life review therapy, called "dear memories" existing of four structured interviews on positive memories from the past. The intervention will be individually administered and consists of four weekly sessions, with every session focusing on a particular life period – childhood, adolescence, adulthood and summary. For each period, 14 questions are prepared that are designed to prompt specific positive memories. For example: ‘’What is the most pleasant situation that you remember from your childhood? The interviewer tries to get a specific view of the situation by asking for more information. Patients receive feedback on how well they are doing in retrieving specific memories.

Contacts

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Eligibility criteria

Inclusion criteria

1. Palliative head and neck and/ or lung cancer patients with a prognose of > 3 months, with a clinical significant level of depressive symptoms (as assessed with the HADS; MINI interview);

2. No severe impediments in oral communication;

3. Capability to express themselves in Dutch.

Exclusion criteria

Psychotic behaviour (delusions or hallucinations) or severe anxiety or depressive symptoms.

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):	01-06-2010
Enrollment:	150
Type:	Actual

Ethics review

Positive opinion

Date:	23-03-2010

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	NL2132
NTR-old	NTR2256
Other	VUmc Amsterdam : WC2009-108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
none