

Effect of life review therapy in depressed palliative cancer patients.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28376

Bron

Nationaal Trial Register

Verkorte titel

SLRUAMRPIDPHANALCP

Aandoening

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

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

Ondersteuning

Primaire sponsor: VU university, VU medical center, Netherlands Cancer Instituut, Ingeborg Douwes Center

Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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 assess 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).

Secondary 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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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 assess 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.

Contactpersonen

Publiek

VU University

Dept of clinical psychology

Van der Boechorststraat 1
Gitta Kleijn
Amsterdam 1081 BT
The Netherlands
+31 (0)20 5988782

Wetenschappelijk

VU University

Dept of clinical psychology

Van der Boechorststraat 1
Gitta Kleijn
Amsterdam 1081 BT
The Netherlands
+31 (0)20 5988782

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Palliative head and neck and/ or lung cancer patients with a prognosis 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-06-2010
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	23-03-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2132
NTR-old	NTR2256
Ander register	VUmc Amsterdam : WC2009-108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

none