

# The development, implementation and evaluation of the meaning-centered group psychotherapy 'Living Meaningfully with Cancer' in the Netherlands

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Purpose of project-We want to develop, implement and evaluate an 8-session meaning-centered group psychotherapy for Dutch cancer patients, on the basis of Breitbart's intervention, entitled 'Group Training Living Meaningfully with Cancer...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON39101

### Source

ToetsingOnline

### Brief title

Training Living Meaningfully With Cancer

### Condition

- Other condition

### Synonym

psychological distress regarding meaning-making in cancer patients

### Health condition

psychologische stress bij kankerpatiënten

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit

**Source(s) of monetary or material Support:** KWF / Alpe d'Huizes

## Intervention

**Keyword:** psycho-oncology, psychotherapy, randomized controlled trial

## Outcome measures

### Primary outcome

Primary outcome: meaning-making

-The Dutch Personal Meaning Profile (39 items) has 5 scales: religion, dedication to life, fairness of life, goal-orientedness, relationships (\*>.80; sufficient validity) (86).

-The Dutch Post Traumatic Growth Scale (21 items) has 5 scales: relationships, viewing new possibilities, personal strength, spirituality, appreciation of life (\*>.80; sufficient validity) (87).

-The Dutch Ryff's conceptual wellbeing scale (52 items) has 6 scales: autonomy, environmental mastery, personal growth, positive relationships, purpose in life, self-acceptance (\*>.80; sufficient validity)(88).

### Secondary outcome

The Dutch Hospital Anxiety and Depression Scale(14 items) has two scales: depression, anxiety(\*>.80; sufficient validity)(89).

-The Dutch Beck Hopelessness Scale(20 items) measures hopelessness(\*>.80; sufficient validity) (90).

-The Dutch Life Orientation Test(10 items) measures optimism(\*>.80; sufficient

validity) (91).

- The Mental Adjustment to Cancer scale (40 items) measures specific responses and coping with cancer (\*>.80; sufficient validity)

- The Dutch EORTC QLW-C30(30 items) measures tumor-specific health-related quality-of-life, functioning, and physical symptoms(\*>.80; sufficient validity)(e.g.92).

## Economic evaluation

The economic evaluation will be conducted as a cost-utility analysis for

(changes in) health-related quality of life. Patient outcome analysis:

Health-related quality of life will be assessed with help of the EQ-5D (15 items) at baseline and 3, 6 and 12 months follow-up. Direct medical and direct non-medical cost data are collected with the TIC-P 39 (35 items), a widely used health service receipt interview in economic evaluations. Unit resource use (GP visits, hospital days, etc.) will be multiplied by their appropriate integral cost prices.<sup>40</sup> Indirect non-medical cost data related to production losses through work loss days and work cutback days will be sampled with the appropriate PRODISQ modules.

## Study description

### Background summary

Background-In the past, when a patient was diagnosed with cancer, this often meant a short remaining time to live. Nowadays, patients live with cancer for a longer time. This also implies a shift in the requested psychological help from palliative/terminal care towards help with finding meaningful ways to continue

their lives, despite physical limitations and uncertainties. Literature shows that meaning-making is important for cancer-patients: 1.meaning-focused coping is at the core of adequate adjustment to cancer; 2.despite a lack of pathological distress, up to 70% of cancer-patients have questions and needs regarding meaning-making; 3.up to 70% of the patients wish to be helped with meaning-making; 4.cancer patients who experience their life as meaningful are better adjusted, have better quality-of-life and psychological functioning. Most psychological interventions focus at teaching adequate coping and preventing/treating psychiatric symptoms, and not at living with cancer. There are few evidence-based interventions to help patients finding ways to live meaningfully with cancer. Breitbart et al developed an 8-session meaning-centered group psychotherapy for cancer-patients in New-York, based on Victor Frankl's logotherapy. The therapy is directed at stimulating the patients' search for meaning, through creativity, experience, attitude and legacy, and consists of didactics, discussion and experiential exercises. Breitbart et al found large improvement in his patients' meaning-making and psychological functioning. These effects ( $d=.8$ ) were larger than the small effects of non-meaning centered psychological interventions. These effects were also larger than other existential therapies which had small to moderate effects, possibly because the latter were often relatively unstructured/non-directive. The effects of Breitbart's therapy may be explained by its: 1.direct focus at meaning-focused coping and goal reengagement, with many sources of meaning; 2.structured/manualized approach; 3.actively stimulating and deepening experiences; 4.practical; 5.providing explanations; 6.unconditional positive regard.

## **Study objective**

**Purpose of project-**We want to develop, implement and evaluate an 8-session meaning-centered group psychotherapy for Dutch cancer patients, on the basis of Breitbart's intervention, entitled 'Group Training Living Meaningfully with Cancer'.

**Purpose of therapy-**The therapy purpose is to help patients to find their own ways to satisfactorily design and live their lives meaningfully within the context of physical limitations and uncertainty of having cancer. Specific purposes are: search for meaning (e.g. reordering/evaluating old meanings, search for new meanings, overcoming practical limitations); concrete goal-reengagement in daily life; learning to distinguish between what can and what cannot be changed; integration of cancer in life history; emotional expression and social support; improved psychological functioning.

**Possible results and relevance-**An evidence-based, manualized intervention will be developed to help patients living meaningfully with cancer despite physical limitations and uncertainty of cancer. This intervention is expected to meet the meaning-centered needs of cancer-patients more explicitly than other

psychotherapies. A practical therapy manual and therapist training protocol will be developed for implementation in other centers for oncological/psychosocial care.

## **Study design**

Plan of investigation-The project will be performed in 5 phases: 1. two focus groups with 6-12 cancer-patients will be performed, and approval by the medical-ethical committees will be obtained; 2.translation/adaptation of therapy and training of therapists, in discussion with an expert-advisory committee; 3.pilot study in 3 groups of 6-8 patients; 4.randomized controlled trial(RCT) in 180 patients (60 intervention-condition, 60 social-support-group-condition, 60 care-as-usual-condition); 5.analyses and generalization phase.

Participants have completed their cancer treatment with curative intent in the Leiden University Medical Center or VU University Medical Center, and are able to follow all therapy sessions.

Outcome measures include valid, reliable outcome-measures of meaning-making and psychological functioning (e.g. personal meaning profile, Ryff's well-being, HADS). To assess possible determinants of efficacy of the intervention, sociodemography, comorbidity, cancer, treatment and copingstyles will also be measured. Questionnaires will be filled-in before the first and after the last sessions, and 3, 6 and 12 months later. 60 patients are needed in each group at the baseline, assuming an effect size of .80, compensation for 30% loss to follow-up, 80% power and 5% p-value. Randomization will be stratified by cancer site and gender.

## **Intervention**

A detailed description and outcomes of the intervention can be found in: Breitbart et al, Psycho-Oncology, 2010. Our intervention is a translation of this study to the situation of Dutch cancer-survivors. The intervention consisted of didactics, discussion and experiential exercises focusing around themes related to meaning and advanced cancer. The therapists focused on the group members' own experiences that are consonant with a sense of meaningfulness, and avoided imposing their theory on them. Group members had the possibility to express emotions and to support each other, but this was limited, to focus on the exercises, didactics and discussions.

Countertransference issues experienced by the psychotherapists were discussed in intervision/supervision. Homework included experiential exercises to do individually or together with relatives/friends, and texts to read (mainly from Frankl). Each session addressed a specific theme: introduction to meaning and the impact of cancer(1-2), historical meanings(3-4), sources of meaning(5-7), and termination(8). See details about the intervention in the research protocol.

## Social-support condition

We assume MCGP is mainly effective because of its specific focus at meaning-making and its structured/manualized nature. Therefore, we want to create a control-condition identical to the MCGP, except for these two elements. The control-condition is a social-support group psychotherapy, following Payne et al as used by Breitbart et al. See details about the control group in the research protocol.

## Study burden and risks

We expect that there are no health risks for participants in this study.

I. Focus group phase- In the focus groups, the participants discuss what they experience as the most important psychological developments since the diagnosis of their cancer, and they describe which kind of help they would like to have received. We expect that this self-reflection is not an additional psychosocial burden for the participants; we base the assumption on our previous experience with focus groups and questionnaires in this populations; the participating cancer patients said that they enjoyed participation, and that it helped them to look back on their psychological experiences.

II. Pilot study and randomized controlled trial phases of the study. We expect that cancer patients who participate in this intervention, are better able to cope with their questions about meaning in life that may be evoked by the diagnosis of cancer. Consequently, the psychopathological symptoms -such as distress, depression, suicidality or the wish for a hastened death- are expected to decrease. We expect that participants in the control groups (both the social support group and the no-intervention group) will not experience distress or other kinds of psychosocial burden as a consequence of participation in this study. All these expectations have been based on studies performed in the Memorial Kettering Sloan Hospital in New York (see: Breitbart et al, Psycho-Oncology, 2010).

Participation may consist of one of the following parts of our study:

(1) focusgroups (max. 12 persons); (2) pilot study (24 persons); (3) randomized controlled trial with a (a) intervention group (training 'Living meaningfully with cancer'), (b) social support control group, (c) no intervention. The participants of the focus groups participate in one discussion meeting in which we discuss their vision about the basic elements of the intervention. The participants in the pilot study follow eight training/therapy sessions of each 2 hours; at the end of each session, they fill-in a short evaluation form. Before the first session they fill in one questionnaire and after the last session they fill in four questionnaires. The participants of the social support group receive eight training/therapy sessions of each 2 hours; before the first session they fill in one questionnaire and after the last session they fill in four questionnaires. The participants in the no-intervention control-group only fill-in five questionnaires. Filling-in these questionnaires

takes about 30 to 45 minutes, the fifth questionnaire takes 15 minutes.

## 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**

received treatment with curative intent for cancer less than 5 years ago

18 years or older

need for help with psychosocial problems(e.g. anxiety, meaning-making, life questions, depressive symptoms, coping)

### **Exclusion criteria**

(severe) cognitive disorders  
receiving psychological treatment  
no mastery of dutch language

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	180
Type:	Actual

## Ethics review

Approved WMO	
Date:	08-03-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	05-06-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	03-07-2013
Application type:	Amendment



Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	22-08-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	27-11-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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	NL34814.058.10