

# Living meaningfully with cancer.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20467

### Source

Nationaal Trial Register

### Health condition

cancer survivors, meaning-making, existential issues.

## Sponsors and support

**Primary sponsor:** VUMC, VU, LUMC

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

## Intervention

## Outcome measures

### Primary outcome

1. The Dutch Personal Meaning Profile (39 items) has 5 scales: religion, dedication to life, fairness of life, goal-orientedness, relationships ( $\alpha > .80$ ; sufficient validity);
2. The Dutch Post Traumatic Growth Scale (21 items) has 5 scales: relationships, viewing new possibilities, personal strength, spirituality, appreciation of life ( $\alpha > .80$ ; sufficient validity);
3. The Dutch Ryff's conceptual wellbeing scale (52 items) has 6 scales: autonomy, environmental mastery, personal growth, positive relationships, purpose in life, self-acceptance ( $\alpha > .80$ ; sufficient validity).

## Secondary outcome

1. The Dutch Hospital Anxiety and Depression Scale(14 items) has two scales: depression, anxiety( $\alpha > .80$ ; sufficient validity);
2. The Dutch Beck Hopelessness Scale(20 items) measures hopelessness( $\alpha > .80$ ; sufficient validity);
3. The Dutch Life Orientation Test(10 items) measures optimism( $\alpha > .80$ ; sufficient validity);
4. The Mental Adjustment to Cancer scale (40 items) measures specific responses and coping with cancer ( $\alpha > .80$ ; sufficient validity);
5. The Dutch EORTC QLW-C30(30 items) measures tumor-specific health-related quality-of-life, functioning, and physical symptoms( $\alpha > .80$ ; sufficient validity);
6. EQ-5D;
7. TIC-P;
8. PRODISQ.

## 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 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 psychopathology, 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 styles and preventing/treating psychiatric symptoms, and not at living with cancer. There are few evidence based interventions to help patients living meaningfully with cancer. Breitbart et al developed an 8-session meaning-centered group psychotherapy for cancer patients in New-

York, based on 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 found large improvement in meaning-making and psychological functioning ( $d=.8$ ). These effects were larger than non-meaning centered psychological interventions. These effects were also larger than other existential therapies, possibly because the latter were often relatively unstructured/non-directive. The effects of Breitbart's therapy could 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.

#### Purpose of project:

We want to develop and evaluate the cost-effectiveness of 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 cancer 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; social support; improved psychological functioning.

#### Plan of investigation:

Before start of the study, 2 focus groups with 6-10 cancer-patients will be performed, and approval by the medical-ethical committee will be obtained. The project consists of 4 phases: 1.translation/adaptation of therapy, training of therapists, in discussion with experts; 2.pilot study in 3 groups of 6-8 patients; 3.randomized controlled trial in 180 patients (60 intervention-condition, 60 social-support-group-condition, 60 care-as-usual-condition); 4.analyses and generalization phase. Participants are no more than 5 years post-diagnosis, are at least 1 year after cancer treatment withtreated with curative intent in Leiden University Medical Center or VU University Medical Center, have completed their treatment and are able to follow all therapy sessions.

Outcome measures include valid, reliable outcomemeasures of meaning-making and

psychological functioning (eg. personal meaning profile, Ryff's well-being, session-rating-scale) and costs (EQ-5D, PRODISC, TIC-P). To assess possible determinants of efficacy of the intervention, sociodemography, comorbidity, cancer, treatment, and copingstyles will be included. Questionnaires will be filled-in before first and after last session, and 3 months later and 6 months later. 60 patients are needed in each group at baseline, assuming an effect size of 0.80, compensation for 30% loss to follow-up, 80% power and 5%-pvalue. Randomization will be stratified by cancersite and gender.

Possible results and relevance:

An evidence-based, manualized intervention will be developed to help patients living meaningfully with cancer despite possible physical limitations and uncertainty. The intervention is expected to meet their meaning-related needs more explicitly than other therapies. More insight will be obtained in determinants of therapy success. A practical therapy manual and therapist training protocol will be developed and made available for implementation in other centers for oncological/psychosocial care.

### **Study objective**

1. Cancer survivors experience more meaning in life after the intervention;
2. Psychological wellbeing in cancer survivors improves after the intervention.

### **Study design**

Before treatment (T0), after treatment (T1), three months after treatment (T2) and six months after treatment (T3).

### **Intervention**

The main purpose of the Meaning-making group intervention is to help patients living satisfactorily with cancer, by sustaining or enhancing a sense of meaning, peace or purpose in their lives. More specific aims are:

1. Stimulating cancer patients to search for meaning in life, despite the limitations and uncertainties of cancer, e.g. by:
  - A. Reordering/evaluating old meanings;
  - B. Searching for new meanings;
  - C. Finding ways to overcome practical limitations.
2. Concrete goal reengagement in daily life, and by doing that: self-transcendence;

3. Learning to distinguish between changing limitations that can be changed, and accepting what cannot be changed;
4. Integration of cancer in one's life history;
5. Expression of feelings;
6. Social support by group members;
7. Improvement of psychological functioning due to improved meaning making.

Control condition:

Social-support group therapy.

We assume meaning-making 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. Each of the 8 sessions has a different theme, which is mentioned at the beginning of the session. Themes are parallel with the MCGP intervention, but the specific content emerges from the patients' experiences. The therapist has an unconditionally positive attitude, stimulates patients to actively share their experiences, and focuses on positive emotions, and expression of existential feelings. The themes of the sessions are:

1. Group members' introductions;
2. Continued introductions;
3. Coping with medical tests and communicating with physicians;
4. Coping with family and friends;
5. Coping with work issues;
6. Coping with body image and physical functioning;
7. Coping with the future;
8. Termination: where do we go from here?

## Contacts

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## Eligibility criteria

### Inclusion criteria

Patients may be included when they are:

1. Diagnosed with cancer at least 1 year earlier less than 5 years ago;
2. Treated with curative intent (patient completed treatment program);
3. Able to attend all therapy sessions;
4. Speak Dutch.

### Exclusion criteria

Patients will be excluded when psychiatric disease is present, which may disable the patients' participation in the MCGP sessions, e.g. psychotic behavior (delusions or hallucinations), severe cognitive impairment, current psychiatric 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):	15-08-2012
Enrollment:	180
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	10-08-2012
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	NL3421
NTR-old	NTR3571
Other	METc LUMC : 2012
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Study results

## Summary results

N/A