

Problem-Solving Therapy to reduce distress in patients with cancer: a randomized clinical trial and investigation of mechanisms of change

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To test the effects of a problem-solving therapy to reduce distress and increase quality of life in patients with cancer. Also to test the mechanisms of change of the therapy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON33783

Source

ToetsingOnline

Brief title

Problem Solving and Cancer

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

Cancer, neoplasm

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Het Koningin Wilhelminafonds/Nederlandse kankerbestrijding

Intervention

Keyword: Cancer, Distress, Problem Solving Therapy

Outcome measures

Primary outcome

Level of distress, measured with the Hopkins Symptom Checklist (HSCL-25)

Secondary outcome

Quality of Life, measured with the RSCL and the WHO-5

Mediating effects, i.e. to see whether improvements in problem solving capacity, perceived control, coping, social support and loss processing are associated with better outcome on distress in both groups.

Another aspect of the study will be a process evaluation. Videotapes of treatment sessions will give information about treatment integrity of the sessions and about (verbal and non-verbal) working elements of the treatment.

Study description

Background summary

We have found that approximately 25% (for male patients) to 35% (females) of cancer patients report clinically significant distress and this is remarkable stable across sites and severities. In our study, we therefore aim at treating these cancer patients to cope more adequately with the stress they encounter.

Given the fact that there is quite some scepticism concerning the alleged efficacy of psychosocial interventions focusing on lowering distress among

cancer patients, there is a pressing need to carry out well-designed effect studies. In addition, since the majority of studies have been carried out in the USA, it is important to replicate findings of these studies in the Dutch healthcare system, so that generalizability of findings to the Netherlands can be assured. Thereby, our study will replicate and extend on a study of Nezu et al. (2003) which has shown positive results and which was carried out on the basis of a well documented treatment protocol.

Study objective

To test the effects of a problem-solving therapy to reduce distress and increase quality of life in patients with cancer. Also to test the mechanisms of change of the therapy.

Study design

A prospective, randomised, controlled multicentre trial. Duration of the follow-up will be 9 months.

Intervention

Problem solving therapy, aimed at improving problem solving capacity. 10 sessions of each 1 hour will be held.

Study burden and risks

Patients in the intervention group will get 10 sessions PST of 1 hour weekly. Both groups will have four measurements with short questionnaires, which will take about 45 min- 1 hour.

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

1) a diagnosis of cancer, 2) a survival rate of 50% or greater (in the following five years) as deemed by the treating physician, 3) age 18-65

Exclusion criteria

1) not being able to speak Dutch, 2) a serious psychiatric disorder existing prior to the diagnosis of cancer which may complicate the treatment, 3) acute suicidal behaviour or 4) receiving psychotherapy for emotional psychological problems.

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2007
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL20781.042.07