Cancer, Attachment, and Resilience

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON29960

Source
ToetsingOnline

Brief title
CARe

Condition

- Other condition

Synonym
Cancer, malignacy

Health condition

mensen met kanker

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Nederlandse Kankerbestrijding/KWF

Intervention

Keyword: adaptation, cancer, psychosocial problems, risk factors

Outcome measures

Primary outcome

Psychological problems are the long-term outcome variables and are conceptualized as psychological symptomathology as described in DSM-IV axis-I (e.g., affective disorders) and the Global Functioning Scale.

Secondary outcome

In addition to insight in the prevalence of psychological problems (i.e., partial DSM-IV, axis-I disorders) in cancer patients, the study will offer information about (i) the intermediate stages of the adaptation process, (ii) risk factors for maladjustemnt and (iii) it will offer preliminary information for the development of interventions that do take individual differences into account.

Study description

Background summary

Cancer diagnosis, treatment and subsequent changes in life are well known to cause emotional distress in people. Although most individuals with cancer are able to adapt to the changes and losses imposed by the illness, others (25-30 %) develop clinically significant problems (e.g., mood and anxiety disorders)(Carlson & Bultz, 2004). One of the key goals in psychosocial oncology is to determine why some people are able to adapt to cancer while others continue to suffer. Insight in the determinants of these individual differences is necessary to design optimal interventions. One of the most widely accepted theories in psychosocial oncology is the stress-coping theory. This theory is limited, however, by inconsistencies, in the ability to explain individual differences and in bridging the gap between theory and praxis

(Brennan, 2001; Somerfield & McCrae, 2000).

Study objective

The purpose of the proposed study is twofold. First, to test a process model of adaptation that distinguishes between the changes in life imposed by the illness (i.e., subjective cancer experience), the immediate (emotional, cognitive, and behvaioral) responses to these changes, and the psychosocial problems that may develop when the immediate responses persist beyond their adaptive benefit. Second, to investigate individual differences in the adaptation process by including intra- and interpersonal factors that may put people at risk for maladjustment. When risk factors can be identified it may be possible to prevent psychological problems and it may provide clues for how to treat psychological problems in oncology.

Study design

In this 4-year prospective study we will follow newely diagnosed cancer patients for 12 months. To be able to assess when and how stressors evolve into psychological problems, assessment will be done every three months, with a total of five assessment points.

Study burden and risks

Both self-report measures and structured (clinical) interviews will be used in order to gain fuller insight in the adaptation processes. A structured interview will take place at T1 (within three months after diagnosis) and T5 (12 months after T1) and will be conducted by trained psychologist. Self-report measures will be completed by participants at all assessment point (T1-T5). The assessment at T1 and T5 will take approximately 60 to 90 minutes and the intermediate assessments will take approximately 30 to 45 minutes. Total assessment time over a one year period will be maximal 5 / 6 hours .

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

A first diagnosis of cervix, bladder, breast, prostate or colon cancer within the last three months
Expected survival of 1.5 years
Age between 30 and 65 years
Written informed consent

Exclusion criteria

History of cancer
Younger than 30 and older than 65 years
Not able to read or speak dutch fluently

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	130
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	01-11-2006
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	NL12034.042.06