Looking beyond return to work: a longitudinal study on health-related work functioning in cancer survivors.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON39291

Source
ToetsingOnline

Brief title
Beyond return to work in cancer survivors

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
cancer, Tumors

Research involving
Human

Sponsors and support

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

Intervention

Keyword: cancer, trajectories, work functioning

Outcome measures

Primary outcome

1. (Health-related) work functioning

2. Employment status

Secondary outcome

3. facets of health / well-being or productivity

- Cancer survivor characteristics (e.g. age, gender, education, occupation, tenure in current job, sickness absence)

- Health and well-being

- Medical factors (e.g. cancer site, received treatments, self-rated health, co morbidity)

- Symptoms (e.g. fatigue, cognitive failures, depression and anxiety, sleep disturbances)

- Function (physical and social functioning)

- Work demands (physical, mental, psychosocial)

- Work environment (e.g. social support, work accommodations)

- Psychological and individual work-related factors (e.g. mastery, job satisfaction)

- Social environmental factors (social support)

Study description

Background summary

Due to earlier diagnosis and better treatment, survival rates are improving across cancer types (Grunfeld et al., 2008). Consequently, an increasing number of individuals are living with cancer as a chronic disease. At the time of diagnosis, approximately half of all cancer patients are employed or available for employment (Verdonck-de et al., 2010). In the Netherlands, about 400.000 individuals are living with cancer and its consequences. Each year 70.000 new cancer cases are diagnosed, of which 30.000 cases are of working age. It is expected that this number will increase until 2015 (Kuijpens, 2008)

Rasmussen and Elverdam (2008) examined the meaning of work and working life after cancer and observed that cancer survivors try to get back to work after treatment and try to re-establish their former structure of everyday-life as a normal and healthy existence. Resuming and maintaining employment after cancer is important for survivors* quality of life (Groenvold, 2010; Kennedy et al., 2007). Work contributes to the individual as a social being and plays a role in establishing the individual*s identity. In contrast, not being able to work after cancer treatment disrupts everyday life, leading to financial problems, reduced quality of life, and social isolation.

Numerous studies have addressed the employment consequences of cancer survivorship, mainly focusing on return to work (RTW) outcomes and work changes (Amir et al., 2007; Roelen et al., 2009; Gudbergsson et al., 2006, 2008; Spelten et al., 2002, 2003; Lindbohm et al., 2011). The literature suggests that between 30 and 90% of those diagnosed with cancer return to work following treatment (Spelten et al., 2003). When returning to work, it is often assumed that the capacities of the cancer survivors have been restored and that they can resume their full duties. However, this assumption might not be correct and does not address the important issues of a sustainable RTW, functioning well at work and a good quality of working life - as observed in other diseases (Bultmann et al., 2007).

The few studies that addressed cancer survivorship and health-related work functioning were performed outside the Netherlands and were cross-sectional. A US study showed that brain tumor survivors reported higher levels of work limitations than a non-cancer comparison group (Feuerstein et al., 2007). From other US studies it is known that breast cancer survivors report higher levels of age-adjusted work limitations compared to a non-cancer group (Hansen et al., 2008). Lavigne et al. (2008) showed that breast cancer survivors reported lower work productivity when compared to the healthy worker norm. Although these studies provide much relevant information about cancer survivorship and health-related work functioning, they cannot be directly translated into the Dutch context. Moreover the studies were not able to describe the course of

health-related work functioning over time due to their cross-sectional design.

Study objective

The overall aim of the proposed longitudinal cohort study is to expand our understanding of health-related work functioning among cancer survivors, who returned to work after first cancer diagnosis and treatment with curative intent during 18 months of follow-up.

The specific research objectives are:

1. To describe health-related work functioning among cancer survivors who returned to work by:
a. examining the course of health-related work functioning in cancer survivors who returned to work over time at a group level (mean level approach).
b. to identify distinct trajectories of health-related work functioning over time in cancer survivors who returned to work (trajectories approach; i.e., to identify subgroups of cancer survivors who show a similar course of work functioning over time, e.g., stable, improved, deteriorated).
c. to investigate whether the course of health-related work functioning at a group level and the distinct trajectories differ by cancer site and cancer treatment.

2. To develop a predictive model including key variables (health status, socio-demographic, clinical, psychological, work and/or social environmental factors) that predict the course of health-related work functioning at a group level and the distinct trajectories of health-related work functioning over time.

Study design

1. Focus group interviews.
Two focus group interviews, each with N=12 participants.
- Cancer survivors who had returned to work in the last three years
- Professionals from the (occupational) health care system (e.g., OP, GP, specialista, company/indusrial welfare worker).

All participants will sign an informed consent. An interiew schedule will be developed, tailored to each group. The focus group interviews will be conducted at the UMCG and led by an external, trained moderator.

2. Main study.
Longitudinal observational cohort study in cancer survivors with an 18 month follow-up from the time of return to work. At baseline, 6, 12 and 18 months,

they will receive the comprehensive questionnaire and at 3, 9 and 15 months they fill out a short, online questionnaire.

When an employee resumes work:
1. An employee of an Occupational Health Service invites the potential participant for the study. If the potential participant agrees to participate, his/her NAW information will be forwarded to H.F. Dorland-Pel (researcher) or J.G. Smink (research assistent).
2. The researcher will provide the employee with further written information about the study. Together with the written information, the researcher will send a written informed consent form and the study questionnaire to the employee. In this informed consent, the employee is asked for permission to obtain administrative data on absenteeism through record linkage with the Occupational Health Service (absenteeism data and diagnosis code) and also for cancer-related factors (cancer site and location, stage, month and year of diagnosis, (type, dose and duration of) treatment) through record linkage with the NCR of the Dutch CCC.
3. When an employee stops working, for whatever reason, he/she will monitored (if possible) throughout the study.
4. Employees can end their participation in the study without stating reasons at any time.

Study burden and risks

1. Focus group interviews.
Participants undergo a group interview, conducted at the UMCG and led by an external, trained moderator. The interview lasts 90-120 minutes and they will give more insight into work functioning problems. There are no expected risks for this investigation.

2. Main study.
The study consists of completing seven questionnaires. The time spent for the comprehensive questionnaire (baseline, 6, 12, 18 months) is estimated to be 30 minutes. The time spent for the short questionnaire (3,9,15 months) is estimated to be 10 minutes. The time spent for the overall study is therefore 150 minutes. There are no expected risks for this investigation.

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. Individuals of working age (i.e. between 18-65 years) with incident cancer.
2. Connected at an Occupational Health Service for their absenteeism.
3. Returned to paid work during the past 8 weeks (minimum of 12 contracted work hours/week).
4. Having had a history of paid work (minimum of 12 contracted work hours/week) for at least 1 year prior to diagnosis.
5. Who are able to understand and complete a questionnaire in Dutch.

Exclusion criteria

1. Recurrent cancer

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2013
Enrollment:	1300
Type:	Actual

Ethics review

Approved WMO Date:	18-10-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-12-2013
Application type:	Amendment
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	NL40766.042.12