Chronic fatigue and return to work in cancer survivors

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The primary objectives are:- to identify predictive factors for fatigue in cancer survivors on long-term sick leave. - to develop a prognostic instrument by which insurance physicians can assess future functional abilities, related to the work...

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON35940

Source
ToetsingOnline

Brief title
Cancer and work

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer, tumor

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Uitvoeringsinstituut Werknemers Verzekeringen (UWV)

Intervention

Keyword: Cancer, Cancer survivors, Disability, Return to work

Outcome measures

Primary outcome

The primary outcome measure of the study is the level of fatigue, measured by the Functional Assessment of Cancer Therapy-Fatigue (FACT-F) scale. This 13-item scale is measured on a 5-point scale (range 0-52) , with 0 being the worst possible score and 52 the best.

Secondary outcome

- perceived work ability, which will be assessed using the first three questions of the Work Ability Index (WAI).

- disability percentage, which is expressed by the percentage of income-loss of the previous job held.

- depression, which will be measured by the Center for Epidemiological Studies

- Depression scale (CES-D). The CES-D is a 20-items questionnaire, measured on a four-point scale.

- quality of life, which will be assessed with the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ C-30). This 30-item list incorporates nine multi-item scales: five functional scales; three symptom scales and a global health and quality-of-life scale.

- coping, which will be measured with the Utrecht Coping List (UCL). The UCL has 47 statements covering seven coping strategies and is scored on a four-point scale.

- work load, work stress and need for recovery. Physical workload will be

measured with a seven-item scale, and work stress and need for recovery will both be measured with a 11-item scale from the Dutch questionnaire on Experience and Judgement of Work (VBBA).

- supervisor and co-worker social support will be measured with two subscales (four items each) of a validated Dutch version of the Job Content Questionnaire (JCQ).

- physical limitations, which will be measured with the mobility and ambulation subscales of the Sickness Impact Profile (SIP). The SIP uses a series of questions with two domains, i.e., physical and psychosocial.

Other study parameters

Both at baseline and one year follow-up, sociodemographics, disease-related data, working hours, and disability percentage, as assessed by UWV, will be gathered. Additional UWV file data, such as reintegration efforts, objection and appeal procedures, and Functional Ability Lists will also be gathered.

Study description

Background summary

Fatigue is a common side effect of cancer and its treatment, as reported by patients all over the world. Prevalence data in previous studies on fatigue show a wide range, i.e., 4-100% percent, due to differences in study design, timeframe, cancer site and stage, and treatment modalities. Apart from hindering patients in daily house-hold activities, leisure-time or social interactions, fatigue can have a significant impact on work ability. Moreover, fatigue is associated with loss of productivity, reduction of working hours and sick leave. Cancer survivors often experience return to work as getting back to normal life and regaining a sense of control. However, fatigue may influence return to work for several years, even after treatment has been completed. It

may even lead to permanent work disability. Therefore, the relationship between cancer related fatigue and work ability deserves our attention. Especially in cancer survivors on long-term sick leave, who report ongoing fatigue. That is, the assessment of disability benefit claims is done by insurance physicians of UWV, after two years of sick leave. For them, cancer related fatigue and the extent it will affect work ability are difficult to assess. Numerous prospective studies have investigated the relationship between fatigue and work ability. Though, most studies focus on the association between fatigue and return to work within two years of sick leave. Therefore, it is necessary to study prognostic factors for fatigue in cancer survivors on long-term sick leave, and to assess the association of fatigue with work ability in these clients. Since fatigue is expected to affect return to work, gaining insight in the course of fatigue may support the insurance physician in the assessment of work ability of cancer survivors on long-term sick leave. In this study, we aim, both quantitatively and qualitatively, to identify predictive factors for fatigue in cancer survivors, who are on long-term sick leave, and its relation with return to work. In addition, we aim to develop a prognostic instrument, by which insurance physicians can assess future functional abilities of these clients.

Study objective

The primary objectives are:
- to identify predictive factors for fatigue in cancer survivors on long-term sick leave.
- to develop a prognostic instrument by which insurance physicians can assess future functional abilities, related to the work perspective, of these cancer survivors.

Secondary objectives are:
- to determine the association between fatigue and return to work in cancer survivors on long-term sick leave.
- to identify predictive factors for a transition in the level of fatigue in cancer survivors on long-term sick leave.
- to identify predictive factors for with fatigue related functional abilities, e.g., physical limitations, in cancer survivors on long-term sick leave.

Study design

There are two elements in this study to answer the objectives:
1. A prospective cohort study: predictors for fatigue in cancer survivors on long-term sick leave will be identified, using questionnaires (at baseline and one year follow-up) and data of the insurance physicians and UWV. Also, the association between fatigue and return to work will be explored. The recruitment of participants will start mid 2011 and will last until mid 2012.

2. A qualitative study will be conducted using focus groups, each of which two insurance physicians, two occupational physicians and two oncologists will participate. Prognostic factors for cancer related fatigue and mediating factors for return to work of cancer survivors will be discussed with these health professionals. They will be asked about their knowledge and experiences, and opinions regarding the importance of these factors will be gathered. Three groups will be formed, with recruitment starting in September 2011. The process of recruitment, formation and preparation of the focus groups, data gathering and data processing will take till September 2012.

Study burden and risks

In this study no interventions will be applied.

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

The study population of the prospective cohort study (n=400) will exist of cancer survivors who apply for a WIA benefit at the head office of UWV in Amsterdam, i.e., they approach a 104 weeks period of sick leave and make a first application for WIA benefit.

Exclusion criteria

1. Clients treated for cancer, who are too ill to visit the UWV office for the WIA assessment.
2. Clients treated for cancer, who do an appeal on WIA benefit due to another somatic or psychiatric disorder.
3. Clients treated for cancer, with prior WAO/WIA benefit.
4. Clients treated for cancer, who are voluntarily insured non-employees.
5. Clients receiving chemo- or radiotherapy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-07-2011
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	22-06-2011
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL35835.029.11