Sustained employability in cancer patients and their partners (STEPS)

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(1) To evaluate the (cost-)effectiveness of an individual rehabilitation program on RTW and continuation of work in cancer patients with an employment contract, compared to care as usual (CAU). In addition, we will investigate the effect of the...

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

Summary

ID

NL-OMON52691

Source
ToetsingOnline

Brief title
STEPS

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Cancer, neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Keyword: cancer patients, employability, partners, randomized controlled trial

Outcome measures

Primary outcome

For both the RCT and the cohort study the primary outcome is sustainable employment expressed in the number of actual working hours.

Secondary outcome

RCT: actual working hours and contractual working hours, readiness for return to work stage (assessed by the Readiness for Return to Work scale); work ability (measured by the Work Ability Index); health-related work functioning (measured by the Work Role Functioning Questionnaire); time to return to work (measured as the number of calendar days between the first day of sick leave and the first day of work, either fulltime or part-time, for at least 28 consecutive days without recurrence); and HRQoL (measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire - Core 30).

Cohort: Sick leave, health-related work functioning, caregiver burden, depression, and HRQoL. Most of these measures correspond to the measures included in the questionnaire for cancer patients in the RCT, with the exception of caregiver burden (measured by the Caregiver Burden Scale).

Study description

Background summary

Each year, approximately 118,500 individuals are newly diagnosed with cancer in the Netherlands, of whom about 40-50% are of working age at time of diagnosis. While about 64% of the patients are eventually able to return to work (RTW), many experience physical and/or psychosocial problems that affect the continuation of their working lives. Intervention programs that have been developed up until now lack scientific evidence regarding RTW, and supportive programs for occupationally active patients who are dealing with long-term consequences of diagnosis and treatment at the workplace are missing completely. Further, it is expected that cancer diagnosis and/or the treatment process may have negative health- and work-related consequences for partners of cancer patients as well. Their problems and needs are currently highly under-recognized.

Study objective

(1) To evaluate the (cost-)effectiveness of an individual rehabilitation program on RTW and continuation of work in cancer patients with an employment contract, compared to care as usual (CAU). In addition, we will investigate the effect of the program on secondary outcomes, e.g., readiness for RTW and health-related quality of life (HRQoL), and perform a process evaluation.

(2) To evaluate health- and work-related consequences of cancer (e.g., sick leave, caregiver burden, HRQoL) in partners of patients. In addition, we will gain insight in health- and work-related experiences and needs among partners of patients, and develop a model to predict employment status in these patients.

Study design

(1) A two-armed randomized controlled trial (one intervention group who receives the intervention program, one control group who receives care as usual, N=118 per group). Participants will be asked to fill in three questionnaires, at baseline (T0), at six (T1), and 12 months (T2) follow-up (45-60m).

(2) A longitudinal cohort study (N=267) of partners of cancer patients. Participants will be asked to fill in three questionnaires, at baseline (T0), at six (T1), and 12 months (T2) follow-up (30, 30 and 15 minutes).

Intervention

One introductory session (1.5h), a maximum of eight individual rehabilitation sessions with an occupational therapist (1h each), potentially a telephone consults (0.5h), and a maximum of two sessions with a re-integration consultant

and/or a relevant party from the workplace (1.5h). The minimum requirements are: the introductory session (1.5h), at least one session with an occupational therapist (1h), and the session with the re-integration consultant (1.5h).

The reintegration consultant is specialized in reintegration consultancy for cancer survivors and can provide information about, for example:
-Efficient communication with an employer about cancer and reintegration
-How to effecitvely build up working hours for employees who have (had) cancer
-Relevant legislation and regulations for employees with cancer and their employers
-The late / long-term effects of cancer (treatment) at work

Study burden and risks

The intervention consists of a maximum of nine sessions with a time investment of maximum 11 hours (without travelling time, see E4). The patients in the control group do not have to invest any additional time. Next to this, we will ask participants (both intervention and control) to fill out questionnaires at three times during the course of the study. Filling out these questionnaires will take approximately 45-60 minutes per questionnaire. Questionnaires will be offered online, unless this is a problem for the patient. In that case, questionnaires will be offered in hard copy. The maximum estimated time that patients will spend on our study will therefore be 14 hours (11 + 3, for the intervention group) and 3 hours (for the control group).

Partners who will participate in our cohort will be asked to fill out questionnaire at 3 occasions (30, 30 and 15 minutes). The estimated time that partners will spend on our study will therefore be 1 hour and 15 minutes.

Apart from this time investment, there is no foreseeable extra burden or risk associated with participating in this study.

Contacts

Public
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7
Amsterdam 1081BT
NL
Scientific
Vrije Universiteit Medisch Centrum

van der Boechorststraat 7

Amsterdam 1081BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For the RCT on cancer patients: The sample will be composed of cancer survivors of working age (18-64 years of age at time of diagnosis), with histologically confirmed cancer and a life expectancy of more than one year. At study entry, eligible cancer survivors have a fixed or temporary employment contract, with at least six months left of their contract, and a history of paid work for at least one year prior to diagnosis (with a minimum of 8 contracted working hours/week). Cancer survivors can both be at work or (partly) on sick leave when entering the study. Cancer survivors will be recruited 3-18 months post-diagnosis. The cut-off for the maximum time post-diagnosis was set at 18 months in order to complete the intervention before a potential WIA assessment, which takes place at 24 months of sick leave to determine whether someone will receive work disability benefits (18 + 6 months intervention = 24 months). Cancer survivors will be eligible for inclusion if they are, or have been, treated with at least radiotherapy and/or chemotherapy. Prior research has shown that cancer survivors who received complex treatments, i.e., chemotherapy, radiotherapy, or a combination thereof, indicated lower workability than cancer survivors who were treated by means of surgery alone [6]. Therefore, we conclude that cancer survivors who have received chemotherapy and/or radiotherapy, alone or in combination with hormonal therapy, immunotherapy, or surgery, could potentially benefit more from the STEPS intervention than cancer survivors who were treated by means of hormonal therapy, immunotherapy, or surgery alone. Patients should have a life expectancy of more than 1 year.

For the partner cohort: Partners are defined as being married to or cohabiting with a cancer survivors at the time of the cancer diagnosis and at study entry.

Eligible partners are between 18-65 years of age, had paid work (i.e., have a fixed or a temporary employment contract, or are self-employed) at the time of diagnosis of the cancer survivors, and have a history of paid work for at least one year prior to diagnosis (i.e., a minimum of 8 working hours/week). Partners of cancer survivors can be at work or (partly) on sick leave when entering the study. Both partners of cancer survivors who accepted the invitation to participate in the RCT and partners of those cancer survivors who declined participation in the RCT will be eligible to participate. For the cohort study, partners of patients who were diagnosed with cancer a maximum of five years ago are eligible.

Exclusion criteria

For the RCT on cancer patients: Cancer survivors will be excluded if their treating physicians consider occupational rehabilitation unfeasible, if cancer survivors have serious cognitive or psychiatric problems, or serious physical comorbidities that would preclude them from participating in an occupational rehabilitation program, and/or if cancer survivors lack basic proficiency in Dutch. cancer survivors participating in concurrent studies or rehabilitation programs aimed at RTW or continuation of work prior to their potential participation in the STEPS study will also be excluded. cancer survivors will be asked about their participation in concurrent studies or rehabilitation programs on the screening questionnaire and during the screening interview by telephone. Furthermore, cancer survivors will be excluded if they are, or have been, treated by means of surgery, immunotherapy, or anti-hormonal therapy alone. Lastly, cancer survivors will be excluded if they refuse the involvement of their employer in the STEPS intervention.

For the partner cohort: Partners will be excluded in case of serious self-reported cognitive or psychiatric problems that would prevent them from completing the questionnaires, and/or in case they are not able to understand and complete a questionnaire in Dutch.

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:	Recruiting
Start date (anticipated):	22-09-2021
Enrollment:	503
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-08-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2023
Application type:	Amendment
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	NL71870.029.19