Re-Employment for Cancer Patients and survivors.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25331

Source
Nationaal Trial Register

Brief title
RE-CAP

Health condition

Cancer patients, cancer survivors, return-to-work, intervention, tailored intervention program, social security safety netter, unemployed, temporary agency worker, sickness benefit, social security agency.

Kanker, kankerpatiënten, werkhervatting, terugkeer naar werk, interventie, interventieprogramma, ondersteuning, werklozen, uitzendkrachten, einde-dienstverbanders, vangnetters, uitkering, UWV.

Sponsors and support

Primary sponsor: VU University Medical Centre/EMGO+ Institute
Source(s) of monetary or material Support: UWV (Social Security Agency)

Intervention

Outcome measures

Primary outcome

Amendment 21-dec-2014: The primary outcome measure of this study is duration until sustainable RTW after sick leave, calculated as the number of days between the day of randomisation and the first day of sustainable RTW. Sustainable RTW is defined as a period of minimum 28 calendar days, during which the cancer survivors is working according to schedule. Work can be either paid work or work resumption with ongoing benefits, e.g., work with therapeutic conditions.

Secondary outcome

Rate of return-to-work during follow-up, readiness to return to work, fatigue, psychological distress, general participation in society, coping, general health and health related quality of life.
Other parameters are: socio-demographic factors, co-morbidity, questions regarding cancer diagnosis and treatment, work-related questions.

Study description

Background summary

As unemployed cancer patients and survivors experience severe challenges regarding return-to-work when compared to employed patients and survivors, it is considered worthwhile to study the effects of a return-to-work intervention program, tailored to the specific needs regarding return-to-work for this group.

Objective:

To evaluate the effectiveness of a tailored intervention program for unemployed sick-listed cancer patients and survivors on return-to-work, compared to care as usual.

Study design:

This study will employ a two-armed RCT with a follow-up period of 12 months.

Study population:

“Study population: Unemployed workers who have been sick-listed due to cancer for 12-36 months
and who have applied for sickness or disability benefits at SSA.”

Intervention:

The participants the intervention group of this study receive a tailored intervention program coordinated by a specialized re-integration agency, including a placement at work, coordinated by a job hunting coach. The intervention will target physical, mental, and rehabilitation problems. The program consists of general components (e.g., coaching) and specialist components (e.g., physical therapy) if necessary. The combination of these components will differ per participant and will be adjusted to the individual needs, capabilities and personal situation of the participant. The program will be offered on a national level in the Netherlands.

Main study parameters/endpoints:

The primary outcome measure of this study is duration until sustainable RTW after sick leave, calculated as the number of days between the day of randomisation and the first day of
sustainable RTW. Sustainable RTW is defined as a period of minimum 28 calendar days, during which the cancer survivor is working according to schedule. Work can be either paid work or work resumption with ongoing benefits, e.g., work with therapeutic conditions.

Study objective

Unemployed cancer patients and survivors face severe challenges regarding return-to-work compared to employed cancer patients and survivors. To accommodate for their specific needs regarding return-to-work, a tailored intervention program was designed, which specifically aims to enhance return-to-work in unemployed cancer patients and survivors. The (cost-) effectiveness of this program will be tested in a randomized controlled trial. We hypothesize that persons in the intervention group of the trial will demonstrate earlier and sustainable return-to-work, compared to the persons in the control group.

Study design

Baseline (T0), 3 months (T1), 6 months (T2), 12 months (T3).

Intervention

The tailored intervention program starts with an introductory interview, during which the tailored intervention program will be explained and obstacles for return-to-work and other forms of activities will be identified. This will also include an assessment of the participants' cognition regarding return-to-work, needs for additional therapy (e.g., physical and/or psycho-educational), and the skills and knowledge of the participant regarding work and job application processes (e.g., the skill to write letters of application). At the end of this meeting, a personalized intervention plan will be composed. The plan will consist of three main components:

1. Coaching: A maximum of 8 sessions during which cancer-related and return-to-work-related problems are addressed (e.g., fatigue);

2. Recovery: Optionally, mental and/or physical components are offered through professional primary and secondary care.

3. Job application: Maximum of 8 sessions during which rehabilitation skills, job application skills are improved and a work profile and a “route to work” are created. When the first part of the intervention is finished, the participant has a conclusive meeting during which his/her own “action to work-plan” is completed, which consists of several components (i.e., curriculum vitae. Next, the participant will be assigned to a job coach at an independent job hunting agency. The job coach will take into account the work(place)profile that was created by the reintegration agency, to determine the suitable type of work, work content, and necessary preconditions for work resumption. To create an actual return-to-work perspective, the participant will be offered the possibility of placement in a temporary (therapeutic) workplace or paid employment for a period of three months minimum.

The control group will receive usual care.

Contacts

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Eligibility criteria

Inclusion criteria

Patients and survivors are eligible to participate in this study, when they are between 18 and 60 years old, when they have a primary diagnosis of cancer and when this diagnosis is registered at UWV, as the main cause for their sick-leave. Furthermore, they must be registered at UWV as a social security safety netter without an employment contract; they must have applied for a sickness benefit and they must be at sick leave for at least 3 months up to 18 months. Patients will be included if they are receiving treatment with curative intent, defined as a 1 year survival rate of ca. 80% at time of diagnosis. In case a patient is still undergoing intensive cancer treatment (chemotherapy, radiotherapy, surgery or a combination of those), he/she will be included at a minimum of 6 weeks after finishing these treatments.

Amendment 21-dec-2014: They must have applied for sickness or disability benefits and must be on sick leave for at least 12 months up to 36 months. Patients will be included if their
health status allows them to participate in the study (based on self-report by the cancer survivor) and if they have no comorbidities (e.g., severe psychological or physical conditions) that would interfere with participating in this study (based on report from the cancer survivor's
general practitioner (GP)).

Exclusion criteria

Patients will be excluded in case of comorbidity of such kind that participating in the tailored intervention program is not possible (assessment by participants' general physician), in case of serious psychiatric disorders, in case of pregnancy, in case of a lack of knowledge of the Dutch language and/or in case of a conflict with UWV regarding a (previous) sickness benefit claim or a long-term disability claim. Additionally, patients will be excluded if they are participating or signed up to be participating in a concurrent scientific study and/or re-integration/rehabilitation program.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	164
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	07-08-2012
Application type:	First submission

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
NTR-new	NL3412

Register	ID
NTR-old	NTR3562
Other	METC VUmc : WC 2011-044
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A