# The effectiveness of a tailored intervention program on return-to-work in unemployed sick-listed cancer patients and survivors: A randomized controlled trial.

Published: 15-01-2013
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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.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Miscellaneous and site unspecified neoplasms benign |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON39528

**Source**
ToetsingOnline

**Brief title**
RE-CAP

### Condition

- Miscellaneous and site unspecified neoplasms benign

**Synonym**
Cancer, Malignities

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum
**Source(s) of monetary or material Support:** UWV via het Kenniscentrum Verzekeringsgeneeskunde (KCVG)

## Intervention

**Keyword:** Cancer, Intervention, Return-to-work, Unemployed

## Outcome measures

### Primary outcome

The primary outcome measure is duration until sustainable RTW after sick leave, calculated as the number of days between the first date of sick leave and the first day the participant returns to work. Any kind of paid work or work resumption with ongoing benefits will be qualified as a return to work.

### 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

Survivorship of cancer is increasing as a result of developments in early detection, treatment and follow-up of cancer patients. Consequently, cancer is perceived as a chronic disease with long-term or permanent health problems. Despite potential (temporary) disabilities, cancer patients are often motivated to return to work (RTW) as they perceive employment a symbol of recovery. RTW also reduces avoidable work incapacity and financial loss. However, RTW can be

a challenge, especially for unemployed persons, since they lack the support of an employer and colleagues. As multiple studies have shown positive health effects of RTW for cancer patients and survivors, the need for RTW interventions in the Dutch health care system is increasingly recognized and acted upon. As a result, several RTW interventions have been developed over the years. However, none of those interventions are specifically aimed at enhancing RTW in unemployed cancer patients and survivors. As unemployed cancer patients and survivors experience even more difficulties in RTW compared to employed patients and survivors, it is considered worthwhile to study the effects of a RTW intervention program, tailored to the specific needs regarding RTW for this group.

**Study 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 randomised controlled trial with 2 arms and a 12 month follow-up period

**Intervention**

The tailored intervention program starts with an introductory interview with the unemployed employee (further referred to as *participant*). During the interview, the tailored intervention program will be explained and obstacles for return-to-work and other forms of activities will be identified by the coach of a re-integration agency. This will also include an assessment of the participants* cognition regarding RTW, 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). Prior to the introductory interview, the participant will be contacted by the coach and will be asked to fill out an intake questionnaire. This questionnaire is specifically designed to obtain insight in the topics mentioned above (e.g., cognition, readiness to RTW, former employment). The results of this questionnaire will be discussed during the introductory interview. Both the results from the questionnaire and the interview will be used to design a tailor-made intervention for the participant. There are several options (or *routes*) to tailor the intervention.

First of all, the coach will decide, together with the participant, whether or not the participant is ready to return-to-work, or needs support and preparation in order to return to work.

Route 1:
The participant is ready to RTW. The coach and participant will develop a work profile together, which incorporates the participant*s capabilities, needs and preferences for a workplace. This section continues in paragraph *Return to work*.

Return to work:
The coach will contact the job hunter from the job hunting agency, to share information about the participants* work profile. The participant has given his informed consent. Then, the job hunter will invite the participant for a meeting to explore job opportunities. The participant will also be asked to decide whether or not future employers may be notified of the medical history of the participant, and the job hunter will take this preference into account. Based on the work profile, the job hunter will start a search for two jobs fitting the profile. These jobs should be for at least three months and may include (1) working in paid employment, (2) working in temporary (partly) paid employment, if possibly this type of work can be arranged with therapeutic conditions. Three weeks after placement, the job coach will contact the participant and the employer at the workplace by telephone, to inform whether placement in the temporary workplace has been successful, and if everything is satisfactory so far. Three months after placement, the researcher from the VU University Medical Center will call the participant to inform him/her about the end of the intervention. If applicable, the participant can continue to work in the new job and will still receive the follow-up questionnaires (T1; 3 months, T2; 6 months and T; 3: 12 months).

The job hunter has to find these jobs within four weeks time after the meeting with the participant. If the job hunter is unable to find these jobs, another job hunter will be involved in order to expand the search for a job. This involvement includes transfer of confidential information about the participant. Therefore, the participant will be informed thoroughly about this procedure. It is important to mention that we only contracted two job hunters for this study, so that transfer of the participants information will remain transparent and confidential. The total search time for a job is three months. If both job hunters do not find a suitable job for the participant by then, or if the participant is not able to return to work, the intervention stops. The participant however still receives usual care by UWV. Therefore, he/she can have support from UWV, when they are still willing to explore further job options within the context of usual care. Regardless of whether the participant returns to work, he/she will still receive the follow-up questionnaires (T1; 3 months, T2; 6 months and T; 3: 12 months).

Route 2:
The participant needs support and preparation to RTW. The coach, using the algorithm, will decide which preparation is needed. Every participant will start with a meeting during which the personal preparation plan is introduced by the coach. During this meeting, topics for coaching will be discussed. The

participant will then receive four sessions of coaching on chosen themes, e.g., how to deal with fatigue, changed life preferences, how to combine work and family et cetera. Also, the coach and participant will develop a work profile together, which incorporates the participant*s capabilities, needs and preferences for a workplace. After the work profile is complete, the coach and participant will decide whether or not the participant is ready to RTW (Route 2A or Route 2B).

Route 2A:
The participant is ready to RTW. The participant will continue as described in Route 1. If necessary, the participant may receive five additional sessions of coaching while returning to work, as the participant may need some support in dealing with problems that arise while returning to work.

Route 2B:
The participant needs more preparation to RTW. The participant receives five additional sessions of coaching on chosen themes. After this, the coach and participant will again decide whether or not the participant is ready to RTW (Route 3A or Route 3B).

Route 3A:
If the participant is ready to RTW, the participant will continue as described in Route 1.

Route 3B:
If the participant is not yet ready, the intervention will stop here. However, there is always the option that UWV can take over again, in case the participant is willing to explore further options offered by UWV. This is part of usual care by UWV, therefore the intervention stops when no job is found within three months. The participant will still receive the follow-up questionnaires (T1; 3 months, T2; 6 months and T; 3: 12 months).

In Route 2 and 3, the coach can also opt for recovery support. This could be meaningful if the participant faces specific mental or physical challenges. If this is the case, the coach will discuss this with the insurance physician of the participant, and the participant may be referred to a physical therapist or a psychologist. Recovery support is covered by the intervention program and the re-integration agency.

The total duration of the program in the most intense route (2B) is six to seven months. In this scenario. The participants receives preparation to RTW for a maximum of four months, including 10 sessions of coaching, job application preparation and possibly recovery support, and placement in a work place for a minimum of three months. During the program, UWV professionals as well as the general practitioner will be notified of the program*s start, content and progress. They will receive a copy of the intervention plan and the evaluation report.

The control group will receive care as usual.

**Study burden and risks**

For the intervention group, we consider the risks associated with participation to be low, as this is a non-medical intervention and the components are offered and guided by specialists in the field of RTW with and after cancer, and job hunting. If medical components are assigned to a participants* individual program (e.g., physical therapy), these will be offered by health professionals who are authorized to provide this care according to the Act of Individual Health Care (BIG). Furthermore, we will only include participants who have finished intensive cancer treatment, thereby limiting the burden of the intervention program to a minimum. The intensity of the program is always discussed with the participant and can also be adjusted along the way, as the participant is in frequent contact with the coach from the re-integration agency.
Benefits for the participants in the intervention group may be established with regard to RTW, quality of life and participation in society.

We expect that there is no additional risk or increased burden on the control group, as they will receive will receive usual care.

# 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

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 6 months up to 60 months. Patients will be included if they finished intensive cancer treatment at least 6 weeks prior to the start of this study (based on self-report by the patient), if their health status allows them to participate in the study (based on self-report by the patient) and if there are no comorbidities of such extent (e.g., severe psychological or physical conditions) that would interfere with participating in this study (based on report from the patient*s general practitioner). In case a patient is still undergoing intensive (cancer) treatment (chemotherapy, radiotherapy, surgery or another type of intensive curative treatment), he/she will be included at a minimum of 6 weeks after finishing these treatments. Patients who are scheduled to undergo such treatments within the next 6 months will also be held to this criterion.

## Exclusion criteria

Patients will be excluded in case of comorbidity of such kind that participating in the tailored intervention program is not possible, 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

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| Study type: | Interventional |
| Intervention model: | Parallel |

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| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |

**Primary purpose:** Treatment

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 10-05-2013 |
| Enrollment: | 164 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 15-01-2013 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 27-03-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 08-10-2013 |
| 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 | NL41957.029.12 |

# Study results

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| Date completed: | 30-04-2016 |
| Actual enrolment: | 171 |