# SusTained Employability in cancer Patients and their partnerS

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25514

**Source**
Nationaal Trial Register

**Brief title**
STEPS

**Health condition**

Cancer

### Sponsors and support

**Primary sponsor:** This research is initiated by Amsterdam UMC, location VUmc and is funded by the Dutch Cancer Society (ref. 11558 / 2018-01)
**Source(s) of monetary or material Support:** This research is funded by the Dutch Cancer Society (ref. 11558 / 2018-01)

### Intervention

### Outcome measures

**Primary outcome**

For both cancer survivors and partners of cancer survivors, the primary outcome ‘working hours’ is operationalized as the number of actual working hours at measurement point. For partners of cancer survivors we will additionally measure health-related quality of life. Health-

related quality of life will be measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire – Core 30 (EORTC QLQ C-30)). This 30-item list consists of five multi-item functional scales (i.e., physical, role, emotional, cognitive, and social), three multi-item symptom scales )i.e., fatigue, pain, and nausea and vomiting), six single-item (i.e., dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial impact), and a two-item global health and quality of life scale, all with a scoring range from 0 to 100. A higher score on the functional and global health and quality of life scales indicates better health-related quality of life, while on the symptom scales, a higher score indicates a higher level of symptom burden. A summary score will be generated, calculated as the mean of all combined scale scores, excluding financial impact and the global health and quality of life scale.

**Secondary outcome**

Secondary outcome measures are:
For both cancer survivors and partners of cancer survivors
•Change in working hours (in %): we will divide actual working hours at follow-up by contractual working hours at baseline, times one hundred.
•Employment status: Asking participants whether they are at work or not at work.
•Sick leave: Asking participants about the number of days they have been on sick leave in the past six months
•Health-related work functioning will be measured using the 27-item Work Role Functioning Questionnaire [10], distinguishing five different work domains: work scheduling demands, mental demands, social demands, physical demands, and output demands (range 0 to 100). Higher scores indicate better work functioning. This questionnaire will only be completed by those who (partly) returned to work.
Only for cancer survivors
•Health-related quality of life: see above how this will be measured.
•Readiness for Return-to-Work (RRTW) will be assessed using the translated and adapted, Dutch version of the original RRTW questionnaire. The systematic translation is currently being performed by our research team;
•Work ability will be assessed using a single question of the Work Ability Index, asking participants to estimate their current work ability compared with their lifetime best (0, cannot work at all, to 10, best ever);
•Time to return to work will be 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 (only for those who are on sick leave);
Only for partners of cancer survivors
•Caregiver burden: Using the ‘Ervaren Druk door Informele Zorg-plus’ (EDIZ) [55], consisting of 15 items, ranging from 0 to 1, higher scores indicate a higher caregiver burden
•Depression: using the Centre for Epidemiological Studies Depression Scale; [56], consisting of 20 items and a range of 0 to 60, a score of 16 and over indicates the possible presence of clinical depression.

# Study description

**Background summary**

Rationale: Each year, approximately 118,500 individuals are newly diagnosed with cancer in the Netherlands, of whom about 40-50% at working age. While about 64% of cancer survivors are eventually able to return to work, 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 return to work. Additionally, supportive programs for occupationally active cancer survivors who are dealing with long-term consequences of diagnosis and treatment at the workplace are missing completely. Next to that, it is expected that cancer diagnoses and/or treatment processes may have negative health- and work-related consequences for partners of cancer survivors. The problems they might face and the needs they might have are currently highly under-recognized.
Objectives: In a randomized controlled trial, we will evaluate the (cost-)effectiveness of an individual rehabilitation program on return to work and continuation of work in cancer survivors with an employment contract, compared to care as usual. In addition, we will perform a process evaluation. Along the trial, we will conduct a cohort study among partners of cancer survivors, to evaluate health- and work-related consequences of cancer. This way, we will gain insight in health- and work-related experiences and needs among partners of cancer survivors, and develop a model to predict health- and work-related outcomes in these partners.
Study designs: A two-armed randomized controlled trial (one intervention group that will receive the intervention program, one control group that will receive care as usual, N=118 per group). Participants will be asked to complete three questionnaires: one at baseline (T0), one at six (T1), and one at 12 months (T2) follow-up (30-45 minutes duration per questionnaire).
In a prospective cohort study, partners of cancer survivors will be asked to complete three questionnaires: one at baseline (T0), one at six (T1), and one at 12 months (T2) follow-up (30-45 minutes duration per questionnaire).
Study populations: 236 cancer survivors of working age (18-63 years) and 267 partners of cancer survivors.
Intervention: The intervention consists of a multidisciplinary rehabilitation program, combining occupational therapy facilitating return to work and work retention (e.g., energy management and self-efficacy training) and reintegration consultation addressing work-related issues (e.g., return to work planning and discussing workplace or task modifications with the supervisor).The intervention will be planned over a period of six months, consisting of: an introductory session (1.5 hours duration), a minimum of one and a maximum of six one-on-one sessions with an occupational therapist (1 hour duration per session), and a minimum of one and a maximum of two sessions with a reintegration consultant, possibly together with a relevant person from the cancer survivor’s workplace (e.g., direct supervisor or human resource officer) (1.5 hours duration).
Main study parameters/endpoints: The primary outcome ‘working hours’ is operationalized as the number of actual working hours at time of measurement. In addition, we will investigate the effect of the rehabilitation program on secondary outcomes, i.e., change in working hours

(%), employment status, time to return to work, sick leave, readiness for return to work, work ability, health-related work functioning, and health-related quality of life. Among partners of cancer survivors, we will assess: working hours per week and health-related quality of life (primary outcomes) and change in working hours (%), employment status, sick leave, health-related work functioning, caregiver burden and depression (secondary outcomes).

## Study objective

We hypothesize that our individual rehabilitation program will be (cost-)effective regarding the primary and secondary health- and work-related outcome measures of work in cancer survivors with an employment contract, compared to care as usual.
Regarding the cohort study, it is hypothesised that living with a cancer survivor will have a substantial negative impact on work- and health-related outcomes of the partners of these survivors. Moreover, factors that that predict the development of these outcomes are expected to be identified.

## Study design

Participants (both cancer survivors and partners) will be asked to complete three questionnaires: one at baseline (T0), one at six (T1), and one at 12 months (T2)

## Intervention

STEPS is a multidisciplinary intervention based on the Stages of Change, and combines work-related occupational therapy and reintegration consultation, to support cancer survivors in their RTW and work retention. The intervention will be delivered by both occupational therapists and reintegration consultants, who tailor the intervention content according to the Stages of Change as measured by the Readiness for Return to Work (RRTW) questionnaire. The STEPS intervention has a maximum duration of 6 months, during which cancer survivors receive a minimum of three and a maximum of nine sessions, depending on their work-related support needs. Based on the outcomes of the RRTW questionnaire, participants will be categorised according to one of the six stages of change (pre-contemplation, contemplation, preparation: self-evaluative, preparation: behavioural, uncertain and proactive maintenance). Within each of these stages, participants will furthermore be given a traffic light designation (i.e. red, orange or green), based on the outcomes of the Return-to-Work Obstacles and Self-Efficacy Scale (ROSES) questionnaire, depicting potential barriers and facilitators regarding sustained employment and their overall progress within the intervention. Based on this categorisation the occupational therapist can, using the STEPS handbook, tailor the intervention provided.

The intervention includes the following elements:
1. Introductory session (1.5 hours duration) that will take place with the occupational therapist and the cancer survivor. The session is aimed at clarifying the cancer survivor’s work-related circumstances, expectations, and support needs, including barriers and facilitators for return to work or work retention, setting work-related goals, and co-developing a plan for the upcoming sessions.

2. A minimum of one and a maximum of six one-on-one sessions (1 hour duration each) with the occupational therapist and the cancer survivor. These sessions are aimed at preparing the cancer survivor for return to work or work retention, using psycho-education, energy management, self-efficacy training, facilitating contact with their employer and occupational physician, and developing and trying out a return to work/work retention plan.
3. A minimum of one and a maximum of two sessions (1.5 hours duration each) with the reintegration consultant and the cancer survivor. These sessions are aimed at providing information regarding the relevant legal framework in the Netherlands, effective communication about reintegration with/after cancer, return to work planning, or the long-term effects of cancer (treatment) on work. These information sessions can take place one-on-one, or together with a relevant person from the cancer survivor's workplace.

# Contacts

**Public**
Amsterdam UMC, location VUmc - Department of Public and Occupational Health
Pieter Coenen

+31204448381
**Scientific**
Amsterdam UMC, location VUmc - Department of Public and Occupational Health
Pieter Coenen

+31204448381

# Eligibility criteria

## Inclusion criteria

The sample will be composed of cancer survivors of working age (18-63 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 work disability assessment, which (in the Netherlands) takes place at 24 months of sick leave to determine whether someone will receive work disability benefits (18 + 6 months intervention = 24 months). Moreover, cancer survivors will be eligible for participation if they are, or have been, treated with at least radiotherapy and/or chemotherapy. Cancer survivors

with additional treatment modalities, besides radiotherapy and/or chemotherapy, will be eligible for participation as well.
Partners of a cancer survivor who participates in the intervention study are eligible. However, both partners of cancer survivors who do and do not participate in the intervention study will be eligible to participate in the cohort study. Partners of cancer survivors who have had a cancer diagnosis no more than 24 months ago and who have a life expectancy of at least one year, are eligible. Partners should be registered at the same address as the cancer survivor at least one year pre-diagnosis. Moreover, eligible partners should be between 18-65 years of age, have a fixed or a temporary employment contract at the time of diagnosis of the cancer survivors, and a history of paid work for at least one year prior to diagnosis (with ≥8 contracted working hours per week). Partners of cancer survivors can both be at work or (partly) on sick leave when entering the study.

### Exclusion criteria

Cancer survivors will be excluded if their treating physicians consider occupational rehabilitation not feasible, 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 return to work or work retention will also be excluded.
Partners will be excluded from participation in the cohort study in case of self-reported serious cognitive or psychiatric problems that would prevent them from completing the questionnaires, and/or in case they are unable to understand and complete questionnaires in Dutch.

## Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Placebo |

### Recruitment

NL
Recruitment status: Pending

| | |
|---|---|
| Start date (anticipated): | 01-08-2021 |
| Enrollment: | 503 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
n/a

## Ethics review

| | |
|---|---|
| Positive opinion<br>Date: | 13-01-2020 |
| 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 | NL9094 |
| Other | METc Amsterdam UMC, location VUmc : 2020.055 |

## Study results

**Summary results**
Results from this research are aimed to be published in peer-reviewed journals and in a PhD

thesis. The protocol of this study will be published, more detailed, in a journal (reference to follow).