

# SusTained Employability in cancer Patients and their partnerS

Gepubliceerd: 13-01-2020 Laatste bijgewerkt: 18-08-2022

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....

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON25514

### Bron

Nationaal Trial Register

### Verkorte titel

STEPS

### Aandoening

Cancer

## Ondersteuning

**Primaire sponsor:** This research is initiated by Amsterdam UMC, location VUmc and is funded by the Dutch Cancer Society (ref. 11558 / 2018-01)

**Overige ondersteuning:** This research is funded by the Dutch Cancer Society (ref. 11558 / 2018-01)

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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.

## Toelichting onderzoek

### Achtergrond van het onderzoek

**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).

## **Doel van het onderzoek**

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 predict the development of these outcomes are expected to be identified.

## **Onderzoeksoptzet**

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)

## **Onderzoeksproduct en/of interventie**

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.

## Contactpersonen

### Publiek

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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  $\geq 8$  contracted working hours per week). Partners of cancer survivors can both be at work or (partly) on sick leave when entering the study.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Placebo

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2021
Aantal proefpersonen:	503
Type:	Verwachte startdatum

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

### Toelichting

n/a

## Ethische beoordeling

Positief advies	
Datum:	13-01-2020
Soort:	Eerste indiening

## Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL9094
Ander register	METc Amsterdam UMC, location VUmc : 2020.055

## Resultaten

### Samenvatting resultaten

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).