To enhance return-to-work in cancer patients.

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The hypothesis is that the patients who were counselled according to the intervention will return-to-work earlier and will have a better quality of life than patients who were counselled according to usual care.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21373

Bron
NTR

Verkorte titel
N/A

Aandoening

Cancer
Kanker

Ondersteuning

Primaire sponsor: Coronel Instituut voor Arbeid en Gezondheid, AMC.
Overige ondersteuning: Stichting Instituut GAK (SIG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Return-to-work and quality of life.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Survival rates of cancer have been increasing in recent years. It is generally assumed that the incidence of cancer in the working population in western countries will increase as well. For many cancer patients, cancer has become a chronic disease which causes poorer general health outcomes in comparison to the general population. The burden of the diseases itself and the treatment affects quality of life in all its aspects and one of these aspects is return-to-work. Earlier research showed that not all cancer patients who were working prior to their diagnosis, returned to work. Moreover, cancer patients have the highest prevalence of work impairments in comparison to patients with other chronic illnesses. To reduce these negative consequences for cancer patients as well as for the society at large an intervention has been developed to enhance return-to-work. The intervention will be carried out by a nurse who will provide counselling according to a special developed protocol. The hypothesis is that the patients who were counselled according to the intervention will return-to-work earlier and will have a better quality of life than patients who were counselled according to usual care.

Objective:
Primary objective: to determine the effect of the intervention on return-to-work and quality of life.
Secondary objectives:
To determine the effect of the intervention on the work ability and on the work limitations. To determine the feasibility of the intervention and the direct and indirect costs of the intervention.

Study design:
Randomised controlled trial with a follow-up of 24 months. Patients will be randomised to a control group a or to an intervention group. Patients in the control group will get care as usual and patients in the intervention group will get the intervention.

Study population:
Patients with a primary diagnosis of cancer, 18 - 60 years old.

Intervention:
A vocational rehabilitation intervention. Patients in the control group will be counselled according to usual care and patients in the intervention group will be counselled according to a special developed protocol (the intervention).

Main study parameters/endpoints:
Return-to-work and quality of life.

Doel van het onderzoek

The hypothesis is that the patients who were counselled according to the intervention will return-to-work earlier and will have a better quality of life than patients who were counselled according to usual care.

Onderzoeksopzet

Baseline, 6,12,18 and 24 months after baseline.

Onderzoeksproduct en/of interventie

A vocational rehabilitation intervention. Patients in the control group will be counselled according to usual care and patients in the intervention group will be counselled according to a special developed protocol (the intervention). The duration of the intervention is at most 14 months.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Primary diagnosis of cancer with a one year survival rate of approximately 80% and treatment with curative intent;

2. Age between 18 and 60 years;

3. Paid employment at the time of diagnosis;

4. Sick listed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Not able to understand, speak, read or write Dutch sufficiently;

2. Severe mental disorder or other severe co-morbidity;

3. Primary diagnosis of cancer has been made more than two months ago;

4. Patients who visit the hospital for a second opinion;

5. Primary diagnosis of testis cancer;

6. Primary diagnosis of non-melanoma or melanoma skin cancer.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2009

Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-02-2009
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	NL1579
NTR-old	NTR1658
Ander register	METC AMC : 08/267
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A