To enhance return-to-work in cancer patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21373

Source
NTR

Brief title
N/A

Health condition

Cancer
Kanker

Sponsors and support

Primary sponsor: Coronel Instituut voor Arbeid en Gezondheid, AMC.
Source(s) of monetary or material Support: Stichting Instituut GAK (SIG)

Intervention

Outcome measures

Primary outcome

Return-to-work and quality of life.

Secondary outcome

1. Work ability;

2. Work limitations;

3. Feasibility;

4. Direct/indirect costs of the intervention.

Study description

Background summary

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.

Study objective

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.

Study design

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

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). The duration of the intervention is at most 14 months.

Contacts

Public
S.J. Tamminga
Coronel Instituut voor Arbeid en Gezondheid, AMC,
Meibergdreef 9/K0-110
Amsterdam 1105 AZ
The Netherlands
+31 (0)20-566 3279
Scientific
S.J. Tamminga
Coronel Instituut voor Arbeid en Gezondheid, AMC,
Meibergdreef 9/K0-110
Amsterdam 1105 AZ
The Netherlands
+31 (0)20-566 3279

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-02-2009
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	NL1579
NTR-old	NTR1658
Other	METC AMC : 08/267
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A