Tailored clinical work related support for patients with gastro intestinal cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25683

Source
Nationaal Trial Register

Brief title
GIRONA

Health condition

Primary health condition: patients diagnosed with a primary gastro intestinal cancer who experience work- related problems.

- gastro intestinal cancer
- work related problems
- occupational support
- tailored support
- return to work

Sponsors and support

Primary sponsor: Dutch Cancer Society
(in Dutch: KWF kankerbestrijding)
Source(s) of monetary or material Support: Coronel Institute of Occupational Health / Academic Medical Center, Amsterdam

Dutch Cancer Society
(in Dutch: KWF kankerbestrijding)

Intervention

Outcome measures

Primary outcome

The primary outcome parameter in this study is return- to- work (RTW).

RTW is defined as time to partial or full RTW, meaning the number of calendar days between first day sick leave and first day at work. The patient must have returned to work (part time or full time) for at least 4 weeks successively.

Secondary outcome

-Work ability

Work ability will be assessed with the first three questions of the Work Ability Index (WAI), using a 10-point scale. These questions concerns the evaluation of current work ability compared to their life time best and current physical and mental work ability with respect to their job demands.

-Work limitations

Work limitations will be measured with the Work Limitation Questionnaire (WLQ), using a 5-point scale. This questionnaire evaluates the work disability and productivity (loss) in people with health problems. This questionnaire consists four subscales (25 items); work scheduling, physical demands, mental demands/ social demands and output demands.

-Quality of life

Quality of life (QoL) will be assessed with the SF-12 (12 items) and the EORTC QLQ-C30 (30 items). We are using two questionnaires to measure QoL; with the SF- 12 we could compare the participants in this study with the normal population and with the QLQ-C30 we could compare the QoL of patients with GI cancer against patients with other cancer diagnosis. These questionnaires provide insight in participants' health, feelings and the ability to carry out usual activities.

-Costs

Direct and indirect costs including:

Costs to carry out the intervention (payment of the disciplines for the intervention meetings /nurse training) [euro’s]
Days of hospital admission [days]

Income [euro’s]

Work adjustments [e.g. no adjustments/reduction working hours/ other tasks plus open question]

Study description

Background summary

This study concerns about the psychological health of cancer patients, for which sustaining at or returning to work is important. Earlier research shows that early support is needed, but that no interventions exist for supporting patients with GI cancer and work- related problems early in the process of diagnosis and treatment. Therefore we have developed an in- hospital program to support the RTW process for GI cancer patients. The program offers tailored support varying the severity of work- related problems of GI cancer patients. The (cost)-effectiveness of the intervention will be determined in a multicentre Randomised Controlled Trial. It will contribute as a foundation for optimising future tailored work- related interventions in cancer care. The intention is to implement the intervention if it has been shown effective.

Study objective

In the intervention group patients with GI cancer and work-related problems will receive tailored support which will lead to a more successful return to work compared to the control group of patients with GI cancer and work -related problems receiving usual care.

Study design

The supportive care consists three counselling meetings.

The first meeting:

Is scheduled before the start of the treatment.

The second meeting:

Will be scheduled in consultation between patient and the supporting discipline after the first meeting (depending on diagnosis / treatment and preferences of the patient) and with a maximum of 3 – 6 months after the first meeting.

The third meeting

If there is an indication, will be scheduled on request / indication of patient and / or the supporting discipline of the second meeting (depending on diagnosis / treatment and preferences of the patient) and with a maximum of 6- 9 months after the first meeting.

Patients will fill in 5 questionnaires

Baseline

3 months

6 months

9 months

12 months

Intervention

Intervention: tailored support for work- related problems

Because work- related problems could differ in severity, the intervention is split into three types of supports namely, support A, support B and support C. Within these different supports the health care discipline that provide the supportive care is different. In support A that will be an oncological nurse, in support B an occupational physician (specialized in RTW of oncological patients) and in support C there will be a multidisciplinary team (including at least an oncological nurse, the treating physician and an oncological occupational physician) that discuss the work- related problems.

Patients are referred to a tailored support in the intervention on the basis of factors that are scored in patient questionnaires within the following categories; clinical history, work, work limitations and health status.

Contacts

Public
Academic Medical Center / Coronel Institute of Occupational Health Room number K0-114

AnneClaire Zaman
P.O. Box 22660

Amsterdam 1100 DD
The Netherlands
+3120-566 4878 / +31642718309
Scientific
Academic Medical Center / Coronel Institute of Occupational Health Room number K0-114

AnneClaire Zaman
P.O. Box 22660

Amsterdam 1100 DD
The Netherlands
+3120-566 4878 / +31642718309

Eligibility criteria

Inclusion criteria

Patients with a primary diagnosis of GI cancer

- Esophagus

- Stomach

- Liver

- Pancreas

- Biliary

- Small Intestine

- Colon

- Rectum

Age between 18 and 63 years old

In paid employment or self-employed at time of diagnosis

Patients on sick leave (partly or entirely) as a result of related- work problems due to cancer

Treatment with a curative intent

Patients with sufficient knowledge of the Dutch language (able to understand, speak, read or write)

Written informed consent

Exclusion criteria

Severe mental disorder or other severe co- morbidity

Patients who will receive primary cancer treatment at another hospital than hospital of recruitment

Patients who visit the hospital for a second opinion

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2015
Enrollment:	310
Type:	Actual

Ethics review

Positive opinion

Date:	06-03-2015
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	NL4920
NTR-old	NTR5022
Other	NL51444.018.14 : UVA2012-5619

Study results

Summary results

-