Tailored clinical work related support for patients with gastro intestinal cancer

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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...

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

Samenvatting

ID

NL-OMON25683

Bron
Nationaal Trial Register

Verkorte titel
GIRONA

Aandoening

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

Ondersteuning

Primaire sponsor: Dutch Cancer Society
(in Dutch: KWF kankerbestrijding)
Overige ondersteuning: Coronel Institute of Occupational Health / Academic Medical Center, Amsterdam

Dutch Cancer Society
(in Dutch: KWF kankerbestrijding)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-03-2015
Aantal proefpersonen:	310
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-03-2015
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	NL4920
NTR-old	NTR5022
Ander register	NL51444.018.14 : UVA2012-5619

Resultaten

Samenvatting resultaten

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