Gastro Intestinal cancer patients Receiving Occupational support Near and After diagnosis

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Primary study objective The primary objective of this study is to determine the (cost-) effectiveness of tailored support for work- related problems of gastro intestinal (GI) cancer patients on return to work compared to GI cancer patients who…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44003

Source
ToetsingOnline

Brief title
GIRONA

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign
- Economic and housing issues

Synonym
Cancer

Health condition

werk- gerelateerde aangelegenheden

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF kankerbestrijding

Intervention

Keyword: Cost- effectiveness, Gastrointestinal cancer, Return to work, Tailored support intervention

Outcome measures

Primary outcome

Return to work

Secondary outcome

Work ability

Work limitations

Quality of life

Costs (direct and indirect costs of the intervention)

Study description

Background summary

Survival rates of cancer have been increasing in the last years due to screening programs, early detection and continuously improving treatments which contributes to less invasive treatments. Early detection and advances in new and less invasive treatments have improved the prognosis for many cancer patients in the recent years. A diagnosis of cancer has therefore for many people changed from a life threatening disease into a chronic condition. Almost half of the people diagnosed with cancer are of working age. The increasing retirement age will additionally increase the number of cancer survivors in the working population. Surely it is important that cancer patients are able to RTW, because of a fulfilling work life is associated with the quality of life and provides a much- needed income. This is underlined by the oncological rehabilitation guideline, which aims at helping cancer patients to enhance

quality of life, daily functioning and labour participation. Most cancer survivors want to resume work after treatment, but regrettably, not all survivors are able to do so.

It is essential to provide a tailored in- hospital based care program to support the RTW process, because many experience difficulties in this process both at the beginning and at the end of the treatment process. So far no in-hospital intervention is equipped for GI cancer patients who are confronted with specific problems such as eating or defecation problems which might interfere with work. Work- related problems could vary in severity, it is of interest to offer tailored support, however there is no screenings instrument yet for detecting the severity of work- related problems.

Therefore we propose to adapt and customize a hospital- based intervention to enhance the RTW of GI cancer patients. The intervention aims at reaching this aim by offering a tailored support in which the severity of work- related problems vary. Based on the patients *answers from a baseline questionnaire and a decision framework, the patient will be referred into one of supports within the intervention with different disciplines who will offer the tailored support. The intervention is innovative based on the current oncological rehabilitation guideline and it blends oncological and occupational care in the clinical setting, which is an essential part of high- quality oncological care.

Study objective

Primary study objective
The primary objective of this study is to determine the (cost-) effectiveness of tailored support for work- related problems of gastro intestinal (GI) cancer patients on return to work compared to GI cancer patients who receive care as usual.

Secondary study objective
The secondary objective of this study is to determine the work disability, work limitations and the quality of life of GI cancer patients who receive the tailored support for work- related problems compared to GI cancer patients who receive care as usual.

Study design

The study will be carried out as a multicentre Randomised Controlled Trial (RCT) with a follow up of 12 months. Patients will be randomised to a control group and will receive care as usual or to an intervention group and will receive the intervention (tailored support with work- related problems).

Intervention

A vocational rehabilitation program whereby a tailored support is offered within the in- hospital setting. Because work- related problems could differ in severity, the intervention is split into three supports namely, support A, support B and support C. Within these different support the health care discipline who 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 occupational physician) that discuss the work- related problems. Before this multidisciplinary meeting the occupational physician first will have a meeting with the patient .The occupational physician will be in lead in the multidisciplinary team consultation and is the designated person that will take care of the feedback towards the patient in another face- to- face meeting.

Study burden and risks

The burden for the patients in the control group will be 2.5 hours for filling out 5 questionnaires over a period of 12 months. The burden for the patients in the intervention groups will be 0.5 hours per meeting for the intervention plus 2.5 hours for filling out 5 questionnaires. The are no risks associated with participation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with a primary diagnosis of gastrointestinal (GI) cancer
Treatment with a curative intent
Age between 18 and 63 years old
In paid employment or self-employed at time of diagnosis
Patients on sick leave as a result of cancer related- work problems
Patients with sufficient knowledge of the Dutch language
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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-05-2015
Enrollment:	310
Type:	Actual

Ethics review

Approved WMO Date:	26-02-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-11-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL51444.018.14
Other	NTR #5022