The (cost-)effectiveness of interdisciplinary Medical Specialist Cancer Rehabilitation

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27675

Source
Nationaal Trial Register

Brief title
TBA

Health condition

oncology

Sponsors and support

Primary sponsor: not applicable
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

- Quality of life: European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, global health status

- Fatigue: Multidimensional Fatigue Index, dimension reduced activity

Secondary outcome

- Physical fitness: maximum oxygen uptake and workload, 1-RM test m. quadriceps and m. biceps
- Psychological distress: Center for Epidemiologic Studies Depression Scale and the State Trail Anxiety Inventory
- Self-efficacy: General Self-Efficacy Scale
- Physical activity level: Short QUestionnaire to ASsess Health enhancing physical activity
- Societal and work participation: the Utrecht Scale for Evaluation of Rehabilitation-Participation

Cost-effectiveness: the five-level version of the EuroQol five-dimensional questionnaire (EQ-5D-5L) and cost questionnaire

Study description

Background summary

Introduction: Improvement in screening, early detection, and effective treatment of cancer has rapidly increased the percentage of cancer survivors.(1) In the Netherlands, the number of people that live with cancer and the physical, mental and social consequences will rise to more than 700.000 in 2020.(2) Cancer survivors suffer from a range of adverse effects, such as fatigue, pain, reduced physical fitness, anxiety and depression, resulting in a lower quality of life, reduced functioning in activities in daily living and less work participation.(3,4) To reduce the societal costs, it is essential that suitable rehabilitation is provided in order to alleviate these symptoms.(1) In the Netherlands interdisciplinary cancer rehabilitation under supervision of a medical specialist is offered and reimbursed by the basic health care insurance since 2011. Evidence for cost-effectiveness of interdisciplinary Medical Specialist Cancer Rehabilitation (MSCR) in cancer survivors is scarce, whereas MSCR is increasingly recommended in national and international guidelines. In addition, hardly any evidence exists on the long-term outcomes of MSCR.
Research question: What is the (cost-)effectiveness of interdisciplinary Medical Specialist Cancer Rehabilitation compared to usual care in patients with complex long-term adverse effects of cancer or the treatment?
Study design: Randomized controlled trial with two groups
Study population: Patients after curative cancer treatment with complex long-term adverse effects of cancer
Intervention: Medical Specialist Cancer Rehabilitation
Usual care: Care as usual; no therapy or monodisciplinary therapy e.g. physical therapy, psychology
Outcome measures: Primary: quality of life, fatigue. Secondary: physical fitness, activity level, self-efficacy, society and work participation, psychological distress
Sample size: 103 patients will be included in each group

Data-analysis: Mixed linear regression models, qualitative research and a cost-utility and effectiveness analysis will be performed.

Study objective

Medical Specialist Cancer Rehabilitation is more (cost-)effective than usual care

Study design

Measurements will be performed at baseline, 12 weeks, 24 weeks, 36 weeks and 52 weeks after starting rehabilitation

Intervention

A patient-tailored Medical Specialist Cancer Rehabilitation program

Contacts

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Eligibility criteria

Inclusion criteria

- people between 18 and 65 years diagnosed with cancer who have finished primary treatment with a curative intent 6-12
months ago
- colon, breast, prostate, bladder, lung, ovarian, uterus, or testis cancer, leukemia, lymphoma, myeloma
- complex adverse effects of cancer or the treatment including 1. fatigue or loss of physical fitness, 2. psychological complaints
such as depression or anxiety, and 3. problems conducting activities in daily life e.g.

housekeeping, self-care, work, family

Exclusion criteria

not applicable

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	186
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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	NL7888
Other	METC UMCG : not applicable yet

Study results