SoFiT: A Study on fatigue in colorectal cancer survivors, a lifestyle intervention

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The objective of the study is investigate the relationship between adherence to the recommendations for cancer prevention of the WCRF and cancer-related fatigue in colorectal cancer survivors.

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54002

Source
ToetsingOnline

Brief title
SoFiT

Condition

- Other condition

Synonym
fatigue

Health condition

vermoeidheid na dikke darmkanker behandeling.

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: World Cancer Research Fund international

Intervention

Keyword: Colorectal cancer, Fatigue, Lifestyle interventie, Survivors

Outcome measures

Primary outcome

The primary outcome is cancer-related fatigue measured via the FACIT-F questionnaire. The FACIT-F is a specialised questionnaire made to score fatigue in chronic illnesses. The FACIT-F is an abbreviation of Functional Assessment of Chronic Illness Therapy - Fatigue.

Secondary outcome

* Investigate (I) whether the changes in the following parameters are associated with changes in CRF and (II) whether the changes in those parameters differ between the intervention group and the wait-list control group

o Skeletal muscle fat infiltration and cross-sectional area in the m. rectus femoris, lateral gastrocnemius and biceps brachialis

o Gut microbiota composition

o HRQoL

o Physical performance

o Sleep quality and duration

o Depression and anxiety.

* To investigate whether differences in CRF between the intervention and control group can be attributed to changes in behavioural determinants.

* Process evaluation

o To investigate adherence of participants to the WCRF cancer prevention guidelines.

o To investigate the cost-effectiveness of the SoFiT trial.

o To investigate the relation between the level of adherence of participants to the WCRF cancer prevention guidelines and its effect on CRF.

o To investigate the experience of participants and relevant stakeholders on the SoFiT intervention.

* To investigate the prolonged effect of the lifestyle intervention on CRF and behaviour change, six months after completion of the intervention on CRF.

Study description

Background summary

More people survive colorectal cancer due to improvements in treatments. These treatments are so far not without side-effects, thus many people who survive colorectal cancer have these side-effects. Cancer-related fatigue is the most common and most invasive side-effect that affects colorectal cancer survivors.

Till now, not enough intervention studies has been done on the effect of a healthy lifestyle, a combination of nutrition and exercise on cancer-related fatigue in colorectal cancer survivors. Research has been done on de effect of nutrition or exercise on lowering cancer-related fatigue. These studies found that exercise can possibly lower cancer-related fatigue, however not enough evidence has been found on the effect of nutrition on cancer-related fatigue. With a healthy lifestyle we mean the recommendations on cancer preventie made by the World Cancer Research Fund. Relationships have been found in cohort studies on these recommendations and cancer-related fatigue. Following the recommendations is associated with a decrease in cancer-related fatigue in colorectal cancer survivors. Furthermore, the intervention studies on cancer-related fatigue in colorectal cancer survivors didn't select on cancer-related fatigue before hand and didn't have cancer-related fatigue as their primary outcome. Therefore we will take cancer-related fatigue as primary outcome, select on cancer-related fatigue before hand and combine nutrition and

exercise as the intervention program.

For more information please see chapter 1 in the protocol.

Study objective

The objective of the study is investigate the relationship between adherence to the recommendations for cancer prevention of the WCRF and cancer-related fatigue in colorectal cancer survivors.

Study design

Participants will be randomised into an intervention or controle group. Participants in the intervention group will increase their adherence to the recommendations of the WKOF by following a lifestyle intervention for 6 months. During these 6 months, they will be guided by a lifestyle coach who will help them with all the different categories of these recommendations with regards to nutrition and exercise. The coach will meet the participants every other weeks to help them improve adherence at home, online or via telephone. Possible SARS-COVID-19 restrictions will be taken into account, so most of the intervention will also be made possible online.

Participants in the controle group will get a light version of the intervention after 6 months, while in the mean time they will act as controle. The light version consist of the materials of the intervention and two personalized coaching sessions with the lifestyle coach.
The researchers will do the measurements at baseline and at the end of the study.

Intervention

A lifestyle intervention in which participants will increase their adherence to the recommendations for cancer prevention of the World Cancer Research Fund compared to baseline.

Study burden and risks

No risk is expected for participants participation in this study. The lifestyle intervention will follow the recommendations of cancer prevention of the WCRF. The intervention will be home-based, which entails that the lifestyle coaches will visit the participants at home to deliver the intervention. Remaining contact will take place via telephone and/or e-mail. The included measurements can be considered mostly non-invasive. Measurements are taken at the homes of participants and questionnaires can be filled out online.
Benefits for the participants may include a decrease CRF, and thus therefore an

improvement of quality of life.

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

* Aged 18 or above
* Completed curative stage I-III colorectal cancer treatment 6 months to 5 years ago
* Live on a reasonable distance from the research center at the Wageningen University & Research (WUR) (i.e. maximum of ± 1 hour away)
* Classified as suffering from CRF through the Functional Assessment of Chronic Illness Therapy (FACIT) - Fatigue Scale questionnaire with cut-off score below 34 indicating fatigue
* Willingness to be randomized into either the intervention or wait-list

control group
* Willing and able to follow the lifestyle intervention
* Able to understand and provide informed consent in Dutch

Exclusion criteria

* Planning to participate or participating in another medical research that could possibly interfere with the study results.
* Excessive alcohol consumption (i.e. on average more than 4 glasses of alcohol per day)
* Chronic drug use and unwillingly to stop using drugs.
* Unable/unwilling to comply with the intervention (e.g. through dementia, Alzheimer or mental illness).

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-01-2022
Enrollment:	184
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2021
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-03-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-07-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL75999.091.21
Other	TBA

Study results

Date completed:	20-01-2025
Results posted:	20-01-2025
Actual enrolment:	161

First publication
20-01-2025