Implementation of the Eetscore in Outpatients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21544

Source
Nationaal Trial Register

Brief title
Eetscore Study

Health condition

Colon cancer, General health, Prevention

Sponsors and support

Primary sponsor: Wageningen University (WUR)
Source(s) of monetary or material Support: Netherlands Nutrition Centre

Intervention

Outcome measures

Primary outcome

The overall score (0-90) of the Eetscore.

Sub scores of the Eetscore are available for the intake of 1) vegetables, 2) fruit, 3) dietary fibre, 4) saturated fatty acids, 5) trans fats, 6) fish, 7) sodium, 8) alcoholic beverages and in addition 9) physical activity.

Secondary outcome

- Quality of Life (SF-12)

- Abdominal circumference

- Body composition (BIA)

- BMI

Study description

Background summary

Rationele: At the Division of Human Nutrition, we developed a validated tool to support dietary advice. With this tool, the Eetscore, we can assess diet quality by evaluating to what extent someone’s intake complies with the dietary guidelines. The Eetscore can be used to monitor the diet of healthy persons and patients with a high risk of disease, disease or recurrence of diseases. Based on the results of the evaluation the patients can receive automatically a targeted dietary advice. The advantage of the tool is that it is much shorter than existing food questionnaires, requires little time to fill out (5-10 minutes), gives feed-back to the patient by a score, and is easily applicable. Hospital Gelderse Vallei, in cooperation with the Division of Human Nutrition, is developing a care path for nutrition. It aims to provide better nutritional care for patients before admission to the hospital, during hospital stay and after their discharge from hospital. The Eetscore could support this carepath.

Objective: To investigate whether the extent to which patients adhere to the Dutch dietary guidelines improves more in out clinic patients, with a positive iFOBT, who receive dietary and physical activity advice by the Eetscore during 3 months, than in out clinic patients, with a positive iFOBT, who receive no advice.

Study design: The whole study will take about 7 months. Four months are needed to recruit participants and to carry out baseline measurements. These baseline measurements consist of filling out the Eetscore and quality of life questionnaire and measuring abdominal circumference and body composition. After completion of the Eetscore questionnaire patients will receive randomly either an advice via the Eetscore application (intervention) or no advice (control). Then, 3 months after the baseline measurements the follow-up measurements (t=3) will be carried out. Also 4 months are reserved for performing these follow-up measurements. These follow-up measurements consist of the same measurements as at

baseline.

Study population: 210 patients, 61-75 years old, who participated in the national screening on colorectal cancer and have a positive iFOBT and comes for an intake at Hospital Gelders Vallei.

Intervention: A 3 months intervention with dietary and physical advice according to the Eetscore.

Main study parameters/endpoints: The main study parameter will be the overall score (0-90) of the Eetscore. Sub scores of the Eetscore are available for the intake of 1) vegetables, 2) fruit, 3) dietary fibre, 4) saturated fatty acids, 5) trans fats, 6) fish, 7) sodium, 8) alcoholic beverages and in addition 9) physical activity.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participants are asked to fill out the Eetscore questionnaire and a questionnaire about their general health. In addition, they have to undergo measurements of waist and body composition by bioimpedance at baseline and at the end of the study. In between they will follow a dietary advice.

Study objective

It is hypothesized that there is a significant improvement in the quality of dietary intake and physical activity in out clinic patients, with a positive iFOBT, who receive nutritional and physical activity advice via the web-based Eetscore application compared to out clinic patients, with a positive iFOBT, who do not receive nutritional and physical activity advice via the Eetscore application.

Study design

At baseline the measurements consist of filling out the Eetscore and quality of life questionnaire and measuring abdominal circumference and body composition. After completion of the Eetscore questionnaire patients will receive randomly either an advice via the Eetscore application (intervention) or no advice (control). Then, 3 months after the baseline measurements the follow-up measurements (t=3) will be carried out. These follow-up measurements consist of the same measurements as at baseline.

Intervention

A 3-months intervention with dietary and physical activity advice according to the Eetscore.

Contacts

Public
MG de Rijk
[default]
The Netherlands
Scientific
MG de Rijk
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

Patients will be included if they:

- have a positive iFOBT,

- have an email account.

Exclusion criteria

Patients will be excluded if they:

- do not have a Dutch eating pattern,

- do not enter the colon care outpatient clinic via the national screening program for colon cancer.

- have an internal electronic device, such as a pacemaker.

Patients diagnosed with colon cancer during the study will be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-05-2015
Enrollment:	172
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41764
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5815
NTR-old	NTR5970
CCMO	NL51456.081.14
OMON	NL-OMON41764

Study results