Physical Activity and Dietary intervention in OVArian cancer (PADOVA)

No registrations found.

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

Summary

ID

NL-OMON24664

Source
NTR

Brief title
PADOVA

Health condition

ovarian cancer

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Dutch Cancer society (KFW kankerbestrijding)

Intervention

Outcome measures

Primary outcome

Body composition, physical function and fatigue

Secondary outcome

Physical activity and fitness, body mass index, diet, health-related quality of life, symptoms of pain, nausea, neuropathy, distress and sleep disturbances, chemotherapy completion rates, a process evaluation and behavior change.

Study description

Background summary

Rationale:
As a consequence of the disease and its treatment, many women with ovarian cancer perceive physical and psychological problems compromising their quality of life. Favourable changes in physical activity, diet, and body composition have been associated with improved health outcomes in patients with cancer during chemotherapy, such as increased quality of life, including physical function and reduced fatigue. Current knowledge on the effect of physical activity and dietary interventions on health outcomes generally relies on studies among patients with breast cancer treated with curative intent. Since ovarian cancer has a very distinct disease and treatment trajectory, as it is often detected at an advanced stage, it is not known whether findings from studies among patients with breast cancer are generalizable to women with ovarian cancer. Except for a few pilot studies, a well-designed randomized controlled intervention trial has not yet been conducted in patients with ovarian cancer.

Objectives:
· The primary aim is to evaluate the effectiveness of a combined supervised exercise and dietary intervention in women receiving chemotherapy treatment for ovarian cancer.
· The secondary aim is to conduct an extensive process evaluation to get insight into how and why this intervention is (in)effective.

Study design:
In this single blind randomized controlled trial, patients with ovarian cancer are randomly allocated to a combined exercise and dietary intervention or a waitlist control group.

Study population:
Adult women (n = 122) with histologically confirmed primary epithelial ovarian cancer who are scheduled to undergo first-line (neo)adjuvant chemotherapy treatment are recruited from the Center for Gynaecological Oncology Amsterdam.

Intervention:
After randomization, patients in both the intervention and wait-list control group will receive a brochure on physical activity, diet and body weight recommendations for cancer survivors.

Patients in the intervention arm will receive two one-hour exercise sessions per week including moderate-high intensity resistance and aerobic exercises supervised by a specially-educated physiotherapist, and an individually tailored 30 minute-dietary counselling session every three weeks during chemotherapy treatment. The intervention starts with the first

cycle of chemotherapy and ends three weeks after the last cycle.

Women in the control group will receive, upon request, three counselling sessions (during 12 weeks) with a dietitian and/or physical therapist after completion of chemotherapy treatment and the first follow-up assessment.

Main study parameters/endpoints: Primary outcomes are body composition, physical function and fatigue. Secondary outcomes include physical activity and fitness, body mass index, dietary intake, health-related quality of life and symptoms related to ovarian cancer and its treatment (pain, fatigue, nausea/vomiting, neuropathy), anxiety and depression, sleep disturbances, chemotherapy completion rates, and behavior determinants. Outcome measures will be assessed at baseline before randomization and the start of chemotherapy (T0), three weeks after completion of chemotherapy (T1), and 12 weeks later (T2). In addition, blood samples will be drawn at T0 and T1, and a process evaluation will be conducted.

Start of study preparation: January 2017
MEC approval: August 2017
Enrollment of first participant: February 2018

Study objective

· The primary aim is to evaluate the effectiveness of a combined supervised exercise and dietary intervention in women receiving chemotherapy treatment for ovarian cancer.
· The secondary aim is to conduct an extensive process evaluation to get insight into how and why this intervention is (in)effective.

We hypothesize that a combined exercise and dietary intervention during chemotherapy treatment for ovarian cancer will prevent gain in fat mass, limit or prevent fatigue, and maintain muscle mass and physical function.

Study design

- T0 before start chemotherapy
- T1 after completion of chemotherapy (18 weeks)
- T2 12 weeks after completion of chemotherapy

Intervention

Patients in the intervention arm will receive two one-hour supervised exercise sessions per week including moderate-high intensity resistance and aerobic exercises, and an individually tailored 30 minute-dietary counselling session every three weeks during chemotherapy treatment. The intervention starts with the first cycle of chemotherapy and ends three weeks after the last cycle.
Women in the wait-list control group will receive a brochure on physical activity, diet and body weight recommendations for cancer survivors. After completion of chemotherapy treatment and the first follow-up assessment, women will receive, upon request, four

counselling sessions (during 12 weeks) with a dietitian and/or physical therapist.

Contacts

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Eligibility criteria

Inclusion criteria

Women (aged ≥ 18 years) who are scheduled for (neo)adjuvant first line chemotherapy treatment for histologically confirmed primary epithelial ovarian cancer are eligible to participate in this study.

Exclusion criteria

- not being able to perform basic activities of daily living
- cognitive disorder or severe emotional instability (e.g. schizophrenia, Alzheimer)
- contraindications of exercise (e.g. heart failure)
- inability to read and write Dutch
- expected to die within three months
- participating in another exercise and/or dietary intervention study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2017
Enrollment:	122
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	01-03-2017
Application type:	First submission

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	NL6145
NTR-old	NTR6300
Other	METC AMC : VU 2015-7950

Study results