Physical Activity and Dietary intervention in OVArian cancer (PADOVA): a RCT evaluating effects on body composition, physical function, and fatigue

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This single blind randomized controlled trial evaluates the effects of a combined supervised exercise and dietary intervention during chemotherapy treatment on body composition, physical function and fatigue (primary outcomes). Secondary outcomes…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55552

Source
ToetsingOnline

Brief title
PADOVA

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Ovarian cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: diet, ovarian cancer, physical activity

Outcome measures

Primary outcome

Primary outcomes are body composition, physical function and fatigue.

Secondary outcome

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, blood samples, sleep disturbances and chemotherapy completion rates.

Additionally, an extensive process evaluation will be conducted to examine how and why the intervention was (un)successful. Clinical parameters (e.g. FIGO stage, comorbidities and survival) will be collected from medical records.

Blood will be drawn for future analyses to examine biological mechanisms linking exercise to clinical outcomes, such as reduced inflammation, improved immune function, vascularization and perfusion, and insulin-like growth factor-axis.

Study description

Background summary

As a consequence of the disease and its treatment, many women with ovarian cancer perceive physical and psychological problems compromising their quality

of life. Physical activity and diet are energy balance related behaviours linked to body composition and have been associated with improved physical function and quality of life, as well as reduced fatigue. In addition, regular physical activity, a healthy diet and body weight have been associated with increased survival. Current knowledge of the effect of physical activity and dietary interventions on health outcomes generally relies on studies among breast cancer survivors treated with curative intent. Except for a few pilot studies indicating that lifestyle interventions are safe and feasible, no studies have focused on women with ovarian cancer. 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 breast cancer are generalizable to women with ovarian cancer, thus a well-designed randomized controlled trial is needed.
The intervention of the PADOVA study is expected to be beneficial for participants (e.g., it is expected the intervention will lead to improvements in body composition, physical function, and fatigue).
Results of the PADOVA study will contribute to further development and implementation of interventions for women with ovarian cancer.

Study objective

This single blind randomized controlled trial evaluates the effects of a combined supervised exercise and dietary intervention during chemotherapy treatment on body composition, physical function and fatigue (primary outcomes). Secondary outcomes include physical activity and fitness, BMI, diet, health-related quality of life and symptoms related to ovarian cancer and its treatment (pain, fatigue, nausea/vomiting, neuropathy), anxiety and depression, sleep disturbances and chemotherapy completion rates.
Additionally, an extensive process evaluation will be conducted to examine how and why the intervention was (un)successful and blood will be drawn for future analyses to examine biological mechanisms linking exercise to clinical outcomes, such as reduced inflammation, improved immune function, vascularization and perfusion, and insulin-like growth factor-axis.

Study design

This will be a single blind, randomized, multi-center study. After baseline measurements participants will be randomized in either the intervention or the waitlist control group. Study parameters will be assessed before start of chemoterapy (T0), after finishing chemotherapy (T1) and 12 weeks later (T2).

Intervention

The intervention group will receive a supervised exercise and dietary intervention during chemotherapy treatment (18 weeks). Supervised one-hour exercise sessions include aerobic and resistance exercises and will be given

twice a week. Tailored dietary counselling is provided by experienced oncological dieticians during face-to-face sessions once every three weeks, aiming to meet dietary recommendations for cancer survivors and to prevent undesired weight gain or weight loss.
Women in the wait-list 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.

Study burden and risks

Previously conducted pilot studies indicate that lifestyle interventions are safe and feasible in patients with ovarian cancer during chemotherapy. The intervention is expected to be beneficial for participants (e.g., it is expected the intervention will lead to improvements in body composition, physical function, and fatigue).
Participation is expected not to cause any additional risks. Venepuncture can cause hemorrhage, the questionnaires could contain confronting questions and incidental findings from the measurements (e.g. arrhythmia) will be reported to the physician. These risks are also described in the patient information letter. The risk of participating in the endurance and strength tests is considered as minimal as participants will be supervised by a trained professional. Tailered counselling will be given by a dietitian or physical therapist specialized in oncology. Futhermore, participation in this trial is expected not to cause any risks.

Meaurements for study outcomes will be conducted in the hospital. Participants will visit the hospital three times over the course of 30 weeks, one visit will take 2 hours. During each of these visits, blood will be drawn and a physical examination (cardiorespiratory fitness, muscle strength, length, weight and body composition) will be conducted. Additionally participants are asked to wear a accelerometer on the right hip for seven consecutive days. A accelerometer is a small light-weight device which detects accelerations. Questionnaires can be filled in at home, one questionnaire will take up approximately 60 minutes to complete.

Participants in the intervention group wll visit the physical therapist twice a week and the dietician once every three weeks. Participants in the control group will visit a dietitian and/or physical therapist if they wish to do so (with a maximum of three sessions per clinician).

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women (aged >= 18 years) who are scheduled for (neo)adjuvant first-line chemotherapy treatment for histologically confirmed primary epithelial ovarian-, fallopian tube or extra-ovarian cancer.

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
- life expectancy < 3 months
- participating in another exercise and/or dietary intervention study
- have had any other type of cancer within the last 5 years.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2018
Enrollment:	122
Type:	Actual

Ethics review

Approved WMO Date:	11-08-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-09-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-07-2021
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	NL61089.018.17
Other	NL6145