

Fast Facts

GOG-0225: CAN DIET AND PHYSICAL ACTIVITY MODULATE OVARIAN, FALLOPIAN TUBE AND PRIMARY PERITONEAL CANCER PROGRESSION FREE SURVIVAL?

PATIENT ELIGIBILITY AND EXCLUSIONS

Eligible Patients

1. Patients with a histological diagnosis of epithelial ovarian cancer, fallopian tube or primary peritoneal carcinoma, clinical stage II, III or IV at diagnosis.
2. Patients with the following histologic epithelial cell types are eligible: serous adenocarcinoma, endometrioid adenocarcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, transitional cell carcinoma, malignant Brenner's Tumor or adenocarcinoma not otherwise specified (N.O.S.). However, the histologic features of the tumor must be compatible with a primary Müllerian epithelial adenocarcinoma.
3. Patients must have completed all primary chemotherapy and consolidation therapy (if administered) at least 6 weeks, and no more than 6 months and 2 weeks, prior to enrollment and must be in complete remission.
Consolidation therapy is defined as any chemotherapy or biological therapy used for a patient who has completed at least four courses of primary chemotherapy and had documented complete remission prior to initiation of such chemo or biological therapy
4. Patients must have achieved a documented complete response to treatment based on normal CA-125 (per the institution's upper limit of normal) and CT scan or MRI with contrast (i.e. there must be no clinical evidence of persistent or recurrent disease based on CA-125 and CT scan or MRI with contrast).
5. Patients must have a GOG Performance Grade of 0, 1, or 2.
6. Patients must not be currently enrolled in an ongoing (participating for 6 months or longer) medically prescribed diet or physical activity regimen.
7. Patients must have no other chronic disease that would preclude randomization into a lifestyle intervention trial. Such diseases include recent myocardial infarction or unstable angina (in the previous 6 months), chronic hepatitis, rheumatoid disease, renal or hepatic disease/dysfunction and diabetics receiving insulin; or other clinical condition limiting ability to walk (recent leg fracture, significant osteoarthritis, related orthopedic conditions, degenerative neurological conditions, etc).
8. Patients must not have a serious psychiatric illness (*e.g.* lifetime bipolar disorder, schizophrenia or other psychosis, serious personality disorder, severe major depressive disorder or recent suicide or psychiatric hospitalization (previous 12 months), or a history of an eating disorder (anorexia nervosa or bulimia nervosa).
9. Patients must complete all pre-entry assessments as outlined in Section 7.1.
10. Patients must have signed an approved informed consent and authorization permitting release of personal health information.
11. Patients must be willing to provide name and appropriate telephone contact information and be willing to be contacted periodically via telephone by The University of Arizona Cancer Center (AZCC) staff for completion of individualized lifestyle intervention coaching and for clarification of patient completed responses if necessary. Patient must be willing to have AFFQ, APAQ, Baseline Questionnaire, and personal contact information sent to AZCC.

12. Only women 18 years and older are eligible.

Ineligible Patients

1. Patients with GOG Performance Grade of 3 or 4.
2. Patients may not have a history of other invasive malignancies within the last five years, with the exception of non-melanoma skin cancer or stage 1A endometrioid adenocarcinoma of the uterus
3. Patients diagnosed with chronic disease/illness precluding their participation (*i.e.*, diabetics receiving insulin, myocardial infarction or unstable angina within previous 6 months, chronic hepatitis, rheumatoid disease, renal or hepatic disease/dysfunction as defined in 3.17 and 3.18).
4. Patients with a histological diagnosis of clinical stage I epithelial ovarian cancer, fallopian tube or primary peritoneal carcinoma.
5. Patients who are currently undergoing treatment (primary or consolidation) for Stage II, III or IV ovarian, fallopian tube or primary peritoneal cancer or who completed treatment less than six weeks ago.
6. Patients with a life expectancy of less than one year.
7. Patients with Body Mass Index (BMI) < 20kg/m².
8. Vegan vegetarians
9. Patients enrolled in a weight loss program or who are taking weight loss medications or dietary supplements and are unwilling to discontinue.
 - a. Patients who have participated in a marathon, triathlon, or other endurance-related physical activity within the previous 24 months.
10. Patients who have had surgery for weight loss are now ineligible.

Note: Women will not be excluded if their baseline lifestyle assessment indicates a healthy eating and moderate physical activity with the exception of the exclusion criteria above. We expect that the intervention proposed here (diet and additional 4000 steps daily to baseline physical activity) will result in significant and sustained improvements in dietary intake and physical activity, even among those currently complying with public health recommendation

SCHEMA

