

# Feasibility Pilot Study of a Standardized Extract of Cultured *Lentinula edodes* Mycelia (AHCC®) on Quality of Life for Ovarian Cancer Patients on Adjuvant Chemotherapy

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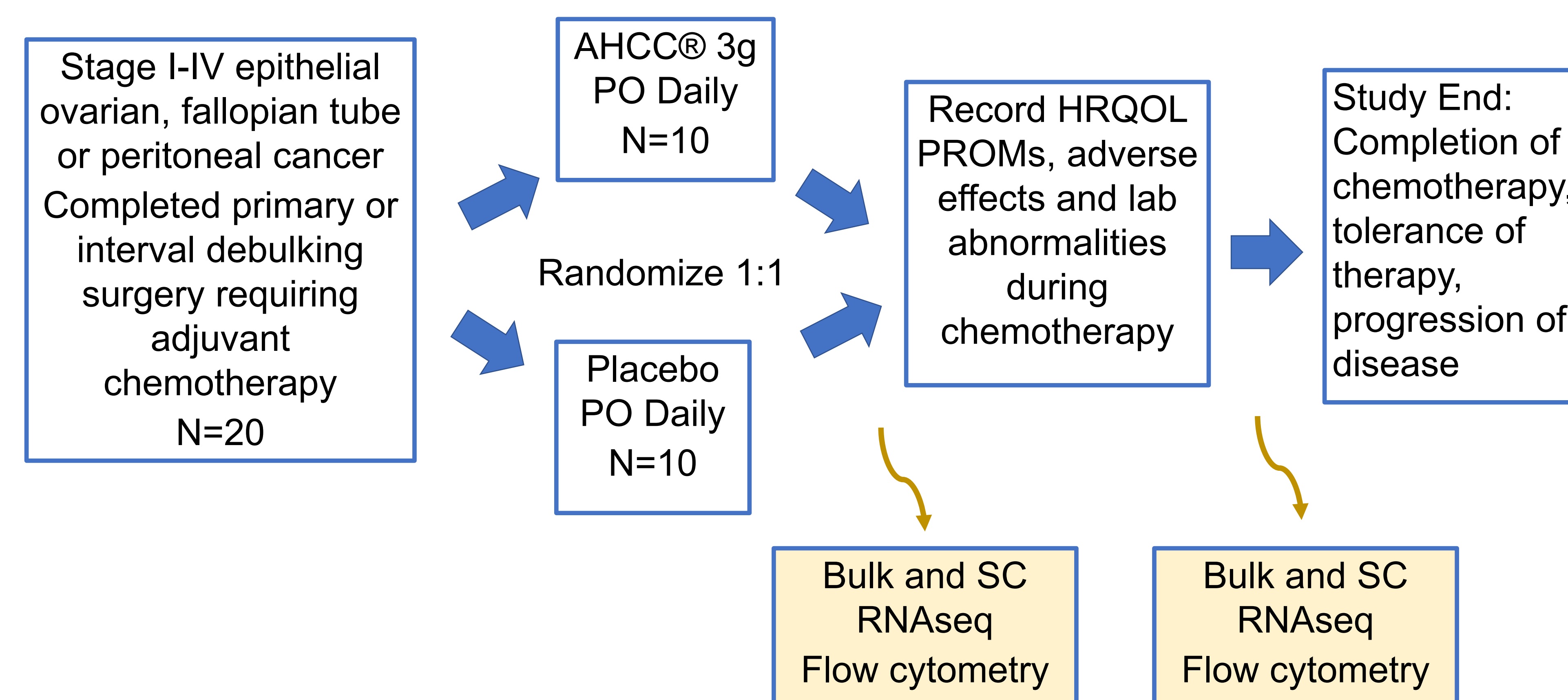
## BACKGROUND

- Ovarian cancer is a deadly gynecologic cancer with most patients diagnosed at advanced stages with quality of life affected by tumor burden, radical surgery and chemotherapy
- More than 60% of gynecologic oncology patients in the U.S. are using complementary and alternative medicine
- Active Hexose Correlated Compound (AHCC®), an extract made from the mycelia of *Lentinula edodes* or shiitake mushroom shown to impact
  - Immune system: activating of CD4+ and CD8+ T-cells, increasing IFN-γ, suppressing IFN-β
  - Chemotherapy side effects: decreasing alopecia, weight loss, renal toxicity and hepatotoxicity, myelosuppression
  - Health-related quality of life (HRQOL): improving GI side effects, less loss of appetite and nausea and vomiting, decreased fatigue
- Objective**: To examine the feasibility of conducting a randomized controlled trial to evaluate the effects of AHCC® on HRQOL in ovarian cancer patients undergoing adjuvant chemotherapy. To compare the effect of AHCC® on HRQOL and adverse events while examining the effects of AHCC® on immune cell components

## METHODS

- A pilot feasibility randomized trial of newly diagnosed ovarian cancer patients undergoing chemotherapy after surgery
- To determine feasibility, we will evaluate the ability to recruit 20 participants from 50 eligible ovarian cancer patients as well as adherence and acceptability
- Participants randomized 1:1 to AHCC® or placebo
- HRQOL Patient Reported Outcomes Measures:
  - Functional Assessment of Cancer Therapy – Ovarian
  - Functional Assessment of Cancer Therapy/Gynecologic Oncology Group – Neurotoxicity
  - Functional Assessment of Cancer Therapy - Endocrine Symptoms
- Adverse events collected from the electronic medical record
- Immune cell components and function evaluated using RNA sequencing and flow cytometry

Figure 1 – Pilot Clinical Trial Design



## RESULTS

Figure 2 – Recruitment to Date

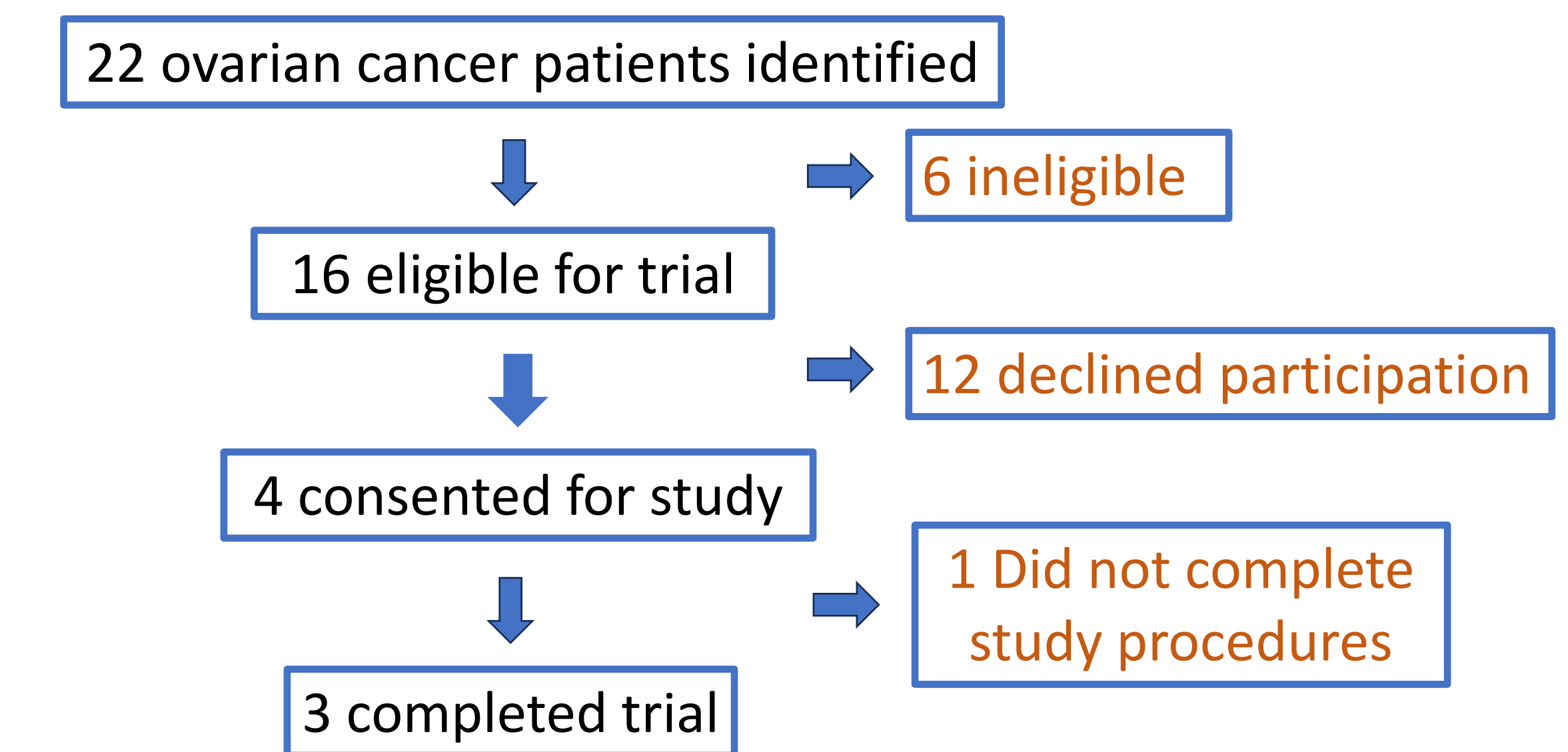
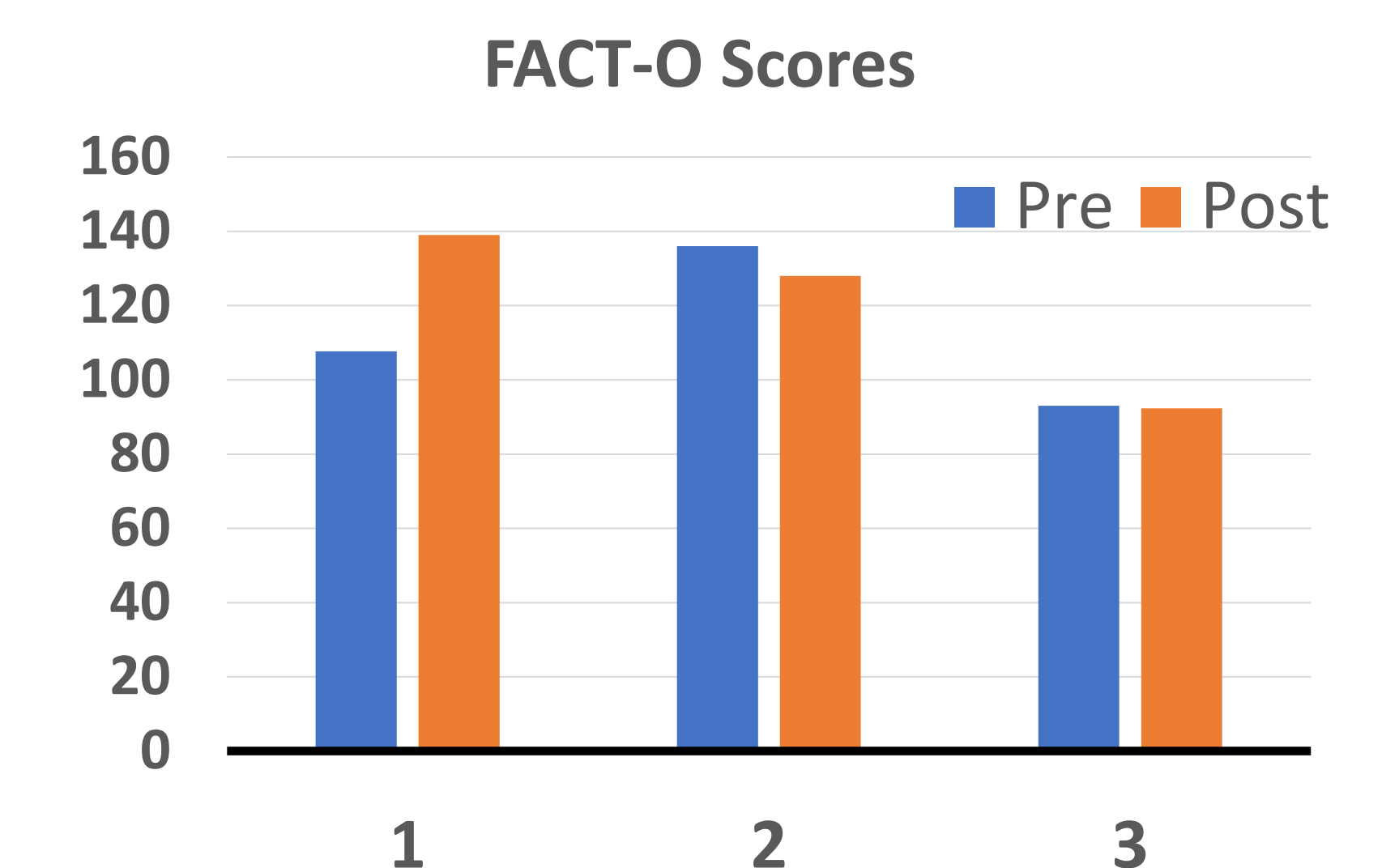


Figure 3 – HRQOL of Subjects 1-3



## CONCLUSION

- From this pilot study, a larger randomized trial of AHCC® may be feasibly performed to evaluate its impact on quality of life and cancer outcomes for patients with ovarian cancer