**CPH 675 HW 3 Question 1:**  Dominic LaRoche and William John Degnan III

1. [50pts] Read the CONSORT statement and the Henke paper. With two partners, go through the checklist, and briefly discuss how this paper did or did not comply with CONSORT reporting standards. Each group of 3 should turn in only one report. Failure to work with a group will result in a deduction of 25 points.

Title/Abstract:

Item 1: a) The title does not indicate that this is an RCT but the abstract does.

b) Abstract follows consort structure

Introduction:

Item 2: a) The introduction provides a background and a specific explanation for the rationale. However, the rationale was not rigorous and the need vs potential costs of the research is not well supported.

b) The objectives are clearly stated but involve seemingly difficult to measure aspects such as quality of life and ability to function in daily life. No specific hypothesis was given.

Methods:

Item 3: a) They don’t specifically state that this is a parallel design, although it is evident from the rest of the paper. It also seems implied 1:1 allocation but this was never explicitly stated.

b) They don’t specifically stat any changes after commencement of the trial but certain patients in the intervention arm were not given the intervention if they had certain clinical symptoms such as fever or infection.

**Participants:**

Item 4: a) They clearly describe both the inclusion and exclusion criteria in the “setting and participants” section.

b) The state that the patients were enrolled at a single clinic but do not state what sort of clinic it was (hospital, cancer center, etc).

**Interventions:**

Item 5: The interventions are well described although they did not state precisely when these trainings were administered, either during the day (e.g. morning or evening) or with respect to chemotherapy treatment. The intervention protocol did not have sufficient detail to reproduce the results.

**Outcomes:**

Item 6: a) The assessment measures were predefined and taken at baseline and after 3 cycles of chemotherapy.

b) No changes to outcomes were indicated

**Sample Size:**

Item 7: a) The sample size calculation was not described in detail and they did not account for drop-out or death. The effect size was not given but stated to be large so would not be suitable for high sensitivity. They did not specify for which outcome the sample size was powered.

b) No interim analyses were described and no stopping rule was put in place, although individual patients could be taken off of the treatment with certain ailments.

**Randomization:**

Item 8: a) They did not describe the method of allocating the sequence other than to say it was done via computer.

b) No details were given re: the randomization method such as blocking or stratification.

Item 9: Since randomization was conducted with a computer the allocation was likely concealed until allocation, although this was not specifically stated.

Item 10: They gave no details on who enrolled patients or who managed the computer that generated the random sequence.

**Blinding:**

Item 11: a) No attempt at blinding was made.

b) There was no attempt conceal treatments.

**Statistical Methods:**

Item 12: a) They did not define how they determined which data were parametric and which was non-parametric. They did not specify how each outcome was specifically analyzed because it wasn’t clear which data belonged to which group. They did not specifically state that they did a per-protocol analysis and they did not conduct an intention-to-treat analysis.

b) They did not specify any subgroup analysis.

**Results**

Item 13: a) They did include a CONSORT flow diagram.

b) They did include losses and reasons for losses.

**Recruitment:**

Item 14: a) They defined the dates for recruitment but not follow-up.

b) They did not give a reason for why the trial was stopped even though they did not reach their desired sample size. It is unclear why they did not reach the desired sample size since they randomized 46 participants (why 46??) but only included 29 (far less than the 42 they stated they needed).

**Baseline Data:**

Item 15: No table was given describing the demographic and clinical characteristics of the two arms.

**Number Analyzed:**

Item 16: They excluded participants who were unable to participate in the interventions at least 75% of the time. This would likely bias the results by filtering the least healthy participants out of the intervention arm.

**Outcomes and Estimation**:

Item 17: a) The estimated effect sizes and confidence intervals were not given directly, although these could be calculated from the information in table 1. Additionally, wow. In the statistical methods they state that they conduct tests on the delta values but in the results this is not clear and appears to be on the group means. The tables provide means and standard deviations but no estimands or standard errors are given.

b) NA

Item 18: They provide differences in the sub-score for the secondary outcome (EORTC QLQ c-30) but do not perform any subgroup analyses for either outcome. They also provide analyses on the ancillary outcomes directly related to the intervention, although these are not given as primary or secondary outcomes.

**Harms:**

Item 19: No harms or unintended effects were given for either group.

**Discussion:**

**Limitations:**

Item 20: They did give limitations of the study. Specifically, they state that there was great variability in the outcome.

**Generalisability:**

Item 21: They do not give any accounting of the generalizability of their study other than to state that results would be more generalizable with a larger sample size. Since they did not give any demographic or clinical information for the participants the generalizability is difficult to assess.

**Interpretation:**

Item 22: The interpretation is consistent with the results but the results are suspect so it is difficult to determine if the interpretation is valid. They did not address the balance between benefits and harms since they didn’t address any intervention harms. This implies that there are no harms but this defies the information given in the introduction.

**Other Information:**

They did not provide any additional information about trial registry, full trial protocol, or funding sources.