Author's response to reviews

Title: Pre-Consultation Educational Group Intervention to Improve Shared Decision-Making in Postmastectomy Breast Reconstruction: Study Protocol for a Pilot RCT

Authors:

Jennica Platt (jennica.platt@mail.utoronto.ca)
Nancy Baxter (baxtern@smh.ca)
Jennifer Jones (jennifer.jones@uhn.ca)
Kelly Metcalfe (kelly.metcalfe@utoronto.ca)
Natalie Causarano (natalie.causarano@uhn.ca)
Stefan O. P. Hofer (Stefan.Hofer@uhn.ca)
Anne O'Neill (Anne.O'Neill@uhn.ca)
Terry Cheng (Terry.Cheng@uhn.ca)
Elizabeth Starenkyj (elizabeth.starenkyj@uhn.ca)
Toni Zhong (toni.zhong@uhn.ca)

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Author's response to reviews: see over
Dear Dr. Vickers and Trials Editorial Board Members,

Thank you for your review of the manuscript. We appreciate your comments and found the feedback to be very thoughtful and helpful. Please find accompanying this letter the revised manuscript with the revised title as requested, “Pre-consultation educational group intervention to improve shared-decision making in postmastectomy breast reconstruction: Study protocol for a pilot randomized controlled trial”.

Response to comments by the reviewer:

1) I would ask the authors to explain the randomization in more step-by-step detail. For example, who the individual is who does the eligibility assessment vis a vis the actual registration.

RESPONSE:

Please see our clarification of randomization, eligibility assessment and participant enrollment in our revised manuscript. Specifically, please note that a biostatistician from our department whom is not involved with our pilot randomized controlled trial will generate the randomization sequence in balanced blocks of 10 and seal the randomized treatment allocation in an opaque envelope. The study coordinator is the individual who is responsible for identification of potentially eligible participants and recruitment into our study. Because our intervention (educational workshop) occurs prior to the initial surgical consultation, it is necessary to identify subjects and determine eligibility via telephone at the time of recruitment and prior to the initial surgical consultation. Interested and eligible participants will be enrolled after providing informed consent over the telephone, and study packages will subsequently be mailed. Upon receipt of signed consent forms through return mail, participants will be officially registered. Once informed consent is obtained from each participant and the baseline questionnaire is returned by mail, the next opaque, sealed envelope in sequence will be opened by the study coordinator to determine the participant’s randomized treatment allocation.

Methods/Design, Page 3:
“Participants

Adult women referred to one of the plastic surgeons for consideration of breast reconstruction will be eligible to participate. The study coordinator is responsible for identification and recruitment of potentially eligible participants. Because the intervention (educational workshop) will occur before the initial surgical consultation, it is necessary to identify subjects from faxed referrals and determine their eligibility via telephone confirmation at the time of recruitment and prior to the initial surgical consultation. Participants will be excluded if they are referred for reconstruction after atypical breast malignancy (ex: angiosarcoma) or metastatic breast cancer, secondary breast reconstruction, have cognitive impairment or uncontrolled psychiatric diagnosis or cannot read or write in English. Once eligibility is confirmed with the study coordinator, subjects who indicate an interest in participation will be enrolled after providing informed consent over the telephone, and study packages will subsequently be mailed. Participants will be officially registered upon receipt of signed consent through return mail. Baseline measures (T0) will be assessed prior to randomization and returned in postage-paid envelopes. Participants in the study and control groups will complete T1 measures approximately 1 week after the initial surgical consultation. Participant timeline is outlined in figure 2.

Randomization and Allocation of Interventions

Once informed consent is obtained from each participant and the baseline questionnaire is returned by mail, the next opaque, sealed envelope in sequence will be opened by the study coordinator to determine the participant’s randomized treatment allocation. A computer-generated random allocation sequence will be created and sealed in opaque envelopes by the program biostatistician independent form the study coordinator with 1:1 allocation to educational group intervention or usual care and balanced in blocks of 10.”
Response to comments by the editorial board:

1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ___________: study protocol for a randomized controlled trial.

RE PonSe:

Please note that we have revised the title of our manuscript accordingly: “Pre-consultation educational group intervention to improve shared-decision making in postmastectomy breast reconstruction: Study protocol for a pilot randomized controlled trial”.

Sincerely,

Toni Zhong, MD, FRSC(C), MHS
UHN Breast Restoration Program
Division of Plastic and Reconstructive Surgery
8N871, 200 Elizabeth St.
University Health Network
Toronto, ON, M5G 2C4