Author's response to reviews

Title: A randomised trial of a nurse and peer led support program to assist women in gynaecological oncology receiving curative radiotherapy: the PeNTAGOn study (Peer and Nurse support Trial to Assist women in Gynaecological Oncology)

Authors:

Penelope Schofield (Penelope.schofield@petermac.org)
Ilona Juraskova (Ilona.juraskova@sydney.edu.au)
Rebecca Bergin (Rebecca.bergin@petermac.org)
Karla Gough (Karla.gough@petermac.org)
Linda Mileshkin (Linda.mileshkin@petermac.org)
Meinir Krishnasamy (Meinir.krishnasamy@petermac.org)
Kate White (Kate.white@sydney.edu.au)
David Bernshaw (David.bernshaw@petermac.org)
Sylvia Penberthy (sylviapenberthy@yahoo.com)
Sanchia Aranda (Sanchia.Aranda@cancerinstitute.org.au)

Version: 3 Date: 11 December 2012

Author’s response to reviews: see over
Trials: Study protocol

Title: A randomised trial of a nurse and peer-led support program to assist women in gynaecological oncology: the PeNTAGOn study (Peer and Nurse support Trial to Assist women in Gynaecological Oncology)

Response to reviewer’s report by Rolf Wahlstrom

Version: 2 Date: 13 November 2012

11/12/2012

Dear Editor:

We thank the reviewer for his positive assessment of the PeNTAGOn study protocol manuscript, insightful comments and detailed corrections.

Please see our responses below to revisions made to the manuscript:

Necessary revisions:

1. Clarify where the study will be conducted. How many sites? Differences between sites? Will sites contribute equally?

   The study will be conducted at six hospital sites across Australia. Two sites are part of a comprehensive cancer centre (Peter MacCallum Cancer Centre). The other sites have cancer centres located within a general hospital. The sites will not contribute equally to recruitment due to differing patient load, however randomisation has been stratified by site. This has been clarified in the text. Pg. 11.

2. How many nurses will be trained? Will there be more than one at each site?

   Two specialist cancer nurses will be trained to provide the consultations at each site to provide cover for leave. Pg. 12

3. How many peer support women will be trained? How many women will maximally be supported by one peer?

   Approximately 30 peers will be trained over the course of the trial, accounting for peers taking breaks or withdrawing / retiring from the study. Each peer will support a maximum of two patients at any one time. pg. 15

4. Added information on “usual practice” in the “usual care arm”: What is the “Pre-treatment usual care”? Does it include visits to nurses or doctors or peer support groups?

   Usual care practice will be monitored yearly with a questionnaire administered to nurses most involved with the usual care of women with gynaecological cancer receiving radiotherapy at each site. This will permit accurate description of any variation in usual care practices across sites. Pg. 17 – 18.

Minor revisions:
1. The hypotheses for the third secondary outcome indicates a lowering of psychosexual functioning, while it should be the opposite. **Hypothesis for third secondary outcome modified to indicate higher sexual functioning (rather than lower).**

2. Table 1: It is a bit confusing that the baseline assessment is called “pre-treatment” as the authors use this term in the text when referring to the first follow-up (Study hypotheses, Primary endpoint). **Modified wording in Study Hypotheses and Primary Endpoint to be consistent with Table 1. This now refers the first follow-up as “first follow-up immediately prior to the first radiotherapy treatment”. Pg. 10**

3. The title should include “radiotherapy” (or maybe even “curative radiotherapy) as this is the main inclusion criterion. **Title now includes “curative radiotherapy”: A randomised trial of a nurse and peer led support program to assist women in gynaecological oncology receiving curative radiotherapy: the PeNTAGOn study (Peer and Nurse support Trial to Assist women in Gynaecological Oncology).**

**Abbreviations:**
List has been updated to include AQ, QoL and MDT. ECOG has been explained in the text (pg. 19), and MDT changed to ‘multi-disciplinary team’ in text (pg. 23).

**References:**
Journal names have been abbreviated, titles not capitalised, all authors listed up to 30, and other small edits repaired.

**Edits:**
Spaces added prior to brackets; headings revised and aligned; indefinite article before RCT repaired to ‘a’ throughout; pronoun repaired to “her”; abbreviated yrs changed to ‘years’.

In addition, we have updated author affiliations, and corrected the term and abbreviation for the supportive care needs survey – short form which uses a revised response scale. The modified questionnaire abbreviation has required changes throughout the article, Tables 1 & 2, and updated Figure 1. Figure 1 has also been modified so the text size is larger and Helvetica font.

We thank the reviewer once again for his comments.

Kind regards,

**Associate Professor Penelope Schofield, PhD**

Scientific Director and NHMRC Fellow
Department of Cancer Experiences Research
Peter MacCallum Cancer Centre
Locked Bag 1, A’Beckett Street
Victoria, 8006 Australia

P: +61 3 9656 3560
F: +61 3 9656 3502
E: penelope.schofield@petermac.org