

## Title

### **Developing an evidence-based, nurse-led psycho-educational intervention with peer support in gynaecological oncology**

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## **ABSTRACT**

**Background:** The physical and psychosocial impact of radiotherapy for gynaecological cancer requires complex interventions to address treatment-related, psychosocial, and psychosexual and survivorship needs. A multi-disciplinary approach is required to address these needs however usual practice is varied and lacks a sound evidence base.

**Objective:** To describe the process of development and pilot testing of a novel evidence-based, complex psycho-educational intervention aiming to improve psychosocial outcomes for gynae-oncology patients treated curatively with radiotherapy.

**Interventions/methods:** The intervention combines tailored nursing consultations with telephone peer support pre-, mid-, end- and post-treatment. The UK Medical Research Council (MRC) framework for developing complex interventions was employed to produce an evidence-based, feasible and acceptable intervention.

**Results:** Intervention manuals and study materials were informed by literature reviews of best-available evidence; relevant theory; and iterative consumer and expert consultations. The nurse manual specified content for consultations providing self-care information, coaching tailored to individual needs and multi-disciplinary care-coordination. The peer manual described phone consultations aimed at providing psychosocial support and encouraging adherence to self-care strategies. Three peers and one nurse underwent rigorous skills and knowledge-based intervention delivery training. The intervention was pilot tested with 6 patients. Qualitative feedback led to minor design and content changes.

**Conclusions:** The intervention was found to be feasible, relevant and acceptable to participants and clinicians, and is currently being tested in a national RCT (PeNTAGOn).

**Implications for practice:** The MRC framework is useful in developing nursing interventions. The specific methods and strategies described are useful for designing future complex studies targeting patient supportive care.

**Keywords: Genital Neoplasms, Female; Evidence-based Nursing; Peer Support; Nursing Interventions; MRC Framework; Radiotherapy; Oncology; Support, Psychosocial.**

## **BACKGROUND**

### **Impact of gynaecological cancer**

Gynaecological cancers (GC) represent significant burden to women around the world.<sup>1</sup> In developed nations, survival rates are improving however incidence is also increasing for GCs such as uterine and ovarian cancer.<sup>2</sup> In Australia, GCs account for 9% of female cancers with around 5000 women expected to be diagnosed each year to 2015.<sup>3</sup> While treatments such as radiotherapy are contributing to improved survival, side-effects of radiotherapy can be distressing and impact both immediate and long-term quality of life (QoL).<sup>4</sup>

Physical side-effects include diarrhoea, bladder dysfunction, menopause, infertility and vaginal side-effects can cause sexual dysfunction.<sup>5</sup> Psychosocial impacts include distress, anxiety and impaired psychosexual function.<sup>6</sup> Timely provision of information about side-effect self-care by health professionals has been linked to better coping, less fear about sexual intercourse and less relationship disruption,<sup>7</sup> and better adherence to post-radiation vaginal rehabilitation.<sup>8</sup> Tailored information is also effective for changing concerns over the course of the illness.<sup>9</sup> However there is limited evidence to guide the preparation and support of women receiving radiotherapy treatment for GC. Standardized, evidence-based interventions are required that address the complex, individual and dynamic nature of issues and concerns of women with GC.

### **A novel model of care for women receiving radiotherapy for gynaecological cancer**

Nurse-led interventions in cancer care are effective in promoting good psychosocial outcomes<sup>10</sup> and can be acceptably delivered by phone and face-to-face.<sup>11</sup> Critically, such interventions build structure and consistency into nursing practice, which can be variable.<sup>12</sup> Multidisciplinary care models integrate support from a number of health professionals and demonstrate success in improving patient QoL and lowering distress.<sup>13</sup> A nurse-led, psycho-educational intervention that

facilitates multidisciplinary referrals, is tailored to patient needs and provides evidence-based strategies for self-care has the potential to address patient psychosocial, psychosexual and physical needs. No randomised controlled trials (RCTs) have been identified that adopt such a model of care for women undergoing treatment for GC. Apart from nurse interventions, peer support programs have also shown promise in addressing patient needs and improving psychosocial outcomes with high patient satisfaction.<sup>14</sup> Telephone support delivered by peer volunteers who receive high quality training and supervision is acceptable to patients and enables access to support for those who are sick or live in remote areas.<sup>15</sup> However, there are no RCTs that investigate peer support interventions from treatment initiation to post-treatment completion for patients with GC.

The intervention described here is internationally innovative in that it synergistically links nurse-led consultations with telephone peer support. It is designed to provide tailored, evidence-based support and self-care strategies for physical, psychosocial and psychosexual impacts of radiotherapy. The intervention facilitates appropriate multidisciplinary team (MDT) referrals and adherence to patient self-care and emotional coping. It is designed to be delivered at key time-points in the illness trajectory, to be accessible to patients in urban and rural areas, and be potentially transferable to other chronic disease settings.

### **Reporting intervention development**

There has been a recent push for detailed reporting of intervention design and content, particularly behavioural, psychological and health-service interventions.<sup>16,17</sup> High-impact peer reviewed journals now require authors to pre- or co-publish a detailed intervention protocol with study results.<sup>18</sup> The intervention developed here is currently being tested in a RCT and the protocol published.<sup>19</sup> However protocols rarely provide sufficient detail on the development

process that led to the final intervention. This process is important to record in order to assess the theoretical, evidence and practical bases of an intervention. It also provides an example for practitioners and researchers in designing, developing and reporting complex interventions.

### **Complex interventions and the MRC framework**

Interventions with several interacting components are termed ‘complex’.<sup>20</sup> Such programs are notoriously difficult to conduct, document and reproduce, and can be costly to implement and evaluate. Nurse-led, psycho-educational interventions are considered complex as they incorporate numerous active components within variable hospital or community systems in different contexts.<sup>16</sup> The UK Medical Research Council’s (MRC) framework for developing and evaluating complex interventions describes a flexible, iterative development and testing process.<sup>20</sup> This framework was chosen because it addresses some common problems of program complexity, advocates a non-linear approach and is highly regarded for nursing research.<sup>21</sup> The framework comprises four elements but this paper focuses on the first two: Development and Feasibility/piloting.

### **Aims and structure**

The purpose of this paper is to describe the development of an evidence-based, complex, nurse-led psycho-educational intervention with peer support, designed to be feasible and acceptable to participants. We also describe additional strategies and techniques used to optimise feasibility and standardisation of the intervention for testing in a future RCT. For clarity, the two MRC elements are reported with a separate method and results section, but have similar aims. The aim of the Development phase was to develop a pilot intervention program based on evidence, theory, and user feedback on feasibility and acceptability. Feasibility/piloting aimed to determine acceptability and feasibility of the intervention in practice.

## **METHOD: MRC element 1 – Development**

The MRC element Development involves 3 components: identifying the evidence base; identifying or developing theory; and modelling processes and outcomes. The first two components are described in the Methods section. The modelling process, including a detailed description of the pilot intervention program, is provided in the Results section.

### *Identifying the evidence base*

#### Evidence for intervention content:

Two literature searches, evidence from the published literature and guidelines from peak organisations were reviewed to inform the intervention content. The first scoping literature review aimed to clarify the key issues experienced by women undergoing radiotherapy for GC. Forty-three potential issues were identified and clustered into three areas: physical symptoms/side-effects, psychological/QoL and psychosexual issues.

The second review aimed to identify evidence-based, non-pharmacological self-care strategies for side-effects of pelvic radiotherapy among GC patients that might be included in the intervention content. Systematic review inclusion criteria were; high quality RCTs addressing side-effects of pelvic radiotherapy (identified in the first literature review) with non-pharmacological interventions for GC patients. In May 2009, MEDLINE, PsychINFO, EMBASE and Cochrane databases were searched for studies published between January 1995 and May 2009. Of the 466 papers identified, 10 were shortlisted by one reviewer (RB). After discussion with a second reviewer (MK), 4 papers considered GC patients alone and adequately meet RCT design criteria.<sup>8,22-24</sup> There was some evidence that relaxation and guided imagery may reduce anxiety, depression and body discomfort for women receiving brachytherapy,<sup>22</sup> and evidence-based, individualised symptom management education could decrease symptom distress in



women receiving external beam radiotherapy.<sup>23</sup> Two trials reported on group psycho-education programs to improve compliance with vaginal dilator use. In the intervention groups, short-term use of vaginal dilators was improved in younger women,<sup>24</sup> and enhanced dilator adherence in all women in the later trial.<sup>8</sup> However all 4 studies had quality issues, such as being underpowered, having non-significant and/or unsustained results for primary outcomes and high participant attrition. There was, therefore, a paucity of quality evidence in the gynae-oncology literature to inform intervention content regarding self-care, particularly in vaginal health and rehabilitation after radiotherapy. At the time of intervention development (February 2009 – February 2011), recommendations regarding vaginal health and dilator use were informed by a 2008 Cochrane review, international guidelines and clinical opinion.<sup>25,26</sup> A later review has questioned current recommendations for vaginal dilators,<sup>27</sup> however guidelines continue to endorse their use.<sup>28</sup> Further evidence informing the content of the intervention included: Level 1 evidence from surgical literature on threatening procedures applied to the radiotherapy context, where sensory and procedural information reduces patient distress, pain and length of hospital stay<sup>29,30</sup>; evidence for effective communication techniques such as motivational interviewing<sup>31,32</sup> to improve patient adherence to self-care; non-pharmacological self-care strategies for side-effects of treatment,<sup>33</sup> and use of the BETTER model for psychosexual assessment to improve patient psychosexual recovery.<sup>7,34</sup> Guidelines for cancer populations also informed intervention content, in particular the Australian Guidelines for the Psychosocial Care of Adults with Cancer.<sup>35</sup> Table 1 summarises the key evidence identified and how this was applied in the development phase.

### **INSERT TABLE 1 HERE**

#### Evidence for intervention design:

Literature specific to the design of nursing interventions suggest researchers optimise

intervention dose and intensity, efficacy, standardisation and minimise participant burden.<sup>16</sup> High intensity psycho-educational interventions and those with multiple or lengthy contacts are often effective in improving patient outcomes.<sup>36</sup> While it is important to design interventions able to affect outcomes, affordability and feasibility are also important considerations. Interventions can be effective but not feasible,<sup>37</sup> or feasible but not of sufficient dose.<sup>38</sup> In this intervention, nurse contacts are supplemented with peer volunteer calls, increasing the dose in a manner that is feasible and affordable. Contacts by phone also minimise patient burden and improve access to the intervention for those who are sick or live long distances from the hospital.<sup>15</sup> Standardisation of the intervention is important as current nursing practice can be variable<sup>12</sup> and also ensures patients receive a similar intervention dose, a key consideration in research trial settings.

### ***Identifying and developing theory***

Two theoretical perspectives informed the intervention development. The nurse-led component of the intervention was informed by Self-Determination Theory (SDT).<sup>39</sup> SDT describes a framework of intrinsic and extrinsic factors influencing human motivation and behaviour. Key elements of nurse intervention consultations are to assess distress, encourage patients to take up new self-care activities and adhere to medical advice using motivational interviewing. These elements relate to SDT principles of promoting patient psychological needs, autonomy and competence.<sup>40</sup> The peer component of the intervention is informed by theory of the benefits of social support. House & Kahn's theory of three resources of peer support is used: social, emotional and informational support.<sup>41</sup> The peer role is designed to provide social support through contact with the woman throughout treatment, listening to her story and sharing the peer's own experience if appropriate. Emotional support is provided by the peer expressing empathy and using appropriate communication skills. Peers provide information support by

encouraging patients to adhere to self-care behaviours and offering information about other support services as required.

### ***Consumer and stakeholder engagement***

The MRC framework recommends that ‘users’ be involved at all stages of intervention development, testing and dissemination. We engaged with a number of user groups to ensure intervention relevance, appropriateness and feasibility. Involving users early in the development process may also enhance dissemination of trial results and intervention implementation into standard care should the program be found to be effective.

### ***Consumer Working Party***

Consumer involvement in all areas of health care research can enhance research processes and outcomes.<sup>42</sup> To further our understanding of the experiences, issues and needs of women with GC, and to obtain feedback on the relevance and perceived usefulness of the proposed intervention, a consumer working party (CWP) was convened. The group consisted of 11 GC survivors from two Australian states. The consumer investigator chaired the CWP (SP) and attended project steering committee meetings three times per year. CWP members reviewed the list of side-effects, psychosocial, and psychosexual issues derived from the first literature review and provided feedback on: 1) relevance of issues, 2) top 5 most important issues, and 3) time when these issues should be addressed. Consumer feedback confirmed the importance of all issues, with each reported as relevant to at least one member of the CWP. Issues were deemed important and relevant throughout treatment, with bowel/anal issues rated ‘most important’ followed by psychological issues (see Figure 1). Most members reported sexual issues as ‘important’, confirming the need to include psychosexual considerations in the intervention. The CWP also identified additional issues, such as financial and family management issues, which

were incorporated into intervention content.

**INSERT FIGURE 1 HERE.**

*Feedback from clinicians, key authorities and organisations*

Other key users consulted were clinicians, relevant organisations and authorities. We sought resources, information, endorsement and expert opinion from these advisors. Clinicians were identified as involved in GC patient care and included radiation oncologists (3), medical oncologist, psychologist, social worker, behavioural scientist, and gynae-oncology and radiation oncology nurses (3) from a metropolitan public cancer hospital in Australia. A psychologist, social worker and psychiatrist were also consulted regarding a MDT referral tool for distressed patients to facilitate appropriate referrals by intervention nurses. Expert clinical advice ensured that key issues and evidence-based practices for self-care were appropriate and in line with clinical opinion, particularly in areas where evidence was lacking (such as the use of dilators). Regular progress update presentations and meetings helped build relationships and trust between researchers and clinical users, enhancing clinical acceptability of the proposed program. Australian education resources such as booklets, DVDs, fact sheets, and websites covering topics like side-effect management, sexuality and mental health issues, were sourced from peak cancer and other health bodies, including the Australian state Cancer Councils and *beyondblue*, a depression and mental health organisation. Resources were reviewed by clinicians and CWP members to ensure they were appropriate, relevant and evidence-based. Endorsed resources were to be provided to patients by the intervention nurse.

**RESULTS: MRC element 1 – Development**

*Modelling process and outcomes*

Modelling involved the synthesis of evidence, guidelines, theory, consumer and clinical input to

develop a pilot intervention. This process occurred iteratively, with the study team modelling intervention design, materials and training programs, modifying as new evidence or guidelines became available and seeking feedback from users. Two additional modelling considerations were important for testing in a research trial setting: choice of outcome measures to assess intervention efficacy, and contextual issues around usual care practices that might impact trial findings and feasibility. The next section describes the key outcomes of the modelling process.

### *Pilot intervention design*

The pilot intervention comprised contacts with a nurse and peer volunteer at specific time-points: pre-, mid-, end- and post-radiotherapy. The design included 3 nurse-led consultations and 5 peer telephone calls. Nurse consultations were face-to-face as patients were coming into hospital during this period. The first three peer telephone calls followed 1 week after the nurse consultations, with the last two calls occurring 2 and 4 weeks post-treatment.

### *Pilot intervention content and materials*

A clinical nurse consultant (SG) was engaged to collate the findings from literature searches and user consultations, and write intervention manuals for nurse and peer that detailed the content of each intervention session. CWP members and clinician users provided feedback on drafts of materials which were iteratively revised. Manuals described the main aims and content of each intervention session, and included example script for each key topic area drawing on appropriate communication techniques.<sup>32</sup> These manuals aimed to encourage consistency of intervention delivery and standardisation of content.

### Nurse contacts:

**Session 1: pre-treatment (1 hour, face to face).** The first nurse contact has four elements:

- (i) *Orientation:* Based on evidence for preparing patients for potentially threatening medical

procedures,<sup>29,30</sup> the patient is taken on a tour of the radiotherapy area followed by a private consultation. The patient's understanding of their diagnosis, treatment plan and specific side-effects expected is assessed and misconceptions clarified.

(ii) *Evidence-based tailored responses:* A core feature of the intervention is tailoring information to individual patient's needs which improves recall.<sup>43</sup> A paper-based communication tool was developed from the first literature review and CWP consultation to tailor nurse sessions. The communication tool comprises a problem checklist of issues for women with GC, together with an effective, brief screening tool for assessing global distress: the distress thermometer (DT).<sup>44</sup> The patient indicates their current level of distress and selects the 3 most important issues they want to discuss. The nurse then tailors the discussion to the woman's supportive care needs and considers possible MDT referrals. Nurses can use the specially-designed MDT referral tool to assist in directing high distress patients to the appropriate service. Vaginal health, psychosexual rehabilitation, dilator use and if appropriate, infertility is introduced in this session. The nurse discusses how to use the dilator and perform Kegel pelvic floor exercises.

(iii) *Coaching:* The nurse provides coaching for self-care of side-effects using motivational interviewing and stress-reduction strategies if required. Anxious patients are trained to use the strategy of controlled breathing with positive self-talk, an easy to learn and effective Cognitive Behavioural Therapy (CBT) to reduce treatment related anxiety.<sup>45</sup>

(iv) *Evidence-based information:* Brief self-care patient information sheets on the issues that patients with GC may experience were developed using best available evidence and consumer and expert consultation. They comprise a brief overview of the issue, non-pharmacological self-care strategies, and additional contacts and services for more information or assistance. Self-care information sheets are used in conjunction with existing information resources. Nurses provide

patients with written information tailored to need, and a contact number at the hospital if they have further questions. To conclude the session, the nurse summarises the meeting, assesses the patient's understanding of topics discussed and prompts for any further questions. The nurse also discusses the peer call and clarifies whether there are any issues the patient does not want to share with the peer, and arranges the next intervention contact. After the session, the nurse contacts the peer to discuss the patient's concerns and individualised self-care plan.

**Session 2: mid-treatment (30 mins, face to face).** Side-effects typically commence mid-treatment, so in this session the nurse primarily coaches the woman in interventions to address treatment side-effects and optimise vaginal health. The importance of regular dilator use is reinforced. In addition, the nurse: i) listens to and acknowledges the patient's experience of treatment, normalises fears and asks about their peer call; ii) elicits and responds to any concerns from the first session, then the patient again completes the problem checklist with DT so new concerns can be addressed or referrals made; iii) elicits and addresses barriers to planned self-care and stress-reduction strategies, and reinforces the importance of adherence, especially to dilator use; iv) prompts for further questions; v) summarises the session and assesses patient understanding; and vi) reminds the patient about the next peer call and who to contact at the hospital if further questions arise. The nurse contacts the peer following the session to discuss patient concerns and self-care plan.

**Session 3: end of treatment (30 mins, face to face).** Research suggests that patients often experience uncertainty and anxiety at the end of treatment.<sup>46</sup> This intervention session has similar structure and goals to previous sessions but focuses on the woman's vaginal health and psychosexual recovery, including how to approach resumption of sexual activity for those who were sexually active before treatment.

Peer contacts:

Peers are matched to patients by medical and personal circumstances. In the pilot intervention design, the first three peer contacts are made around 1 week after the nurse sessions. The final two peer calls take place 2 and 4 weeks post-treatment. Calls follow a basic structured format: i) introduction or greeting, ii) listen to the woman's story so far, iii) review patient concerns and individualised self-care plan or strategies provided by the nurse; assess the woman's understanding of, and encourage adherence to, self-care strategies, iv) problem-solve barriers to self-care and/or encourage contact with the nurse or doctor for complex problems, v) encourage access to additional information and support if needed, such as the Cancer Council, vi) summarise the call and assess understanding, vii) discuss the next call, then conclude the contact. Peers also discuss psychosexual concerns and adherence to use of vaginal dilators if relevant. Figure 2 demonstrates the final intervention after testing this pilot program. The figure outlines key time-points, content of sessions and strategies employed to reduce variation and encourage standardisation of the intervention. Note the most significant change after pilot testing is the substitution of the 2 week post-treatment peer call with a nurse call.

**INSERT FIGURE 2 HERE.**

*Nurse and peer recruitment and training*

As the nurse and peer volunteers are the active ingredient, or 'drug' equivalent in this intervention, modelling the nurse and peer recruitment and training process was important. As for a clinical drug trial, the intervention needed to be delivered in a standard way, by those with similar skills, adhering to the study protocol so that patients received a consistent dose.

Additionally, peers and nurses required ongoing supervision, including feedback on sessions and emotional support, to ensure they were confident in delivering the intervention and to avoid



attrition or burnout. Peer and nurse recruitment and training processes are described in Figure 3.

### **INSERT FIGURE 3 HERE**

#### *Modelling context - usual care practices*

The MRC framework addresses the importance of context when considering the practical effectiveness, feasibility and variability of the proposed intervention between individuals, hospitals and locations.<sup>20</sup> Variation in standard care is common and often not easily changed or standardised. Nevertheless, the intervention and its comparator must be described to meet RCT reporting criteria such as CONSORT<sup>47</sup> to assist interpretation of results.

An online survey of usual care practices and recommendations for women receiving radiotherapy for GC was designed and distributed to the 5 treatment centres in publically funded Australian hospitals recruited to the RCT. The survey was completed by nurse(s) principally involved in the care of women receiving radiotherapy between February and July 2010 (n=12). Most nurses (81%) reported that information and education about side-effects was *always* given to women. In contrast, only half the nurses responded that information / education about psychosocial and sexual issues was *always* provided at their centre. Variation in practice was particularly apparent in the prescription of vaginal dilators and rationale for use. With evidence lacking and clinical opinion divided,<sup>25,27</sup> it was not feasible to mandate or standardise dilator care in this intervention. As tailoring is integral to this intervention, a degree of flexibility was permissible. Hence, it was specified that nurses would coach patients in vaginal dilator use according to their centre's usual practice. Such program flexibility and understanding of current clinical care would be helpful for practitioners seeking to introduce new or improved practices.

#### *Modelling outcome measurement*

Choosing suitable outcome measures to capture how the intervention was proposed to impact

patient outcomes was important to future testing in a RCT. Outcomes of interest were psychological distress, symptom distress or burden, supportive care needs, quality of life, sexual function, preparation for treatment and adherence to vaginal self-care. A multi-step task to choosing measures for these outcomes began by identifying several reliable and validated questionnaires from the literature. Consultation with experts in psychosocial measurement followed to determine the most appropriate measures for this particular study, and the most appropriate time-points to administer surveys. Study-specific items were developed for outcomes where there were no existing measurement tools, specifically, a vaginal health self-care adherence questionnaire. A survey was developed for testing in the Feasibility/piloting phase.

**METHOD: MRC element 2 – Feasibility/piloting**

In the MRC framework, Feasibility/piloting refers to a process of testing procedures with the aim of assessing perceived relevance, acceptability and clinical feasibility of the intervention. Pilot testing was approved by the local HREC (study no: 09/07).

Sample: Patients, peers and an intervention nurse were recruited at a metropolitan public cancer hospital in Australia. Patients were eligible for the study if they had a diagnosis of GC, were scheduled to receive curative radiotherapy and could read and write English. Eleven patients were approached and 6 agreed to participate. The nurse had extensive experience in gynaecology and was trained for the intervention. Three peers were identified by Cancer Council staff (1) or clinicians (2), and completed training. Other intervention clinical users, staff involved in GC patient care during radiotherapy, were consulted and included gynaecology-radiation oncologists, nurse co-ordinator, radiation nurses and radiation therapists.

Procedures: Patients were identified in gynaecology-radiation oncology outpatient clinics and eligibility confirmed with the treating clinician. Patients completed the pilot intervention and 3 draft

surveys: pre-treatment, on the first day of radiotherapy, and 4 weeks post-treatment.

Evaluation methods: Qualitative feedback on intervention feasibility and acceptability was collected from peer volunteers and the nurse through reflective diaries and regular communication with the research team. Patients completed semi-structured interviews with the research assistant after select intervention sessions and surveys. Interviews were conducted by phone or face-to-face with notes taken throughout. Phone interviews were recorded but face-to-face interactions were not as they were conducted in public clinical areas.

Analysis of interviews involved repeated listening of recordings and organisation of notes by the research assistant into related areas of concern or positive experience. These were presented to the research team throughout the testing period, the feedback was discussed and potential changes were considered. Patient consent rate and completion of intervention sessions was tracked to evaluate dose acceptability. Clinical users were consulted about the impact of the intervention pilot testing through meetings or during update presentations. Patient survey data was not analysed due to the limited number of participants but were assessed in interviews for acceptability, comprehension and relevance to patients. See Table 2 for the patient interview schedule.

## **INSERT TABLE 2**

### **RESULTS: MRC element 2 – Feasibility/piloting**

#### Patient semi-structured interviews

Semi-structured, face-to-face or telephone interviews (15 interviews) demonstrated the intervention to be highly acceptable and useful, a view which was maintained throughout the length of the program. Women found the intervention to be relevant and appreciated extra nursing contact and speaking with someone who had survived the cancer experience. Patient

responses were highly positive regarding the peer component, *“that was fantastic, because you had someone who had gone through it and who was a bit further on in the stage of the cancer...and she gave me some helpful tips as well”* (Patient 2) and nurse component, *“[the nurse] is very helpful because I can tell her the problem that I have...and she helps me, direct me to the right person to talk to, how to go about it...I think she also made some appointments for me...so she helps me a lot”* (Patient 6).

Patients attended all nurse sessions, but some peer calls were missed due to peer unavailability and one patient felt she did not need post-treatment peer calls. All sessions were intended to be face-to-face, however half the patients preferred the first nurse session by telephone to avoid an extra trip to the hospital. Some patients had difficulty understanding and completing certain questionnaire items, highlighting the need for formatting changes and revised measure selection.

#### Intervention nurse and peer responses

The intervention nurse found most sessions acceptable and relevant to perceived patient needs. The duration of delivery of intervention sessions was initially found to be longer than estimated, however consultation time reduced as the nurse became more familiar with session structure and content. The nurse found pre-treatment telephone consultations challenging for rapport building and had difficulty delivering content over the lengthy session time (1 hour). In response, a module on phone communication skills was incorporated into the nurse training program. Peer volunteers greatly appreciated feedback provided from the study team after their first few calls with a patient. For the nurse handover to peers, volunteers requested a written summary of each patient’s needs to complement the verbal handover. Peers also wanted guidance on where the patient could access support post-intervention. One peer found adherence to the structured call protocol difficult, but this improved over time.

The pilot intervention design included 2 peer calls post-treatment, however both the nurse and peers suggested substitution of one post-treatment peer call with a nurse phone session. This ensured that the nurse could respond to any ongoing treatment side-effects which were likely to peak soon after radiotherapy completion. The content of this final post-treatment nurse call was similar to the two previous sessions but without the problem checklist.

#### Feedback from clinicians

Consultation with hospital clinicians indicated a good fit with practice. However there were initial concerns by nurse and radiation therapists about intervention content overlapping with information already provided as part of standard care. Meetings were arranged with staff to emphasise the unique features of the intervention compared to standard care, such as the additional support from peers linked to nurses and the standardised but tailored delivery of evidence-based information. This reassured clinicians that work was not being duplicated nor patient time being wasted, and clarified the importance of this intervention to meet specific patient needs and potentially improve outcomes. Practitioners might consider such communication strategies and pilot testing processes useful to identify and address similar roadblocks among clinical teams to practice change. Engagement with clinical ‘users’ early may also enhance future acceptance of this novel model of care should the program be successful. During the pilot period, the influence of the Institute of Medicine (IOM) report regarding cancer survivorship was increasing.<sup>48</sup> The study project team agreed that patients should receive a survivorship booklet and DVD from the Cancer Council, and tailored Survivorship Care Plan (SCP) in the nurse end-of-treatment session as per IOM recommendations. With the patient’s permission, the nurse also faxes the SCP the patient’s primary care provider.

#### Summary of key revisions and improvements

After pilot-testing, several changes were made to the intervention design. The main modifications were substitution of the 2-week post-treatment peer contact to a nurse contact and mode of delivery of nurse sessions expanded to allow telephone contacts if patients preferred. The SCP and survivorship resources were added to intervention content for nurse end of treatment session, and other minor revisions were made to improve nurse and peer training and information exchange. Additional feasibility considerations, such as patient trial recruitment rates, and other key revisions are summarised in Table 3.

### **INSERT TABLE 3**

## **DISCUSSION**

The numerous psychosocial, physical and psychosexual impacts of treatment for GC require complex psycho-educational intervention. To our knowledge, there are no interventions targeting all these elements, and none delivered as nurse-led consultations integrated with peer support. The development of this intervention was guided by the MRC framework and comprised several stages. Relevant evidence and best practice was investigated through literature reviews in relevant fields and expert and consumer consultation. This generated a comprehensive understanding of the problem and identified appropriate evidence-based solutions and theory. Intervention content and materials incorporated these findings and were designed to produce a standardised intervention that was flexible enough to be tailored to patient needs. These materials included 2 intervention manuals, 2 training workshops, self-care information for patients, a communication tool to tailor nurse sessions to patient's specific needs and a referral tool. The survey of usual care practice highlighted contextually important hospital variation, particularly in dilator prescription. Standardisation was not possible, but as the intervention content was designed to be individualised, context-specific differences could be incorporated without

affecting intervention dose or intensity. Pilot testing confirmed the intervention to be highly acceptable, useful and relevant to patients, peers and clinicians, and feasible in practice. Testing also identified elements of the intervention needing minor modification such as intervention training content, delivery method and dose, and also highlighted important considerations for future research such as expected patient recruitment and peer retention rates.

The MRC framework provides guidelines, but lacks practical examples and specific techniques to design robust nurse-led interventions. For example, the involvement of consumers in the development process is highly encouraged in the framework, but few methodological examples are provided. Here, we describe the establishment of a consumer group that was consulted throughout intervention development. Group members confirmed that literature review findings and intervention design were relevant, appropriate and acceptable. Other researchers also report engaging consumers in developing a complex nurse-led intervention,<sup>49</sup> but involvement of a team of consumers is uncommon.

Many psychological, behavioural change and nurse-based interventions lack efficacy which may be attributed to lack of methodological rigour.<sup>36</sup> Insufficient description of the intervention also limits scientific replication.<sup>17</sup> Other difficulties include inadequate means of measuring the impact of complex interventions, insufficient statistical power, prohibitive costs, poor adherence and contextual issues such as variation in nursing practice.<sup>12,50</sup> The future evaluation of this intervention in an RCT and potential implementation into usual clinical practice were important considerations in the development stage. While the MRC framework promotes early thinking about implementation, it is unclear what action might be taken to achieve this. We have provided examples of strategies which practitioners testing their own new or improved clinical practices may find helpful to improve both the methodological rigour of the intervention for testing in an

RCT, such as producing standardised intervention materials and training, and implementation considerations like enhancing clinical acceptability of the novel program through regular communication, consultation for intervention content and addressing concerns throughout development and testing. We also collaborated with organisations to promote and support the intervention, potentially improving uptake and dissemination.

Perhaps the greatest limitation of the MRC framework approach to complex intervention development relates to the lack of evidence-base for the framework itself. The ideal, best-practice method to produce the most relevant, effective and feasible complex intervention is yet to be elucidated, a point that the guideline authors themselves concede.<sup>20</sup> Despite this, in describing and publishing our development approach, we contribute to a growing literature describing the process of complex intervention development.

## **CONCLUSION**

To our knowledge, this is the first psycho-educational intervention which links a series of nursing consultations with telephone peer support thus extending the MDT beyond the acute care setting. The MRC guidelines proved useful in providing broad recommendations for intervention development, such as establishing the evidence-base, developing theory and testing procedures. We have provided additional detail on the specific techniques and methodologies used during development and testing, including the creation of standardised materials with significant consumer and clinician consultation in a systematic, iterative fashion to improve intervention feasibility and potential dissemination. Such strategies may also be useful to practitioners introducing evidence-based practice changes into standard care. The result here is a novel, highly relevant and acceptable nurse-led psycho-educational intervention which could be implemented into standard practice if successful.



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## **FIGURE LEGENDS**

### **Figure 1. Top issues identified as 'most important' by Consumer Working Party.**

Figure 1 legend: Bar-graph of the issues voted 'most important' by members of the consumer working party.

### **Figure 2. Final intervention design and key features.**

Figure 2 legend: Diagram of the final intervention design after pilot testing. Intervention sessions occur at time-points pre-, mid-, end- and post-treatment. Key features and content of intervention sessions by nurse and peer are displayed in the square text-boxes. Strategies and tools created during the development process to improve the study standardisation and reduce possible variation are listed in the oval text-box.

### **Figure 3. Peer and Nurse recruitment and training process.**

Figure 3 legend: Modelling the process for peer recruitment and training was developed in collaboration with organisers of the 'Cancer Connect' program, a cancer volunteer telephone support service run by a community-based cancer organisation (Cancer Council Victoria). Nurse training was developed based on core competencies for intervention delivery. Figure 3 demonstrates – from top to bottom – the recruitment, training and assessment stages for both peer volunteers and intervention nurses. The figure also contains an overview of the content of peer and nurse training workshops in text-boxes: 'peer / nurse workshop modules.'

**Table 1. Key Evidence and Best Practice Principles Applied in Intervention****Development.**

<b>Evidence</b>	<b>Source – evidence, guidelines, theory</b>	<b>How informed intervention</b>
Preparing patients for threatening medical procedures - providing sensory and procedural information and addressing patient's fears results in less pain, distress and fewer days in hospital.	Surgical meta analyses (Suls et al, 1989; Hathaway, 1986)	Principle adapted to radiotherapy context: first intervention session with nurse at hospital prior to treatment starting and includes a tour /orientation to the radiotherapy area with nurse. Nurses trained in delivering sensory and procedural information, and when to modify this for anxious patients.
Communication skills training improves basic and specific communication skills in: <ul style="list-style-type: none"> <li>- Psychosexual assessment (BETTER model) for nurses.</li> <li>- Motivational interviewing improves behaviour change and/or patient adherence to self-care behaviours.</li> </ul>	<p>Psychosocial guidelines (National Breast Cancer Centre and National Cancer Control Initiative, 2003)</p> <p>Communication systematic review (Gysels et al, 2004)</p> <p>BETTER model for psychosexual communication (Mick et al, 2003)</p> <p>Motivational interview reviews (Rubak et al, 2005)</p>	<p>Nurse and peer training includes comprehensive communication skills training with practice and feedback opportunities.</p> <p>Nurses receive training with BETTER model for performing psychosexual assessments, and motivational interviewing techniques to enhance adherence to self-care recommendations. Eg. Vaginal dilator use.</p>
Tailoring information improves recall; enhances medication/ treatment adherence; enhances patient self-care; less fear about sexual intercourse and less relationship disruption.	<p>Tailored, evidence-based information (Ley, 1979)</p> <p>Psychosexual adjustment (Juraskova et al, 2003)</p>	<p>Discussion tool was developed through literature review &amp; consumer consultation for nurse to tailor information. The woman identifies three issues of most concerns to her from a list to discuss in the consultation.</p> <p>Care plan devised with patient based on self-care for specific issues identified.</p>
Distress screening with distress thermometer identifies patients with elevated global distress.	<p>Distress screening in psychosocial guidelines (National Breast Cancer Centre and National Cancer Control Initiative, 2003)</p> <p>Distress thermometer (Jacobson et al, 2005)</p>	Communication tool includes brief distress thermometer completed by the patient in the first three nurse consultations.
Multidisciplinary care can improve cancer patient QoL.	<p>Multidisciplinary care (Rummans et al, 2006)</p> <p>Psychosocial guidelines (National Breast Cancer Centre and National Cancer Control Initiative, 2003)</p>	A referral pathway tool was developed to assist nurses to make referrals to appropriate multidisciplinary services for distressed patients.
CBT for distress.	Coping with stress (Kaplan et al, 1982)	Nurses trained in delivery of two simple CBT techniques, controlled breathing and positive self-talk.
Chemotherapy side-effect, non-pharmacological self-	Systematic review (Lotfi-Jam et al, 2008)	Evidence-based interventions included in patient information sheets and used in nurse

care review found several effective interventions also applicable to radiotherapy side-effects.		consultations for side-effects common across chemotherapy and radiotherapy treated patients or for those having concurrent treatments (eg. diarrhoea, constipation, fatigue).
Survivorship Care Plans for cancer survivors	IOM Survivorship Report (IOM, 2006)	Survivorship Care Plan provided to patients at end-of-treatment nurse intervention session.

Abbreviations: BETTER, Bring up, Explain, Tell, Timing, Educate, Record; CBT, Cognitive Behavioural Therapy; IOM, Institute of Medicine; QoL, Quality of Life.

**Table 2. Patient Semi-structured Interview Schedule**

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<b>Questions</b>
<ul style="list-style-type: none"><li>• Was the program useful?</li><li>• What were the most useful/helpful aspects of the nurse/peer contacts?</li><li>• Areas for improvement? How can the sessions/calls be better?</li><li>• Were the facilitators interesting/helpful? Could their delivery be improved?</li><li>• Other topics that should have been covered?</li><li>• Any topics that weren't relevant to you?</li><li>• Was the amount of information covered in the sessions acceptable? Too much, not enough?</li><li>• So far, have the number &amp; timing (i.e. pre/mid/end and post-radiotherapy) of nurse/peer sessions been acceptable?</li><li>• Where the session times convenient for you?</li><li>• Did you have any difficulties or problems with the Questionnaire sets?</li><li>• Do you think the time required to complete each Questionnaire set was acceptable?</li><li>• Do you think the number of Questionnaire sets was acceptable?</li><li>• Other comments/suggestions?</li></ul>

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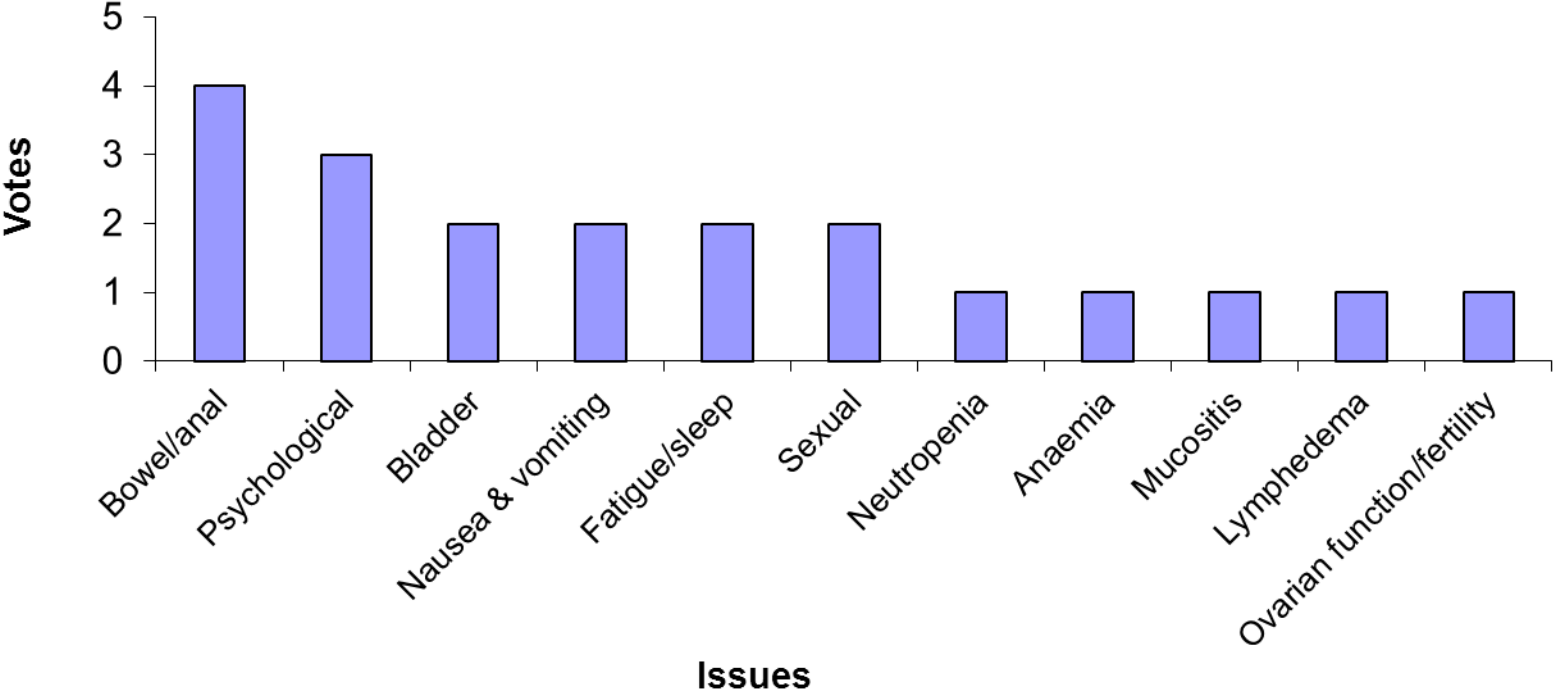
**Table 3. Revisions and Improvements to the Intervention After Pilot Testing.**

<b>Revision</b>	<b>Detail</b>
Dose change	<ul style="list-style-type: none"> <li>• The 2-week post intervention session modified from peer to nurse phone call.</li> <li>• Developed an additional patient resource – a Survivorship Care Plan summarising treatment and post-treatment care to be given to the patient in the end-of-treatment nurse session as per IOM recommendations for cancer survivors (IOM, 2006).</li> </ul>
Practice changes	<ul style="list-style-type: none"> <li>• Peers sent a 2-page written patient care plan completed by the nurse describing prescribed self-care strategies for patients. This assists peer recall of issues and self-care strategies to follow-up with the participant, and guide interactions with patients.</li> <li>• Participant questionnaire reformatted to enhance comprehension.</li> <li>• Added a phone communication module to nurse training.</li> </ul>
Feasibility consideration	<ul style="list-style-type: none"> <li>• 50% of patients preferred pre-treatment nurse consultation by phone rather than face-to-face. Protocol amended to include phone consultation option.</li> <li>• Consent rate was lower than anticipated (60% versus 70%). Although the small sample size requires cautious interpretation of this result, clinical opinion suggests that this group of patients may be highly anxious so consent rates are likely to be moderate. This is important for estimating recruitment rates for larger RCT.</li> </ul>
Training	<ul style="list-style-type: none"> <li>• Nurse training module on telephone communication skills added.</li> <li>• Development of a DVD and addition of role-play in nurse training to better prepare nurses to deliver the intervention.</li> <li>• Feedback for the first 5 intervention sessions delivered by nurse or peer to be reviewed by study communications specialist to encourage confidence in intervention delivery.</li> </ul>
Peer recruitment and retention	<ul style="list-style-type: none"> <li>• Peer withdrawals were higher than expected (due to work commitments and personal reasons). Therefore, it will be necessary to recruit, screen and train a high number of volunteers for larger RCT given the risk of drop-out.</li> </ul>

Abbreviations: IOM, Institute of Medicine; RCT, Randomised controlled trial.



**Figure 1. Top issues identified as 'most important' by Consumer Working Party.**



**Figure 2. Final intervention design and key features**

