Peer support after treatment with curative intent: The PeNTAGOn Study

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## Faculty Disclosure

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Unique but universal

- A recognition that each person’s journey is unique

- Some themes are universally shared by those who have walked the same path

- Shared experience is very valuable
PeNTAGOn: Peer & Nurse support Trial to Assist women in Gynaecological Oncology:

A National Phase III Trial

Principle Investigator: Professor Penelope Schofield

Trial Funded by Cancer Australia/Beyondblue and NHMRC
Background

Pelvic radiotherapy for GC can have distressing physical, emotional and sexual side effects, and impact on psychosocial functioning and intimate relationships.

Current guidelines advocate the use of vaginal dilators to minimise vaginal stenosis and agglutination, however patient adherence is suboptimal

30% of GC patients experience anxiety prior to and at treatment completion, which further impacts sexual functioning and QoL

Comprehensive treatment preparation and support addressing patients’ needs throughout the treatment journey may improve patient treatment readiness and reduce patient distress and psychosexual dysfunction
Aim & hypotheses

To test the effectiveness of a telephone-based peer support intervention with standardised nurse consults to improve outcomes for women receiving radiotherapy with curative intent for gynaecological cancer.

**Hypotheses:** Compared to usual care, intervention patients will report:

- Lower psychological & symptom **distress**, 
- Better **preparation** for treatment 
- Lower **needs** (informational and psychological), 
- Higher **quality of life** 
- Less **psychosexual dysfunction & vaginal atrophy/narrowing**
Design

Multi-site pragmatic RCT with follow ups at immediately prior to first treatment, 4 weeks, 6 months and 12 months post-treatment

Randomisation

Post- baseline measures, patients were randomised 1:1 to intervention or usual care

**Stratification:** treating hospital and treatment type EBR (+/- brachy) or EBR (+/- brachy) plus chemo.
Eligibility criteria

Inclusion criteria:
- have a confirmed diagnosis of gynaecological cancer;
- be scheduled to receive EBRT/BRT with curative intent to the pelvis,
- be aged 18 years or older,
- be able to read and write English

Exclusion criteria:
- a severe psychiatric or cognitive disorder,
- treatment with palliative intent,
- or previous treatment with radiotherapy
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): study protocol for a randomised controlled trial

Penelope Schofield\textsuperscript{1,2,3*}, Ilona Juraskova\textsuperscript{4}, Rebecca Bergin\textsuperscript{1}, Karla Gough\textsuperscript{1}, Linda Mileshkin\textsuperscript{1,2,5}, Meinir Krishnasamy\textsuperscript{1,3}, Kate White\textsuperscript{6,7}, David Bernshaw\textsuperscript{1,5}, Sylvia Penberthy\textsuperscript{1} and Sanchia Aranda\textsuperscript{1,3,8}

Abstract

Background: Women who undergo radiotherapy for gynaecological cancer (GC) can experience distressing side effects which impact on psychosocial functioning and intimate relationships. Cancer-related distress may be ameliorated by comprehensive preparation for treatment and addressing women’s informational, physical, psychological and psychosexual needs. This paper describes the protocol for a multisite randomised controlled trial (RCT) testing a novel intervention package which combines tailored specialist nursing consultations and telephone peer support with the primary aim to reduce psychological distress. Secondary aims assess patient quality of life, symptom distress, unmet supportive care needs, preparation for treatment, psychosexual functioning and vaginal stenosis.
The Intervention

Nurse:
- Treatment orientation
- Side-effects
- Self-care plan
- Coaching (esp. dilator use)
- Psychosexual rehabilitation
- MDT care coordination
- Survivorship care plan to pt & GP

One & half days of training & ongoing supervision

Manual includes:
- Evidence based recommendations,
- Need assessment tool
- Self-care brochures.

Peer:
- Empathy,
- Share experiences
- Encourage adherence to self-care plan.
- Appropriate link with the nurse, &
- Provided with side-effects management plan.

Two days of training & ongoing supervision

Manual includes:
- Detailed guide for phone conversations
- Specific topics to cover and
- Effective communication techniques

Nurse session 1 (Pre-treatment)
- Nurse contact with Peer – concerns & self-care

Peer call 1 (~1wk after nurse session 1)
- Referrals/info

Nurse session 2 (mid-treatment - wk 3)
- Nurse contact with Peer – concerns & self-care

Peer call 2 (~1wk after nurse session 2)
- Referrals/info

Nurse session 3 (end-of-treatment: wk6 EBRT, or end of BCY.)
- Nurse contact with Peer – concerns & self-care

Peer call 3 (~1wk after nurse session 3)
- Referrals/info

Nurse session 4 (telephone) (2wks after end-of-treatment)
- Nurse contact with Peer – concerns & self-care

Peer call 4 (4wks after end-of-treatment)
Developing an Evidence-Based, Nurse-Led Psychoeducational Intervention With Peer Support in Gynecologic Oncology

**Background:** The physical and psychosocial impact of radiotherapy for gynecologic cancer requires complex interventions to address treatment-related, chronic health effects, and the need for ongoing support during and after treatment. A nurse-led psychoeducational intervention can provide comprehensive care, addressing information needs, emotional support, and facilitating access to other resources.
Primary endpoint: Psychological distress

- HADS Total scores did not differ significantly between study arms at randomisation (p = 0.29), then exhibited a similar pattern of change over time (p = 0.15).
Secondary endpoints: Preparation for treatment

- **Sensory/psychological** and **Procedural concerns** scores differed between study arms at randomisation (both $p < 0.001$), then showed different patterns of change over time (both $p < 0.001$).

- **Sensory/psychological** and **Procedural concerns** were fairly stable in the Usual care arm, whereas concerns decreased in the Intervention arm.
Secondary endpoints: 
Supportive care needs

- **Health system and information** and **Sexuality** scores differed between study arms at randomisation (both $p = 0.03$) then exhibited different patterns of change ($p = 0.007$ and $0.03$, respectively).

- For **Health system and information**, the reduction of needs was greater for the Intervention arm.

- For **Sexuality**, needs decreased in the Intervention arm and increased in the Usual care arm.
Conclusions

- By informing women about treatment procedures and promoting patient adherence to self-care, PeNTAGOn successfully address a significant gap in healthcare provision.
Investigators

Chief investigators
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- Prof Sanchia Aranda
- Dr Ilona Juraskova
- Dr Linda Mileshkin
- Prof Kate White

Clinical Investigators
- Dr David Bernshaw
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- Ms Alison Hocking
- Prof Madeline King
- A/Prof Karla Gough