Peer support after treatment with curative intent: The PeNTAGOn Study

Professor Penelope Schofield

Professor of Health Psychology, Swinburne University

Head of Behavioural Science, Peter MacCallum Cancer Centre

Faculty Disclosure

X	No, nothing to disclose
	Yes, please specify:

Company Name	*Honoraria/ Expenses*	*Consulting/ Advisory Board*	*Funded Research*	*Royalties/ Patent*	*Stock Options*	*Ownership/ Equity Position*	*Employee*	*Other (please specify)*
Example: company XYZ	x		x		x			

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*

Australian Government
National Health and Medical Research Council
NHMRC

Australian Government
Cancer Australia

beyondblue

KNOW ING

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

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

Schofield et al. Trials 2013, 14:39
http://www.trialsjournal.com/content/14/1/39

TRIALS

STUDY PROTOCOL Open Access

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[1,2,3*], Ilona Juraskova[4], Rebecca Bergin[1], Karla Gough[1], Linda Mileshkin[1,2,5], Meinir Krishnasamy[1,3], Kate White[6,7], David Bernshaw[1,5], Sylvia Penberthy[1] and Sanchia Aranda[1,3,8]

Abstract

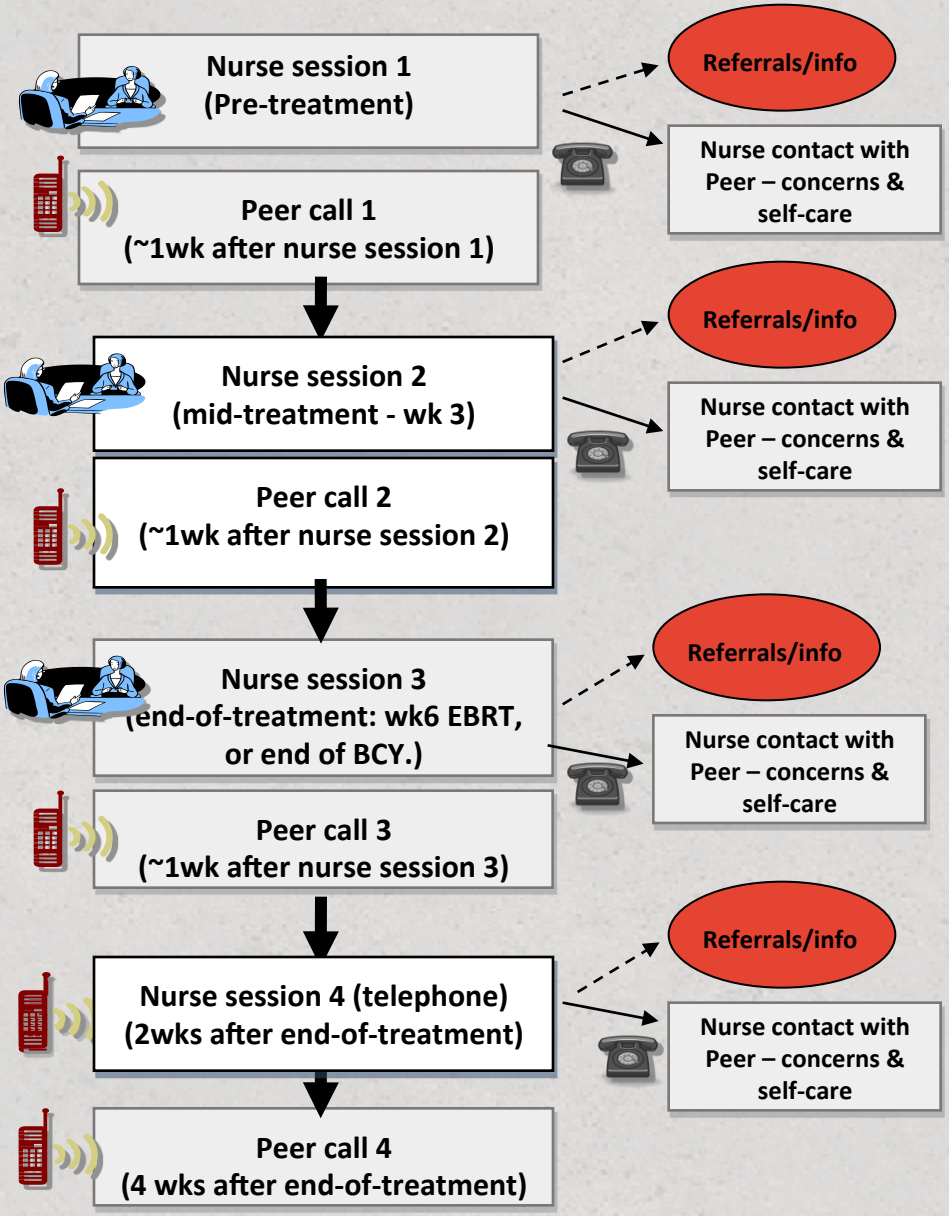
Background: Women who undergo radiotherapy for gynaecological cancer (GC) can experience distressing side effects which impact on psychosocial functioning and intimate relationships. Cancer-related distress may be ameliorated by comprehensive preparation for treatment and addressing women's informational, 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 co-ordination
- 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

KNOW ING

Rebecca J. Bergin, BA&Sc(Hons)
Suzi M. Grogan, MN, RN
David Bernshaw, MD
Ilona Juraskova, PhD
Sylvia Penberthy, RN
Linda R. Mileshkin, MD
Meinir Krishnasamy, PhD
Alison C. Hocking, BSW
Sanchia K. Aranda, PhD
Penelope E. Schofield, PhD

Developing an Evidence-Based, Nurse-Led Psychoeducational Intervention With Peer Support in Gynecologic Oncology

KEY WORDS
Evidence-based nursing

Background: The physical and psychosocial impact of radiotherapy for gynecologic cancer requires complex interventions to address treatment-related,

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

- Prof Penelope Schofield
- Prof Sanchia Aranda
- Dr Ilona Juraskova
- Dr Linda Mileshkin
- Prof Kate White

Clinical Investigators

- Dr David Bernshaw
- Prof Jonathon Carter
- Prof Michael Jackson
- Prof Russell Hogg
- Dr Robyn Cheuk

Associate Investigators

- Mrs Sylvia Penberthy (dec)
- Dr Amanda Horden
- Ms Alison Hocking
- Prof Madeline King
- A/Prof Karla Gough