Exploration of the role of specialist nurses in the care of women with gynaecological cancer:

a systematic review.

Submitted by

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ABSTRACT

Background: The needs of women with gynaecological cancer are significant and in some ways unique compared with those of other cancer types. Specialist nurses provide tailored care for women with gynaecological cancer yet their role varies across sectors and states and is not guided by competency standards and minimum educational requirements like their specialist breast nurse counterparts. There is a need to synthesise evidence evaluating the effectiveness of specialist nurses in the gynaecological-oncology setting.

Aim: The main aim of this systematic review was to evaluate interventions by specialist nurses in their role of caring for women with gynaecological cancer. Three specific review questions were addressed that considered: the effect of specialist nurse interventions on quality of life, satisfaction with care and psychological outcomes; the most effective interventions categorised according to four main domains of care; and the effect of varied timing in the continuum of care, duration, intensity and modes of delivery of specialist nurse interventions on outcomes.

Method: Both randomised controlled trials (RCTs) and non-randomised studies (NRS) testing interventions by specialist nurses in the gynaecological-oncology setting were included in this review. Nine major databases were searched and studies were assessed against set inclusion criteria. Included studies were critically appraised and a risk of bias assessment performed to evaluate quality. Data were extracted independently by three reviewers. Data were insufficiently similar to enable meta-analysis.

Results: Nine studies (6 RCTs and 3 NRS) were included in the systematic review. Assessment of the risk of bias revealed that the quality of the RCTs was mixed and highlighted the inherent flaws of non-randomised study designs. Results for the RCTs and NRS were reported separately to enable distinction between evidence levels. Studies varied greatly in the type of intervention provided and the tools used to measure outcomes, contributing to mixed results. Strong positive results were recorded in the three studies measuring satisfaction with care. Seven of the nine

included studies reported at least one positive interventional effect on outcomes of interest.

Conclusions: The review demonstrated some positive effects of interventions by specialist nurses for women with gynaecological cancer, though these must viewed in conjunction with the assessment of evidence quality. This systematic review has contributed to our understanding of the patient-centred aspects of the specialist nurse role and further research is required to evaluate the role overall.

DECLARATION

This thesis doesn't contain any material which has been accepted for the award of any other degree or diploma in any university and that, to the best of my knowledge and belief, the thesis contains no material previously published or written by another person except when due reference is made in the text of the thesis.

Signed: 

Olivia Yvonne Cook

Date: 20/ 02 /2014

Authorship declaration

School/Centre: *School of Nursing and Midwifery (Peninsula Campus), Faculty of Medicine, Nursing and Health Sciences*

In accordance with the NH&MRC/AVCC Guidelines for Responsible Practices in Research and Problems of Research Misconduct,

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TABLE OF CONTENTS

Table of Contents continued

Table of Contents continued

List of Figures

List of Tables

CHAPTER 1: INTRODUCTION, BACKGROUND AND AIM

Introduction

This systematic review aims to explore the role of specialist nurses in the care of women with gynaecological cancer. This will be achieved by systematically evaluating papers which have focussed on interventions by specialist nurses to determine the effect of such on three main outcome variables: quality of life; satisfaction with care and psychological outcomes. This review also aims to determine how effective interventions by specialist nurses are in the gynaecological-oncology setting in each of four main patient-centred domains of care including: information and education provision; social, emotional and psychological support; physical and practical support; and psychosexual care. The effects of the timing, duration, frequency, intensity and mode of delivery of the interventions on outcome measures will also be evaluated. The background section of this systematic review provides a précis of the incidence and mortality of the gynaecological cancers, the supportive needs of gynaecological cancer patients and what is currently known about the role of the specialist nurses in the gynaecological-oncology setting. A comparison is made between the role of specialist nurses in gynaecological-oncology with that of specialist breast nurses. This systematic review includes evaluation of both randomised controlled trials (RCTs) and non-randomised studies (NRS) testing interventions by specialist nurses in the gynaecological-oncology setting. Nine major databases were searched and studies were assessed against set inclusion criteria. Included studies were critically appraised and a risk of bias assessment performed to evaluate quality. Data were extracted independently by three reviewers and a comprehensive narrative analysis completed, reported according to level of evidence. Results, limitations of the included studies and of the methodology of this review, and recommendations for further research were all discussed.

Background

Gynaecological Cancer – Incidence and Survival

The gynaecological cancers are a group of cancers affecting the female reproductive organs and are named according to their site of origin. The most common of these are cancer of the uterus, ovary, cervix and vulva. As a group, the gynaecological cancers account for 18.6% of cancers found in women throughout the world (Sankaranarayanan & Ferlay, 2006). In Australia, gynaecological cancers account for 9.4% of reported cancer cases in women, making them the fourth most common form of cancer in women after breast, bowel and melanoma forms (Cancer Australia, 2012). Most recently published Australian statistics from 2008 report that of the gynaecological cancers, uterine cancer is the most common with 2,016 new cases reported, followed by ovarian cancer with 1,272 cases, cervical cancer with 778 cases and vulva, vaginal and other gynaecological cancers forming the remaining 468 cases (Cancer Australia, 2012).

Treatment of the gynaecological cancers usually requires surgery in the first instance, and may then be followed up with adjuvant chemotherapy, radiotherapy and/or hormone treatment. Surgical treatment usually involves total hysterectomy, bilateral salpingo-oopherectomy (BSO) and possible pelvic lymph node dissection in the case of ovarian, uterine and cervical cancer but may be restricted to wide local excision of the tumour in the case of cancer of the vulva (The Cancer Council NSW, 2011a; The Cancer Council NSW, 2011b). The five-year survival rates in Australia for each of the gynaecological cancers are as follows: uterine cancer 82%, cervical cancer 72%, vulva cancer 71% and ovarian cancer 43% (Cancer Australia, 2012). Uterine cancer is often diagnosed in its early stages and treatment is often curative as indicated by the fairly high five-year survival rate. Conversely, less than half of the women diagnosed with ovarian cancer today will be alive in five years time. This is attributable to diagnosis often occurring in the later, advanced stages of disease

leading to a poor prognosis and survival rate (The Australian Cancer Network and National Breast Cancer Centre, 2004). The main reasons for late diagnosis are the vague and indiscriminate symptoms that women with ovarian cancer present with including abdominal bloating, increased abdominal girth, indigestion, lack of appetite, change in bowel habits, urinary frequency or incontinence, fatigue and abdominal and/or pelvic pain - all of which may easily be overlooked by women and primary caregivers (The Cancer Council NSW, 2012). The experience of women with gynaecological cancer can vary greatly based on the site of their primary cancer, stage of disease at diagnosis and the type of treatment received.

The nursing care needs of women with gynaecological cancer

The nursing care needs of women with gynaecological cancer can be significant and extend beyond the already busy role of the staff nurses caring for them on the surgical, chemotherapy or radiotherapy units in which they receive their treatment. Specialist nurses are vital to ensuring that these additional care needs are met. These needs may be categorised under four main domains of care: education and information; social, emotional and psychological; physical and practical; and psychosexual.

Information helps cancer patients to cope with their fears, control and understand their situation, be involved in their care, plan and prepare for the future and has a positive effect on their feelings and attitudes (Sainio & Eriksson, 2003). Koutsopoulou, Papathanassoglou, Katapodi, and Patiraki (2010) found that specialist nurses were the preferred information providers to cancer patients at specific times during their treatment. Women with gynaecological cancer want to be involved in their care but require complete, un-embellished information and education, at times suitable to their needs, in order to do this (Ekwall, Ternestedt, and Sorbe, 2003).

Psychosocial needs, that is, the social, emotional and psychological needs of people with cancer, are often significant and will vary along the disease trajectory from diagnosis to palliation (National Breast Cancer Centre & National Cancer Control Initiative, 2003). This is certainly true for women with gynaecological cancer. These women fear their cancer returning or spreading, they suffer with sadness, depression and anxiety, worry about those close to them and feel uncertain about the future (Beesley et al., 2008; Steele & Fitch, 2008). Adding to this, women with gynaecological cancer may have very practical social concerns to manage such as the cost of care (National Breast Cancer Centre & National Cancer Control Initiative, 2003; Wainer, Willis, Dwyer, King, & Owada, 2012) and a disruption to their working life (Grunfeld & Cooper, 2012; Gudbergsson et al., 2011). Whilst some of these areas are not the expertise of a specialist nurse, it highlights the important role they have to play in identifying these issues with patients and making referral to social work services or other as necessary.

Physical and practical care is a large part of the specialist nurse role and can be considered as care relating to the symptoms of disease and side effects of treatment. Physical symptoms and side effects suffered by women with gynaecological cancer may include, but are not limited to nausea and vomiting, pain, lymphoedema, gastrointestinal issues, cognitive problems and fatigue. These symptoms may occur as a result of surgical intervention, chemotherapy, radiotherapy or as a result of the progression of the disease. Different side effects can be expected for each of the treatments for gynaecological cancer and the specialist nurse has a role to play in preparing the patients for such and providing expert care to manage them. Post abdominal surgery for gynaecological malignancy, women may experience nausea and vomiting, pain, insomnia, fatigue, constipation and appetite loss (Minig et al., 2013). Radiotherapy post-surgery has been shown to decrease appetite, increase

bowel motions and increase pain and vaginal burning (Caffo et al, 2003), fatigue (de M Alcântara-Silva, Freitas-Junior, Freitas, & Machado, 2013) and cause long term urinary dysfunction, abdominal symptoms and lymphoedema (Le Borgne et al., 2013). Nausea, vomiting and appetite loss were reported by patients receiving chemotherapy for ovarian cancer (Penar-Zadarko, Binkowska-Bury, Wolan, Gawelko, & Urbanski, 2013). Ovarian cancer patients have also been reported to experience pain that impacted their quality of life (Portenoy et al., 1994) and impaired cognitive function (Correa & Hess, 2012). Adding to this, gynaecological cancer patients may experience lower limb lymphoedema (LLL) when surgical dissection or irradiation of the pelvic lymph nodes is required to treat advanced malignancy. Treatment of LLL is most effective when preventative care is instituted early (Liao, Li, & Huang, 2012; Lockwood-Rayermann, 2007) and specialist nurses are well positioned to assess for LLL and refer for specialist treatment as needed.

Whilst the informational and supportive needs of gynaecological cancer patients could easily be paralleled to sufferers of other cancer types, the psychosexual needs of this group are unique and significant. Women treated for early stage disease may only experience short-term sexual difficulties; however those treated for advanced or recurrent disease, involving radiotherapy, experienced prolonged problems (Jensen et al. 2003; Jensen et al. 2004). Stead, Fallowfield, Selby, and Brown (2007) found that it was generally not until after treatment that women started to think about sexual functioning, with the period of diagnosis and treatment seeing women focussed on enduring their treatment and considering their future. The responsibility of psychosexual care seems to fall to the specialist nurse in the gynaecological-oncology setting (Stead, Fallowfield, Brown, & Selby, 2001) and such care must be provided in an open, but highly sensitive, manner.

Defining the role of Specialist Nurses in gynaecological-oncology

It is the objective of the National Gynaecological Cancer Service Delivery and Resource Framework that all women in Australia with gynaecological cancer be managed by a multidisciplinary team (MDT) that includes specialist nurses (Cancer Australia & The Royal Australian College of Obstetricians & Gynaecologists, 2011). Yet, little is written about the specific role and function of the specialist nurse in the gynaecological-oncology setting, or how nurses in this role are guided and governed in their practice. Throughout Australia, gynaecological-oncology specialist nurses practice under varying role titles including gynaecological cancer nurse consultant, cancer care coordinator or gynaecological clinical nurse specialist, depending on the state and sector in which they are employed. The gynaecological cancer nursing workforce is small and fragmented, and to date there are no specific competency standards or post-graduate qualifications in place to govern, formalise or standardise nursing practice in this specialised field. This is in contrast to the development and formalisation of the Specialist Breast Nurse (SBN) role in Australia in recent years. In 2007, the Competency Standards and Educational Requirements for Specialist Breast Nurses in Australia were released (Yates et al., 2007). These guidelines were developed in response to evidence that, although SBNs made an important contribution to improved outcomes for women with breast cancer, there was significant variation in how the role functioned between individual nurses and settings and the credentials held by them (Yates et al., 2007). This had the potential to contribute to varied outcomes for women with breast cancer and stimulated the need for standardisation (Yates et al., 2007).

Without such competency standards and minimum educational requirements for specialist nurses in the gynaecological field we must look to other, more generalised documents for definition and guidance. Cancer Australia and The Royal Australian College of Obstetricians & Gynaecologists (2011) determines that the roles of nurses working in gynaecological cancer care be considered within the context of The National Professional Framework for Cancer Nursing

(EdCaN Framework). The EdCaN Framework applies the national nursing competency standards developed by the Australian Nursing and Midwifery Council (ANMC) to the context of cancer control and details competency standards for nurses across four levels, including that of specialist cancer nurse (Aranda & Yates, 2009). The framework provides a broad and generalised tool to guide gynaecological-oncology specialist nurses in their practice. Cancer Australia and The Royal Australian College of Obstetricians & Gynaecologists (2011, p. 46) offers a useful interpretation of the framework as it applies to the gynaecological cancer specialist nurse, stating that they play a significant role in:

> ...assessing women's needs, responding to needs and ensuring appropriate referral, providing information, support and specialist nursing skills to women, facilitating coordinated care within and across services and sectors, professional development and mentoring for general nursing staff, strategic service planning and involvement in research and national and international networking.

Whilst the involvement of a specialist nurse is thus recognised as important to the optimal care of women with a gynaecological cancer, there is a gap in the literature relating to the evaluation of the role. There is no known literature evaluating the overall role of the specialist nurse in the gynaecological-oncology setting. However, fragmented evidence does exist evaluating the more patient-centred aspects of the role which may be categorised into four main domains of care including: information and education, psychosocial care, physical and practical care and psycho-sexual care. This systematic review was conceptualised in response to an absence of synthesised evidence pertaining to the effectiveness of specialist nurses in caring for women with gynaecological cancer. Other systematic reviews have considered educational interventions (Chow, Chan, & Chan, 2012) and psychosocial interventions (Hersch, Juraskova, Price, & Mullan, 2009) for women with gynaecological cancer, but both include interventions by professionals other than specialist nurses. In

order to evaluate the role that specialist nurses have to play in the care of women with gynaecological cancer, it is necessary to critically and systematically review all studies where specialist nurses only execute, or have developed, the tested intervention. Likewise, studies with interventions falling under all or any of the four main domains of care provided by specialist nurses are included in this systematic review to enable a comprehensive understanding of the patient-focussed aspects of the role.

Aim and Review Questions

The main aim of this systematic review was to evaluate interventions by specialist nurses in their role of caring for women with gynaecological cancer. The specific review questions addressed were:

1. How do interventions by specialist nurses affect quality of life, patient satisfaction and psychological outcomes in women with gynaecological cancer?
2. How effective are interventions by specialist nurses in gynaecological oncology in each of the following domains of care:
    a. Informational and educational?
    b. Social, emotional and psychological?
    c. Physical and practical?
    d. Psychosexual?
3. What is the effect when specialist nurse interventions are delivered:
    a. at various points on the continuum of care?
    b. in varying intensity, frequency or duration?, or
    c. via different modes of delivery?

The following chapter reports on the methodology of this systematic review including the inclusion criteria, search strategy, process of study selection and appraisal, and data extraction. Following on from this, the results of the search

strategy are presented along with a description of the included studies according to the outcome variables and the categorisation and characteristics of the tested interventions. The findings of the reviewed studies are then presented in response to the three specific review questions. Discussion of the limitations of the included studies, limitations of the methodology of this systematic review and recommendations for future research also follow.

CHAPTER 2: METHODOLOGY

Inclusion Criteria

Types of Studies

Originally set to include only randomised controlled trials (RCTs), the inclusion criteria were extended prior to execution to also include non-randomised studies that tested a specialist nurse intervention. It was considered that some aspects of care provided by a specialist nurse, such as the facilitation of group therapy, were not suitable for study by randomised controlled trial. Thus, extension of the criteria was instituted to ensure that studies that provided evidence of the effects of interventions which cannot be randomised could be evaluated (Reeves, Deeks, Higgins & Wells, 2008). Inclusion and evaluation of non-randomised studies may also have allowed for examination of the case for undertaking a randomised trial or may be useful to inform the design of future randomised trials (Reeves et al., 2008). Mixed method studies were also eligible for inclusion providing the quantitative arm met the aforementioned criteria. Studies that were not reported in English were not included as the reviewer comprehends English only. Studies published before 1993 were excluded. It was anticipated that as the topic became popular in the late 1990s-2000s a cut off date of twenty years prior would allow for all relevant studies relating to the role of the specialist nurse in gynaecological-oncology to be captured. This was ratified by the small number of studies excluded when date ranges were applied to each of the database searches.

Types of participants

Studies including women over the age of 18 years with a confirmed primary gynaecological malignancy including cancer of the uterus, cervix, vagina, vulva, ovary or fallopian tubes were considered for review. The participants could

have been at any point on the continuum of care including diagnosis; undergoing hospital based treatment or ambulatory treatment including surgery, chemotherapy, radiotherapy, brachytherapy or hormone treatment; completion of treatment and in the survivorship phase; recurrence of disease or palliative care phase. Women receiving concurrent treatments for example 'chemo-radiation' may also have been included. Studies that include both women with gynaecological cancer and women with other primary cancers such as breast cancer were included in the review if sufficient information was provided to enable extraction of data relating to the women with gynaecological cancer only. Where the study sample includes women with known mental illness, and this is not controlled for, such studies were excluded.

Types of Interventions

Interventions provided by or developed by a gynaecological-oncology specialist nurse were considered for review. Studies including interventions from both a gynaecological-oncology specialist nurse and other health professional were included if sufficient information was available to enable a causal effect to be established for the intervention of the specialist nurse. The interventions must relate to the informational, educational, social, emotional, psychological, psychosexual, physical or practical needs of the participants. The interventions may have occurred at any point on the continuum of care. Longitudinal studies involving interventions at more than one point on the continuum of care were also considered for inclusion in order to evaluate the effect of time on outcomes. Likewise, the duration or frequency of the intervention was not a limitation to inclusion. Studies with interventions relating to more than one of the identified needs were also permitted for inclusion, along with studies with different modes of delivery such as group-based, telephone-based, written or verbal interventions.

Types of Outcomes

The outcome measures were narrowed to include quality of life (QOL), satisfaction with care, and psychological outcomes. Studies that included other outcome measures were eligible for inclusion providing they also included one of the three main outcome measures.

Search Strategy

A comprehensive search strategy was employed to ensure that all published data relating to the topic was considered for inclusion in the systematic review. As described and recommended by Bettany-Saltikov (2010a), the Population, Intervention, Comparative Intervention and Outcomes (PICO) approach was utilised to break-down the main research question into the components identified in Table 1 'Main research question in PICO form' below. From this, synonyms for each of the 'PICO' components, other than the comparative intervention, were identified and the search strategy created as included in Appendix 1'. It was decided that excluding the comparative intervention search terms would ensure that the search results were not too narrow. All keywords under each of the 'PICO' headings were individually entered into a given database and combined using the Boolean operator "OR". That is, the population keyword searches 1-24 were entered then combined with "OR". This process was repeated for intervention keywords 25-57 and outcome keyword searches 58-73. The three combined results were then searched with "AND" to yield the final search results for that database. An example of the search results for the combined EBSCO Host search of CINAHL Plus and MEDLINE is included in Appendix 2. Databases searched for published material included: CINAHL Plus, MEDLINE, Joanna Briggs Institute EBP database, EMBASE, AMED, PsycINFO, Cochrane Library, Proquest Health and Medical Complete and Scopus. All databases were initially accessed from their date of inception to the current date but searches were limited to publications from 1993 to the

current date. A hand search of bibliographic and reference lists of background and included articles was also conducted to mitigate possible bias in database search systems. The Networked Digital Library of Theses and Dissertations was accessed to gain full text versions of unpublished theses. An accurate record of all search strategies and results was maintained to enable replication of the review if necessary.

Table 1: Main research question in PICO form

P - Population	I - Intervention	C – Comparative Intervention	O - Outcomes
Women with gynaecological cancer	Specific intervention by a gynaecological-oncology specialist nurse	No involvement of the gynaecological-oncology specialist nurse or standard care	Effect on women with gynaecological cancer

Study Appraisal and Selection

The abstracts of all results from the above mentioned database searches were manually reviewed to determine if they met the set inclusion criteria for the review. Studies possibly fitting the inclusion criteria were short-listed and full text accessed if available. Studies were then assessed utilising the Inclusion Criteria Assessment Form, an adapted version of that suggested by Bettany-Saltikov (2010b). Prior to use the form was piloted on a number of articles and adapted as required to create the final version included in Appendix 3. Short-listed studies were assessed as 'included', 'excluded' or 'unsure'. Those assessed as 'included' or 'unsure' were subject to further critical appraisal via the Critical Review Checklist (Appendix 4) a purposefully created tool using the

‘critical review guidelines for quantitative studies’ in Schneider, Whitehead, LoBiondo-Wood, and Haber (2013, p. 303) and with reference to the ‘Critical appraisal checklist for experimental studies’ utilised by Chow et al. (2012, pp. 4129-4131). Prior to use, this form was piloted on a number of articles. A critical reading checklist (Monash University Library, 2013) was also utilised to critique and record each ‘included’ or ‘unsure’ study. If, after further appraisal, the initial reviewer remained unsure as to whether the study should be included in the systematic review, the study was reviewed by a second and third reviewer and an outcome determined. Studies assessed as suitable for inclusion in the systematic review were also subject to second and third review to confirm inclusion.

Quality of the included RCTs was assessed utilising the Cochrane Collaboration tool for assessing risk of bias (Cochrane Statistical Methods Group & Cochrane Bias Methods Group, 2008). Studies were assessed across six domains including: selection bias, performance bias, attrition bias, detection bias, reporting bias and any other possible forms of bias. Results were tabulated and discussed in the following chapter under the section ‘Quality of Included Studies’. As there is a high risk of bias inherent in the design of non-randomised studies, assessing them against the same criteria for RCTs does not allow for identification of weaknesses in the study design but does serve to demonstrate heterogeneity and assist in interpretation of the findings (Reeves et al., 2008). Thus, the same Cochrane Collaboration tool for assessing risk of bias in RCTs was used but adapted to include a section to assess for the risk of bias due to confounding as recommended in Cochrane Statistical Methods Group & Cochrane Bias Methods Group (2008).

Data Extraction

Data extraction from the critically appraised studies was completed with the use of Appendix 5 'Data Extraction Form'. This form was developed to extract clinical and demographic data plus information that relates to the specific review questions. The data extraction form was created with consideration of the guidelines provided by Bettany-Saltikov (2010b) and review of the data extraction form used by Chow et al. (2012) in a similar systematic review and was piloted on a number of articles prior to use. Data extraction was performed independently by two reviewers for each included study and results compared. If consensus was not achieved a third reviewer was available to resolve any discrepancies.

Data Synthesis

Data extracted from the studies were collated and summarised in Table 3 'Data Table' included in the following chapter to allow for direct comparison of findings. This data table categorises each included study according to clinical characteristics, intervention characteristics and outcome measures. Throughout the results section of this review, RCTs and non-randomised studies are analysed and considered separately so that distinction can be made between the two levels of evidence. This review has a very wide scope with varying interventions tested and three broad outcome measures considered, thus making meta-analysis of the findings problematic. Meta-analysis of findings that are at risk of bias will compound such errors (Reeves et al., 2008) and for this reason meta-analysis was not performed. In light of this, a comprehensive narrative analysis of findings was conducted, with no statistical analysis included. Findings of the included studies were synthesised in relation to each of the specific review questions and reported accordingly within the

results chapter following. As recommended by Reeves et al. (2008) in regard to narrative analysis, comment is made on each study in relation to each review question in order to ensure that bias is not introduced by inappropriately highlighting the results of one study over another. Results of this systematic review were then further considered and contextualised in the Chapter 4 Discussion.

CHAPTER 3: RESULTS

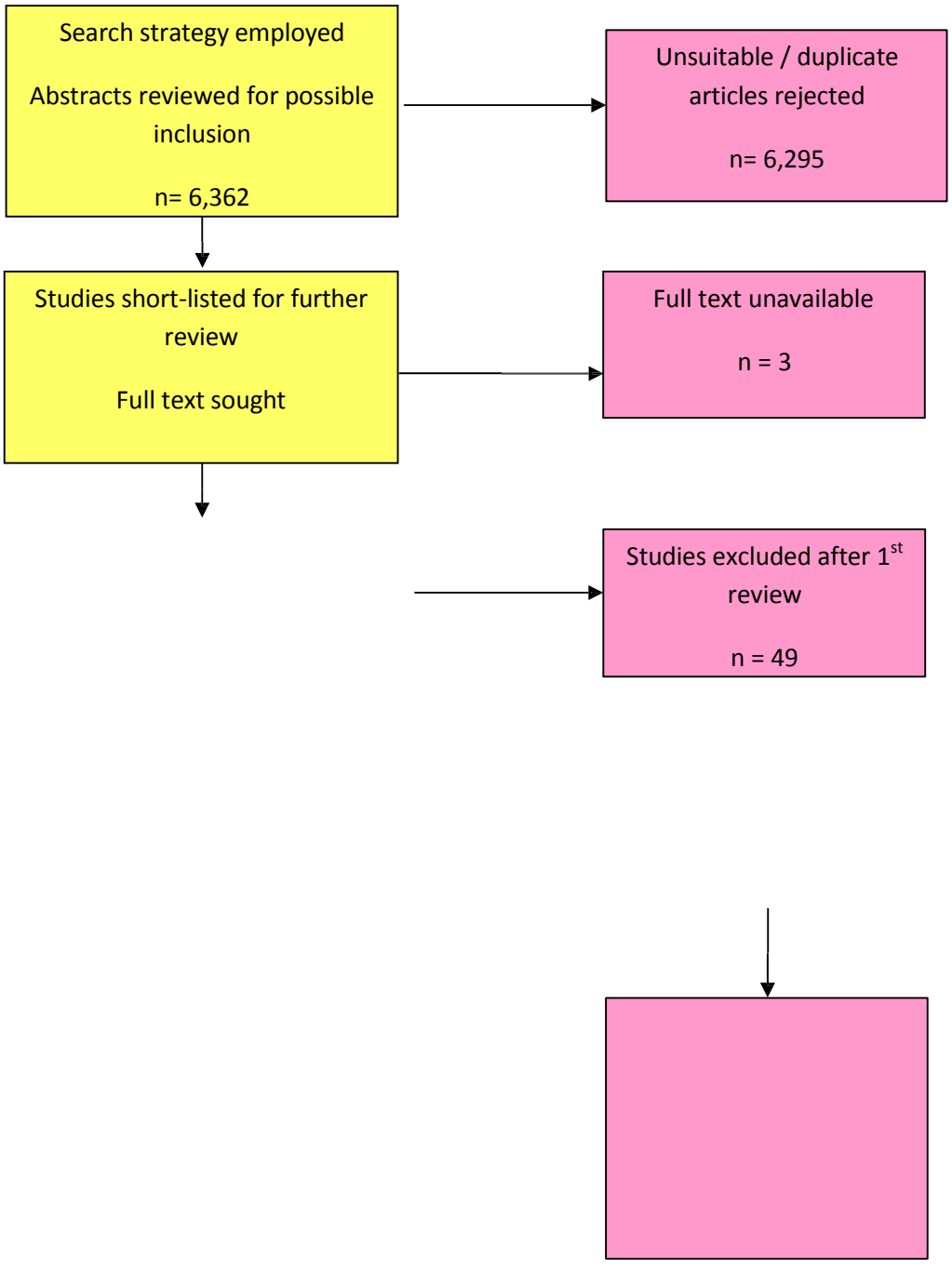
Search Results

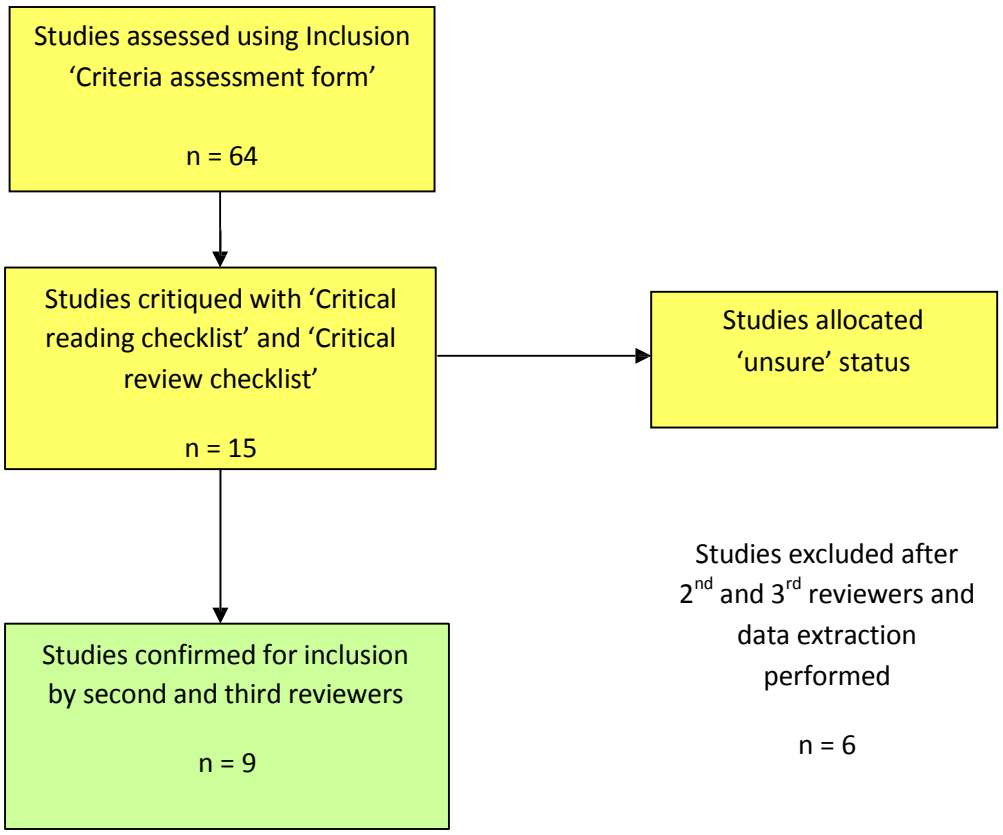
Figure 1 below summarises the process of searching for and selecting articles for inclusion in the systematic review. The search strategy yielded 6,362 results for review. The abstracts were reviewed of all 6,362 results leading to the rejection of 6,295 unsuitable or duplicate articles. The remaining 67 articles were short-listed and further reviewed for suitability for inclusion in the systematic review. The Inclusion Criteria Assessment form (Appendix 3) was completed for 64 of the short listed articles as full text was not available for three short-listed articles. Of the 64 assessed articles 49 were excluded from the systematic review. The main reasons for exclusion were that the article was not presenting primary quantitative research, that there was no intervention tested or the intervention was not provided by a specialist nurse, that the population was not women with gynaecological cancer. A table listing all excluded studies and the reason for exclusion is included in Appendix 6.

Of the remaining 15 studies, 9 clearly met the inclusion criteria and were further critiqued using Critical Review Checklist (Appendix 4) and endorsed by second and third reviewers. The remaining 6 studies that were assessed as 'unsure' for inclusion were also further critiqued and reviewed by second and third reviewers. Of these 6 studies, 4 included participants that had cancers other than gynaecological cancer (B. Given et al., 2002; C. Given et al., 2004; McLachlan et al., 2001; Tamminga et al., 2013). Data extraction utilising Data Extraction Form (Appendix 5) was performed on these four studies to enable further critique. All four studies were subsequently rejected as insufficient data or analysis was presented to determine an outcome for the gynaecological cancer participants only. For the remaining two studies, Kelly, Faught, and Holmes (1999) and Levine and Silver (2007) that were allocated the status of 'unsure', data extraction was also performed. Likewise, data was insufficient to

warrant inclusion in the systematic review. The remaining nine studies were thus included in the systematic review upon the consensus of all reviewers. Details of the included studies can be found in Appendix 7.

Figure 1: Flow chart of search results and study selection process




Studies assessed using Inclusion 'Criteria assessment form'
n = 64
Studies critiqued with 'Critical reading checklist' and 'Critical review checklist'
n = 15
Studies allocated 'unsure' status
Studies excluded after 2nd and 3rd reviewers and data extraction performed
n = 6
Studies confirmed for inclusion by second and third reviewers
n = 9

Quality of Included Studies

This systematic review included both RCTs and NRSs and when categorised according to the NHMRC Levels of Evidence (Schneider, Whitehead, LoBiondo-Wood, & Haber, 2013, p. 322), ranged from Level II to Level IV as shown in Table 2 below.

Table 2 Categorisation of each study according to the NHMRC Levels of Evidence

Study Reference	Brief Description	Study Type	NHMRC Level of Evidence
Randomised Control Trials			
Maughan and Clarke (2001)	Specialist Nurse Intervention Vs Usual Care Control	RCT + Qualitative	II
McCorkle et al. (2009)	Advanced Practise Nurse +/- Psychiatric Consultant Liaison Nurse Vs Attention Control Group	RCT	II
Nolte et al. (2006)	Video intervention re alopecia Vs Standard Care Counselling	RCT + Qualitative	II
Otis-Green et al. (2008)	Ovarian cancer psycho-educational program Vs Standard Care + written material	RCT + Qualitative	II
Velji (2006)	Individual symptom education program Vs Usual Care	RCT	II
Ward et al. (2000)	Individualised information re pain Vs Usual Care	RCT	II
Non- Randomised Studies			
Carlsson and Strang (1998)	Support group participation Vs no participation	Quasi-experimental + Qualitative.	III-2
Seibaek and Petersen (2009)	Nurse-led rehabilitation program Vs usual care	Prospective Cohort study.	III-2
Cox et al. (2008)	Nurse-led telephone follow-up in place of medical follow-up.	Case Series. One group pre-test post-test	IV

A risk of bias assessment was completed for all included randomised control studies utilising the Cochrane Collaboration tool for assessing risk of bias (Cochrane Statistical Methods Group & Cochrane Bias Methods Group, 2008). Appendix 8 includes the Assessment of Bias Summaries for each of the six included studies and rates each domain of bias as high, unclear or low. These results are combined below in Table 3 Risk of Bias Table – Randomised Control Trials.

The same Cochrane Collaboration tool for assessing risk of bias in RCTs was also used to assess risk of bias in the three included non-randomised studies, but was adapted to include a section to assess for the risk of bias due to confounding as recommended in Cochrane Statistical Methods Group & Cochrane Bias Methods Group (2008). Confounding is when "… selection bias produces imbalances in prognostic factors associated with the outcome of interest" (Cochrane Statistical Methods Group & Cochrane Bias Methods Group, 2008, p.412). Table 4 'Risk of bias table – non-randomised studies' presents the results of the assessment of risk of bias for the three non-randomised studies included in the review and summaries of the risk assessment for each study are included in Appendix 9.

Sequence allocation, defined as the rule for allocating interventions to participants based on a chance/random process (Cochrane Statistical Methods Group & Cochrane Bias Methods Group, 2008), was rated as low in three of the RCTs indicating that suitable randomisation techniques were used in those studies with a low risk of bias. The remaining three RCT studies stated that participants were randomly assigned though did not provide detail of the method used and were thus assessed as unclear. The domain of selection bias also includes an assessment of allocation concealment, and determines whether the forthcoming allocation of interventions to participants is concealed from those involved in enrolment into the trial (Cochrane Statistical Methods Group & Cochrane Bias Methods Group, 2008). As for sequence allocation,

three RCTs were assessed as a low risk of bias in regard to allocation concealment. Likewise the remaining three RCTs were assessed as unclear as details of their randomisation process were not made explicit.

Selection bias, defined as systematic differences between the characteristics of participants in compared groups, is probable in non-randomised studies and is the main difference between randomised trials and non-randomised studies. Control groups were included for the non-randomised studies except one (Cox et al., 2008), though admission to these was voluntary and non-randomised in the case of Seibaek and Petersen (2009) and Carlsson and Strang (1998). This was owing to the fact that support group-based interventions were tested in these studies and involvement in such groups must be voluntary on the patients' part thus not allowing for randomisation. However, this did result in high risk ratings for items assessed under the selection bias domain as would be expected. Carlsson and Strang (1998) did note potentially confounding differences between their intervention and control groups, however did not adequately control for this during analysis. As the Seibaek and Petersen (2009) study was an after-only, non-equivalent control study there was no baseline data upon which confounding variables could be identified and controlled for during analysis.

Equivalency of groups at baseline differed among the nine studies. Ward et al. (2000) claimed that control and intervention groups were comparable at baseline and Otis-Green et al. (2008) stated the same; however their demographic data was presented for the group as a whole thereby not allowing for verification of this statement. Nolte et al. (2006) only provided evidence that control and intervention groups were equivalent on outcome variables at baseline and did not provide or discuss demographic data. Maughan and Clarke (2001) stated that their groups were equivalent at baseline however noted that later in the study 20% of the intervention group participants commenced adjuvant therapy compared with only 5% of the control group.

Similarly, Velji (2006) found that their groups were equivalent on all characteristics except for cancer type and chemotherapy status with a greater proportion of the control group diagnosed with cervical cancer and therefore a greater proportion also receiving chemotherapy compared with the intervention group. McCorkle et al. (2009) noted differences between their intervention and control groups however adequately controlled for this using mixed effects regression models. Thus, although the assessment of confounding variables was confined to the non-randomised studies, the RCTs would also be assessed as high or unclear risk given the lack of attempt to identify and control for such variances between groups.

Blinding of study participants and research personnel reduces the risk that knowledge of which intervention was received, rather than in the intervention itself, affects outcomes and outcome measures and is assessed under the domain of performance bias (Cochrane Statistical Methods Group & Cochrane Bias Methods Group, 2008). Risk of performance bias was assessed as high or unclear in all of the RCTs mainly owing to the fact that most of the interventions required active participation and, if informed consent had been obtained, participants would have been aware that they were receiving the intervention. The exceptions to this were McCorkle et al. (2009) and Ward et al. (2000) who explicitly stated that blinding of participants was achieved. The only study that reports blinding of those involved in data collection was Velji (2006). Risk of performance bias was considered high for each of the non-randomised studies given the lack of blinding in all cases.

The attrition bias domain assesses for incomplete outcome data and refers to missing data due to exclusions or attrition and the extent to which this effects estimates. Mixed results were found for this domain for the RCTs as can be seen in Table 3. Likewise, the domain of reporting bias assesses for whether

selective outcome reporting has occurred and the assessment results for RCTs under this domain were also mixed. In regard to the non-randomised studies, both Carlsson and Strang (1998) and Cox et al. (2008) were assessed as low risk in regard to reporting bias given that both studies reported adequately on all pre-specified outcome measures. This was a strong point of these studies that were otherwise weakened by their lack of randomisation or control.

Table 3: Risk of bias table – randomised control trials

	Selection Bias		Performance Bias	Attrition Bias	Detection Bias	Reporting Bias	Other Bias
	Sequence Allocation	Allocation Concealment					
Maughan & Clarke (2001)	LOW	LOW	HIGH	LOW	HIGH	HIGH	HIGH
Mc Corkle et al (2009)	LOW	LOW	HIGH	LOW	LOW	LOW	_
Nolte et al. (2006)	UNCLEAR	UNCLEAR	UNCLEAR	HIGH	LOW	UNCLEAR	_
Otis-Green et al. (2008)	UNCLEAR	UNCLEAR	HIGH	HIGH	UNCLEAR	HIGH	HIGH
Velji (2006)	LOW	LOW	UNCLEAR	LOW	LOW	LOW	_
Ward et al. (2000)	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	UNCLEAR	_

Adapted from Cochrane Statistical Methods Group & Cochrane Bias Methods Group (2008, p.204)

HIGH = High risk of bias, LOW = low risk of bias, UNCLEAR = uncertain risk of bias

Table 4: Risk of bias table – non-randomised studies

	Selection Bias		Confounding Bias	Performance Bias	Attrition Bias	Detection Bias	Reporting Bias
	Sequence Allocation	Allocation Concealment					
Carlsson & Strang (1998)	HIGH	HIGH	HIGH	HIGH	HIGH	UNCLEAR	LOW
Seibaek& Petersen (2009)	HIGH	HIGH	HIGH	HIGH	HIGH	HIGH	HIGH
Cox et al. (2008)	N/A	N/A	N/A	HIGH	HIGH	HIGH	LOW

Adapted from Cochrane Statistical Methods Group & Cochrane Bias Methods Group (2008, p.204)

HIGH = High risk of bias, LOW = low risk of bias, UNCLEAR = uncertain risk of bias, N/A = no comparator

Sample size was small in most cases ranging from 17-137 participants with most research designed as pilot studies. Of the larger studies, both Nolte et al. (2006) and Velji (2006) performed power analysis to determine adequate sample size to detect changes. The sample sizes in each of these studies were adequate to achieve 80% power estimation. McCorkle et al. (2009) was also larger in size but did not provide details of power analysis. Validated and reliable instruments were utilised in most studies to measure outcome variables and authors provided evidence of this. In some cases, investigators created their own instruments such as the QOL-OC created by Otis-Green et al. (2008) which was subjected to parametric testing. Two of the three instruments used to measure patient satisfaction were researcher-created (Otis-Green et al., 2008; Ward et al. 2000).

Clinical Characteristics of Included Studies

Together, the nine studies in this systematic review included a total of 632 participants. This is quite a low number due to most being pilot studies, and the effect this had on the quality of evidence was discussed in the previous section. The mean age for participants was provided for eight of the nine studies from which a total mean age of 57.6 years was calculated, close to the average age of 61.9 years of gynaecological cancer sufferers at diagnosis (Cancer Australia, 2012). Two studies included only participants with ovarian cancer (Cox et al., 2008; Otis-Green et al., 2008) and Velji (2006) excluded patients with ovarian cancer as that study was considering patients undergoing radiotherapy treatment. The other six studies were heterogenous in regard to gynaecological cancer type. Most of the studies were also heterogenous with regard to the staging of disease and anti-cancer treatment received. Table 5, below, includes a summary of the clinical characteristics of the participants of each study.

Outcome Measures of Included Studies

Three main outcomes were set as inclusion criteria for this systematic review: quality of life (QOL), satisfaction with care and psychological outcomes. Studies with additional outcomes were permitted for inclusion providing one of the three main outcome variables was also measured. QOL was measured as an outcome in six of the nine included studies. All six studies utilised a different instrument to measure QOL thus preventing meta-analysis of data on this outcome variable. The instruments utilised in each study are noted in Table 5 'Data Table' below and further description of the instruments is provided in the context of the results. Satisfaction with care was elicited quantitatively in three of the included studies. Like quality of life, psychological outcomes were measured in six studies with a total of seven different instruments used. Two studies, McCorkle et al. (2009) and Otis-Green et al. (2008) utilised the Mischel Uncertainty in Illness Scale (MUIS) and the Psychological Distress Thermometer (DT) to measure uncertainty and distress respectively, however McCorkle only collected baseline distress scores in order to determine the need for the involvement of the psychiatric liaison nurse. The instruments used to measure psychological outcomes in the six studies are noted in Table 5. A total of ten other instruments were utilised by the included studies to measure additional outcomes including symptom distress (Symptom Distress Scale, SDS), sexual functioning (Lasry Sexual Functioning Scale), fatigue (Brief Fatigue Inventory, BFI), pain (Brief Pain Inventory –Short Form, BPI-SF and Pain Management Index, PMI), nausea and vomiting (Rhodes Index of Nausea and Vomiting, INVR), medication side effects (Medication Side Effects Checklist, MSEC), pelvic symptoms (Pelvic Symptoms Inventory, PSI), barriers (Barriers Questionnaire, BQ) and another researcher created a tool to measure perceived knowledge (Carlsson & Strang, 1998). These outcome measures do not form part of the analysis of this systematic review.

Interventions of Included Studies

Interventions were categorised according to the domain of care they related to: informational or educational; social, emotional or psychological; physical or practical; or psychosexual. The interventions of four studies encompassed all four domains of care (Cox et al., 2008; Maughan & Clarke, 2001; McCorkle et al., 2009; Seibaek & Petersen, 2009). Whilst the modes of delivery differed, the interventions described in these four studies comprised comprehensive care from a specialist nurse. Alternatively, Nolte et al. (2006) tested a specific intervention within the physical and practical care domain relating to the symptom of alopecia. The other four studies provided primarily education and information based interventions, with some encompassing other domains of care too.

Five of the studies executed their interventions between diagnosis, treatment and completion of treatment phases. Cox et al. (2008), Ward et al. (2000) and Seibaek and Petersen (2009) all executed their interventions post-treatment, or during the survivorship or disease progression stages on the continuum of care. Carlsson and Strang (1998) had a heterogenous sample spanning all points on the continuum of care. The mode of delivery of interventions differed though most occurred as one-on-one contacts between the specialist nurse and the participant. Two of these studies (McCorkle et al., 2009; Ward et al., 2000) also included telephone contact as part of their intervention and the intervention by Cox et al. (2008) was performed as telephone contact exclusively. Carlsson and Strang (1998) and Seibaek and Petersen (2009) both tested group interventions and Nolte et al. (2006) was the only study to deliver their intervention via video. In some studies participants were welcome to bring along a partner or support person, though lack of data precludes analysis of the effect of this. The frequency at which the interventions occurred differed from 1-18 contacts with the overall mean number of contacts calculated at 5.4. The shortest intervention was the single 45-minute video viewing implemented by Nolte et al. (2006). The longest intervention duration was by Cox et al. (2008) who provided 3 monthly phone calls for 10 months.

Table 5: Data Table

		Randomised Controlled Trials						Non Randomised Studies		
		Maughan & Clarke 2001	McCorkle et al 2009	Nolte et al 2006	Otis-Green et al 2008	Velji 2006	Ward et al 2000	Cox et al 2008	Carlsson & Strang 1998	Seibaek & Peterson 2009
Primary Cancer Site	Cervix	✓	●	✓		✓	✓		✓	✓
	Ovary	✓	✓	✓	✓	?	✓	✓	✓	✓
	Uterus	✓	?	✓		✓	✓		✓	✓
	Vulva	✓	?						✓	
	Other	✓				✓	✓		✓	✓
FIGO Stage of Cancer	Early Stage		✓		✓	✓		✓	✓	✓
	Advanced Disease		✓	✓	✓	✓	✓	✓	✓	
	Undetermined	✓								
Time since diagnosis (mths)		Diagnosis	?	?	Mean 2 years	0-3 mths	Mean 18 mths	?	?	3-6 mths
Type of Treatement Received	Surgery	✓	✓	?	✓	✓	?	?	?	✓
	Chemotherapy	?	?	✓	?	✓	?	?	?	
	Radiotherapy	✓	?	?		✓	?	?	?	
	Combination		?			?	?	?	?	
INTERVENTION										
Category of Intervention	Information or Education	✓	✓		✓	✓	✓	✓	✓	✓
	Social, emotional or psychological	✓	✓		✓			✓	✓	✓
	Physical or practical	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Psychosexual	✓	✓					✓	?	✓
Point on Continuum of Care that intervenion occurred	Diagnosis	✓						✓		
	During treatment	✓	✓	✓	✓	✓			✓	
	Post treatment				✓		✓	✓	✓	✓
	Surviorship						✓	✓		
	Recurrance/Disease progression						✓	✓	✓	
Mode of Delivery of Intervention	One on one	✓	✓		✓	✓	✓			
	Group								✓	✓
	Telephone contact		✓				✓	✓		
	Video			✓						
Frequency / Duration of Intervention	Frequency	4 visits	18 contacts	1 contact	4 sessions	6 sessions	3 contacts	3 mthly for 10 mths	7 sessions	4 sessions
	Duration	?	6 months	45 mins	1hr each	20-30mins each	?	20 mins	1.5-2hrs each	3 hours each
OUTCOME MEASURES										
Quality of Life	SF-36									✓
	FACT-O							✓		
	SF-12		✓							
	EORTC QLQ C30	✓								
	FACT-G						✓			
	Researcher created				✓					
Satisfaction with Care					✓		✓	✓		
Psychological outcomes	POMS								✓	
	CES-D		✓							
	MUIS		✓		✓					
	DT		✓		✓					
	BC SCS			✓						
	SOC									✓
	HADS					✓				
Other	SDS		✓			✓				
	Lasry Sexual Functioning Scale	✓								
	BFI					✓				
	BPI-SF					✓	✓			
	INVR					✓				
	PMI						✓			
	MSEC						✓			
	PSI					✓				
	BQ						✓			
	Researcher created								✓	

Legend: ● Included in study ✕ Not included in study ? Unclear if included ✓ Positive outcome

Effective specialist nurse interventions on quality of life, satisfaction with care and psychological outcomes

Quality of life – randomised controlled trials

As noted earlier, four different instruments were utilised in the four RCTs measuring QOL, making meta-analysis impossible. All of the QOL measurement tools utilised by researchers in this review were self-reporting. The strongest effect on QOL was observed by McCorkle et al. (2009), though this was variable based on the level of intervention that occurred. McCorkle et al (2009) utilised the tool Short Form 12 (SF-12) to measure quality of life, a 12-item questionnaire that is a shortened version of Short-Form 36 (SF-36) and covers physical functioning, role limitations due to physical health problems, bodily pain, general health perception, vitality, social functioning, role limitations due to emotional problems and general mental health (Marosszeky, 2005). Before adjustment there was significant difference between active and control groups on some variables including SF-12 Mental with the active group scoring lower. The intervention by McCorkle et al (2009) involved either care from an Advanced Practice Nurse (APN) alone or the care of the APN plus additional care from a Psychiatric Consultant Liaison Nurse (PCLN) if deemed necessary. Post adjustment it was found that when considering the APN intervention versus control, the control group performed better on SF-12 Physical. When the effect of PCLN was added to the APN intervention a statistically significant improvement (p = 0.0023) in SF-12 Mental was seen. When considering the effect of the PCLN on its own, a significant improvement was seen for both SF-12 Mental (p= 0.0001) and SF-12 Physical (p< 0.0001) scores.

Only one other RCT reported a positive interventional effect on quality of life. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire C30 (EORTC QLQ-C30) is a 30-item cancer specific quality of life measurement tool. Participants in the study by Maughan and Clarke

(2001) achieved better global health status than controls (p=0.04) when tested with the EORTC–QLQ C30. Less sleep disturbance in the intervention group was also noted (p=0.02). Two RCTs, Ward et al. (2000) and Otis-Green et al. (2008) found no significant effect of their respective pain and psycho-educational interventions on any aspect of QOL.

Quality of life – non-randomised studies

Functional Assessment of Cancer Therapy - Ovarian (FACT-O) is a quality of life measurement tool that includes the 27-item Functional Assessment of Cancer Therapy – General (FACT-G) which is divided into four subscales: physical well-being, social well-being, emotional well-being and functional well-being, along with an additional 12 specific questions relating to ovarian cancer (Grzankowski & Carney, 2011). Utilising FACT-O, Cox et al. (2008) were able to demonstrate a statistically significant change (p=0.016) in emotional well being post intervention. Overall, QOL was high and stable with improvement post intervention, though not significant. Other aspects of QOL remained stable in this group who were exposed to a nurse-led telephone follow-up program. Seibaek and Petersen (2009) observed improvement in both their intervention and control groups on aspects of QOL as measured by SF-36 (described earlier), however this was only statistically significant for the intervention group. Difference between groups was not reported. Curiously, other QOL data was omitted without explanation and only the scores showing improvement between 3 and 12 months were provided (bodily pain p = 0.034, vitality p = 0.0075 and physical function p = 0.0019). With a high risk of reporting bias, the effect on QOL for this intervention can only be considered inconclusive.

Overall, of the six studies measuring quality of life as an outcome, four presented positive results for the involvement of a specialist nurse in the care of women with gynaecological cancer, however these results must be considered alongside the quality assessments of that evidence.

Satisfaction with care – randomised controlled trials

Satisfaction with care was elicited in two RCTs utilising investigator-created tools to measure it. Between the two studies, satisfaction with the care received was very high. Otis-Green et al. (2008) asked patients to rate the helpfulness of their ovarian cancer psycho-educational intervention on a scale of 0 (not helpful) to 4 (extremely helpful) resulting in a mean score of 3.38. Likewise 86% of patients in the Ward et al. (2000) study found their individualised pain intervention helpful. Ninety-five percent (95%) of respondents learned something new from the intervention and 82% found that the intervention increased their comfort in taking analgesia and made them less worried about addiction.

Satisfaction with care- non-randomised studies

Cox et al. (2008) was the only non-randomised study to measure satisfaction with care. The researchers had participants rate their experience of phone follow-up on a scale of 1 to 10, receiving a mean score of 8.24. They asked patients what their preferred mode of follow-up was and 73% stated nurse-led telephone follow-up compared with 18% preferring appointments with the doctor and 9% who were unsure.

Overall, the three studies measuring patient satisfaction with care all yielded positive results.

Psychological outcomes – randomised controlled trials

Psychological outcomes were measured in four of the six randomised controlled trials. As for the quality of life outcomes in their study, McCorkle et al. (2009) found that the interventional effects on the psychological outcomes were enhanced by the inclusion of the psychiatric consultant liaison nurse (PCLN). In

the study uncertainty was measured by the Mishel Uncertainty in Illness Scale (MUIS), a 30-item self-administered tool that considers uncertainty in symptomatology, diagnosis, treatment, relationships with caregivers and planning for the future. Uncertainty improved greatly (p = 0.006) for the intervention group in this study compared with controls but this was further enhanced when the effect of the PCLN was considered (p = 0.0181). McCorkle et al. (2009) also measured depression in this group with the Centre for Epidemiological Studies Depression Scale (CES-D) a 20-item questionnaire that assesses depressed and positive affect, somatic/physical symptoms of distress and perceptions regarding interactions with others (Psycho-Oncology Co-Operative Research Group, 2011). Unexpectedly there was no significant difference between the intervention and controls groups with regard to depressive symptoms as measured by the CES-D and depressive symptoms were not responsive to the intensified intervention of the PCLN.

McCorkle et al. (2009) and Otis-Green et al. (2008) are closely comparable studies in terms of their intervention type, timing and mode of delivery, yet have yielded conflicting results in regard to uncertainty. Otis-Green et al. (2008) found no significant difference between groups in regard to uncertainty, also measured by the MUIS. It was impossible to perform meta-analysis for this outcome measure given that the mean and standard deviation data provided by Otis Green et al. (2008) were for the entire sample only and not the comparative groups. Nolte et al. (2006) were surprised to find that their video intervention relating to chemotherapy-induced alopecia did not affect a change in self esteem. They did report that a small but statistically significant (value not provided) change in body image between groups, with a positive effect for the intervention group. They reported that their results were not congruent with previous studies. Velji (2006) reported no significant effect on anxiety or depression over time or between groups as measured by the Hospital Anxiety and Depression Scale (HADS), a 14-item self-reporting tool to measure anxiety and depression within hospital and outpatient settings (Psycho-Oncology Co-

Operative Research Group, 2011). Thus, there is mixed level II evidence for the effect of specialist nurse interventions on psychological outcomes.

Psychological outcomes – non-randomised studies

The two non-randomised, support-group intervention studies also reported mixed results for psychological outcomes. Carlsson and Strang (1998) found that at baseline the intervention group were more confused and angry than the controls ($p<0.05$) which significantly improved compared to the controls post-intervention but only when scores were combined with anxiety ($p<0.05$). As confusion and anger did not improve in a statistically significant way when analysed as single results, it can be deemed that this was not a positive result. Seibaek and Petersen (2009) reported a statistically significant increase in coping between 3 and 12 months ($p=0.0001$) with no similar increase in the control group.

When considered together, the results of the six studies which measured psychological outcomes were mixed. Only three were able to effect a positive change in these variables including uncertainty, body image and coping.

Effective specialist nurse interventions in each of the domains of care

Effective interventions in each domain of care – randomised controlled trials

Two of the six included RCTs, tested interventions which covered all four domains of care. Each of these studies reported a positive effect of their intervention on at least one variable of interest but these were different. The comprehensive interventions elicited positive effects on global health and sleep (Maughan & Clarke, 2001) and uncertainty (McCorkle et al., 2009). Whilst these studies included psychosexual care as part of their intervention, only

Maughan & Clarke (2001) purposefully measured sexual functioning as an outcome via the Lasry Sexual Functioning Scale. Though not a formal outcome of interest in this review, they did find that their intervention led to a trend in higher sexual functioning of intervention group participants yet this was not statistically significant. Of the remaining four RCTs, three were categorised as educational/informational. Both Velji (2006) and Ward et al. (2000) provided educational interventions that were jointly classified as physical/practical being related to symptom management. Only Ward et al. (2000) demonstrated a positive effect on outcomes of interest, reporting a high level of patient satisfaction from their individualised pain management intervention. Likewise, the study by Otis-Green et al. (2008) reported that their intervention did not impact QOL, distress or uncertainty but did report a high level of satisfaction with their educational program. The remaining RCT was categorised as physical/practical being a video intervention for managing alopecia (Nolte et al., 2006). This intervention did affect a small change on body image but did not affect self esteem as expected.

Effective interventions in each domain of care – non-randomised studies

As for the RCTs, the two non-randomised studies that included comprehensive interventions, encompassing all domains of care, elicited positive effects on emotional well being (Cox et al., 2008), and coping, bodily pain, vitality and physical functioning (Seibaek & Petersen, 2009). The remaining non-randomised study (Carlsson & Strang, 1998) covered all domains of care except psychosexual care. As discussed earlier Carlsson and Strang (1998) did not observe improvement in intervention subjects on psychological outcomes however intervention subjects did report an improvement in knowledge as a result, an additional outcome considered by the study.

Overall, the comprehensive specialist nurse interventions encompassing all four care domains, were the most effective. Interestingly, the primarily educational

interventions did not affect quality of life or psychological outcomes but did report high levels of patient satisfaction.

Effective timing, delivery, and intensity of specialist nurse interventions

Whilst the variables of timing, mode of delivery and intensity of specialist nurse interventions were not analysed by any of the studies included, this systematic review provides an opportunity to consider any potential effect of such on outcomes. Patients' needs may vary depending on their position on the continuum of care and different interventions may be more or less effective depending on the timing of provision.

Effective timing, delivery, and intensity – randomised controlled trials

Four of the included RCTs involved interventions executed from diagnosis to completion of treatment. Three studies (Maughan & Clarke, 2001; Mc Corkle et al., 2009; Nolte et al., 2006) reported positive results, yet Velji (2006) did not. The intervention group in the Otis-Green et al. (2008) study were at various points on the continuum of care when they received the intervention, ranging from currently receiving treatment to post-treatment. These women ranged from 6 months to 18 years post diagnosis. Interestingly, subjects from two studies (Nolte et al., 2006; Otis-Green et al., 2008), provided feedback that whilst they were satisfied with the interventions, they would have preferred them to be delivered closer to diagnosis or prior to the commencement of chemotherapy respectively. This demonstrates that an intervention may be acceptable to patients but may not impact outcome variables if it is not delivered at the most sensitive time. Whilst no effect was found by Velji (2006) for the main outcome variables of this review, a clinically significant reduction in

symptom distress was seen in the intervention group compared with the control group. The remaining RCT (Ward et al., 2000) provided a pain management intervention at the other end of the disease trajectory from post-treatment phase to disease recurrence/progression. Although there was no impact on quality of life, the participants in Ward et al. (2000) were satisfied with the intervention received.

An alteration in the intensity of given interventions really only occurred in Mc Corkle et al. (2009) whereby the effect of the Advanced Practice Nurse was 'intensified' by the inclusion of a Psychiatric Consultant Liaison Nurse in the care of the intervention group as discussed earlier. The RCTs included the second longest intervention of regular contacts over 6 months (McCorkle et al., 2009) and the shortest, the video intervention lasting just 45 minutes (Nolte et al., 2006). Both reported positive results though Nolte et al. (2006) could be considered a weak positive result. The two RCTs where participants received interventions that involved telephone contact reported high levels of satisfaction with their care (Ward et al., 2000) and improved quality of life and decreased uncertainty (Mc Corkle et al., 2009).

Effective timing, delivery, and intensity – non-randomised studies

Two of the non-randomised studies provided interventions in the post-treatment phase or during disease recurrence/progression. Cox et al. (2008) and Seibaek and Petersen (2009) both reported positive effects on QOL for their interventions delivered during the follow-up period and immediately post-treatment respectively. The remaining non-randomised study included participants at various points on the disease trajectory including those newly diagnosed, receiving treatment or following up as outpatients. This study did not positively impact outcomes of interest. Cox et al. (2008) and Carlsson & Strang, (1998) provided two of the three longest interventions included in the review, 10 months and 7 weeks respectively, with both studies reporting

positive results in at least one of the outcomes of interest. As for the RCTs, patients receiving an intervention that involved telephone contact reported high levels of satisfaction with their care and also expressed a preference for telephone follow-up over usual physician appointment due to greater convenience (Cox et al., 2008). Group-based interventions were also successful with Carlsson & Strang (1998) and Seibaek & Peterson (2009) both reporting positive results in outcome measures of interest.

The mean number of contacts across all included studies was 5.4 and the results were mixed with regard to the number of contacts received during the interventions. As results were mixed, a definitive conclusion on the best timing, delivery and intensity of interventions is not possible. However, the results do indicate that interventions encompassing all domains of care and that include telephone contact are the most successful.

CHAPTER 4: DISCUSSION

This paper has reported on the methodology and results of a systematic review of studies relating to the care of women with gynaecological cancer by specialist nurses. Several positive effects resulted from the interventions, most notably a high level of patient satisfaction with care, however some interventions failed to affect outcome measures. Mixed results were also found in other systematic reviews of gynaecological cancer populations (Chow et al., 2012; Hersch et al., 2009) and a similar review of the care provided by specialist breast nurses (Cruickshank, Kennedy, Lockhart, Dosser & Dallas, 2008). These mixed results warrant further analysis and may be considered in regard to limitations of the studies themselves and also with regard to the methodological limitations of this systematic review.

Limitations of included studies

Whilst several of the studies considered in this review reported positive results for interventions provided by specialist nurses, some researchers were surprised that their interventions did not elicit a positive effect or elicited a weaker than expected positive effect. Several explanations may be offered to explain this result. Of significance were the three studies in which the control groups received attention to a level that could be akin to an intervention (Mc Corkle et al. 2009, Nolte et al. 2006, Otis-Green et al. 2008). Each of these studies rightly indentified that it would have been unethical to have provided no treatment at all to their control group participants. Gynaecological-oncology patients are a vulnerable population, as all cancer populations are, and it should be common practice that these women receive information, education and psychosocial support as part of their routine care. However, it is reasonable to speculate that this ‘treatment’ received by the control groups may have elicited an ‘intervention-like’ effect and thus diluted or masked any positive effect of the

actual intervention being tested. Indeed this highlights the barriers to experimental study of this vulnerable population. Likewise, some researchers believed that the 'usual care' provided to control group participants was already of a high and acceptable standard to patients. Ward et al. (2000) proposed that patients within control groups from whom baseline data was collected may have become 'sensitised' or more aware of issues relating to their care and may have been prompted to seek assistance or information elsewhere. This may have confounded the results of such studies. All of these factors may have contributed to the unexpectedly low number of positive outcomes for the specialist nurse interventions.

Small sample size was a limitation of both individual studies and of this systematic review with most included studies being pilot-sized. Whilst these small studies did not purport to test a hypothesis, and thus do not risk presenting a type II error, the generalisability of results is limited. It will always be difficult to recruit large numbers of participants in the gynaecological-oncology field given that incidence is relatively low compared with other cancers such as breast cancer. To recruit large numbers, studies must be conducted over long periods of time or across multiple sites, making research more difficult. This problem is amplified when it is desirable to study women with a particular type of gynaecological cancer or receiving a particular type of treatment, further limiting the size of the population from which sampling occurs. Yet, this is important when there is significant variation between the experiences of women with regard to variables such as cancer type, treatment received and time since diagnosis as discussed below.

A further limitation of two studies (Nolte et al 2006 and Otis-Green et al 2008), and possibly others, was the timing of the intervention. Participants in the study by Nolte et al. (2006) did not receive the videotape intervention relating to alopecia until after hair loss had occurred and those in the study by Otis-Green et al. (2008) received their educational intervention months to years after diagnosis. The studies were only able to report a weak-positive and no positive

effect respectively on their tested outcome measures other than patient satisfaction. Participants in both studies did feedback that they would have preferred to have received the intervention earlier in the disease/treatment process. This highlights the importance of timing of specialist nurse interventions to achieve maximum effect.

Limitations in methodology of systematic review

Limitations in the methodology of this systematic review must also be discussed. Firstly, the decision to include quantitative studies other than RCTs may be considered a weakness and was based on the fact that not all aspects of the specialist nurse role can be studies under randomised conditions. This has thus allowed for the evaluation of group-based specialist nurse interventions, which cannot be studied under randomised conditions as they require voluntary participation. Thus, the inclusion of evidence at levels III-IV helps to broaden our understanding of how specialist nurses may be effective in caring for women with gynaecological cancer. This understanding could have been further extended had the qualitative data that accompanied three of the included studies also been analysed. This review had a very wide scope with varying types of interventions tested and three broad outcome measures, thus making meta-analysis of the findings problematic. Of the two studies that were comparable on intervention type and one outcome measure (McCorkle et al. 2009; Otis-Green et al. 2008), one was assessed as a high risk for reporting bias (Otis-Green et al., 2008). Had meta-analysis of these findings been undertaken, these errors may have been compounded and for this reason meta-analysis was not performed. The variable interventions and outcome measures included in this systematic review have precluded meta-analysis and subsequently the creation of a higher level of evidence.

Several studies were narrowly excluded from this review on the basis that they also included patients with cancer types other than gynaecological cancer (B. Given et al., 2002; C. Given et al., 2004; McLachlan et al., 2001; Tamminga et al., 2013). This excluded some high quality RCTs that would have made a contribution to the overall evaluation of the specialist nurse role, however the presentation of data in these studies did not allow for specific analysis of the gynaecological-oncology participants only. Similarly, some studies exclusively researched gynaecological-oncology patients yet the interventions tested were provided by professionals other than specialist nurses (Anderson et al. 2011; Brotto et al., 2008; Henry et al., 2010; Geller et al., 2010; Peterson & Quinlivan, 2002). These add to our knowledge of what interventions are effective in the care of women with gynaecological cancer, but do not contribute to our understanding of the specialist nurse role.

Restricting the outcome measures that were analysed to quality of life, patient satisfaction and psychological outcomes, limited the exploration of other outcomes that may be affected by the involvement of a specialist nurse. Of particular note was the exclusion of symptom severity as an outcome measure. It became apparent after the inclusion criteria was set and executed, that symptom severity may be amenable to the care of specialist nurses and was measured in several studies including three in this review (Mc Corkle et al. 2009, Velji 2006, Ward et al. 2000)) and others narrowly excluded (C. Given et al., 2004; Grenier et al., 2007). As providing advice and care regarding the symptoms of disease and side effects of treatment form an important part of the clinical role of the specialist nurse, the inclusion of this outcome measure could have further improved our understanding. Similarly, the exclusion of sexual functioning as an outcome measure prevented the opportunity to effectively evaluate interventions within the psychosexual care domain. Within this review, evaluation of psychosexual interventions was limited to their impact on quality of life, satisfaction with care and psychological outcomes. Including sexual

functioning as an outcome of interest would have allowed a complete evaluation of psychosexual interventions tested.

When studying cancer populations, quality of life is an extremely well used outcome measure. Yet is it the best measure of the effectiveness of the specialist nurse in caring for people with cancer? Many variables effect quality of life in gynaecological cancer patients, particularly the point on the disease trajectory which they are on, the type of cancer they have and the type of treatment received. Longitudinal studies of gynaecological cancer patients have found that quality of life is low during treatment (Minig et al., 2013) but improves post-treatment (Penar-Zadarko et al., 2013). Minig et al. (2013) also found in their study that ovarian cancer patients reported greater negative impact in almost all quality of life items compared to the patients with other gynaecological cancers. Greimel, Winter, Kapp, and Haas (2009) found that cervical cancer patients who were treated with surgery and radiotherapy experienced significantly lower quality of life compared with those treated with surgery with or without chemotherapy. Quality of life of those treated with surgery alone or surgery and chemotherapy returned to a level post-treatment that was comparable to that of women without a history of cancer, but remained low for those treated with radiotherapy which is also supported by the results of Le Borgne et al. (2013). These studies highlight that particular cancer types, treatments and stages of the disease process have a significant impact on quality of life of women.

Specialist nurses simply may not, in all cases, be able to amend the significant attack on quality of life that particular treatments and times bring to women with gynaecological cancer. For this reason it could be speculated that while quality of life measurement allows for contextualisation with other research of women with gynaecological cancer, it is not necessarily a good measurement of the

effectiveness or success of the specialist nurse in caring for such patients. Two of the studies in this review (Otis-Green et al. 2008 and Ward et al. 2000) that did not demonstrate a difference in quality of life between groups did report very high levels of patient satisfaction with care. Thus, future research interested in learning how effective specialist nurses are in caring for women with gynaecological cancer may consider outcome measures that are more sensitive and appropriate than quality of life. Measurement tools that relate to the symptoms of disease and side-effects of treatment such as fatigue, pain, nausea and vomiting for example, may be more sensitive in detecting the effect of symptom management strategies of the specialist nurse. Likewise, a tool that measures perceived level of knowledge might better capture the effects of the educational efforts of the specialist nurse. Along with this, purposefully created questionnaires that determine how helpful, timely, appropriate and supportive the care of the specialist nurse is, should be utilised in any future research that is aimed at evaluating the role of the specialist nurse.

Recommendations for future research

This systematic review has highlighted that there is a dearth of evidence assessing the role of the specialist nurse in the gynaecological-oncology setting. Whilst experimental study of women with gynaecological cancer poses ethical challenges, more larger-scale studies are needed to determine the effect of specialist nurses in meeting the needs of these women. Additionally, this systematic review has only considered evidence pertaining to the patient-centred aspects of the overall role of the specialist nurse in the gynaecological oncology setting. It has not considered the effectiveness of various other aspects of the specialist nurse role such as: coordinator and collaborator within the multidisciplinary team, clinical expert and staff educator, researcher and strategic planner. This role interfaces with many health professionals and services and their experience of the role may also be valid.

An understanding of the proportion of women with gynaecological cancer that have been cared for by a specialist nurse should be sought, to help understand their experience of this care. Along with this, there is a need to survey the specialist nurses working in the gynaecological-oncology field themselves and determine what their role is and how they are guided in their practice. This would allow identification of any variations in the way that the role is executed across sectors and states and help determine if there would be benefit in standardising the role.

CHAPTER 5: CONCLUSION

This systematic review has considered both randomised control trials and non-randomised studies testing interventions by specialist nurses in their care of women with gynaecological cancer. The review was broad in its scope, considering various intervention types that were categorised into four main domains of care, and three different outcome measures. Variability in the intervention types and tools to measure outcomes between included studies made analysis and synthesis of results difficult. Whilst several positive results were reported for the outcome measures of interest, these must be considered carefully with regard to the quality assessments of the evidence, particularly those of the non-randomised studies. Nevertheless, this systematic review has been the first to amalgamate evidence relating to the patient-centred aspects of the specialist nurse role in the gynaecological-oncology setting, thus contributing to the overall evaluation of this role. Publication of these results are in draft and are being prepared for submission to the International Journal of Nursing Practice. Further research is needed to evaluate other aspects of this role in order to determine whether patients and the nursing profession would benefit from standardisation of specialist nursing in the gynaecological-oncology setting, as has been achieved by their specialist breast nurse counterparts.

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Appendix 1: 'PICO' search strategy

Population	Intervention	Outcomes
1. Gyn*ecological cancer	25. specialist nurse	58. Quality of Life
2. Female genital neoplasm	26. cancer nurse	59. Patient Satisfaction
3. Gyn*ecological malignancy	27. gyn*ecological specialist nurse	60. Patient involvement
4. Gyn*ecological tumo*r	28. clinical nurse specialist	61. Adjustment to illness
5. Cervical cancer	29. cancer care coordinator	62. psychological outcomes
6. Cervical tumo*r	30. cancer care consultant	63. anxiety
7. Cervical neoplasm	31. social support	64. depression
8. Cervical malignancy	32. emotional support	65. self esteem
9. Ovarian cancer	33. psychological support	66. body image
10. Ovarian tumo*r	34. psychosocial care	67. self-concept
11. Ovarian neoplasm	35.support group	68. mood
12. Ovarian malignancy	36. psychotherapy	69. social functioning
13. Uterine cancer	37. cognitive therapy	70. sexual functioning
14. Uterine tumo*r	38.information provision	71. sexuality
15. Uterine neoplasm	39. patient education	72. satisfaction with care
16. Uterine malignancy	40. psychosexual care	73. empowerment
17. Endometrial cancer	41. psychosexual support	
18. Endometrial tumo*r	42. physical support	
19. Endometrial neoplasm	43. clinical care	
20. Endometrial malignancy	44. practical support	
21. Vulva* cancer	45. nausea	
22. Vulva* tumo*r	46. vomiting	
23. Vulva* neoplasm	47. Emesis	
24. Vulva* malignancy	48. Lymph*edema	
	49. Fatigue	
	50. Pain	
	51. Gastrointestinal	
	52. Cognitive Function	
	53. Cost of care	
	54. Work	
	55. Employment	
	56. Sick Leave	
	57. Power of Attorney	

Appendix 2: EBSCO Host combined CINAHL Plus and MEDLINE search results.

#	Query	Results	#	Query	Results
S78	S25 AND S59 AND S77	950	S62	"patient satisfaction"	95,396
S77	S61 OR S62 OR S63 OR S64 OR S65 OR S67 OR S68 OR S69 OR S70 OR S71 OR S72 OR S73 OR S74 OR S75 OR S76	898,661	S61	"quality of life"	250,395
S76	"empowerment"	15,467	S60	S25 AND S59	6,452
S75	"satisfaction with care"	2,500	S59	S26 OR S27 OR S28 OR S29 OR S30 OR S331 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 OR S42 OR S43 OR S44 OR S45 OR S46 OR S47 OR S48 OR S49 OR S50 OR S51 OR S52 OR S53 OR S54 OR S55 OR S56 OR S57 OR S58	2,059,983
S74	"sexuality"	34,148	S58	"power of attorney"	976
S73	"sexual functioning"	2,484	S57	"sick leave"	8,736
S72	"social functioning"	8,122	S56	"employment"	99,401
S71	"mood"	62,652	S55	"work"	719,948
S70	"self concept"	63,049	S54	"cost of care"	4,106
S69	"body image"	21,747	S53	"cognitive function"	20,451
S68	"self esteem"	20,181	S52	"gastrointestinal"	285,211
S67	"depression"	338,809	S51	"pain"	608,397
S66	"anxiety"	182,520	S50	"fatigue"	83,939
S65	"psychological outcomes"	1,331	S49	"lymph*edema"	10,617
S64	"adjustment to illness"	584	S48	"emesis"	5,744
S63	"patient involvement"	1,539	S47	"vomiting"	64,475

#	Query	Results		#	Query	Results
S46	“nausea”	55,601		S23	“vulva* malignancy”	50
S45	“practical support”	513		S22	“vulva* neoplasm”	18
S44	“clinical care”	11,801		S21	“vulva* tumo*r”	93
S43	“physical support”	278		S20	“vulva* cancer”	1,326
S42	“psychosexual support”	6		S19	“endometrial malignancy”	146
S41	“psychosexual care”	7		S18	“endometrial neoplasm”	22
S40	“patient education”	120,578		S17	“endometrial tumo*r”	225
S39	“information provision”	1,041		S16	“endometrial cancer”	11,333
S38	“cognitive therapy”	24,872		S15	“uterine tumo*r”	385
S37	“psychotherapy”	87,278		S14	“uterine neoplasm”	56
S36	“support group”	4,086		S13	“uterine malignancy”	135
S35	“psychosocial care”	1,473		S12	“uterine cancer”	2,340
S34	“psychological support”	2,637		S11	“ovarian malignancy”	687
S33	“emotional support”	5,543		S10	“ovarian neoplasm”	442
S32	“social support”	68,238		S9	“ovarian tumo*r”	4,716
S31	“cancer care consultant”	0		S8	“ovarian cancer”	36,011
S30	“cancer care coordinator”	10		S7	“cervical malignancy”	137
S29	“clinical nurse specialist”	2,968		S6	“cervical neoplasm”	115
S28	“gyn*ecological specialist nurse”	0		S5	“cervical tumo*r”	633
S27	“cancer nurse”	167		S4	“cervical cancer”	31,343
S26	“specialist nurse”	1,049		S3	“gyn*ecological tumo*r”	136
S25	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24	84,728		S2	“gyn*ecological malignancy”	525
S24	“female genital neoplasm”	57		S1	“gyn*ecological cancer”	2,222

Appendix 3: Inclusion criteria assessment form

Citation:_____

_____

_____

Record Number: _____

Reviewer 1:_____Date: _____

Reviewer 2:_____Date: _____

Criteria	Yes	No	Unsure
1. Study • Randomised Controlled Trial? • Quantitative? _____ • Mixed Method? _____ • Published 1993 or after?			
2. Participants • Women only? • Over 18 years old? • Primary gynaecological cancer? • Known mental illness excluded?			
3. Interventions • Provided by a specialist nurse? • Involvement of other health professional? • Informational or educational? • Social, Emotional or psychological? • Physical or practical? • Psychosexual?			
4. Outcomes • QOL • Patient Satisfaction • Psychological outcomes • Other _____			
Included in Systematic Review – Reviewer 1			
Included in Systematic Review – Reviewer 2			

Appendix 4: Critical review checklist

Citation:_____

_____

_____

Record Number: _____

Reviewer 1:_____ Date: _____

Reviewer 2:_____ Date: _____

Title and Abstract	**Comments**
Is the title congruent with the text?	
Were the aims and/or objectives stated?	
Did the abstract contain sufficient information about the stages of the research process?	
Background	
Is the motivation for the study demonstrated through the literature review?	
Are the stated limitation and gaps in the reviewed literature appropriate and convincing?	
How was the investigation carried out?	
Is the hypothesis stated? Scientific or Null?	
Does the hypothesis indicate that the researcher is interested in testing for differences between groups or for relationships?	
Sample and Intervention	
Is the sample described?	
Is the sample size large enough to prevent an extreme score affecting the summary statistics used?	
How was the sample size determined?	
Was assignment to the treatment group random?	
Was the intervention adequately described?	
Were participants treated in the same way except for the intervention?	
Were participants blinded to intervention allocation?	

Data Collection	Comments
How were the data collected (questionaires or other tools)?	
Who collected the data? Were they blind to the intervention allocation?	
Are the data adequately described?	
What is the origin of the measurement instruments?	
Are the instruments adequately described?	
How were the data collection instruments validated?	
How was the reliability of the measurement instruments assessed?	
Were the otucomes measured in the same way for all groups?	
Findings	
Were the control and intervention groups comparable at commencement?	
Were the reasons for participant withdrawal noted?	
Was appropriate statistical analysis used?	
Were the findings expected?	
Is there enough information present to judge the results?	
Are the results clearly and completely stated?	
Ethical issues discussed?	
Identification of limitations or gaps in the study?	
Were suggestions for further research made?	
Were implications for practice stated?	
Was there sufficient information in the report to replicate the study?	

Comments:_____

Appendix 5: Data extraction form

Citation: _____

_____

_____

Record Number: _____

Reviewer 1: _____ Date: _____

Reviewer 2: _____ Date: _____

Aims / Objectives of the Study:

_____

_____

_____

Country / Setting: _____

Participant Details

Sample Characteristics	**Intervention Group 1**	**Intervention Group 2**	**Control Group 3**
Sample Size			
Mean Age			
Primary Cancer Site (n, %): Cervix Ovary Uterus Vulva Other			
FIGO Stage of Cancer I II III IV Undetermined			

Sample Characteristics	**Intervention Group 1**	**Intervention Group 2**	**Control Group 3**
Time since diagnosis			
Time since completion of treatment			
Types of treatment received: Surgery Chemotherapy Radiotherapy Hormonal Combination			
Marital Status: Single Coupled Divorced /Separated Widowed			
Other:			

Intervention Details

Categorisation of Intervention: Information or Education Social, emotional or psychological Physical or practical Psychosexual	
Description of Intervention	
Point on the Continuum of Care that intervention occurred	
Frequency / Duration / Intensity of intervention	
Mode of Delivery of intervention	
Outcome Measures:	

Result Details

Outcomes	Intervention Group 1	Intervention Group 2	Control Group 3

Discussion

Appendix 6: Excluded studies and reason for exclusion

Record No.	Reference	Reason for exclusion
#04	Booth, K., Beaver, K., Kitchener, H., O'Neill, J., & Farrell, C. (2005). Women's experiences of information, psychological distress and worry after treatment for gynaecological cancer. *Patient Education & Counseling, 56*(2), 225-232.	No intervention tested.
#21	Given, C., Given, B., Rahbar, M., Jeon, S., McCorkle, R., Cimprich, B., Bowie, E. (2004). Effect of a cognitive behavioral intervention on reducing symptom severity during chemotherapy. *Journal of Clinical Oncology, 22*(3), 507-516.	Study included patients with cancer types other than gynaecological. None of 3 main outcome measures included.
#53	Given, B., Given, C. W., McCorkle, R., Kozachik, S., Cimprich, B., Rahbar, M. H., & Wojcik, C. (2002). Pain and fatigue management: results of a nursing randomized clinical trial. *Oncology Nursing Forum, 29*(6), 949-956. doi: 10.1188/02.ONF.949-956.	Excluded due to only 27% of patients having gynae cancer.
#27	Levine, E. G., & Silver, B. (2007). A pilot study: evaluation of a psychosocial program for women with gynecological cancer. *Journal of Psychosocial Oncology, 25*(3), 75-98.	No intervention is tested.
#34	McLachlan, S., Allenby, A., Matthews, J., Wirth, A., Kissane, D., Bishop, M., Zalcberg, J. (2001). Randomized trial of coordinated psychosocial interventions based on patient self-assessments versus standard care to improve the psychosocial functioning of patients with cancer. *Journal of Clinical Oncology, 19*(21), 4117-4125.	Excluded due to there being only 77/450 (17%) patients with gyn cancer in the study.
#58	Tamminga, S. J., Verbeek, J., Bos, M., Fons, G., Kitzen, J., Plaisier, P. W., de Boer, A. (2013). Effectiveness of a hospital-based work support intervention for female cancer patients - a multi-centre randomised controlled trial. *Plos One, 8*(5), e63271-e63271. doi: 10.1371/journal.pone.0063271.	Excluded based on only 34% participants having gynae cancer.

Record No.	Reference	Reason for exclusion
#02	McCorkle, R., Jeon, S., Ercolano, E., & Schwartz, P. (2011). Healthcare utilization in women after abdominal surgery for ovarian cancer. *Nursing Research, 60*(1), 47-57. doi: http://dx.doi.org/10.1097/NNR.0b013e3181ff77e4.	Healthcare utilisation is not an included outcome measure.
#03	Jefferies, H. (2002). Ovarian cancer patients: are their informational and emotional needs being met? *Journal of Clinical Nursing, 11*(1), 41-47. doi: http://dx.doi.org/10.1046/j.1365-2702.2002.00570.x.	Inadequate description of data to enable systematic analysis. Research question not adequately answered.
#06	Ahlberg, K. & Nordner, A. (2006). The importance of participation in support groups for women with ovarian cancer. *Oncology Nursing Forum, 33*(4), E53-E61.	Qualitative only.
#07	Amsterdam, A. & Krychman, M. L. (2006). Sexual dysfunction in patients with gynecologic neoplasms: a retrospective pilot study. *The Journal of Sexual Medicine, 3*(4), 646-649.	Intervention was provided by gynaecologists and psychologists.
#08	Barg, F. K., Pasacreta, J. V., Nuamah, I. F. & Robinson, K. D. (1998). A description of a psychoeducational intervention for family caregivers of cancer patients. *Journal of Family Nursing, 4*(4), 394-413.	Relates to caregivers not patients. Cancer type is not specified. Outcome measures not reported in this paper.
#09	Börjeson, S., Hursti, T. J., Tishelman, C., Peterson, C., & Steineck, G. (2002). Treatment of nausea and emesis during cancer chemotherapy. Discrepancies between antiemetic effect and well-being. *Journal of Pain and Symptom Management, 24*(3), 345-358.	Unequal treatment of groups prevents determination of effect of nursing intervention.
#10	Brotto, L. A., Heiman, J. R., Goff, B., Greer, B., Lentz, G. M., Swisher, E., Van Blaricom, A. (2008). A psychoeducational intervention for sexual dysfunction in women with gynecologic cancer. *Archives of Sexual Behavior, 37*(2), 317-329.	Intervention not provided by specialist nurse.
#11	Caffo, O., Amichetti, M., Mussari, S., Romano, M., Maluta, S., Tomio, L., & Galligioni, E. (2003). Physical side effects and quality of life during postoperative radiotherapy for uterine cancer. Prospective evaluation by a diary card. *Gynecologic Oncology, 88*(3), 270-276.	Whilst diary care was administered by a nurse daily it could not be considered an intervention.

Record No.	Reference	Reason for exclusion
#13	Chan, R., Webster, J., & Bennett, L. (2009). Effects and feasibility of a multi-disciplinary orientation program for newly registered cancer patients: design of a randomised controlled trial. *BMC Health Services Research, 9*(1), 203. doi: http://dx.doi.org/10.1186/1472-6963-9-203.	Design only and not exclusive to gyn patients.
#14	Donnelly, C. M., Blaney, J. M., Lowe-Strong, A., Rankin, J. P., Campbell, A., McCrum-Gardner, E., & Gracey, J. H. (2011). A randomised controlled trial testing the feasibility and efficacy of a physical activity behavioural change intervention in managing fatigue with gynaecological cancer survivors. *Gynecologic oncology, 122*(3), 618-624.	Intervention provided by physiotherapist not specialist nurse.
#15	Cleary, V., McCarthy, G., & Hegarty, J. (2012). Development of an educational intervention focused on sexuality for women with gynecological cancer. *Journal of Psychosocial Oncology, 30*(5), 535-555. doi: 10.1080/07347332.2012.703767.	Details intervention development only. Likely that the completed study would meet inclusion criteria.
#16	Dawes, H. A., Docherty, T., Traynor, I., Gilmore, D. H., Jardine, A. G., & Knill-Jones, R. (2007). Specialist nurse supported discharge in gynaecology: a randomised comparison and economic evaluation. *European Journal of Obstetrics, Gynecology, & Reproductive Biology, 130*(2), 262-270.	Includes patients with benign gynae conditions only. Interesting to consider role of specialist gynae nurse including benign and malignant conditions.
#17	de Wit, R., & van Dam, F. (2001). From hospital to home care: a randomized controlled trial of a pain education programme for cancer patients with chronic pain. *Journal of Advanced Nursing, 36*(6), 742-754. doi: 10.1046/j.1365-2648.2001.02047.x.	Results not detailed enough to extract data on gynae-onc patients only. Intervention by district nurses not specialist cancer nurse.
#18	Ell, K., Vourlekis, B., Xie, B., Nedjat-Haiem, F. R., Lee, P-J., Muderspach, L., Palinkas, L. A. (2009). Cancer treatment adherence among low-income women with breast or gynecologic cancer: a randomized controlled trial of patient navigation. *Cancer, 115*(19), 4606-4615. doi: 10.1002/cncr.24500.	Not clear who provided intervention ?social worker.

Record No.	Reference	Reason for exclusion
#19	Faithfull, S., & White, I. (2008). Delivering sensitive health care information: challenging the taboo of women's sexual health after pelvic radiotherapy. *Patient Education & Counseling, 71*(2), 228-233.	Survey of SN's rather than testing an intervention by them.
#20	Geller, M. A., Downs, L. S., Judson, P. L., Ghebre, R., Argenta, P. A., Carson, L. F., Petzel, S. V. (2010). Learning about ovarian cancer at the time of diagnosis: video versus usual care. *Gynecologic Oncology, 119*(2), 370-375. doi: 10.1016/j.ygyno.2010.06.032.	Intervention developed by gynaecological oncologist. Can't really be classified as a nursing intervention.
#22	Hanks, G. W., Robbins, M., Sharp, D., Forbes, K., Done, K., Peters, T. J., Bidgood, C. (2002). The imPaCT study: a randomised controlled trial to evaluate a hospital palliative care team. *The British Journal of Cancer, 87*(7), 733-739. doi: http://dx.doi.org/10.1038/sj.bjc.6600522.	Study includes non-cancer patients and does not included sufficient data on cancer patients to determine if gyn-onc patients are included.
#23	Henry, M., Cohen, R., Lee, V., Sauthier, P., Provencher, D., Drouin, P., Mayo, N. (2010). The Meaning-Making intervention (MMi) appears to increase meaning in life in advanced ovarian cancer: a randomized controlled pilot study. *Psycho-Oncology, 19*(12), 1340-1347. doi: 10.1002/pon.1764.	Intervention delivered by a psychologist.
#24	Kendrick, M., Ercolano, E., & McCorkle, R. (2011). Interventions to Prevent Postoperative Complications in Women With Ovarian Cancer. *Clinical Journal of Oncology Nursing, 15*(2), 195-202. doi: 10.1188/11.CJON.195-202.	No intervention tested.
#25	Landsbergen, K. M., Brunner, H. G., Manders, P., Hoogerbrugge, N., & Prins, J. B. (2010). Educational-support groups for BRCA mutation carriers satisfy need for information but do not affect emotional distress. *Genetic Counseling (Geneva, Switzerland), 21*(4), 423-437.	Participants only carried gene mutation, not yet diagnosed with malignancy. Intervention carried out by social worker.

Record No.	Reference	Reason for exclusion
#26	Lerman, R., Jarski, R., Rea, H., Gellish, R., & Vicini, F.(2012). Improving Symptoms and Quality of Life of Female Cancer Survivors: a Randomized Controlled Study. *Annals of Surgical Oncology, 19*(2), 373-378. doi: http://dx.doi.org/10.1245/s10434-011-2051-2.	Only 4/116 participants had gynaecological cancer. Unsure if specialist nurse provided intervention.
#28	Liao, S-F., Li, S-H., & Huang, H-Y. (2012). The efficacy of complex decongestive physiotherapy (CDP) and predictive factors of response to CDP in lower limb lymphedema (LLL) after pelvic cancer treatment. *Gynecologic Oncology, 125*(3), 712-715. doi: http://dx.doi.org/10.1016/j.ygyno.2012.03.017.	Intervention provided by PT not nurse specialist.
#29	Mann, K. (2011). Education and Health Promotion for New Patients With Cancer: A Quality Improvement Model. *Clinical Journal of Oncology Nursing, 15*(1), 55-61. doi: 10.1097/00002820-200501000 - 00005.	Participants included any cancer type and no detailed analysis of such provided. Would have been suitable for incl. if gyn patients.
#30	Manne, S. L., Kashy, D. A., Rubin, S., Hernandez, E., & Bergman, C. (2012). Therapist and Patient Perceptions of Alliance and Progress in Psychological Therapy for Women Diagnosed With Gynecological Cancers. *Journal of Consulting & Clinical Psychology, 80*(5), 800-810.	Intervention by psychologist.
#31	Manne, S. L., Rubin, S., Edelson, M., Rosenblum, N., Bergman, C., Hernandez, E., Winkel, G. (2007). Coping and communication-enhancing intervention versus supportive counseling for women diagnosed with gynecological cancers. *Journal of Consulting and Clinical Psychology, 75*(4), 615-628.	Intervention by psychologist.
#32	Manne, S.L., Winkel, G., Rubin, S., Edelson, M., Rosenblum, N., Bergman, C., Rocereto, T. (2008). Mediators of a Coping and Communication-Enhancing Intervention and a Supportive Counseling Intervention Among Women Diagnosed With Gynecological Cancers. *Journal of Consulting & Clinical Psychology, 76*(6), 1034-1045.	No intervention tested, related to psychological outcomes not nursing.

Record No.	Reference	Reason for exclusion
#35	Newton, M. J., Hayes, S. C., Janda, M., Webb, P. M., Obermair, A., Eakin, E. G., Beesley, V. L. (2011). Safety, feasibility and effects of an individualised walking intervention for women undergoing chemotherapy for ovarian cancer: a pilot study. *BMC Cancer, 11*, 389-389. doi: 10.1186/1471-2407-11-389.	Intervention provided by exercise physiologist.
#37	O'Sullivan, C. K., Bowles, K. H., Jeon, S., Ercolano, E. & McCorkle, R. (2011). Psychological Distress during Ovarian Cancer Treatment: Improving Quality by Examining Patient Problems and Advanced Practice Nursing Interventions. *Nursing Research And Practice, 2011*, 351642-351642. doi: 10.1155/2011/351642.	Secondary analysis of already included study.
#39	Palmer, C., Pratt, J., Basu, B., & Earl, H. (2006). A study to evaluate the use of CA125 in ovarian cancer follow-up: A change in practice led by patient preference. *Gynecologic Oncology, 101*(1), 4-11.	Intervention provided by doctors.
#40	Petersen, R. W., & Quinlivan, J. A. (2002). Preventing anxiety and depression in gynaecological cancer: a randomised controlled trial. *BJOG: An International Journal of Obstetrics & Gynaecology, 109*(4), 386-394.	Intervention provided by doctors.
#41	Schofield, P., Juraskova, I., Bergin, R., Gough, K., Mileshkin, L., Krishnasamy, M., Aranda, S. (2013). 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. *Trials, 14*, 39-39. doi: 10.1186/1745-6215-14-39.	Protocol only. Meets inclusion criteria otherwise.

Record No.	Reference	Reason for exclusion
#42	Schroder, M., Mell, L. K., Hurteau, J. A., Collins, Y.C., Rotmensch, J., Waggoner, S. E., Mundt, A. J. (2005). Clitoral therapy device for treatment of sexual dysfunction in irradiated cervical cancer patients. *International Journal of Radiation Oncology, Biology, Physics, 61*(4), 1078-1086.	Couldn't be considered a 'specialist nurse' intervention.
#43	Schulman-Green, D., Ercolano, E., Dowd, M., Schwartz, P., & McCorkle, R. (2008). Quality of life among women after surgery for ovarian cancer. *Palliative & Supportive Care, 6*(3), 239-247. doi: http://dx.doi.org/10.1017/S1478951508000497.	No intervention tested.
#44	Scott, J. L., Halford, K., & Ward, B. G. (2004). United We Stand? The Effects of a Couple-Coping Intervention on Adjustment to Early Stage Breast or Gynecological Cancer. *Journal of Consulting & Clinical Psychology, 72*(6), 1122-1135.	Intervention provided by psychologists.
#45	Anderson, C., Carter, J., Nattress, K., Beale, P., Philp, S., Harrison, J., & Juraskova, I. (2011). "The booklet helped me not to panic": a pilot of a decision aid for asymptomatic women with ovarian cancer and with rising CA-125 levels. *International Journal of Gynecological Cancer: Official Journal of the International Gynecological Cancer Society, 21*(4), 737-743. doi: 10.1111/IGC.0b013e3181fe8b57.	Intervention completed by doctors.
#46	Barbera, L., Fitch, M., Adams, L., Doyle, C., Dasgupta, T., & Blake, J. (2011). Improving care for women after gynecological cancer: the development of a sexuality clinic. *Menopause (10723714), 18*(12), 1327-1333.	No specific intervention is tested. Data relates mainly to nursing assessment rather than evaluation of effect.
#47	Brand, A. H., Do, V., & Stenlake, A. (2012). Can an educational intervention improve compliance with vaginal dilator use in patients treated with radiation for a gynecological malignancy? *International Journal of Gynecological Cancer: Official Journal of the International Gynecological Cancer Society, 22*(5), 897-904. doi: 10.1097/IGC.0b013e31824d7243.	Doctor-led intervention.

Record No.	Reference	Reason for exclusion
#48	Caldwell, R., Classen, C., Lagana, L., McGarvey, E., Baum, L., Duenke, S. D., & Koopman, C. (2003). Changes in sexual functioning and mood among women treated for gynecological cancer who receive group therapy: A pilot study. *Journal of Clinical Psychology in Medical Settings, 10*(3), 149-156.	Psychologist intervention.
#49	Chun, N. (2011). [Effectiveness of PLISSIT model sexual program on female sexual function for women with gynecologic cancer]. *Journal of Korean Academy of Nursing, 41*(4), 471-480.	Study published in Korean.
#50	Davis, J. (2005). What does your community offer to support patients with gynecologic cancers? Ohio clinical nurse specialist involved in twice-monthly support group for gynecologic cancer survivors. *ONS News, 20*(9), 7-7.	Review article only.
#51	Dumrongpakapakorn, P., Hopkins, K., Sherwood, P., Zorn, K., & Donovan, H. (2009). Computer-mediated patient education: opportunities and challenges for supporting women with ovarian cancer. *Nursing Clinics of North America, 44*(3), 339-354. doi: 10.1016/j.cnur.2009.06.00.	Review article only.
#52	Elliot, Emma. (2013). Supporting patients following pelvic radiotherapy for endometrial cancer. *British Journal of Nursing, 22*(10), S24.	Literature review.
#54	Sawan, S., Mugnai, R., Lopes, A., Hughes, A. & Edmondson, R. J. (2009). Lower-limb lymphedema and vulval cancer: feasibility of prophylactic compression garments and validation of leg volume measurement. *International Journal of Gynecological Cancer: Official Journal of the International Gynecological Cancer Society, 19*(9), 1649-1654. doi: 10.1111/IGC.0b013e3181a8446a.	Doctor-led intervention.

Record No.	Reference	Reason for exclusion
#55	Stevinson, C., Steed, H., Faught, W., Tonkin, K., Vallance, J. K., Ladha, A. B. & Courneya, K. S. (2009). Physical activity in ovarian cancer survivors: associations with fatigue, sleep, and psychosocial functioning. *International Journal of Gynecological Cancer: Official Journal of the International Gynecological Cancer Society, 19*(1), 73-78. doi: 10.1111/IGC.0b013e31819902ec.	No intervention tested.
#57	Sellers, T. & Schermer M. S. (2000). A Model of Collaborative Healthcare in Outpatient Medical Oncology. *Families, Systems, & Health Spring, 18*(1), 19-33.	Breast cancer patients only.
#59	Walker, L. M., Bischoff, T. F., & Robinson, J. W. (2010). Supportive expressive group therapy for women with advanced ovarian cancer. *International Journal Of Group Psychotherapy, 60*(3), 407-427. doi: 10.1521/ijgp.2010.60.3.407.	Qualitative study, psychologist-led.
#60	van de Poll-Franse, L. V., Nicolaije, K. A. H., Vos, M. C., Pijnenborg, J., Boll, D., Husson, O., Kruitwagen, R. (2011). The impact of a cancer Survivorship Care Plan on gynecological cancer patient and health care provider reported outcomes (ROGY Care): study protocol for a pragmatic cluster randomized controlled trial. *Trials, 12*, 256-256. doi: 10.1186/1745-6215-12-256.	Protocol only, no results available.
#62	Grenier, N., Lebel, V., Gill, M., Mullen, T., Mitchinson, K., Sebborn, K., & Pouliot, J. (2007). Effectiveness of a nursing support program for patients with recurrent ovarian cancer receiving pegylated liposomal doxorubicin (CAELYX/DOXIL). *Canadian Oncology Nursing Journal, 17*(3), 133-140.	Only outcome measure is symptom presence and severity. None of the 3 major outcome measures of this review are used.
#61	Kelly, D. F., Faught, W. J., & Holmes, L. A. (1999). Ovarian cancer treatment: the benefit of patient telephone follow-up post-chemotherapy. *Canadian Oncology Nursing Journal, 9*(4), 175-178.	Relevant but insufficient data included to allow inclusion in systematic review.

Record No.	Reference	Reason for exclusion
#64	Chi, G. (2009). *Music relaxation video and pain control: a randomized controlled trial for women receiving intracavitary brachytherapy for gynecological cancer*, Texas Woman's University. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&db=jlh&AN=2011032662&site=ehost-live.	No full text available only details of conference proceedings.
#65	Varre, P. (1999). Regular counselling by an oncology nurse increases coping with side effects during outpatients radiotherapy of gynecological malignancies [abstract no: 18]. *European Journal of Cancer, 35*(Suppl 4), S10.	No full text available only details of conference proceedings.
#66	Yang, E. J., Lim, J. Y., Rah, U. W., & Kim, Y. B. Effect of a pelvic floor muscle training program on gynecologic cancer survivors with pelvic floor dysfunction: a randomized controlled trial. *Gynecologic Oncology, 125*(3), 705-711.	No full text available.

Appendix 7: Summary of interventions and results for included studies

Study / Population Details	Record No	Intervention	Control	Outcome Measures	Results
Cox et al. (2008). • Pilot Study n=46. • Case Series. One group pre-test post-test.	#05	• Nurse-led telephone follow-up 3 monthly for 10 months. • Provided blood results, tailored info, practical advice, coping strategies and referrals.	• No control.	• QOL (FACT-Ovarian Quality of Life assessment with a subscale of concerns specific to ovarian cancer). • Satisfaction and experience of care (validated questionnaire).	• Nurse led telephone follow-up seemed to be convenient for Ca Ovary patients. • Intervention may have improved QOL though this may have been due to the passing of time.
Maughan and Clarke (2001). • Mixed Methodology study RCT plus Qual interviews. • n=36. • Mean age: 50 yrs.	#01	• Post op specialist nursing intervention. • All 4 care domains. • 3x home visits.	• Standard information and nursing care.	• Quality of life EORTC QLQ-C30. • Sexual Functioning Lasry Sexual Functioning Scale.	• Demonstrated that the involvement of a specialist nurse could positively influence QOL and sexual functioning. • Some gynae onc patients needs were unmet incl fertility issues and needs of partners. • Qualitative data supported RCT results.

Study / Population Details	Record No	Intervention	Control	Outcome Measures	Results
McCorkle et al. (2009). • RCT. • N=123, control = 60, APN = 63, APN+ PCLN = 32/63. • 62%ovarian cancer, rest other gynae cancers or abdo metastases. • Data collection at baseline, 1,3 and 6 months.	#33	• Specialised nursing intervention (+/- psychiatric consultant liaison nurse). • 6 months of tailored, specialised care. 18 contacts, 2 per week for 1st month, 2 per month for next 5 months.	• Attention control group of symptom management toolkit only (8 contacts, research assistant provided 1 x home visit, 3 wkly phone calls in 1st month then monthly phone calls for remaining 5 months).	• Centre for epidemiological studies – Depression Scale (CES-D). • Mischel Uncertainty in Illness Scale (MUIS). • Symptom distress Scale (SDS). • QOL SF-12. • Distress Thermometer (DT).	• APN intervention resulted in significantly less uncertainty. • APN + PCLN resulted in significantly less uncertainty, symptom distress and better SF-12 mental and physical QOL over time.
Nolte et al. (2006). • Randomised clinical trial. • N=136, 68 in each group. • Reliability of instruments determined via prior studies.	#36	• Nurse-created video tape intervention for alopecia.	• Control group also received standard counselling regarding hair loss (description provided) prior to first course of chemo.	• BS-SCS was used to measure body-image and self esteem. • Researcher created questionnaire used to determine hair-loss. • Qualitative data collected on satisfaction with video intervention.	• The videotape intervention did not have a significant effect on self esteem. • The majority of patients in the study did not experience the decline in body image usually associated with alopecia.

Study / Population Details	Record No	Intervention	Control	Outcome Measures	Results
Otis-Green et al. (2008). • Mixed method including pilot RCT. • N=33, exp=18, control= 15. • Data collected at baseline, 1 and 3 months.	#38	• Intervention included 4 x 1hour teaching visits (nurse+ social worker) + written material. • QOL tool was developed by researchers, other tools externally validated.	• Control group received written material plus support from nurse as required	• QOL Ovarian Cancer Tool (developed by investigators). • Psychological Distress Thermometer (DT). • Mishel Uncertainty in Illness Scale (MUIS). • Intervention Evaluation Form.	• No significant differences b/w groups on QOL, DT, MUIS at any time points. • Overall group showed improved psychological well-being, social well being and overall QOL.
Carlsson and Strang (1998). • Quasi-experimental, no randomisation. • n = 36 intervention, n = 25 control. • Mean age 56.5. • Different stages of disease	#12	• Support group for gynae-onc patients and their families. • Facilitated by oncology nurse. • 7 sessions, 1.5-2 hours each. • 3-8 participants per group.	• Usual care, no participation in support group (due to geography).	• Perceived Knowledge (investigator created). • Profile of Mood States (POMS).	• Patients in intervention group had higher degree of confusion and anger at baseline. • No stat.sig. improvement after the intervention compared with controls for total POMS scores. • Significant demographic differences between groups at baseline. • Intervention group reported limited knowledge at baseline but that increased significantly post intervention.

Study / Population Details	Record No	Intervention	Control	Outcome Measures	Results
Velji (2006). • n = 137, 67 intervention, 70 control. • Mean age 58.7. • Excluded ovarian cancer patients. • Other gyn cancers included, all stages. • Research assistant blinded to allocation.	#63	• Six Session Individualised Symptom Education Program (ISEP) lasting 7-9 weeks coinciding with radiotherapy treatment.	• Usual Care.	• Symptom Distress Scale (SDS). • Brief Fatigue Inventory (BFI). • Brief Pain Inventory Short Form (BPI-SF). • Rhodes Index of Nausea and Vomiting (INVR).	• Improvement in symptom distress was seen between T1 and T3 after rising between T1 and T2 for both intervention and control. This was stat sig for intervention group p = 0.04. • No significant effect on other outcome measures.
Ward et al. (2000).	#67	• Individually tailored information regarding pain barriers and side effects of analgesia. Booklet also provided.	• Care as usual though booklet was provided post-testing.	• BQ Barriers Questionnaire. • PMI Pain Management Index. • MSEC Medication Side Effect Checklist. • BPI Brief Pain Inventory. • Pain Interference. • FACT-G QOL. • Satisfaction.	• No significant differences between groups at baseline. • No differences between groups in any of the outcome measures post intervention. • All patients showed a decline in barriers. • All patients had decreased pain interference.

Study / Population Details	Record No	Intervention	Control	Outcome Measures	Results
Seibaek and Petersen (2009). • Prospective Cohort study. After-only non-equivalent control group Data collected at 3, 6, 12 months, prospective survey. • n=20.	#56	• Nurse-led rehabilitation program. • Intervention consisted of 4 group sessions facilitated by specialist nurses.	• Voluntary admission to control group. • Care as usual.	• QOL SF-36. • Sense of Coherence (SOC) evaluates coping.	• They found statistically significant improvement in all areas in the intervention group however they started from a lower base than the controls.

Appendix 8: Summary assessment of risk of bias - RCTs

Study Details: Maughan and Clarke (2001)

Study type: RCT

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	LOW	"carried out by a medical colleague unconnected with the trial, using a computerized random number table and sealed envelope system".
Allocation Concealment	LOW	As above.
Performance bias		
Blinding of participants and outcome assessors	HIGH	The researcher also provided the intervention.
Attrition bias		
Incomplete outcome data	LOW	"two women died during the course of the study, one each from the active and control arms".
Detection bias		
Blinding of outcome assessment	HIGH	The researcher also provided the intervention.
Reporting bias		
Selective reporting	HIGH	No data tables included, not all components of QOL questionnaire commented on.
Other bias	HIGH	AS researcher also provided intervention the objectivity of the entire study is questionable.

Study Details: Mc Corkle et al 2009

Study type: RCT

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	LOW	"consented patients were randomized into the intervention or control group using the sealed envelope technique" p. 63.
Allocation Concealment	LOW	"sealed envelope technique" p. 63
Performance bias		
Blinding of participants and outcome assessors	HIGH	Participants blinded, APN not "single-blind randomized clinical trial" p. 63. Interventionist blinding not possible.
Attrition bias		
Incomplete outcome data	LOW	"Of the 149 patients who enrolled, 4 were excluded for lack of complete baseline data, 123 patients of 145 completed 3 outcome measures at 6 months. Twenty-two women did not complete the study: died during study (19), not feeling well (2), too anxious / overwhelmed (1)" p. 63. The remaining 123 were well matched demographically and clinically, but not at baseline on CES-D, uncertainty and SF-12-Mental. These were adequately controlled for during analysis. No power analysis was performed so difficult to determine effect of attrition on this.
Detection bias		
Blinding of outcome assessment	LOW	Self-reporting questionnaires used for data collection thus no need for blinding of outcome assessment.
Reporting bias		
Selective reporting	LOW	Results for all outcome measures presented in tables.
Other bias		

Study Details: Nolte, Donnelly, Kelly, Conley & Cobb, 2006

Study type: RCT

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	UNCLEAR	"random assignment" was claimed however details of assignment method were not provided.
Allocation Concealment	UNCLEAR	No detail provided on allocation method.
Performance bias		
Blinding of participants and outcome assessors	UNCLEAR	Could be assumed to be No blinding if informed consent had been obtained but is not clearly stated.
Attrition bias		
Incomplete outcome data	HIGH	190 entered study, 3 excluded due to alopecia unrelated to cancer or chemotherapy. 187 included and evaluated for hair loss prior to 3rd chemo. 51 lost due to no hair loss, refusal to participate or disease progression. 136 allocated to intervention/control. Demographic and clinical comparison of groups not provided thus impossible to determine equivalency of groups.
Detection bias		
Blinding of outcome assessment	LOW	Self assessment tool used for data collection.
Reporting bias		
Selective reporting	UNCLEAR	No reporting of demographic data. Data provided relate to entire group not intervention/control.
Other bias		

Study Details: Otis-Green, Ferrell, Sun, Spolum, Morgan & MacDonald (2008)

Study type: RCT

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	UNCLEAR	State that "women meeting study criteria were randomly assigned to the control or intervention group" p. 215 No detail of method provided.
Allocation Concealment	UNCLEAR	No detail of randomisation method provided.
Performance bias		
Blinding of participants and outcome assessors	HIGH	"Clinically licensed registered nurse and social work research specialists provided the educational intervention, collected all patient data and recorded key post-intervention themes" p. 216. Participant blinding not specified, assumed not.
Attrition bias		
Incomplete outcome data	HIGH	"two women died of the disease during the course of the study" p. 217. Not specified if these were from control or intervention group. As sample size is small this may have significant impact on results.
Detection bias		
Blinding of outcome assessment	UNCLEAR	Some outcome measures known to be self-reporting though not specified for the researcher created tool.
Reporting bias		
Selective reporting	HIGH	Omission to report results according to group allocation, most reported for total group thus not allowing for analysis of interventional effect.
Other bias	HIGH	Small sample size.

Study Details: Velji (2006)

Study type: RCT

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	LOW	"randomisation was stratified by site and centrally controlled using a telephone-based, computerized randomisation service" p.39 Completed by research coordinator.
Allocation Concealment	LOW	"as the research assistant administered the questionnaires to the participants, they were blinded to treatment allocation" p. 39.
Performance bias		
Blinding of participants and outcome assessors	UNCLEAR	Blinding of research assistant achieved as per above comment. Blinding of participants unlikely if informed consent was obtained.
Attrition bias		
Incomplete outcome data	LOW	"Attrition rate of 7%, did not impact on power to detect significant changes between groups" p. 102.
Detection bias		
Blinding of outcome assessment	LOW	"as the research assistant administered the questionnaires to the participants, they were blinded to treatment allocation". p. 39 Questionnaires were also self-assessment.
Reporting bias		
Selective reporting	LOW	Thesis, not published article. All outcomes reported according to protocol.
Other bias		

Study Details: Ward, Donovan,Owen, Grosen & Serlin (2000)

Study type: RCT

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	UNCLEAR	p. 398 “once consent was obtained, women completed demographic and baseline measures and were randomly assigned to information or control”. No detail of randomisation method provided.
Allocation Concealment	UNCLEAR	No detail of randomisation method provided.
Performance bias		
Blinding of participants and outcome assessors	UNCLEAR	No detail regarding blinding of participants though possibly as p. 398 “they were not told the specific purposes of the study, but were given details of what would be expected of them in terms of time and effort”.
Attrition bias		
Incomplete outcome data	UNCLEAR	“Of the 43 women who completed baseline measures….25 completed measures at all three time points. There were no significant differences with respect to demographic and clinical information between those who completed post-test and/or follow-up measures and those who did not” Disease progression and death most common reasons for attrition. Drop-out rates similar between groups.
Detection bias		
Blinding of outcome assessment	UNCLEAR	p. 397 “if patients had a scheduled clinic visit that corresponded with post-test and follow-up, they were asked by someone other than the baseline research nurse (who had presented the intervention) to complete the measures”. Not all outcome measures were self reporting.
Reporting bias		
Selective reporting	UNCLEAR	Demographic data provided for group as a whole, not according to group allocation.
Other bias		

Appendix 9 : Summary assessment of risk of bias – non-randomised studies

Study Details: Carlsson & Strang (1998)

Study type: Non-Randomised, Quasi-experimental

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	HIGH	No randomisation. Patients "who lived relatively close to the hospital and had a reasonable possibility of participating were invited to the programme" p. 271. Control group was formed from "25 patients from distant parts of the region who were unable to participate due to geographic difficulties" p. 271. Authors claim that study is quasi-experimental but allocation to groups was actually according to patient preferences and location differences.
Allocation Concealment	HIGH	As per above.
Confounding	HIGH	Statistically significant variation between groups on some demographics and clinical characteristics, though no statistical adjustment occurred.
Performance bias		
Blinding of participants and outcome assessors	HIGH	Participation was voluntary so no blinding of participants. Blinding of those collecting data, unsure. Blinding of interventionists not possible.
Attrition bias		
Incomplete outcome data	HIGH	"only those patients and NOK who participated in more than half of the session were included in the evaluation" p 271 Number of data excluded is not stated or reasons for attrition.
Detection bias		
Blinding of outcome assessment	UNCLEAR	Unsure if those collecting data were blinded, not likely as controls completed their questionnaires by post.
Reporting bias		
Selective reporting	LOW	All of the study's pre-selected outcomes were reported.

Study Details: Seibaek & Peterson (2009)

Study type: Non-Randomised, Prospective Cohort study.

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	HIGH	"the women were included on a totally voluntary basis as they chose themselves if they wanted to be part of an intervention group or part of the control group". Allocated according to patient preferences.
Allocation Concealment	HIGH	Concealment not achieved.
Confounding	HIGH	No attempt to control for selection bias, no comparison made between groups at baseline.
Performance bias		
Blinding of participants and outcome assessors	HIGH	Participation was voluntary so no blinding of participants. Blinding of those collecting data, unsure. Blinding of interventionists not possible.
Attrition bias		
Incomplete outcome data	HIGH	8/30 questionnaires lost to intervention group, 5/30 questionnaires lost to control group over course of study. Illness, unknown reasons. Thus more data collected for controls.
Detection bias		
Blinding of outcome assessment	HIGH	No blinding.
Reporting bias		
Selective reporting	HIGH	Only 4 parts of the SF-36 were reported and all had positive results.

Study Details: Cox et al (2008)

Study type: Case Series. One group pre-test post-test

Domain	Judgement	Supporting description
Selection bias		
Random sequence generation	N/A	One group only study.
Allocation Concealment	N/A	One group only study.
Confounding	N/A	One group only study.
Performance bias		
Blinding of participants and outcome assessors	HIGH	No blinding.
Attrition bias		
Incomplete outcome data	HIGH	"withdrawn or followed up in medical care n=9". As one of the outcome measures relates to preference for nurse-led telephone contact compared with usual medical follow-up this may have altered results.
Detection bias		
Blinding of outcome assessment	HIGH	No blinding.
Reporting bias		
Selective reporting	LOW	All pre-determined outcome measures were reported adequately.