**A systematic review of clinical trials led or delivered by cancer nurses**

**Authors:**

**Charalambous A, Wells M, Campbell P, Torrens C, Ostland U, Oldenmenger W, Patiraki E, Sharp L, Nohavova I, Domenech-Climent N, Eicher M, Farrell C, Larsson M, Olsson C, Simpson M, Wiseman T, Kelly D.**

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**Abstract**

**Background**: Advances in research and technology coupled with an increased cancer incidence and prevalence has resulted in significant expansion of cancer nurse role, in order to meet the growing demands and expectations of people affected by cancer (PABC). Cancer nurses are also tasked with delivering an increasing number of complex interventions as a result of on-going clinical trials in cancer research. However much of this work is undocumented, and we have little insight about the nature of interventions currently being designed or delivered by cancer nurses.

**Objectives**: To identify and synthesise the available evidence from clinical trials on interventions delivered or facilitated by cancer nurses.

**Data sources and review methods**: A systematic review of randomised controlled trials (RCT), quasi-RCTs and controlled before and after studies (CBA) of cancer nursing interventions aimed at improving the experience and outcomes of PABC. Ten electronic databases (CENTRAL, MEDLINE, AMED, CINAHL, EMBASE, Epistemonikos, CDSR, DARE, HTA, WHO ICTRP) were searched between 01 January 2000 and 31 May 2016. No language restrictions were applied. Bibliographies of selected studies and relevant Cochrane reviews were also hand-searched. Interventions delivered by cancer nurses were classified according to the OMAHA System. Heat maps were used to highlight the volume of evidence available for different cancer groups, intervention types and stage of cancer care continuum.

**Results**: The search identified 22450 records; we screened 16169 abstracts and considered 925 full papers, of which 214 studies (248270 participants) were included in the evidence synthesis. The majority of studies were conducted in Europe (n=79) and USA (n=74). Interventions were delivered across the cancer continuum from prevention and risk reduction to survivorship, with the majority of interventions delivered during the treatment phase (n=137). Most studies (131/214) had a teaching, guidance or counselling component. Cancer nurse interventions were targeted at primarily breast, prostate or multiple cancers. No studies were conducted in brain, sarcoma or other rare cancer types.

The majority of the studies (n=153) were nurse-led and delivered by specialist cancer nurses (n=74) or advanced cancer nurses (n=29), although quality of reporting was poor.

**Conclusions**: To the best of our knowledge, this is the first review to synthesise evidence from intervention studies across the entire cancer spectrum. As such, this work provides new insights into the nature of the contributions that cancer nurses have made to evidence-based innovations, as well as highlighting areas in which cancer nursing trials can be developed in the future.

**Contribution of the Paper**

**What is already known about the topic?**

* Cancer nurses play a central role in the care of patients with cancer and are the largest single profession working in this field.
* Cancer nurses have employed a range of research approaches, including clinical trials.
* Trials by nurses have contributed to the evidence base for clinical innovations.
* The complexity of cancer care, and the demand for evidence-based innovations, will increase with rising demand.

**What this paper adds**

* A clear summary of the current trial evidence relating to cancer nursing interventions, using the OMAHA classification
* Evidence that cancer nursing interventions may be delivered at all stages of the cancer care continuum, but that the majority have focused on adults in the treatment stage
* The majority of cancer nurse-led interventions are delivered by specialist and / or advanced cancer nurses, but details of interventionists are poorly described in trials
* Cancer nurse-led trial evidence focusses primarily on mixed cancer groups, or on people with breast or prostate cancer, highlighting gaps for future research.

**INTRODUCTION**

Cancer nurses represent the largest group of healthcare professionals providing care to people affected by cancer (PABC) across all age groups and settings (WHO, 2012). Cancer nurses now play a central role in the care of PABC including screening, early detection, assessment, education, administration of treatments, supportive care including identification/management of symptoms, side-effects and complications; coordination of care, palliative and end of life care (Ferrell et al., 2010, Fox et al., 2017, Klemp, 2015).

Different drivers have contributed to the rapid development of new and more independent nursing roles and functions for cancer nurses. First, contemporary cancer treatment is becoming increasingly complex and individualized, characterised by constant advances in therapy such as treatments relying on molecularly targeted agents and immunotherapies that require the adoption of a more personalised approach to care (Clauser et al., 2011). Second, the continuing shift from hospitalised cancer care to outpatient-based care has promoted the development of more independent roles for nurses, including symptom management and follow-up interventions (Bergin et al., 2016, Latter et al., 2017). Third, the specialty of cancer nursing has expanded rapidly, driven in part by current fiscal challenges in the global economy and a range of workforce pressures within the field of oncology, but also in response to the changing demographics and expectations of PABC. These economic and political drivers have resulted in greater substitution of roles and task-shifting from physicians to specialized or advanced nurses, e.g. nurse practitioners.

Cancer nursing also requires a strong evidence-base, necessitating significant scientific investment in order to keep pace with the changing landscape in cancer care. It is imperative that the increasingly complex interventions, often delivered by cancer nurses, are underpinned by robust research evidence which can help demonstrate effectiveness.

In order to ascertain the current state of trials- based evidence, and to ensure suggestions for new and sustainable healthcare services and interventions, there is a need to understand what contribution cancer nurses have already made to enhance patient-focused innovations. In 2015, the European CanCer Organisation (ECCO) supported an initiative to increase the recognition of cancer nursing, resulting in the Recognising European Cancer Nursing (RECaN) project. The first phase of this ambitious project was to conduct a systematic review to document the interventions delivered by cancer nurses; to identify the way that cancer nurses have contribute to such interventions and to determine the effectiveness of them. Here, we present the findings related to these two aims.

**METHODS**

We conducted a systematic review of randomised controlled trials (RCT), quasi-RCTs and controlled before and after studies (CBA) of cancer nursing interventions aimed at improving the experience and outcomes of PABC. Our review was conducted to agreed methodological and reporting standards (Higgins and Green, 2011, Liberati et al., 2009). The review analysis and inclusion criteria were specified in advance and documented in a protocol (Campbell et al., 2017). The review protocol is registered in PROSPERO (ID= CRD42016048760).

**Identification of studies for inclusion**

Multiple electronic databases (Medline, AMED, Epistemonikos, CINAHL, Embase, Cochrane Central Register of Controlled, DARE, HTA, CDSR), clinical trial registries (WHO ICTRP) from 01 January 2000 to 30 May 2016 were systematically searched. No language restrictions were employed. Bibliographies of selected studies and relevant Cochrane reviews were also hand-searched in order to identify any further relevant studies not detected by the electronic search.

A comprehensive search strategy was developed, combining key terms using a series of free text terms and MESH terms for: profession and/role (e.g. nurse; nurse practitioner; cancer nurse; oncology nurse) and Cancer (e.g. neoplasm; tumour etc). An example search strategy is provided in Supplementary Table 1.

***Eligibility criteria***

Cancer nursing interventions were defined, following a pragmatic approach, as any intervention(s) delivered by a nurse to a person with cancer, using the Canadian Association of Nurses in Oncology (CANO) definition for generalist, specialist and advanced oncology nurse (CANO, 2016). We included RCTs, quasi-RCT and CBA studies.

All other study designs or CBA studies in which historical data was used as a comparison, but was collected for a different purpose at the time were excluded. We also excluded studies on any pharmacological or surgical only intervention, or any intervention delivered by healthcare professionals who are not professionally qualified nurses (e.g. support staff). We excluded all studies, where interventions were aimed at nurses e.g. through education, without any associated patient-reported outcome data.

**Study selection**

One reviewer (PC) conducted the searching and initial screening. Two reviewers (PC, CT) independently applied the predefined selection criteria to the remaining records. Consensus meetings with a third reviewer (MW) were organised to discuss any disagreement regarding selection. Full publications were retrieved for studies that met the selection criteria and for those for which this was unclear.

**Data collection and management**

One review author (CT) systematically extracted key information relating to the intervention in accordance with the Template for Intervention Description and Replication (TIDieR) guidelines (i.e. procedures, intervention provider and training, mode and location of intervention delivery and the regime) (Hoffmann et al., 2014). A second review author (PC) checked these data and any disagreements that arose were resolved by discussion between the review authors. Where insufficient information was available, requests were sent to the original authors.

**Mapping and coding categories**

Following data extraction, all included studies were coded by cancer type, stage of cancer trajectory, care setting, level of nurse involved and nature of intervention.

***Cancer trajectory, type and care setting***

Included studies were coded according to the stage of the cancer care continuum in which the intervention was delivered (i.e. prevention and risk reduction, screening, diagnosis, treatment, survivorship or end of life), using the cancer care continuum framework.

Insert figure 1 about here

Reviewers also independently coded the type of cancer using the National Cancer Research Institute’s Clinical Studies Groups as a guide <http://csg.ncri.org.uk/groups/clinical-studies-groups/> . This included 15 possible codes: advanced cancer, bladder and renal (including penile), brain (includes CNS), breast, colorectal/anus, gynaecological, haematological oncology (leukaemias and myeloma), head and neck, lung, lymphoma, prostate, sarcoma, skin cancer, testis, upper gastro-intestinal (includes neuroendocrine). Where more than one type of cancer was described, reviewers classified this as ‘multiple’. Studies that screened participants for cancer were coded separately.

Studies were also coded according to the setting of care e.g. hospital inpatient or outpatient setting, home or primary care setting.

***Level of Nurse***

Three reviewers with content expertise (UO, EP, TW) coded the level of nurse responsible for delivering the intervention using the CANO classifications of generalist, specialist and advanced nurse (CANO, 2016).

***Classification of interventions***

A series of team discussions were held to reach consensus on methods for grouping interventions from the included studies into relevant categories. Using an iterative process, involving discussion between pairs or groups of review authors with expertise relating to cancer nursing (MW, UO, EP, ME, LS, ML, CO, MS, CF, WO), an agreement was reached to use the categories proposed by the OMAHA nursing intervention classification as these were deemed more relevant to the aim of this review (OMAHA, 2016, Topaz et al., 2014).

This classification system includes four core categories:

1. Case Management
2. Surveillance
3. Teaching, Guidance, and Counselling
4. Treatments and Procedures

Two independent reviewer pairs were asked to consider both the *nature* of the role taken by the nurse in the intervention as well as what the intervention actually was. Table 1 summarises the different OMAHA categories and approaches agreed *a priori* by the reviewers when coding the interventions. The methodological application of the OMAHA categories, tasks and components for the classification of cancer nursing will be published in more detail elsewhere.

**Data synthesis**

Data from all included studies were synthesised within evidence tables and narrative, categorised according to OMAHA categories. Heat maps were generated in Excel (Microsoft). Conditional formatting was employed and those values with the highest frequency were assigned a green colour, middle values a yellow colour and lowest values a red colour.

**RESULTS**

**Results of the search**

Our searching identified 22450; screened 16169 abstracts and considered 925 full papers. Results of the search are displayed in Figure 1. Of the 925 potentially relevant studies, 518 studies were excluded. Reasons for exclusion were primarily due to inadequate description of the interventionist, or the intervention did not include a cancer nurse or the study design failed to meet selection criteria. We identified 83 studies as on-going (i.e. published protocols or on-going trials) and 18 studies as awaiting assessment (i.e. studies requiring translation or missing information sought but not available or full text papers were unavailable), leaving 316 reports of 214 unique studies that were eligible for inclusion within the qualitative synthesis (Supplementary Tables 2 – 5) (Figure 1).

**Description of included studies**

We included a total of 214 studies (248270 participants) in this review. Geographical locations of the included studies are shown in Supplementary Tables 2 –5. The majority of studies were conducted in Europe (n=79) or USA (n=74). Of the 214 included studies, 153 were nurse-led and 61 studies were facilitated by cancer nurses, as part of a wider multidisciplinary team.

The distribution of OMAHA heat map categories across all the included studies for cancer type is shown in Figure 2 and data are presented by trajectory in Figure 3. The greatest number of studies focused on teaching, guidance and counseling interventions in patients with multiple (two or more types) cancers and those with breast cancer. Studies on rare cancers were scarce.

**Intervention descriptions**

In the following section, a brief overview of the interventions categorised according to the OMAHA nursing intervention classification is given:

1. Case management (n=38) (Supplementary Table 2)
2. Surveillance (n= 27) (Supplementary Table 3)
3. Teaching, counselling and guidance (n=131) (Supplementary Table 4)
4. Treatment and procedures (n = 18) (Supplementary Table 5)

***Case management***

Thirty-eight studies (57913 participants) were categorised as case management, most commonly employing a parallel RCT design (n=26). The sample size varied across studies from 20 – 49311 participants. Most studies included 101 – 500 participants (n=27). Case management studies involved adult (or older adult) participants in 37 studies; only one trial included a mixed population of people with cancer and their carers (Supplementary Table 2).

Over half of the studies in this category included participants with a range of different cancer types (classed as ‘multiple’) (n=20) (Supplementary Table 2, Figure 2). The majority of these studies were focused on the phase of cancer treatment (n=20) and end-of-life (n=12) (Figure 3).

The most common focus of case management interventions was the provision of supportive care or psychosocial and/or psychosexual care. Other common components of these interventions were the management of signs and symptoms, primarily emotional and continuity of care (Supplementary Table 2). Specialist oncology nurses (n=13) or advanced cancer nurses (n=12) delivered the majority of interventions (n=23), however a variety of descriptors were used to document their professional roles, education and training (Supplementary Table 2, Figure 4).

The number of contacts for delivering case management interventions were clearly reported in 23 studies and ranged from 1- 18 contacts (face-to-face and telephone), Supplementary Figure 5a. The length of interventions ranged widely from 1.5 to 260 weeks (Supplementary Figure 5b). The amount of time attributed to case management interventions delivered by cancer nurses ranged from 120 to 1377 minutes per participant (Supplementary Table 2).

***Surveillance***

Twenty-seven studies (4892 participants) were included in the surveillance category. All of the participants were adults. Sample size ranged from 43 – 775 participants. Six studies included less than 100 participants with the majority of studies (n=21) including between 101 – 500 participants.

The majority of studies in this category focused on women with breast cancer (n=8). Over half of the interventions in 16/27 studies were delivered in the treatment phase of the cancer trajectory. However, a third of studies classed as surveillance interventions (9/27) took place in the survivorship phase. The descriptions of components involved interventions aimed at assessment, managing signs and symptoms, encouraging self-management and supportive care.

Specialist nurses delivered the majority of surveillance interventions; however once again a variety of descriptors were used to document their professional education and training (Figure 4, Supplementary Table3)

All of the interventions were delivered on a 1-to-1 basis. Most studies included face-to-face and telephone contact; 8 were telephone interventions only (no face-to-face contact) and 4 had additional e-health / computer delivered components. Interventions were mainly delivered in an outpatient or home based environment. The intervention regime varied across studies from 1 to 25 sessions; total amount of time attributed to the interventions ranged from 30 to 675 mins (n=14 studies) and was delivered over 1 week to 260 weeks (Supplementary Figure 5a-b, Supplementary Table 3).

***Teaching, guidance and counselling***

The majority of studies were categorised as teaching, guidance and counselling (n=131; 181604 participants). Although most of the studies were conducted with adults, 15/131 had a mixed population, including people with cancer and their partners (n=9/16), or people with cancer and Health Care Personnel (HCP - 6/16); 1/16 included family members, HCP and people with cancer. Five studies in this category included children and young people as participants. The sample size across studies ranged from 18 – 138392 participants, with most studies ranging between 101 – 500 participants (n=62). Studies on screening recruited the highest number of participants. The interventions in this category were delivered to people with multiple types of cancer (n=45) but women with breast cancer (n=34) and men with prostate cancer (n=13) also received teaching, guidance and counselling interventions (Figure 2). Interventions in this category were delivered across the entire cancer care continuum with the majority delivered in the treatment phase of the cancer trajectory (86/131) (Figure 3).

The main components of the interventions delivered in this category comprised of education and provision of psychosocial and psychosexual support or helping people with cancer manage symptoms (e.g. pain management, fatigue). Other interventions focused on exercise, genetics and activities aimed at promoting self-management and self-care (Table 4).

Although cancer nurses delivered the majority of interventions; details reporting their education and training were often vague, describing nurses as “experienced’ or “trained’; with details of education unreported in over a third of studies (n=52/131) (Supplementary Table 4).

Where reported most interventions were provided in broadly similar settings to those described in other intervention categories. Most interventions were provided on an individual and face-to-face basis; although a number of trials delivered the intervention in a group setting. Intervention regime varied across studies from 1 to 18 sessions (or contacts); total amount of time attributed to the interventions ranged from 3 to 1260 minutes delivered over 1 week to 104 weeks.

***Treatment and procedures***

Eighteen studies (3390 participants) were included in the treatment and procedures OMAHA category. The majority of studies were conducted with adults (n=14); 3 studies included children and young people only. Sample size varied across studies from 7 – 844 participants. The majority of studies included less than 100 participants (n=11). Participants had more than one type of cancer (‘multiple’) in 5/18 (Supplementary Table 5). Interventions in 15/18 studies were delivered in the treatment phase of the cancer trajectory.

The main components of the interventions delivered in this category comprised screening procedures (e.g. endoscopy or colonoscopy), interventions targeting signs and symptoms in people affected by cancer using techniques such as massage, Hickman line insertions or decision algorithms. Other interventions focused on medication administration (Supplementary Table 5) and activities aimed at improving physical care including exercise and lymphatic drainage in women with breast cancer. Specialist cancer nurses delivered the intervention in 4 studies, but the education and training details in the majority of this category (n=10) were unclear (Figure 4).

Most interventions were provided on an individual and face-to-face basis. Where reported, the interventions were provided primarily in the hospital setting and were delivered in single session (n=9) (Table 6). However, the amount of time attributed to the interventions varied widely across studies from a single (brief 15 minute) intervention to more time intensive intervention of 21 sessions delivered over 72 weeks (Supplementary Figure 5a-b).

**DISCUSSION**

**Key findings**

Our review presents evidence of cancer nurses being actively engaged in a large number of trials, delivering complex, often very diverse, interventions across the entire cancer spectrum. Interventions were often multifaceted, with the majority of interventions targeting PABC in the treatment phase, and delivered in a variety of settings. Interventions included direct care, psychological support, teaching, assessment and monitoring, care management and coordination, and were delivered face-to-face; via telephone and online; to individuals and groups. The interventions varied in duration and intensity with the majority requiring between 1-6 sessions (contacts), delivered over 13 – 26 weeks, and therefore consuming a significant time resource. In the context of a rapidly developing evidence base, the multidimensional role played by cancer nurses in studies documented in this review, covers all areas of the ICN definition of nursing (ICN, 2002), providing the first broad picture of cancer nursing interventions delivered within clinical trials.

The majority of interventions in this review were nurse-led, but cancer nurses also clearly facilitated a number of interventions as part of a wider team. With multi professional teams, consisting of medical, nursing, allied professionals, and diagnostic experts, now firmly established at the heart of cancer care (Taylor et al., 2013), cancer nurses have established a core co-ordination role within these teams by acting as the patient’s key worker and thereby a consistent point of reference through the care pathway (Lafferty et al., 2011). The importance of such coordinating roles is also supported by shifts in healthcare delivery models, towards greater outpatient care, within an environment in which rising health care costs (e.g. an ageing population, expansion of health care coverage for the previously uninsured) and an economic downturn have intensified the pressure for cost control (Beans, 2016).

The majority of trials in this review recruited adults; we identified few studies involving children and adolescents or young adults. Furthermore, most studies recruited patients with two or more types of cancer; fewer studies focused solely on PABC diagnosed with a single cancer type (i.e. breast, prostate and colorectal/anus cancer). The review identified no nurse-led or nurse-facilitated studies in people diagnosed with brain, bladder and renal, skin cancer, sarcomas and testis cancers. The lack of studies in these areas could be explained by the type of study design criteria in our review, and it is likely that other study designs (e.g. qualitative studies) with fewer ethical barriers may have explored the experiences of these groups and PABC diagnosed with other ‘rarer’ cancers in more detail. Importantly, our review highlights a gap in the current evidence base, suggesting a need for high quality cancer nursing trials in these groups.

Cancer nursing interventions were delivered across the continuum from prevention and risk reduction to survivorship. Most interventions were delivered during the treatment and survivorship phases. Fewer interventions were delivered during the diagnostic phase. This was a surprising finding as an increasing body of literature strongly supports the presence of a nurse during the diagnosis of cancer (Gilbert et al., 2011, Mertz et al., 2017). Perhaps less surprisingly, the majority of cancer nursing interventions in this review were classified as teaching, guidance and counselling interventions, with fewer interventions focused on case management, surveillance or treatment. Cancer nurses have traditionally had a significant role to play in supporting patients through information, education and psychological support, but are also increasingly engaged in delivering complex treatments, undertaking diagnostic procedures, leading follow-up and survivorship care and managing treatment pathways. Robust evidence to underpin these interventions is urgently needed.

Most trial interventions were delivered by specialist or advanced cancer nurses. This has clear implications for education and workforce planning. This finding supports the benefits gained from providing a career structure for cancer nurses, with relevant education, that promotes research skills and the necessary mentoring and support. The rising demand likely to be placed on cancer services in the future supports the need for more nurse-led interventions that reflect the needs of different cancer patient groups; but are also effective and affordable (NHS, 2017) (Kelly and Charalambous 2017).

However, in this review nurse trialists often failed to report interventionist details adequately (qualifications and training) in 40% of the included studies. Trialists should therefore, be encouraged to provide full descriptions and profiles of the interventionists using recent reporting guidelines (TiDIER) (Hoffmann et al., 2014). Such detail is essential if we are to capture all interventions delivered by cancer nurses and understand the full extent (and impact) of cancer nursing involvement in trials.

**Strengths and Limitations**

The study has a number of strengths and limitations. While we are confident we have identified most published trials of relevance to the review it is possible, despite our best efforts, that we may be unaware of additional work. For example, we were unable to include a number of trials because details of the interventionist were not reported, or were reported only poorly. Although we contacted the original authors where possible, some data pertaining the reviewed studies were unavailable.

The use of the OMAHA classification system (OMAHA, 2016, Topaz et al., 2014), although a widely employed measure to categorise general nursing interventions, may have oversimplified the scope of some interventions. However, we are unaware of any cancer nursing-specific intervention classification systems. An area that has not received adequate attention in the reviewed studies, nor has been captured in this review, is the translational impact by findings being taken up in practice. Whether, and to what extent, these trials have led to the implementation of cancer nursing interventions, especially in other practice settings, remains unknown.

Furthermore, the degree to which these findings support the call for upskilling cancer nurses in specific areas of practice has not been established. It is, however, likely that the interventions evaluated in the 214 trials in this review, represent only a fraction of those actually delivered by cancer nurses across the globe.

Previous reviews of cancer nursing interventions have focused solely on one type of intervention, or type of cancer (Campbell et al., 2017). Despite its limitations, this review provides the first comprehensive picture of the cancer nurse interventions that have been utilized across clinical settings, at different points of the cancer trajectory and aimed at diverse cancer populations.

**Conclusion**

Our review has clearly captured the breadth and scope of cancer nurses in delivering interventions within a trial design. Cancer nurses are performing multiple and complex roles in a variety of settings across the care continuum. The roles are diverse, requiring considerable expertise in many specialist areas of cancer care, in addition to research skills. This review provides novel insights to enhance our current understanding of cancer nurses’ evolving roles as clinical trialists, and identifying the focus, to date, for the delivery of complex interventions by cancer nurses. As such, it forms the basis of an ongoing dialogue which we hope will transform awareness of the level of contribution that cancer nurses are making to improve cancer care. The review has clear relevance to the European context, having been conducted by members of the European Oncology Nursing Society, but also has global currency given the rising demand now being placed on cancer services around the world.

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* drafting the article or revising it critically for important intellectual content.
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Affiliations

* University of Surrey School of Health Sciences, Faculty of Health & Medical Sciences, Standard Buildings, Office 2.4, 2nd Floor, 94 Hope Street Glasgow, G2 6PH, United Kingdom