Full title: Recognising European Cancer Nursing: Protocol for a systematic review and meta-analysis of the evidence of effectiveness and value of cancer nursing

Running Head: Recognising European Cancer Nursing Review Protocol

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Vice-Chair: Kathy Oliver (UK) - International Brain Tumour Alliance (IBTA)
Sarper Diler (TR) - Myeloma Patients Europe (MPE)
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Geoffrey Henning (UK) - EuropaColon and Global Colon Cancer Alliance
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Bert van Herk (NL) - Lung Cancer Europe (LuCE)
Anita Waldmann (DE) - MDS Alliance
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Conflict of interest
No conflict of interest has been declared by the authors.

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Authors’ contributions
DK, AC, MW conceived of the study and participated in its design and coordination and helped to draft the manuscript. PC and CT drafted the manuscript. Other authors all participated in defining the scope of the review, and its design and coordination. All co-authors will be involved in either classifying interventions or assessing risk of bias. All authors have read and approved the final manuscript.
Abstract

**Aim:** To identify, appraise and synthesise the available evidence relating to the value and impact of cancer nursing on patient experience and outcomes.

**Background:** There is a growing body of literature that recognises the importance and contribution of cancer nurses, however a comprehensive review examining how cancer nurses impact on care quality, patient outcomes and overall experience of cancer, as well as cost of services across the entire cancer spectrum is lacking.

**Design:** A systematic review and meta-analysis using Cochrane methods.

**Methods:** We will systematically search 10 electronic databases from 2000, with pre-determined search terms. No language restrictions will be applied. We will include all randomised and controlled before-and-after studies that compare cancer nursing interventions to a standard care or no intervention. Two reviewers will independently assess the eligibility of the studies and appraise methodological quality using the Cochrane Risk of Bias tool. Disagreements will be resolved by discussion, and may involve a third reviewer if necessary. Data from included studies will be extracted in accordance with the Template for intervention Description and Replication reporting guidelines. Missing data will be actively sought from all trialists. Data will be synthesised within evidence tables and narrative to answer three key questions. If sufficient data are available, we will perform meta-analyses.

**Discussion:** This review will allow us to systematically assess the impact of cancer nursing on patient care and experience. This evidence will be used to determine implications for clinical practice and used to inform future program and policy decisions in Europe.

**Systematic review registration:** The protocol is registered on PROSPERO as record no. CRD42016048760

**Summary statement: Why is this study or review needed?**

- Cancer nurses play a central role in caring for individuals diagnosed and living with, and beyond cancer. However in some countries across Europe, there is little recognition of the value of cancer nursing.
- There is an emerging literature that recognises the importance of cancer nurses in caring for people with cancer; however a systematic review examining the impact and value of cancer nursing across the cancer spectrum is lacking.
- This review is designed to systematically identify the roles and types of intervention activities currently undertaken by cancer nurses; and determine the effectiveness and cost-effectiveness of interventions delivered by cancer nurses in improving the experience and outcomes of people with cancer.

**Keywords:** Nursing, cancer, cost, effectiveness, nurse-led, oncology PROMS, patient care
INTRODUCTION
Cancer is a leading cause of death worldwide. Recent studies estimate that 14.1 million new cases will be diagnosed each year; in more than half of these, patients will die as a direct result of the original cancer diagnosed (Torre et al. 2015). The impact of cancer on the individual, their family and wider society is incalculable.

The cancer care pathway has been described as “complex, lengthy and disjointed, involving a wide variety of healthcare professionals in a range of care settings” (Henry 2015). As such, there is a need for an integrative role in cancer services, and this is typically fulfilled by the cancer nurse (Tiffany 1987).

Within the multi-disciplinary team, cancer nurses play an important, and often-varied role, in caring for individuals diagnosed with cancer in order to provide the best possible care. They deliver essential nursing care, patient, family, and community education and support; implement early detection programs; administer, monitor and in some settings evaluate treatments; identify and manage complications; provide supportive and palliative care; and lead and collaborate on clinical research (Beck 2016, CANO 2016, EONS 2012, ONS 2016).

There is clear evidence linking cancer nurses care to improved patient outcomes. For example, specialist cancer nursing provision has been associated with improved management of chronic problems in cancer patients; positively impacting on patient knowledge and self-management; marked improvement in patient symptoms and a reduction in the rate of emergency admissions, length of hospital stays and fewer follow-up appointments (Corner et al. 2013, Sussman et al. 2011, Cockle-Hearne et al. 2013, Mick 2008, Rueda et al. 2011). Patient experience surveys in the UK have consistently identified the presence of a clinical nurse specialist as the factor most likely to be associated with a good experience of cancer care (Quality Health 2014).

Previous reviews have synthesised the evidence for specific nurse-led interventions, for example, psychosocial and supportive care nursing interventions in breast cancer (Cruickshank et al. 2008, Eicher et al. 2006); nurse-led interventions involving telephone contact in women with gynaecological cancer (Cook et al. 2015); psychotherapeutic, psychosocial and educational interventions in patients with lung cancer (Rueda et al. 2011) and active surveillance and nurse-led care related to radiotherapy treatment and patients' experiences of radiotherapy treatment in men diagnosed with prostate cancer (Tarnhuvud et al. 2007, Madsen and Symes 2013). However, none have focused on the impact of cancer nursing on patients’ experiences and outcomes across the spectrum of cancer.

Background
Facilitating the recognition of oncology nursing across Europe
There is a general consensus that cancer nurses make a valuable and unique contribution to the quality and effectiveness of cancer treatment and care. However, there is little agreement about the role of the cancer nurse, and what training or education elements are important for the continued growth of the profession. As a result, there is significant variation in the provision and recognition of cancer nurses across Europe (Sermeus et al. 2011, Aiken et al. 2014).
Although several professional bodies have made attempts to clarify the role, a lack of consensus regarding terminology continues to impede research and clinical practice (EONS 2012, CANO 2016, ONS 2016). One survey recently reported a wide variety of job titles across 17 countries in Europe (see Figure 1 – additional online only file), and identified 7 titles in the UK alone (Kav 2013).

This lack of agreement means that it is “difficult to gain any consistency or nationwide agreement on the qualifications and qualities that are required by specialist nurses” (Henry 2015).

Consequently, in 2015, the European Cancer Organisation (ECCO) Board decided that one of its top priorities would be to encourage the recognition of oncology nursing across Europe. In the same year – the European Oncology Nursing Society (EONS), Europe’s largest cancer nursing organisation – set its strategic aim as: ‘To strengthen EONS political voice and impact society across Europe’. This complementary and synergistic approach resulted in a new three-stage project that was launched on 7 March 2016 – the Recognising European Cancer Nursing (RECaN) project (Trueland 2016). Stage one will include a systematic review of the impact of cancer nursing on patient experience and outcomes.

Preliminary scoping work

In order to develop an informed, consensual research protocol, designed to meet the aims of the EONS and ECCO joint project, key preliminary scoping work was first completed. This involved consultation and collaboration with the review authors, who comprised of selected experts in cancer nursing and research methods (see Table 1 for a summary of their expertise).

To inform the protocol development and decisions of the working group, an initial scoping review of the literature was completed. This scoping review involved systematic searching of 8 electronic databases:

- Allied and Complementary Medicine Database (AMED);
- Cochrane Central Register of Controlled Trials (CENTRAL);
- Cochrane Database of Systematic Reviews (CDSR);
- Database of Abstracts of Reviews of Effectiveness (DARE);
- Health Technology Assessment (HTA);
- Cumulative Index of Nursing and Allied Health Literature (CINAHL);
- Medical Literature Analysis and Retrieval System Online (MEDLINE);
- Excerpta Medica Database (EMBASE)

We searched each database from inception onwards, combining the search terms cancer nursing with terms for cancer (see Appendix 1 for an example search string). This work will form the basis for an evidence map of the role and impact of cancer nursing and will be published in more detail elsewhere.

A protocol was initially drafted by two members of the research team (PC, CT) with specialist input from MW, and then further refined by expert members of the working group. The identified
definitions and key areas of the protocol were considered and discussed by members of the working group at a face-to-face meeting in June 2016.

Discussion amongst expert members led to consensus over:
(1) definitions of cancer nursing which should be used within the research protocol, and
(2) key criterion underpinning the review (e.g. participant group; outcome measures and specific research questions to be addressed within the research). These are described in detail below.

As a group of nurses with a vested interest in cancer nursing and its value, we recognise the potential for conflicts of interest. All of our consensus decision meetings are therefore being recorded, to ensure transparency and enhance clarity around decisions. Data extraction is being independently conducted by two systematic reviewers, neither of whom are nurses (see Table 1). All co-authors have been involved in defining the scope of the review.

Finally, it was agreed by all review authors that the active involvement of people affected by a cancer was critical to the success of the project; ensuring that the review would have real relevance, reach and engagement. We will consult patient representatives through ECCO Patient Advisory Committee (EPAC) at key stages in the review process and sought their initial views on the protocol.

THE REVIEW

Aim
To identify, appraise and synthesise the available evidence relating to the value and impact of cancer nursing on patient experiences and outcomes.

Research questions:
Specifically, this review will seek to:
1. Identify the roles and types of intervention activities that have been performed by cancer nurses;
2. To determine the effectiveness and cost-effectiveness of interventions delivered by cancer nurses in improving the experience and outcomes of patients with cancer.
3. Explore whether there is a relationship between cancer nurse education and training and patient experiences and outcomes.

Design
We plan to undertake a systematic review and meta-analysis using standard Cochrane methods (Higgins and Green 2011) and will report the data using well established methodology (Liberati et al. 2009).

Definition of a Cancer Nurse
At present there is no universally accepted definition of a cancer nurse (Henry 2015). Nurses who work with people with cancer are referred to in various ways, for example, oncology nurses (Banerjee et al. 2016, Sherner 2016, Yu 2016); advanced practice nurses (Hendricks-Ferguson et al. 2015, Gosselin et al. 2015, McCorkle et al. 2015, Spoelstra et al. 2016); specialist cancer nurses

Furthermore, many of the definitions are based around either cancer nurses’ role (or the scope of the role); purpose; context and where care is being delivered; type or severity of cancer, and education/training or a combination of these factors. The ECCO PAC representatives highlighted the need for clarity when defining a cancer nurse, stating that “there are many names for them, and the different academic degree is very confusing for patients”.

The expert group recognised the need to employ a broad definition that would allow the reviewers to be able to capture all nursing involvement, delivered at any stage of the patient journey (i.e. prevention and risk reduction, screening, diagnosis, treatment, survivorship, end-of-life care or anywhere along the continuum).

The expert group considered a number of definitions from position papers and other relevant literature that were extracted during the scoping review. They agreed that the Canadian Association Nursing Organisation (CANO) definition for generalised, specialist and advanced oncology nurse – using the word ‘cancer’ instead of ‘oncology’ provided a flexible structure (Tiffany 1987, CANO 2016).

As such, the following definitions will be employed in the review:

- **Generalist nurse**: defined as a nurse educated to degree level and may care for cancer patients in their daily caseload;
- **Specialist cancer nurse**: educated to a degree level (or higher) with formal training in cancer who cares for cancer patients as a specialised population;
- **Advanced cancer nurse**: educated at a post-graduate level and is considered an expert in at least one aspect of cancer nursing.

We acknowledge that this definition may not be relevant or applicable to all international settings, and where nursing interventions are delivered to people with cancer by practitioners with alternative education/qualifications. Therefore we will judge whether these are equivalent to our definition of a cancer nurse, and will document the relevant information relating to education and qualifications.

**Criteria for considering studies for this review**

We plan to include any study that meets the following criteria:

**Types of studies**

We will include all relevant published:

- randomised controlled trials (RCTs),
- quasi-RCTs
- cluster RCTs (cRCT)
- controlled before and after studies (CBAs)
For the purpose of this review, we have defined CBA studies as trials in which an outcome measurement(s) has been measured at baseline, and post-intervention for both groups.

We will exclude case studies, surveys, reviews, editorials, policy reviews and statements, qualitative studies, and commentaries. The nature and focus of evidence excluded from the review will be captured in summary within the evidence map. Only studies published in peer-reviewed journals will be included. We will employ no language restrictions, but will limit the studies to those published from 1st January 2000 onwards.

**Types of participants**
Cancer nurses work across a spectrum of cancer and across population groups (e.g. children and young people diagnosed with cancer). As such, the expert working group (Table 1) felt that the review should reflect this, and include any study with participants diagnosed with cancer irrespective of their age.

**Types of interventions**
We will include any interventions delivered by a cancer nurse across the trajectory from prevention to end of life. The review will exclude any pharmacological or surgical only intervention, or any intervention delivered by healthcare professionals who are not professionally qualified nurses (e.g. support staff).

**Types of comparisons**
We will use direct pairwise comparisons and will plan to compare the following:
1. Cancer nurse delivered interventions versus no intervention
2. Cancer nurse delivered interventions versus standard or usual care (i.e. with no specialist cancer nurse intervention)
3. One cancer nurse delivered intervention versus another cancer nurse delivered intervention
4. One cancer nurse delivered intervention compared with an intervention delivered by other healthcare professionals.

**Types of outcome measures**
The primary outcomes of interest to this review are:
1. Quality of life indicators as measured by a validated scale (e.g. EORTC QLQ-C30); well-being; symptoms (e.g. fatigue; nausea; vomiting); anxiety; depression; coping; social or financial functioning
2. Cost effectiveness and other economic measures such as the cost of intervention; resource implications; cost-utility

Secondary outcome measures will comprise:
1. Mortality
2. Recurrence/progression-free survival (PFS) / disease free survival
3. Patient reported cancer specific outcomes measured by, for example, the Cancer Rehabilitation Evaluation System (CARES; CARES-SF), Cancer Survivor Unmet Needs Measure (CaSUN)
4. Self-management / activation
5. Patient safety
6. Adverse events
7. Carer burden
8. Physiological indicators
9. Impact on policy
10. Participant satisfaction (measured using a validated scale)
11. Service provision
12. Other outcomes not pre-specified but considered to be important during the review

We will consider outcomes at the end of the intervention (immediate), up to one-year post-intervention (≤ 12 months), and more than one-year post-intervention (>12 months).

ECCO PAC representatives were asked to comment on the relevance of the outcome measures listed above, and agreed that quality of life indicators were the most important measure. They also emphasised the need for adherence to therapy and key symptoms such as sleep problems to be considered.

Further, the ECCO PAC highlighted the importance of carer burden as a secondary outcome measure, arguing, “for some cancers in particular such as brain tumours, carers play a huge role because the patient’s physical and cognitive abilities are often severely compromised”.

**Ethical considerations**
There are no ethical issues.

**Validity and reliability of review**
We have developed this protocol in accordance with the PRISMA protocol checklist (PRISMA-P) (Moher et al. 2015). We will conduct the systematic review and meta-analysis according to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2011) and report the data following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Liberati et al. 2009).

**Search methods for identification of studies**
We will systematically search the following electronic databases from 1st January 2000.
- Medline
- AMED
- Epistemonikos
- CINAHL
- Embase
- Cochrane Central Register of Controlled Trials
- CDSR
- DARE
- HTA
- Clinical trial registries to identify any on-going trials (e.g. WHO ICTRP)

A comprehensive search strategy will be developed according to the following search architecture and adapted for each database as required.
We will combine 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). Boolean operators will be used in order to maximise the penetration of terms searched, and appropriate “wild cards” will be used to account for plurals, variations in databases and spelling. An example search strategy is provided in Appendix 1. We will look for additional studies by checking the reference lists of all included articles.

**Data collection and analysis**

**Selection of studies**

One review author (PC) will read the titles of the identified references and eliminate any obviously irrelevant studies (e.g. not cancer related condition). We will obtain the abstracts for the remaining studies and then, based on the inclusion criteria (study design, diagnosis of cancer); two review authors (PC, CT) will independently rank these as relevant, irrelevant or unsure. We will exclude all studies ranked as irrelevant by both review authors, and obtain the full text of all remaining studies. Two review authors will independently assess the full texts of studies ranked as relevant or unsure for inclusion, and any disagreements will be resolved through discussion. If there is disagreement between reviewers, they will reach consensus through consideration and discussion of the full paper, involving a third reviewer if necessary.

**Data extraction and management**

We will systematically extract information relating to:

- Study characteristics (author, date of publication and country of the study)
- Aims of the study
- Study design and methodology (e.g. research design, randomisation, stratification)
- Participant characteristics
- Intervention details; these will be reported in accordance with the template for intervention description and replication (TIDieR) checklist (Hoffmann et al. 2014). The TIDieR checklist supports complete descriptions of complex interventions to facilitate transparency and replication in a research or clinical context. We will extract data relating to the intervention rationale, materials, procedures, provider (including their expertise, qualifications and any specific training), delivery mode, dose, tailoring, modification, adherence and related aspects of fidelity. ECCO PAC representatives underscored the importance of the context of the care provided as an important consideration.
- Outcomes assessed. Details of each assessed outcome will be documented, including time points for data collection.
- Effectiveness data. Quantitative data relating to the effect of the intervention will be documented.
- Number of participants contributing to data will be documented. Results of any statistical comparisons or tests will be extracted. No data relating to qualitative outcomes will be extracted.

One reviewer (CT) will systematically extract the data, using a data collection form that has been specifically designed for this study. A second reviewer from the research team will independently check the data entry.
Data from the included studies will be processed as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and it will be managed using the RevMan Analyses statistical programme in Review Manager (The Nordic Cochrane Centre 2014).

Measures of treatment effect
When appropriate, the results of included studies will be combined for each outcome in a formal meta-analysis to produce an overall estimate of treatment effect. For dichotomous data, risk ratio (RR) and 95% confidence intervals will be derived using a fixed effects model and, for continuous data, weighted mean differences (WMD), weighted by the inverse of the variance.

Dealing with missing data
We will deal with missing data according to the recommendations in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2011). Where data is not reported adequately, attempts will be made to acquire the necessary information from the authors. We plan to assess whether the results were reported on attrition bias, and if not, whether the number and reasons for withdrawal and dropout were sought.

Assessment of heterogeneity
Trials will only be combined if they are thought to be clinically similar. Heterogeneity between trials will be assessed by visual inspection of plots of the data, the Chi^2 test for heterogeneity and the I^2 statistic (Higgins and Green 2011). We will define the thresholds for interpretation of the I^2 statistic according to the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green 2011). Where we observe important heterogeneity (based of the I^2 value together with significant evidence of heterogeneity as per the Chi^2 test P value), we will employ a random effects model (Higgins and Green 2011).

Assessment of reporting biases
We are planning to investigate the possibility of publication bias with a funnel plot in comparisons within which we can include 10 or more studies. We will also reduce the effect of reporting bias by including studies - not just publications – thereby minimising the introduction of duplicate publications of the same dataset.

Data Synthesis
Data from included studies will be synthesised within evidence tables and narrative. We will group evidence according to type of outcome assessed. Where more than one study has assessed the same outcome, we will tabulate all effectiveness data and details of relevant studies. We will pool data from studies that are judged to be clinically homogeneous and tabulate this data using Review Manager 5.3 software (The Nordic Cochrane Centre 2014). If sufficient data are available, we will perform meta-analyses. When studies are statistically heterogeneous, we will use a random-effects model; otherwise, we plan to use a fixed-effect model. When using the random-effects model, we will conduct a sensitivity analysis using the fixed-effect model to reveal differences in results. We will include a 95% confidence interval (CI) for all estimates. We will present results separately for RCTs and CBA studies.
We plan to carry out three separate syntheses – each answering one of the research questions.

Assessment of risk of bias in included studies
Two review authors from the research team will independently assess the methodological quality of included studies using the relevant risk of bias assessment tool from the Cochrane Collaboration (Higgins and Green 2011).
We will assess the methodological quality across the following domains:

- randomisation (i.e. sequence generation and concealment of randomisation). We will not judge CBA studies for the quality if random allocation because this item is not applicable to non-randomised studies.
- blinding (participants, carers, outcome assessors);
- selection bias in analysis (based on assessment of withdrawals) and dropouts (incomplete data; use of an intention to treat analysis);
- selective reporting;
- other potential sources of bias (e.g. provision of clear inclusion/exclusion criteria; baseline similarity of randomised groups).

Assessment of quality of evidence
We will use the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (Guyatt et al. 2008) to make a judgment on our confidence in the evidence relating to each specific outcome, ranking confidence in the evidence as high, moderate, low or very low. These are defined as:

- High quality, when further research is very unlikely to change our confidence in the estimate of effect;
- Moderate quality, when further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate;
- Low quality, when further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; or
- Very low quality, when we are very uncertain about the estimate.

Judgement of GRADE quality will be agreed through discussion involving at least three reviewers, and involving additional reviewers where there is disagreement. Furthermore, we will highlight where there is high or moderate quality evidence of an intervention having (i) benefit, (ii) harm or (iii) no benefit or harm.

Subgroup analysis
Where feasible we will perform subgroup analyses based on:

1. Type of cancer
2. Age group as reported by trialists (e.g. “paediatric” / “young adult or young person” / “adult” / “older adult”)
3. Stage of cancer (prevention, early diagnosis, treatment, survivorship period, end-stage cancer)
4. Category of cancer nurse involved (generalist nurse / specialist nurse / cancer nurse specialist)
Sensitivity analysis
We will conduct a sensitivity analysis when indicated to test the robustness of the meta-analysis by omitting studies judged as high risk of bias.

DISCUSSION
The value and impact of cancer nursing is widely acknowledged as beneficial for patients. However, the roles of cancer nurses are often poorly reported, and their unique contribution to the cancer care pathway is not always captured. Furthermore, there are wider concerns about making the most of the available workforce - including nursing - across Europe, as well the ‘greying’ of the nursing workforce, and the rising expectations of patients. As such, there is an urgent need for robust evidence of the effectiveness of cancer nurses and their impact on patient experiences and outcomes.

This planned systematic review and meta-analysis will therefore bring together all of the available studies that have evaluated the effectiveness of cancer nurses on patient experiences and outcomes in cancer care. This synthesis will also examine whether specialist cancer nursing training and education has any impact on the quality of care.

Limitations
There are some limitations to our review. Reports and case studies highlighting the importance of specialist nurses in supporting decision making, linking services, providing emotional support and information will not meet the criteria for the review, but still illustrate the impact nurses have on improving quality of life for people affected by cancer (Macmillan Cancer Support n.d.) Papers published before 2000 will not be included, and the review will not synthesise evidence from studies using qualitative or survey designs. However, we are conducting a concurrent ‘evidence mapping’ exercise, which will consider all types of study design since 2000 and will enable us to provide an overview of how the cancer nursing landscape has changed over the last fifteen years.

CONCLUSION
This review will be the first to synthesise evidence for cancer nursing across the whole cancer care continuum. Commissioned by key European cancer organisations, the review’s findings will be used to help influence policy and practice across the continent, highlighting the potential for specialist cancer nurses to impact on patient outcomes and experiences and providing the evidence to underpin developments in education and clinical practice so that the value of cancer nursing is recognised and optimised in all European countries. There is potential to enhance the role of specialist cancer nurses and this review will help in this process by clarifying the contribution that nursing has made.

List of abbreviations
CBA: Controlled before-after studies
cRCT: Cluster randomised controlled trial
GRADE: Grading of Recommendations, Assessment, Development and Evaluation
qRCT: quasi-randomised controlled trial
RCT: Randomised controlled trials
TIDieR: Template for intervention description and replication

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<thead>
<tr>
<th>Name</th>
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<th>Summary of expertise</th>
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<tr>
<td>Iveta Nohavova</td>
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<td>Cancer nursing, tobacco control, lung health research methods (qualitative research)</td>
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<td>UK</td>
<td>Cancer nursing, radiotherapy, supportive care interventions, survivorship, head &amp; neck cancer, patient experiences, research methods (complex interventions, qualitative research and RCTs)</td>
</tr>
<tr>
<td>Theresa Wiseman</td>
<td>UK</td>
<td>Cancer nursing/developing advanced practice roles patient experience developing services and intervention to enhance experience of cancer care. Research methods – mixed methods research / qualitative research / improvement science</td>
</tr>
</tbody>
</table>