

“I Can’t Sleep!”: Gathering the evidence for an innovative intervention for insomnia in cancer patients

by Nancy (Surya) A. Absolon, Tracy L. Truant, Lynda G. Balneaves, Frankie Goodwin, Rosemary L. Cashman, Margurite E. Wong, and Manisha B. Witmans

Abstract

Sleep-wake disturbances, in particular insomnia, are experienced by 30%-75% of oncology patients, yet no effective interventions have been designed to address this distressing symptom in the ambulatory setting. In response to an identified gap in care, I share the development and evaluation of an innovative sleep intervention

designed specifically for the ambulatory setting. Preliminary findings, as well as an informative blueprint for conducting point-of-care research, are described. As a “bedside” nurse it is possible and within our moral imperative and social justice mandate to take action to find evidence-informed solutions to improve care for populations of patients experiencing gaps in care. The “I” used throughout the article refers to the lead author Surya.

This paper arose because of a vision and a commitment I had to help cancer patients improve their quality of sleep. I will share with you my journey as a clinical nurse in radiation oncology who is conducting research at the “bedside.” It is my hope that this article will encourage you, in some way, to move forward with your own ideas about improving patient care, or perhaps realize that it is possible to conduct research even if you have doubts and don’t know where to start. My intent is to share an informative blueprint that has helped me be successful as a point-of-care researcher. It is my wish that you are inspired in some way.

Background

I begin by sharing a bit of personal background about a pilot study that I launched to evaluate a sleep intervention for people with cancer. I learned about the sleep intervention from Maharishi Krishnananda Ishaya (MKI), a teacher of meditation of The Ishayas’ Ascension of the Bright Path (The Bright Path, 2008). As a lifelong student and more recent teacher of meditation myself, I understood the potential value of meditation as a sleep aid, with its calming effects on the sympathetic nervous system, ability to calm the mind of intrusive thoughts, and ability to be easily learned by just about everyone (Bhasin et al., 2013; Hubbling, Reilly-Spong, Kreitzer, & Gross, 2014). I became curious about the potential use of this meditation technique as a sleep aid in the cancer population with which I had recently begun to work in an ambulatory cancer centre.

Insomnia and cancer:

State of the science

Insomnia, which is the most common sleep-wake disturbance in cancer patients (Sateia & Lang, 2008), may include trouble falling asleep, or difficulty staying asleep with nighttime awakenings, early morning awakening with inability to return to sleep or a subjective experience of non-restorative sleep (Savard & Morin, 2001). My review of the literature on cancer and insomnia revealed some startling facts. Sleep-wake disturbances, particularly insomnia, are regularly experienced by 30%-75% of oncology patients (Lee, Cho, Miaskowski, & Dodd, 2004). This persistent and distressing symptom (Berger, 2009) is seldom addressed or identified by health care professionals (HCPs) (Howell, Oliver, Keller-Olaman, Davidson, Garland, Samuels, et al., 2012) and is under-reported by patients (Davidson, Feldman-Stewart, Brennenstuhl, & Ram, 2007), which may lead to unnecessary morbidity (Matthews, Berger, Schmiege, Cook, McCarthy, Moore, et al., 2014). The under reporting of sleep-wake disturbances has been attributed to patients framing the symptoms as normal and a temporary reaction to cancer

About the authors



Nancy (Surya) A. Absolon, RN, BA, BScN, Radiation Therapy Oncology Nurse, Vancouver Centre, British Columbia Cancer Agency, Vancouver, BC, Canada



Tracy L. Truant, RN, MSN, PhD(c), School of Nursing, University of British Columbia, Vancouver, BC, Canada



Lynda G. Balneaves, RN, PhD, Associate Professor, School of Nursing, University of British Columbia, Vancouver, BC, Canada



Frankie Goodwin, RN, BN, Manager, Clinical Services Ambulatory Care, Vancouver Centre, British Columbia Cancer Agency, Vancouver, BC, Canada



Rosemary L. Cashman, RN, MA, MSc(A), NP(A), Nurse Practitioner, Vancouver Centre, British Columbia Cancer Agency, Vancouver, BC, Canada



Margurite E. Wong, RN, MSN, Clinical Educator (Adult/Older Adult), Pacific Spirit Community Health Unit, Vancouver Coastal Health, Vancouver, BC, Canada



Manisha B. Witmans, MD, FRCPC, FAAP, FASM, Clinical Associate Professor, University of Alberta, Edmonton, AB, Canada

Address for correspondence: Nancy (Surya) A. Absolon, RN, BA, BSN, Radiation Therapy Oncology Nurse, Vancouver Centre, British Columbia Cancer Agency, 600 West 10th Avenue, 2nd Floor, Radiation Therapy ACU Station A, British Columbia Cancer Agency, Vancouver, BC V5Z 4E6

Email: nabsolon@bccancer.bc.ca

or treatment, or not amenable to treatment by HCPs (Howell et al., 2012). Insomnia frequently occurs as part of symptom clusters in the cancer population (McMillan, Tofthagen, & Morgan, 2008), with insomnia occurring concurrently with pain, fatigue, anxiety and depression.

The Oncology Nursing Society's (2013) Research Evidence Table for Sleep-Wake Disturbances reports that there are currently no evidence-based pharmacological interventions that have proven to be effective in managing sleep-wake disturbances in cancer patients. Despite holding some promise, medications such as Desyrel, Remeron, Paxil and Effexor (antidepressants), along with Zolpidem (nonbenzodiazepine hypnotic) are only in the beginning stages of being evaluated in the context of sleep-wake disturbances in cancer patients (Oncology Nursing Society, 2013).

Effective interventions for insomnia in cancer patients

Although there is a paucity of studies evaluating interventions that specifically focus on sleep disturbance in cancer patients (Langford, Lee, & Miaskowski, 2012), there is emerging evidence that identifies promising non-pharmacologic interventions for insomnia in cancer patients. Cognitive behavioural therapy (CBT) and mindfulness-based stress reduction (MBSR) are two such promising interventions. These mind-body therapies provide the underpinning of the brief sleep intervention evaluated in this study.

Cognitive behavioural therapy (CBT) is considered "likely to be effective" as a strategy to address insomnia according to the Oncology Nursing Society (ONS, 2013) and has been shown to improve sleep quality in cancer patients (Howell et al., 2014). CBT is comprised of three components: educational, behavioural and cognitive. Applied to insomnia, these components are targeted through strategies such as sleep hygiene education, stimulus control, sleep restriction, relaxation and cognitive therapy (Morin, 2004). CBT is designed to reduce perpetuating factors of insomnia such as maladaptive sleep behaviours and address myths commonly associated with achieving optimal sleep (Savard & Morin, 2001). It is a safe, well-tolerated therapy usually conducted over a six- to 10-week period, requiring significant time commitment from patients (Woodward, 2011). The need for routine screening, assessment and management of cancer-related sleep disturbances, and to include CBT as part of standard care in adult cancer populations has been supported within Canadian (Howell et al., 2012) and American (ONS, 2013) guidelines.

The MBSR program typically runs over six to 10 weeks and guides individuals to reduce stress through mindful meditation. This includes non-judgmental awareness, being present in the moment, acceptance, and breath and bodywork, as well as educational material on stress and coping (Kabat-Zinn, 1982; Kabat-Zinn, 1990). The guiding purpose for MBSR is to assist individuals to modify their outlook of stressful situations and decrease psychophysiological arousal (Garland et al., 2014). MBSR has not been associated with any side effects (Hubbling et al., 2014).

Evidence supports the use of MBSR in cancer populations to promote relaxation and quality of life and decrease symptoms such as fatigue, distress, mood disturbance, and fear of recurrence (Carlson & Garland, 2005; Lengacher, Jim, Reich, Ramesar, Carranza, Paterson, et al., 2012; Lengacher, Reich, Post-White, Moscoso, Shelton, Barta, et al., 2012; Musial, Bussing, Heusser, Choi, & Ostermann, 2011). However, the effectiveness of MBSR specifically for addressing insomnia has not been established (ONS, 2013).

Overall, this review of the literature identifies a gap in insomnia interventions in the cancer population. Further, although MBSR and CBT have been identified as being potentially effective, these interventions require significant time to learn and practice, which is not congruent with a busy ambulatory oncology care setting. Effective interventions to address insomnia that can be easily and quickly learned in the ambulatory setting are needed. Beginning research has begun to address this issue by evaluating a shortened patient-controlled CBT intervention program (Kwekkeboom, Abbott-Anderson, & Wanta, 2010), as well as decreased time commitment (Savard, 2011).

What is going on in my own clinical setting with respect to insomnia?

Armed with the knowledge from the literature review, I wondered how many of the patients in the ambulatory radiation oncology setting where I work experienced insomnia. Did these patients report their sleep issues? Were my colleagues regularly assessing for insomnia? Who was offering evidence-informed solutions to address insomnia?

An informal survey of all of my patients over a period of a few weeks was carried out, asking about the quality of their sleep. Not surprisingly, more than half of these patients said they were not sleeping well and wanted to improve their sleep quality. Further, informal surveys of the clinical ambulatory care environment revealed few of my nurse colleagues had the opportunity to assess or intervene for sleep issues. Despite a symptom management guideline for sleep-wake disturbances being available to nurses to direct their practice in this area, the majority of nurses replied that they usually only addressed this symptom when the patient disclosed a sleep issue, which was rarely. Not enough time, little knowledge about effective interventions for insomnia, and a model of care that was dependent on patients actively reporting their symptoms were reported by nurses as barriers to addressing patients' sleep issues.

Symptom clusters

I also discovered in my practice that cancer patients experiencing insomnia frequently reported other symptoms concurrently, such as fatigue and pain, especially patients who were receiving chemotherapy. While interventions to address pain and fatigue are important, so are interventions to address insomnia, as it can have serious negative effects on managing the other two symptoms and overall quality of life (Langford et al., 2012). Interventions to address insomnia can have beneficial effects on reducing all three symptoms within this symptom cluster (Kwekkeboom, Cherwin, Lee, & Wanta, 2010; Lengacher, Reich, et al., 2012). A symptom cluster is a group of two or more symptoms that occur together, are linked to one another, and are independent of other symptoms (Kim, McGuire, Tulman, & Barsevick, 2005). There is growing recognition of the importance of considering symptoms together rather than individually (Kim et al., 2005).

Addressing the gap: A pilot test of the brief sleep intervention

With the knowledge that there is a gap in care related to insomnia, and that no evidence-informed interventions are available to effectively address insomnia, I decided to formally test the meditation-based sleep intervention that I learned years earlier. As advocates for our patients, it is important that nurses take action to address gaps in care that will improve quality of life.

The brief sleep intervention. Originally developed by Singh (1998), revised by Maharishi Krishnananda Ishaya and further revised by the author, the intervention (See Figure 1) includes three components; abdominal breathing, visualization involving the pineal gland to promote melatonin production¹, and intonation that involves saying the word “ohm” (Singh, 1998). The intervention draws upon tenets of CBT and MBSR with the addition of intonation and is packaged into a brief 15 minute strategy to be practised daily before sleep. Anecdotal evidence of its effectiveness reports that sleep quality improved and insomnia was lessened in a small mixed population of healthy volunteers and people with cancer (Singh, 1998). This intervention was predicted to be easily taught by nurses in the clinical setting and quickly taken up by cancer patients. In addition, it was hypothesized that if practised daily, the intervention would improve patients’ sleep quality, sleep duration, sleep onset latency, and habitual sleep efficiency as well as reduce sleep disturbance, daytime dysfunction, and use of sleep medication.

After reviewing the literature review and brief sleep intervention with clinical, professional practice, and operational leadership, it was determined that pilot testing the intervention was an important and feasible first step to address insomnia in the ambulatory setting. With support of researchers at the University of British Columbia School of Nursing, a proposal to pilot test the feasibility and efficacy of the brief sleep intervention was written and a small internal research grant to conduct the pilot was secured. Additional clinical champions were identified to participate in the recruitment and general facilitation of the project and a review of the model of care within the ambulatory radiation oncology department was conducted to reveal opportunities to operationalize a pilot of the brief sleep intervention. Ethical approval from the UBC Behavioural Ethics Research Board was also obtained prior to start of the pilot study.

The context for the pilot study

The ambulatory radiation therapy care area at the Vancouver Centre, British Columbia Cancer Agency (BCCA), was selected as the setting in which to pilot test the brief sleep intervention. Supportive leadership, a team of engaged nurses, and other interprofessional health care providers, and a large patient population (approximately 200 patients per day) assessed by either a registered nurse (RN) or licensed practical nurse (LPN) were among the factors influencing this decision. To help prepare the nurses to participate in the pilot, education sessions about insomnia in the cancer population were offered, including how to screen, assess, and manage insomnia based on current evidence. Information about the pilot study was then introduced, and discussion about what constitutes “standard practice” with regard to teaching patients about and intervening for insomnia was agreed upon. For those patients not participating in the pilot study, the agreed upon standard of practice for insomnia included symptom assessment and management techniques such as sleep hygiene, stimulus control, and general relaxation techniques.

Included in the pilot were participants who were over 19 years old and registered in the BCCA Radiation Therapy Program, were within six months of diagnosis and/or treatment, and who had self-identified as experiencing insomnia within the past four weeks. Participants excluded were those with pre-existing sleep disorders such as sleep apnea and narcolepsy, non-English

speaking patients, and those unable to provide consent for participation. Potential participants who were on dexamethasone had to be tapering off to be included in the study and their daily dose could not exceed 4 mg.

To facilitate recruitment, small yellow reminder cards with inclusion criteria were inserted into new patient package handouts, and attached to the front of follow-up patient charts. Prior to the start of each clinic, potentially eligible patients were identified, and a letter of information was also attached to their charts. Throughout the day, as nurses assessed patients’ needs, the letter of information was distributed to eligible patients with sleep issues. Physicians also identified patients and handed out the study information. Patients were instructed to contact the principal investigator if they were interested in participating in the study. In addition, posters were placed around the cancer centre in public areas to advertise the study.

Figure 1.

Script

Sleep Intervention

Introduction: Many cancer patients report that they do not sleep well. Using this simple sleep intervention, which consists of abdominal breathing, visualization, and intonation (making a specific sound), may help you to sleep better.

Time: This intervention will take about 15 minutes to do. It should be done each evening, preferably at bedtime, and can be performed lying down or sitting up.

1. For the first 5 minutes, focus on your breathing. Each in-breath and out-breath should be done through the nose and with the abdomen (not with the chest). Put your hand over your abdomen to feel it rise and fall. Spend the same amount of time on the in breath and out breath. Keep your breath connected, flowing, and smooth. We will now do this part together for a little while.
2. For the second 5 minutes, keep the breath smooth and on the inward breath through the nose, imagine that you are making the pineal gland (in the centre of the skull) light up like an intensely bright light. It doesn’t matter if you don’t actually see a bright light. On the out-breath, through the nose, imagine that the pineal gland is sending the whole body what it needs to be healthy. If there is a specific area that needs healing, focus your attention on only that part of the body. We will now do this part together for a little while.
3. For the final 5 minutes, continue the same method for the in-breath, and on the out-breath make a sound “OM”. At first this should be loud enough so you can hear it clearly but, with practice, you can intone the sound quietly enough that someone sitting 15 feet away from you wouldn’t be able to hear it. We will now do this final part together for a little while.

Sleep Intervention adapted from: Singh, Ranjie N. (1998) *Self-Healing: Powerful Techniques*. Health Psychology Associates Inc., London, ON, Canada. (pp. 51-53). ©

1. The circadian rhythm of melatonin released from the pineal gland matches regular sleep hours, and the daily onset of melatonin secretion is linked with the beginning of the sharpest increase in night-time sleepiness (Brzezinski, Vangel, Wurtman, Norrie, Zhdanova, Ben-Shushan, et al., 2005; Paul, Gray, Kenny, & Pigeau, 2003).

Methodology

The pilot study used a pre-post, mixed methods approach to assess the feasibility and efficacy of using the brief sleep intervention to address insomnia. After obtaining informed consent, and successfully completing the two screening tests Mini Mental State Exam (MMSE) to assess cognitive status and the Pittsburgh Sleep Quality Index (PSQI), (Buysse, 1989) (to validate an ongoing sleep issue), participants completed baseline measures. These included a demographic form, an anxiety assessment, and a sleep diary. The demographics captured information such as sleep medications and history of insomnia. Participants were then instructed to use a sleep diary daily to document their practice of using the brief sleep intervention before retiring for the night (i.e., whether or not they used the intervention, ease of use, and sleep quality). Participants were taught the brief sleep intervention in the ambulatory setting.

The researcher contacted the participant by phone one week later to offer support for using the diary and consistent use of the brief sleep intervention. At completion of the study (four weeks), post-implementation measures were completed (PSQI and anxiety assessment), and focus interviews were conducted to capture some of the more subjective and experiential aspects of practising and adhering to the intervention.

What we learned

The specific outcomes of this study are under analysis. Instead, I offer a brief overview of the preliminary findings of the feasibility and efficacy of using this brief sleep intervention in the clinical setting, as well as insights, lessons learned, and recommendations for others interested in conducting clinical research in their setting. It is my hope that these contextual elements will support other nurses who are considering embarking on a similar journey to address a gap in care through research.

Preliminary findings. The preliminary findings of this pilot study look promising. In terms of feasibility, the intervention appeared realistic and practical with high levels of adherence. The intervention was perceived to be easy to teach and patients found it helpful and easy to practise. Some significant improvements in sleep quality were noted upon post-intervention assessment.

What I found inspiring were participants' stories shared during the qualitative interviews. I discovered that this form of data collection was incredibly helpful in understanding the context within which to interpret the quantitative measures of sleep quality. Although the quantitative data we collected were an important part of the results, the qualitative data allowed me to see what was really going on with participants and the effect of the intervention on their lives. Participants also offered feedback on how to improve teaching and the timing of the intervention within the cancer trajectory, strategies to streamline its use to fit their lives, and gratitude for offering an intervention they could take with them wherever they went.

Insights and lessons learned

Throughout this project I saw I am well positioned, as a radiation oncology nurse, to identify unmet needs and address gaps in care, not only for individuals in my care, but also for populations of patients experiencing distressing symptoms, such as insomnia. Although I hesitated at first due to the sheer magnitude of the research project and my role, as a point-of-care health professional rather than a "researcher", I decided to move forward and explore how I could potentially test the intervention. I had to do it for, if I did not, I would always wonder whether or not the intervention was successful. With the support of an interprofessional team, we can promote change and perhaps inspire others to become leaders (or champions) for change.

Hold the vision. It goes without saying that there were challenging times, especially within a fiscally constrained environment. However, by continuing to stay open, moving forward and remembering my vision, support would always appear along the way. I asked when I needed help and it would sometimes come out of the blue to help the study along the way. I learned to never give up.

This project addresses an important gap in care that nurses are perfectly aligned to address. In fact, it is within nursing's social justice mandate and moral imperative to advocate and *act* to improve care for not only the individuals in our care, but also populations of patients experiencing similar challenges (Canadian Association of Nurses in Oncology, 2006; Canadian Nurses Association, 2009, 2010).

Gather support. Obtaining the support of my professional practice leader, clinical leader, and the operational leader for radiation therapy was also crucial to get the study off the ground and maintain it over the three-year period it took to complete the study. This formal support included receiving assistance with research activities, such as ethics applications and statistical analysis, as well as coverage for the investigators' time. I was most fortunate to receive regular time at work to complete the study. This crucial support from the clinical and operational leaders also created the expectation that clinical staff and colleagues were to participate and engage in the study. This engagement was facilitated by understanding that: a) the study would address an important gap in care; b) the intervention, if determined to be effective, would be easily implemented in clinic with cancer patients; and c) the intervention would not add costs to implement in clinic if found to be helpful.

Securing funding from grants offered through the cancer centre was key for the successful and timely completion of the pilot study. Dissemination of research findings at conferences and opportunities to connect with other like-minded clinician-researchers on the topic at both national and international levels was also supported and facilitated by operational support within the radiation therapy department.

Engaging the interprofessional team, which included radiation oncology nurses, radiation therapists, oncologists, and clerks was another important ingredient for success. The team's participation was not only vital for recruitment of participants, but also to raise the profile of the need to consistently and proactively address patients' sleep issues. Two nursing colleagues were instrumental in consistently obtaining informed consent and administering the screening measures. These nurses also functioned as additional contact persons about the study, and regularly assisted me with my clinic to free time to complete the study baseline visits and teach the brief sleep intervention to participants.

Clinical colleagues were invited to participate in the study through education sessions, emails, posters, and small cue cards about the study placed on charts throughout the cancer centre. These avenues, as well as informal verbal reminders and discussions during clinic, helped to keep the study visible and assist with recruitment. For example, I noted that some radiation oncologists were not recruiting in certain tumour site groups. I approached one oncologist and asked him what his thoughts were on sleep issues in his patients. By having this discussion, he realized that patients he thought were ineligible (e.g., a patient waking up because they had pain while on treatment) were, indeed, potentially eligible and he was able to refer a patient for the study by the end of the conversation.

Finding solutions. Conducting a nurse-led study in the clinical setting was not without its challenges. Although this study had the potential to enhance the voice of nursing and foster the independent role of nurses, not all nurses were initially eager to participate. A significant barrier identified to moving the study forward was

limited nursing time with patients, where nurses felt they did not have the time to recruit patients. To minimize the impact of study recruitment on the time nurses had with patients, each morning I identified eligible patients and placed recruitment cards and study information on the front of the chart. This alerted the nurse to potential sleep issues in these patients and streamlined the recruitment process.

In addition to evaluating the feasibility and effectiveness of the brief sleep intervention, implementing the study in the clinical setting had many additional benefits. Unmet needs related to sleep in the cancer population were highlighted and awareness of this gap in care created a stimulus for action. The ongoing education and dialogue about the evidence and theory underlying insomnia interventions gave credibility to MBSR and CBT, and the brief sleep intervention being tested. Exploration of Health Care Professionals' roles in addressing complex symptoms and symptom clusters that include insomnia was fostered through dialogue among the interprofessional health care team members regarding insomnia. Nurses became active participants in the critical thinking process around improvements in care related to insomnia, thus positively affecting the work environment to be solution-focused, thereby enhancing patient care. Further, this visible example of nurse-led research demonstrated to others that it is well within the role of radiation oncology nurses to address gaps in patient care through research.

Communication. Ongoing communication was vital for keeping my clinical colleagues informed and up to date on the study progress. This was achieved at staff meetings, and through emails and informal discussions in clinic. Within these emails and face-to-face communication, I expressed gratitude to my colleagues to show appreciation for their ongoing efforts, and offered study progress updates of recruitment rates and time lines. These communication strategies were effective in fostering ongoing problem solving with respect to recruitment and keeping the profile of the study high and recruitment rates consistent. Also, by connecting with those HCPs who had referred patients for the study, I was able to better understand why some patients who were referred did not participate in the study.

Looking to the future

This study offered an opportunity to pilot test an innovative intervention to address insomnia in the clinical setting. Through this process, I also discovered the challenges and rewards of leading and engaging others in clinically based research. While holding a vision for improving insomnia in cancer patients and with the support of the clinical team, leaders, and researchers, this vision

is well on its way to being realized. If the pilot study preliminary findings are an indication of the final results, it is likely that we will proceed with a larger randomized controlled trial to test the brief sleep intervention. This intervention may become a valuable addition to symptom management guidelines for sleep-wake disturbances.

As oncology nurses, we are well positioned to address this frequent and distressing symptom for the individuals within our care. Further, we have a moral imperative and mandate to advocate and take action to find evidence-based solutions to improve care for populations of patients experiencing gaps in care, such as insomnia in the cancer population. I am grateful for the enthusiasm and support received to be able to enact this aspect of nursing care to benefit populations of individuals experiencing insomnia. ❏

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