

## ARTICLE

# Including the Patient Voice in Patient-Centered Outcomes Research in Integrative Oncology

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## Abstract

The objective of this paper is to describe our experience as patient advisors as we work on a Patient-Centered Outcomes Research Institute–funded project, CHOosing Options for Insomnia in Cancer Effectively (CHOICE). The CHOICE Study is a comparative effectiveness trial comparing acupuncture with cognitive behavioral therapy for insomnia in cancer survivors. We describe the composition of the patient advisory panel, the patient engagement process, and our contributions throughout the study, and we highlight some of our successes so far. Our motivation to contribute to the research process and our hopes for the future of patient-centered outcomes research are discussed.

Patient and stakeholder engagement is a process built on trust, mutual respect, and willingness to collaborate (1). It does not start, nor end, with a specific research protocol. Here we describe our experience as patient advisors on a Patient-Centered Outcomes Research Institute–funded project, CHOosing Options for Insomnia in Cancer Effectively (CHOICE). The CHOICE Study is a comparative effectiveness trial comparing acupuncture with cognitive behavioral therapy for insomnia (CBT-I) in cancer survivors (2).

The CHOICE patient advisory board consists of eight individuals, heterogeneous in their experience of cancer, who work diligently with the research team to maintain the patient-centeredness of this randomized controlled trial. The Principal Investigator and research team spent six years building relationships with us and other stakeholders in preparation for this study. This pre-engagement process aided in the development of the research questions and approach. In the study design phase, we helped develop two primary patient-oriented research questions: 1) “Is acupuncture or CBT-I more effective for treating insomnia in individuals with cancer?” and 2) “Given my situation, which of the two treatments is better for treating insomnia in patients like me?” The advisory board also reviewed the inclusion/exclusion criteria for the study and identified specific areas where the exclusion criteria could be relaxed to be more generalizable without jeopardizing the scientific rigor.

Based on the feedback we provided, the research team incorporated a secondary patient-reported outcome to capture the experience of mental fatigue associated with poor sleep. The patient advisory panel also felt strongly that the study would benefit from incorporating patient interviews to better understand the factors shaping patient decision-making, experience, satisfaction, and outcome. This led to the mixed-methods design as part of the clinical trial.

Each patient advisor has contributed to the execution of the study in a way that is consistent with our interests and skills. During the recruitment phase, several members of the patient advisory board promoted awareness of the study through their connections with the cancer support community. Our advisory members also partnered with the study team and members of the Abramson Cancer Center's Office of Diversity to speak about the CHOICE Study at local cancer support groups and events. As a result of these efforts, the study boasts 32% minority enrollment. This substantial achievement will help reduce disparities in the understanding of the cancer experience and how best to treat common side effects, like insomnia (3), pain (4), and hot flashes (5), in diverse populations. We have helped create a study website as well as a patient-centered blog to reach potential participants and provide evidence-based information about research in an easy-to-understand format. All these efforts have helped the study reach its enrollment goals ahead of schedule.

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As preliminary findings from the qualitative interviews become available, we will use our connections to cancer support organizations to ascertain how closely nonparticipant survivors' realities mirror themes from the qualitative interviews. As the study moves into the dissemination phase, we intend to expand the study's web-based presence and develop patient decision-making materials in order to effectively translate our study findings to patient, stakeholder, and research audiences to ensure that the findings are communicated in understandable and usable ways. Throughout the entire study, the researchers have continually sought our feedback to enhance patient/stakeholder engagement and address specific patient-centered research questions that will ultimately improve clinical care.

As cancer survivors, the meaning we assign our cancer journey and the purposes we uncover from it inform our worldview (6). Our contributions to the CHOICE study have given us a voice among those who shape the evolution of future cancer care. We hope to inspire other researchers and patients to embrace patient-centered integrative oncology studies. We believe patient-centered outcomes research is essential for improving how, when, and where integrative therapies like acupuncture and CBT-I are offered to cancer patients. We describe our past two years as CHOICE Study patient advisors as "gratifying," "healing," "paying it forward," and "giving back." Ultimately, we all hope to leave the oncology waiting room a better place than we found it.

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## Note

CHOICE Study Patient Advisory Board members: Bill Barbour, Winifred Chain, Linda Geiger, Donna-Lee Lista, Jodi MacLeod, Alice McAllister, Hilma Maitland, and Ned Wolff.

## References

1. Frank L, Basch E, Selby JV, Patient-Centered Outcomes Research Institute. The PCORI perspective on patient-centered outcomes research. *JAMA*. 2014; 312(15):1513–1514.
2. Garland SN, Gehrman P, Barg FK, Xie SX, Mao JJ. CHOosing Options for Insomnia in Cancer Effectively (CHOICE): Design of a patient centered comparative effectiveness trial of acupuncture and cognitive behavior therapy for insomnia. *Contemp Clin Trials*. 2016;47:349–355.
3. Garland SN, Carlson LE, Stephens AJ, Antle MC, Samuels C, Campbell TS. Mindfulness-based stress reduction compared with cognitive behavioral therapy for the treatment of insomnia comorbid with cancer: A randomized, partially blinded, noninferiority trial. *J Clin Oncol*. 2014;32(5): 449–457.
4. Mao JJ, Xie SX, Farrar JT, et al. A randomised trial of electro-acupuncture for arthralgia related to aromatase inhibitor use. *Eur J Cancer*. 2014;50(2):267–276.
5. Mao JJ, Bowman MA, Xie SX, Bruner D, DeMichele A, Farrar JT. Electroacupuncture versus gabapentin for hot flashes among breast cancer survivors: A randomized placebo-controlled trial. *J Clin Oncol*. 2015;33(31): 3615–3620.
6. Garland SN, Stainken C, Ahluwalia K, Vapiwala N, Mao JJ. Cancer-related search for meaning increases willingness to participate in mindfulness-based stress reduction. *Integr Cancer Ther*. 2015;14(3):231–239.