

# Palliative Care and Phase 1 Trials

Intervention to improve quality of life and provide education

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**BACKGROUND:** Patients in phase 1 clinical trials often have significant symptom burdens and quality-of-life concerns that increase as they progress along the cancer trajectory and experience drug toxicities from the clinical trial.

**OBJECTIVES:** The interdisciplinary intervention described is aimed at providing optimum palliative care to support patients with solid tumors participating in a phase 1 clinical trial.

**METHODS:** The intervention includes a baseline evaluation using quantitative surveys, a comprehensive palliative care assessment by a research nurse based on patient baseline evaluation, and a goals-of-care discussion by the treating oncologist. The second component includes an interdisciplinary meeting where palliative care recommendations are made, followed by two patient education sessions.

**FINDINGS:** The initial experience with the palliative care intervention suggests a need for support for this population, as well as potential benefits from integrating palliative care for patients enrolled in phase 1 clinical trials.

## KEYWORDS

palliative care; phase 1 clinical trials; quality of life; symptom burden

## DIGITAL OBJECT IDENTIFIER

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**PHASE 1 CLINICAL TRIALS OFFER THE OPPORTUNITY TO ADVANCE SCIENCE** in oncology and improve survival. This article describes the development of an intervention and a study in progress supporting the need for integration of palliative care for patients on clinical trials. In addition, the literature is reviewed to illustrate the palliative care needs of patients in phase 1 trials.

Patients enrolled in phase 1 clinical trials are generally less symptomatic and have higher function than patients with advanced disease. However, patients in phase 1 trials still have a significant symptom burden. A study by Hui et al. (2010) reported that patients in phase 1 trials had better performance scores (Eastern Cooperative Oncology Group, 0–4), but a symptom burden similar to other patients with cancer, with an average pain score of 5.3 on a 0–10 scale (with 10 indicating worst pain) and a fatigue score of 5.7 on a 0–10 scale (with 10 indicating worst fatigue). Ninety percent of patients in phase 1 trials experienced fatigue, but only 24% experienced vomiting (Parsons, Baracos, Dhillon, Hong, & Kurzrock, 2012). In a study by Finlay, Lu, Henderson, O'Dwyer, and Casarett (2009), patients in phase 1 trials had a symptom burden similar to non-enrolled patients, but after adjustments for performance status scores, the patients in phase 1 trials were more likely to have 5 of the 10 symptoms assessed with the Memorial Symptom Assessment Scale, with greater severity for 6 of 10 symptoms.

In addition to a baseline symptom burden, phase 1 trials are known to increase patient symptoms. As patients progress on the cancer trajectory, performance status worsens and symptoms increase. Clinical trial drugs may have toxicities that cause side effects and increase clinic visits, time away from family, and diagnostic testing. Targeted therapy may cause side effects in addition to existing disease and medication side effects (Cassel et al., 2016). These contribute to a decrease in quality of life (QOL).

Research has revealed that patients in phase 1 trials are highly motivated and willing to take treatment chances. In a report by Agrawal et al. (2006), 90% of patients in a phase 1 trial would risk taking an unproven drug with a 10% chance of mortality. In the same study, 84% of patients said they were aware of hospice and palliative care options, but only 6% had considered these options. However, more recent research reflects patients' unwillingness to participate in clinical trials, with only 35% of Americans saying that