Neurooncol Pract. 2025 Apr 12;12(5):850-862. doi: 10.1093/nop/npaf038. eCollection 2025 Oct.

FearLess in Neuro-Oncology: Phase I trial targeting fear of cancer recurrence in patients with primary malignant glioma and their caregivers

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PMID: 41080203 PMCID: PMC12508744 (available on 2026-04-12) DOI: 10.1093/nop/npaf038

Abstract

Background: Individuals with glioma endorse high fear of cancer recurrence or progression (FCR), yet existing interventional studies for FCR exclude glioma patients. Components of existing FCR interventions are not entirely translatable to those with glioma as they were designed for non-central nervous system (non-CNS) cancer populations with less risk for recurrence, minimal-to-no neurologic sequelae, and different sources of worry.

Methods: A two-stage Phase I ORBIT Model process was employed: Phase Ia included consultation with international FCR experts and two advisory boards toward the development of an intervention targeting FCR in neuro-oncology. Recommendations resulted in a 6-module mindfulness-based cognitive-existential intervention: *FearLess in Neuro-Oncology*. Phase Ib included a quasi-experimental pilot trial of telehealth *FearLess* in patients (n = 6), caregivers (n = 6), and patient-caregiver dyads (n = 10) with a primary aim of assessing feasibility/acceptability and an exploratory aim of characterizing change in FCR and other psychological outcomes.

Results: Phase Ia results supported an individual- or dyadic-level intervention with an emphasis on the inclusion of caregivers, a focus on individuals affected by malignant gliomas, and strategies to address glioma-specific FCR hypervigilance symptoms. Our phase Ib trial demonstrated adequate rates of enrollment, measure completion, retention, and satisfaction; however, screening rates (successful screening of those interested) were lower among caregivers.

Conclusion: Findings support continued optimization of *FearLess in Neuro-Oncology*. Targeted recruitment strategies are needed to reach caregivers, who engaged with and benefitted from the intervention, but were difficult to enroll and retain when not participating as a dyad. Participants reported high perceived benefit and utility of the strategies learned in the intervention.