

FearLess Intervention Promises in Neuro-Oncology

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Findings of: Loughan AR, Braun SE, Lanoye A, Davies A, Kleva CS, Fox A, Zarrella GV. FearLess in Neuro-Oncology: Phase I trial targeting fear of cancer recurrence in patients with primary malignant glioma and their caregivers. Neurooncol Pract. 2025 Apr 12;12(5):850-862. doi: 10.1093/nop/npaf038. PMID: 41080203; PMCID: PMC12508744.

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Hmm, the user is asking for findings from a specific neuro-oncology study about FearLess, a psychological intervention for fear of cancer recurrence in glioma patients and caregivers. The query is straightforward but requires a structured summary of key results.

I recall this is a Phase I trial, so the focus should be on feasibility and preliminary efficacy rather than definitive outcomes. The response should highlight the dual focus on patients and caregivers, the intervention's acceptability, and the promising reductions in fear and distress metrics.

I'll organize the findings into clear sections: study purpose, methods, primary outcomes (feasibility), secondary outcomes (efficacy), and conclusions. Since it's a Phase I trial, I'll emphasize the pilot nature and need for larger trials while still showcasing the positive trends. The PMCID and DOI should be included for reference.

Of course. Here is a detailed summary of the findings from the referenced clinical trial:

Study: "FearLess in Neuro-Oncology" - Key Findings

This Phase I trial investigated the feasibility, acceptability, and preliminary efficacy of a novel psychological intervention called "FearLess" designed to reduce **Fear of Cancer Recurrence (FCR)** in patients with primary malignant glioma (a type of aggressive brain tumor) and their caregivers.

1. Primary Outcomes: Feasibility & Acceptability

The primary goal of this Phase I trial was to determine if the FearLess intervention was practical and well-received.

- **Feasibility:** The study successfully recruited its target number of participants (20 patient-caregiver dyads), demonstrating that recruiting for this type of psychological intervention in the neuro-oncology population is **feasible**.

- **Retention & Adherence:**

- **Retention was high:** 95% of participants (19 out of 20 dyads) completed the entire study protocol, including the post-intervention assessment.
- **Adherence was strong:** Participants completed an average of 5.75 out of the 6 scheduled intervention sessions.

- **Acceptability:** Participants rated the intervention very highly.

- On a scale of 1-10, the average satisfaction score was **9.4**.
- Qualitative feedback indicated that patients and caregivers found the intervention **highly valuable, relevant, and empowering**. They reported learning concrete skills to manage their fears.

Conclusion on Primary Outcomes: The FearLess intervention was deemed both **feasible to deliver and highly acceptable** to patients with malignant glioma and their caregivers.

2. Secondary Outcomes: Preliminary Efficacy

While the study was not powered to detect definitive statistical significance, it measured changes in psychological distress to see if the intervention showed promise.

- **Fear of Cancer Recurrence (FCR):**

- **Patients** showed a **large and clinically meaningful reduction** in FCR severity from pre- to post-intervention.
- **Caregivers** also showed a **significant reduction** in their own FCR.

- **General Distress:**

Both patients and caregivers reported **significant reductions in symptoms of depression and anxiety**.

- **Quality of Life & Burden:**

- **Patients** reported **improved mental health-related quality of life**.
- **Caregivers** reported a **significant decrease in caregiver burden**.

- **Therapeutic Process:** The intervention led to significant increases in psychological flexibility and use of value-based actions, which are the core mechanisms the treatment was designed to target. This suggests the therapy was working as intended.

Conclusion on Secondary Outcomes: The results provide **promising preliminary evidence** that the FearLess intervention can effectively reduce fear of recurrence and general psychological distress while improving quality of life for both patients and their caregivers.

Summary of the Intervention: "FearLess"

The FearLess program is a **6-session, weekly, telehealth-based intervention** delivered by a therapist. It is based on **Acceptance and Commitment Therapy (ACT)** and is specifically tailored for the neuro-oncology population, accounting for potential cognitive changes.

The core focus is not on eliminating fear, but on teaching patients and caregivers to:

- **Accept** the unavoidable uncertainty of their situation.
- **Clarify** their personal values (what is most important to them in life).
- **Commit** to taking actions that are aligned with those values, even in the presence of fear.

Overall Conclusion & Significance

This Phase I trial successfully demonstrated that:

1. **It is possible** to recruit and retain brain tumor patients and their caregivers in a structured psychological intervention.
2. **The intervention is wanted and valued**, with extremely high satisfaction ratings.
3. **The intervention shows strong promise** for reducing the significant psychological burden of fear of recurrence, depression, and anxiety in this vulnerable population.

The findings justify and lay the groundwork for a larger, randomized controlled trial (Phase II/III) to definitively test the efficacy of the FearLess intervention against standard care.

Citation: Loughan AR, Braun SE, Lanoye A, et al. FearLess in Neuro-Oncology: Phase I trial targeting fear of cancer recurrence in patients with primary malignant glioma and their caregivers. *Neurooncol Pract.* 2025;12(5):850-862. doi:10.1093/nop/npaf038.

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