



# Clinical trial of feasibility for mindfulness intervention for patients with newly diagnosed high grade glioma

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## Abstract

**Purpose** With a bleak prognosis for malignant glioma, maintaining quality of life (QoL) and decreasing distress are essential in patient clinical care. Mindfulness meditation is a mind-body therapy that is being investigated as a non-pharmacological strategy to alleviate cancer symptoms and improve QoL. Given the potential of this intervention, we hypothesized that mindfulness meditation is feasible and may benefit patients with brain tumors on active therapy by decreasing stress and anxiety.

**Methods** Patients with newly diagnosed WHO grade 3–4 malignant glioma were enrolled to evaluate the feasibility of a mindfulness intervention that coincided with standard of care chemoradiation. The intervention consisted of six weekly one-hour telephone-based mindfulness sessions followed by one in-person mindfulness session. QoL was measured by standardized patient-reported outcome questionnaires pre- and post-intervention. Feasibility was assessed within three domains: acceptability, demand, and implementation.

**Results** Over a four-month period, 27 patients were offered the opportunity to participate in this study, of which 15 participated. Median age at enrollment was 60 years (range 28–76 years), with enrollees being predominantly female (73.3%) and white (100%). The average percentage of sessions that the patient attended was 82.86% (SD = 28.16). Of the 10 patients who completed the exit interview, 70% indicated they would continue practicing mindfulness. For patients that attend all seven sessions, >50% of patients found the sessions beneficial.

**Conclusions** Mindfulness intervention during active treatment for patients with high grade glioma is feasible. Given these results, a larger study has the potential to benefit patients with high grade glioma on active treatment.

**Keywords** High grade glioma · Mindfulness · Feasibility · Quality of life · Distress

Dina M. Randazzo: Included posthumously.

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## Abbreviations

FACIT-F	Functional Assessment of Chronic Illness Therapy – Fatigue
FACIT-Sp12	Functional Assessment of Chronic Illness Therapy – Spirituality
FACT- Br	Functional Assessment of Cancer Therapy - Brain
FACT-Cog	Functional Assessment of Cancer Therapy – Cognition
FFMQ-SF	Five Facet Mindfulness Questionnaire – Short Form
GBM	Glioblastoma
HADS	Hospital Anxiety and Depression Scale
KPS	Karnofsky Performance Status
NCCN	National Comprehensive Cancer Network
WHO	World Health Organization

PRTBTC	Preston Robert Tisch Brain Tumor Center
PSQI	Pittsburgh Sleep Quality Index
QoL	Quality of Life
RDSP	Research Data Security Plan

## Introduction

High grade gliomas (WHO grade 3–4) represent the most common malignant brain tumors in the adult US population [1, 2]. Patients with these tumors, in particular glioblastoma IDH wildtype (WHO grade 4), will experience a shortened life expectancy despite aggressive therapies such as surgery, radiation therapy, and chemotherapy. From diagnosis to end of life, patients with high grade glioma are likely to have impairment in quality of life (QoL), leading to physical and psychosocial distress. These challenges often are observed during the earlier stages of their initial standard of care chemoradiation [2].

The main QoL areas of concern for patients with malignant primary brain tumors include fatigue, sleep, pain, seizures, mood, and cognitive impairment; with fatigue being the primary determinant of reduced QoL in malignant glioma patients [3]. While many studies have identified how QoL is impaired in brain tumor patients, interventions to improve QoL and distress remain limited. Previous studies have shown that QoL can be prognostic for overall survival (OS) [2], even furthering the importance of maintaining or, if possible, improving the QoL in this patient population [4].

One potential intervention that could impact QoL is mindfulness meditation, a mind-body therapy that is gaining acceptance in oncology [5]. The benefits of mindfulness can extend to reducing distress levels [6, 7]. Mindfulness has been extensively studied in various oncology fields, including breast [8, 9], prostate [10, 11], and others [12], but has not been studied in the brain tumor population. The mindfulness meditation practice teaches the patient to be engaged in the present experience without distraction by thoughts of previous experiences or an anticipated future, thus providing a method of coping with stressful experiences [5]. Many mindfulness meditation programs include 7–10 weekly, one to three-hour, in-person group sessions followed by a silent retreat. Group sessions consist of instruction on meditation fundamentals, including mindful body movement and breath awareness. Participants are often encouraged to practice mindfulness individually on a daily basis, which may be guided by an audio recording [5, 13].

Previous research has reported that patients with primary brain tumors use complementary and alternative medicine (CAM) interventions, including mindfulness meditation. In a retrospective analysis of 845 primary brain tumor patients, 76% reported using CAM, with meditation being the third

most commonly reported self-help practice [14]. In another study of 470 patients, 77% of patients with GBM reported using CAM [15]. These studies demonstrate brain tumor patients are interested in CAM and that a significant proportion are already incorporating mindfulness meditation practices.

Mindfulness meditation practice may benefit the newly diagnosed brain tumor patient by decreasing stress and anxiety, and by providing a means to cope with their diagnosis. Mindfulness meditation may serve as a way to mitigate the patient's anxiety and fear, ultimately decreasing their distress and improving QoL during this stressful time. Given that mindfulness meditation is a learning experience and provides a coping tool, it can potentially benefit the brain tumor patient throughout their disease trajectory. Similar to early palliative care interventions, adding a mindfulness intervention at the start of the therapeutic journey for high-grade glioma patients could be challenging; therefore, finding a feasible and acceptable way to deliver this intervention during chemoradiation has the potential to transform the patient experience.

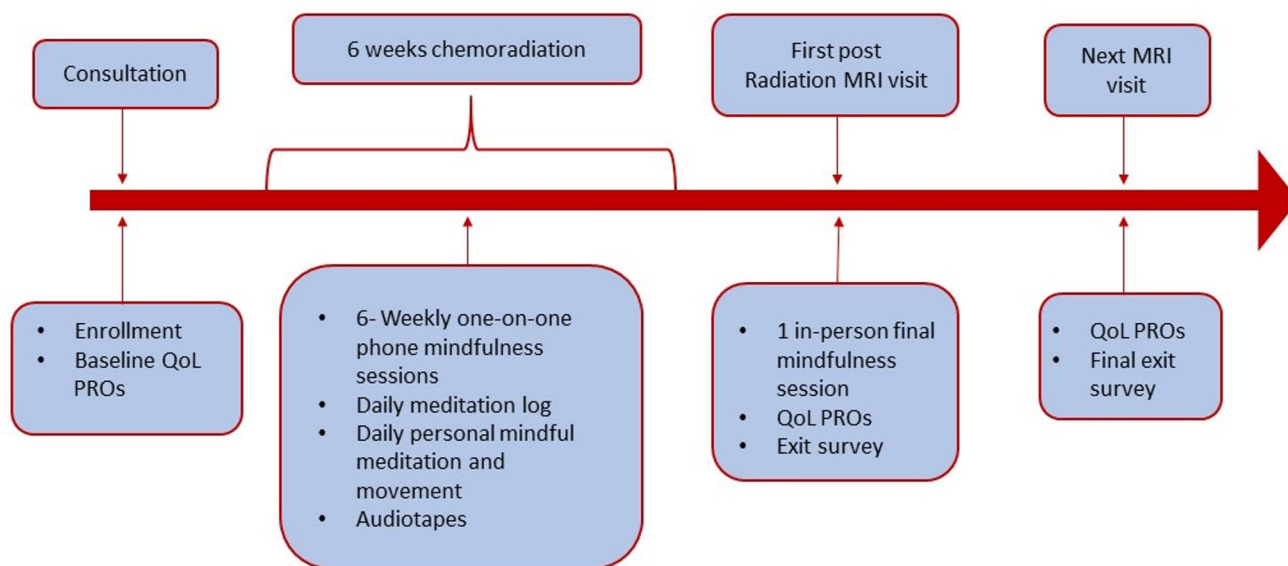
This pilot study tested the feasibility of implementing a mindfulness intervention for newly diagnosed malignant glioma (WHO grade 3–4) patients beginning during the first week of standard of care chemoradiation.

## Methods

### Design

This single-institution, single-arm study is designed to evaluate the feasibility of a mindfulness intervention in newly diagnosed malignant glioma patients during standard of care chemoradiation (Fig. 1) (NCT03915912, Registration Date 4/12/2019). Approval was obtained from the institutional review board at Duke University. The procedures used in this study adhere to the tenets of the Declaration of Helsinki. Informed consent was obtained for all participants. Following informed consent, patients completed baseline assessments, including patient-reported outcomes (PROs) for QoL, distress, and cognitive testing. Patients then began the mindfulness intervention, consisting of six weekly telephone-based mindfulness sessions followed by one in-person mindfulness session. Post-treatment measures and an exit survey (survey A) were administered following the one in-person mindfulness session. Two months later, the QoL, cognition, and distress assessments were repeated, and a final exit survey (survey B) was administered. The *exit survey (survey A)* asked the patient about their individual mindfulness practice during the intervention, their intention to continue the practice beyond participation in this study,

## STUDY SCHEMA



**Fig. 1** Study Schema: quality of life (QoL), patient-reported outcomes (PROs) A schematic representation of the study design, illustrating the flow of participants through the mindfulness intervention study. Key phases include recruitment, eligibility screening, baseline assessments,

6 weekly one-on-one telephone-based mindfulness sessions, one in-person mindfulness session, and follow-up assessments for QoL and distress

their satisfaction with the services received, and their perception of the program’s effectiveness. The *final exit survey (survey B)* asked the patient about their mindfulness practice since the exit survey, and their intention to continue with the mindfulness practice. Demographic data, such as age, marital status, education, employment, date of diagnosis and death, tumor grade, histology, and type of treatment were collected.

### Inclusion / Exclusion criteria

The inclusion criteria were the following: 1) Histologically confirmed, newly diagnosed WHO grade 3 or 4 malignant glioma, 2)  $\geq 18$  years of age, 3) Karnofsky Performance Status (KPS)  $\geq 70$ , 4) National Comprehensive Cancer Network (NCCN) distress scale  $\geq 4$  OR at least one of the following problems indicated on the NCCN distress thermometer worksheet: depression, fears, nervousness, sadness, worry, loss of interest in usual activities, sleep, memory, or fatigue, 5) Planned 6-week standard of care chemoradiation regimen, 6) Have access to phone and internet, 7) Ability to communicate in English, and 8) Written informed consent. The exclusion criteria included the following: (1) Patients who were previously or currently practicing or participating in mindfulness meditation practice, (2) Intermittent or active psychosis, (3) Psychiatric hospitalization within the

last 6 months, and (4) hospitalized in a rehab facility within the last 6 months for treatment of substance abuse.

### Study intervention

The study intervention consisted of seven mindfulness sessions (six 1-hour telephone sessions and one 1-hour in-person session, delivered by a trained therapist). Telephone-based training sessions accommodated busy patient schedules and long-distance patients, given that many patients seen at this clinic travel long distances for clinic visits. The six-weekly telephone-based mindfulness sessions occurred in a one-on-one format. They were followed by one in-person, one-on-one session at the post-chemoradiation standard of care clinic visit for these patients.

The telephone mindfulness sessions considered the following topics: Mindfulness and healing; understanding stress; abiding in kindness and self-compassion; working with difficult emotions; finding peace/deepening practice; review and lessons learned; going forward, living fully. Additionally, patients were provided with supplemental materials, including website references and guided audio-tape meditations to guide their individual practice outside of the weekly guided sessions. At the start of each telephone session, the therapist reviewed the patient’s mindfulness practice over the previous week, including any barriers they encountered in their mindfulness practice. The trained

mindfulness therapists documented the aforementioned information and patient attendance by completing a survey implemented by RedCap.

The in-person mindfulness session was about one hour and occurred at the patient's standard of care clinic visit after completing six telephone-based mindfulness sessions and chemoradiation. The in-person session consisted of a review of mindfulness practices, acknowledgment of patient practice, and how to sustain a mindfulness practice going forward, at the discretion of the mindfulness therapist. Every attempt was made to have the patient interact with the same therapist throughout all seven mindfulness sessions, both telephone and in-person session(s).

It is key to note that the rationale for mainly conducting telephone-based sessions was that our facility is a tertiary referral center, with patients traveling for consultations but not necessarily receiving standard-of-care chemotherapy and radiation at our facility. To provide this clinical trial opportunity to a broader range of our populations, the decision was made to conduct most sessions by telephone.

### Measures of feasibility and acceptability

The feasibility of this study was assessed within three main areas of focus: acceptability, demand, and implementation. The *acceptability* of the intervention was evaluated by the number of sessions that the patient attends, patients' satisfaction with mindfulness sessions (from the exit survey (survey A)), the percentage of patients who intend to continue meditation during the two months after study completion (from the exit survey (survey A)), and the percentage of patients who continued meditation during the two months after study completion (from the final exit survey (survey B)). *Demand* was assessed by the total time required to enroll fifteen patients, and the percentage of patients offered the study who enrolled in the study. In terms of *implementation*, feasibility was determined by the percentage of patients who completed the study questionnaires. The percentage of patients who completed each questionnaire at each time point was calculated. All questionnaires needed to be done to count for questionnaire completion.

A frequency distribution was generated that describes the number of sessions that the patient attended. The intervention will be considered potentially feasible if >50% of patients attend at least three of the six telephone-based mindfulness sessions and the in-person session. However, other factors as measured by the various endpoints described above and described below will also be considered in the final deliberation of feasibility.

Fifteen patients were accrued to this exploratory pilot study to assess the feasibility of conducting a mindfulness meditation intervention among patients newly diagnosed

with high grade glioma. A comparison of changes observed in this study and those observed in the historical control group was dependent on the actual number of patients with follow-up assessments in each group. For power calculation, it was assumed that about 12 mindfulness patients and 80 control subjects at a particular time point, the comparison will have 80% power to detect a large effect size (standardized mean difference of 0.87) with a two-tailed t-test ( $\alpha=0.05$ ).

### QoL PROs and distress scores

QoL/distress assessments were conducted at screening, after completion of chemoradiation, and at follow-up, and included the Functional Assessment of Cancer Therapy-Cognitive Function (FACT-Cog) [16], the Pittsburgh Sleep Quality Index (PSQI) [17], the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) [18], the Functional Assessment of Cancer Therapy-Brain (FACT-Br) [19], the Five Facet Mindfulness Questionnaire – short form (FFMQ-SF) [20], the Functional Assessment of Chronic Illness Therapy-Spiritual Well-Being (FACIT-Sp12) [21], the NCCN Distress Thermometer with Symptom Inventory [22, 23], and the Hospital Anxiety and Depression Scale (HADS) [24].

### Statistical analysis and sample size considerations

Multiple descriptive analyses were performed to summarize the results of this study. For the primary endpoint of feasibility, frequency distributions were calculated to summarize patient attendance at mindfulness sessions and patient and therapist responses to study surveys. The total time to enroll 15 patients was calculated as the number of months from the beginning of recruitment until 15 patients were enrolled who also completed a baseline mindfulness session. For the exploratory objectives relating to QoL and cognition, the mean and standard deviation of scores and score changes from baseline for each subscale were calculated at each assessment.

All analyses of summary statistics were performed using SAS 9.4 (SAS Institute, Cary, NC) while data visualizations were created using the R software, version 4.3.2 (R Foundation for Statistical Computing, Vienna, Austria), and the ggplot2 package, version 3.4.4 (H. Wickham. ggplot2: Elegant Graphics for Data Analysis. Springer-Verlag New York, 2016).

**Table 1** Patient demographics

	All Patients	
	N	%
<b>Total</b>	15	100.0
<b>Gender</b>		
Female	11	73.33
Male	4	26.67
<b>Race</b>		
White	15	100.00
<b>KPS</b>		
70	3	20.00
80	6	40.00
90	6	40.00
<b>Education Level</b>		
High School	2	13.33
College	6	40.00
Graduate School/Professional Degree	7	46.67
<b>Marital Status</b>		
Married	12	80.00
Divorced	2	13.33
Partnership/Living with Significant Other	1	6.67
<b>Newly Diagnosed</b>		
Yes	15	100.00
<b>Histology</b>		
Glioblastoma	10	66.67
Gliosarcoma	1	6.67
Astrocytoma (WHO grade 3)	4	26.67
<b>NCCN Distress Score at Baseline</b>		
<4	6	40.0
≥4	9	60.0

## Results

### Patient characteristics

Between April and July 2019, 27 patients were approached for participation, and 17 patients consented to participate in the study. Before starting the study, two patients withdrew and did not participate in any mindfulness sessions. One patient withdrew because one enrolled in a different clinical trial. One patient withdrew in light of a post-operative infection that required further treatment and surgery. Fifteen patients participated in mindfulness sessions during chemoradiation. The time period to enroll these fifteen patients was 3.88 months.

The patient demographics and characteristics are summarized in Table 1. The median age was 60 years (range 28–76 years). Most patients were female (73%), and all patients enrolled were white. All patients had a high-grade glioma, with Grade 4 being the most common diagnosis (73%). The mean NCCN distress score at the screening time was 4.8 (SD=3.14) (scores scale from 0 to 10 with lower scores indicating less distress).

**Table 2** Feasibility outcomes during mindfulness study. Evaluation of study feasibility, detailing patient session attendance, mindfulness practice rates, receptiveness to mindfulness training, and patient-reported benefits

Outcome Descriptor	Number of Patients (%)
Number of sessions patient completed	1–3 sessions: 3 / 15 (20%) 4–6 sessions: 5 / 15 (33.3%) 7 sessions: 7 / 15 (46.7%)
Number of sessions where patient reported practicing mindfulness weekly	None: 2 / 15 (13.3%) 1–4 sessions: 6 / 15 (40%) 5–7 sessions: 7 / 15 (46.7%)
Number of sessions where patient reporting sessions were beneficial	1–3 sessions: 3 / 15 (20%) 4–6 sessions: 4 / 15 (26.7%) 7 sessions: 8 / 15 (53.3%)
Patient receptive to mindfulness training	Yes: 13 / 15 (86.7%) No: 2 / 15 (13.3%)
Exit Survey (Survey A): How would you rate the quality of the course?	Good to Excellent: 8 / 10 (80%) Fair to Subpar: 2 / 10 (20%)
Exit Survey (Survey A): Will you continue your meditation practice?	Yes: 8 / 10 (80%) No/Unanswered: 2 / 10 (20%)

### Descriptors of the intervention

Of the 15 patients who participated in the study, 73% of the patients attended 6 or 7 sessions with the therapists, and 66.6% of patients reported mindfulness practice in the past week at 5 or 6 sessions. Most of these sessions occurred without the caregiver present. Almost without exception, the therapist believed the patient benefitted from the session and was receptive to mindfulness training.

### Feasibility

Feasibility was assessed using the following focus areas: (1) Demand, (2) Acceptability, and (3) Implementation. To assess the feasibility of the mindfulness intervention, we measured the frequency of session attendance, weekly mindfulness sessions, perceived benefit of sessions, and participant receptivity to mindfulness training (Table 2).

**Demand** Demand was assessed by the total time required to enroll 15 patients, and the percentage of patients offered the study who enrolled in the study. As noted earlier, 56% (15/27) of the patients who were approached to participate in the study participated. These 15 patients were accrued over a period of 3.88 months.

**Acceptability** The acceptability of the intervention was assessed by the number of sessions that the patient attended, patients' satisfaction with mindfulness sessions, the percentage of patients who intended to continue meditation during the 2 months after study completion, and the percentage of patients who continued meditation during the 2 months after

**Table 3** Mean scores and mean change from baseline in Patient-Reported outcomes scores and NCCN distress score during mindfulness study

Score	All Patients			Patients with Baseline and Follow-up							
	Baseline			Baseline		Post-Intervention (Follow-up)		Change from Baseline			
	N	Mean	Std Dev	N	Mean	Std Dev	Mean	Std Dev	Mean	Std Dev	
Brain Cancer Subscale (range 0–76)	15	49.07	11.8	7	51.00	12.25	57.14	17.32	6.14	11.16	
FACT-Br: TOI (range 0-132)	15	86.13	20.06	7	89.71	16.70	99.57	26.71	9.86	18.82	
FACT-Br: Total (range 0-184)	15	127.31	20.88	7	131.76	16.35	144.93	28.74	13.17	23.37	
NCCN distress score (range 0–10)	15	4.80	3.14	9	5.11	2.85	3.89	3.69	-1.22	3.38	

study completion. Greater than 50% of the patients completed the QoL questionnaires at the post-chemoradiation, in-person visit. 60% of patients completed one or more of the QoL questionnaires at the final follow-up visit. 73% study participants attended 6 or 7 sessions, while 2 study participants (13%) attended only 1 or 2 sessions (Table 2). These data indicate that the intervention was feasible given the attainment of pre-specified criteria: >50% of patients attended  $\geq 3$  telephone-based mindfulness sessions and the in-person session.

The percentage of patients who intended to continue meditation during the 2 months after study completion, and the percentage of patients who continued meditation during the 2 months after study completion were collected from 10 patients on the exit survey (survey A) form that was collected at the last session. Table 2 provides a summary of responses to select questions on that questionnaire.

10 patients completed the exit survey (survey A), 9 of whom also completed the final exit survey (survey B). In terms of satisfaction, 8 of 10 patients rated the mindfulness course as “good” or better. Regarding post-study intentions, 7 of 10 patients expressed their intention to continue practicing mindfulness during the exit interview. Subsequently, during the final exit survey (survey B), 7 out of 9 patients confirmed that they indeed continued their mindfulness practice during the 2 months following the study completion.

**Implementation** We assessed the feasibility of longitudinal evaluation of QoL administered within the context of a mindfulness intervention study. Specifically, the percentage of patients who completed each questionnaire at each time point was calculated. At baseline, all patients completed the QoL/PRO questionnaires. Of the 15 patients, 9 provided assessments at their post-chemoradiation session, and 7 provided assessments at the subsequent follow-up.

Patients reported several reasons for not completing follow-up assessments, including hospitalizations. Some patients experienced severe health issues that required hospitalizations, scheduling conflicts or personal reasons. A few patients withdrew from the study without specifying their reasons.

## Quality of life and distress assessments

QoL and distress were assessed using patient-reported outcomes (PROs) at three timepoints: baseline (screening), post-chemoradiation, and follow-up post-intervention. The key measures used for these assessments included the Functional Assessment of Cancer Therapy-Brain (FACT-Br), which evaluates QoL specific to brain cancer and the NCCN Distress Thermometer, which assesses emotional distress.

Baseline measurements on QoL in this study indicated moderate levels of distress typical in glioma patients, with an average NCCN score of 4.8 (SD=3.14), and a FACT-Br score of 127.31 (SD=20.88), indicating cognitive and physical challenges (Table 3). The post-treatment average NCCN score was 3.5 (SD=3.47) (lower score=less distress) and FACT-Br score was 144.93 (SD=28.74) (higher score=better responses). These scores show a trend towards stabilization and a possible decrease in distress in glioma patients, though statistical significance was not achieved due to sample size limitations (Table 3).

## Discussion

This study demonstrates that a mindfulness intervention for newly diagnosed brain tumor patients is feasible during standard of care chemotherapy and radiation therapy and deliverable via telephone-based sessions. Mindfulness meditation practice may benefit the newly diagnosed brain tumor patient by decreasing stress and anxiety, and by providing a means to cope with their new diagnosis. The highest levels of distress in the brain tumor population have been shown to occur right after diagnosis [25, 26], with 77% of patients finding the diagnosis itself highly distressing [25]. The physical, psychological, and emotional effects have a rapid onset such that a once self-sufficient person becomes reliant on a caregiver for day-to-day activities, with a significant reduction in QoL and increased levels of distress. It is exceedingly difficult for a person to cope with all these changes at once as well as the anxiety and fear of the brain tumor recurring and their impending death. Mindfulness meditation may serve to mitigate the patient’s anxiety and fear, ultimately decreasing their distress and improving QoL

during this tumultuous and stressful time. Given that mindfulness meditation is a learning experience and provides a coping tool, it can potentially benefit the brain tumor patient throughout their disease trajectory. Given the challenges inherent to clinical research in glioma, especially in interventions aimed at QoL improvements, the feasibility of implementation is a crucial first step. This trial assesses the feasibility and acceptability of a mindfulness intervention to target distress and anxiety symptoms in patients with WHO grade 3 or 4 malignant glioma patients. Our findings indicate that this mindfulness intervention surpassed the predefined feasibility benchmark of >50% patient attendance, with 73.3% of participants attending the majority of the seven sessions. Additionally, the enrollment time for all patients was less than 6 months. This level of engagement is promising, suggesting that mindfulness may be a viable, non-pharmacological approach to supporting QoL in WHO grade 3–4 malignant glioma patients.

Our center is a tertiary referral center that sees patients from all 50 states and some international locations. Commonly, patients are seen by our providers for the initial visit for diagnosis, prognostication, and initial treatment planning, but the course of radiation therapy with chemotherapy for newly diagnosed high grade gliomas will occur in the community. Because of this situation, telephone-based individual mindfulness sessions were chosen to make the intervention more accessible, less time-intensive, and less expensive, as they do not require frequent travel over long distances.

Similar to this current study, others have explored other types of meditation in brain tumor patients to promote wellness and maintaining quality of life. One such study was an online couple-based meditation intervention for patients with brain tumors and their care partners [27]. This study focused not only on patients with primary brain tumor but also metastatic brain tumors and enrolled 35 dyads to receive couple-based meditation program or usual care. The study aimed to have the dyads attend four weekly sessions and the mean session attendance was 3.33, thus it was deemed to be feasibility. Moreover, in another study by Milbury and colleagues, they evaluated the feasibility of integrating yoga into the treatment journey for glioma patients and their care partners [28]. They divided the intervention into dyad yoga intervention, care partner only yoga intervention, and usual care dyad. Interestingly, the yoga intervention was more feasibility in the care partner only group in comparison to the dyad. It is key to point out that our study focused only on the patient's experience, but with results from Milbury and colleagues study on dyad yoga intervention versus care partner only yoga intervention, one could posit that choosing the "correct" population to intervene with on these types of intervention requires careful consideration. Studying

high grade glioma patients alone provides insight into their individual symptoms, cognitive function, and QoL without external influences, allowing a more precise assessment of disease-related changes. In contrast, studying patients with their caregivers as a dyad captures the dynamics of shared decision-making, emotional support, and caregiver burden, which directly impacts clinical outcomes and adherence. Comparing these approaches could clarify how social and environmental contexts modify patient QoL and outcomes. Integrating both perspectives in this mindfulness can help learn not only about the feasibility and acceptability of the intervention but also how it can impact QoL beyond the patient's own experience. Moreover, a dyadic approach would give one a more effective, family-centered model of care for patients with newly diagnosed high grade glioma.

The main limitation of this trial was its small sample size. The lack of a control group in this pilot study is a limitation and precludes our ability to assess efficacy of mindfulness meditation. This study focused on feasibility metrics such as demand, acceptability, and implementation, allowing for the exploration of patient engagement and program practicality. Additionally, the high dropout rate, while common in glioma studies due to health complications, highlights the need for future research that considers the frequent disruptions faced by this patient population. Retention rates in this study are comparable to that seen in longitudinal studies of QoL in patients with malignant gliomas, where maintaining long-term follow-up remains a challenge [29, 30]. Because the sample size is small, one cannot avoid the possibility of selection and expectation bias.

Despite the higher incidence of gliomas in males, our study sample was predominantly female (73%). This discrepancy may warrant further exploration of gender-based differences in willingness to enroll in mindfulness-based interventions, interest levels, accessibility, or other factors. Further demographic information from the groups enrolled in this study reveals a subset of patients more accepting of mindfulness; this pattern may guide recruitment in further mindfulness intervention studies. Additionally, our study population lacked ethnic diversity as the entire population was white. Future studies must aim to enroll more diverse populations and probe all patients—males and females—who decline to participate in studies such as this one, and why they decline. Factors to focus on can include time commitment, work obligations, travel time, trust in research, and perceptions of benefit or risk.

Another notable limitation, particularly for informing the secondary endpoints such as QoL PROs, is the absence of a control group. This study was designed to generate pilot data for a larger, more comprehensive study that could better evaluate the effects of a mindfulness intervention on

patient-reported QoL during chemoradiation for patients with newly diagnosed high-grade glioma.

Despite these limitations, the findings of this preliminary study are encouraging. Overall, the intervention and study procedures were feasible based on the short time it took to recruit subjects, the high number of sessions attended by each subject, the subjects' high satisfaction with the program, and the high number of QoL PROs completed. Based on the exit survey, this intervention received positive feedback, with 70% of patients indicating intentions to continue the mindfulness practice post-study. This trial's high engagement rate and positive feedback on the study suggest that mindfulness holds promise as a supportive technique for glioma patients experiencing QoL challenges. Particularly for this study, telephone-based sessions are feasible and can be used to reach a broader patient population. Possible opportunities to improve this study include the inclusion of caregivers alone or as dyads with patients, and, instead of telephone-based sessions, the use of smartphone technologies such as digital applications. This study was designed for feasibility, but a larger study is needed to determine if mindfulness can improve the QoL for patients.

## Conclusions

Mindfulness meditation practiced by the primary brain tumor population is feasible given (1) the short enrollment time to accrue subjects, (2) the number of sessions attended, (3) the subjects' satisfaction with the program, and (4) the number of QoL PROs completed. Moreover, this intervention is feasible during active chemoradiation in this patient cohort. These preliminary findings suggest that a larger study in the high-grade glioma population during active treatment is warranted to evaluate further mindfulness meditation's benefits.

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**Author contributions** Conceived and designed the analysis, DR, JEH, EB, MLA, MPP, MOJ, KBP. Collected the data, KR, DR, NC, JEH, EB, MLA, JYK, MPP, JTL, MOJ, MK, AD, DMA, HSF, KBP. Contributed data or analysis tools, KR, NC, JEH, EB, MLA, JYK, MPP, JTL, MOJ, MK, AD, DMA, HSF, KBP. Performed the analysis, KR, JEH, EB, KBP. Wrote the paper, KR, JEH, EB, KBP. Other Contributions (paper editing, paper reviewing, critical appraisal, etc.), KR, NC, JEH, EB, MLA, JYK, MPP, JTL, MOJ, MK, AD, DMA, HSF, KBP.

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**Data availability** Data available on request.

## Declarations

**Ethics approval and consent to participate** This study was approved by the Duke University Institutional Review Board. Written informed consent was obtained from all participants prior to enrollment.

**Competing interests** The authors declare no competing interests.

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