Citation review options

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Findings of:

Ramamurthy K, Randazzo DM, Cort N, Herndon JE 2nd, Buckley E, Affronti ML, Kim JY, Patel MP, Low JT, Johnson MO, Khasraw M, Desjardins A, Ashley DM, Friedman HS, Peters KB. Clinical trial of feasibility for mindfulness intervention for patients with newly diagnosed high grade glioma.

J Neurooncol. 2025 Nov 5;176(1):71. doi: 10.1007/s11060-025-05325-1. PMID: 41191167.

Here's a full breakdown of the article you cited:

1. Annotated Vancouver-style Bibliographic Entry

Ramamurthy K, Randazzo DM, Cort N, Herndon JE 2nd, Buckley E, Affronti ML, Kim JY, Patel MP, Low JT, Johnson MO, Khasraw M, Desjardins A, Ashley DM, Friedman HS, Peters KB. Clinical trial of feasibility for mindfulness intervention for patients with newly diagnosed high grade glioma. *J Neurooncol*. 2025 Nov 5;176(1):71. doi:10.1007/s11060-025-05325-1. PMID: 41191167.

Annotation: This paper reports a feasibility pilot study of a mindfulness-based intervention (MBI) in newly diagnosed WHO grade III–IV glioma patients during standard chemoradiation. The authors focus on feasibility (acceptability, demand, implementation) and report good session attendance, patient satisfaction, and willingness to continue. They argue that their results support scaling to a larger trial.

2. Summary (with Key Methods & Results)

Here's a summary of the study, including objectives, methods, findings, and conclusions:

Background / Rationale

- High-grade glioma (HGG, WHO grade 3–4) has a poor prognosis, and patients often experience high psychological distress.
- Mindfulness meditation is increasingly used as a non-pharmacological strategy in oncology to reduce distress and improve quality of life (QoL). <u>PubMed +1</u>
- The authors hypothesized that a mindfulness intervention during active treatment (chemoradiation) would be feasible and potentially beneficial in this population.

Study Design & Methods

- Population: Newly diagnosed HGG (grade III–IV) patients. <u>PubMed +1</u>
- Intervention: Six weekly 1-hour telephone-based mindfulness sessions, followed by one in-person session. <u>PubMed +1</u>
- **Timing**: The intervention was delivered concomitant with standard-of-care chemoradiation. PubMed

Outcome Measures:

- Feasibility assessed via three domains: acceptability, demand, and implementation. PubMed
- Quality of life assessed with standardized patient-reported outcome (PRO) questionnaires, preand post-intervention. <u>PubMed</u>
- Exit interview to gauge participant satisfaction and intention to continue mindfulness.
 PubMed
- Sample Size: Over 4 months, 27 patients were approached; 15 enrolled. PubMed
- **Demographics**: Median age 60 (range 28–76); 73.3% female; all participants reported as White in this cohort. PubMed

Results

- Adherence: On average, participants attended 82.9% of the 7 sessions (SD = 28.16%). PubMed
- Acceptability / Satisfaction: Among the 10 who completed the exit interview, 70% said they would continue practicing mindfulness. <u>PubMed</u>
- Perceived Benefit: For those who attended all 7 sessions, more than 50% reported the sessions were beneficial. <u>PubMed</u>
- **Feasibility Conclusion**: The authors conclude that the mindfulness intervention is feasible in this patient population, even during the demanding phase of chemoradiation. PubMed

Limitations (implied / likely)

- Small sample size (n = 15), which limits generalizability.
- Homogeneous sample in terms of race (100% White in this cohort) may not reflect broader patient population. <u>PubMed</u>
- Feasibility study, not powered to evaluate efficacy (e.g., changes in QoL or distress) in a definitive way.
- Potential self-selection bias: patients willing to enroll in mindfulness may already be more motivated / less burdened.

Conclusion & Implication

- The study demonstrates that a structured mindfulness program can be delivered to HGG patients during chemoradiation with good adherence and positive patient feedback.
- Because of the favorable feasibility outcomes, the authors suggest that a larger study (e.g., randomized controlled trial) is warranted to test efficacy.

3. Comparison with Other Supportive-Care / QoL Interventions in High-Grade Glioma

Putting this study in context, here are how other interventions in HGG or malignant glioma compare and where this mindfulness pilot fits in:

1. CALM (Managing Cancer and Living Meaningfully)

- A phase IIa proof-of-concept trial of CALM psychotherapy was done in malignant glioma.
 PubMed
- In that study (n = 14 initially, 12 evaluable), there was a **75% retention rate**. PubMed
- They saw reductions in death anxiety, generalized anxiety, and depression, and increased spirituality; QoL remained stable. <u>PubMed</u>
- Comparison: CALM is a structured, semi-structured psychotherapeutic intervention rather than
 a purely mindfulness meditation approach. Both aim to reduce distress, but CALM may target
 meaning, existential distress, and death anxiety more directly, while mindfulness focuses on
 stress regulation, emotional awareness, and acceptance.

2. Early Palliative Care (GLIOSUPPORT)

- The GLIOSUPPORT feasibility study tested integrated early palliative care in newly diagnosed glioblastoma. <u>PubMed</u>
- They achieved a 60% adherence (visits) rate, showing feasibility, and noted trends in QoL and neuropsychological measures.
- Comparison: Palliative care interventions are broader, addressing symptom management, psychological support, advance care planning, and family communication. Mindfulness is more focused on internal coping, stress management, and perhaps emotional regulation rather than medical decision-making or end-of-life planning.

3. Mindfulness / Yoga Trials in Glioma / Brain Tumor Patients

- There is a protocol for an online yoga intervention (YINOTA-O trial) specifically for high-grade glioma patients + their caregivers.
- Yoga interventions combine physical activity, breathwork, and potentially mindfulness; they may benefit both emotional distress and physical functioning.
- Comparison: The Ramamurthy et al. mindfulness trial uses telephone + in-person sessions, not physical movement. It addresses feasibility of mindfulness per se; yoga is more comprehensive in physical + mental intervention.

4. Earlier Feasibility Mindfulness Pilot

- There was a prior pilot feasibility study reported in an abstract / conference (Neuro-Oncology) in 2019, by Randazzo, Herndon, Affronti, et al., very similar design (6 weekly phone sessions, then 1 in-person).
- That pilot used QoL measures (FACT-Br, FACT-Cog, PSQI, fatigue, mindfulness questionnaires) to gauge feasibility.
- **Comparison**: The 2025 study seems to be the logical continuation / formal reporting of that pilot feasibility work, now as a full clinical trial.

4. Critical Assessment & Potential Next Steps

- Addresses a major unmet need: psychological distress in HGG, which often gets less attention than survival-focused research.
- Innovative delivery: telephone-based sessions make the intervention accessible even during intensive chemoradiation; fewer clinic visits may reduce burden.
- High adherence (average ~83%) and good acceptability suggest patients find it manageable and meaningful.
- Exit interviews help understand patients' perspectives qualitatively, not just quantitatively.

Weaknesses / Challenges

- Small, homogeneous sample: limits external validity, especially across more diverse populations (ethnicity, socioeconomic status).
- No control group: because it's a feasibility trial, we cannot infer causality or efficacy the
 improvements (or perceptions of benefit) could relate to many factors (e.g., being part of a study,
 attention from staff).
- Lack of long-term follow-up (beyond exit interview) unclear if patients sustain mindfulness practice or derive long-term benefits.
- Potential selection bias: those who agree to enroll may already be more motivated, more
 psychologically stable, or more open to mind-body therapies, possibly inflating feasibility metrics.
- The "in-person" session is only one; might limit development of a sustained group/community practice, though telephone sessions help.

Recommendations / Next Steps

- Conduct a randomized controlled trial (RCT): Compare mindfulness intervention vs usual care (or alternative support) to test efficacy on QoL, distress, anxiety, depression, symptom burden.
- Include **diverse populations**: Expand beyond a predominantly white sample, to assess feasibility and acceptability across different socio-demographic groups.
- Extend **follow-up period**: Assess maintenance of mindfulness practice, long-term QoL, mental health outcomes, maybe even survival / functional outcomes (if relevant).
- Explore hybrid delivery: Combine in-person, telephonic, and digital (apps/guided meditation) to improve scalability.
- Integrate **caregiver component**: potentially involve caregivers in mindfulness sessions, or design parallel sessions; caregiver burden is high in HGG.
- Evaluate **cost-effectiveness**: to justify implementation in standard neuro-oncology supportive care pathways.

If you like, I can **pull together all recent (2023–2025) clinical trials of psychosocial or mindfulness-based interventions in high-grade glioma** (or neuro-oncology more broadly), to see where the field is going. Do you want me to do that?

Yes, please

Great — I pulled recent (2023–2025) clinical trials, pilot studies, protocols and reviews of mindfulness / psychosocial / supportive-care interventions for people with high-grade glioma or primary brain tumours. Below is a concise, curated list with one-line summaries and citations so you can jump to the source. If you want, I'll next produce annotated Vancouver-style bibliography entries for the items you pick.

Recent (2023–2025) psychosocial / mindfulness / supportive-care trials & protocols — quick curated list

- Ramamurthy et al., 2025 feasibility trial of mindfulness during chemoradiation
 Feasibility pilot of a 6× telephone + 1 in-person mindfulness program for newly diagnosed high-grade glioma patients; good adherence and acceptability reported. <u>PubMed</u>
- 2. Rabe et al., BMJ Open protocol (2024) multicentre RCT protocol: mindfulness-based yoga for HGG + caregivers

A multicentre randomized controlled trial protocol to evaluate a mindfulness-based yoga course (patient + caregiver) for high-grade glioma; useful to watch as it progresses to results. <u>BMJ Open</u>

3. LaTCH-BRAINS (Pike et al.), 2025 — randomized telehealth cognitive intervention for primary brain tumour patients

A randomized controlled telehealth group cognitive intervention trial (aims to improve cognition/QoL after primary brain tumour diagnosis) — relevant as a scalable psychosocial approach. OUP

Academic

4. Diplock et al., 2024 — brief mindfulness-based intervention (bMBI) in adult brain-tumour survivors

Feasibility/efficacy testing of a brief MBI for brain tumour survivors with elevated depressive symptoms — suggests mind-body approaches can be delivered in this population. <u>Taylor & Francis</u> Online

5. NeuroPathways intervention (ClinicalTrials.gov NCT05976490)

Registered study testing an information + support intervention for patients with malignant (high-grade) brain tumours — an example of formalized supportive-care research in HGG. ClinicalTrials.gov

- 6. "Empower GBM" pilot (2025) patient–caregiver supportive-care intervention

 A recent pilot developing/testing a structured supportive-care program (patient + caregiver) for glioblastoma highlights increased emphasis on dyadic interventions. PMC
- 7. Systematic / narrative updates & reviews (2024–2025)

Reviews and evidence syntheses in 2024–2025 highlight growing supportive-care evidence for non-pharmacological interventions (mindfulness, yoga, telehealth CBT/eMBCT, early palliative care) in brain tumour populations. These summarize feasibility signals and call for larger RCTs. ScienceDirect +1

Short synthesis — what this recent literature shows

• **Feasibility is repeatedly supported**: multiple small pilots and protocols (including Ramamurthy 2025 and Diplock 2024) report feasible delivery (telephone/telehealth/hybrid) and acceptable adherence in people with brain tumours. PubMed +1

- Larger RCTs are in planning / early execution: multicentre protocols (e.g., Rabe 2024 mindfulness-yoga) and telehealth RCTs (LaTCH-BRAINS) indicate the field is moving from feasibility to efficacy testing.
 BMJ Open +1
- Intervention formats vary: purely mindfulness programs, mindfulness-based yoga, telehealth cognitive groups, information/support packages, and dyadic patient—caregiver programs showing diversification in approach and delivery (remote and hybrid models are common).
 ClinicalTrials.gov +1
- **Evidence gaps**: few large, well-powered RCTs specifically in newly-diagnosed HGG; limited diversity in some pilot cohorts; long-term follow-up and caregiver-inclusive endpoints are still needed. Reviews call for larger, multi-site RCTs and inclusion of heterogeneous populations. <u>ScienceDirect +1</u>

Suggested next steps I can take for you — pick any (I can do them now)

- Produce **annotated Vancouver-style bibliography entries** (like the one I made for Ramamurthy 2025) for any or all of the studies above.
- Compile a **table** (author, year, design, population, intervention, delivery, primary endpoints, sample size, status/results) for 2023–2025 trials/pilots (I can present as a neat table).
- Do a **deeper literature sweep** focused only on randomized controlled trials (exclude protocols/pilots) between 2020–2025 and annotate efficacy outcomes.
- Draft a short **methods template** for an RCT of mindfulness in newly diagnosed HGG (sample size estimate, outcomes, assessment schedule) if you're planning a trial.

Which would you like me to do next? (I'll start immediately on the option you choose.)

First 3

Nice — here are the three deliverables you asked for:

(1) Annotated Vancouver-style bibliography entries for the first three studies, (2) a concise table of 2023–2025 trials/pilots I found, and (3) a focused sweep of randomized controlled trials (RCTs) in 2020–2025 with brief annotations of efficacy outcomes. I cited the source(s) for each item so you can open them directly.

1 — Annotated Vancouver-style bibliography entries

Ramamurthy K, Randazzo DM, Cort N, Herndon JE 2nd, Buckley E, Affronti ML, Kim JY, Patel MP, Low JT, Johnson MO, Khasraw M, Desjardins A, Ashley DM, Friedman HS, Peters KB. Clinical trial of feasibility for mindfulness intervention for patients with newly diagnosed high grade glioma. *J Neurooncol*. 2025 Nov 5;176(1):71. doi:10.1007/s11060-025-05325-1. PMID:41191167.

Annotation: Single-arm feasibility pilot delivering six weekly 1-hour telephone mindfulness sessions + one in-person session to newly diagnosed WHO grade III–IV glioma patients during chemoradiation. Reported high adherence (mean attendance ≈82.9%), favourable acceptability (70% of exit-interview respondents would continue), and conclusion that the intervention is feasible and supports progression to larger trials. PubMed

Rabe A, Keßler AF, Hagemann C, Schubert J, Jentschke E, et al. Study protocol for a multicentre randomised controlled trial evaluating the efficacy of an online yoga intervention in high-grade glioma patients and their caregivers: the YINOTA-O trial. *BMJ Open*. 2024;14:e075698. doi:10.1136/bmjopen-2023-075698.

Annotation: Multicentre RCT protocol comparing a mindfulness-based online yoga course (patient + caregiver) versus waiting-list control, with planned endpoints including emotional distress, QoL, and stress-related physiological parameters. Useful as a near-term source of higher-quality evidence once results are published. BMJ Open +1

Pike KE, et al. A randomized controlled trial of a telehealth group cognitive intervention (LaTCH-BRAINS) to improve cognition after primary brain tumour diagnosis. *Neuro-Oncology Advances / Neuro-Oncology Applications* (2025).

Annotation: A randomized telehealth group cognitive rehabilitation program for primary brain tumour patients (high- and low-grade included) reporting improved memory outcomes and reduced access barriers through remote delivery; demonstrates scalability of telehealth psychosocial/cognitive interventions. (Published 2025 — trial report/abstract available). OUP Academic +1

2 — Concise table of recent (2023–2025) trials / pilots / protocols (selected)

#	Citation (short)	Design / population	Intervention (delivery)	Primary endpoint(s)	N / Status / Key result
1	Ramamurthy et al., 2025. J Neurooncol. <u>PubMed</u>	Single-arm feasibility pilot; newly diagnosed HGG (WHO III–IV)	6× weekly 1-hr phone mindfulness sessions + 1 in- person session	Feasibility: acceptability, demand, implementation; PROs (QoL)	N=15 enrolled; mean attendance ≈82.9%; 70% of exit respondents would continue — feasible. PubMed
2	Rabe et al., 2024. YINOTA-O protocol (BMJ Open). BMJ Open +1	Multicentre RCT (planned); HGG patients + caregivers	Online mindfulness- based yoga course (instructors) vs waiting list	Emotional distress, QoL, physiological stress markers	Protocol published 2024; trial ongoing/planned (watch for results). BMJ Open
3	Pike et al., 2025. LaTCH-BRAINS (randomized). OUP Academic +1	Randomized telehealth group cognitive rehab; primary brain tumour survivors (high + low grade)	Telehealth group cognitive training (structured program)	Cognitive outcomes (memory, attention), QoL	Reported improved memory outcomes (2025 report). OUP Academic
4	Diplock et al., 2024. bMBI pilot (Cancer Survivorship Research & Care). <u>Taylor &</u> <u>Francis Online +1</u>	Pilot RCT / pilot efficacy?; adult brain tumour survivors with depressive symptoms	Brief mindfulness- based intervention (bMBI), delivery mixed/tele	Depressive symptoms, feasibility	Pilot reported feasibility and signals of efficacy for depressive symptoms (2024). Taylor & Francis Online
5	NeuroPathways (NCT05976490). ClinicalTrials.gov. ClinicalTrials.gov +1	Pilot / pilot RCT arms planned; malignant/high- grade brain tumours	Information guide + four 1:1 coaching sessions (behavioral/support)	Feasibility, acceptability (supportive care)	Registered — pilot & pilot RCT arms; status: registered (check ClinicalTrials.gov for updates). ClinicalTrials.gov

#	Citation (short)	Design / population	Intervention (delivery)	Primary endpoint(s)	N / Status / Key result
6	Empower GBM pilot (Leo et al., 2025). PubMed +1	Pilot supportive- care program for glioblastoma patient- caregiver dyads	Structured patient– caregiver supportive program	Distress, QoL, caregiver burden	Pilot describes development and initial testing; emphasizes dyadic approach — results supportive of feasibility. PubMed
7	C-SMART / other combined telehealth programs (2023–2024 trials/protocols)	Various (glioma / brain cancer survivors)	Cognitive + mindfulness + rehab packages (telehealth)	Function, cognition, QoL	Ongoing/early data indicate usability and benefit signals; many are feasibility/early efficacy stage. withpower.com +1

Notes: I selected studies and registered trials that specifically target psychosocial, mindfulness, cognitive rehabilitation, or dyadic supportive-care interventions in primary brain tumour or high-grade glioma populations between 2023–2025. For ongoing registry entries (ClinicalTrials.gov) check the trial record for recruitment/status updates. ClinicalTrials.gov +1

3 — Focused RCT sweep (2020–2025): randomized trials and their annotated efficacy outcomes

Below I list randomized (or cluster-randomized) trials in brain-tumour / glioma populations (2020–2025) that test psychosocial/mind-body/cognitive interventions, with short annotations of the efficacy outcomes reported or the trial status.

1. LaTCH-BRAINS — telehealth group cognitive intervention (Pike et al., 2025)

- Design: Randomized controlled trial (telehealth group cognitive rehabilitation) for primary brain tumour survivors.
- Efficacy outcome(s): Reported improved memory outcomes and benefits across high- and low-grade participants; demonstrates telehealth is effective and scalable for cognitive support.
 OUP Academic +1

2. GLIOPT cluster-randomized study (Germany) — psychosocial care screening / services (Renovanz et al. / Kuchen et al., results 2025)

- Design: Cluster-randomized trial (2019–2023 recruitment / analyses reported 2025) testing screening implementation and utilization of specialized psychosocial services in glioma outpatient care.
- Efficacy outcome(s): Improved identification/referral to psychosocial services (implementation outcome); helps show system-level interventions can change access to care. See summary and implementation results.

3. ReMind / Cognitive rehabilitation RCTs (earlier foundational RCTs, extensions into 2020s)

Design: Randomized trials of cognitive rehabilitation in glioma patients (face-to-face and remote adaptations). Prior RCTs (Gehring et al. et al.) showed improvements in objective memory/attention and reduced cognitive complaints; newer hybrid/remote adaptations continue to demonstrate benefits and are being evaluated in 2021–2025 follow-ups. Frontiers

4. C-SMART and other telehealth eclectic programs (2023 onward)

- Design: Telehealth programs combining cognitive strategies + mindfulness + rehabilitation (variant trial designs, some randomized pilot RCTs).
- Efficacy outcome(s): Early reports indicate usability and signals of cognitive and functional benefit; many are feasibility/early efficacy and require full-scale RCTs for firm conclusions.
 withpower.com +1

5. Making Sense of Brain Tumour Program / other home-based psychosocial RCTs (2020s)

Design: Some community/home-based psychosocial programs have been tested in randomized formats (e.g., "making sense" style interventions adapted for brain tumour caregivers/patients). Outcomes vary, with modest improvements in distress/QoL in some trials. See systematic reviews for pooled signals. ejoncologynursing.com +1

Caveats & synthesis about efficacy (2020–2025)

- The RCT evidence base specifically in high-grade glioma patients is still relatively small; many trials in the 2020–2025 window are feasibility/pilot designs or target broader "primary brain tumour" populations (including low-grade tumours and survivors).
- Where randomized data exist (cognitive rehab telehealth, system-level psychosocial screening),
 benefits are seen in targeted outcomes (memory/cognitive performance, improved service uptake, distress reduction). However, large multisite RCTs powered for patient-level QoL endpoints in newly diagnosed HGG remain limited hence the emphasis on protocols (e.g., YINOTA-O) and on scaling feasible pilots (e.g., Ramamurthy 2025).
 BMJ Open +2 OUP Academic +2

Quick conclusions & suggested next steps (I can run immediately)

- The field is moving from feasibility pilots (many telehealth/mindfulness pilots) into larger RCTs / multicentre trials (YINOTA-O, LaTCH-BRAINS, NeuroPathways pilot→RCT). BMJ Open +2 OUP Academic +2
- Evidence to date (2020–2025) shows promising signals for cognitive rehabilitation (telehealth) and feasibility/acceptability for mindfulness-based interventions, but definitive efficacy in newly diagnosed HGG (on QoL, survival, long-term distress) requires larger, more diverse RCTs. <u>OUP</u> Academic +1

If you want now, I can:

- Expand the table into a downloadable CSV/Excel and include direct links to each paper/registry entry.
- Produce annotated Vancouver entries for any other items in the table (I can do the remaining entries the same way).

 Draft a compact RCT methods template (sample size, primary/secondary endpoints, assessment schedule) tailored for a mindfulness RCT in newly diagnosed HGG. 								