

Neuro-oncology anywhere 242: Pilot study evaluating telehealth and in-person assessments in patients with glioma receiving oral chemotherapy—Clinical trial in progress.

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Background: Gliomas are the most common primary central nervous system (CNS) malignancy in adults, accounting for 26.3% of all brain tumors. Care at high volume centers is associated with an overall survival benefit, but access to in-person evaluations can be challenging due to disease-related neurological disability and loss of income. Telehealth represents a convenient and efficient alternative to in-person evaluations, but acceptability and comparative safety of this care delivery modality has not been prospectively evaluated among glioma patients undergoing chemotherapy. **Methods:** This single-arm non-randomized pragmatic clinical trial evaluates patient satisfaction with, and safety of video-enabled telehealth assessments compared to in-person evaluations for patients with glioma undergoing temozolomide chemotherapy. The study includes adult patients with a diagnosis of glioma requiring adjuvant temozolomide chemotherapy. Participants act as their own controls, alternating between in-person and telehealth assessments while undergoing chemotherapy dosed per standard of care. Monitoring labs are completed locally and transmitted electronically. For participants without access to Wi-Fi or a device (e.g. mobile phone or computer), cellular-enabled tablet devices are provided to facilitate appointments and completion of electronic study components. All participants who travel to in-person appointments are reimbursed for travel expenses. The primary outcome measure is patient satisfaction with care delivered, as measured by institutional Press-Ganey survey scores obtained following telehealth and in-person assessments. A key secondary outcome measure is completion rate of planned oral chemotherapy, tracked using a digital pill diary incorporated into our institutional electronic health record. The digital diary allows real-time tracking of chemotherapy adherence and adverse events experienced by participants. Other secondary outcomes include acute care utilization days following telehealth and in-person visits (defined as emergency department evaluations and days of inpatient stay), neurologic disability as measured by the Neurologic Assessment in Neuro-Oncology (NANO) scale, and disease related quality of life measured by the EORTC QLQ-C30. All participant surveys are self-reported and completed electronically. This decentralized pragmatic clinical trial provides unprecedented, prospective real-world data on utilization of telehealth services compared to in-person visits for patients undergoing chemotherapy for glioma. We expect the data generated to inform the design and conduct of future decentralized interventional neuro-oncology trials. NCT06625047 opened for enrollment in October 2024, 16 of 30 intended participants were accrued as of January 2025. Clinical trial information: NCT06625047. Research Sponsor: Mayo Clinic.