PROTOCOL TITLE:
Psychological Intervention for Caregivers of Patients with Malignant Gliomas
NCT 03735498

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Contents

1.0 Objectives

1.1 Study Rationale

Our primary goal is to conduct a pilot study of a population-specific psychological intervention aimed at decreasing anxiety and promoting coping in caregivers of patients with malignant gliomas**. In this initial phase of the research, we will pilot the intervention with 25 malignant glioma caregivers in order to assess feasibility and acceptability of the intervention.**

1.2 Specific Aims

1) To refine a caregiver-directed intervention and study protocol based on acceptability feedback from an open pilot study with exit interviews.

2.0 Background

2.1 Introduction

Malignant gliomas are the most common types of brain tumors and have a disease course characterized by high symptom burden and rapid cancer progression.[1,2] Survival of patients with glioblastoma, the most common type of malignant glioma, is on the order of 15 months, even in patients treated aggressively with chemotherapy and radiation.[1,3,4] Thus, a diagnosis of malignant glioma has a significant impact on a patient's family and friends ("caregivers"). There is increasing recognition that caregivers who experience substantial distress related to their loved one's serious medical illness have worse physical and psychological health, which also may negatively impact the patient's health and outcomes.[5-14] Caregivers of patients with brain tumors face significant challenges due to the impact of the cancer on the patients' central nervous system. Specifically, these caregivers must cope with their loved one's progressive cognitive decline, personality and behavior changes, and accumulation of neurological deficits as the disease progresses.[15-18] This is physically, financially and emotionally draining, and caregivers of patients with malignant gliomas experience poor quality of life and high rates of psychological distress.[19-21] We conducted a prospective study of patients with newly diagnosed malignant glioma and their caregivers (DF/HCC 15-500), with preliminary results demonstrating that **more than 50% of caregivers had clinically significant anxiety at the time of their loved one's diagnosis, with almost two-thirds endorsing anxiety over their course of illness.** Despite the high rates of distress in caregivers of patients with malignant gliomas, few interventions have been developed to address the unique supportive care and coping needs of this highly burdened caregiver population.[19]

The goal of this proposal is to pilot a population-specific psychological intervention aimed at decreasing anxiety and promoting coping in caregivers of patients with malignant gliomas. Our intervention is based on a conceptual framework for caregiver-directed interventions developed by our multi-disciplinary team. We recently used this framework to develop an intervention for caregivers of patients undergoing bone marrow transplantation, which was highly acceptable and beneficial to caregivers who participated in the open pilot study. While the proposed intervention is based upon this framework, we have used qualitative data collected from caregivers of patients with malignant glioma

(DF/HCC 15-500 and DF/HCC 18-171) to refine the intervention and ensure that it is targeted to the specific needs of this caregiver population. Our study population will include caregivers within the first six months of their loved one's diagnosis with malignant glioma who report clinically significant anxiety. We opted to enroll caregivers with clinically significant anxiety as they are in greatest need of a behavioral intervention focused on their distress and concerns about their loved one's health and diagnosis. Enrolled caregivers will participate in six weekly, cognitive-behavioral therapy-based, individual sessions with a mental health clinician, designed to provide them with the strategies and coping skills to manage the distress related to their loved one's illness. Findings from this project may inform the development of a future randomized efficacy trial to demonstrate the impact of the intervention on caregivers' psychological outcomes, coping, and well-being.

3.0 Inclusion and Exclusion Criteria

The population for this study will include English-speaking adults (age ≥ 18) who are the primary caregiver for an individual diagnosed with a malignant glioma within the past 6 months and present for cancer care at the Massachusetts General Hospital Cancer Center, Boston, MA. The caregiver must also have at least mild anxiety symptoms, defined as a 7-Item Generalized Anxiety Disorder (GAD-7) score of 5 or greater. See Table 1 for a summary of study inclusion/exclusion criteria:

Table 1. Study Inclusion/Exclusion Criteria

Inclusion Criteria	**Exclusion Criteria**
Age ≥ 18	Deemed inappropriate for the study by the patient's clinician or the study PI
Identified by a patient with a malignant glioma (WHO Grade III or IV glioma) as the patient's primary caregiver	
The patient is receiving care at the MGH Cancer Center	
The patient was diagnosed with a malignant glioma within the past 6 months	
Able to speak and read in English	
Generalized Anxiety Disorder 7-item (GAD-7) score ≥5	
Participants may or may not be pregnant.	

Rationale for inclusion/exclusion: This research is focused on developing an intervention for caregivers with malignant gliomas. Only participants within 6-months of their loved one's brain tumor diagnosis are eligible to participate, as the intervention is targeted at the stressors caregivers may face during this time. Participants must be able to speak and read in English as we do not have the resources to conduct the intervention in additional languages. Participants must report clinically significant anxiety symptoms, defined as a Generalized Anxiety Disorder Scale (GAD-7) score ≥5, as our intervention intends to address anxiety symptoms in caregivers. Caregivers deemed inappropriate for the study by the patient's clinician or the study PI will be ineligible to participate. Pregnant women will be included in the study. Adults unable to consent, individuals who are not yet adults, and prisoners will not be included.

Screening for eligibility

Study staff will review the outpatient clinic schedule for the Yawkey 9E Brain Tumor Clinic to identify patients with malignant gliomas. To facilitate identification of potential participants and assess eligibility, study staff will review minimum necessary medical record data via a HIPAA waiver. This will ensure that caregivers are potentially eligible to participate in the study prior to contacting them to obtain informed consent. Prior to contacting potential participants identified via screening, the patient's primary treating oncologist will be contacted to inform them that we plan to approach the patient's caregiver for study participation and to inquire about any concerns regarding study participation. If clinicians have specific concerns about the appropriateness of enrolling a particular caregiver, we will not contact that caregiver.

4.0 Study-Wide Number of Subjects

N/A

5.0 Study-Wide Recruitment Methods

N/A

6.0 Multi-Site Research

N/A

7.0 Study Timelines

As this cognitive-behavioral therapy-based intervention consists of 6 weekly or biweekly sessions with a mental health clinician, an individual subject will participate for approximately 6 to 12 weeks. We anticipate that all study subjects will be enrolled within 18 months and that the study will be complete by January 2020.

8.0 Study Endpoints

The primary endpoint of this study is feasibility of the intervention. In an exploratory analysis, we will examine preliminary efficacy of the intervention in improving caregiver-reported outcomes from baseline to post-intervention.

9.0 Procedures Involved

9.1 Recruitment

Study staff will review the outpatient clinic schedule for the Yawkey 9E Brain Tumor Clinic to identify patients with malignant gliomas. To facilitate identification of potential participants and assess eligibility, study staff will review minimum necessary medical record data via a HIPAA waiver. This will ensure that caregivers are potentially eligible to participate in the study prior to contacting them to obtain informed consent. Prior to contacting potential participants identified via screening, the patient's primary treating oncologist will be contacted to inform them that we plan to approach the patient's caregiver for study participation and to inquire about any concerns regarding study participation. If clinicians have specific concerns about the appropriateness of enrolling a particular caregiver, we will not contact that caregiver.

9.2 Enrollment

A member of study staff (e.g. PI, Research Assistants) will obtain informed consent in person prior to initiating any study measures. Participants will be consented next time they are in clinic. Research

assistants, all of whom previously have received CITI and consent training, will be provided study-specific recruitment training. Caregivers who would like more time to consider participation at in-clinic approach are able to take the consent forms home with them to review. Caregivers will be provided with study staff contact information if any questions or concerns regarding the research arise.

9.3 Registration

Study staff will register eligible participants in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC SOP REGIST-101 after the participant completes the brief enrollment survey. Caregivers who report GAD-7 scores <5 will be considered ineligible for the study and will not be registered in OnCore. If a caregiver's GAD-7 score renders them ineligible but they are still interested in the study, we will re-approach them in 3 months to re-administer the GAD-7. Caregivers who do not complete the brief enrollment survey will not be registered in OnCore.

9.4 Study design

This study will be a prospective, single-arm pilot study to assess feasibility and acceptability of a psychological intervention for caregivers of patients with malignant gliomas. We will use qualitative data to refine a multicomponent psychological intervention specifically targeting the needs of caregivers of patients with malignant gliomas who are within the first 6 months of diagnosis. We will collect demographics at baseline and will ask caregivers to complete a questionnaire pre- and post-intervention to assess caregivers' self-reported information about mood, caregiver burden, coping, quality of life and illness understanding.

9.5 Selection of Instruments

9.5.1 7-Item Generalized Anxiety Disorder (GAD-7)

The GAD-7 (Appendix 31.01)[22] is a valid self-report measure for assessing generalized anxiety[24] in patients with cancer.[23] Patients indicate how often they have been bothered by symptoms over the last 2 weeks using a likert-type scale ranging from 0 (Not at all) to 3 (Nearly every day). Scores of 5 to 9 are categorized as mild anxiety, scores of 10 to 14 as moderate anxiety, and scores of 15 or greater as severe anxiety. Patients with scores ≥ 5 on the GAD-7 (mild symptomatology) will be eligible for participation.[25] The estimated time for completing this scale is 1-3 minutes.

9.5.2 Hospital Anxiety and Depression Scale (HADS)

We will use the Hospital Anxiety and Depression Scale (HADS) to assess symptoms of depression and anxiety in all study participants. The HADS is a 14-item questionnaire that contains two 7-item subscales assessing depression and anxiety symptoms during the past week (Appendix 31.02)[26]. Used extensively in samples of patients with cancer and their caregivers, the questionnaire consists of a four-point item response format that quantifies the degree to which participants experience mood symptoms. Scores on each subscale range from 0 to 21, with a cutoff of 8 or greater denoting clinically significant anxiety or depression. The estimated time for completing this scale is 2-5 minutes.

9.5.3 Brief Demographic Survey

This includes self-reported information about participants' gender, race, ethnicity, religion, education, relationship status, household members, employment status, relationship to the patient, and years they have known the patient. It is estimated that these questions (Appendix 31.03) will take approximately 1-3 minutes to complete.

9.5.4 Locator Form
This includes self-reported contact information for participants and information necessary for registration in OnCore, including full name, address, phone number(s), email address, and date of birth. It also asks participants their preferred mode of communication with the study team (phone, text, or email). It is estimated that these questions (Appendix 31.04) will take approximately 1-3 minutes to complete.

9.5.5 Caregiver Quality of Life (QoL)
We will use the CareGiver Oncology QoL questionnaire (CarGOQoL), a 29-item, well-validated instrument specific to caregivers for patients with cancer, to measure family caregiver QoL in multiple domains.[27] It is estimated that the CarGOQoL (Appendix 31.05) will take approximately 2-4 minutes to complete.

9.5.6 Caregiving Burden
Caregiving burden will be measured using the Caregiver Reaction Assessment (CRA).[28] It is estimated that this tool (Appendix 31.06) will take approximately 3-5 minutes to complete

9.5.7 Self-Efficacy
We will use the Lewis Cancer Self-Efficacy Scale (CASE) to measure caregivers' confidence in managing the impact of their loved one's illness.[29] The CASE questionnaire is included as Appendix 31.07 and will take approximately 2-4 minutes to complete.

9.5.8 Perceived Coping Skills
We will use the Measure of Current Status (MOCS) to assess caregivers' self-perceived status on skills targeted by the intervention including ability to relax, recognizing stress-inducing situations, restructuring maladaptive thoughts, and coping.[30] The MOCS is included as Appendix 31.08. It is estimated that the MOCS will take approximately 2-4 minutes to complete.

9.5.9 Qualitative Exit Interview
We will use a semi-structured interview guide that will explore 1) caregiver perception of the acceptability and content of the intervention; and 2) caregiver perceptions of the benefits of receiving the intervention. Facilitators will use probes to obtain comprehensive understanding of the caregivers' perspectives. The semi-structured interview guide is detailed in Appendix 31.09. The interview will last approximately 30 minutes.

9.6 Description of Intervention

We utilized the findings from our longitudinal and qualitative studies and a thorough review of the literature to identify the necessary components of our planned caregiver intervention. The preliminary content includes three essential components: 1) a psychoeducational component to address preparedness, manage expectations, and develop caregiving skills; 2) a psychosocial component focusing on coping strategies, mindfulness, and facilitating acceptance while living with uncertainty; and 3) a self-care

component to promote caregiver health and well-being. We anticipate that the psychological intervention will consist of six individual sessions (45 minutes each), which will provide sufficient dose to promote effective coping and reduce caregiving burden. Whenever possible, we will coordinate sessions with hospital and clinic visits or conduct them via phone or video conference (using a HIPAA-compliant video platform provided by MGH TeleHealth) to minimize participant burden and facilitate adherence. The intervention will be delivered by a social worker or psychologist in the MGH Cancer Center, specifically trained on the intervention content and delivery. Interventionists may contact caregivers directly via text message, phone call, or email to coordinate session scheduling only. No identifying information will be shared via text or email; these will be used solely for scheduling purposes. In the Locator Form (Appendix 31.04), participants will be asked to indicate their preferred method of communication (phone call, text, or email), and the study team will use this response to determine how to contact participants. In this pilot study, we will enroll 25 caregivers of patients with malignant gliomas to assess fidelity and acceptability of the intervention. Attached as Appendix 31.15 is the Intervention Manual for our Psychological Intervention for Caregivers of Patients with Malignant Gliomas, which will be used as the basis for the intervention. We have refined the intervention to tailor it to the needs specific to this population of caregivers, based on our qualitative interview data.

9.7 Instrument Administration

A member of study staff trained in qualitative interviewing will facilitate the interviews over the phone or in person using a semi-structured interview guide with open-ended questions and response probes (Appendix 31.09), and the interview will last approximately 30 minutes. All interviews will be audio-recorded; study staff will ask for permission to turn on the audio-recorder prior to beginning each interview. A script for administration of the qualitative interview over the phone is included as Appendix 31.14.

The brief enrollment survey (Appendices 31.03, 31.04) and the 7-item Generalized Anxiety Disorder measure (Appendix 31.01) may be completed by participants via mail correspondence, online using a secure website (REDCap), over the phone, or in clinic at MGH, in accordance with participant preferences and availability. The message templates for administration of the GAD-7 and enrollment survey by mail and REDCap are included as Appendices 31.11 and 31.12, respectively. A script for survey administration over the phone is included as Appendix 31.13. Only participants who have a GAD-7 score ≥5 will be registered in OnCore and complete the qualitative interview. Caregivers with GAD-7 scores <5 will be considered ineligible for the study. If a caregiver is ineligible based on his or her GAD-7 score but is still interested in the study, we will re-approach in 3 months and re-administer the GAD-7.

10.0 Data and Specimen Banking

N/A

11.0 Data Management and Confidentiality

11.1 Sample size and power calculations

We will recruit and consent 25 caregivers for the open pilot. We chose the sample size of 25 caregivers based on the feasibility of completing the project in a timely fashion, given the rarity of this disease. It is

expected that it will take approximately twelve to eighteen months to complete accrual for the study. The proposed sample size is also sufficient to provide us with preliminary data that can be utilized to determine the effect size and adequately power a multi-center randomized controlled trial in the future.[54,55]

11.2 Analysis Plan

Feasibility will be defined by rates of enrollment and participation. We will report the proportion of eligible caregivers who agree to participate in the intervention and the proportion of intervention visits completed by each participant. Additionally, we will examine reasons for declining participation, incomplete session attendance, and early withdrawal from the study. The intervention will be deemed feasible if at least 70% (+/- 18%) of eligible caregivers are enrolled in the study and if at least 70% of enrolled participants complete ≥50% of the sessions.[31-34] We will use descriptive statistics to summarize the demographic and clinical characteristics of caregivers enrolled in the study. We will audio-record and transcribe the individual semi-structured exit interviews and analyze qualitative data according to NIH Best Practices for Mixed Methods Research in the Health Sciences.[35] Study staff will independently review the transcripts to create a thematic framework for interpretation. Two individuals, including the Principal Investigator, will independently code the data to enhance validity and credibility, until high reliability is achieved (Kappa>0.80). The planned sample size will allow us to collect comprehensive feedback and ensures sufficient number of participants to achieve thematic saturation. In an exploratory analysis, we will also examine changes in caregiver-reported outcomes from baseline to post-intervention using paired t-tests.

11.3 Data Collection

Data will be collected primarily in the form of caregiver interviews. Interviews will be audio recorded on a digital recorder, and the audio files will be stored in an encrypted computer drive on the secure Partners network. Caregivers will complete the 7-Item Generalized Anxiety Disorder scale (GAD-7) to determine whether they are eligible to participate in an interview. We will also gather demographic and contact information about our sample via a brief enrollment survey. Specifically, we will collect data on:

Data	At screening	Pre-Intervention	Post-Intervention
7-Item Generalized Anxiety Disorder (GAD-7)	X		
Demographics	X		
Locator Form (Contact Information)	X		
Hospital Anxiety and Depression Scale (HADS)		X	X
CareGiver Oncology QoL questionnaire (CarGOQoL)		X	X

Caregiver Reaction Assessment (CRA)		X	X
Lewis Cancer Self-Efficacy Scale (CASE)		X	X
Measure of Current Status (MOCS)		X	X
Qualitative Exit Interview			X

To safeguard participant information and confidentiality, all data will be stored in locked cabinets in study staff's offices, in password-protected computer files, and in REDCap databases, all of which are accessible only to trained and IRB-approved study staff. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept separately under lock and key or in a separate password protected document accessible only by study staff.

As part of the NIH data sharing directive, deidentified data from this study will be transferred to the PCRC De-identified Data Repository located at the University of Colorado. Any deidentified data that are collected and entered will remain in the PCRC Data Repository indefinitely. All future data analysis will be performed on de-identified data in the PCRC Data Repository. While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, participant identities will not be revealed. Data will be presented in aggregate reports without patient-level identifiers.

Consistent with the PCRC Data Sharing Policy, the data from this study will be deidentified and will be transferred and stored on a server maintained by the PCRC at the University of Colorado (U of CO). U of CO's Office of Information Technology (OIT) Department provides University employees with centralized file sharing services. Centralized file servers are Windows-based virtual systems hosted in OIT's vmware server environment. These servers are proactively monitored by the automated monitoring system, patched on a monthly basis with latest security patches and updates, and backed up nightly by OIT's Enterprise backup solution, consistent with good data storage practices.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A. This study does not involve more than Minimal Risk to subjects.

13.0 Withdrawal of Subjects

We do not anticipate that any research participants will be withdrawn from the study without their consent. If a participant requests withdrawal from the study, we will ask them if they are comfortable sharing the reason for withdrawal to ensure that there are no adverse events to report to the IRB. We will ask the study participant if they are still willing to permit the study team to continue to monitor their health record, but withdraw from all other study procedures.

14.0 Risks to Subjects

We do not anticipate that participants in the psychological intervention or qualitative interviews will experience any serious adverse reactions. If a participant expresses distress during the psychological intervention visits or exit interviews, they will be reassured by the psychologist and the research staff that

they can stop the intervention and they need not answer any of the interview questions which they find upsetting. They will also be reminded that study participation is voluntary. If participants remain distressed, both the Principal Investigator and the oncologist will be notified. Additionally, we will offer participants who remain distressed an opportunity to meet with either the principal investigator (Dr. Deborah Forst) or a clinical psychologist (Dr. Joseph Greer, a co-investigator) to help address their distress. Should participants require further support, we will offer them an opportunity to meet with the MGH Neuro Oncology Clinic social worker for additional follow-up.

15.0 Potential Benefits to Subjects

Preliminary data have demonstrated that more than 50% of caregivers of patients with malignant gliomas have clinically significant anxiety at the time of their loved one's diagnosis, with almost two-thirds endorsing anxiety over their course of illness. The proposed psychological intervention aims to decrease anxiety and promote coping in this highly burdened caregiver population. Participation in this study may help to improve caregivers' mental health by addressing their unique supportive care and coping needs.

16.0 Vulnerable Populations

We plan to include pregnant women in this study. As this is a psychological and behavioral study only, additional safeguards are not needed for this population. No other vulnerable populations will be included in this study.

17.0 Community-Based Participatory Research

N/A

18.0 Sharing of Results with Subjects

We will provide the research team contact information to each participant and encourage them to contact us if they would like to receive updates and information on the research findings.

19.0 Setting

Study staff will review the outpatient clinic schedule for the Yawkey 9E Brain Tumor Clinic to identify patients with malignant gliomas. Staff will approach the caregivers of these patients in clinic to obtain consent and administer surveys and questionnaires. Intervention sessions will be administered in person here at MGH. Qualitative exit interviews may be administered in person at MGH or over the phone.

20.0 Resources Available

20.1 Team Qualification and Oversight

The overall PI of the project (Dr. Forst) is responsible for full oversight of the project. Dr. Forst currently has 60% of her time protected to conduct research activities. She will be meeting with study staff on weekly basis (and more often as urgent issues arise) to ensure the study process is being followed accurately and to address potential challenges or issues as they may arise. Dr. Forst is a member of the MGH Cancer Outcomes Research Program (CORe). CORe has extensive experience conducting supportive care intervention studies in oncology and has the necessary expertise to ensure the success of the proposed project. Research coordinators, all of whom previously have received CITI and consent training, will be provided study-specific recruitment training.

20.2 Other Resources

There are approximately 100 new malignant glioma patients in the Yawkey 9E Brain Tumor Clinic each year, so we will need to recruit about 33% of these patients' caregivers in order to reach our target accrual of 25 caregivers over the course of 18 months.

See Section 14.0 for a description of the resources available to subjects given possible consequences of the research.

21.0 Prior Approvals

We will obtain IRB approval prior to initiating any study procedures.

22.0 Recruitment Methods

Study staff will review the outpatient clinic schedule for the Yawkey 9E Brain Tumor Clinic to identify patients with malignant gliomas. To facilitate identification of potential participants and assess eligibility, study staff will review minimum necessary medical record data via a HIPAA waiver. This will ensure that caregivers are potentially eligible to participate in the study prior to contacting them to obtain informed consent. Prior to contacting potential participants identified via screening, the patient's primary treating oncologist will be contacted by email to inform them that we plan to approach the patient's caregiver for study participation and to inquire about any concerns regarding study participation. The email template for obtaining permission from oncologists is included as Appendix 31.10. If clinicians have specific concerns about the appropriateness of enrolling a particular caregiver, we will not contact that caregiver.

A member of study staff (e.g. PI, Research Assistants) will obtain informed consent in-person prior to initiating any study measures. Research assistants, all of whom previously have received CITI and consent training, will be provided study-specific recruitment training. Caregivers who would like more time to consider participation at in-clinic approach are able to take the consent forms home with them to review. Caregivers will be provided with study staff contact information if any questions or concerns regarding the research arise.

Study staff will register eligible participants in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC SOP REGIST-101 after the participant completes the brief enrollment survey. Caregivers who report GAD-7 scores <5 will be considered ineligible for the study and will not be registered in OnCore. Caregivers who do not complete the brief enrollment survey will not be registered in OnCore.

23.0 Local Number of Subjects

A total of 25 subjects (excluding screen failures) will be accrued locally. We expect more than 50% to demonstrate at least mild anxiety (GAD-7 score of 5 or greater) so total accrual of no more than 50 caregivers including screen failures should be necessary.

24.0 Provisions to Protect the Privacy Interests of Subjects

To safeguard participant information and confidentiality, all data will be stored in locked cabinets in study staff's offices, in password-protected computer files, and in REDCap databases, all of which are accessible only to trained and IRB-approved study staff. Participants' data will be identified by an ID

number only, and a link between names and ID numbers will be kept separately under lock and key or in a separate password protected document accessible only by study staff.

25.0 Compensation for Research-Related Injury

We do not anticipate any research-related injury due to involvement in this supportive care intervention.

26.0 Economic Burden to Subjects

There will be no financial burden on study participants.

27.0 Consent Process

As stated previously, a member of study staff (e.g. PI, Research Assistant) will obtain informed consent in-person during clinic appointments or infusion prior to initiating any study measures. Research assistants, all of whom previously have received CITI and consent training, will be provided study-specific recruitment training. Caregivers who would like more time to consider participation at in-clinic approach are able to take the consent forms home with them to review. Caregivers will be provided with study staff contact information if any questions or concerns regarding the research arise.
We will follow all the requirements of SOP: Informed Consent Process (CON-100) in obtaining informed consent for study participants.

28.0 Process to Document Consent in Writing

As stated previously, all caregivers participating in the study will provide written informed consent.

29.0 Drugs or Devices

N/A

30.0 References

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31.0 Appendix

31.01 7-Item Generalized Anxiety Disorder (GAD-7)

GAD-7

Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every Day
1 Feeling nervous, anxious or on edge	0	1	2	3
2 NOT being able to stop or control worrying	0	1	2	3
3 Worrying too much about different things	0	1	2	3
4 Trouble relaxing	0	1	2	3
5 Being so restless that it is hard to sit still	0	1	2	3
6 Becoming easily annoyed or irritable	0	1	2	3
7 Feeling afraid as if something awful might happen	0	1	2	3

31.02 Hospital Anxiety and Depression Scale (HADS)

INSTRUCTIONS: Read each item and please select the answer which comes closest to how you have been feeling, on the average, IN THE PAST WEEK:

1. I feel tense or "wound up."
   a. Most of the time
   b. A lot of the time
   c. From time to time, occasionally
   d. Not at all

2. I still enjoy the things I used to enjoy.
   a. Definitely as much
   b. Not quite as much
   c. Only a little
   d. Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen.
   a. Very definitely and quite badly
   b. Yes, but not too badly
   c. A little, but it doesn't worry me
   d. Not at all

4. I can laugh and see the funny side of things.
   a. As much as I always could
   b. Not quite so much now
   c. Definitely not so much now
   d. Not at all

5. Worrying thoughts go through my mind.
   a. A great deal of the time
   b. A lot of the time
   c. From time to time but not too often
   d. Only occasionally

6. I feel cheerful.
   a. Not at all
   b. Not often
   c. Sometimes
   d. Most of the time

7. I can sit at ease and feel relaxed.
   a. Definitely
   b. Usually
   c. Not often
   d. Not at all

8. I feel as if I am slowed down.
   a. Nearly all the time
   b. Very often
   c. Sometimes
   d. Not at all

9. I get a sort of frightened feeling like "butterflies" in the stomach.
   a. Not at all
   b. Occasionally
   c. Quite often
   d. Very often

10. I have lost interest in my appearance.
   a. Definitely
   b. I don't take so much care as I should
   c. I may not take quite as much care
   d. I take just as much care as ever

11. I feel restless as if I have to be on the move.
   a. Very much indeed
   b. Quite a lot
   c. Not very much
   d. Not at all

12. I look forward with enjoyment to things.
   a. As much as I ever did
   b. Rather less than I used to
   c. Definitely less than I used to
   d. Hardly at all

13. I get sudden feelings of panic.
   a. Very often indeed
   b. Quite often
   c. Not very often
   d. Not at all

14. I can enjoy a good book or radio or TV program.
   a. Often
   b. Sometimes
   c. Not often
   d. Very seldom

31.03 Brief Demographic Survey

1. Gender
   - ☐ Man
   - ☐ Woman
   - ☐ Specify: _____

2. Relationship to patient
   - ☐ Married or living as if married
   - ☐ Non-cohabiting relationship
   - ☐ Divorced/Separated
   - ☐ Child (daughter or son)
   - ☐ Parent (mother or father)
   - ☐ Sibling (brother or sister)
   - ☐ Friend
   - ☐ Other (please specify)_____

3. Race
   - ☐ American Indian or Alaskan native
   - ☐ Asian
   - ☐ African American or Black
   - ☐ Hispanic
   - ☐ Native Hawaiian or other Pacific Islander
   - ☐ White
   - ☐ Other (please specify) _____

4. Ethnicity
   - ☐ Hispanic or Latino
   - ☐ Not Hispanic or Latino

5. Religion
   - ☐ Catholic
   - ☐ Protestant
   - ☐ Jewish
   - ☐ Muslim
   - ☐ None
   - ☐ Other (please specify)_____

6. Please indicate your highest or current education level
   - ☐ 11th grade or less
   - ☐ High school graduate or GED
   - ☐ 2 years of college/AA degree/Technical school training
   - ☐ College graduate (BA or BS)
   - ☐ Masters degree
   - ☐ Doctorate/Medical degree/Law degree

7. Relationship status
   - ☐ Married or living with someone as if married
   - ☐ Non-cohabiting relationship
   - ☐ Single, never married
   - ☐ Divorced or separated
   - ☐ Loss of long-term partner/widowed
   - ☐ Other (please specify) _____

8. Please indicate who (if anyone) you live with (you may check more than one box)
   - ☐ Self only
   - ☐ Partner/Spouse
   - ☐ Roommate/Friend
   - ☐ Dependent Children
     If yes, specify number(s) _____
     If yes, specify age(s) _____
   - ☐ Group home/Residential
   - ☐ Independent Child
   - ☐ Dependent Adult
   - ☐ Parent
   - ☐ Other (please specify) _____

9. Employment Status: (you may check more than one box)
   - ☐ Full time work
   - ☐ Part time work
   - ☐ Retired
   - ☐ Paid leave
   - ☐ Unpaid leave
   - ☐ Other (please specify) _____

10. What is your annual combined household income?
   - ☐ Less than $25,000
   - ☐ $25,000 – 50,000
   - ☐ $51,000 -100,000
   - ☐ $101,000 – 150,000
   - ☐ Greater than $150,000

11. Please indicate how long you have known

the patient: _____ years

12. Do you live in the same residence as the patient?
   - ☐ Yes
   - ☐ No

31.04 Locator Form

Locator Form

Please complete the following legibly.

Full name: _____

Address: _____

_____

_____

Cell phone: _____

Home phone: _____

Work phone: _____

Email address: _____

What is your preferred contact method for scheduling? (circle one): **phone call / text message / e-mail**

Date of birth (month/day/year): _____ / _____ / _____

31.05 Caregiver Oncology Quality of Life

Concerning the person you help, have you:

1. Been worried, anxious?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

2. Been sad, depressed?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

3. Felt emotionally tired, worn out?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

4. Been stressed?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

5. Felt a lack of freedom?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

6. Been bothered by the feeling of being confined?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

7. Been bothered by the fact that your life was entirely devoted to the care recipient?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

8. Been embarrassed to be the only person to provide assistance?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

9. Been satisfied with information given by health care providers (doctors, nurses…)?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

10. Been reassured by the health care providers (doctors, nurses…)?
   - ☐ Never/ Not at all
   - ☐ Rarely / a little bit
   - ☐ Sometimes / Somewhat
   - ☐ Often / A lot
   - ☐ Always / Very Much

11. Felt that your role as caregiver was recognized by health care providers (doctors, nurses…)?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

12. Had financial difficulties?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

13. Had other difficulties (lodging, transportation…)?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

14. Encountered difficulties in the administrative process (health insurance paperwork and other paperwork related to the cancer illness)?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

15. Experienced feelings of guilt?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

16. Been bothered by a feeling of helplessness against the disease?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

17. Felt a feeling of injustice, anger, or rebellion?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

18. Had sleeping difficulties?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often/ A lot
- ☐ Always / Very Much

19. Had problems with your appetite?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

20. Been physically tired, worn out?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

21. Had the impression that your health was fragile?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

22. Felt you made a difference for the person you are helping?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

23. Felt useful?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

24. Could rest, relax??

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

25. Could take care of yourself, pay attention to your own health?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

26. Been assisted, supported, understood by your family?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

27. Been assisted, supported, understood by your friends?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

28. Had difficulties in your intimate, emotional life?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Much

29. Had a satisfying love and sexual life?

- ☐ Never/ Not at all
- ☐ Rarely / a little bit
- ☐ Sometimes / Somewhat
- ☐ Often / A lot
- ☐ Always / Very Mu

31.06 Caregiver Reaction Assessment

Please answer the following items with regards to caring for your loved one during their illness.

	Strongly agree	**Agree**	**Neither agree or disagree**	**Disagree**	**Strongly disagree**
I feel privileged to care for my loved one					
Others have dumped caring for my loved one onto me					
My financial resources are adequate to pay for things that are required for caregiving					
My activities are centered around care for my loved one					
Since caring for my loved one, it seems like I am tired all the time					
It is very difficult to get help from my family in taking care of my loved one					
I resent having to take care of my loved one					
I have to stop in the middle of work					
I really want to care for my loved one					
My health has gotten worse since I have been caring for my loved one					
I visit family and friends less since I have been caring for my loved one					
I will never be able to do enough caregiving to repay my loved one					
My family works together at caring for my loved one					
I have eliminated things from my schedule since caring for my loved one					
I have enough physical strength to care for my loved one					
Since caring for my loved one, I feel my family has abandoned me					
Caring for my loved one makes me feel good					
The constant interruptions make it difficult to find time for relaxation					
I am healthy enough to care for my loved one					
Caring for my loved one is important to me					
Caring for my loved one has put a financial strain on the family					
My family (brothers, sisters, children) left me alone to care for my loved one					
I enjoy caring for my loved one					

It is difficult to pay for my loved one's health needs and services					

31.07 Lewis Cancer Self-Efficacy Scale

CASE: Cancer Self-efficacy Scale

Patient Version

Instructions:

We would like to know how confident or sure you feel about some of these areas that arise when you are going through **the experience of caring for a loved one with cancer**. Please rate your degree of confidence for each sentence by circling a number from 0 to 10 using the scale shown. When you choose a higher number, you are telling us you are more confident.

Rate the confidence you feel TODAY	**Not at all confident**										**Very confident**
1. I am confident that I can use information and resources to cope with the demands of my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
2. I am confident that I can call on my inner strengths to pull myself through my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
3. I am confident that I have what it takes to help my family through my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
4. I am confident that I can maintain close communication with my loved one about their illness.	0	1	2	3	4	5	6	7	8	9	10
5. I am confident that I can take the necessary steps to work through the demands of my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
6. I am confident that I have what it takes to help my family handle this illness.	0	1	2	3	4	5	6	7	8	9	10
7. I am confident that I can handle the challenges of my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
8. I am confident that I have ways to manage the uncertainty brought on by my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
9. I am confident that I can manage difficult interactions with my loved one's doctors, nurses, and other health care providers.	0	1	2	3	4	5	6	7	8	9	10
10. I am confident that I am can put my loved one's illness into proper perspective in my life.	0	1	2	3	4	5	6	7	8	9	10

Rate the confidence you feel TODAY	**Not at all**										**Very**

	confident										confident
11. I am confident that I have the ability emotionally to help my family work through the issues caused by my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
12. I am confident that I can deal with the physical changes caused by my loved one's illness.	0	1	2	3	4	5	6	7	8	9	10
13. I am confident that I can manage what is being asked of me despite this illness.	0	1	2	3	4	5	6	7	8	9	10
14. I am confident that I have the skills to deal with the pressures the illness is causing in my close relationships.	0	1	2	3	4	5	6	7	8	9	10
15. I am confident that I have ways to manage the side effects caused by treating the cancer.	0	1	2	3	4	5	6	7	8	9	10
16. I am confident that I can keep a positive outlook in spite of the demands of this illness.	0	1	2	3	4	5	6	7	8	9	10
17. I am confident that I have ways to manage the stress associated with this illness.	0	1	2	3	4	5	6	7	8	9	10

31.08 Measure of Current Status

People have different levels of various skills for responding to the challenges and demands of everyday life. The following items list several things that people are able to do--to a greater or lesser degree--to deal with daily stresses. For each item, indicate how well you currently can do what it describes. Please don't indicate what you think you should be able to do, or what you wish you could do. Be as accurate as you can in reporting your degree of confidence about being able to do each of these things. Choose from the following responses:

	I cannot do this at all	I can do this just a little bit	I can do this a medium amount	I can do this pretty well	I can do this extremely well
I am able to use muscle relaxation techniques to reduce any tension I experience	0	1	2	3	4
I become aware of any tightness in my body as soon as it develops	0	1	2	3	4
I can clearly express my needs to other people who are important to me	0	1	2	3	4
I can easily stop and re-examine my thoughts to gain a new perspective	0	1	2	3	4
It's easy for me to decide how to cope with whatever problems arise	0	1	2	3	4
I can easily recognize situations that make me feel stressed or upset	0	1	2	3	4
When problems arise I know how to cope with them	0	1	2	3	4
I notice right away whenever my body is becoming tense	0	1	2	3	4
It's easy for me to go to people in my life for help or support when I need it	0	1	2	3	4
I am able to use mental imagery to reduce any tension I experience	0	1	2	3	4
I am confident about being able to choose the best coping responses for hard situations	0	1	2	3	4
I can come up with emotionally balanced thoughts even during negative times	0	1	2	3	4
I can ask people in my life for support or assistance whenever I need it	0	1	2	3	4

31.09 Qualitative Exit Interview

INTRODUCTION

You recently took part in a study that was designed to help caregivers of with brain tumors cope most effectively with their loved ones' illness. We are now interested to know about your satisfaction with different aspects of this research study so that we continue to shape how to provide it to patients. There is no right or wrong answer. Your answers will be kept confidential and will not affect your participation in future research studies or your access to medical care.

First, I am going to ask you some questions about the timing of the sessions you had and how they were delivered.

1. This study was scheduled to start within 6 months after your loved one's diagnosis. How do you feel about the timing of the program?

   A. Right time
   B. Too early in treatment
   C. Too late in treatment

   Additional Comments:

2. This study was scheduled to continue for 6 weeks. How do you feel about the length of the program?

   A. Right time
   B. Too short
   C. Too long

   Additional Comments:

3. What prevented you from attending the intervention sessions? What would help you attend more of these sessions?

4. The research study was designed so that sessions can be scheduled over the phone or through telemedicine (videoconference) when in-person visits were not possible. How do you feel about the phone or video sessions?

   A. Great
   B. In-person was better
   C. Not sure

   Additional Comments:

   Additional Probe: Would you have preferred all sessions to be delivered over the telephone or telemedicine for convenience?

5. How do you feel about the total number of visits included in this research study (six visits total)?

   A. Right amount

   Additional Comments:

B. Too few

C. Too many

6. How do you feel about the amount of time each session lasted?

A. Right amount

B. Too short

C. Too long

Additional Comments:

Now I am going to ask you some questions about the material covered in your visits.

7. During these sessions, you may have learned about strategies to help you cope most effectively with your loved ones' illness. How helpful did you find these strategies?

A. Helpful

B. Not helpful

C. Not sure

Additional Comments:

Additional Probe: The interviewer can remind the caregiver about specific strategies such as acceptance, mindfulness, problem-solving, self-care, communication techniques, etc. Also ask which of these strategies was the most helpful

8. Since going to the study visits, how often have you used any of these strategies on your own?

A. Daily

B. Few times/ week

C. Once or twice

D. Never

Additional Comments:

9. During these sessions, you may have learned about skills or strategies that would help you gain more confidence in your ability to care for your loved one. How helpful was it to learn about these skills or strategies?

A. Helpful

B. Not helpful

Additional Comments:

C. Not sure

Additional probe: Which of these strategies was the most helpful?

10. Since going to the study visits, how often have you used any of the skills or strategies on your own?

A. Daily
B. Few times/ week
C. Once or twice
D. Never

Additional Comments:

11. During these sessions, you may have learned about skills or strategies that would help take better care of yourself during your loved ones' illness. How helpful was it to learn about these skills or strategies?

A. Helpful
B. Not helpful
C. Not sure

Additional Comments:

Additional probe: Which of these strategies was the most helpful?

12. Since going to the study visits, how often have you used any of the skills or strategies on your own?

A. Daily
B. Few times/ week
C. Once or twice
D. Never

Additional Comments:

13. During these sessions, you may have learned about skills or strategies that would help communicate more effectively with your loved one. How helpful was it to learn about these skills or strategies?

A. Helpful
B. Not helpful
C. Not sure

Additional Comments:

Additional probe: Which of these strategies was the most helpful?

14. Since going to the study visits, how often have you used any of the skills or strategies on your own?

    A. Daily
    B. Few times/ week
    C. Once or twice
    D. Never

    Additional Comments:

15. Is there anything else that you found helpful about this program?

16. Is there anything else that you found *not* helpful about this program?

17. What other kinds of programs focusing on improving your well-being (if any) would have been helpful *soon after* to your loved one's diagnosis?

18. What other kinds of programs focusing on improving your well-being (if any) would have been helpful *later on* following your loved one's diagnosis?

19. What other kinds of programs focusing on improving your well-being (if any) would be helpful to you now?

20. People learn information in different ways. What would you prefer in terms of how the intervention is administered?

    A. One-on-one visit with a clinician
    B. Reading information from a pamphlet
    C. Watching an informational video
    D. Telephone contact with a clinician
    F. Getting information from a mobile app

    Additional Comments:

G.	Video (skype-like) sessions	
H.	Group-based sessions with other caregivers	

21. Is there anything else that you would like to add that we have not discussed?

31.10 Oncologist Permission to Approach Email Template

Dear [Oncologist],

The caregiver of your patient, [**Patient Name] (MRN)**, is potentially eligible for Dr. Forst's pilot study of a psychological intervention aimed at decreasing anxiety and promoting coping in caregivers of patients with malignant gliomas. Would it be alright if I approached [patient] and his/her caregiver, if present, before after his/her appointment with [provider] on **[date] at [time]** to introduce the study and see if they're interested in participating?

Thank you!
[Staff Name]

31.11 Letter Template for At-Home Survey Completion by Mail

Dear [Caregiver],

Thank you so much again for your interest in our study assessing the effectiveness of a psychological intervention for caregivers of loved ones with malignant gliomas. The attached questionnaires will help us determine whether or not you are eligible to participate in the study. Once you've completed them, please mail them back in the enclosed prepaid and addressed envelope. Don't hesitate to reach out if you have any questions about questionnaires or the study!

Thank you,
[Staff Name]
[Staff Phone]
[Staff email]

31.12 Template for REDCap Survey Invitation

Dear [Caregiver],

Thank you so much again for your interest in our study assessing the effectiveness of a psychological intervention for caregivers of loved ones with malignant gliomas. Please find below a link to some questionnaires which will help us determine whether or not you are eligible to participate in the study. Please don't hesitate to reach out if you have any questions about questionnaires or the study!

Thank you,
[Staff Name]
[Staff Phone]

31.13 Phone Script for Survey Administration

Hello, this is [staff name] calling from Massachusetts General Hospital. How are you today?

Thank you so much for your interest in our study assessing the effectiveness of a psychological intervention for caregivers of loved ones with malignant gliomas. As I mentioned when we spoke in clinic, we have a few surveys which will help us to determine whether or not you're eligible for the study. Do you have about 10 minutes now to complete them over the phone with me?

(*If yes*): *Complete GAD-7 (*Appendix 31.01*) with caregiver and score immediately.*

> *If eligible (GAD-7 score ≥5): Continue to Demographics Survey (*Appendix 31.03*) and Locator Form (*Appendix 31.04*)*
>
> > *When complete:* Thank you so much for your time today! We will be in touch with you soon to begin scheduling your sessions with a psychologist or social worker. If you have any questions, please don't hesitate to reach out. I can be reached at [staff contact information]. I hope you have a great day!
>
> *If ineligible (GAD-7 score <5):* Thank you so much for your time and interest! Unfortunately, based on your answers to this questionnaire, you are not eligible for the study at this time. However, if you'd like any more information about support for caregivers, we'd be happy to reach out to your loved one's

oncologist to have them refer you to the Brain Tumor Clinic social worker. Is this something you would be interested in?

(If yes): Okay, I will go ahead and contact [oncologist's name] about this for you!
(If no): Okay! You can always talk to [oncologist's name] if you feel like this might be a helpful resource later.

Thank you so much for your time today! We really appreciate your interest in the study and are sorry that you're not eligible at this time. Please don't hesitate to reach out if you have any questions. I can be reached at [staff contact information]. I hope you have a great day!

(*If no*): When would be a more convenient time for me to call you?

When alternate call is scheduled: Thank you so much! I look forward to speaking with you on [date] at [time]. Have a great day!

Voicemail script:
Hello, this is [name] calling from Massachusetts General Hospital. I'm reaching out to get in touch with [caregiver name] regarding a research study that he/she was interested in participating in. Please give me a call back when you have a chance. I can be reached at [staff contact information]. Thank you!

31.14 Phone Script for Exit Interview

Hello, this is [staff name] calling from Massachusetts General Hospital. How are you today?

You recently took part in a study that was designed to help caregivers of patients with brain tumors cope most effectively with their loved ones' illness. We are now interested in asking you some questions about your satisfaction with various parts of this study so that we can continue to improve it. This interview will take approximately 30 minutes. Is this still a convenient time for you?

(*If yes*): *Proceed to the Interview Guide (*Appendix 31.09*)*
(*If no*): Would it be okay if I gave you a call at another time? *Select a different time for the interview.*

Voicemail script:
Hello, this is [name] calling from Massachusetts General Hospital. I'm reaching out to get in touch with [caregiver name] regarding a research study that he/she has been participating in. Please give me a call back when you have a chance. I can be reached at [staff contact information]. Thank you!

31.15 Caregiver Intervention Manual for Psychological Intervention for Caregivers of Patients with Malignant Gliomas

Caregiver manual provided as separate attachment.