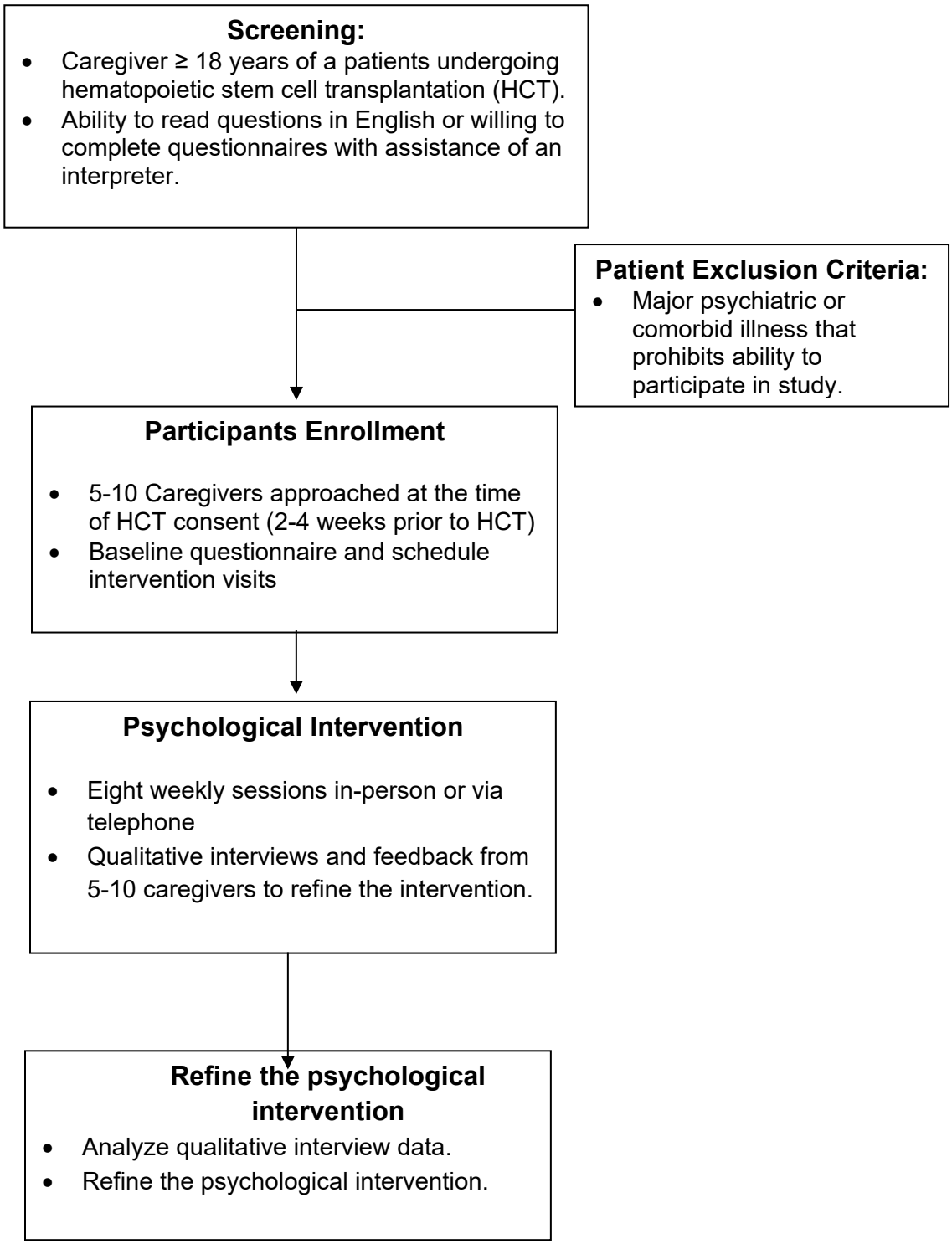
Psychological Intervention to Promote Coping for Caregivers of Patients Undergoing Hematopoietic Stem Cell Transplantation (HCT)
Protocol version 1/ 10-3-2016

**SECTION 1:**
**Protocol Schema**




SECTION 2: BODY OF PROTOCOL

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# 2 Introduction

## *2.1 Overview*

This protocol proposes to begin Phase 1 of a two phase project to develop and test a multicomponent psychological intervention for caregivers of patients undergoing hematopoietic stem cell transplantation (HCT). During HCT, patients receive high-dose chemotherapy, which is associated with multiple toxicities and leads to burdensome physical symptoms and a prolonged hospitalization. Moreover, during the first 100 days post-transplant while the patient continues to experience many challenging physical symptoms, both patients and their families attend multiple outpatient appointments, manage complex medication schedules, and cope with the uncertainty of the patient's prognosis. Thus, the family and close friends (i.e. caregivers) of patients undergoing HCT are substantially impacted by the patient's illness.

Despite the immense physical and psychological burden experienced by caregivers of patients undergoing HCT, few interventions have been developed to address their needs during the transplant. Prior research on caregivers' intervention has been challenging with many inconclusive or negative studies due to poorly defined interventions that are not specific to a particular population. Thus, there is a critical need to develop population-specific interventions with a sound methodological approach to address the specialized needs of caregivers and provide them with the necessary skills to care for and cope with their loved ones' illness.

We conducted a prospective longitudinal study of patients and caregivers during hospitalization for HCT, which clearly delineated the needs of caregivers during the transplant process. We utilized our data and a systematic review of the literature to develop a preliminary multicomponent psychological intervention to promote effective coping and caregiver well-being. In this proposed project, we will proceed in two phases that incorporate sequential mixed qualitative and quantitative methods. At this time, we are seeking IRB approval for phase 1 procedures only. During phase 1, we will obtain qualitative data from 5-10 caregivers who will participate in the psychological intervention during their loved ones' HCT course to refine the intervention content and schedule to specifically meet the needs of caregivers.

After finalizing the psychological intervention in Phase 1, we will then seek IRB approval to conduct Phase 2 of the project. Phase 2 will only begin after Phase 1 is completed and an amendment has been filed and approved by the IRB. During phase 2, we will conduct a pilot randomized controlled trial of the intervention versus usual care in 100 caregivers to assess the feasibility and preliminary efficacy of the intervention for improving caregiver QOL, mood, caregiving burden, and self-efficacy. The proposed project builds a strong foundation for the development of an innovative psychological intervention that will be tested in a future R01-funded trial.

## *2.2 Background and Significance*

**Caregivers of patients undergoing HCT experience tremendous burden caring for their loved ones**

HCT is a commonly utilized treatment modality for patients with hematologic malignancies.[1] During HCT, patients receive high-dose chemotherapy, which is associated with multiple toxicities and leads to both burdensome physical symptoms and a prolonged hospitalization.[2-6] This phase of their illness often carries the highest degree of morbidity as patients cope with symptoms from both their underlying malignancy and from prior therapies.[7] Moreover, during the first 100 days post-transplant while the patient continues to experience many challenging physical symptoms, both patients and their families attend multiple outpatient appointments, manage complex medication schedules, and cope with the uncertainty of the patients' prognosis.[8,9] Consequently, the family and close friends (i.e. caregivers) of patients undergoing HCT are substantially impacted by the patient's illness. Watching a loved one struggle with the side effects during HCT can be emotionally challenging.[7] Depending on the age and relationship of the caregiver, supporting a loved one through HCT may lead to significant disruptions in the caregiver's personal life, including difficulties in maintaining responsibilities at home and work.[10-12] Studies have shown that caregivers experience the highest distress immediately before and during their loves ones'

hospitalization for HCT, with subsequent life disruptions seen in the first three months after transplant.[7-9] Hence, caregivers of patients undergoing HCT are a highly vulnerable population with substantial caregiving burden that results in significant physical and psychological distress.

**Addressing the needs of caregivers is necessary to improve both patients' and caregivers' outcomes**

Caregiving burden often leads to substantial negative effects on caregivers' quality of life (QOL) and mood.[13] In fact, more than a quarter of caregivers of HCT recipients experience significant depression and anxiety symptoms.[7-9] Fatigue, sleep disturbances, and difficulty maintaining work are common challenges seen in this population.[11,12,14-16] We have conducted a prospective longitudinal study of patients and caregivers during hospitalization for HCT (see preliminary studies), which demonstrates that caregivers experience a substantial decline in QOL and increase in depression symptoms during the HCT process.[7] Hence, addressing the needs of caregivers has the potential to substantially impact their experience and overall QOL.[7] Moreover, as caregivers provide the majority of care for patients undergoing HCT, attending to their needs is an essential step in ensuring the delivery of high-quality care for patients with hematologic malignancies.[8,9,17]

**Interventions to promote coping and reduce burden for caregivers of patients undergoing HCT are lacking**

Despite the significant physical and psychological burden experienced by caregivers of patients undergoing HCT, interventions to address their needs during the acute transplantation process are lacking.[7,8,18] One study examined the effect of problem-solving intervention for caregivers after patients' hospitalization for HCT.[18] However, the intervention did not address the needs of caregivers immediately before and during the transplant hospitalization, when caregivers report the highest physical and psychological distress.[7] No interventions have been developed to improve caregivers' QOL and mood at their most challenging times during their loved ones' hospitalization for HCT and in the first 100 days post-HCT.

**Developing a population-specific psychological intervention for caregivers is critical to its success**

Based on a number of recent studies, researchers have demonstrated increasing interest in developing population-specific interventions to address the specialized needs of caregivers and provide them with the necessary skills to care for and cope with their loved ones' illness.[7,8,18-20] While the emerging data on caregivers' interventions are encouraging, poorly defined interventions and outcome measures have hampered the field substantially.[8,17,18] These methodological shortcomings have resulted in many inconclusive or negative studies, impeding the development of well-conceptualized and sufficiently powered randomized studies.[17]

Research suggests that caregivers of HCT recipients may benefit from a multicomponent psychological intervention to promote effective coping and caregiver well-being.[8,21] These components include 1) a psycho-educational component to enhance preparedness, manage expectations, and develop caregiving skills; 2) a psychosocial component to promote coping strategies and facilitating acceptance while living with uncertainty; and 3) a self-care component to enhance positive health behaviors and promote their well-being.[8,21]

**We propose to develop a multicomponent psychological intervention for caregivers during HCT**

Due to the immense caregiving needs during the first 100 days post-HCT, we propose a multi-component psychological intervention for caregivers. We will utilize mixed qualitative and quantitative methods to refine the intervention and to assess its feasibility and preliminary efficacy in improving caregivers' QOL, caregiving burden, mood, and self-efficacy. Our planned intervention is built upon a strong methodological foundation and the findings of a rigorous longitudinal study (see preliminary studies), which described comprehensively the experience patients undergoing HCT and their caregivers during the acute phase of transplantation.[7,22]

**Preliminary Studies:**
*QOL and Mood of Patients and Caregivers During Hospitalization for HCT*[23]: We conducted a prospective longitudinal study to investigate the impact of hospitalization for HCT on QOL and mood of patients and caregivers. We enrolled 95% (n =90) of potentially eligible patients undergoing HCT and 70% of their caregivers. We assessed longitudinal QOL and mood both weekly during the transplant hospitalization and at a follow up outpatient clinic visits, with a missing data rate of only 20%. We demonstrated that caregivers' QOL declined over time, with significant decreases in both physical and mental health. Moreover, we showed that caregiver depression symptoms increased dramatically during the HCT hospitalization. This work demonstrates our research team's success in conducting longitudinal studies in patients undergoing HCT and their caregivers. Additionally, the findings from this work were used to develop a palliative care intervention specifically addressing the needs of patients undergoing HCT. Our team utilized the data from this study to develop the psychological intervention targeting the specific needs of this population that we hope to further refine and test in this project.

*Inpatient palliative care integrated with transplant care improves patient-reported outcomes*[24]*:* Based upon on our prior study describing QOL and mood in patients undergoing HCT,[25-27] we developed a palliative care intervention targeting the specific needs of this population. We enrolled 160 of 186 (86%) eligible patients in 16 months, with only one participant withdrawing from the study. Compared to transplant care, the palliative care intervention led to a rapid and dramatic improvement in patients' QOL, depression, anxiety, and symptom burden. This work highlights our research team's experience conducting supportive care interventions targeted to the specific needs of the population, and our ability to successfully recruit and enroll patients with hematologic malignancies for intervention studies.

## 3 Objectives

The objective for Phase 1 of the study is described below.

**Objective 1:** To refine a multicomponent psychological intervention to promote effective coping and reduce caregiving burden of FC of patients undergoing HCT.

## 4 Research Subject Selection

### *4.1 Study Subject Selection:*

During phase 1, we will use qualitative data to refine the multicomponent psychological intervention specifically targeting the needs of caregivers during their loved ones' hospitalization for HCT and in the first 100 days post-HCT. We will recruit 5-10 adult caregivers of patients undergoing HCT at MGH to participate in phase 1 of this project. Caregivers will be recruited during the patient transplant consent visit, which typically occurs 2-4 weeks prior to admission for HCT. Caregivers are required to attend the HCT consent visit with the patient.

*Caregivers Eligibility Criteria:*
1) Adult caregivers (≥18 years) of patients undergoing HCT at MGH.
2) A relative or a friend who either lives with the patient or has in-person contact with him or her at least twice per week and is identified as the primary caregiver for transplant
3) Ability to speak English or able to complete questionnaires with minimum assistance of an interpreter.

*Caregivers Exclusion Criteria:*
1) Significant uncontrolled psychiatric disorder (psychotic disorder, bipolar disorder, major depression) or other co-morbid disease (dementia, cognitive impairment), which the treating clinician believes prohibits the ability to participate in study procedures.

# 5 Research Subject Entry

## *5.1 Study Research Subject Entry*

A total of 5-10 caregivers of patients undergoing HCT will particpiate in phase 1 of this study. The research team will review the transplant clinic schedule to identify potentially eligible caregivers for study participation. We will approach caregivers to participate in phase 1 during the outpatient clinic visit when their loved ones' consent for HCT, which typically occurs 2-4 weeks prior to HCT. Patients are required to be accompanied by a caregiver for the consent visit. The research team will contact eligible participants' oncology clinicians to inform them that we plan to approach the caregiver and inquire about any concerns regarding their participation. If the clinician objects to the caregivers' participation, we will document the reason and not approach those individuals.

If the oncologist has no concerns regarding the caregivers' participation, the research staff will approach eligible caregivers immediately after the transplant consent clinic visit. The research assistant (RA) will review the consent form with potential participants, which will clearly detail the nature of the study procedures and the time requirement. The RA will obtain written informed consent from participants and provide them with a copy of the signed consent form.

Enrolled caregivers will complete a baseline self-report questionnaire (Appendix A) at the time of obtaining informed consent for the study or within the 72-hour window from study enrollment. Caregivers who provide informed consent and complete the baseline questionnaire will then be registered with ODQ and scheduled for their first study intervention visit either in-person or via telephone. The RA will be responsible for contacting ODQ. The ODQ will require a copy of the caregivers' informed consent and eligibility checklist.

## 5.2 REGISTRATION PROCEDURES

### *5.2.1* Registration process for DF/HCC and DF/PCC Institutions Registrations

After completion of baseline questionnaires, caregivers will be registered centrally with the DF/HCC Office of Data Quality (ODQ) central registration system. Registration Process for DF/HCC Institutions DF/HCC Standard Operation Procedures for Human Subject Research Titled Subject Protocol Registration (SOP# REGIST-101) must be followed. For each study participant, we will complete the following registration procedures:

- We will obtain written informed consent from the participant prior to the performance of any protocol specific procedures or assessments.
- We will complete the ODQ protocol-specific eligibility checklist using the eligibility assessment documented in the research chart. Only eligible participants will be registered. To be eligible for registration to the protocol, the participant must meet all including and exclusion criterion as described in this protocol and reflected on our eligibility checklist.
- We will fax the eligibility checklist(s) and all pages of the consent form(s) to the ODQ at 617-632-2295.
- The ODQ Registrar will a) review the eligibility checklist, b) register the participant on the protocol, and c) randomize the participant when applicable.
- An email confirmation of the registration will be sent to the Overall PI, study coordinator(s), treating investigator, and registering person immediately following the registration.

We are requesting a a HIPAA Waiver of Alteration to Use or Disclose of Protected Health Information from the IRB. This waiver is being requested to identify potential participants from a minimal chart review.

In accordance with the DF/HCC policy, this Waiver: (1) is being sought solely to review Protected Health Information as necessary to prepare a research protocol, (2) will not include removing Protected Health Information from the Covered Entity by the researcher, and (3) the Protected Health Information for which we are requesting access is necessary for the research purposes.

### *5.2.2* Registration Process for Other Investigative Sites: Not applicable

## 5 Study Design and Methods

### *5.1 Design/ Study Type*

During phase 1, we will use qualitative data to refine a multicomponent psychological intervention specifically targeting the needs of caregivers' during their loved ones' hospitalization for HCT and in the first 100 days after transplant.

**Phase 1 Intervention Refinement:** We utilized the findings from our longitudinal study and a thorough review of the literature to identify the necessary components of our planned caregiver intervention, as depicted in Table 1.[7,8,21] 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 eight individual sessions (30-45 minutes each) starting prior to admission for HCT and continuing until day + 70 after HCT, which will provide sufficient dose to promote effective coping and reduce caregiving burden. We will coordinate sessions with hospital and clinic visits or conduct them via phone to minimize participant burden and facilitate adherence. Dr. Jacobs (a behavioral psychologist and researcher) will deliver the intervention. Dr. Jacobs has extensive experience as a therapist on NIH-funded trials. During phase 1, we will refine the intervention based on qualitative interviews and feedback from 5-10 caregivers who will attend the psychological intervention sessions. We will then finalize the study intervention manual, which will be used in phase 2.

**Table 1 Potential Intervention Topics Based on Preliminary Conceptual Model**

| Session | Behavioral Target | Skill Area | Topics |
|---|---|---|---|
| 1 | **Introduction** | Psychoeducation | ➢ Introduce intervention purpose and goals<br>➢ Explore how FC cope with the HCT process<br>➢ Manage expectations for HCT, acknowledge and normalize fears |
| 2,3 | **Coping & managing emotions** | Psychosocial | ➢ Explore strategies for balancing acceptance and change-oriented coping approaches.<br>➢ Introduce mindfulness to observe the HCT experience (thoughts, feelings, loved ones' symptoms) in an objective, nonjudgmental fashion<br>➢ Explore the use of mindfulness to cope with HCT-related uncertainty<br>➢ Identify ways to support loved ones during HCT hospitalization |
| 4,5 | **Preparedness & caregiving skills** | Psychoeducation | ➢ Identify caregiving needs in the immediate post-HCT period<br>➢ Help FC gain more confidence in responding to physical and psychosocial issues post-HCT<br>➢ Elevate FC sense of self-efficacy<br>➢ Enhance FC communication with the health care team |
| 6 | **Healthy behaviors & self-care** | Self-care | ➢ Identify and explore FC needs<br>➢ Introduce strategies for stress management, and promotion of self-care behaviors (sleep, healthy diet, exercise, and seeking support) |
| 7 | **Interpersonal relationship** | Psychosocial | ➢ Identify attitudes and beliefs about FC relationship to the patient |

| | | | |
|---|---|---|---|
| | | | ➢ Identify differences between assertive, passive, aggressive behaviors<br>➢ Introduce strategies to encourage relationship-enhancing behaviors |
| 8 | **Program overview** | All | ➢ Summarize and review main content of the intervention<br>➢ Address additional challenges and problems<br>➢ Brainstorm strategies to maintaining use of skills over time. |

**Utilizing data from phase 1 to refine the intervention:** We will utilize the qualitative data obtained from phase 1 and clinicians' experience to finalize the multicomponent psychological intervention. Specifically, we will refine the following aspects of the intervention:

- ***Intervention content:*** We will use caregivers' feedback to confirm the relevance of the intervention content, and to revise content as needed. For instance, if caregiver report that they would have liked to focus on more active coping strategies, we will increase the balance between change- and acceptance-oriented (e.g., mindfulness) approaches. To further enhance the intervention, we also may integrate caregivers' real-life concerns as examples throughout the protocol when introducing the use of coping skills and strategies.
- ***Program structure and schedule:*** We anticipate that caregivers will have different needs during their loved ones' hospitalization for HCT vs. the immediate post-transplant period. However, we will use caregivers' feedback to guide the order and timing of the eight intervention sessions during these two periods. Additionally, we may revise session number (8 sessions) or length (30-45 min per session) based on caregivers' feedback about participation burden and utility.
- ***Program modality:*** We will use exit interview data to determine whether the delivery of the intervention visit in-person or over the phone was acceptable to participants.
- ***Additional areas of concern:*** We will identify any additional areas of concern from caregivers that were not addressed specifically in the intervention and integrate them in a revised intervention manual.

### *5.2 Selection of study instruments*

**Baseline questionnaire:** During the baseline questionnaire, we will obtain demographic data including age, gender, race, ethnicity, religion, relationship status, relationship of the caregiver to the patient, education level, and annual household income [Appendix A].

**Qualitative interview guide:** 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 B. The interview will last approximately 30 minutes. The participants will not be required to complete any additional study instruments. The qualitative interview will be conducted in-person or over the telephone (Appendix C).

**Training of research coordinator to conduct qualitative interviews:** We will utilize the MGH Cancer Outcomes Research Group (CORe) extensive experience training research assistants to conduct semi-structured qualitative interviews with the use of the interview guide. The research assistant will first complete an initial training with Dr. Elyse Park, a psychologist with extensive experience conducting qualitative interviews. They will then conduct mock practice interviews with the presence of both Dr. El-Jawahri (PI) as well as Dr. Park (co-investigator). They will be provided direct feedback regarding their qualitative interview technique. Lastly, the research assistant will be supervised by Dr. El-Jawahri, Dr. Jacobs (a psychologist and co-investigator) or Dr. Park during their first two qualitative interviews with

study participants to ensure appropriate interview techniques. Of note, the research assistant will utilize a semi-structured interview guide (Appendix C) for all interviews.

### *5.3 Description of Intervention*

The multicomponent psychological intervention is described in detail in section 5.1. It entails eight individual sessions (30-45 minutes each) starting prior to admission for HCT and continuing until day + 70 after HCT, which will provide sufficient dose to promote effective coping and reduce caregiving burden. We will coordinate sessions with hospital and clinic visits or conduct them via phone to minimize participant burden and facilitate adherence. Dr. Jacobs (a behavioral psychologist and researcher) will deliver the intervention. Dr. Jacobs has extensive experience as a therapist on NIH-funded trials.

### *5.4 Data Collection*

We will audio-record all qualitative exit interviews and save them on HIPPA-compliant electronic storage. We will transcribe the interviews and we will save the text documents on HIPPA-compliant electronic storage for qualitative analysis. All additional data will be stored in locked cabinets at MGH as well as password-protected computer files, accessible only to trained study staff. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept in a separate file under lock and key.

### *5.5 Description of Study Process*

#### 5.5.1 Study Instrument Administration

After signing consent, we will schedule caregivers for their intervention visits with Dr. Jacobs. Upon completion of the intervention visits around day +90 (+/- 15 days) post-HCT, the trained research assistant or the principal investigator will conduct the qualitative exit interviews with study participants using a semi-structured interview guide (Appendix B). The interview will last approximately 30 minutes. Participants will be asked to be frank and will be reminded that there is no right or wrong answer to any question. Participants will also be reminded that they may refuse to answer any question that they choose. Drs. Areej El-Jawahri (Principal investigator), and Jamie Jacobs (clinical psychologist and co-investigator) will be available to provide support and supervise the qualitative interview process.

#### 5.5.2 Intervention Administration

Please see sections 5.1 and 5.3 as discussed previously regarding the intervention visits.

#### 5.5.3 Special Concerns

We do not anticipate any complications with this study. 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 to 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. Areej El-Jawahri) or a clinical psychologist (Dr. Jamie Jacobs, a co-investigator) to help address their distress.

**5.5.4 Compensation:** There will be no compensation for participating in this study.

### *5.6 Adverse Reactions and Their Management*

#### *5.6.1 Reporting Adverse or Unanticipated Events*

We do not anticipate any harm with our study procedures. While some topics probed during the intervention are sensitive in nature, no adverse or unanticipated events occurred in previous studies of psychological interventions conducted by our research group. Additionally, our research team has extensive experience conducting psycho-behavioral interventions and qualitative interviews on sensitive topics without any adverse events. Should adverse or unanticipated events occur during the course of the study, a trained study staff member will report the events to the IRB as soon as they are discovered.

#### *5.6.2 Anticipated 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 to 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. Areej El-Jawahri) or a clinical psychologist (Dr. Jamie Jacobs, a co-investigator) to help address their distress.

#### *5.6.3 Reaction Management*

Should caregivers experience distress during the intervention or the qualitative exit interview, Drs. Areej El-Jawahri (oncologist) and Jamie Jacobs (clinical psychologist) will be available to address their acute needs. Should participants require further support, we will offer them an opportunity to meet with the outpatient social worker for additional follow-up.

## 6 Ethical and Legal Issues

### *6.1 Confidentiality*

All patient information will remain confidential and stored on Partners computers. Identifiers such as name will only be used during the initial data retrieval process and can be destroyed once all data records have been obtained and data analysis completed.

## 7 Statistical Analysis

### *7.1 Study Endpoints:*

#### *7.1.1 Primary Endpoint:*

The primary endpoint of Phase 1 is developing a finalized version of the psychological intervention for caregivers of patients undergoing HCT based on the findings from the qualitative data analysis.

### *7.2 Sample Size Calculation:*

We will recruit and consent 5-10 caregivers for Phase 1. Based on our team's prior qualitative research experience, we believe that this sample size will be sufficient to achieve thematic saturation.

### *7.3 Analysis Plan:*

**Phase 1 Data Analysis and Interpretation:** We will use descriptive statistics to summarize the demographic and clinical characteristics of the caregivers enrolled in the study. Our planned sample size (n = 5-10) will allow us to collect comprehensive feedback about the intervention and ensure that we have sufficient number of participants to achieve thematic saturation. The qualitative component of the

exit interviews will 1) explore caregiver perception of the acceptability and content of the intervention; and 2) explore caregiver perceptions of the benefits of receiving the intervention. We will also evaluate the acceptability of the intervention by exit interview responses. We will analyze the qualitative data from the exit interview according to the NIH-Best Practices for Mixed Methods research in Health Sciences for applicability, preferences, clinical relevance, intervention length/timing, and challenges.[28] Study staff will independently review the qualitative interview transcripts to create a thematic framework for interpretation. Two independent coders (Drs. Jacobs and El-Jawahri) will independently code the data to enhance validity and credibility, until high reliability is achieved (Kappa >0.080). Discrepancies will be resolved by comparison to raw data and reviews by Drs. Temel, Jacobs, El-Jawahri, and Park.

We will utilize the qualitative data obtained from phase 1 and clinicians' experience to finalize the multicomponent psychological intervention. Specifically, we will refine the following aspects of the intervention:

- ***Intervention content:*** We will use caregivers' feedback to confirm the relevance of the intervention content, and to revise content as needed. For instance, if caregiver report that they would have liked to focus on more active coping strategies, we will increase the balance between change- and acceptance-oriented (e.g., mindfulness) approaches. To further enhance the intervention, we also may integrate caregivers' real-life concerns as examples throughout the protocol when introducing the use of coping skills and strategies.
- ***Program structure and schedule:*** We anticipate that caregivers will have different needs during their loved ones' hospitalization for HCT vs. the immediate post-transplant period. However, we will use caregivers' feedback to guide the order and timing of the eight intervention sessions during these two periods. Additionally, we may revise session number (8 sessions) or length (30-45 min per session) based on caregivers' feedback about participation burden and utility.
- ***Program modality:*** We will use exit interview data to determine whether the delivery of the intervention visit in-person or over the phone was acceptable to participants.
- ***Additional areas of concern:*** We will identify any additional areas of concern from caregivers that were not addressed specifically in the intervention and integrate them in a revised intervention manual.

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# 9 Appendices

## Appendix A: Baseline Questionnaire

### Caregiver Demographics

Please check the appropriate box or boxes.

1. Date of birth (mm/dd/yyyy) _____

2. Gender
   - ☐ Man
   - ☐ Woman
   - ☐ Other

3. Relationship to patient
   - ☐ Married or living as if married
   - ☐ Non-cohabiting relationship
   - ☐ Divorced/Separate
   - ☐ Child (daughter or son)
   - ☐ Parent (mother or father)
   - ☐ Sibling (brother or sister)
   - ☐ Friend
   - ☐ Other family

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

5. Race (please check all that apply)
   - ☐ American Indian or Alaskan native
   - ☐ Asian
   - ☐ African American or Black
   - ☐ Native Hawaiian or other Pacific Islander
   - ☐ White
   - ☐ Other (please specify) _____

6. Religion
   - ☐ Catholic Christian
   - ☐ Other Christian (such as Protestant, Orthodox, etc.)
   - ☐ Jewish
   - ☐ Muslim
   - ☐ Atheist
   - ☐ None
   - ☐ Other (please specify)_____

7. 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

8. Current employment status
   (please check all that apply):

   - ☐ Employed (full-time or part-time)
   - ☐ Caring for home or family (not currently employed and not looking for paid work)
   - ☐ Unemployed and looking for work
   - ☐ Unable to work due to illness or disability
   - ☐ Retired
   - ☐ Student
   - ☐ Other (please specify) _____

9. Please indicate how long you have known the patient: _____ years

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

Your name: _____

Please enter your email address
(will only be used if necessary):
_____

What is the best phone number to use if we needed to reach you?

_____

**Appendix B: Qualitative Interview Guide**

**INTRODUCTION**

You recently took part in a study that was designed to help caregivers of patients undergoing hematopoietic stem cell transplantation (HCT) 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 1-2 weeks prior to HCT. How do you feel about the timing of the program?

   A. Right time
   B. Too soon before transplant
   C. Too close to time of transplant

   Additional Comments:

2. This study was scheduled to continue through day +70 after HCT. How do you feel about the timing of the program?

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

   Additional Comments:

3. The research study was designed so that sessions were scheduled along with your other medical appointments whenever possible. How do you feel about the convenience of attending the sessions?

   A. Convenient
   B. Not convenient
   C. Not sure

   Additional Comments:

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

5. The research study was designed so that sessions can be scheduled over the phone when in-person visits were not possible. How do you feel about the phone 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 for convenience?

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

   A. Right amount
   B. Too few
   C. Too many

   Additional Comments:

7. How do you feel about the amount of time each visit 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.

8. 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

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

| | |
|---|---|
| A. Daily<br>B. Few times/ week<br>C. Once or twice<br>D. Never | Additional Comments: |

10. 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<br>B. Not helpful<br>C. Not sure | Additional Comments: |

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

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

| | |
|---|---|
| A. Daily<br>B. Few times/ week<br>C. Once or twice<br>D. Never | Additional Comments: |

12. 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<br>B. Not helpful<br>C. Not sure | Additional Comments: |

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

13. 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:

14. 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?

15. 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:

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

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

18. What other kinds of programs focusing on improving your well-being (if any) would have been helpful *prior* to your loved ones' stem cell transplantation?

19. What other kinds of programs focusing on improving your well-being (if any) would have been helpful *immediately after* your loved ones' stem cell transplantation?

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

21. 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<br>B. Reading information from a pamphlet<br>C. Watching an informational video<br>D. Telephone contact with a clinician<br>F. Getting information from a mobile app<br>G. Video (skype-like) sessions<br>H. Group-based sessions with other caregivers | Additional Comments: |

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

**Appendix C: Qualitative Interview Phone Script**

Hello—is [name of caregiver] there? Hi, my name is [research coordinator's name] I work at the MGH Cancer Center, and I am calling about the quality of life research study in which you are participating. Is now a good time to talk briefly?

If yes→ *Move on to next section.*

If no→ "Is there a better time at which I could call back?"

As a final part of the study procedures, we would like to ask you to complete an exit interview over the phone. As we discussed previously, we will audio-record our conversation to help improve the intervention for future research studies. Do you have about 30 minutes to complete it with me now?

If yes→"Great, thank you."
*Proceed to administering the qualitative interview (Appendix B).*

If no→ "Is there a better time at which I we could complete the interview?"