# PROTOCOL TITLE:

A dyadic intervention for young adult patients with cancer and their partner caregivers

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## VERSION NUMBER:

1.4

## DATE;

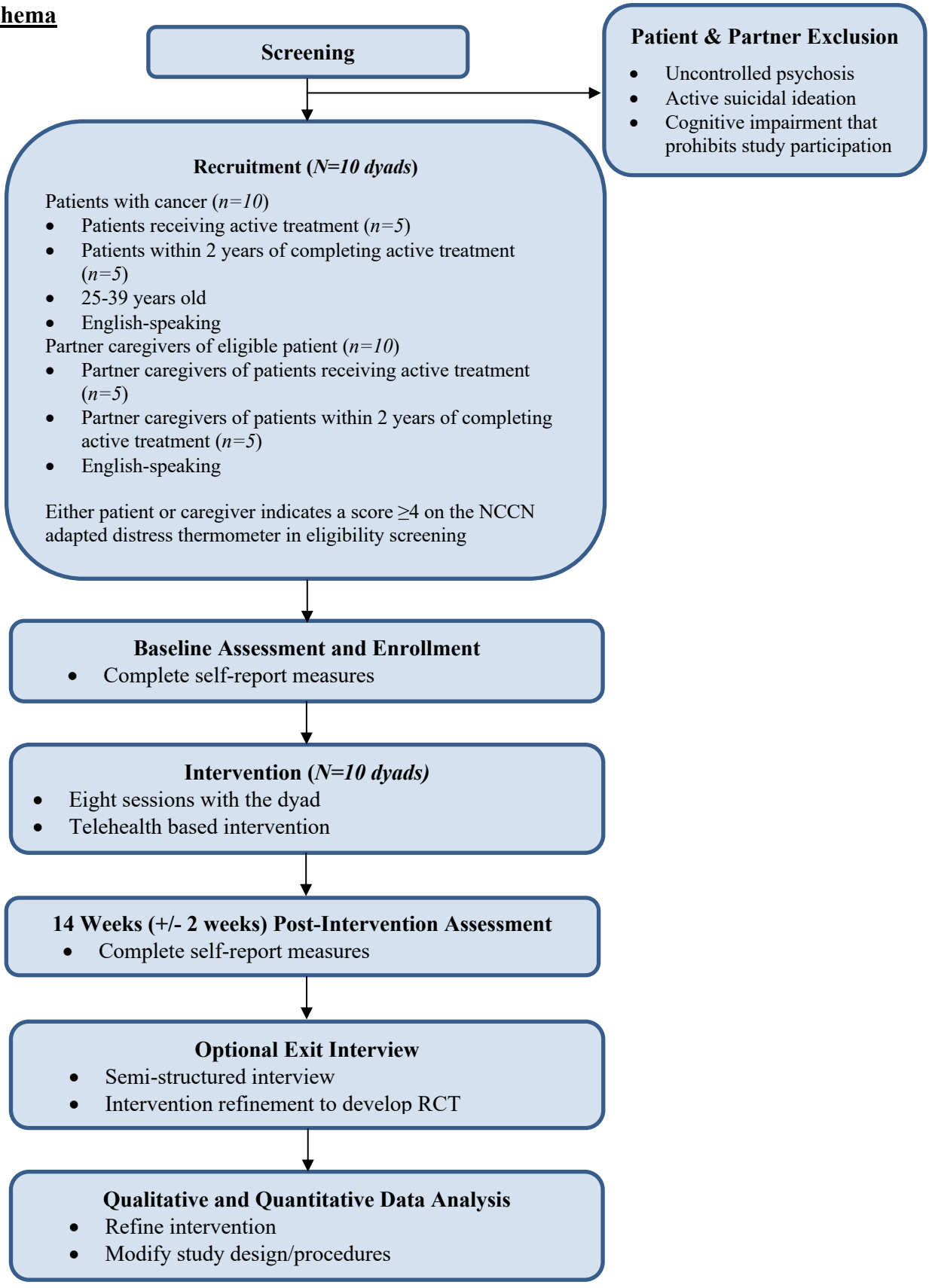
12/19/2024

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**Protocol Schema**



# 1.0 Objectives

## *1.1 Overview*

This protocol proposes the initiation of Phase 2 of a two-phase mixed-methods study to develop and test a dyadic intervention to reduce distress in young adult patients with cancer and their partner caregivers. In Phase 2 of this study, we will conduct a single-arm pilot intervention with young adult dyads (N=10 dyads) to examine acceptability and feasibility of the eight-session intervention. The preliminary data obtained from this study will be used to inform adaptations to revise or modify the intervention. Findings will then inform a future pilot RCT to formally explore feasibility and acceptability prior to a full-scale efficacy trial. This project is funded by the American Cancer Society and the Harvard Club of New York Foundation.

## *1.2 Specific Aims*

Primary Aim: To refine the intervention and study design based on a small open pilot trial and semi-structured exit interviews with young adult dyads with cancer (N=10 dyads).

*Hypothesis 1: The study will be feasible, defined by recruitment (enrollment rate ≥ 50%), retention (follow-up assessment completion rate ≥ 70% of all participants who complete baseline) and attendance (attendance rate of at least 70% of participants completing at least 6 of 8 sessions [75%]).*

*Hypothesis 2: The study will be acceptable demonstrated by ≥ 75% of participants reporting average satisfaction scores greater than the scale's mid-point (Client Satisfaction Questionnaire[CSQ]).*

# 2.0 Background

## *2.1 Prior Research and Current Gaps in Knowledge*

**Young adult patients with cancer have distinct unmet psychosocial needs.** Approximately 89,000 young people are diagnosed with cancer each year in the United States,[1] and cancer is the leading disease-related cause of death in young adults ages 20-34.[2] These young adults experience significant medical and psychosocial challenges that are exacerbated by the timing of their cancer diagnosis within the developmental lifespan.[3,4] A cancer diagnosis and treatment disrupts the realization of typical age-related pursuits such as creating an autonomous lifestyle, attaining career growth, achieving financial independence, pursuing romantic relationships, and starting a family.[4,5] As evidence, approximately 78% of young adults with cancer ages 26-39 report cancer-related financial toxicities, which is significantly more than other age groups,[6] and up to 51% report fertility-related concerns.[7,8] Consequently, young adults with cancer report poorer quality of life (QOL), greater distress, and worse mental health than other age groups with cancer.[5,9,10]

**The partner caregivers of young adults with cancer may have even more unmet needs.** The over 6 million family cancer caregivers in the U.S.[11] have a rising burden due to better survival rates and shifts towards outpatient cancer care.[12] "Partner" caregivers are the spouse, domestic partner, or significant other caring for someone with cancer.[13] They are

often the patient's primary coping resource[14] and assume a range of household and medical responsibilities.[15] It is well-documented that family caregivers often have more unmet psychosocial and physical health needs than patients themselves.[15,16] Importantly, the partner caregivers of young adult patients have added burden due to the developmental context of the relationship[17] and how this affects communication, roles, and responsibilities.[18-20] Not surprisingly, QOL in partners of young adults is worse than that of partners of older cancer survivors,[21] and partners of young adult patients report more depression, worse sexual functioning, lower marital satisfaction, and lower overall well-being.[22] Young adult caregivers are also likely to take forced time off from work with long-term financial and career ramifications.[23]

**Avoidance of young adult-specific challenges negatively affects the relationship.** Topics that are relevant to the young adult cancer experience are often avoided, including 1) treatment-related fertility risks and reproductive options,[24,25] 2) sexual health and treatment-related sexual dysfunction,[26,27] 3) financial toxicities and work restrictions,[28-30] 4) long-term and late onset treatment sequelae that limits functioning,[31] and 5) prognosis and end-of-life care preferences.[32,33] Avoidance of these topics exacerbates distress in both partners[4] and negatively affects the romantic relationship;[34,35] evidence suggests that younger couples have poorer dyadic coping than middle-aged couples.[36] In addition, couples with communication difficulties (e.g., holding back from discussing cancer-related concerns)[37-39] experience greater distress and poorer relationship functioning and QOL,[40-43] which can result in the relationship's dissolution.[44] Furthermore, patients and partners respond to cancer as an interdependent system in which one partners' emotional well-being influences the other.[45,46] In fact, one study found that younger couples demonstrated a stronger relationship interdependence and this predicted adaptive and maladaptive coping behaviors.[36] Overcoming reluctance to discuss cancer-related challenges may result in better communication, intimacy, and emotional support for young couples.[47]

**Couple-based interventions improve dyadic coping and relationship outcomes.** Couples that engage in communication and joint dyadic coping report high relationship functioning, QOL, and adjustment to cancer.[39,48-51] Correspondingly, the past two decades have seen an increase in couple-based interventions in cancer that focus on improving communication and coping.[17,52,53] A meta-analysis revealed overall benefits of couple-based interventions for multiple QOL domains for patients (g=0.25-0.31) and their partners (g=0.21-0.24).[53] Certain couple-based interventions resulted in more sustained intervention effects than patient-directed interventions.[54] Interventions have demonstrated efficacy for improving dyadic-level adjustment, communication, relationship functioning, anxiety, depression, perceived stress, and fatigue.[17,52,55,56] However, there are very few couple-based interventions for young couples with cancer[17,57] and little understanding of which couples may benefit from certain interventions.[58,59]

**Couple-based interventions for young adult patients and their partner caregivers are lacking.** First, all intervention studies in young couples have been in breast cancer[54,56,60-64] and researchers have emphasized for the need for young couple-based interventions across cancer types.[17] Second, of the exploratory studies examining distress in young adult patients and their caregivers, the majority enrolled parental caregivers, leaving the needs of partners uncharacterized.[65,66] Third, few programs are tailored to the needs of young adults with cancer and the NCI considers this to be a health disparity and priority area.[67] Fourth, while most interventions have been conducted in-person or by telephone,[17]

researchers have advocated for the need to understand young couples' preferences for the use of technology platforms that might be more feasible for young adults who are working or caring for young children.[17,68] Fifth, several reviews have noted that dyadic intervention development has often neglected to examine acceptability and barriers to participation.[17,53]

**The proposed mixed-methods study will overcome prior limitations by developing, refining, and evaluating a couple-based telehealth intervention for young adults with cancer and their partner caregivers.** Overall, researchers have advocated against a "one-size fits all" approach[36] in favor of developing more targeted couple-based interventions. In order to develop a targeted intervention, we will proceed in two stages within the NIH Stage Model of Behavioral Intervention Development.[69,70] Phase 1 is currently underway and will inform the development of the intervention based on an existing efficacious couple-based intervention in oncology.[60,71] This intervention is informed by the qualitative analysis of semi-structured interviews from Phase 1 with young adult patients and their partner caregivers, a review of the literature, and expert input from psychologists and oncologists. Phase 2 will entail a single-arm pilot with young adult dyads to examine acceptability and make modifications. Findings will be used as preliminary data inform a future pilot RCT that will formally explore feasibility and acceptability prior to a full-scale efficacy trial.

### *2.2 Preliminary Data.*

**Preliminary Studies**

In a previous study of caregivers of patients undergoing transplant, young adult caregivers (age ≤39) demonstrated significantly higher levels of anxiety ($M_{diff}$=2.38, $SE_{diff}$=.84, p=.005) and depressive symptoms ($M_{diff}$=1.93, $SE_{diff}$=.45, p=.011) than caregivers greater than 39 years of age, confirming the psychosocial needs of this population.[75] We also published findings showing that depressive and anxiety symptoms were interrelated in patients with newly diagnosed cancer and their caregivers,[76] demonstrating the necessity for a dyadic intervention. We conducted a qualitative analysis of cancer caregiver distress in which we identified that inequity in relationship roles, avoidance of difficult topics, and protective buffering were major sources of distress;[77] these behaviors are modifiable with a couple-based intervention. In a RCT of a skills-based intervention for caregivers of patients undergoing stem cell transplant, intervention-related increases in self-efficacy and stress coping skills led to improvements in QOL and reductions in depressive symptoms in the intervention group, suggesting that these skills are essential.[78] Finally, we are currently conducting a study in patients with cancer and their caregivers assessing the efficacy of two caregiver-specific interventions. Our enrollment rates show strong feasibility, with 82/93 (88%) eligible caregivers and 41/41 (100%) eligible patients enrolled.

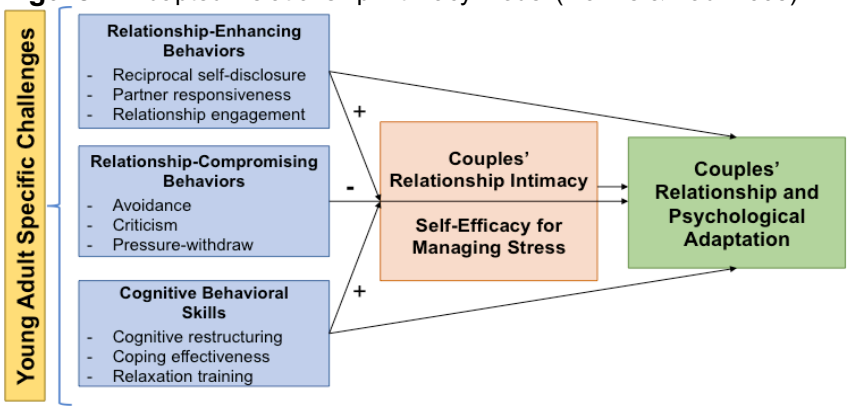
### *2.3 Scientific Background and Rational.*

**Theoretical Frameworks**

The intervention will be adapted based on an efficacious couple-based intervention[60,71] developed by study consultant Dr. Sharon Manne, an expert in couple-based interventions, and Dr. Giselle Perez, an expert in young adult patients with cancer. The intervention will also be informed by The Relationship Intimacy Model of Couple Psychosocial Adaptation to Cancer (see Figure 1),[14] which has been used to guide interventions for couples with cancer.[71] This model is an overarching, heuristic model that focuses on intimacy as a

primary mechanism for promoting couples' adaptation by increasing "relationship-enhancing" and decreasing "relationship-compromising" behaviors. "Relationship-Enhancing" behaviors include *reciprocal self-disclosure* about cancer-related concerns, *partner responsiveness* to promote understanding and acceptance, and *relationship engagement* about the effect of cancer on the relationship. "Relationship-Compromising" behaviors include *avoidance* of true worries about cancer, *criticism* about how each partner is coping, and *pressure-withdraw* (i.e., the pattern of withdrawal following pressure to talk about a cancer-related problem). In line with Social Cognitive Theory (SCT),[74] we will also incorporate targeted cognitive-behavioral therapy skills for increasing self-efficacy. SCT posits that self-efficacy is a key contributor to behavior change and that emotional disclosure facilitates cognitive processing and mitigates intrusive thoughts.[74] Prior research has demonstrated that increases in self-efficacy over time drives improvements in QOL and reductions in depressive symptoms.[82]

**Figure 1.** Adapted Relationship Intimacy Model (Manne & Badr 2008)




**Summary:** These preliminary data demonstrate that young adults with cancer experience unique psychosocial distress specific to the timing of cancer within their developmental trajectory. Furthermore, given that distress is interdependent in patients and their partner caregivers, a dyadic intervention addressing couple's distress as a unit is essential. Finally, incorporating skills to enhance relationship communication and intimacy while promoting self-efficacy and coping are modifiable targets of a couple-based intervention in cancer and are in line with the Relationship Intimacy Model of Couple Psychosocial Adaptation to Cancer[16].

## 3.0 Inclusion and Exclusion Criteria

### *3.1 Screening Procedures*

Young adult patients with cancer and partner caregivers will be recruited from the oncology clinics at Massachusetts General Hospital (MGH) Cancer Center and three MGH-affiliate sites (MG North Shore, MG Newton-Wellesley, MG Emerson). Study staff at MGH will screen the clinic schedules for potentially eligible patients, beginning with the most common cancers in young adults: brain tumors, breast cancer, lymphoma, and colorectal cancer and may also screen in other disease groups as needed. Study staff will preliminarily review the electronic health record (EHR) for demographic and clinical eligibility criteria and request permission from a member of the care team to approach patients and/or partner

caregivers about the study. Specifically, study staff will email the oncology provider (i.e., oncologist, nurse practitioner) to inquire if they have any reservations about the study team approaching the patient and/or caregiver for study participation (see Appendix 31.1).

We are requesting a partial waiver of HIPAA Authorization for our team to perform an initial screening process that requires review of the electronic medical record. This waiver is being requested to allow the research team to screen the oncology clinic schedules and identify potential study patient participants from a minimal chart review. In accordance with the DF/HCC policy: (1) this Waiver is being sought solely to review Protected Health Information (PHI) as necessary to prepare a research protocol; (2) the Waiver will not include removing PHI from the Covered Entity by the researcher, and (3) the PHI for which we are requesting access is necessary for research purposes.

### *3.2 Inclusion and Exclusion Criteria*

The eligibility criteria (Table 1) were selected to maximize homogeneity in the sample and target a population in late young adulthood that is known to have similar life experiences and developmental considerations as it relates to their cancer. As the intervention will be conducted dyadically, both the patient and their partner must be eligible to participate. The study will have a total accrual goal of 10 dyads consisting of young adult patients with cancer (n=10) and their partner caregivers (n=10). The recruitment will aim to enroll an equal representation of patients and partner caregivers during and after treatment.

The sample for this single-arm pilot study includes individuals who are able to read and respond in English only. This is due to the narrow scope of this single-arm study (N=10 dyads) and the necessity to maintain homogeneity in a pilot sample. Based on the findings of this pilot study, future studies may propose adaptation and scientific validation of the intervention under study so that it is tailored for individuals who do not speak English.

| **Table 1. (N=10 dyads)**<br>**Patient Inclusion Criteria** |
|---|
| 1. Currently receiving active cancer treatment (n=5) or are within two years of completing active treatment (n=5) at MGH |
| 2. 25-39 years of age |
| 3. English-speaking |
| 4. Either patient or caregiver indicates a score ≥4 on the NCCN adapted distress thermometer study screening questions |
| **Patient Exclusion Criteria** |
| 1. Uncontrolled psychosis, active suicidal ideation, or cognitive impairment |
| **Partner Inclusion Criteria** |
| 1. Are the partner of an individual between the ages of 25-39 who is currently receiving treatment at MGH (n=5) or who has completed cancer treatment at MGH within the past two years (n=5) |
| 2. English-speaking |
| 3. Either patient or caregiver indicates a score ≥4 on the NCCN adapted distress thermometer study screening questions |

| **Partner Exclusion Criteria** |
| --- |
| 1. Uncontrolled psychosis, active suicidal ideation, or cognitive impairment |

### *3.3 Special Populations*

Pregnant women may be included in this study if they meet other conditions for study eligibility. Special populations including adults unable to consent, individuals who are not yet adults, or prisoners, will not be included in this study.

Couples will be eligible to participate if one of the partners indicates a ≥4 on the NCCN adapted distress thermometer during the screening portion of the approach call. For couples who are not eligible due to not scoring a 4 or greater, study staff will reapproach approximately 6 months after first screening conversation.

## 4.0 Study-Wide Number of Subjects

We propose a single arm dyadic intervention to reduce distress in young couple dyads (N=10 dyads) consisting of young adult patients with cancer (n=10) and their partner caregivers (n=10).

## 5.0 Study-Wide Recruitment Methods

### *5.1 Recruitment and Enrollment Procedures*

The following recruitment procedures will be executed at the lead site, MGH Boston, and at all MGH-affiliate study sites (MG North Shore, MG Newton-Wellesley, MG Emerson). The MGH-affiliate sites will not have any responsibilities regarding recruitment or enrollment. All study sites will be open through the DF/HCC IRB as the IRB of record.

Participants will be recruited through the following three methods:

EHR Screening: As detailed above (Section 3.1), study staff will screen the MGH cancer center clinics at MGH Boston and MGH affiliate sites for potentially eligible patients (under the use of a HIPAA waiver, submitted to the DF/HCC IRB). The study staff will reach out to eligible patients and partner caregivers with the recruitment script to assess fit and eligibility for the study (Appendix 31.2).

The Partners Rally Recruitment Portal: Study staff will submit a recruitment advertisement to the Partners Rally Recruitment Portal (Appendix 31.3). Through this portal, interested and potentially eligible patients and partner caregivers will be able to send in their contact information to the study staff. The study staff will reach out to interested patients and partner caregivers with the recruitment script to assess fit and eligibility for the study (Appendix 31.2).

Provider referral & Self-Referral: Patients and/or partner caregivers may be referred by clinician or via self-referral through study flyers (Appendix 31.4), online advertisements (Appendices 31.5), or social media (Instagram, Facebook, and Twitter) (Appendix 31.5). If a patient is referred by a cancer center clinician or via self-referral (i.e., Study Flyer or

Social Media), the study staff will reach out to interested patients and use the recruitment script to assess fit and eligibility for the study (Appendix 31.2).

If patients or caregivers are not available, study staff will leave a voicemail (Appendix 31.6). We will aim to enroll an equal representation of patients and partner caregivers during and after treatment. Upon receiving clinician approval, trained study staff will approach eligible dyads remotely to explain the study and perform verbal consent procedures over the telephone.

If the patient and caregiver express interest or if clinician approval is acquired and the dyad is eligible, trained study staff will approach them remotely to explain the study and perform verbal consent procedures over the phone. The verbal consent forms will describe all study procedures, information about potential risks and benefits of participation, and information regarding who they can contact for further questions. We are requesting a waiver of written documentation of consent. This study meets the requirements for a waiver as it is a minimal risk study, and all study procedures can be communicated verbally. Verbal consent will allow study staff to address barriers to study enrollment, more easily reach partner caregivers, and allow for greater flexibility while assuring patient and caregiver safety in response to changing healthcare practices due to the COVID-19 pandemic. Study staff will obtain signed HIPAA authorizations remotely (e.g., signing and sending back via mail, or electronically via REDCap). For authorizations obtained through REDCap, participants will be able to type in their name and check an assurance certifying that the typed name acts as an electronic signature. Our group has used this method successfully in several supportive care trials at MGH in patients with cancer.

The consent form will include all the study procedures, information about potential risks and benefits of participation, and the study staff's contact information for further questions. It will also state that participation is voluntary, that participants can refuse to answer any questions, that they can withdraw from the study at any time, and that study participation is in no way related to their medical care.

*5.2 Participant Communication.*

At the time of approach, study staff will ask for the preferred participant communication methods. Study staff will fill out a Participant Locator Form (Appendix 31.7) for the participant to indicate best contact and backup contacts (i.e., telephone, email, SMS text messaging, or in-person).

SMS Messaging. Participants may elect to provide permission to receive SMS messaging via an online service (GoogleVoice) regarding the study that study staff will monitor. Before doing so, participants will be informed of the limitations of GoogleVoice, particularly emphasizing that is not a HIPAA-compliant online service and therefore does not offer protection over their Protected Health Information (PHI). Participants will be advised to not use SMS messaging in the case of an emergency, but instead should contact their care team or emergency services. If participants still prefer SMS text messaging, this form of communication will be brief and contain limited information about study reminders, scheduling, and follow-up. Study staff will follow the templates as outlined in

Appendix 31.8 for SMS communication. In extenuating circumstances and under the discretion of the study staff, study staff may stray from the templates for SMS messaging to address other scheduling or reminder situations. Study staff will not use SMS messaging to screen, send PHI, discuss personal medical history, or other sensitive information. If a participant begins to discuss one of these sensitive topics over SMS messaging, study staff will direct the participant to call them to discuss it further over the telephone.

Send Secure Email. Participants will be provided with the Partners Privacy language regarding encrypted emails and given the opportunity to opt-out of Send Secure emails.

# 6.0 Multi-Site Research

### *6.1 Multi-Site Study Conduct*

This study will be conducted at the lead site MGH Boston, and participants will be recruited from MGH Boston, and MGH affiliate sites (MG North Shore, MG Newton-Wellesley, MG Emerson). Study staff at MGH Boston will maintain the full responsibility of recruitment and enrollment at MGH Boston and MGH affiliate sites. All sites are on record by the DF/HCC IRB. Study staff at MGH Boston will communicate with providers at the satellite sites regarding permission to approach patients and/or caregivers over the telephone as detailed in Sections 3.1 and 5.1. Providers at the MGH affiliate sites may offer referrals to the study staff at MGH Boston. All participants will be registered and enrolled on OnCore through MGH Boston, regardless of where a participant's primary oncologist is located. All participants will complete the intervention and all study procedures through study staff at MGH Boston.

### *6.2 Multi-Site Communication*

As stated in Section 6.1, study staff at MGH Boston will communicate with providers at MGH affiliate sites to ask for permission to approach dyads over the telephone.

### *6.3 Multi-Site Confidentiality.*

All data will be stored and maintained by the lead site study staff at MGH Boston. The lead site MGH Boston will be solely responsible for the recruitment and enrollment for the study including the management and storage of all participant and study data. This study does not involve participant specimen collection.

# 7.0 Study Timelines

Table 2 depicts the overall study timeline:

| Time Point | Study Procedure |
|---|---|
| Months 0-3 | • Finalize and submit Institutional Review Board application for approval<br>• Train study staff on study procedures, recruitment, and data collection |
| Months 3-14 | • Enroll and conduct pilot study of the intervention with up to 10 dyads |
| Months 14-20 | • Complete data analysis and submit manuscripts |

| | |
|---|---|
| | • Prepare and submit grant proposal for large-scale randomized control trial |

Each dyad will be enrolled for an approximately 20 weeks total.

# 8.0 Study Endpoints

*8.1 Primary Endpoint:*

The primary endpoints of this study are feasibility and acceptability as measured by participant rates of enrollment (≥50%), participant retention (≥70%), intervention attendance (≥70% attending at least 6 of 8 sessions), and intervention satisfaction (≥75% reporting average satisfaction greater than the CSQ's midpoint.

*8.2 Exploratory Endpoints:*

- Changes in distress levels (HADS*), quality of life (PROMIS-AYA Health Status* for patients and CarGOQoL* for caregivers), relationship quality (Protective Buffering, Perceived Disclosure and Responsiveness*), relationship intimacy (PAIR*, PROMIS Sexual Function) coping skills (Measure of Current Status- Part A*), and caregiving self-efficacy (Lewis Cancer Self-Efficacy Scale*).

Exploratory endpoints will be examined using relevant sociodemographic and clinical/treatment-related factors as potential covariates.

# 9.0 Procedures Involved

*9.1 Study Design*

This is a small open pilot intervention trial. Findings from this small open pilot intervention trial will be used to further refine the intervention and provide preliminary data for a pilot RCT to formally explore the feasibility and acceptability of the intervention. Participants will complete pre- and post-intervention questionnaires based on self-reported measures in addition to providing feedback in an optional semi-structured exit interview. Findings will be used as preliminary data to inform a future pilot RCT that will formally explore feasibility and acceptability prior to a full-scale efficacy trial.

*9.2 Intervention*

**Intervention.** We will conduct a small open pilot intervention trial with 10 young adult dyads (N=10 dyads) to examine the acceptability and feasibility of the intervention.

The intervention is a dyadic-based telehealth intervention with eight sessions lasting 60 minutes and an optional 20–30-minute exit interview. The intervention will be based on an efficacious couple-based intervention[60,71] developed by Dr. Manne (consultant) and informed by The Relationship Intimacy Model of Couple Psychosocial Adaptation to Cancer,[14] which has been used to guide interventions for couples with cancer (see Section 2.3).[71] In line with Social Cognitive Theory (SCT),[74] we will also incorporate targeted cognitive-behavioral therapy skills for increasing self-efficacy. Sessions will explore improving communication, practicing relaxation techniques to manage stress, and learning coping strategies both as an individual and together as a couple. Sessions will also explore

improving sexual and intimacy as a couple, learning ways to better offer and receive support, exploring shifts in relationship roles, managing stress, and practice acceptance and mindfulness in the present.

We have developed the Intervention Workbook (Appendix 31.9), which will be given as a workbook to study participants to facilitate their engagement in the session based on interviews in the Qualitative Phase of this study (22-101).

Participants will complete pre- and post-intervention self-report questionnaires and will provide feedback in an optional exit interview. We will audio-record all semi-structured interviews and save them on HIPAA-compliant electronic storage. The questionnaires and interviews will be analyzed quantitatively and qualitatively to inform adaptations to the intervention for a follow-up pilot RCT. Each participant will receive remuneration of up to $40 total ($20/assessment).

**Session Monitoring and Fidelity.** Dr. Jamie Jacobs and Dr. Giselle Perez, the study Co-PIs, will train pre- and post-doctoral fellows, licensed psychologists, and qualified clinical psychology practicum students in the MGH Cancer Center to deliver the intervention and provide weekly supervision. Interventionists will complete a post-session survey following each session (Appendix 31.10). Trained study staff will also monitor intervention fidelity by reviewing 10% of audio-recorded sessions using a checklist of intervention topics (fidelity goal ≥90% of topics). We will audio record 80% of sessions and 10% of the sessions will be randomly selected for treatment fidelity review. Interventionists will receive feedback to increase adherence to the protocol of the intervention.

**Retention.** Study staff will make efforts to promote retention by accurately explaining the study expectations for the dyads during the recruitment process, collecting locator information, and reimbursing participants up to $40 for their time and energy on assessments ($20 per assessment).

### *9.3 Study Instruments*

The following questionnaires have been selected to reflect the theoretical intervention targets and the aims of the study. All participants will complete the baseline questionnaire following informed consent**.** The post-intervention questionnaire will be completed 14 weeks from completion of the baseline questionnaire (+/- two weeks). Table 3 details the schedule for administering all study assessments (see Appendix 31.11). We anticipate that 15-20% of post-intervention assessments will be out of window due to patients and their partner caregivers' individual schedules or treatment interfering with the completion of these assessments.

**Table 3. Questionnaires**

| **Instrument / Measure** | **Screening** | **Pre-intervention** | **Post-intervention (14 weeks +/- two weeks)** |
|---|---|---|---|
| Patient Chart Review | X | | |
| Screening Questions | X | | |

| | | | |
|---|---|---|---|
| NCCN Distress Thermometer | X | | |
| Sociodemographic | | X | |
| Caregiver Oncology Quality of Life Questionnaire (CarGOQoL) ** | | X | X |
| PROMIS AYA Health Status Profile | | X | X |
| Hospital Anxiety and Depression Scale (HADS) | | X | X |
| Measure of Current Status- Part A (MOCS) | | X | X |
| Lewis Cancer Self-Efficacy Scale | | X | X |
| Project ForTe Survey Questions | | X | X |
| Personal Assessment of Intimacy in Relationships (PAIR) | | X | X |
| Perceived Disclosure and Responsiveness/Closeness Scale | | X | X |
| PROMIS Sexual Function and Satisfaction with Sex Life (SexFS) | | X | X |
| Client Satisfaction Questionnaire – 8 Item (CSQ) | | | X |
| Daily Protective Buffering Measure | | X | X |
| Economic Strain and Resilience in Cancer (ENRICh) | | X | |
| Optional Semi-structured Exit Interview | To be conducted within a few weeks after completion of post-intervention assessment | | |
| **CarGOOoL and Lewis Cancer Self-Efficacy Scale - Administered to partner caregivers only | | | |

**Screening:**

EHR Factors: Study staff will collect needed information from a potential participant's EHR to determine initial eligibility.

Screening Questions: Patients will be asked if they have a partner caregiver (a spouse, partner, significant other, etc.). Partner caregivers will be asked if they have uncontrolled psychosis, active suicidal ideation, or cognitive impairment.

National Comprehensive Cancer Network (NCCN) Distress Thermometer (included as part of Study recruitment script in Appendix 31.2): The NCCN Distress Thermometer is a valid, one-item measure for assessing distress in many cancer populations.[83] This measure is scored on a range of 0 (no distress at all) to 10 (extremely distressed), and a score of 4 has been identified as an appropriate cut-off to measure significant distress.[84] Patients or caregivers who indicate a score of ≥ 4 on the distress thermometer will be eligible for participation.

**Study Measures:**

Sociodemographic Questionnaire (Appendix 31.11): Self-reported sociodemographic questionnaire for young adult patients and their partner caregiver. Patients' self-reported sociodemographic questionnaire will include gender, sexual orientation, race/ethnicity, religion, relationship status, educational level, employment status, income, living situation, and number of children. Caregivers' self-reported sociodemographic questionnaire will include age, gender, sexual orientation race/ethnicity, religion, relationship status with the patient, education level, employment status, income, living situation, number of children, how long they have known the patient for, and if they live with the patient.

Caregiver Oncology Quality of Life Questionnaire (CarGOQoL) [85]: The CarGOQoL is a multidimensional quality of life assessment for caregivers to patients with cancer. The measure encompasses 10 dimensions: relationship with health care, coping, self-esteem, private life, social support, leisure time, psychological well-being, physical well-being, burden, and administration and finances. This assessment is a 29-item questionnaire.

PROMIS AYA Health Status Profile[87]: The PROMIS AYA Health Status Profile tool asses seven domains in the Adolescent and Young Adult (AYA) cancer population: anxiety, depression, fatigue, physical function, pain, emotional support, and cognitive function. This 29-item tool is answered on a scale of 1 to 5 and is developed from Roth, et al. 2023.

Hospital Anxiety and Depression Scale (HADS)[88]: The HADS is a valid self-report measure for assessing anxiety and depressive symptoms. The 14-item measure contains seven questions to assess depressive symptoms and seven questions to assess anxiety symptoms to distinguish between the two. Patients indicate how they have been feeling on an average over the past week. Each item is answered on a scale of 1 to 4.

Measure of Current Status – Part A (MOCS)[91, 89]: The MOCS is a multidimensional questionnaire assessing coping skills that measures self-perceived status on five domains: one's ability to recognize situations that cause stress, to readapt thoughts that are maladaptive, to relax when desired, to communicate needs, and to be able to recognize which coping strategies are appropriate in certain scenarios. The 13-item assessment is answered on a scale of 0 (I cannot do this at all) to 4 (I can do this extremely well).

Lewis Cancer Self-Efficacy Scale[92, 90]: The Lewis Cancer Self-Efficacy Scale assesses caregiver's self-efficacy about managing the illness. This 20-item questionnaire is answered on a scale of 0 (not at all confident) to 10 (very confident). Questions on this scale will be adapted to be appropriate to patients and caregivers.

Project ForTe Survey Questions (In Development): The Project ForTe Survey question assesses relationship quality and communication. The 12-item survey is answered on a scale of 1 (strongly agree) to 5 (strongly disagree).

Daily Protective Buffering Measure[98]. This is a 3-item measure of protective buffering adapted from the Berlin Social Support Scale to reflect daily events. Protective buffering, which is a pattern of communication characterized by intentional withholding in communication, is rated on a 4-point scale from 1 (not at all) to 4 (very strongly). Higher scores reflect more protective buffering. The scale shows good within-person and between-person reliability.

Personal Assessment of Intimacy in Relationships (PAIR)[96, 92]: The Personal Assessment of Intimacy in Relationships assess five domains of relationship intimacy: social, emotional, recreational, sexual, and intellectual. The 18-item scale is measures on a scale of 1 (Does not describe me/my relationship at all) to 5 (Describes my/my relationship verry well)

PROMIS Sexual Function and Satisfaction with Sex Life (SexFS)[93]: The PROMIS Sexual Function and Satisfaction with Sex Life scale measures self-reported outcomes in relation to sexual function and satisfaction across multiple domains. The 7-item scale is answered on a scale of 1 to 5.

Client Satisfaction Questionnaire (CSQ)[97,94]– 8 Item: The validated measure CSQ is used to assess the satisfaction of services provided to the participants. The 8-item questionnaire is answered on a scale of 1-4. The CSQ will be used during the post-intervention questionnaire to examine intervention acceptability.

Perceived Disclosure and Responsiveness/Closeness[89,90,95,96]: The Perceived Disclosure and Responsiveness/Closeness assessment is a multidimensional relationship questionnaire. The 11-item assessment is answered on a scale of 1 (not at all) to 7 (very much).

Economic Strain and Resilience in Cancer (ENRICh)[94,97]: The Economic Strain and Resilience in Cancer tool assess multiple dimensions of financial hardship including behavioral and psychosocial or material domains. The 15-item scale is answered on a scale of 0 (least hardship) to 10 (most severe hardship).

**Optional Semi-Structured Exit Interview:**

At the end of the intervention, participants will be offered an optional brief semi-structured interview to gain feedback about the acceptability of the intervention (see Appendix 31.16 for semi-structured interview guide). A study staff member not involved with the intervention delivery will conduct the interview. Results from the interview will be used to inform and adapt the intervention for further studies.

### *9.4 Data Collection*

Participants will be given the option to complete the above instruments either on paper, over a secure REDCap portal, or over the telephone. Assessments will be sent to participants at the start of the window. Study staff will follow-up periodically during the window up to ensure participants received the assessment and completion of the assessments. Assessments completed on paper will be entered into the secure REDCap database by study staff.

Enrolled patients and partner caregivers will receive a copy of the intervention workbook, a study information sheet, and roadmap of the study intervention (Appendices 31.9, 31.12, 31.13). Both the enrolled patient and partner caregiver will receive their own copy of the Intervention Workbook (Appendix 31.9).

We will audio-record 80% of intervention sessions to monitor fidelity in delivering the intervention, and we will record all semi-structured interviews to facilitate transcription and qualitative data analysis. All audio recordings will be saved on HIPAA-compliant electronic storage. The interviews will be transcribed through the transcription service TranscribeMe. Once interviews are transcribed and reviewed by the research team for completeness, the audio recordings will be destroyed.

# 10.0 Data and Specimen Banking: Not applicable

# 11.0 Data Management and Confidentiality

## *11.1 Data Analysis*

Data analysis for Phase 2 will be used to determine the acceptability, feasibility, and to make modifications of the intervention prior to a RCT.

**Primary Aim: To refine a brief, couple-based intervention and study design for young adult patients with cancer (ages 25-39) and their partner caregivers based on a small open pilot trial and optional semi-structured exit interviews (N=10 dyads).**

*The study will be feasible, defined by recruitment (enrollment ≥50%), retention (completion of follow up assessments ≥70% of all participants who complete baseline), and attendance (attendance rate of at least 70% of participants completing at least 6 of 8 sessions [75%]).*

*The study will be acceptable demonstrated by ≥75% of participants reporting average satisfaction scores reporting average satisfaction greater than the CSQ scale's midpoint.*

Descriptive statistics will be used to characterize the sample. Study staff will conduct exploratory analyses to examine whether participants' baseline sociodemographic characteristics are associated with post-intervention outcomes using Fisher's exact tests and paired samples t-tests. We will also conduct paired samples t-tests to examine mean change scores from pre- to post-intervention on distress, QOL, relationship quality, relationship intimacy, coping skills, and caregiving self-efficacy. Study staff will interpret 95% Confidence Intervals and Cohen's d effect sizes (D=[(Mean 1)–(Mean 2)]/pooled Standard Deviation); however, this will be simply descriptive as this study is not powered to produce statistically significant findings. The sample size is justified by our prior work[93] showing that 5-10 participants are sufficient to gain important insights about the intervention and acceptability prior to an RCT.

## *11.2 Power Calculation*

The primary objective of this open pilot trial (N=10 dyads) is to demonstrate feasibility and acceptability as defined by participant rates of enrollment (≥50%), participant retention

(≥70%), intervention attendance (≥70% attending at least 6 of 8 sessions), and intervention satisfaction (≥75% reporting average satisfaction greater than the scale's midpoint). The study will have a total accrual goal of 10 dyads (N=10 dyads) consisting of young adult patients with cancer (n=10) and their partner caregivers (n=10); The sample size of 10 dyads is based on our prior studies and how many participants are necessary to gather meaningful information about the acceptability and feasibility of an intervention. Future power calculations will be conducted to determine the necessary sample size for the next phase of testing this intervention.

*11.3 Data Storage*

**Handling of Study Documents**. Study source documents, including but not limited to signed verbal or written informed consent forms, completed eligibility checklists, participant questionnaires, and OnCore enrollment confirmation, will be scanned and stored electronically as certified copies on a secure drive only available for access to trained study staff working with the documents. The drive will be only accessible with proper invitation to the drive by the Principal Investigator through their Massachusetts General Brigham (MGB) account, which will require personal username and password information to access. Trained study staff will follow specific standard operating procedures for handling source documents and certifying each copy appropriately. The procedures are as follows: after source documentation is filled out by the participant, study staff will collect the original source document. The study staff member scanning documents will be kept as consistent as possible throughout the duration of the study to ensure uniformity among source documentation handling. Location, time, and date of the scanning of the document will be recorded at the time of scanning. Study staff will fill out the Source Documentation Certified Copy Cover Sheet (Appendix 31.14) and include this as the first page of the electronic version of the source document.
After the source document is scanned and the corresponding electronic document is confirmed to be legible, all facing the correct direction, and together as a single document, it will be collected and destroyed immediately. Study staff will destroy the original copy of the source document by following MGH procedures of destroying documents with Personal Health Information (PHI). Electronic versions of source documents will allow study staff to access these documents regardless of where the original copy is stored, which may be inconvenient, increase study staff burden, and study cost if storage of documents is far from the location where research activities will be conducted or required to be placed in long term storage. This process has been developed streamlined, and successfully implemented in DF/HCC Protocol #17-201. Source documents will be uploaded to Dropbox, a cloud-based storage that is compliant with Mass General Brigham's policies and procedures. If a patient is consented verbally, the study staff will document the verbal consent process by entering their own name along with the date, and the completed version of the digital consent form will be saved as the completed, original source document and a certified copy cover sheet will not be used.

**Audio Recordings.** We will audio-record 80% of intervention sessions and all exit interviews, and save them on HIPAA-compliant electronic storage. The exit interviews will be professionally transcribed by TranscribeMe, which is fully compliant with HIPAA requirements for Medical Transcriptions and has extensive security measures for privacy and security of personal health information and data protection. No additional

identifying information, apart from the recorded voice of participants, will be included in the audio file sent to TranscribeMe. We will delete audio recordings after all interviews have been conducted and analyzed in this phase of the study. This will comply with DFCI policy for electronic data storage. Transcripts will be saved on HIPAA-compliant electronic storage for qualitative analysis.

All additional data will be stored in 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, password-protected file.

**Missing Data**

The primary end point is based on acceptability and feasibility of the study. The existence of missing data will provide essential information about feasibility and acceptability of the intervention and the study assessments (length and content).

**Data Safety**

Participant data will be collected using Research Electronic Data Capture (REDCap). We will maintain a separate list of patient names and study IDs, which will be saved in password-protected files. Participants will be identified on study forms by case number only to protect confidentiality. Identifiers such as names will only be used during the initial data retrieval process and will be destroyed once all data records have been obtained and data analysis has been completed.

This study does not involve participant specimen collection. As detailed in Section 11.3, study source documents, including but not limited to signed verbal or written informed consent forms, completed eligibility checklists, participant questionnaires, and OnCore enrollment confirmation, will be scanned and stored electronically as certified copies on a secure drive only available for access to trained study staff working with the documents. Trained study staff is responsible for receipt or transmission of the data. Data collected via mail or in-person will be transported in folders by trained study staff to protect PHI.

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

### *12.1 Data and Safety Monitoring Plan*

The purpose of the data and safety monitoring plan is to establish standards that will ensure that this protocol complies with Federal Regulations, Health Insurance Portability and Accountability Act (HIPAA) requirements, and applicable Dana-Farber Harvard Cancer Center (DF/HCC) Standard Operating Procedures.

General Approach: We have developed a comprehensive data and safety monitoring plan for the proposed project. Throughout the award period, weekly meetings will take place with the research team: Jamie Jacobs, PhD, and study staff. Specifically, meetings will include ongoing review of study protocol, assessment procedures, and issues related to recruitment, data collection, and management. Study staff will also discuss any human subject issues that arise.

General Roles and Responsibilities: We will use several coordinated strategies to monitor study recruitment, enrollment, and retention, as described in the following table. We will also closely track collection of patient-reported assessments, as these measures are an essential aspect of our study procedures and outcomes. For all strategies identified in the table, we will develop study tracking forms that will be reviewed at the weekly team meetings. Study tracking forms will be used to create a record of all decisions made and actions taken. Reports will be sent ahead of the meetings, detailing study progress and setting the agenda. The following monitoring and reporting steps will be taken for each study activity:

| Study Activity | Monitoring and Reporting Mechanism |
|---|---|
| **Recruitment** | • The designated study staff will generate a weekly report outlining the number of participants approached and reasons for ineligibility or disinterest in study participation. |
| **Informed Consent** | • The study staff will generate a weekly report detailing the number of participants who consented to the study.<br>• The PI will go through any issues related to informed consent with the study staff weekly or earlier if urgent. |
| **Enrollment** | • The study staff will generate a weekly enrollment report. |
| **Assessments** | • The study staff will conduct a review for completeness and accurate data entry.<br>• The study staff will maintain participant records of distress levels at each timepoint and follow Reaction Management if required. |
| **Intervention** | • The PI and trained study staff will review at least 10% of audio-recorded treatment sessions.<br>• The study staff will maintain a record of participant progress in sessions, including attendance. |
| **Retention** | • The study staff will generate a weekly report detailing completion of follow-up assessments and retention strategies implemented for each participant.<br>• The study staff will generate a weekly report of all participants who withdraw from study. |
| **Analysis** | • The PI will work closely with study biostatistician, Nora Horick, on all qualitative and quantitative analyses. |

Specific PI Roles and Responsibilities
I will be responsible for all aspects of conducting the protocol; I will:

- Oversee the coordination, development, submission, and approval of the protocol to the DF/HCC as well as subsequent amendments.
- Ensure that the investigators and study staff are qualified and appropriately resourced to conduct the protocol.
- Carry out a Data and Safety Monitoring Plan as detailed in this document.

- Ensure that each participating study staff member receives adequate protocol training prior to enrolling participants and throughout the trial's conduct as needed.
- Monitor progress and overall conduct of the study.
- Conduct review of 10% of intervention sessions for process and content fidelity.
- Conduct weekly supervision for clinical protocol interventionists.
- Review data and maintain timely submission of data for study analysis.
- Ensure compliance with all requirements as set forth in the Code of Federal Regulations, DF/HCC, HIPAA requirements, and the approved protocol.
- Commit to provisions that the protocol will not be rewritten or modified by anyone other than the overall PI.
- Monitor accrual and address concerns if accrual goals are not met.

The Massachusetts General Hospital Cancer Center is expected to comply with all applicable federal regulations and requirements, the protocol and HIPAA requirements. Specifically, it will:

- Oversee the data collection process.
- Maintain documentation of Serious Adverse Events (SAE) reports and deviations/violations.
- Maintain regulatory documents which include but are not limited to the following: IRB approvals/notifications, confirmation of Federal wide Assurances (FWAs), all SAE submissions, screening logs, and IRB approved consents.
- Conduct regular communications with the PI and maintain documentation of relevant communications.
- Document the delegation of research specific activities to study personnel.
- Maintain regulatory files.
- Have office space, office equipment, and internet access that meet HIPAA standards.
- Participate in quality assurance activities and meet with monitors or auditors at the conclusion of a visit to review findings.
- Promptly provide follow-up and/or corrective action plans for any monitoring queries or audit findings.

**Informed Consent Requirements.** The DF/HCC approved the verbal consent will be reviewed in real time with the patient prior to enrollment. This application is seeking a waiver of written consent.

**Protocol Confidentiality.** All documents, investigative reports, or information relating to the participants are strictly confidential. Confidentiality is assured as participants will be identified on all study materials only by participant number, visit number, and date of visit. By recording the study data in this manner, the information can be considered 'de-identified,' and therefore compliant with the Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") of HIPAA. Participants' data will be kept in a computer file that is password protected and this password will be changed whenever the staff changes. This password-protected file will be stored on the encrypted MGH

network drive. Only the Principal Investigator and study staff will have access to the data. We will keep a link between participant number and participant's name in a separate file, also password protected (with a different password).

**Data Management Organizational Structure Data**. Study forms will undergo a systematic and rigorous editing process prior to being keyed into the database. The research assistant will routinely evaluate the data and discuss any problems and questions with the study staff, myself, and mentors at the regular weekly team meetings. Data management formal reports on record status across the three following domains will be employed: entered, verified, and edited. These reports of data records will be evaluated once a month during the final team meeting of the month. All study data (including data from the Electronic Health Record) will be stored on the encrypted MGH network drive on hospital computers and will be password protected. To ensure data protection, backup copies automatically generated by MGH computer systems will be available.

**Data Safety and Monitoring Plan**. The following procedures will be followed, in compliance with NIH requirements, to ensure the safety of study participants and the validity and integrity of data:

- Data Repository: The MGH Cancer Outcomes Research Program (CORE) has coordinated research initiatives over the past ten years that have established procedures and technologies for data collection and management. Dr. Jacobs will oversee all aspects of data collection for the study and the research assistant will have the operational responsibility of data management. We will develop a study specific data management protocol and standard operating procedures for the creation and testing of all study forms, data collection, quality control, and data extraction. These forms will be standardized. We will provide ongoing oversight of data management throughout the study and will be responsible for generating reports and datasets for quality control and data analysis. All data management activities will utilize REDCap, a HIPAA-secure, web-based survey application for electronic collection and management of research and clinical trial data. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the study staff with planning assistance from Partners HealthCare Research Computing, Enterprise Research Infrastructure & Services (ERIS) group. REDCap provides an intuitive interface for users to enter data and have real time validation rules (with automated data type and range checks) at the time of entry. Data management reports will be generated weekly and discussed during the study staff meetings.
- Serious Adverse Events: Expedited review will occur for all events meeting the Food and Drug Administration (FDA) definition of a SAE (i.e., any fatal event, immediately life-threatening event, permanently or substantially disabling event, event requiring or prolonging inpatient hospitalization, Unanticipated Problems [UPs], or any congenital anomaly). This also includes any event that a study investigator judges to impose a significant hazard, contraindication, side effect, or precaution. For purposes of this study, all SAEs will be required to be reported to the PI, the DF/HCC IRB, and federal agencies (National Cancer Institute, FDA, and the NIH Office of Biotechnology Activities), regardless of any judgment of

their relatedness to the study. All relevant information will be reported to the study investigators for each SAE including information about the event and its outcome, study condition, concomitant medications, the subject's medical history and current conditions, and all relevant laboratory data. Notification by secure e-mail of all related study forms shall be made to the DF/HCC IRB within 24 hours of the occurrence of any SAE. Information will be reviewed and a determination made of whether there was any possible relevance to the study interventions. Reporting to NIH will be made according to their respective regulations governing SAE reporting.

- Non-Serious Adverse Events: At weekly meetings, the study staff will discuss summaries of the numbers and rates of adverse events by treatment group. These reports will include types of events, severity, and treatment phase.
- Other Safety-Related Reports: At weekly meetings, the study staff will discuss summary reports of treatment retention and reasons for dropout or withdrawal by treatment group.
- Study Stopping Rules: We do not have a pre-specified stopping rule given the low-risk nature of the proposed study. However, if at any point the DF/HCC or the study investigators judge that the risks of study procedures outweighs the benefits, the project will be stopped immediately.
- Procedures to ensure confidentiality, preparation of reports, minutes, and recommendations: We will work with the CRC to prepare study reports and circulate them to the study staff during the weekly scheduled project meetings. These reports will include overall study progress and safety data. At the conclusion of each research group meeting, the investigators will determine whether any changes in the conduct of the trial are recommended.

# 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 to withdraw from the study, we will ask if they are comfortable sharing the reason for withdrawing to ensure that there are no necessary serious adverse events to report to the IRB. Subsequently, we will ask the participant if they are still willing to permit the study staff to continue to access their EHR.

# 14.0 Risks to Subjects

## *14.1 Anticipated Reactions*

As this is a low-risk, social/behavioral study, there are no ingested medications and no biomedical procedures. It is unlikely that participants will be at any risk for physical harm due to study participation. Participants may find some of the questions to be emotionally upsetting, and if so, they may experience some distress.

**Reaction Management.** The consent form will include all study procedures, information about potential risks and benefits of participation, and information regarding whom the participant can contact for further questions. It also will state that participation is voluntary, that participants can refuse to answer any question, that they can withdraw from the study at any time, and that study participation is in no way related to their medical care. All study

staff will complete the required human subjects training before they can work on any human subject aspects of the study.

If a participant expresses distress during the intervention or optional semi-structured exit interview, they will be reminded that study participation is voluntary. If participants remain distressed, they will be referred to the MGH Oncology Social Work Service within their respective disease center and/or offered an opportunity to meet with a psychologist in the Psychiatric Oncology Service at the MGH Cancer Center to help address their distress.

For all participant assessments given throughout the study, study staff will review assessments upon receipt from participants for completion and to assess distress. On the HADS, participants who endorse ≥11 on even items for a more severe range for depression will be called by qualified study staff (e.g., Drs. Jacobs, Perez, or qualified clinical psychology practicum students and fellows). If a participant completes the distress assessment online through the secure REDCap portal, a study staff member will check the responses and notify the PI for follow-up if needed within 72 hours of assessment completion. If a participant completes assessments on paper, study staff will check the responses and notify the PI for follow-up if needed within 72 hours of receipt. If the participant needs further outpatient services for depression, including pharmacotherapy, or is at risk for self-harm requiring hospitalization, study staff will make the necessary referrals for treatment. For example, for participants who are distressed but in no danger to self or others, study staff will refer either to the MGH Oncology Social Work Service or to the MGH Outpatient Psychiatry Department (617-724-5600), including the Cognitive-Behavioral Therapy Program. If suicidality or risk of harm to others is otherwise discovered at any study visit, the participant will be referred to appropriate services. Specifically, in the case that hospitalization is required, study staff will contact and escort the participant to the MGH Acute Psychiatry Service (617-726-2995), with the aid of the MGH Police & Security if necessary (617-726-2121). If a referral for outpatient services is made, or the participant requires escort to the MGH Acute Psychiatry Service, study staff will notify the health care team, including the primary oncologist.

### *14.2 Reporting Adverse or Unanticipated Events*

We do not anticipate any harm with our study procedures. While some topics probed during the intervention sessions or optional exit interviews may be 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 supportive care interventions and qualitative interviews on sensitive topics without any adverse events. Reportable adverse events would include a breach of confidentiality. Should adverse or unanticipated events occur during the study, a trained study staff member will report the events to the IRB as soon as they are discovered.

## 15.0 Potential Benefits to Subjects

There are few resources for young adult patients with cancer and their partner caregivers to meet their distinct unmet psychosocial needs regarding depression, distress, and a lowered QOL. Psychosocial distress in addition to avoidance may negatively impact a young adult dyadic relationship. Couple-based interventions have demonstrated improved dyadic coping and relationship outcomes; however, these intervention studies have mainly been conducted in samples of patients with breast cancer and may not be generalizable to

young adult patients with cancer and their partner caregivers. The proposed intervention was directly informed by qualitative interviews with young adult patients with cancer and their partner caregivers to ensure that the intervention is beneficial and applicable to the targeted young adult dyadic population. The risk to participants from participating in the study is small (and will be minimized by procedures outlines above), and the overall risk to benefit ratio is favorable.

## 16.0 Vulnerable Populations

Adults who are unable to consent, individuals who are not yet adults, and prisoners will not be included in this study. Pregnant women are eligible and will be included in this study. As this is a low-risk study and a supportive care trial, we do not anticipate any additional harm to pregnant women.

## 17.0 Community-Based Participatory Research: Not applicable

## 18.0 Sharing of Results with Subjects

Participants in the study may express interest in learning about the results of the study. In this case, their contact information will be collected and securely stored by study staff. Upon competition of data collection for the study, study staff will provide interested participants with an abstract of the study results.

## 19.0 Setting

### *19.1 Location*

Participants at MGH Boston will be approached via telephone or in-person after receiving permission from their oncology provider. Participants from MGH satellite sites will be contacted via telephone.

## 20.0 Resources Available

### *20.1 Team Qualifications*

Dr. Jamie Jacobs (licensed clinical psychologist) is responsible for full oversight of the project at MGH and participating affiliate MGH institutions. She will meet with the study CRC weekly (and more often as urgent issues arise) to ensure the study process is being followed accurately and to address potential challenges or issues that may arise. Dr. Jacobs is a member of the MGH Cancer Outcomes Research and Education Program (CORE). CORE has extensive experience conducting multi-site trials of supportive care interventions in oncology and has the necessary expertise to ensure the success of the proposed project.

Dr. Giselle Perez is a licensed clinical psychologist in the Center for Psychiatric Oncology & Behavioral Sciences at the Mass General Cancer Center and a member of the Cancer Outcomes Research & Education Program. Dr. Perez is the Associate Director of the Adolescent and Young Adult Cancer Program, the Director of the Adolescent and Young adult Research, the Director of the Mind Body Program for Cancer Survivors, and an Assistant Professor of Psychology at Harvard Medical School. She will contribute expertise regarding care for young adult patients with cancer.

*20.2 Site Resources*

The MGH Cancer Center sees hundreds of patients with all stages and forms of cancer every year, and so we are confident in our ability to meet accrual goals. We have completed enrolled of 20 couples in 8 months during Phase 1 and are confident in our ability to enroll even more since this is offering an intervention to everyone enrolled.

## 21.0 Prior Approvals: Not applicable

## 22.0 Recruitment Methods

As described in Section 5.0, all recruitment methods will be centrally located and executed by study staff at the lead site, MGH Boston. Recruitment strategies that will be employed include screening, Partners Rally Recruitment Portal, and provider and self-referral.

## 23.0 Local Number of Subjects

The study will have a total accrual goal of N=10 dyads consisting of young adult patients with cancer (n=10) and their partner caregivers (n=10) across the lead site, MGH Boston, and the MGH-affiliate sites. The recruitment will aim to enroll an equal representation of patients and partner caregivers during and after treatment.

## 24.0 Provisions to Protect the Privacy Interests of Subjects

As detailed in the Data Safety Monitoring Plan (Section 12.0), all participants will receive a confidential and unique number identifier. All participants will be identified in study assessments only by their number identifier. Identifiers, such as name, will only be used during the initial data retrieval process and will be destroyed once all data records have been optioned and data analysis has been completed as previously described.

## 25.0 Compensation for Research-Related Injury

As this is a low-risk study and a supportive care trial, we do not anticipant any research-related injury due to involvement in the study.

## 26.0 Economic Burden to Subjects

There will be no additional costs for participants as part of their participation in the study. We do not anticipate any financial burden on study participants as participants will not be billed for intervention visits. Additionally, telehealth does not require additional trips to the hospital and can be done at the convenience of one's home.

Study participants will be compensated for their time and energy in completing the two study questionnaires (pre- and post-intervention). Participants will be compensated up to $40 total ($20/assessment) (Appendix 31.15).

## 27.0 Consent Process

Study staff will consent participants over the telephone or in-person using recruitment scripts (Appendix 31.2). We will follow the requirements of the Policy: Informed Consent Process (DF/HCC CON-100) to obtain informed consent verbally or in-person. The verbal consent scripts will include all the study procedures, information about potential risks and benefits of participation, and the study staff's contact information for further questions. They will also state that participation is voluntary, that participants can refuse to answer

any questions, that they can withdraw from the study at any time, and that study participation is in no way related to their medical care.

**Verbal Consent Process**. If the patient or caregiver expresses interest and is eligible, study staff will proceed with obtaining verbal consent over the telephone. The verbal consent forms will include all the study procedures, information about potential risks and benefits of participation, and the study staff's contact information for further questions. Potential participants will be given ample opportunity to ask questions and take time to consider their participation in the study. If a potential participant does not answer the telephone, study staff will leave a voicemail (Appendix 31.6).

We are requesting a waiver of written documentation of consent for the participants who are consented verbally over the telephone. This study meets the requirements for a waiver as it is a minimal risk study, and all study procedures can be communicated verbally. Verbal consent will allow study staff to address barriers to study enrollment, more easily reach partner caregivers, and allow for greater flexibility while assuring patient and caregiver safety in response to changing healthcare practices due to the COVID-19 pandemic.

Study staff will obtain signed HIPAA authorizations remotely (e.g., signing and sending back via mail or electronically via REDCap) or in-person. For HIPAA authorizations obtained through REDCap, participants will be able to type in their name and check an assurance certifying that the typed name acts as an electronic signature.

**In-Person Informed Consent Process.** Interested and eligible participants undergoing in-person informed consent will be presented with a detailed consent form and HIPAA authorization form to be signed by each participant following explanations by study staff. The consent form will include all the study procedures, information about potential risks and benefits of participation, and the study staff's contact information for further questions. It will also state that participation is voluntary, that participants can refuse to answer any questions, that they can withdraw from the study at any time, and that study participation is in no way related to their medical care. If the patient or partner caregiver indicates that they are not interested in the study, the study staff will collect the reason for refusal.

**Enrollment Procedures.** When informed consent is obtained from the participant, study staff will complete the eligibility checklist using the eligibility assessment documented in the participant's medical record and/or research chart. To be eligible for registration to the protocol, the participant must meet all inclusion and exclusion criteria as described in the protocol and reflected in the eligibility checklist. Institutions will register participants who meet eligibility criteria and provide consent in the Clinical Trials Management System (CTMS) OnCore as required per DF/HCC policy *Subject Protocol Registration (Policy #:* REGIST-101). Both members of the dyad will be registered on OnCore after both individuals have provided informed consent. An email confirmation of the registration will be sent to the PI and CRC (Registering Person) immediately following the completed registration. Non-English-speaking subjects, subjects not yet adults, cognitively impaired subjects, and adults unable to provide consent will not be a part of the study.

## 28.0 Process to Document Consent in Writing

### *28.1 Documentation of Consent*

As stated above (Section 27.0), all participants must provide informed consent in order to partake in the study. We will follow all the requirements of the Informed Consent Process (CON-100) to obtain informed consent. Enrolled participants will provide verbal informed consent. When participants are consented over the telephone, the study staff will document the verbal consent process by entering their own name in the consent form along with the date. Participants consented verbally will receive an unsigned copy of the consent form.

If a participant consents verbally, we will obtain HIPAA authorizations remotely (e.g. signing and sending back via mail or electronically via REDCap), or in-person.

## 29.0 Drugs or Devices: Not Applicable

## 30.0 References


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# 31.0 Appendices

*31.1 Suggested Clinician Email Template*

Dear [Dr./NP/PA PROVIDER NAME],

I am a research coordinator working with Drs. Jacobs and Perez on a couples-based intervention for young adult patients with cancer (age 25-39) and their partner caregivers. Our study aims to help young adults with cancer and their partners manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment by providing eight sessions lasting about 60 minutes held over telehealth with a therapist.

Your patient and/or their partner caregiver may be eligible for our study:

| Patient Name | Patient MRN | Caregiver Name |
|---|---|---|
| | | |

I would like to approach them regarding the study. Please let me know at your earliest convenience if I can contact this patient and/or this caregiver either in-person or over the telephone.

Please feel free to let me know if you have any questions or concerns.

Thank you!

Kind regards,
[Email signature]

*31.2 Suggested Recruitment Script:*

Hello! Is this (patient name)?

Hi (patient name), this is (study staff name) and I'm a research coordinator calling from the MGH Cancer Center. How are you today?

I'm calling about a research opportunity that (Provider Name) thought you might be interested in. It's a program for young adult couples that are coping with cancer to help manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment. Do you have some time to talk right now?

Do you have someone that has been helping to care for you (a spouse, partner, significant other) during this time?

IF yes: continue to section A.

IF no: Explain that this study for young adult couples and thank them for their time.

A. Great! In this study, we are providing a program for couples that are coping with cancer which includes topics that we've found are important to young adult couples who have been through a cancer diagnosis. In the sessions you would learn about strategies to improving communication, managing stress, and improving sexual and intimacy skills.
Both you and your partner would participate in eight sessions lasting about 60 minutes held over telehealth with a therapist. Since the sessions are held via videoconferencing, you do not have to return to the hospital for any extra visits, and you can complete the sessions from the comfort of your own home. We aim for your sessions to be weekly or biweekly, and we will of course work with your schedule to find times that fit best.

   Does this sound like something you may be interested in?

IF yes: Continue to section B to review the verbal consent with the participant.

IF no: Continue to section E

B. That's wonderful! I would love to give you some more information about the study. The sessions would be audio-recorded, and the recordings would be de-identified and only accessible to members of the study team. Along with the program sessions, you would both be complete two surveys that should take about 30 minutes each, one before you start the therapy, and one 14 weeks after you've completed all eight sessions. There is an optional exit interview where you can provide us feedback on the program and how we can improve the program.

   <u>You as the patient</u> would be sent a HIPAA form that allows study staff to securely store your health information on an MGH-approved database. All information is

kept confidential and only accessible to only trained study staff. I would email you the form to look over and if you agree you can add in your eSignature once you've reviewed it. Last, we like to compensate participants for their time and energy so you and your partner would each receive up to $40 for completing those surveys ($20/assessment) Those are the main points of the study - do you have any questions I can answer?

IF yes, common questions:

- **Why do you need my PHI? What would you be accessing?** We would be accessing information relevant to your cancer – things like your diagnosis, staging and treatment. It would be helpful to have this information to better contextualize the interview and your responses.
- **What is the Program?** There are currently very few programs for young adult couples that are coping with cancer, so we are developing this program to improve joint coping and strengthen relationships for couples like yourself as you're going through treatment or after treatment.
- **Why are you recording the session? Where are these audio files stored**? In a secure MGH-approved storage system that can only be accessed by people on the study team that have with passwords. There will not be any personal information (like your names) recorded on the transcripts. We are recording them so we are able to keep track of your input and answers to use for development of our program.
    - What do you do with recordings after?
        - We will archive the files.
- There's no cost to participating in the study and will not be documented in your medical record.

IF no: Continue to Section C

C. There are some things that would be helpful for me to know first. The next step is to learn about how you've been doing and how you've been feeling lately. Thinking back on the last couple of weeks, on a scale of 0 being no distress and 10 being extreme distress, how would you say your current level of distress is?

For caregivers: One of the things we have to make sure of is that you are in a mental state to be able to complete this study from beginning to end. Do you mind if I ask you a few sensitive questions to just make sure of that? Thank you, the first question is, have you been diagnosed with any cognitive impairment like dementia or other brain-related condition that interferes with your ability to understand instructions or remember things? Have you recently had thoughts or a plan to take your life in some way?

Thank you so much for sharing this information with us. It looks like you would be a good fit for the program. So, like I said, this program for couples that are coping with cancer would be with both you and your partner. If you would like to chat with your

partner about the study tonight, then I can give you a call back tomorrow if that sounds okay.

Is the participant eligible by patent or caregiver indicating a score ≥4 on the NCCN adapted distress thermometer?

IF yes: Continue to section D

IF no: Continue to section E

If you have no other questions, I want to note three things that are a part of research *(review the verbal consent will be reviewed in real time with the prospective participant, including risks and benefits of participating).*

D. This is a program for couples that are coping with cancer where you and your partner will participant in eight therapy sessions and answer questions through two surveys that should take around 20-30 minutes each. You can participate in an optional exit interview where you can provide us feedback on the program and ways we can refine the program.
- This is a completely voluntary study, so if you want to withdraw at any point that is completely fine.
- Everything is kept confidential and stays within our study, and your participation will not affect your / your partner's care.

Can I take this conversation as verbal consent for this study? I'll sign this consent form and send you a copy for your own records. What is a good email I can send this to?

Great! Next, I'll send over that HIPAA Authorization form I mentioned that you'll just have to add your eSignature to and the first survey. This shouldn't take you more than 20-30 minutes to complete. Would you like these sent secure?

Wonderful, you should be receiving those in your inbox in the next few minutes here.

E. Thank you so much for your time and for letting me tell you a little bit about this study. Please don't hesitate to reach out with questions or if anything changes in the future.

*31.3 Rally Ad*

**Rally Ad**

**Headline:** Program for young adult patients and their partner caregivers that are coping with cancer

**Summary (240 characters):** If you were diagnosed with cancer in the last two years and are a young adult (age 25-39), you and your partner may be eligible for this study. Couples will participate in a program to support young adults with cancer and their partners manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment.

**Project Title:** Program for young adult patients and their partner caregivers that are coping with cancer
**Categories:** Cancer, Caregivers, Telehealth

**Funding Sources:** Harvard Club of New York Foundation, American Cancer Society Institutional Research Grant, Claflin Distinguished Scholar Award

**Institutions conducting research**: Massachusetts General Hospital

**IRB Organization:** DF/HCC Dana Farber Cancer Institute

**Recruitment start date:** September 2024
**Recruitment end date:** May 2025

**What are you studying?**
Young adult patients with cancer and their partner caregivers have unique unmet needs and specific challenges due to the timing of a cancer. The purpose of this study is to refine a program for young adult patients with cancer and their partner caregivers to help couples manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment. Participation may include 8 therapy sessions lasting 60 minutes and an optional semi-structured exit interview.

**Why is it important?**
There is currently a lack of support for young adult patients with cancer and their partner caregivers. The aim of the study will be to help young adults with cancer and their partners manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment.

*31.4 Suggested Recruitment Flyer*

# Are you or your partner a young adult patient at Mass General Cancer Center?

## Are you between the ages of 25-39?

You may be eligible for a research study

- Researchers at the MGH Cancer Center are conducting a study to learn how to best support **young adults with cancer and their partners**
- Participation includes a **eight, weekly, hour-long sessions**



**To learn more, visit:**
massgeneral.org/cancer-center/caregiving-research

For more information, contact the study coordinator [study coordinator name], at caregivingresearch@mgh.harvard.edu, or 857-600-0315.

Mass General Brigham
Mass General Cancer Center

*31.5 Suggested Social Media Post*

**Instagram and Facebook**




The timing of a cancer diagnosis in the lifetime of young adult patients and their partner caregivers can have specific challenges. We are offering a program for couples that are coping with cancer with young adult patients with cancer and their partners (e.g., spouse, domestic partner, significant other) here at #MGH. The aim of the program will be to help young adults with cancer and their partners manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment.

If you or your partner have received cancer care at MGH and would like more information about the study, contact the MGH Cancer Center study team, led by Drs. Jamie Jacobs and Giselle Perez.

**Twitter**

New #research at the Mass General Cancer Center led by investigators Dr. Jamie Jacobs and Dr. Giselle Perez is studying how to best support young adults with #cancer and their partners manage the stressors and challenges they may face throughout a diagnosis of cancer and treatment. If you are interested in participating, contact the MGH study team.

### *31.6 Suggested Voicemail Script*

Hi this is [study staff name] calling from Massachusetts General Hospital. I'm calling to get in contact with [name]. This is not an urgent call - I'm just reaching out about a program you might be interested in. Please feel free to give me a call back whenever you get the chance. I can be reached at [telephone number]. Thank you!

*31.7 Participant Locator Form*

**PARTICIPANT LOCATOR FORM**

**Participant name:** _____

**Mailing address:** _____
(Street) (Apt.)

_____
(City, State, Zip)

**Preferred telephone:** Please indicate: Mobile Home Work Other

_____

**Alternate telephone:** Please indicate: Mobile Home Work Other

_____

**If you would like to receive SMS text messaging reminders, please check the box below:**

- I give permission to the Young Adult Couples and Cancer study team to contact me regarding this research study, using the mobile telephone number provided;
- I understand that any communication using SMS with the study team is NOT HIPAA-compliant, not encrypted, and does not guarantee confidentiality.
- I understand that this number is not monitored regularly and should not be used for urgent or emergency situations.

☐ By checking this box, participant understands and gives their verbal permission to contact me through SMS messaging.

**Email address:** _____

**If you would like to receive emails without encryption, please check the box below:**

- I understand that any communication using non-encrypted emails with the study team is NOT HIPAA-compliant and does not guarantee confidentiality.

☐ By checking this box, participant understands and gives their verbal permission for the study team to contact me through non-encrypted email messaging.

**Circle preferred survey delivery method:** email via hard-copy mail

**Can study staff leave voicemails regarding your participation in the study (Please circle one)? Y N**

---

**IN CASE WE HAVE TROUBLE REACHING YOU, PLEASE PROVIDE ONE OTHER PERSON WE COULD CONTACT** (This is optional and will not affect your participation in the research study).

**Contact name:**

_____

(Last) (First) (M.I.)

**Relationship to participant:**

_____

**Preferred telephone:**

_____

**Alternate telephone:**

_____

*31.8 Suggested SMS and Email Communication*

**Email Reminder Templates**
[The following templates will be used for emailing depending on context and status of a participant through the protocol. Under no circumstances will study staff ever screen or discuss personal medical history, exchange personal health information, or other sensitive information via email. If a participant introduces sensitive information, including but not limited to the examples just listed, into an email, the study staff member will direct the participant to call them to discuss it further over the telephone.]

**Initial Enrollment email.**
Subject line: "Young Adult Couples and Cancer Study at MGH"

Hello [participant name],

It was a pleasure speaking with you today! I just wanted to follow up with the documents I mentioned that contain all the information about the study that we discussed over the telephone. Additionally, please see attached a copy of the consent form for your records.

You should receive a link to the first survey by email today. Please let me know if you have any questions or concerns - thank you so much

Thanks!

[Study staff name]

[Study Staff Contact Information]

**Electronic HIPAA Authorization Email Template**
Subject line: "Young Adult Couples and Cancer Study Study HIPAA Authorization"

Hi [participant name],

Thank you for participating in our research study! To allow study staff to access health information, I've included a link to the HIPAA authorization form. All information is kept confidential for only trained study staff and will be stored securely.

Thanks,
[Study Staff Name]

[Study Staff Contact Information]

[REDCap-generated link]

**Intervention session reminder:**
Hello _____,

We are reaching out regarding the Young Adult Couples and Cancer Study at MGH. This is a reminder that you have a session tomorrow at _____. Please sign on to the session using the telehealth link sent to you over email. Please contact [study staff contact] if you have any questions.
Thank you,
[Study Staff Member]

**Questionnaire reminder:**
Hello _____,
We are reaching out regarding the Young Adult Couples and Cancer Study at MGH. This is a reminder that it is time to complete the [pre-program / post-program] questionnaire, which will take roughly 20-30 minutes. You have received the questionnaire via [email/mail]. Please contact [study staff contact] if you have any questions.
Thank you,
[Study Staff Member]

**SMS Reminder Templates**
The following templates will be used for SMS messaging depending on context and under the discretion of trained study staff. Section 5.2 describes the details of SMS

**Questionnaire reminder:**
Hello _____, this is a message from the Young Adult Couples and Cancer Study at MGH. This is a reminder that it is time to complete the [pre-/post-program] questionnaire. This questionnaire will take roughly 20-30 minutes. You have received the questionnaire via [email/mail]. Please contact [study staff contact] if you have any questions. Thank you.

**Intervention session reminder:**
Hello _____, this is a message from the Young Adult Couples and Cancer Study at MGH. This is a reminder that you have session [#] tomorrow at _____. Please sign on to the session using the [telehealth/zoom] link sent to you over email. Please contact [study staff contact] if you have any questions. Thank you.

**Exit interview reminder:**
Hello _____, this is a message from the Young Adult Couples and Cancer Study at MGH. This is a reminder that you have an exit interview tomorrow at _____. Please sign on to the interview using the [telehealth/zoom] link sent to you over email. Please contact [study staff contact] if you have any questions. Thank you.

*31.9 Workbook*

The workbook will be included in a separate packet.

*31.10 Suggested Post-Session Survey*

**Dyad Intervention post-session survey**

- Dyad study ID
- Interventionist
- Date of session
- Session administered
- How long was the session approximately (in minutes)?
- Session Notes
    - Please note anything important about the session or scheduling
- Review of Homework Practice
    - Were the participants assigned homework for this session?
    - Please rate the patient's overall adherence to the homework:
        - 1. Did not complete
        - 2.
        - 3. Does some homework
        - 4.
        - 5. Satisfactory job
        - 6.
        - 7. Excellent compliance
    - Please rate the caregiver's overall adherence to the homework:
        - 1. Did not complete
        - 2.
        - 3. Does some homework
        - 4.
        - 5. Satisfactory job
        - 6.
        - 7. Excellent compliance

### *31.11 Study Assessments*

Study assessments are included in a separate packet.

*31.12 Suggested Study Information Sheet*

## Young Adult Couples and Cancer Study

### What is the purpose of this study?

Young adults with cancer and their partner caregivers have unique unmet needs. The timing of a cancer diagnosis in the lifetime of young adult patients with cancer and their partner caregivers can have specific challenges. We are conducting a brief, joint program with young adult patients with cancer and their partners (e.g., spouse, domestic partner, significant other) to better understand these challenges as we develop a program for couples that are coping with cancer. We are hoping this program will help young adults with cancer and their partners manage the stressors and challenges they face throughout a diagnosis of cancer and treatment.

### What will I be asked to do?

The program will teach you techniques to improve communication, manage stress, improve sexual and intimacy as a couple, explore shifts in relationship roles, and practice mindfulness. The program is delivered via eight sessions lasting about 60 minutes, delivered virtually by telehealth. Participants will also be asked to complete a survey before the program and a survey after program. Each individual will be compensated up to $40 for their time in completing the two study assessments ($20/assessment).

### Who can participate in this study?

Patients may be eligible to participate in this study if they are:

- 25-39 years old
- Have any stage of cancer
- Are a patient at MGH who is currently in active cancer treatment or has completed treatment within two years
- Have an eligible partner (e.g., spouse, domestic partner, significant other) who help provides care
- Are English-speaking

Partners may be eligible to participate in this study if they are:

- Are the partner of an eligible patient
- Are English-speaking

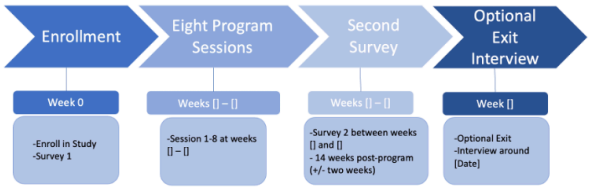
### Whom do I contact if I qualify and want to join the study?

Please contact [CRC Name] at [CRC email] or caregivingresearch@mgh.harvard.edu.

*31.13 Suggested Roadmap*

## Participant Roadmap

Welcome to the YAD Study! Here is a roadmap of what to expect as a participant in this study.




Mass General Brigham
Mass General Cancer Center

If you have any questions please contact [study coordinator names] at [study coordinator emails] or at [study phone number].

*31.14 Source Document Certified Copy Cover Sheet*

Mass General Brigham
Mass General Cancer Center

Cancer Outcomes Research and Education Program (CORE)
Nashua Building, Suite 960
125 Nashua St, Boston, MA 02114

Source Documentation – Certified Copy Cover Sheet

Type of Document: _____
Pages (including cover sheet): _____

This form serves to verify that the following scanned copy is of the exact original document, includes all pages, is legible, and confirms all wet-ink signatures.

Location Scanned: _____

Time & Date Scanned: _____

Scanned by:

_____
_____
*Signature* *Date*

_____
_____
*Printed* *Title*

*31.15 Remuneration Form*

DF/HCC Protocol [insert protocol #]

**Remuneration Form**

Remuneration for interview participation.

Participant Name _____

Participant MRN _____

SSN or ITIN _____

Mailing Address _____

_____

_____

For study team:

☐ Baseline - $20 Date completed: _____

☐ Post-Intervention - $20 Date paid: _____

*31.16 Suggested Semi-Structured Interview Guide*

**Introduction**

Thank you for participating in this study!

The purpose of this study is to understand your experience as a young couple, as one of you is undergoing treatment for cancer and the other is playing a supportive role (or as one of you has recently finished treatment for cancer and other has been playing a supportive role). We understand that this can be very stressful time, especially for young couples, so we are also looking for your input about a program we are developing to help both young adults with cancer and their partners manage the challenges they encounter during or after treatment.

As we discussed, this interview will be audio-recorded so that we can keep track of your input and use it to form our program. All your comments will be kept confidential, and nothing you say will be shared with your medical team or documented in your medical record. Also, we want to hear both of your perspectives during this interview, so we may ask the interview questions to each of you. There are no right or wrong answers to these questions. It is very important for us to hear your thoughts and feelings on the program, so we can improve it for the future. However, you do not need to answer any questions you don't feel comfortable with.

Are you okay with this interview being audio-recorded?

This interview will take 15-30 minutes. If at any time you have a question, or would like to take a break, please let me know. Do you have any questions before we begin?

(TURN ON RECORDER)

1. How did you feel about the number of sessions in the Young Adult Couples and Cancer Study?
2. How did you feel about how long each session lasted?
3. How satisfied were you with the information you received?
4. What were the most helpful and least helpful aspects of the study sessions?
5. Have you used any of the skills that you learned?
   Probe: Relaxation skills, skills for coping with symptoms, etc.
6. How did you feel about the couple structure for the sessions?
   Probe: Would you have liked to have some sessions together and some alone with the therapist?
7. How did you feel about the videoconference?
   Probe: Would you have liked to have sessions in-person?
8. How did you feel about the questionnaires?
   Probe: Too long?
   Probe: Was anything confusing?
9. How did you feel about the number of times we asked you to complete the questionnaires?
10. Do you have any suggestions for how to improve our program?
11. Did anything get in the way of you being able to participate?

12. Would you recommend this to other young adult patients with cancer and their partner caregivers?