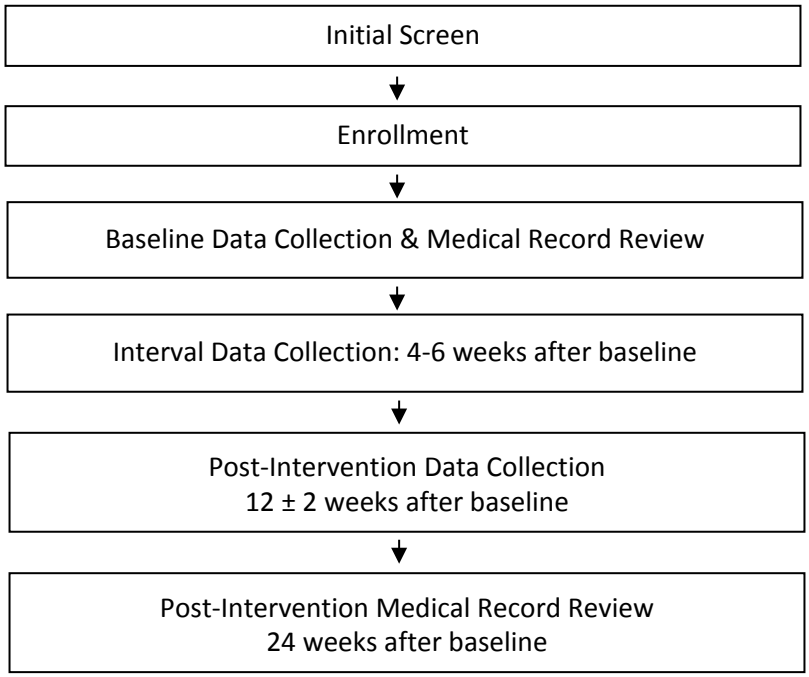
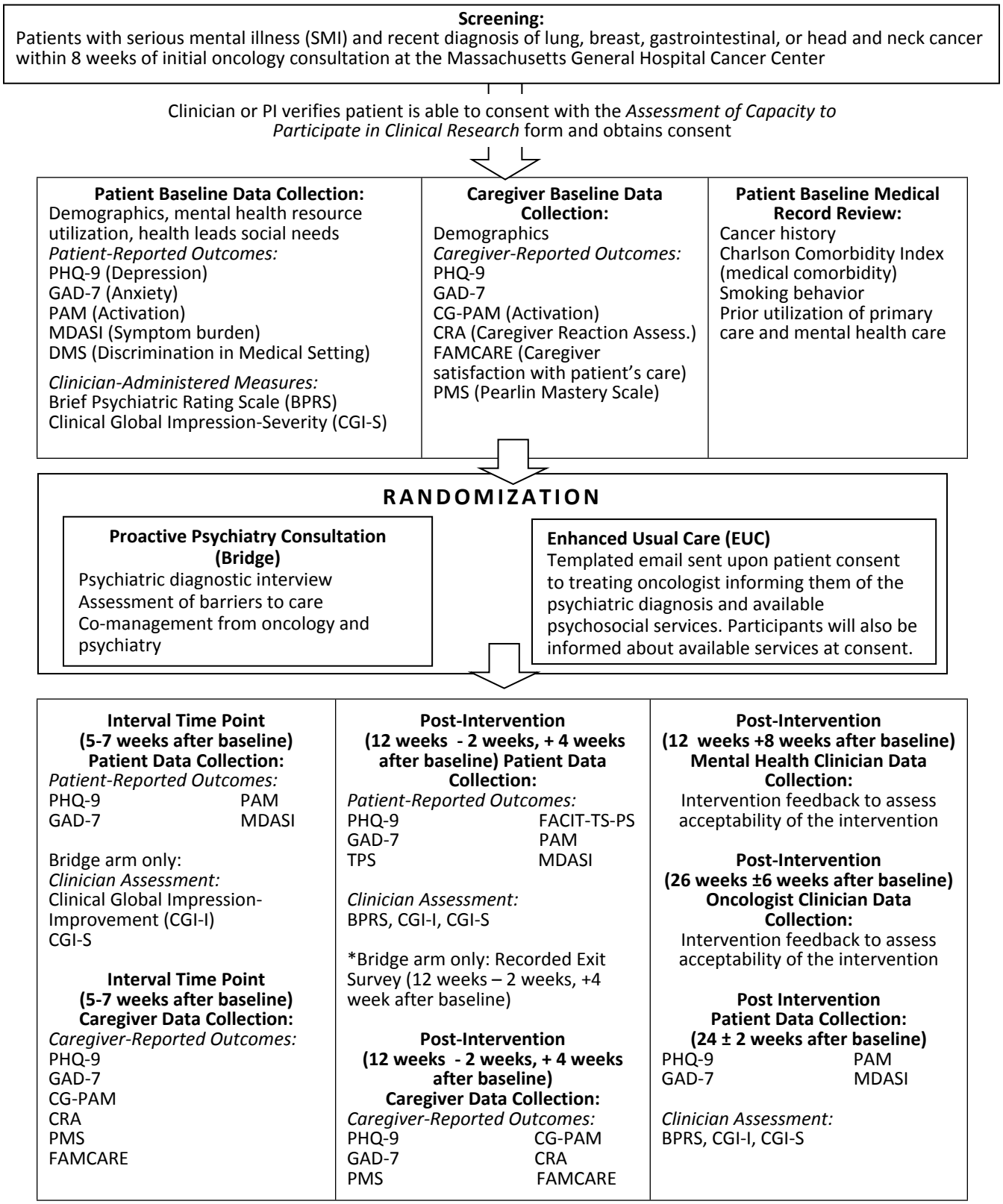
DF/HCC SOCIAL-BEHAVIORAL RESEARCH PROTOCOL
Bridge: Proactive Psychiatry Consultation and Case Management for Patients with Cancer:
Version 11.0 - 9.30.2021

SECTION 1: Protocol Schema

Open Pilot



Randomized Controlled Trial



	*Bridge arm only: Recorded Exit Survey	**Post-Intervention (24 weeks after baseline)** **Medical Record Review:** Completion of guideline-concordant, timely cancer treatment Health care utilization Communication between oncology and mental health team

SECTION 2: Body of Protocol

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1.0 INTRODUCTION

1.1 Overview

Disparities in cancer treatment markedly increase cancer mortality for patients with serious mental illness (SMI). SMI, including schizophrenia, bipolar disorder, and severe major depression, affects nearly 13 million U.S. adults who die 15-30 years earlier than the general population,[1-3] with cancer as the second leading cause of death.[3] Patients with SMI are more likely to be diagnosed with metastatic disease[4,5] and less likely to receive timely, stage-appropriate treatment.[2,4,6,7] Although health disparities research in cancer is a priority,[8-10] patients with SMI have been understudied and excluded from clinical trials. Without targeted interventions, patients with SMI will continue to experience decreased access to cancer care and die prematurely from cancer. Despite the challenges of oncology care for patients with SMI, few studies have identified remediable drivers of inequities in cancer treatment. High rates of smoking, medical comorbidity, and lack of stable primary care affect cancer outcomes but do not account for survival disparities.[11-13] Patient, clinician, and healthcare systems-level factors may impact care delivery: psychiatric symptoms including cognitive disorganization may impair the patient's understanding of a cancer diagnosis; oncologists may lack expertise in communicating with patients with mental illness; and mental health care is frequently segregated from cancer care. Thus, oncologists often need to make cancer treatment decisions without access to a complete medical history or psychiatric consultation. Collectively, these challenges increase the risk of cancer care disruptions defined as delays to treatment initiation, deviations from stage-appropriate treatment, and interruptions in treatment. In our retrospective cohort study of 95 patients with schizophrenia treated for breast cancer at an NCI-designated comprehensive cancer center, one half of patients experienced clinically significant cancer care disruptions; lack of psychiatric treatment at cancer diagnosis was the strongest predictor of disruptions in cancer care.[14] Qualitative interviews with clinicians underscored the need for an interdisciplinary team and timely psychiatry consultation.[15] Approaches that promote early co-management of cancer and SMI are urgently needed to improve outcomes in this underserved population.

1.2 Background and Rationale

SMI, defined as schizophrenia, bipolar disorder, and severe major depression, affects nearly 10 million U.S. adults, who on average die 15-30 years earlier than the general population.[1-3] Eighty percent of this premature mortality is due to medical illness, and cancer is the second leading cause of death.[3,16] More than 40% of people with SMI receive no mental health treatment.[17,18] Furthermore, comorbid mental illness is associated with increased utilization of the emergency department, longer hospitalizations, and 2-3 times greater healthcare costs.[19-21] Patients with schizophrenia and bipolar disorder experience disproportionate rates of poverty, homelessness, and social isolation, which represent additional risk factors for decreased access to cancer care.[11,13,22-24]

Delays to cancer diagnosis and inequities in cancer treatment contribute to markedly greater cancer mortality for patients with SMI.[6,25-27] Compared to individuals without mental illness, patients with schizophrenia have 2-4 times greater mortality from breast, lung, colorectal, and oral cancers.[2,6,11,26] Patients with SMI have decreased access to cancer prevention and screening and are more likely to present with metastatic disease.[4,5,28]

Additionally, patients with SMI are less likely to receive guideline-concordant cancer treatment including chemotherapy, radiation, and surgery; these inequities in treatment contribute to increased cancer mortality.[2,4,6,7] Patients with schizophrenia are also less likely to have a palliative care consultation at the end of life.[29,30] Inequities in cancer treatment and mortality persist in countries with universal health care and are not explained by differences in socioeconomic status.[2,23,31] Patient, clinician, and systems-based factors affect cancer care for patients with SMI.[22] Psychiatric symptoms including cognitive disorganization and agitation can impact a patient's ability to communicate effectively with the oncologist, leading to delays in treatment.[2,4,7,32] Physicians with limited experience with SMI may attribute physical complaints to a psychiatric illness, leading to missed and delayed diagnoses.[33,34] Mental health care is segregated from cancer care, and oncologists receive limited training in SMI. Collectively, these challenges increase the risk of inequities in cancer treatment that contribute to poor survival. Without changes in healthcare delivery, patients with SMI will remain at high risk for premature mortality from cancer.

Engaging informal caregivers for cancer patients is one important strategy to improve patient care and outcomes, especially for those with SMI. As cancer care shifts from the hospital to the community, informal caregivers have increased responsibility with managing complex medications and coordinating complex care. However, clinicians rarely include the caregiver in cancer care, and many caregivers feel unprepared, anxious, and depressed.[35-37] Including caregivers may improve patient outcomes and utilization of care.[36] For example, family caregiving mastery (perceived control over cancer care), predicted survival of patients with glioblastoma.[38] Caregivers for patients with SMI and cancer often experience additional challenges: patients with SMI may experience cognitive deficits that can impact their adherence to medication and how they report their symptoms.[39] Moreover, patients may have limited insight into the need for cancer treatment and miss appointments. In such circumstances, patients and oncologists find it more difficult to establish a therapeutic alliance.[15] Caregivers act as advocates to ensure that clinicians ask about and respect patients' wishes (Preliminary Studies). Thus, including caregivers may not only improve caregiver outcomes but also improve cancer care for patients with SMI.

Caregivers for patients with SMI are understudied.[40] They are likely to be children, siblings, or community mental health staff. The NCI has prioritized research including caregivers who are adult children/siblings and who are caring for patients underrepresented in cancer research.[36] Patients with SMI, particularly schizophrenia, may spend the majority of their adult lives in residential homes with limited family contact. In our feasibility study conducted in 2015 (n=30), "Proactive Psychiatry Consultation for Patients with Cancer", some patients identified community mental health staff as their caregivers, who accompanied them to oncology appointments. Although staff are paid, they receive minimal training in managing acute medical conditions. In our feasibility study, 85% of caregivers recognized the significant challenges of caregiving and asked for assistance in advocating for patients, especially those with limited insight.[41]

Although leading oncology organizations prioritize research to ameliorate disparities in outcomes for vulnerable populations,[10] the disparity in cancer survival

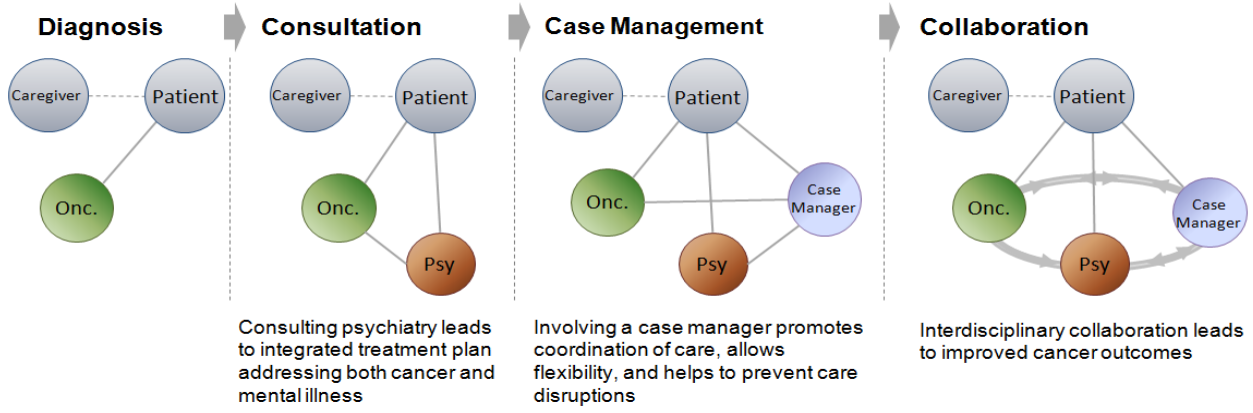
experienced by patients with SMI is unrecognized and understudied. Patients with SMI are commonly excluded from clinical trials. For example, mental illness is listed as an exclusion criterion on 20% of lung cancer interventional trials on clinicaltrials.gov.[42] The integration of psychosocial cancer care is recognized as an important component of quality cancer care, and distress screening is a national mandate and accreditation standard.[43,44] New models of integrated cancer and mental health care are needed to meet mandates for accreditation and promote timely, flexible, responsive care.

Collaborative care is a patient-centered, evidence-based approach to integrate behavioral health informed by Wagner's Chronic Care Model.[45] The proposed intervention is informed by the Chronic Care and Collaborative Care models, which aim to bridge the community and healthcare system as well as engage the patient and clinician, thereby improving health outcomes. Collaborative care utilizes an interdisciplinary team (i.e., a nurse or case manager embedded within the medical team) to identify patient goals and engage patients in their care. Case managers use evidenced-based treatments and facilitate rapid access to psychiatry. Patient outcomes are tracked using validated measures over time. Collaborative care was first tested in primary care, with multiple randomized trials demonstrating improved depression, functioning, patient satisfaction, and cost-effectiveness compared to enhanced usual care.[46-49] More recently, collaborative care has been adapted to treat depression in patients with cancer, and a systematic review showed that collaborative care interventions appear superior to other psychosocial interventions for these patients.[50-55] Furthermore, among patients with bipolar disorder, collaborative care increases access to primary care and improves physical health outcomes.[56-58] **However, no collaborative care studies to date have targeted patients with preexisting SMI and cancer, a population that requires a rapid response and specialty expertise.**

Conceptual Model

We developed the Proactive Psychiatry Consultation intervention (Bridge) for patients with SMI (Figure 1).[59] Bridge, is a 12-week patient and caregiver-centered intervention. At the time of cancer diagnosis, the oncologist and psychiatrist co-manage the patient and adapt cancer treatment. Bridge is informed by the Chronic Care Model: The case manager (social worker) engages the patient and caregiver, coordinates care, and facilitates communication among clinicians. In addition, the case manager promotes self-management and patient and caregiver engagement in care. Bridge decreases the severity of psychiatric symptoms.

Figure 1: The Bridge Care Model for Patients with SMI at Cancer Diagnosis[59]



Innovation

The proposed study is highly innovative in terms of the target population, the intervention, and the approach. First, individuals with SMI are understudied and frequently excluded from clinical trials. Second, collaborative care has not been adapted to patients with both SMI and an acute medical condition like cancer, which requires a rapid response, specialty expertise, and co-management across systems. Third, we are engaging underrepresented caregivers: adult children, siblings, parents and community mental health staff. Fourth, we have developed and piloted the first intervention in our feasibility study targeting patients with SMI at the time of cancer diagnosis and now propose the first RCT of an intervention for this vulnerable population. Fifth, we are utilizing a mixed methods approach including qualitative interviews with multiple stakeholders to determine strategies to implement Bridge effectively in the community.

Support from Additional Preliminary Studies

Patients with SMI experience frequent and significant disruptions in their cancer care. We developed a framework to identify disruptions in cancer care and examined modifiable predictors of disruptions for patients with SMI. In a retrospective cohort study of 95 patients with preexisting schizophrenia treated for breast cancer at the Dana-Farber/Harvard Cancer Center, 50% of patients experienced clinically relevant care disruptions defined as delays to diagnosis and treatment initiation, deviations from stage-appropriate treatment recommended by the clinician, and interruptions in planned cancer treatment. After adjusting for age, insurance, and having a primary care physician, lack of psychiatric treatment at cancer diagnosis was the strongest predictor of delayed treatment.[14] Compared to 1.5% of patients without mental illness nationally, 23% of patients with schizophrenia had a delay of more than 90 days from diagnosis to surgery.[25] More than one quarter of these patients had delays to chemotherapy and radiation.[60,61] Oncologists documented a treating psychiatrist in only 31% of patients and consulted psychiatry for less than 10% of their patients. Patients without a documented psychiatrist were four times more likely to have cancer care disruptions.[14] Increasing access to psychiatric treatment at cancer diagnosis may decrease disruptions in cancer care.

We interviewed 33 oncology and mental health clinicians to identify strategies to address barriers to cancer care for people with SMI. Clinicians emphasized the need for 1) increased access to psychiatry consultation at cancer diagnosis, 2) improved communication among oncology clinicians and community mental health clinicians, and 3) an interdisciplinary patient-centered approach to build trust and address complex patient needs including the social determinants of health.[15] These data support the need for a multi-level, health systems intervention to identify SMI and promote joint management of cancer and SMI by psychiatry and oncology. To ameliorate inequities in cancer outcomes for individuals with SMI, it appears critical to address patient, clinician, and health-systems factors including the stigma of mental illness.

From 2015-2016, we conducted a feasibility study (n=30) to assess the feasibility and acceptability of Bridge including identifying and enrolling patients and completing the study. Participants had SMI (schizophrenia, bipolar disorder, and severe MDD) and a recent diagnosis of lung, breast, gastrointestinal, or head/neck cancer (i.e., cancers with mortality disparity in

patients with SMI).[6,7,11,26,27] Due to the demand for such an intervention, we completed recruitment ahead of schedule in 5 months. Eighty-eight percent of patients or their guardians consented to the trial (goal 50%), and 88% completed all assessments (goal 75%). Psychiatric symptoms improved as measured by the Brief Psychiatric Rating Scale[62] (baseline mean total BPRS 45.6, 12 week BPRS 41.0, p=0.018). During the trial, we became aware that caregivers frequently played a central role in the patients' cancer care. We asked patients to identify a caregiver, defined as a person who accompanied them to cancer center appointments or participated in medical decision-making. Patients were not required to have a caregiver to participate in the feasibility study. In exit interviews, 85% of caregivers (n=20) reported that the intervention addressed the challenges of caregiving for patients with SMI and cancer. Furthermore, 85% of oncology clinicians (n=26), reported that the intervention positively impacted cancer care. Five patients who had delays in their cancer care ranging from 4 weeks to 15 months prior to the intervention, received recommended cancer treatment during the study. We now propose to conduct an open pilot study and single-site RCT to refine the intervention and assess the preliminary efficacy of Bridge in decreasing disruptions in cancer care.

Next Steps

Our qualitative research, retrospective cohort study, and feasibility study of Bridge have highlighted the importance of developing and implementing a model of care that helps connect cancer care and mental health care. This single-site RCT will prepare our research team for a pragmatic, multi-site, hybrid effectiveness-implementation trial of integrated psychiatry and cancer care, utilizing robust research and training plans to implement and disseminate the model on a larger scale. We will use the information gathered in this trial to further refine our model of proactive psychiatric consultation.

2.0 OBJECTIVES

Our overall goal in this program of research is to eliminate disparities in cancer mortality of patients with SMI. With this proposed single-site RCT, we will assess the preliminary efficacy of the Bridge model and create an implementation strategy that can be tested in a larger scale, R01-funded trial to investigate the effectiveness of Bridge in improving cancer care for patients with SMI and their caregivers.

Specific Aims

Aim 1: To refine the patient and caregiver intervention, pilot patient and caregiver measures, and finalize the intervention manual in the open pilot in preparation for conducting the RCT.

Aim 2: To assess the impact of the Proactive Psychiatry Consultation intervention (Bridge) on cancer care

Hypothesis 1: Compared to enhanced usual care (n=60), patients randomized to Bridge (n=60) will be less likely to experience cancer care disruptions (delays to treatment initiation, deviations from stage-appropriate treatment, and interruptions), have shorter time to cancer treatment initiation, and have improved healthcare utilization (fewer missed oncology appointments and decreased unplanned acute care).

Aim 3: To assess the impact of Bridge on patient and caregiver-reported outcomes
Hypothesis 2a: Patients randomized to Bridge will have greater improvement in psychiatric symptoms, engagement in cancer care, and satisfaction with cancer care compared to patients in enhanced usual care.
Hypothesis 2b: Caregivers of patients randomized to Bridge will have decreased caregiver burden, and greater improvement in caregiving mastery, engagement in cancer care, and satisfaction with care, compared to caregivers in enhanced usual care.

Aim 4: To develop metrics for disruptions in cancer care based on cancer type, stage and other clinical characteristics.

3.0 PART 1 - OPEN PILOT

3.1 Aim: To refine the patient and caregiver intervention, pilot patient and caregiver measures, and finalize the intervention manual in the open pilot in preparation for conducting the RCT.

3.2 Design/Study Type

Open Pilot: Refining Bridge and Study Procedures (Months 0-2): We will conduct an open pilot with 8 patients with SMI and cancer and their caregivers (n=7). We will test the procedures to identify, screen, and consent patients and caregivers as well as pilot validated self-report measures and refine the intervention. The open pilot, a critical component to develop the intervention, will enable the team to assess the feasibility and acceptability of the revised caregiver procedures and measures. Additionally, we will pilot the qualitative exit surveys for oncology and mental health clinicians, developed in partnership with clinicians, patients and caregivers and informed by the constructs from the Conceptual Framework of Intervention Research (CFIR).[63,64] Based on the open pilot, we will refine the intervention manual and final measure selection. **The study team will submit an amendment to the IRB noting any protocol changes before beginning the RCT.**

3.2 Research Subject Selection

Patient Participants:
The following inclusion criteria will be used:

1. Age > 18 years old
2. Verbal fluency in English
3. SMI (Schizophrenia spectrum disorder, bipolar disorder, or major depressive disorder with prior psychiatric hospitalization) confirmed by diagnostic evaluation of study psychiatrist
4. Invasive breast, lung, gastrointestinal, or head and neck cancer (suspected or confirmed according to documentation by the oncologist or pathology)
5. Oncology consultation at MGH Cancer Center within the past 8 weeks

The following exclusion criteria will be used:

1. Have cognitive impairment severe enough to interfere with completing brief study assessments or providing informed consent (and does not have a guardian who can provide consent)
2. Refuse participation

Rationale: Individuals with SMI including schizophrenia, bipolar disorder, and severe major depression die 15-30 years earlier than the general population. Patients with SMI experience disparities in cancer treatment that contribute to increased risk of cancer mortality. Importantly, psychiatric treatment may influence the delivery of guideline concordant care for this underserved population. Our previous research study of patients with schizophrenia and breast cancer treated at the Dana-Farber/Harvard Cancer Center (DF/HCC) identified that the lack of psychiatric treatment at the time of cancer diagnosis was a key predictor of cancer care disruptions. Stakeholders called for a team-based approach and early psychiatry involvement. Therefore, we hypothesized that the time of cancer diagnosis was a critical target of our intervention because at this critical time we can facilitate the collaboration between oncology and psychiatry and influence cancer treatment decision-making. We will include patients with breast, lung, gastrointestinal, and head and neck cancers because of documented disparities in mortality from these specific cancer sites in patients with SMI.[6,7,11,26,65] We will include patients with uncontrolled psychiatric symptoms and co-morbid substance use to ensure that we are not excluding patients who can benefit from the intervention and that we are capturing a sample that is clinically relevant to the practicing oncologist because of their significant barriers to engaging in their cancer care. We will exclude patients receiving cancer care at a separate institution since our intervention consists of intensive collaboration between multiple disciplines within MGH. Coordinating this care for patients receiving care at a different hospital is not feasible in this single-site study. However, patients with outside mental health clinicians will be integrated into the study. Like our feasibility study, we will establish communication with outside mental health clinicians at the time of study enrollment. The goal is not to assume responsibility for mental health care, but instead to act as a bridge to communication and to provide focused consultation from a psychiatric oncologist regarding barriers to cancer care. We will communicate with all mental health clinicians at the beginning and conclusion of the study to ensure that direct communication is established between the oncology team and the (outside) community mental health team. This model of care is utilized frequently within our consultation psychiatry group. We will exclude patients with low English literacy to ensure participants can complete study assessments. This will allow us to validate the study questionnaires within this patient population. Future trials may tailor this trial for non-English speaking patients.

Given the prevalence of guardians for the most vulnerable patients and the low risk of this study, we will allow guardians to provide consent for patients to participate. Participants will also be asked for their assent to participate in the study. As we found during our feasibility study, cognitive deficits in processing speed and understanding of complex, abstract language is challenging for many patients with schizophrenia and some patients with bipolar disorder. Additionally, the symptom of paranoia (strong fear about the intentions of others) and institutional distrust, pose barriers to the act of signing legal documents. We found that utilizing a verbal consent process administered by a clinician with expertise with serious mental illness led to the most opportunity to answer questions, use concrete language, and repeat information in digestible quantities. The clinicians will complete the Assessment of Participation to Consent form, which

offers an additional process to protect patients and ensure full understanding of the risk and benefits. If needed or preferred by patients, patients can fill out the questionnaires with the guidance of a caregiver or with study staff.

Caregiver Participants:
The following inclusion criteria will be used:

1. Age > 18 years old
2. Verbal fluency in English
3. Family or community-based caregiver who accompanies the patient to medical appointments or participates in decision-making about cancer care
4. Patient participant identifies or confirms caregiver's involvement, provides permission to contact caregiver

Rationale: We are interested in caregivers who are actively and consistently involved in the patients SMI and/or cancer care. From our previous work, we know that these caregivers may be family members (frequently children, siblings, or parents) or community mental health staff. Although there are differences in the type of relationship, both family caregivers and community caregivers provide considerable informational, instrumental, and emotional support for patients with SMI and cancer, and therefore are key partners in the intervention. Moreover, exit interview data from our previous research and clinical experience underscore the unmet needs of caregivers and their role in facilitating the patient's cancer treatment. Caregivers will need basic English literacy to complete study questionnaires and will be valuable to pilot measures of caregiving experience, mastery, anxiety and depression symptoms, and engagement in the patient's cancer care.

Clinician Participants:
The following inclusion criteria will be used:

1. Are an oncologist or oncology nurse practitioner primarily providing direct oncology care at the MGH Cancer Center; or are a licensed community mental health clinician (e.g. psychiatrist, psychiatric nurse practitioner, psychologist, social worker, licensed mental health clinician, or mental health nurse) with greater than one year treating patients
2. Had a patient who participated in the study

Rationale: We will include clinicians with direct experience with our open pilot study so that they can provide informative, personal insights and suggest ways in which we can improve for the randomized-controlled trial during the qualitative exit interviews.

3.4 Research Subject Entry

Patient Recruitment:

In partnership with the Research Patient Data Registry (RPDR) team at MGH, we are developing a population-based system to establish a cohort of MGH patients with SMI and a recent diagnosis of breast, lung, gastrointestinal, or head and neck cancer. Our eligibility criteria for patients, caregivers, and oncologists are listed above. We will update this registry every 24 hours to rapidly detect patients with SMI and track cancer treatment. Additionally, study staff will review

new consultation lists regularly distributed by oncology clinics and continue to receive referrals from oncologists, social workers, and community mental health providers. Based on enrolling 30 patients in less than 5 months in the feasibility study, we estimate that we will randomize at least 90 patients in 16 months (1-2 patients per week) if the consent rate is lower than estimated from the feasibility study.

Study staff involved in recruitment include myself (principal investigator), a trained, Collaborative Institutional Training Initiative (CITI)-certified research assistant, and CITI-trained clinicians with expertise working with patients with mental illness and cancer including: a social worker (case manager), and a psychiatrist (study clinician). Our proposed study procedures are based on our prior research with individuals with SMI through the MGH Schizophrenia Program (particularly regarding protection of vulnerable populations) and our research group's experience with recruitment of patients for our feasibility study. We previously obtained permission from the clinical directors of the four disease clinics in which we will recruit, and these procedures worked well in the feasibility study. We will screen patients for history of SMI in the following ways:

1) The research assistant will review the breast, gastrointestinal, thoracic, and head and neck oncology schedules of new patient evaluations which are distributed weekly. To facilitate identification of potential participants and confirm eligibility, study staff may review minimal data in the patients' electronic medical record including medications (antipsychotics and mood stabilizers) and past medical history.
2) We will collaborate with disease-center specific social workers and oncology clinicians in breast, gastrointestinal, thoracic, and head and neck oncology clinics who are integral parts of the cancer team and frequently involved with individuals with SMI when starting cancer treatment.
3) We will provide education to access nurses who are often the first point of contact for new patient referrals to the cancer clinics. We will also remain in communication with community-based cancer navigators who work with patients who have challenges accessing cancer care.
4) We will collaborate with the inpatient oncology consultation service and psychiatry consultation service to identify patients with SMI and cancer newly diagnosed during a hospitalization.

MGH study staff will approach patients after permission to do so has been obtained from the patients' clinicians (see Open Pilot Appendix F). If potential subjects do not have an upcoming oncology appointment within a week, study staff will send a recruitment letter and study fact sheet (Open Pilot Appendices B, C) to the patient's home with the permission of their physician. If the patient does not respond within a week, study staff may call the patient to go through the letter with the patient and ask if they are interested in meeting with the study PI. Any study activities will be coordinated with scheduled oncology appointments when possible to minimize patient burden.

All clinicians who are recruited will be caring for patients who are participating in the study and will have already received communication from the study team during the trial. We will reach out to clinicians via email or phone to participate in exit interview (see Open Pilot Appendices R-T) Mental health clinicians may be from both MGH or the community (outside MGH).

Enrollment: After referral from the oncology team, the PI or a study clinician will meet privately with each patient to confirm eligibility, explain participation in the open pilot, and

review risks and benefits. If a study clinician (physician, psychologist, or social worker) determines that the patient has the capacity to provide informed consent, they will sign the Assessment of Capacity to Participate in Clinical Research form (validated in clinical research with patients with schizophrenia)[66,67] and used in our feasibility study, which verifies that the patient is interested in participating, understands that participation is voluntary, and understands that declining participation will not affect his or her medical treatment. Patients who are judged to have capacity will then meet with the PI or study clinician to review the study protocol and consent form and obtain informed consent. If the subject would like to have family or residential staff present, they will be invited and encouraged to participate**.** Subjects will be informed that they are free not to participate in the study and may withdraw consent to participate at any time. They will be told which alternative treatments are available if they refuse to take part and that such refusal will not prejudice future treatment and informed of situations in which a breach of confidentiality is possible (such as a psychiatric emergency). Subjects will be given the opportunity to ask questions. Once enrolled, patients will be asked to identify a caregiver. Once screened as eligible for participation, the PI or study clinician will then perform the same consent procedures with the caregiver. A patient's participation does not depend on the caregiver's participation. The study protocol will be submitted in full to the DF/HCC IRB for review and approval. We will make efforts to enroll participants of a minority background within each clinic.

Patient Retention: Successful retention procedures based on experience with the feasibility study and prior projects will be implemented. The research assistant will track retention and the PI and case manager will proactively monitor the process of cancer treatment and maintain communication with the participant's oncology team. Study visits will be scheduled concurrently with medical visits. The case manager will be in communication with each patient participant at least every 2 weeks, and each caregiver participant at least every 4 weeks. The amount of contact will be individually tailored to each participant's needs, following the principles of patient-centered care. We will collect extensive locator information on patients in the event that participants move, change their care from MGH Cancer Center to a different cancer center, or otherwise lose contact. Retention will also be facilitated because patients consult regularly with their oncology care team during the course of active treatment and this open pilot will be focused on that time period.

3.4.1 Registration Procedures

General Guidelines for DF/HCC and DF/PCC Institutions

Institutions will register eligible participants in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC SOP REGIST-101. When required by REGIST-101, registration must occur prior to the initiation of protocol-specific procedures or assessments.

3.5 METHODS

3.5.1 Selection of Instruments

Clinician-Administered Measures

1. **The Brief Psychiatric Rating Scale (BPRS),** 24 items, is used extensively in bipolar disorder, schizophrenia, and major depression, strong psychometric properties and sensitivity to change[62]

2. **The Clinical Global Impression-Severity (CGI-S)** scale (range 1-7) is a brief measure that has good face validity with clinicians in terms of assessing current illness severity (based on observed and reported symptoms, function and behavior. It is correlated with the BPRS, and could be integrated into the process of cancer care with minimal burden on patients or oncology teams[68 89]

3. **The Clinical Global Impression-Improvement (CGI-I)** scale (range 1-7) rates clinically meaningful change in the patient condition from the baseline of the study. The CGI-I score generally tracks with the CGI-S score such that improvement in one follows the other.[89]

4. **The psychiatric diagnostic interview and assessment of barriers to care** will be conducted by the PI, a psychiatrist with expertise in cancer care and SMI and/or care manager, a licensed SW with extensive oncology experience (intervention only). The interview will be informed by relevant modules of the MINI CR[69] (including psychosis and major mental illness) and criteria established by the Diagnostic and Statistical Manual, Version 5. Additionally, the psychiatrist will assess the severity of current psychiatric symptoms, past psychiatric history, substance use, confirm medications, and confirm the presence of mental health clinicians and family supports. The interview will assess barriers and facilitators to cancer care, patients' understanding of their cancer diagnosis, and identify the patient's current priorities for treatment. The assessment will take approximately 30 minutes and the psychiatrist and case manager will share information to minimize patient burden.

Patient and Caregiver Self-Report Assessments

1. **Demographics** will include items about the patient's race, ethnicity, relationship status, work status, education, income, and housing status. The resource utilization questions will include previous contact with mental health treaters and primary care.

2. **The Patient Health Questionnaire-9 (PHQ-9)** is a brief, 9-item depression screen that has been used extensively in medically-ill populations, has been validated in cancer patients, and used in prior supportive care studies[70-73]

3. **The Generalized Anxiety Disorder 7-Item Scale (GAD-7)** is a 7-item self-report scale to screen for generalized anxiety disorder and assess its severity[74]

4. **The Functional Assessment of Chronic Illness Therapy-Treatment Satisfaction-General (FACIT-TS-PS Version 4)** is a 16-item instrument measuring communication with the physician and trust in the care team[75]

5. **Discrimination in Medical Settings Scale (DMS)** is a 7-item measure of perceived discrimination in healthcare settings, adapted from the Everyday Discrimination scale.[90] The measure has excellent internal consistency, reliability, and validity and has been used in medically-ill and underserved populations. We will pilot the DMS scale in patients with SMI.

Patient Self-Report Assessments

1. **Patient Activation Measure (PAM)** is a 13-item measure of patient activation that captures ability to participate in cancer care, validated in patients with SMI and cancer[76]

2. **The M.D. Anderson Symptom Inventory (MDASI)** is a 19-item instrument that assesses the most common physical and psychological symptoms related to cancer[77]

3. **Health Leads Social Need Screening Toolkit** is a validated brief screening tool that assesses the social determinants of health which focuses on remediable measures of material hardship linked with poor health outcomes[78]

4. **Psych Resource Utilization Questionnaire** is a description of mental health services utilized.

5. **Trust in Physician Scale (TPS)** is an 11-item measure to assess a patient's interpersonal trust in his or her physician.[91] We will pilot the TPS in patients with SMI.

Caregiver Self-Report Assessments

1. **Caregiver Patient Activation Measure (CG-PAM)** is a 13-item measure of caregiver activation and participation in the patient's cancer care[79]

2. **The Caregiver Reaction Assessment** is a 23-item measure of caregiver burden with 5 subscales, 1 positive, validated in caregivers of cancer patients[80]

3. **The Pearlin Mastery Scale** is a 7-item measure of mastery, perception of being able to impact and have control over care, validated in caregivers of cancer patients[81]

Medical Record Review

We will review the EHR to identify time to cancer treatment (interval from initial oncology consultation to cancer treatment initiation), missed oncology appointments, ED visits and medical and psychiatric hospitalizations. Additionally, we will assess the systems-level factor of integration of care by tracking the number of joint oncology and psychiatry visits. Data on healthcare utilization will be obtained by review of the MGH EHR and the Massachusetts All

Payers Claims Database which includes private and public claims for healthcare (inpatient, outpatient, ED, pharmacy) received Massachusetts residents.[82]

- Patient demographics (e.g., age, sex)
- Cancer diagnosis and treatment factors
- Mental illness diagnosis
- Smoking behavior
- Primary care visits
- Mental health visits
- Missed oncology appointments
- Emergency room visits
- Medical and psychiatric hospitalizations
- Documented communication between oncology and mental health team

Intervention Feedback

We will gather patient, caregiver, oncology and mental health clinician perspectives on the feasibility, acceptability, and usefulness of the open pilot by conducting brief semi-structured surveys (5-10 minutes) at 12 ± 2 weeks post-intervention on the feasibility and usefulness of the intervention. The surveys will be completed via email, in-person, or by phone according to the participant's preference. Qualitative responses will be recorded and transcribed verbatim. After obtaining consent, we will record the initial proactive psychiatry consultation to elucidate intervention components and assess intervention fidelity. Study staff will be trained in qualitative methods by the PI and co-investigator and Director of the MGH Qualitative Research Unit, Elyse Park, PhD.

3.5.2 Description of Intervention

Intervention Model of Proactive Psychiatry Consultation and Case Management (Bridge): In this open pilot, the goal will be for patients to have psychiatry involved within 8 weeks of their initial oncology consultation. The PI has published a 2014 review in *Cancer* that identified key components of an initial oncology consultation for patients with SMI.[22] The intervention is designed to be flexible and tailored to the individual patient's needs. Patients who do not wish to see a psychiatrist in the office may be seen in infusion, the hospital, or together with the oncology clinician. The psychiatrist will optimize the management of mental illness and collaborate with the oncologist to guide the delivery of optimal cancer treatment. The case manager will function as a point of contact for the patient to promote self-management, increase engagement in cancer care, identify and engage the caregiver when present, and bridge communication between cancer and mental health clinicians. Grounded in the principles of collaborative care and drawing from our retrospective cohort study at the MGH Cancer Center and qualitative interviews from oncologists, mental health clinicians, and patients with a history of SMI and cancer, and our previous feasibility study, Bridge incorporates the following key components.

(1) Patient-centered care individualized for the patient's needs and goals for treatment
(2) Assessment by psychiatrist of the severity of the patient's symptoms and psychiatric history focused on potential impact on cancer treatment and identification of barriers to treatment

(3) Engagement of a case manager who builds a relationship with the patient to promote self-management and adherence with cancer care, coordinates communication among clinicians
(4) Collaboration with SW and oncology team to address barriers and facilitators to cancer treatment
(5) Ongoing availability of the psychiatrist for consultation in the patient's care including regular communication with the oncology clinicians involved in the patient's care, tracking of psychiatric symptoms and quality of life, and monitoring of the process of cancer treatment

The below table details the components of the Bridge intervention:

Assessment and Follow-Up	Communication	Case Management/Social Work
1.Initial assessment by psychiatrist of psychiatric symptoms and barriers to cancer care, note in EHR 2. Recommendations emailed to oncologist, SW, and community mental health team 3. Study staff review patient location daily for encounters	1.Psychiatrist proactively reviews EHR weekly 2.Psychiatrists emails oncology clinicians at least every 2 weeks during intervention 3. Co-management: At least one joint visit between oncology and psychiatry or telephone discussion about cancer care management 4. Psychiatrist and CM available by page	1. Assess barriers to cancer care 2. Identifies family/community caregiver and establishes direct communication 3. Communicates with patient once every two weeks, has direct phone line w/text 4. Bridges clinician-to-clinician communication

3.5.3 Data Collection

We will collect and enter all patient data using written forms which the RA will enter into a Research Electronic Data Capture (REDCap) database. The REDCap Survey is a tool for building and managing online surveys. Our research team has extensive experience using REDCap and will create and design the surveys in a web browser, with institutional information technology support. The REDCap Survey system offers secure, HIPAA compliant, web-based applications that provide an initiative interface for participants to enter data, with real-time validation rules (automated data type and range checks) at the time of entry. Medical record review data will also be collected and entered electronically using REDCap.

The following table depicts the measures and time points for the proposed data collection.

Data	Baseline	6 Weeks	Post-Intervention	
			12 Weeks ± 2 weeks	24 weeks
Clinician-Administered Measures				
Psychiatric symptoms (BPRS)	X		X	
Psychiatric illness severity (CGI-S)	X	X	X	
Psychiatric illness improvement (CGI-I)		X	X	
Patient and Caregiver Self-Report				
Depression and anxiety symptoms (PHQ-9, GAD-7)	X	X	X	
Satisfaction with cancer care (FACIT-TS-PS)			X	
Discrimination in healthcare (DMS)	X	X	X	
Patient Self-Report				
Patient Activation Measure (PAM)	X	X	X	

Symptom burden (MDASI)	X	X	X	
Trust in Physician Scale (TPS)	X		X	
Resource utilization and social needs screening	X			
Caregiver Self-Report				
Caregiver Patient Activation Measure (C-PAM)	X	X	X	
Caregiver burden (Caregiver Reaction Assessment)	X	X	X	
Caregiver mastery (Pearlin Mastery Scale)	X	X	X	
Medical Record Review				X

3.5.4 Description of Study Process

Study Instrument Administration

Patients will complete the baseline survey in the outpatient clinic, in the infusion suite, or during hospitalization. If patients and/or caregivers refuse or are unable to complete the questionnaires on the computer, they will be permitted to use paper versions. The RA will contact patients (in person or via telephone) no more than 4 times over the course of two weeks to remind them to complete and return the surveys. If study participants fail to complete to surveys within two weeks of the expected time point, we will report the data as missing and document the reason for incompletion. If participants are not able to return to the clinic and prefer to complete study assessments at their houses, a study clinician or trained research assistant will provide that option to subjects. The 12-week assessment of the BPRS will be completed by an independent study assessor who is blinded to intervention arm. The 12-week clinician exit surveys can be completed via email, phone, or in person, whichever is least burdensome for the clinicians. Responses will be recorded and transcribed verbatim.

Intervention Administration

The intervention, proactive psychiatry consultation and case management, will be administered in a way that supports the privacy of the patient. Patients will be offered to be seen in a private room. They will be informed that elements of the psychiatric consultation will become parts of their medical record and that they psychiatrist will be in communication with the oncology team regarding elements of the consultation that may impact their cancer care.

Special Concerns

We anticipate that psychiatry consultation with completion of questionnaires constitute a low-risk study. The PI, a psychiatrist with expertise in patients with SMI will be available as a resource if there are any concerns about impact of the intervention on the patients or caregivers who are involved in the study.

Compensation

We will provide $25 to participating patients and caregivers after completion of initial questionnaire and evaluation, and an additional $25 after completion of the exit interview, for a total of $50. No compensation will be provided for oncology clinicians or mental health clinicians who participate in the study.

3.5.5 Adverse Reactions and Their Management

Reporting Adverse or Unanticipated Events

Anticipated Reactions

As this is a behavioral study, there are no ingested medications, and no biomedical procedures. It is unlikely that participants will be at any risk for physical harm because of study participation. Should participants exhibit or express distress or anger, they will be reassured by the Research Assistant that they need not answer any questions which they find upsetting. They will also be reminded that study participation is voluntary. If participants remain distressed, both the Principal Investigator and the oncology team will be notified. Should several participants express distress over an individual item, the research team will review the questionnaire and contact the IRB to consider removing it from the study.

If distressed patients need outpatient services for increased psychiatric symptoms, the social worker from the disease center will be contacted. If they require further outpatient psychiatric services or are at risk for self-harm requiring hospitalization, the PI (a licensed psychiatrist), study clinician (a licensed social worker) or designee (a doctoral-level psychologist or psychiatrist) will make the necessary referral for treatment, or be in communication with the subject's oncology and community mental health team.

If participants report severe distress or suicidal ideation during the interview or while completing any of the questionnaires, the research team will inform the participants that there is an obligation to report this to the patients' primary oncology team and social worker. The PI will be available by page if there are any urgent concerns regarding patient safety. Surveys will also be scored in real time. If a study staff member identifies patient distress via survey responses, the study staff member will page the PI Kelly Irwin, MD (a licensed psychiatrist), study clinician Amy Corveleyn (a licensed social worker), co-investigator April Hirschberg, MD (a licensed psychiatrist) or other designee who will be available to evaluate and meet with the patient to determine if the patient requires further intervention for his or her symptoms. The PI will also assess for any suicidal ideation and ensure that the patient is not at any risk for self-harm. The patient will remain on study or be referred to a higher or more intensive level of care as appropriate.

Reaction Management

If distressed patients need outpatient services for anxiety or depression, or if they are at risk for self-harm requiring hospitalization, the PI or designee (a doctoral-level licensed psychiatrist or psychologist) will make the necessary referrals for treatment. For instance, patients who are distressed but not a danger to self or others may be referred to a counselor at MGH oncology social work. If suicidality or risk of harm to others is otherwise discovered at any study visit, the participant will be referred to appropriate services. In case the hospitalization is required for a participant at MGH Cancer Center, the PI will contact and escort the patient to the MGH Acute Psychiatry Service (617-726-2995), with the aid of the MGH Police & Security if necessary (617-726-2121).

3.6 Statistical Analysis

3.6.1 Analysis plan.

Aim 1: To refine the patient and caregiver intervention, pilot patient and caregiver measures, and finalize the intervention manual in the open pilot in preparation for conducting the RCT.

During an open pilot of 8 patients and 7 caregivers, exit interview data and individual interview data with oncology and mental health clinicians will be used to refine and strengthen the intervention protocol and assess the acceptability of the measures and study procedures. The results of the open pilot will inform the RCT. The study team will submit an amendment to the IRB reflecting any changes to the intervention protocol before moving forward with the RCT.

4.0 PART 2 – RANDOMIZED-CONTROLLED TRIAL

4.1 Aims

Aim 2: To assess the impact of the Proactive Psychiatry Consultation intervention (Bridge) on cancer care

Hypothesis 2: Compared to enhanced usual care (n=60), patients randomized to Bridge (n=60) will be less likely to experience cancer care disruptions (delays to treatment initiation, deviations from stage-appropriate treatment, and interruptions), have shorter time to cancer treatment initiation, and have improved healthcare utilization (fewer missed oncology appointments and decreased unplanned acute care).

Aim 3: To assess the impact of Bridge on patient and caregiver-reported outcomes

Hypothesis 3a: Patients randomized to Bridge will have greater improvement in psychiatric symptoms, engagement in cancer care, and satisfaction with cancer care compared to patients in enhanced usual care.

Hypothesis 3b: Caregivers of patients randomized to Bridge will have decreased caregiver burden, and greater improvement in caregiving mastery, engagement in cancer care, and satisfaction with care, compared to caregivers in enhanced usual care.

4.2 Study Design

Conducting the Randomized Controlled Trial (Months 3-39): Over 3 months, we will pilot the randomized trial procedures with 3 patients in each arm (n=6) and their caregivers. Over the next 33 months, we will conduct a RCT (n=120) to compare the impact of the Bridge model with enhanced usual care on disruptions in cancer care (primary outcome). We selected enhanced usual care as the control to ensure that if a patient screens positive for SMI, that diagnosis is shared with the treating oncologist. We will use qualitative and quantitative methods to assess cancer treatment, psychiatric symptoms, engagement in cancer care, and care utilization, while gathering feedback from stakeholders on their intervention.

Primary Outcome: **Our primary outcome is the proportion of patients who experience clinically relevant disruptions in cancer care (defined as at least one delay to cancer diagnosis or treatment, deviation from stage-appropriate cancer treatment, or interruption in planned treatment) within 6 months of study enrollment.** The study team previously operationalized the process of identifying cancer care disruptions from the EHR in a

cohort of patients with breast cancer and schizophrenia.[14] Study investigators will apply that framework and NCCN guidelines to create metrics for lung, gastrointestinal, and head/neck cancer that will be reviewed by disease-center specific oncologists to define clinically relevant delays, deviations from stage-appropriate treatment, and interruptions. Trained study staff will use the metric to assess for cancer care disruptions via EHR review at 24 weeks and extract a summary of cancer care. A consensus panel of disease-specific oncologists who are blinded to intervention arm will review all patients at 24 weeks of care and evaluate for disruptions. Two disease-center specific oncologists will review, and if disagreement, the third oncologist will resolve the discrepancy.

Secondary Outcomes and Covariates: We will also collect secondary outcome measures from patients and caregivers to assess psychiatric symptoms and illness, depression and anxiety, satisfaction with cancer care, activation, symptom burden, caregiver burden, and caregiver mastery. EHR and Administrative data: To explore the potential impact of Bridge on cancer treatment, we will assess the proportion of recommended cancer treatment received.

4.3 Research Subject Selection

The research subject selection for patients, caregivers, and clinicians will remain the same as outlined in Section 3.3, with the exception of the changes below:

Patient Participants:
The following inclusion criteria will be used:

1. Age ≥ 18 years old
2. Verbal fluency in English
3. Serious mental illness (Schizophrenia spectrum disorder, bipolar disorder, or major depressive disorder with prior psychiatric hospitalization) confirmed by study clinician at consent
4. Invasive breast, lung, gastrointestinal, or head and neck cancer (suspected or confirmed Stage I-III, or Stage IV cancer that can be treated with curative intent according to judgment by the oncologist.)
5. Medical, surgical, or radiation oncology consultation at MGH Cancer Center within the past 8 weeks or a referral placed to the MGH Cancer Center and planned or recommended follow-up

The following exclusion criteria will be used:

1. Have cognitive impairment severe enough to interfere with completing brief study assessments or providing informed consent (and does not have a guardian who can provide consent)
2. Recurrence of the same cancer type

NOTE: Trained oncology disease champions (oncologists or nurse practitioners) may consent patient and caregiver participants. These champions will be added as formal study staff with the appropriate CITI training certificates before they are able to consent.

Caregiver Participants:

The following inclusion criteria will be used:

1. Age ≥ 18 years old
2. Verbal fluency in English
3. Identified or confirmed by the patient or guardian as a caregiver
4. Caregiver may be a relative, friend, or community mental health staff upon whom the patient relies for support and who is involved in their medical care
5. The caregiver should either live with the patient or have contact with the patient once per week (on average)
6. Patient or guardian must provide permission to contact caregiver

NOTE: We would like to specify that the verbal consent process can be completed with participants in-person or via phone.

Clinician Participants:
The following inclusion criteria will be used:

1. Are an oncologist or oncology nurse practitioner primarily providing direct oncology care at the MGH Cancer Center; or are a licensed community mental health clinician (e.g. psychiatrist, psychiatric nurse practitioner, psychologist, social worker, licensed mental health clinician, mental health nurse, or a prescribing primary care physician or nurse practitioner)
2. Had a patient who participated in the study

NOTE: We would like to remove the clinician inclusion criteria from the eligibility checklist and no longer use it for clinician eligibility documentation. Since clinicians are not registered on Oncore for this study and many eligibility checklist items are not applicable, the study team (with IRB approval) will record clinician eligibility and consent internally. The ODQ approved eligibility checklist will continue to be used for patient and caregiver participants.

4.4 Research Subject Entry

Recruitment: Specifically, for the RCT: we will approach all oncology clinicians who have a patient enrolled in the study, whether on the Bridge or EUC arm. We will approach only the mental health clinicians who participate in the Bridge arm of the trial given they will be able to provide feedback on the intervention.

Patients must be consented by a study clinician (licensed mental health clinician, such as a psychiatrist or case manager) or a trained physician (oncologist or nurse practitioner). Given the nature of the intervention and the primary outcome of impact on cancer care, we want to target patients who will receive additional cancer-directed treatment. Caregivers may be consented by any member of trained study staff.

All other recruitment procedures will follow Section 3.4, with the exception of the following added language:

Referrals from Department of Mental Health funded sites: Participants may learn about the study through the patient fact sheet or recruitment letters (Appendices RCT B, C, & D) or through providers from Massachusetts General Hospital, or providers from Department of Mental Health (DMH) funded sites. Recruitment flyers may be distributed by providers in the context of a medical encounter, or they may be distributed at conferences geared towards the population of people with cancer and a mental illness. MGH and DMH providers may learn about the study through the clinician fact sheet (Appendix RCT A) and/or an email from the study staff outlining the aims and eligibility requirements for participants (Appendix RCT E). Providers may only refer patients they encounter as they provide usual clinical care for them; they will not screen medical records or access personal health information for the purposes of identifying eligible patients. If a patient is identified during normal clinical treatment by their provider as being potentially eligible for the study, the patient will be provided with a brief overview of the study through a patient fact sheet (Appendix RCT B). The patient may be offered the option to contact the study staff directly or may offer their provider permission to allow the study team to contact them. The provider may only collect the name of the patient and contact information, which will then be sent to the study staff at MGH. MGH study staff may use this contact information only to reach out to the interested patient to determine ultimate eligibility for the study. Though participants will be referred by providers from DMH funded sites, all recruitment and research activities will be conducted by staff at the MGH and all participants will be accounted for by the DF/HCC IRB. The research relationship between the DF/HCC and referring DMH funded sites will be collaborative and used only to identify potentially eligible patients to the study staff at the MGH, not to collect or analyze study data. Providers will not play a role in the study further than directing potential participants to the study staff at the MGH, unless the provider is identified as a caregiver or is a community mental health clinician for the patient that is engaged in the coordination of care and contacted for an exit interview. After potentially eligible patients are identified to the study team, a member of the study staff will contact the patient by phone or in person at an upcoming clinic visit to screen them for eligibility. Study staff will maintain confidentiality during any phone outreach and will not make any mention of the individuals' mental illness or cancer diagnosis when leaving voicemails.

Referrals from the MGH Collaborative Care and Community Engagement Program: We will receive referrals of eligible patients from the Collaborative Care and Community Engagement Program, an initiative based in Massachusetts General Hospital and run by the PI (Kelly E. Irwin, MD, MPH) and study clinician (Amy E. Corveleyn, MSW, LICSW). By receiving these referrals, we will be able to proactively identify patients from community mental health centers with the goal of approaching them to confirm eligibility at their first appointment in the MGH Cancer Center. Patient health information will not be screened for trial eligiblity until a referral to the MGH Cancer Center is placed. The study team may provide standard

language to assist community members in making the first appointment for the patient at MGH Cancer Center.

Recruitment through the Partners Rally Recruitment Portal: We will submit a recruitment advertisement to the Partners Rally Recruitment Portal to allow interested and potentially eligible patients to send their contact information directly to the study team. The study team will then reach out to interested patients to assess fit and eligibility for the study. The study team will advertise the Partners Rally recruitment method for the study on social media sites and through email as well.

Enrollment: See Section 3.4, with the added language below:

We would like to correct the erroneous language in section 3.4 – the sentence reads: Patients who are judged to have capacity will then meet with the PI or study clinician to review the study protocol and consent form and obtain informed consent. We would like to remove "review the study protocol" as the physical protocol is not reviewed with participants or provided to them. Only the relevant study procedures are discussed. The sentence should now read: Patients who are judged to have capacity will then meet with the PI or study clinician to review the consent form and obtain informed consent.

Additional Language: Patients will be asked to complete baseline demographic and study questionnaires ideally in-person at the time of consent, or alternatively via email, telephone, or mail within two weeks of consent. An in-person BRPS assessment with a trained assessor will also be completed within this window. If it is not possible to complete the assessment in person, 18 questions of the BPRS may be completed via phone, or the entire assessment can be completed via video conferencing. Once baseline measures are completed, patients will be registered for study randomization. Please see Section 4.5.4 Description of Study Process for more details regarding instrument administration.

Randomization: Patients will be randomized in a 1:1 fashion to Bridge or EUC, stratified by the presence of a caregiver, using a randomization sequence generated by the MGH Biostatistics Unit. Patients must complete their baseline assessments before being randomized and if a caregiver is identified, he or she must consent within one week of the patient's consent date. Bridge: The patient will receive a comprehensive assessment of barriers to care by the psychiatrist and/or case manager, co-management from oncology and psychiatry including at least one joint appointment with psychiatry and oncology, and follow up with a case manager to promote engagement in cancer care and strengthen communication. Participants will be asked to identify a family or community caregiver, but patients without caregivers can enroll in the trial. Study staff will then contact caregivers, explain the rationale for caregiver involvement and document consent for the trial.
Enhanced usual care (EUC): Study staff will send a templated email to the treating oncologist (see RCT Appendix G) for every patient who consents to the trial, prior to randomization. The email informs the oncologists of the psychiatric diagnosis and available psychosocial services.

Study staff will also inform every patient and caregiver who consents of available psychosocial services through a flier (RCT Appendix BB).

Patient Retention: Based on attrition in the feasibility study (2 patients withdrew out of 30), we estimate that approximately 12 patients will withdraw from the randomized controlled trail out of 120. Retention procedures will be followed as detailed in Section 3.4 (pending any changes detailed in the amendment)

4.4.1 Registration Procedures

Like the open pilot, institutions will register eligible participants in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC SOP REGIST-101. When required by REGIST-101, registration must occur prior to the initiation of protocol-specific procedures or assessments. Participants in the brief three month pilot period (3 patients in each arm (n=6) and their caregivers; see page 22, paragraph 1) will not be registered in Oncore; this pilot is a review of procedures and is not included in statistical analysis.

4.5 Methods

4.5.1 Selection of Instruments

Patient, caregiver, and clinician administered measures: the measures used will be the same as listed in Section 3.5.1, with the following changes:

Clinician Administered Measures

1. **The Brief Psychiatric Rating Scale (BPRS),** 24 items, is used extensively in bipolar disorder, schizophrenia, and major depression, strong psychometric properties and sensitivity to change[62]

   Note: The BPRS will be audio-recorded and conducted by a trained study clinician.

Patient Self-Report Assessments

1. **Patient Activation Measure (PAM)** is a 10-item measure of patient activation that captures ability to participate in cancer care, validated in patients with SMI and cancer[76]

2. **Health Leads Social Need Screening Toolkit** is a validated brief screening tool that assesses the social determinants of health which focuses on remediable measures of material hardship linked with poor health outcomes[78]

Note: this measure will be included in the baseline assessment (given to both the Bridge and EUC arms). If a patient in the EUC arm screens positive, the study team will refer the patient to social work.

3. **Discrimination in Medical Settings Scale (DMS)** is a 7-item measure of perceived discrimination in healthcare settings, adapted from the Everyday Discrimination scale.[90] The measure has excellent internal consistency, reliability, and validity and has been used in medically-ill and underserved populations. We will pilot the DMS scale in patients with SMI. Note: the prompt has been altered to be more clear for participants completing the measure on their own.

4. 5. Trust in Physician Scale (TPS) is an 11-item measure to assess a patient's interpersonal trust in his or her physician.[91] We will pilot the TPS in patients with SMI. Note: the prompt has been added as it was missing in the open pilot. We have also changed "primary care doctor" to "cancer care doctors" in the prompt.

Caregiver Self-Report Assessments

1. **Caregiver Patient Activation Measure (CG-PAM)** is a 10-item measure of caregiver activation and participation in the patient's cancer care[79]

2. **FAMCARE - 2** is a 17-item tool used to measure family satisfaction with advanced cancer care. FAMCARE – 2 is one of the main versions of the FAMCARE Scale. FAMCARE-2 refers more to a team approach to care, references more symptoms than pain alone, and offers more response options compared to FAMCARE. Our study team has modified the question prompts to say "team" rather than "palliative care team", as patients on study will not all be receiving palliative care.[83]

3. The Pearlin Mastery Scale is a 7-item measure of mastery, perception of being able to impact and have control over care, validated in caregivers of cancer patients[81]
We have added a general prompt as this was missing in the open pilot.

Medical Record Review: See Section 3.5.1 (pending any changes in the amendment)

Intervention Feedback: We will gather patient, caregiver, mental health clinician(Bridge arm only) and oncology clinician (Bridge arm and EUC arm) perspectives on the feasibility, acceptability, and usefulness of the intervention and participation in the enhanced usual care arm by conducting brief semi-structured surveys (5-10 minutes) on the feasibility and usefulness of the intervention. The patient and caregiver exit surveys will occur during a 4 week period in the 12 week window, the mental health clinician exit surveys will occur at 1220 weeks post-baseline, and the oncology clinician exit surveys will occur at 20-32 weeks post-baseline.

4.5.2 Description of Intervention: See the edited table below. Note: The specified communication intervals are the minimum required from baseline to 12 weeks; additional communication is at the clinical discretion of the study team. If caregivers are no longer involved in the patient's cancer care, clinicians will assess the need to continue to conduct outreach.

Note: Communication is defined as an attempted outreach via phone, email, or text.

Note: A patient navigator has been added to the study team and will assist with the responsibilities of the psychiatrist and the social work case manager, including expanding our capacity to see patients in the community. The navigator will be trained in completion of the BPRS and have ongoing supervision by a social worker or other study clinician. The navigator has received clinical training in the psychiatric symptoms measured by the BPRS.

Assessment and Follow-Up	Communication	Case Manager/Social Work
1.Initial assessment (via phone or in-person) by study clinician of psychiatric symptoms and barriers to cancer care, note in EHR 2. Recommendations emailed to oncologist, SW, and community mental health team at beginning and conclusion of study 3. Study staff review patient location daily for encounters	1. Study clinician or study navigator proactively reviews EHR weekly and communicates with patients bi-weekly 2. Study clinician emails oncology clinicians monthly during intervention 3. Co-management: At least one joint visit between oncology and psychiatry or telephone discussion about cancer care management 4. Psychiatrist and CM available by page 5. Direct communication established between community mental health clinicians and oncology team	1. Assess barriers to cancer care 2. Identifies family/community caregiver and establishes direct communication. 3. Conducts a caregiver risk assessment 4. Case manager or navigator communicates with caregiver monthly 5. Bridges clinician-to-clinician communication

During the 12-24 week period, for each patient the study team will conduct a monthly chart review, and a study clinician will communicate at least once with the patient's oncology team, and communicate monthly with patients and caregivers.

4.5.3 Data Collection: See Section 3.5.3, and the following additional language:

Additional Language: All patient information, including audio recordings, will remain confidential and stored on Partners computers and in REDCap. All data and recordings will be labeled with a unique study ID number which will be assigned to participants at the time of enrollment, and which only the study team will have access to. All audio recordings will be transcribed verbatim, and the transcriptions will be stored on Partners computers. All audio recordings will be deleted from the recording device after they are transcribed and fully analyzed. Since these records necessarily contain patient identifiers, only study staff will have access to them. Identifiers such as name will only be used during the initial data retrieval process and can be destroyed once all data records have been obtained and data analysis completed.

Data	Baseline	5-7 Weeks	Post-Intervention	
			12 Weeks - 2 weeks, +4 weeks	24 ± 2 weeks
Clinician-Administered Measures				
Psychiatric symptoms (BPRS)	X		X	X
Psychiatric illness severity (CGI-S)	X	X	X	X
Psychiatric illness improvement (CGI-I)		X	X	X
Patient and Caregiver Self-Report				
Depression and anxiety symptoms (PHQ-9, GAD-7)	X	X	X	X
Discrimination in Medical Settings (DMS)	X			
Patient Self-Report				
Satisfaction with cancer care (FACIT-TS-PS)			X	
Patient Activation Measure (PAM 10)	X	X	X	X
Symptom burden (MDASI)	X	X	X	X
Trust in Physician Scale (TPS)			X	
Resource utilization Questionnaire	X		X	X
Health Leads Social Needs Screening Toolkit	X			
Caregiver Self-Report				
Caregiver Patient Activation Measure (CG-PAM 10)	X	X	X	
Caregiver burden (Caregiver Reaction Assessment)	X	X	X	
Caregiver mastery (Pearlin Mastery Scale)	X	X	X	
Caregiver Satisfaction with Patient Care (FAMCARE 2)	X	X	X	
Medical Record Review				X

4.5.4 Description of Study Process: Intervention administration and special concerns will follow the same guidelines in the RCT as the open pilot (Section 3.5.4). Please see below for revised study instrument administration and compensation sections:

Study Instrument Administration

Patients will complete the baseline survey in the outpatient clinic, in the infusion suite, or during hospitalization. The baseline, and all future study assessments will occur in a private consultation room or office space to ensure patient confidentiality. If patients and/or caregivers refuse or are unable to complete the questionnaires in person, they will be permitted to do so via email or phone with a study clinician or trained research assistant. The RA will contact patients (in person or via telephone) no more than 4 times over the course of two weeks to remind them to complete and return the surveys. If study participants fail to complete to surveys within the expected window, we will report the data as missing and document the reason for incompletion.

Patients must be approached and consented to the study within 8 weeks of oncology consultation at MGH. If the patient consents to the study, they must complete the baseline assessments (clinician and self-report assessments) within two weeks. The baseline BPRS will be audio-recorded (after obtaining written consent for audio recordings) and conducted by a trained study clinician. If no caregiver is identified for the patient, the patient will then be randomized in a 1:1 fashion to either the Bridge arm or the EUC arm, and registered in OnCore. If a caregiver is identified and the patient gives permission to contact a caregiver, the study team will reach out to consent the caregiver. The caregiver must consent to the study within one week of the date the patient consented. If the caregiver does not consent to the study within this one week window,

the caregiver is no longer eligible to participate. Once the patient completes baseline assessments, the patient and caregiver will be randomized together to either the Bridge arm or the EUC arm and the patient will be registered in OnCore. The caregiver has two weeks to complete the baseline assessment from the date of caregiver consent. When the caregiver completes the baseline assessment, he or she will be registered in OnCore. If the caregiver fails to complete the baseline assessment within the two-week window from consent, he or she will no longer be eligible to participate in the study. If the patient identifies a change in their primary caregiver throughout the course of the study, the study team reserves the right to enroll the new caregiver in the study and collect their reported outcomes, per the PI's discretion. The study team will document the date of the caregiver switch in the Participant Tracking Log. This change does not prevent the study team from providing support to or collecting data from the previous caregiver, per clinical judgement.

The caregiver risk assessment must be completed by the case manager (if unavailable, may be conducted by another study clinician) in-person or via phone with the caregiver within one month of the caregiver baseline completion. With permission, the caregiver risk assessment, the joint visit with the oncology team, all BPRS assessments, and the initial clinical assessment with the patient (caregiver may or may not be present) will be audio-recorded for data analysis and fidelity purposes. We will obtain written consent from patients and caregivers for all study recordings before their first recorded assessment. At the time of each subsequent recording, the study staff will verbally re-confirm permission to record the current assessment or visit. We will record at least 85% of all joint visits and assessments, excluding the baseline BPRS, which occurs prior to patient randomization, due to the difficulty of obtaining written consent for audio-recording during a phone consent. These recordings will be reviewed by the principal investigator and trained study staff to ensure key domains are covered. Feedback and targeted training will be provided weekly to study clinicians until fidelity is achieved.

In the event that a participant consents to the study over the phone but will not be coming into MGH in the near future, study staff will begin the electronic informed consent (EIC) process for audio-recording study assessments and visits. Participants will be asked to provide verbal permission and a preferred email address to be sent an email with a link through REDCap. The REDCap link will direct participants to an encrypted REDCap portal; the Electronic/Paperless Consent Template Project will be used. This process begins with the participant verifying their date of birth and full name in order to enter the portal. Additionally, this portal will have the electronic (paperless) consent form, exactly identical in content to the paper version, to guide the participant through the consent discussion with study staff over the phone. At any point, if a participant would prefer to receive a hard copy of the consent form, the EIC process will stop and study staff will send the participant two copies of the consent form in the mail with a prepaid envelope to send it back. The participant will be given ample opportunity to ask questions and take their time to consider if they want their study assessments to be recorded. From there, participants will digitally sign and date the consent form for recordings. The study staff will then sign and date the consent form as the consenting investigator and send a digital or paper copy of the signed consent form per the participant's preference, sent via Send Secure email if digitally or informed and given the opportunity to opt-out of Send Secure using the Partners Send Secure opt-out language.

Subsequent assessment windows for both patients and caregivers will be anchored on the date of the **patient's** baseline completion. The 6-week assessment must be completed 5-7 weeks

after baseline. The 12-week assessments must be completed 10-16 weeks after baseline. The 24 week assessments (patients only) must be completed 22-26 weeks after baseline. The 12-week exit surveys for patients, caregivers, and mental health clinicians, and the 24-week exit survey for oncology clinicians, can be completed via email, phone, or in person, whichever is least burdensome. Responses will be recorded and transcribed verbatim. Upon study completion, the study team will thank each patient and caregiver participant with a handwritten card. Mental health clinicians must complete exit surveys from 12- 20 weeks after the patient baseline assessment, and oncology clinicians must complete exit surveys from 20-32weeks after baseline.

Compensation

Due to the added 24 week time point for patient participants, the $50 remuneration will be distributed as follows: $20 after completion of baseline questionnaire and clinician assessment; $10 after completion of 12 week questionnaire, exit interview, and clinician assessment; $20 after completion of 24 week questionnaire and clinician assessment.

Remuneration for caregivers and clinicians will remain the same as stated in the open pilot compensation section (3.5.4).

NOTE: Patients and caregivers will be given the option to accept, decline, or donate their remuneration back to the program.

4.5.5 Adverse Reactions and Their Management:

Anticipated Reactions has been revised to the following:

As this is a behavioral study, there are no ingested medications, and no biomedical procedures. It is unlikely that participants will be at any risk for physical harm because of study participation. Should participants exhibit or express distress or anger, they will be reassured by the Research Assistant that they need not answer any questions which they find upsetting. They will also be reminded that study participation is voluntary. If participants remain distressed, both the Principal Investigator and the oncology team will be notified. Should several participants express distress over an individual item, the research team will review the questionnaire and contact the IRB to consider removing it from the study.

Participants who endorse > 0 on the PHQ-9 item #9 ("thoughts that you would be better off dead or hurting yourself in some way") or endorse ≥ mild suicidality (3) on the Brief Psychiatric Rating Scale will be assessed by a licensed mental health clinician (the PI Kelly Irwin, MD, MPH a licensed psychiatrist; study clinician Amy Corveleyn, MSW, LICSW; co-investigator April Hirschberg, MD, a licensed psychiatrist; or other designee). The clinician will evaluate the participant in-person or via phone to assess for suicidal ideation, determine if the patient is at any risk for self-harm, or initiate further intervention for his or her symptoms. Study clinicians will tailor individualized follow-up via mail, phone, or text with participants as deemed clinically necessary.

If a participant completes the study questionnaires with a research assistant or online through the secure REDCap portal, a study staff member will score the responses and notify a licensed mental health clinician on study staff or designee who will follow-up within 72 hours of assessment receipt. If a participant endorses a score greater than 0 on question #9 of the PHQ-9

and is unable to be reached by the study team for a follow-up risk assessment within 72 hours, the study clinician will reach out to an appropriate member of the healthcare team or an emergency contact to notify them of this response and decide further steps to ensure participant safety.

Reaction Management has been revised to the following:

If distressed participants require further outpatient psychiatric services or are at risk for self-harm requiring hospitalization, the PI (a licensed psychiatrist), study clinician (a licensed social worker) or designee (a doctoral-level psychologist or psychiatrist) will make the necessary referrals for treatment, or be in communication with the participants' oncology and community mental health team. The participant will remain on study and be referred to a higher or more intensive level of care as appropriate.

Note: these procedures will be consistent for participants in both arms of the randomized trial.

Additional Language: Identification of adverse events may come through notification from the study participant, caregiver, clinician, or from review of the EHR. In such circumstances, the PIs and investigative team will follow the following procedures:

Serious Adverse Events: The study team will adhere to the Department of Mental Health guidelines on adverse event reporting. However, given that this study is a minimal risk intervention, we do not anticipate any study-related events meeting the 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, or any congenital anomaly). This study population is comprised of individuals diagnosed with cancer and a serious mental illness who frequently experience disease worsening, high rate of symptoms, and hospitalizations from the underlying disease and/or side effects of treatment. Therefore, regular fluctuations in cancer-related or mental health-related symptoms, disease worsening, hospitalizations, emergency department visits, and even deaths are to be expected throughout the study, and we will not consider or report such events as SAEs in this trial.

Non-Serious Adverse Events: The IRB will be provided with unblinded summaries of study related non-serious adverse events by treatment group at the continuing reviews. These reports will include types of events, severity, and treatment phase.

4.6 Statistical Analysis:

4.6.1 Primary and Secondary Endpoints

Our primary outcome is the proportion of patients who experience clinically relevant disruptions (defined as at least one delay to cancer treatment initiation, deviation from stage-appropriate cancer treatment, or interruption in planned treatment) within 6 months of study enrollment. The study team previously operationalized the process of identifying cancer care disruptions from the EHR in a cohort of patients with breast cancer and schizophrenia.[84] Based on that validated

framework and NCCN and Commission on Cancer guidelines, study investigators met with thoracic, gastrointestinal, and head and neck oncologists (medical, surgical, and radiation oncologists) and developed metrics for cancer care disruptions based on cancer type, stage, and other clinical characteristics. These metrics included: delays to treatment initiation, deviations from stage-appropriate treatment, and interruptions in cancer treatment (e.g. > 8 weeks between surgery and post-operative chemoradiation for squamous cell head and neck cancer). The research team and consensus panel of oncologists operationalized disruptions conservatively (clearly different from standard of care), and acknowledged that it may be warranted to modify treatment due to comorbidity or treatment toxicity; study staff will track treatment toxicity documented by the oncology team. Study staff will use the metric as a checklist to extract a summary of cancer treatment received at 24 weeks. Subsequently, a consensus panel of disease-center specific oncologists blinded to study arm will review all summaries and evaluate for disruptions. Two disease-center specific oncologists will review independently, and a third oncologist will resolve any discrepancy. This consensus panel approach has been utilized for review of clinically relevant oncology outcomes.

EHR and Administrative data: To explore the potential impact of Bridge on cancer treatment, we will assess the proportion of recommended cancer treatment received. Study staff will review the initial cancer treatment plan, extract the amount of radiation and chemotherapy received at 24 weeks, and calculate the percentage of recommended radiation and chemotherapy received. Staff will track documented reasons for missed treatment (e.g. toxicity). We will assess time to cancer treatment (interval from initial oncology consultation to cancer treatment initiation), missed oncology appointments, ED visits, and hospitalizations. Although most cancer care will occur within one system, psychiatric visits may occur outside MGH and would not be captured by the EHR. Therefore, we will link data from the Massachusetts All Payer Claims Database (APCD) on outpatient and inpatient claims for study participants. Such linkages require partnership with state agencies; Dr. Sanders, medical director of the Massachusetts DMH, supports these efforts

4.6.2 Sample Size and Power Calculation

We used our previous study results along with published rates of patients with SMI and cancer who receive appropriate cancer care to estimate the detectable effect size of this RCT. Given 8% attrition in our feasibility study, we will estimate 10% attrition in the RCT to account for randomization procedures. We will target an enrollment of 120 patients for a sample size of 108 completers. With a sample size of 108 completers, 50% disruptions in enhanced usual care, and 25% cancer disruptions in Bridge, we will have at least 80% power to detect a significant difference between Bridge and EUC using a two-tailed Fisher's exact test with an alpha of 0.05. Based on enrolling 30 patients in < 5 months in the feasibility study, we estimate that we will randomize at least 120 patients in 33 months (1-2 patients/week) accounting for a lower consent rate given the feasibility study was not randomized. Based on our feasibility study, we estimate that two-thirds of the 120 patients will identify a caregiver, resulting in a sample size of 80 caregivers, and 72 caregivers who complete the intervention. Based on our experience in the feasibility study, we estimate that we have a sufficient sample size of patients and caregivers to detect a clinically meaningful difference.

4.6.3 Stratification factors and intervention allocation plan for randomized studies:

We will stratify by presence of caregiver to ensure equal representation of caregivers in the Bridge and EUC arms.

4.6.4 Stratification factors and their impact on design.

We will stratify by presence of caregiver to ensure equal representation of caregivers in the Bridge and EUC arms. We have chosen to stratify by presence of a caregiver because having a caregiver involved could be related to the impact of the intervention on disruptions in cancer care.

4.6.5 Analysis Plan:

Aim 2: To assess the impact of the Proactive Psychiatry Consultation intervention (Bridge) on cancer care

Hypothesis 1: Compared to enhanced usual care (n=60), patients randomized to Bridge (n=60) will be less likely to experience cancer care disruptions (delays to treatment initiation, deviations from stage-appropriate treatment, and interruptions), have shorter time to cancer treatment initiation, and have improved healthcare utilization (fewer missed oncology appointments and decreased unplanned acute care).

Prior to analysis, we will assess the extent and pattern of missing data (e.g. if at random) and if missing ≥ 5%, we will consider using missing imputation techniques (e.g., EM algorithm, multiple imputation) to augment data. Given our primary outcome is based on EHR review, we do not anticipate missing data. Further, we anticipate low rates of missing data for patient-reported outcomes given rare missing data in the pilot (8%), and exclusion of patients with advanced cancer. Our primary outcome is the proportion of patients who experience at least one clinically relevant disruption in cancer care within 6 months according to the consensus panel of disease-specific oncologists. We will use logistic regression to compare the proportion of patients who experience disruptions in cancer care in the Bridge and EUC arms along with baseline covariates that may be imbalanced between study groups (e.g., sex, age, cancer type and stage), while not overfitting the model. We will use Cox Proportional Hazards modeling to assess the impact of the Bridge vs. EUC on time to cancer treatment. With respect to proportion of recommended cancer treatment received, missed appointments, ED visits, and hospitalizations, we will use appropriate tests (e.g., independent-samples t-test, nonparametric Wilcoxon rank-sum test, Poisson) according to the outcome distributions. *Power Analysis*: We used our previous study results along with published rates of patients with SMI and cancer who receive appropriate cancer care to estimate the detectable effect size of this pilot RCT. With a sample size of 108 patient completers, 50% disruptions in EUC, and 25% cancer disruptions in Bridge, we will have 82% power to detect a significant difference between Bridge and EUC with an alpha of 0.05.

Aim 3: To assess the impact of Bridge on patient and caregiver-reported outcomes

Hypothesis 2a: Patients randomized to Bridge will have greater improvement in psychiatric symptoms, engagement in cancer care, and satisfaction with cancer care compared to patients in enhanced usual care.

Hypothesis 2b: Caregivers of patients randomized to Bridge will have decreased caregiver burden, and greater improvement in caregiving mastery, engagement in cancer care, and satisfaction with care, compared to caregivers in enhanced usual care.

With the longitudinal data structure, we will use linear mixed models to examine change between groups in psychiatric symptoms (BPRS). We will explore differences in depression and anxiety symptoms (PHQ-9, GAD-7), patient engagement (PAM) and cancer symptoms (MDASI). The linear mixed models will allow us to account for dependency among means over time and control for demographic and clinical factors when examining change between groups across time points

(baseline, 6, 12, and 24 weeks for patients, baseline, 6, and 12 weeks for caregivers). Based on our pilot, we estimate that 2/3 of the 120 patients will identify a caregiver, yielding a sample size of 80 caregivers.

4.6.6 Missing Data Issues

Prior to analysis, we will assess the extent and pattern of missing data and if missing ≥5%, we will consider using missing imputation techniques (e.g., EM algorithm, multiple imputation) to augment data. The analyses will initially focus on the study completers to estimate the effect of care delivery intervention in patients with serious mental illness and cancer who complete the intervention without imposing assumptions about missing data. We will also use the intention-to-treat principle with all randomized subjects, conducting sensitivity analyses to explore how various assumptions about missing data and differences between completers and non-completers affect the estimated outcomes. If data appear to be missing at random, we will employ multiple imputation methods. However, if we find that patients do not complete the study because of disease worsening, suggesting missing data are not random, we will employ maximum likelihood estimation from incomplete data, under the direction of our biostatistician, Dr. Yuchaio Chang.

5.0 PART 3 – Delphi Consensus Method

5.1 Aim: To develop metrics for disruptions in cancer care based on cancer type, stage and other clinical characteristics.

5.2 Study Design:

This is a descriptive, iterative study conducted at four times points using the Delphi Method.[85] The first questionnaire for each cancer specialty will consist of open-ended questions measuring how oncology clinicians would define a clinically significant disruption in care for under-represented and underserved populations.

A second questionnaire will be generated based on the results of round one analysis. This will include a sample metric for each cancer specialty, compiled by the PI. Each item on the metric will be ranked from 1 (irrelevant) to 5 (relevant) for the second questionnaire of the Delphi process. The survey will contain the list of items to be ranked followed by an open-ended question at the end of the survey to provide panelists a way to suggest additional items to be considered in the third questionnaire.[85]

The third questionnaire will be generated based on the results of the second round of analysis. Each panelist's previous response, as well as the group median, will be displayed alongside each survey item. Panelists will be asked, but not required, to provide reasoning for any survey question they responded to that was discordant with the majority. Any additional

survey items suggested in the open-ended response of the previous questionnaire will also be included for consideration if the study team deems them appropriate. Survey results will be collected and analyzed in a process identical to the one performed after round two.

The final questionnaire will include the updated group median and individual ratings will then be sent to all panelists. The results of the Delphi procedure will be the creation of specialized metrics to identify clinically relevant delays, deviations from stage-appropriate treatment, and interruptions in care for breast, thoracic, gastrointestinal, and head and neck cancer.

5.3 RESEARCH STUDY SELECTION

Inclusion Criteria	Exclusion Criteria
1. Oncology clinicians in fields related to medical, surgical, or radiation oncology, specializing in either breast, thoracic, gastrointestinal, or head and neck cancer, and providing care at an academic institution or community health center.	1. Unwilling or unable to participate in all four rounds of questionnaires
2. Verbal fluency in English	

5.4 RESEARCH STUDY ENTRY

From our own clinical practice and research experience, we will select oncology clinicians from academic institutions or community health centers who we believe to have significant expertise in either breast, thoracic, gastrointestinal, or head and neck specialties. Once 100 prospective panelists have been identified (25 for each cancer specialty), an introductory email will be sent from the PI to each potential panel member detailing why the individual was contacted and a brief overview of the Delphi method (Delphi Consensus Method Appendix A). The email will also convey the estimated time commitment required, study duration, and compensation ($100.00) offered for their active participation. An emailed response affirming interest in the study from the prospective panelist, will both confirm study participation and denote informed consent. We expect at least 20 members out of the 25 initially contacted for each cancer specialty to agree to participate in the study, with 15-25 panelists being standard for the Delphi process.

Clinician participants will not be registered in Oncore, nor will they be counted towards the overall accrual goal for the study.

5.5 METHODS

5.5.1 SELECTION OF INSTRUMENTS

The initial iterations of the metrics used for each cancer type will be created by the PI, and reviewed by oncologists with experience in the four cancer types. These metrics include: delays to treatment initiation, deviations from stage-appropriate treatment, and interruptions in cancer treatment (e.g. > 8 weeks between surgery and post-operative chemo-radiation for squamous cell head and neck cancer). We will administer several demographic questions with items pertaining to a participants' age, years practicing, extent of experience with and comfort treating patients with cancer and under-represented populations. The estimated time to complete each round of questionnaires will be 20 minutes.

5.5.2 DESCRIPTION OF INTERVENTION

This is a descriptive, iterative study conducted at four times points using the Delphi Method.

5.5.3 DATA COLLECTION

Data will be collected from survey responses from expert participants regarding clinically relevant delays, deviations from stage-appropriate treatment, and interruptions in cancer care. All precautions to safeguard participant information and confidentiality will be followed as stated in section 4.5.3.

5.5.4 DESCRIPTION OF STUDY PROCESS

Information will be collected from participants at four time points through email correspondence. All emails containing the electronic links to questionnaires will be sent by the PI or RA using a structured template based on the results of the former iterations of questionnaires. Each questionnaire should take no longer than 20 minutes to complete.

Compensation: We will offer participants a $100 check for remuneration at study completion of all four rounds of questionnaires. Participants will have the option to opt out of remuneration if that is their preference.

5.5.5 ADVERSE REACTIONS AND THEIR MANAGEMENT

Reporting Adverse or Unanticipated Events: We do not anticipate any adverse reactions as a result of study participation. The PI will be responsible for ensuring that any adverse events are reported to the DF/HCC IRB, as necessary. Study staff will report adverse events to the IRB as soon as they are discovered and discussed with the PI or designee (within 24 hours). The PI will be responsible for cataloguing and tallying adverse events, and will report these events to the DF/HCC IRB. The necessary written forms provided by the DF/HCC IRB will be used to report adverse events.

Anticipated Reactions: We do not anticipate any adverse reactions as a result of study participation. Emails containing electronic links to questionnaires will assure participants that they may skip any questions they wish.

Reaction Management: The PI will be available to discuss any concerns that arise from completing the surveys. If study participants become distressed while completing the survey, the PI, who is a psychiatrist, will be available to discuss any concerns.

5.6 STATISTICAL ANALYSIS

This study involves data collection at four time points. We will use descriptive analyses to characterize the sample at round one, and will continually use qualitative analyses to explore oncologist's perceptions about the cancer care disruptions.

Study Endpoints: The endpoint will be the four metrics that emerge from the expert panelists on cancer care disruptions.

Sample Size: We expect at least 20 members out of the 25 initially contacted for each cancer specialty to agree to participate in the study (total N=80), which will be a sufficient sample size as 15-25 panelists are standard for the Delphi process.[86]

6.0 PART 4 – Qualitative Interviews

6.1 AIM: To elucidate stakeholder perceptions about the core intervention components and approaches for overcoming barriers to implementation and dissemination of the Bridge intervention within the cancer center and the community.

6.2 STUDY DESIGN

This is a descriptive study at a single time point. We will use qualitative assessment methods to characterize the sample and explore participant perceptions regarding barriers to implementation and sustainable dissemination of the Bridge intervention in community settings. We will conduct qualitative interviews with 30 stakeholders (10 patients, 10 caregivers, and 10 mental health clinicians) to learn what would be most helpful in replicating the Bridge intervention at other sites.

Compensation: We will offer participants $30 (in cash or check form, depending on preference) for remuneration after completing the qualitative interview. Participants will have the option to opt out of remuneration if that is their preference

6.3 RESEARCH STUDY SELECTION

Patient Participants:
The following inclusion criteria will be used:

1. Participated in the 24-week Bridge Study
2. Completed the Bridge Study intervention within the last 18 months
3. Capacity and willingness to complete a 30-minute semi-structured, audio-recorded interview

Caregiver Participants:
The following inclusion criteria will be used:

1. Age ≥ 18 years old
2. Verbal fluency in English
3. Previously identified or confirmed by the patient or guardian as a caregiver
4. Caregiver may be a relative, friend, or community mental health staff upon whom the trial participant/patient relies for support and who is involved in their medical care
5. The caregiver should either live with the patient or have contact with the patient once per week (on average)
6. May or may not have been enrolled as a caregiver in the Bridge Study
7. Regardless of whether they were enrolled as a caregiver in the Bridge Study, the trial participant for whom the caregiver provided support for must have completed the intervention within the last 18 months
8. Capacity and willingness to complete a 30-minute semi-structured, audio-recorded interview

Clinician Participants:
The following inclusion criteria will be used:

1. Are a licensed community mental health clinician (e.g. psychiatrist, psychiatric nurse practitioner, psychologist, social worker, licensed mental health clinician, mental health nurse, or a prescribing primary care physician or nurse practitioner)
2. Had at least one patient who participated in the study

a. RESEARCH STUDY ENTRY

We will utilize purposive sampling of patient participants, caregiver participants, mental health clinician participants (including a mixture of prescribing and non-prescribing mental health clinicians) to ensure thematic saturation." Study staff trained in qualitative methods will contact eligible participants via phone, email or in-person to consent them to the qualitative interview and schedule a time to conduct the interview. Study staff will outreach to potential participants no more than three times to request participation in the interview. We are requesting to waive the written documentation of participants' informed consent and in its place, secure their verbal consent to participate the qualitative interviews to provide feedback that will be used to refine the Bridge Intervention. This waiver would grant us the ability to accept verbal consent in lieu of the traditionally signed consent form. Our research presents no more than minimal risk of harm to subjects, and does not involve procedures where written documentation of consent would normally be required outside of the research context. Participants will be reminded during the

data collection process that their participation is voluntary, and that they have the right to withdraw from the study at any time. In addition, we will inform the participants about the confidentiality measures that the research group will take during the process. Only members of the research team will have access to the data, and the recorded responses will not contain identifiable or confidential information. The verbal consent process will include pertinent information on study design, risks and benefits, and voluntary nature of the research and confidentiality. The consent process will be executed in a manner consistent with the IRB approved protocol, and the most recent version of the IRB-approved protocol will be used. Participants will be encouraged to review the Qualitative Interview Information Sheet in its entirety, before verbally consenting. Participants will be given a copy of the Qualitative Interview Information Sheet to keep.

Patients and caregivers: Individuals will provide their written consent to be audio-recorded (if they have not already signed the Participant Written Consent for Recordings form during the study, see Appendix L) during the qualitative interviews, as these recordings will be utilized to gather feedback to systematically strategies to implement Bridge effectively in the community. The consent process and the interview will be performed by a study staff member.

Clinicians: Clinician participants will provide verbal consent only.

METHODS

6.5.1 SELECTION OF INSTRUMENTS

Our interview guide comprises broad questions about stakeholders' understanding of barriers and facilitators to cancer care for individuals with severe mental illness, from initial diagnosis to end of life. Our interview guide was reviewed by psychiatrists and psychologists with experience in qualitative interviewing and research concerning cancer-related disparities. The estimated time to complete the qualitative interview is 30 minutes.

6.5.2 DESCRIPTION OF INTERVENTION

This is a descriptive study at a single time point.

6.5.3 DATA COLLECTION

Data will be collected from interviews of participants about implementation of the Bridge intervention for patients with severe mental illness and cancer. The interviews will be audio-recorded and transcribed for further qualitative analysis.

To safeguard participant information and confidentiality, all data will be stored in locked cabinets at MGH as well as password-protected computer files, accessible only to trained study staff. Participants' data will be identified by an ID number only, and a link between names and ID numbers will be kept in a separate file under lock and key. Participants' Social Security

Number/Individual Taxpayer Identification Number and address, which may need to be collected for the purposes of subject remuneration, will be kept in a separate password-protected computer file, and will be destroyed following completion of the study.

6.5.4 DESCRIPTION OF STUDY PROCESS

Information will be collected from participants at a single time point. Interviews may be conducted by phone, virtual video-conferencing technology (e.g., Zoom) or in-person, and the method chosen will be based on the participants' preference. All interviews will be conducted by study staff trained in qualitative interviewing methods using a structured guide (see RCT Appendix; pages 283-289 [Appendix HH] for patient interview guide, pages 290-300 [Appendix II] for caregiver interview guides, and pages 301-307 [Appendix JJ] for mental health clinicians). The interview will last approximately 30 minutes and will be completed in one study visit.

We will recruit and consent 30 participants (10 patients, 10 caregivers [a mix of family/friends and community mental health clinicians], and 10 mental health clinicians).

Instrument Administration: The trained study staff member will use a semi-structured interview guide, including open-ended questions and response probes, to obtain comprehensive data collection and to clarify responses. These questions and response probes will inquire about participants' experience with the Bridge intervention for individuals with severe mental illness and cancer, and the insights they gained from those experiences regarding barriers and facilitators to cancer care that may help to disseminate this intervention to other sites. The interview guide will be tailored to the type of participant (e.g., patient vs. caregiver vs. mental health clinician). We will also ask a few survey questions about participants' demographics and experience with patients with severe mental illness and cancer. Participants will be asked to be frank and will be reminded that there is no right or wrong answer to any question. Participants will also be reminded that they may refuse to answer any questions that they choose.

Compensation: We will offer participants $30 (in cash or check form, based on preference) for remuneration. Participants will have the option to opt out of remuneration if that is their preference.

6.5.5 ADVERSE REACTIONS AND THEIR MANAGEMENT

Reporting Adverse or Unanticipated Events: We do not anticipate any adverse reactions as a result of study participation. The PI will be responsible for ensuring that any adverse events are reported to the DF/HCC IRB, as necessary. Study staff will report adverse events to the IRB as soon as they are discovered and discussed with the PI or designee (within 24 hours). The PI will be responsible for cataloguing and tallying adverse events, and will report these events to the DF/HCC IRB. The necessary written forms provided by the DF/HCC IRB will be used to report adverse events.

Anticipated Reactions: We do not anticipate any adverse reactions as a result of study participation. Emails containing electronic links to questionnaires will assure participants that they may skip any questions they wish.

Reaction Management: The PI will be available to discuss any concerns that arise from completing the surveys. If study participants become distressed while completing the survey, the PI, who is a psychiatrist, will be available to discuss any concerns.

6.6 STATISTICAL ANALYSIS

This study involves data collection at a single time point. We will use descriptive analyses to characterize the sample and will use qualitative analyses to explore patients', caregivers', and mental health clinicians' perceptions about the care of patients with serious mental illness and cancer, and how to best implement this care at other sites.

6.6.1 STUDY ENDPOINTS

The endpoint will be the qualitative themes that emerge related to stakeholders' perceptions of barriers and facilitators to cancer care for individuals with SMI, including cancer screening, diagnosis, treatment, communication among providers, and end-of-life care.

6.6.2 SAMPLE SIZE AND POWER CALCULATION

We will recruit and consent 30 participants (10 patients, 10 caregivers, and 10 mental health clinicians). Based on our team's prior qualitative research experience, we believe that this sample size will be sufficient to achieve thematic saturation (i.e. the point at which no new data emerge).

6.6.3 ANALYSIS PLAN

The interviews will audio-recorded and transcribed, and then coded to explore themes. Under the supervision of the PI, content analysis will be used to explore the themes identified. Major and minor themes will be extracted through an iterative process. Responses will be coded for frequency, intensity, and extensiveness. To ensure consistency (reliability), two study staff members will analyze the data independently. Kappa coefficients of agreement will be generated; discrepancies will be resolved by reviewing raw data. For quality assurance and accuracy (validity), the PI will review the notes from each interview. NVIVO software will be utilized in the thematic analysis.

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7.0 APPENDICES

Part 1 - Open Pilot:

A. Clinician Fact Sheet
B. Patient Fact Sheet
C. Patient Recruitment Letter
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E. Clinician Recruitment Email
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G. Telephone Script (Recruitment)
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Part 2 - RCT:

A. Clinician Fact Sheet
B. Patient Fact Sheet
C. Patient Recruitment Letter
D. Caregiver Recruitment Letter
E. Clinician Email (Recruitment)
F. Clinician Approval to Approach Email
G. Clinician Email (Sent at Patient Consent)
H. Response to Direct Referral to Principal Investigator
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J. Patient Verbal Consent
K. Caregiver Verbal Consent
L. Participant Written Consent for Recordings
M. Assessment of Capacity to Participate in Clinical Research
N. Patient Baseline Questionnaire
O. Patient Interval Questionnaire
P. Patient 12-week Questionnaire
Q. Patient 24-week Questionnaire
R. Patient 12-week Exit Survey (Bridge arm only)
S. Caregiver Baseline Questionnaire
T. Caregiver Interval Questionnaire
U. Caregiver 12-week Questionnaire
V. Caregiver 12-week Exit Survey (Bridge arm only)
W. Clinician-Administered Assessments
X. Oncology and Mental Health Clinician Email Consent
Y. Oncology Clinician Exit Survey (EUC)
Z. Oncology Clinician Exit Survey (Bridge)
AA. Mental Health Clinician Exit Survey
BB. Caregiver Risk Assessment Semi-Structured Guide (Family and Caregiver Versions)
CC. Patient Initial Assessment Semi-Structured Guide
DD. Psychosocial Resources Flyer
EE. Partners Rally Recruitment Advertisement
FF. Clinician Flyer
GG. Qualitative Interview Guide: Persons with cancer and mental illness
HH. Qualitative Interview Guide: Caregivers of persons with cancer and mental illness
II. Mental Health Clinician Qualitative Interview Guide
JJ. Qualitative Interviews Verbal Consent

Part 3 – Delphi Consensus Method

A. Clinician Introductory Email

A. Clinician Fact Sheet

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

Proactive Psychiatry Consultation and Case Management for Patients with Serious Mental Illness and Cancer

WHY: Individuals with serious mental illness (SMI) die nearly 25 years younger than the general population and are significantly more likely to die from cancer. • Diagnosed with more advanced stage cancer • Less likely to receive recommended cancer treatment • Collaborative care can improve cancer outcomes but hasn't been tested in patients with SMI
WHAT: Open pilot study combining screening, proactive psychiatry consultation at cancer diagnosis, and case management at the MGH Cancer Center. • Patient-centered care • Collaborative care strengthening communication among providers • Case manager linked to patient throughout cancer treatment

WHO: Patients with SMI and recent diagnosis of cancer.

- Diagnosis of psychotic disorder (schizophrenia, schizoaffective disorder), bipolar disorder, or major depressive disorder with prior psychiatric hospitalization
- Diagnosed with breast, lung, GI, or head and neck cancer within 8 weeks of initial oncology consultation at MGH
- Are ≥ 18 years of age
- Have verbal fluency in English

HOW: Enrollment

* **If you know of a patient who may be eligible for this study please contact:**
    - **Kelly Irwin, MD: kedwards7@mgh.harvard.edu, (617) 643-4453**
    - **Catherine Callaway: ccallaway@mgh.harvard.edu, (617) 726-2297**

* Dr. Irwin will meet with patients at their convenience to confirm eligibility, explain study procedures, and obtain consent.

Study Activities

* After consent, participants will complete a psychiatric assessment with Dr. Irwin focused on decreasing symptoms and identifying barriers to care. Participants will complete a brief questionnaire at enrollment, 6 weeks, and 12 weeks.
* Dr. Irwin will communicate recommendations to the participant's oncology team and SW and remain available for ongoing consultation.
*A social work case manager will communicate directly with participants to promote self-management, coordinate care, bridge communication with providers and document in medical record.
* Participants can receive up to $50 for participation in the study.

Additional Questions

* If you have or encounter additional questions about this study, please contact Kelly Irwin and/or Catherine Callaway.

CANCER CENTER

Bridge: Early Psychiatry Consultation and Case Management Study for Patients with Cancer

Why participate in this study?

- We're conducting a study to understand if having a psychiatrist and case manager be part of your care team improves your cancer care.

Who can participate?

- Patients who have recently been diagnosed with cancer and are getting their care at the MGH Cancer Center and have a history of mental health concerns, including depression, bipolar disorder, and schizophrenia.

What does the study involve?

- You will be connected to a psychiatrist and case manager who will be a part of your cancer care team.
- You will be asked to complete 3 brief surveys over 12 weeks and will be reimbursed $50.
- Participation involves no additional cost beyond usual care.

Do I have to participate?

- Participation is completely voluntary and will not affect the care you receive at Massachusetts General Hospital.

What are the benefits of the study?

- A psychiatrist and case manager will be available to you and communicate with your oncology team throughout your treatment.
- Your participation can help us learn how to provide better care for people with cancer and mental health concerns.

What are the risks of the study?

- This is a minimal risk study.
- You may experience distress when responding to certain survey questions. You do not have to answer any questions that you find upsetting, and you may stop participating in the study at any time.
- In every study, there is a risk for some loss of privacy regarding your health information. The study team will work to minimize this risk as much as possible.

Questions? Please contact Catherine Callaway (617) 726-2297, ccallaway@partners.org, or Dr. Kelly Irwin at (617) 643-4453, kedwards7@partners.org

C. Patient Recruitment Letter

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

HARVARD MEDICAL SCHOOL

Date

Joan R, Patient
29 High Street
Boston MA

Dear Mr./Ms. Patient,

I am writing to tell you about a research study that is being conducted at the Massachusetts General Hospital (MGH) Cancer Center by Kelly Irwin, MD, and a team of MGH researchers and clinicians. You are receiving this letter because you have recently been diagnosed with lung, gastrointestinal, breast, or head and neck cancer and may receive cancer care at MGH. (Name of Dr/NP who gave permission to contact) believes you may be a good fit for this program and gave us permission to contact you.

The goal of this study is to understand if having a psychiatrist and case manager be part of your care team improves your cancer care.

If you join this research study, you will have a psychiatrist and case manager as part of your cancer care team.

It will take you about 3 months to complete this research study. You will be asked to complete a set of questionnaires with the help of a clinician at 3 points in time; at the first visit (30-45 minutes), at 6 weeks (10 minutes), and 3 month follow-up (20 minutes). Questionnaires can be completed via email, phone, or in-person, whichever you prefer.

Please contact the principal investigator Dr. Kelly Irwin, at (617) 643-4453 if you would like to learn more about the study. Taking part in this research study is your choice and will not impact the care you receive at MGH. If you do not want to participate in the research study, please call us within one week at (617)726-2297. If we do not hear from you, someone from the study team will call to see if you might want to hear more about the research study.

Attached is a fact sheet which will provide more information about the study. Thank you for thinking about being part of this research study.

Sincerely,

Oncologist/Cancer Clinic Tumor Site Study Liaison
Massachusetts General Hospital Cancer Center

Kelly Irwin, MD
(617) 643-445

D. Caregiver Recruitment Letter

MASSACHUSETTS GENERAL HOSPITAL CANCER CENTER

HARVARD MEDICAL SCHOOL

Date

Joan R, Caregiver
29 High Street
Boston MA

Dear Mr./Ms. Caregiver,

I am writing to tell you about a research study that is being conducted at the Massachusetts General Hospital (MGH) Cancer Center by Kelly Irwin, MD, and a team of MGH researchers and clinicians. You

are receiving this letter because you have been identified as a caregiver for someone who has recently been diagnosed with lung, gastrointestinal, breast, or head and neck cancer and may receive cancer care or monitoring at MGH. (Name of Dr/NP who gave permission to contact) believes him/her may be a good fit for this program and (patient name) gave us permission to contact you.

The goal of this study is to understand if having a psychiatrist and case manager be part of a patient's care team improves his/her cancer care.

If you join this research study, a psychiatrist and case manager will be a part of (patient name)'s cancer care team and will be available to you throughout treatment.

It will take you about 3 months to complete this research study. You will be asked to complete a set of questionnaires with the help of a clinician at 3 points in time; at the first visit (30-45 minutes), at 6 weeks (10 minutes), and 3 month follow-up (20 minutes). Questionnaires can be completed via email, phone, or in-person, whichever you prefer.

Please contact the principal investigator Dr. Kelly Irwin, at (617) 643-4453 if you would like to learn more about the study. Taking part in this research study is your choice and will not impact the care (patient name) receives at MGH. If you do not want to participate in the research study, please call us within one week at (617)726-2297. If we do not hear from you, someone from the study will be calling to see if you might want to hear more about the research study.

Attached is a fact sheet, which will provide more information about the study. Thank you for thinking about being part of this research study.

Sincerely,

Oncologist/Cancer Clinic Tumor Site Study Liaison	Kelly Irwin, MD
Massachusetts General Hospital Cancer Center	(617) 643-4453

E. Clinician Recruitment Email

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Dear Dr. _____,

Dr. Kelly Irwin is conducting an open pilot study focused on patients with both cancer and severe mental illness (SMI) including schizophrenia, schizoaffective disorder, bipolar disorder, and major depressive disorder with prior hospitalization. The goal of the study is to pilot patient and caregiver measures and refine an innovative model of care that incorporates proactive psychiatry consultation, collaborative care strengthening communication among providers, and engagement of a case manager at cancer diagnosis to optimize cancer care for patients with SMI. We are recruiting patients with SMI and a recent diagnosis of breast, lung, GI, or head and neck cancer (within 8 weeks of initial oncology consultation at the MGH Cancer Center). If you know of a patient who may be eligible for this study, please contact Dr. Irwin (kedwards7@mgh.harvard.edu, 617-643-4453) or Catherine Callaway (ccallaway@mgh.harvard.edu, 617-726-2297). Dr. Irwin will meet with patients at their convenience to confirm eligibility, explain study procedures, and obtain consent. If you have any additional questions about this study, please contact Dr. Irwin and/or Catherine Callaway.

Thank you,

F. Clinician Approval to Approach Email

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer
PI: Kelly E. Irwin, MD, MPH

Hello,

I am a research coordinator working with Dr. Kelly Irwin on an open pilot study to refine an innovative model of care that incorporates proactive psychiatry consultation and case management for patients with serious mental illness and a recent cancer diagnosis.

Your patient(s) **[name] [MRN]** is (are) potentially eligible for the study and I would like to approach him/her/them during his/her/their upcoming appointment. Please let me know at your earliest convenience if I have your permission to approach this patient. If I do not hear from you, I will request your permission in person to approach this patient.

Study participation does not preclude you or the rest of the patient's care team for consulting psychiatry per your clinical judgment.

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

Thank you,
Catherine Callaway

G. Telephone Script

Proactive Psychiatry Consultation Telephone Script

Hi is this (patient name)? My name is _____ and I'm calling from Massachusetts General Hospital Cancer Center. I am calling about a letter that you may have received in the mail about a proactive psychiatry consultation program that you may be eligible for. Did you receive this letter?

NOT RECEIVED: I am happy to give you a brief overview if you have a couple of minutes. Would that be ok?

> YES: Great. This program tests a new model of collaborative care that includes meeting with a psychiatrist and a social worker, known as our case manager, for patients at the MGH Cancer Center. We want to understand whether this model of care helps patients get the best possible cancer care. As part of the study, will be connected to a psychiatrist and a case manager who will be a part of your cancer care team. The psychiatrist and case manager will follow you for 3 months. We will ask you to complete a brief questionnaire at 3 different times during the study which will be coordinated with other appointments whenever possible, and can be completed via phone, email, or in-person. Your participation is completely voluntary and will not impact the care you receive at MGH.
>
> NO: Is there a better time for me to call you back?

YES RECEIVED: That's great to hear! Did you have a chance to look over it and think about if you might be interested in participating?

> YES: Wonderful! Do you have any questions about the program?
>
> NO: I am happy to give you a brief overview if you have a couple of minutes. Would that be ok?
>
> > YES: Great. This program tests a new model of collaborative care that includes proactive psychiatry consultation and a social work case manager for patients at the MGH Cancer Center. We want to understand whether this model of care helps patients in navigating cancer care. As part of the study, you will be connected to a psychiatrist and a case manager who will be a part of your cancer care team. It will take you about 3 months to complete the study, and we will ask you to complete a brief questionnaire at 3 different points of the study, and can be

completed via email, phone, or in-person. Of course, participation is completely voluntary and will not impact the care you receive at MGH.

NO: Is there a better time for me to call you back?

PATIENT WANTS TO ENROLL: Great. The next step is to arrange a time for you to meet with the psychiatrist or case manager and learn more about the study. We will try to coordinate the meeting with an upcoming oncology appointment. The total visit should take about one hour to complete. (If they have an upcoming appointment): I noticed you have an appointment on _____ (specific day), are you able to have the study appointment at that time? If not, when are you able to come in for this visit?

PATIENT INELIGIBLE/WANTS TO ENROLL: Unfortunately, you're not eligible to participate in this study but we are happy to refer you to the oncology social worker.

PATIENT WANTS TO THINK ABOUT IT: Sure, I understand. Can I give you a call in the next week to see what you are thinking and answer any questions?

PATIENT REFUSES: No problem. You do not have to answer this question, but, if you are willing, may I ask why? Your response to this question will not affect your care in any way.

VOICEMAIL: Hello this message is for (patient name). Hi (patient name), my name is ____, and I'm calling from the MGH Cancer Center about a letter that you should have received in the mail about a program that you may be eligible for. Please give a call back at _____ and let me know a good time to contact you.

H. Patient Verbal Consent

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Principal Investigator: Kelly Irwin, MD
Contact information: Call 617-643-4453

Purpose of the Research

It is challenging to cope with cancer. We are conducting a study to understand if having a psychiatrist and case manager as part of your cancer care team at the time of cancer diagnosis might improve your cancer care. Many people with illnesses like major depression, schizophrenia and bipolar disorder face barriers to receiving high quality cancer care. It can be difficult to get to appointments, have many different doctors, and experience depression or worry. Better communication between the patient, the oncology team, and mental health providers may improve care. As for all patients, it is important for people with mental illness to have access to high quality cancer treatment that is patient-centered and coordinated. Having a case manager and psychiatrist at the cancer center may help patients to receive the cancer care that they need.

Study Information

We are asking you to participate in this study because we think you may benefit from this intervention. If you participate in this study, a psychiatrist and case manager will be a part of your cancer care team. They will be available to you and communicate with your oncology team throughout your treatment. The case manager will help identify your needs, find resources, and communicate with the people who support you.

You will complete a set of questionnaires (about 30 minutes) and have a study clinician review your mental health history and communicate it to your oncology team. At 6 weeks, we will ask you to complete a second set of questionnaires (about 10 minutes), and a third set of questionnaires in three months (about 20 minutes) with study staff. These questionnaires can be completed over the phone, by email, or in-person, whichever is least burdensome. We will also ask you to identify a caregiver who is part of your cancer care. This can be a family member, friend, or community-based staff member who comes to visits with you or talks with your doctors. Choosing not to identify a caregiver will not prevent you from participating in this study.

Potential Risks and Discomforts

This study does not have any physical risks. You will not be injured or become physically sick because of participating in this study. Some of the items on the questionnaire may be upsetting. If any of the questions upset you, you can talk to your doctor or members of the study team. The research assistant and study clinician will be available to you throughout your participation in the study. You can also meet with our case manager or the principal investigator, a licensed psychiatrist, for additional support who can refer you to additional services as needed. If your responses indicate that you are in severe distress, a study clinician will call you to follow-up and assess your safety. At that point, you may be offered a referral to

appropriate services, which you may accept or decline. Your healthcare team may be notified of this referral.

Your responses to the questionnaires will be written down on paper or completed online. Your responses will not become part of your medical record, and they will not be seen by your care providers. We will also look at relevant parts of your MGH medical record, and store relevant data from your medical history. That data will be used only by study staff and will be protected by a password. Your identity will be kept confidential and we will be extremely careful to protect your privacy. If you receive the intervention, our psychiatrist and case manager will document their contacts with you in the medical record and share relevant recommendations with your oncology team. Taking part in this research study will not lead to added costs to you or your insurance company beyond usual care.

Benefits

You will be linked to a psychiatrist and case manager as part of your cancer care team during cancer treatment. We will give you $25 after completing the first set of questionnaires and another $25 after completing the third set of questionnaires in the form of cash or check, to thank you for your time.

Confidentiality

There is little risk involved with study participation. We will be extremely careful to protect your privacy and health information by locking survey material in file cabinets and storing data on password protected computers. Only our study team can access this information. Your responses will be kept confidential. You can stop participating in the study at any time. If the results of this research study are published in a medical journal, they will not identify individual patients. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. For example, if we are concerned about your safety or the safety of others, we may need to discuss this information with your medical team.

Participation

Please note that participation in this study is completely voluntary and will not affect your medical care at the Massachusetts General Hospital. You can stop participating in the research study at any time, and you can still get your medical care from your hospital or Investigator. We appreciate your time and consideration.

Contact Information

If you have questions about the study, please contact:

Research assistant: Catherine Callaway (617-726-2297), M-F 9am-5pm.
Principal investigator (licensed psychiatrist): Dr. Kelly Irwin Irwin (617-643-4453)

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

I. Caregiver Verbal Consent

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Caregiver Consent

Principal Investigator: Kelly Irwin, MD

Contact information: Call 617-643-4453

Purpose of the Research

It is challenging to cope with cancer. We are conducting a study to understand if having a psychiatrist and case manager as part of the cancer care team at the time of cancer diagnosis might improve patients' cancer care. Many people with illnesses like major depression, schizophrenia and bipolar disorder face barriers to receiving high quality cancer care. It can be difficult to get to appointments, have many different doctors, and experience depression or worry. Better communication between the patient, caregivers, the oncology team, and mental health providers may improve care. As for all patients, it is important for people with mental illness to have access to high quality cancer treatment that is patient-centered and coordinated. We want to understand if is helpful for patients with mental illness to be connected to a case manager and psychiatrist at the cancer center.

Study Information

We are asking you to participate in this study because you are a caregiver for an individual who may benefit from this intervention. During the study, the patient will be connected to a psychiatrist and case manager who will be a part of their cancer care team. They will be available to him/her and communicate with the oncology team throughout cancer treatment. A case manager will help identify the patient's needs, find resources, and communicate with the people who support him/her.

You will complete a brief set of questionnaires by phone, email, or in-person, whichever is least burdensome, which will take about 30-45 minutes. In 6 weeks, we will ask you to complete a second set of questionnaires, which will take about 10 minutes. In three months, we will ask you to complete a third set of questionnaires with study staff, which will take about 20 minutes.

Potential Risks and Discomforts

This study does not have any physical risks. You will not be injured or become physically sick because of participating in this study. Some of the items on the questionnaire may be upsetting. If any of the questions upset you, you can talk to members of the study team. The research assistant and study clinician will be available to you, and you can also meet with our case manager or the principal investigator, a licensed psychiatrist, for additional support who can refer you to additional services as needed. If your responses indicate that you are in severe distress, a study clinician will call you to follow-up and assess your safety. At that point, you may be offered a referral to appropriate services, which you may accept or decline. Your healthcare team may be notified of this referral.

Your responses to the questionnaires will be written down on paper or completed online. Your identity will be kept confidential and we will be extremely careful to protect your privacy. That data will be used only by study staff and will be protected by a password.

Benefits

We hope that participation will help us to understand the needs of caregivers for patients with cancer and mental illness and help us to support patients coping with these challenges and the network of people who support them. We will give you $25 after completing the first set of questionnaires and another $25 after completing the third set of questionnaires in the form of cash or check, to thank you for your time.

Confidentiality

There is little risk involved with study participation. We will be extremely careful to protect your privacy by locking survey material in file cabinets and storing data on password protected computers. Only our study team can access this information. Your responses will be kept confidential. If the results of this research study are published in a medical journal, they will not identify individuals.

Participation

Please note that participation in this study is completely voluntary. You can stop participating in the research study at any time, and leaving the research study will not affect your loved one's medical care. You can still get your medical care from your hospital or Investigator. We appreciate your time and consideration.

Contact Information

If you have questions about the study, please contact:

Research assistant: Catherine Callaway (617-726-2297), M-F 9am-5pm.
Principal investigator (licensed psychiatrist): Dr. Kelly Irwin Irwin (617-643-4453)

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

J. Assessment of Capacity to Participate in Clinical Research

Proactive Psychiatry Consultation for Patients with Cancer

Proposed questions to assess capacity to participate in clinical research:

1) Do you want to participate in this research study?
2) What is the study about?
3) What benefits do you get from participating in this study?
4) Why do you want to participate?

In his/her answers to the above questions, the research subject has indicated that

- ❑ **He/she *communicates the choice* to participate in the proposed research study.**
  Participation is his/her choice. The participation is voluntary.

- ❑ **He/she has a *factual understanding* of the research study.**
  Aims Institutional affiliations of the researcher
  Methods Anticipated benefits
  Sources of Funding Potential Risks
  Possible conflicts of interest Discomfort it may entail

- ❑ **He/she has an *appreciation* of the significance of the facts about research participation.**
  This is a research study, not treatment. There might be no immediate benefit.

- ❑ **He/she is able to *reason* about research participation.**
  Cognitive limitations considered. Limitations due to psychosis considered.
  Limitations due to affective state considered.

SUMMARY STATEMENT

- ❑ **Informed consent obtained.**
- ❑ **Subject has capacity to provide informed consent to participate in research despite the following (potentially limiting) factors:**

_____

_____

_____

_____ _____

Signature **Date**

K. Patient Baseline Questionnaires

PATIENT ASSESSMENT CHECKLIST

Date: _____

Study ID: _____ Time point: **Baseline**

	Patient-Reported Measures	Date
1	BACKGROUND INFORMATION	
2	PSYCH RESOURCE UTILIZATION QUESTIONNAIRE	
3	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
4	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
5	PATIENT ACTIVATION MEASURE (PAM)	
6	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	
7	DISCRIMINATION IS MEDICAL SETTINGS SCALE (DMS)	
8	TRUST IN PHYSICIAN SCALE (TPS)	
9	HEALTH LEADS SOCIAL NEED SCREENING TOOLKIT	
10	PARTICIPANT LOCATOR FORM	

Demographics

Please check the appropriate box or boxes.

1. Gender

   ☐ Man

   ☐ Woman

   ☐ Other

2. Ethnicity

   ☐ Hispanic or Latino

   ☐ Not Hispanic or Latino

3. Race (please check all that apply)

   ☐ American Indian or Alaskan native

   ☐ Asian

   ☐ African American or Black

   ☐ Native Hawaiian or other Pacific Islander

   ☐ White

   ☐ Other (please specify) _____

4. Religion

   ☐ Catholic Christian

   ☐ Other Christian (such as Protestant, Orthodox, etc.)

   ☐ Jewish

   ☐ Muslim

   ☐ Atheist

   ☐ None

   ☐ Other (please specify)_____

5. Current relationship status

   ☐ Married or living with someone as if married

   ☐ Non-cohabiting relationship

   ☐ Single, never married

   ☐ Divorced/Separated

   ☐ Loss of long term partner/ Widowed

6. Please indicate your highest or current education level

   ☐ 11th grade or less

   ☐ High school graduate or GED

   ☐ 2 years of college/AA degree/Technical school training

   ☐ College graduate (BA or BS)

   ☐ Masters degree

   ☐ Doctorate/Medical degree/Law degree

7. What is your annual combined household income?

- ☐ Less than $25,000
- ☐ $25,000 – 50,000
- ☐ $50,000 -100,000
- ☐ $100,000 – 150,000
- ☐ Greater than $150,000

8. Please indicate who you live with (you may check more than one box)

- ☐ By myself
- ☐ Partner/Spouse
- ☐ Roommate/Friend
- ☐ Children under 18
- ☐ Children over 18
- ☐ Group home/assisted living/nursing home
- ☐ Parent
- ☐ Other (please specify) _____

9. Current employment status

(please check all that apply):

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

10. Aside from mental health professionals, is there a medical health professional you see most often (a primary care provider)?

- ☐ Yes
- ☐ No

11. If yes, who is your primary care provider?

_____

12. When was your last visit to your primary care provider?

_____

Resource Utilization Questionnaire

1. Are you currently receiving any of the following mental health services at MGH? Please check all that apply:

   - ❑ No services at this time
   - ❑ Support Group
   - ❑ Social Worker
   - ❑ Psychologist
   - ❑ Psychiatrist
   - ❑ Other:_____

2. Are you currently receiving any of the following mental health services outside of MGH? Please check all that apply:

   - ❑ No services at this time
   - ❑ Support Group
   - ❑ Social Worker
   - ❑ Psychologist
   - ❑ Psychiatrist
   - ❑ Case manager
   - ❑ Day program
   - ❑ Visiting nurse (VNA)
   - ❑ Department of Mental Health (DMH) Services
   - ❑ Other:_____

3. Have you ever been hospitalized for mental illness (such as depression, anxiety, bipolar disorder, or schizophrenia)?

   - ❑ Yes
   - ❑ No

   3a. If yes, have you been hospitalized more than once?

   - ❑ Yes
   - ❑ No

   3b. When was your last hospitalization _____

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Patient Activation Measure (PAM)

1. When all is said and done, I am the person who is responsible for managing my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important factor in determining my health and ability to function	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident I can tell my health care provider concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand the nature and causes of my health condition(s)	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know the different medical treatment options available for my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain the lifestyle changes for my health that I have made	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent further problems with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new situations or problems arise with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

MDASI

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
1. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
2. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
3. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
4. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
5. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
6. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
7. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
8. You problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
9. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
10. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
11. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
12. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
13. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items **in the last 24 hours**:

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	Interfered Completely 10
14. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
15. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
16. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
17. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
18. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
19. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

Discrimination in Medical Settings Scale

In your prior experiences receiving health care, how often did the following experiences happen to you?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (Asked only of those answering "Sometimes" or more frequently to at least one question.): What do you think is the main reason for these experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

RECOMMENDED OPTIONS
1. Your Ancestry or National Origins
2. Your Gender
3. Your Race
4. Your Age
5. Your Mental Illness
6. Your Religion
7. Your Weight
8. Some other Aspect of Your Physical Appearance
9. Your Sexual Orientation
10. Your Education or Income Level

Trust in Physician Scale (TPS)

1. I doubt that my doctor really cares about me as a person	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. My doctor is usually considerate of my needs and puts them first	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I trust my doctor so much that I always try to follow his/her advice	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. If my doctor tells me something is so, then it must be true	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I sometimes distrust my doctor's opinion and would like a second one	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I trust my doctor's judgment about my medical care	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I feel my doctor does not do everything he/she should for my medical care	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I trust my doctor to put my medical needs above all other considerations when treating my medical problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. My doctor is a real expert in taking care of medical problems like mine	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I trust my doctor to tell me if a mistake was made about my treatment	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I sometimes worry that my doctor may not keep the information we discuss totally private	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Health Leads Social Need Screening Toolkit

Preferred Language:_____ Best time to call:_____

	Yes	No
1. In the last 12 months, did you ever **eat less than you felt you should** because there wasn't enough money or food?		
2. In the last 12 months, has your **utility company shut off your service** for not paying your bills?		
3. Are you worried that in the next 2 months, you **may not have stable housing?**		
4. Do problems getting **child care make it difficult for you to work** or study? (*leave blank if you do not have children*)		
5. In the last 12 months, have you needed to see a doctor, **but could not because of cost?**		
6. In the last 12 months, have you ever had to go without health care because you didn't have **a way to get there?**		
7. Do you ever need help **reading hospital materials?**		
8. Are you **afraid you might be hurt** in your apartment building or house?		
9. If you checked YES to any boxes above, **would you like to receive assistance** with any of these needs?		
10. **Are any of your needs urgent?** For example: I don't have food tonight, I don't have a place to sleep tonight		

PARTICIPANT LOCATOR FORM

Participant name: _____

Home address: _____

(Street) (Apt.)

_____

(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email: (will only be used if necessary):

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 phone:

_____

Alternate phone:

_____

L. Patient Interval Questionnaire

PATIENT ASSESSMENT CHECKLIST

Date: _____
Study ID: _____ Time point: **6 Weeks**

	Patient-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	DISCRIMINATION IN MEDICAL SETTINGS SCALE (DMS)	
4	PATIENT ACTIVATION MEASURE (PAM)	
5	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Discrimination in Medical Settings Scale

In your prior experiences receiving health care, how often did the following experiences happen to you?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (Asked only of those answering "Sometimes" or more frequently to at least one question.): What do you think is the main reason for these experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

RECOMMENDED OPTIONS
1. Your Ancestry or National Origins
2. Your Gender
3. Your Race
4. Your Age
5. Your Mental Illness
6. Your Religion
7. Your Weight
8. Some other Aspect of Your Physical Appearance
9. Your Sexual Orientation
10. Your Education or Income Level

Patient Activation Measure (PAM)

1. When all is said and done, I am the person who is responsible for managing my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important factor in determining my health and ability to function	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident I can tell my health care provider concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand the nature and causes of my health condition(s)	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know the different medical treatment options available for my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain the lifestyle changes for my health that I have made	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent further problems with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new situations or problems arise with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

MDASI

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	**As Bad As You Can Imagine** 10
20. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
21. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
22. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
23. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
24. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
25. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
26. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
27. You problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
28. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
29. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
30. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
31. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
32. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items in the last 24 hours:

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	Interfered Completely 10
33. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
34. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
35. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
36. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
37. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
38. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

M. Patient 12 Week Questionnaire and Exit Feedback

PATIENT ASSESSMENT CHECKLIST

Date: _____
Study ID: _____ Time point: **12 Weeks**

	Patient-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TREATMENT SATISFACTION-PATIENT SATISFACTION (FACIT-TS-PS)	
4	DISCRIMINATION IN MEDICAL SETTINGS SCALE (DMS)	
5	PATIENT ACTIVATION MEASURE (PAM)	
6	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	
7	TRUST IN PHYSICIAN SCALE (TPS)	
8	PSYCH RESOURCE UTILIZATION QUESTIONNAIRE	
9	PARTICIPANT FEEDBACK	

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

FACIT-TS-PS (Version 4)

These questions are about the quality of the health care services you are currently receiving. All of your responses will be kept confidential. Please mark one answer for each of the following questions.

	Physician Communication	No, not at all	Yes, but not as much as I wanted	Yes, almost as much as I wanted	Yes, and as much as I wanted
TS9	Did your doctor(s) give explanations that you could understand?	0	1	2	3
TS10	Did your doctor(s) explain the possible benefits of your treatment?	0	1	2	3
TS11	Did your doctor(s) explain the possible side effects or risks of your treatment?	0	1	2	3
TS12	Did you have an opportunity to ask questions?	0	1	2	3
TS13	Did you get to say the things that were important to you?	0	1	2	3
TS14	Did your doctor(s) seem to understand what was important to you?	0	1	2	3
TS15	Did your doctor(s) show genuine concern for you?	0	1	2	3
TS16	Did your doctor(s) seem to understand your needs?	0	1	2	3
TS18	Were you able to talk to your doctor(s) when you needed to?	0	1	2	3

TS27	Were you encouraged to participate in decisions about your health care?	0	1	2	3
TS28	Did you have enough time to make decisions about your health care?	0	1	2	3
TS30	Did your doctor(s) seem to respect your opinions?	0	1	2	3

	Confidence and Trust	**No, not at all**	**Yes, but not as much as I wanted**	**Yes, almost as much as I wanted**	**Yes, and as much as I wanted**
TS34	Did you feel that the treatment staff answered your questions honestly?	0	1	2	3
TS35	Did the treatment staff respect your privacy?	0	1	2	3
TS36	Did you have confidence in your doctor(s)?	0	1	2	3
TS37	Did you trust your doctor(s)' suggestions for treatment?	0	1	2	3

	Overall	**No**	**Maybe**	**Yes**
TS38	Would you recommend this clinic or office to others?	0	1	2
TS39	Would you choose this clinic or office again?	0	1	2

Poor	**Fair**	**Good**	**Very Good**	**Excellent**

TS40	How do you rate the care you received?	0	1	2	3	4

Thank you! Do you have any comments?

_____

_____

_____

_____

_____

_____

_____

_____

Discrimination in Medical Settings Scale

In your prior experiences receiving health care, how often did the following experiences happen to you?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (Asked only of those answering "Sometimes" or more frequently to at least one question.): What do you think is the main reason for these experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

RECOMMENDED OPTIONS
1. Your Ancestry or National Origins
2. Your Gender
3. Your Race
4. Your Age
5. Your Mental Illness
6. Your Religion
7. Your Weight
8. Some other Aspect of Your Physical Appearance
9. Your Sexual Orientation
10. Your Education or Income Level

Patient Activation Measure (PAM)

1. When all is said and done, I am the person who is responsible for managing my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important factor in determining my health and ability to function	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell when I need to go get medical care and when I can handle a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident I can tell my health care provider concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand the nature and causes of my health condition(s)	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know the different medical treatment options available for my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain the lifestyle changes for my health that I have made	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent further problems with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new situations or problems arise with my health condition	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes like diet and exercise even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

M.D. Anderson Symptom Inventory

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	**As Bad As You Can Imagine** 10
39. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
40. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
41. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
42. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
43. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
44. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
45. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
46. You problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
47. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
48. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
49. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
50. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
51. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items in the last 24 hours:

	Did Not Interfere										Interfered Completely
	0	1	2	3	4	5	6	7	8	9	10
52. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
53. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
54. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
55. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
56. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
57. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

Trust in Physician Scale (TPS)

1. I doubt that my doctor really cares about me as a person	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
2. My doctor is usually considerate of my needs and puts them first	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
3. I trust my doctor so much that I always try to follow his/her advice	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
4. If my doctor tells me something is so, then it must be true	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
5. I sometimes distrust my doctor's opinion and would like a second one	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
6. I trust my doctor's judgment about my medical care	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
7. I feel my doctor does not do everything he/she should for my medical care	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
8. I trust my doctor to put my medical needs above all other considerations when treating my medical problems	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
9. My doctor is a real expert in taking care of medical problems like mine	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
10. I trust my doctor to tell me if a mistake was made about my treatment	Disagree Strongly	Disagree	Agree N/A	Agree Strongly
11. I sometimes worry that my doctor may not keep the information we discuss totally private	Disagree Strongly	Disagree	Agree N/A	Agree Strongly

Resource Utilization Questionnaire

Please answer the following questions if you have a psychiatrist, social worker, case manager, or therapist that you saw ***before*** your diagnosis of cancer.

1. How many times have you seen your psychiatrist since you learned of your cancer diagnosis?
   - ❑ I did not have a psychiatrist before my cancer diagnosis
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

2. How many times have you seen or talked with your therapist or social worker since you learned of your cancer diagnosis?
   - ❑ I did not have a therapist or social worker before my cancer diagnosis
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

3. How many times have you seen or talked with your case manager since you learned of your cancer diagnosis?
   - ❑ I did not have a case manager before my cancer diagnosis.
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

4. Have you been hospitalized for your mental illness (such as depression, anxiety, bipolar disorder, or schizophrenia) since you learned of your cancer diagnosis?
   - ❑ Yes
   - ❑ No

PATIENT -12-WEEK PARTICIPANT FEEDBACK

We are now interested to know about your satisfaction with different aspects of this intervention. There is no right or wrong answer. Your answers will be kept confidential and will not affect your participation in future research studies, or your access to care at MGH or affiliated sites. **As a reminder, you participated in a research study of an intervention that involved a psychiatrist (Dr. Irwin or Dr. Hirschberg) and a social work case manager (Amy Corveleyn) in your cancer care team.**

1. From your perspective, how useful was the intervention **in your cancer care?**

Very useful Somewhat useful A little bit useful Not at all useful

2. How useful were the following parts of the intervention?

Involving psychiatry early in your cancer care	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with your psychiatrist, **(Dr. Irwin/Dr. Hirschberg)** in person	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach your psychiatrist **(Dr. Irwin/Dr. Hirschberg)** by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach your case manager, Amy, by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Communicating with your community mental health clinicians	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with your cancer and psychiatry teams together	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Helping with barriers to your care (e.g. rides to the hospital, insurance, housing)	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Addressing your psychiatric symptoms and medications	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Involving your caregiver in your cancer care	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me

3. What did you think was the **most useful** part about the intervention?

_____

_____

4. What do you feel could be **improved** about the intervention?

_____

_____

5. What else, if anything, would you like to add about the intervention that we did not discuss? _____

_____

_____

Thank you for being a part of the Proactive Psychiatry Consultation for Patients with Cancer Study. Your feedback is valuable to us and we appreciate your responses.

N. Caregiver Baseline Questionnaire

CAREGIVER ASSESSMENT CHECKLIST

Date: _____

Study ID: _____ Time point: **Baseline**

	Caregiver-Reported Measures	Date
1	BACKGROUND INFORMATION	
2	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
3	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
4	CAREGIVER PATIENT ACTIVATION MEASURE (CG-PAM)	
5	CAREGIVER REACTION ASSESSMENT	
6	DISCRIMINATION IN MEDICAL SETTINGS SCALE (DMS)	
7	PEARLIN MASTERY SCALE	
8	PARTICIPANT LOCATOR FORM	

Demographics

Please check the appropriate box or boxes.

10. Gender

- ☐ Man
- ☐ Woman
- ☐ Other

11. Ethnicity

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino

12. Race (please check all that apply)

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

13. Religion

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

14. Current relationship status

- ☐ Married or living with someone as if married
- ☐ Non-cohabiting relationship
- ☐ Single, never married
- ☐ Divorced/Separated
- ☐ Loss of long term partner/ Widowed

15. Please indicate your highest or current education level

- ☐ 11th grade or less
- ☐ High school graduate or GED
- ☐ 2 years of college/AA degree/Technical school training
- ☐ College graduate (BA or BS)
- ☐ Masters degree
- ☐ Doctorate/Medical degree/Law degree

16. What is your annual combined household income?

- ☐ Less than $25,000
- ☐ $25,000 – 50,000
- ☐ $50,000 -100,000
- ☐ $100,000 – 150,000
- ☐ Greater than $150,000

17. Please indicate who you live with (you may check more than one box)

- ☐ By myself
- ☐ Partner/Spouse
- ☐ Roommate/Friend
- ☐ Children under 18
- ☐ Children over 18
- ☐ Group home/assisted living/nursing home
- ☐ Parent
- ☐ Other (please specify) _____

18. Current employment status

(please check all that apply):

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

10. Aside from mental health professionals, is there a medical health professional you see most often (a primary care provider)?

- ☐ Yes
- ☐ No

11. If yes, who is your primary care provider?

_____

12. When was your last visit to your primary care provider?

_____

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Caregiver Activation Measure (CG-PAM)

Please indicate how much you agree or disagree with each statement as it applies to you personally as the caregiver/carer for _____. There are no right or wrong answers, just what is true for you as a caregiver/carer. If the statement does not apply to you, circle N/A

1.	I am responsible for seeing that this person's health is managed properly.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in this person's healthcare is one of the most important factors in determining her/his health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of this person's prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell when this person needs to get medical care and when I can handle the problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident I can tell a doctor or nurse the concerns that I have about this person's health even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can carry out medical treatments I need to do for this person at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand the nature and causes of this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	I know the different medical treatment options available for this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I am able to help this person maintain lifestyle changes, like healthy eating or exercising, for her/his condition.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can work out solutions when new situations or problems arise with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13.	I am confident I can help this person with lifestyle changes, like healthy eating and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Caregiver Reaction Assessment

Circle the number corresponding to your answer

Questions:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I feel privileged to care for ___.	1	2	3	4	5
2. Others have dumped caring for ___ onto me.	1	2	3	4	5
3. My financial resources are adequate to pay for things that are required for caregiving.	1	2	3	4	5
4. My activities are centered around care for ___.	1	2	3	4	5
5. Since caring for ___, it seems like I'm tired all of the time.	1	2	3	4	5
6. It is very difficult to get help from my family in taking care of ___.	1	2	3	4	5
7. I resent having to take care of ___.	1	2	3	4	5
8. I have to stop in the middle of work.	1	2	3	4	5
9. I really want to care for ___.	1	2	3	4	5
10. My health has gotten worse since I've been caring for ___.	1	2	3	4	5
11. I visit family and friends less since I have been caring for ___.	1	2	3	4	5
12. I will never be able to do enough caregiving to repay ___.	1	2	3	4	5
13. My family works together at caring for ___.	1	2	3	4	5
14. I have eliminated things from my schedule since caring for ___.	1	2	3	4	5
15. I have enough physical strength to care for ___.	1	2	3	4	5
16. Since caring for ___, I feel my family has abandoned me.	1	2	3	4	5
17. Caring for ___ makes me feel good.	1	2	3	4	5
18. The constant interruptions make it difficult to find time for relaxation.	1	2	3	4	5
19. I am healthy enough to care for ___.	1	2	3	4	5

20. Caring for ___ is important to me.	1	2	3	4	5
21. Caring for ___ has put a financial strain on the family.	1	2	3	4	5
22. My family (brothers, sisters, children) left me alone to care for ___.	1	2	3	4	5
23. I enjoy caring for ___.	1	2	3	4	5
24. It's difficult to pay for ___'s health needs and services.	1	2	3	4	5

Discrimination in Medical Settings Scale

In your experience as a caregiver for this patient, how often have you witnessed the patient experience the following in the his/her health care?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (Asked only of those answering "Sometimes" or more frequently to at least one question.): What do you think is the main reason for the patient's experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

RECOMMENDED OPTIONS
1. Ancestry or National Origins
2. Gender
3. Race
4. Age
5. Mental Illness
6. Religion
7. Weight
8. Some other Aspect of Physical Appearance
9. Sexual Orientation
10. Education or Income Level

Pearlin Mastery Scale

1. There is really no way I can solve some of the problems that I have	Strongly Disagree	Disagree	Agree	Strongly Agree
2. Sometimes I feel that I'm being pushed around in life	Strongly Disagree	Disagree	Agree	Strongly Agree
3. I have little control over the things that happen to me	Strongly Disagree	Disagree	Agree	Strongly Agree
4. I can do just about anything I really set my mind to	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I often feel helpless in dealing with the problems of life	Strongly Disagree	Disagree	Agree	Strongly Agree
6. What happens to me in the future mostly depends on me	Strongly Disagree	Disagree	Agree	Strongly Agree
7. There is little I can do to change many of the important things in my life	Strongly Disagree	Disagree	Agree	Strongly Agree

PARTICIPANT LOCATOR FORM

Participant name: _____

Home address: _____

(Street) (Apt.)

_____

(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email: (will only be used if necessary):

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 phone:

_____

Alternate phone:

_____

O. Caregiver Interval Questionnaire

CAREGIVER ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Time point: **6 Weeks**

	Caregiver-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	DISCRIMINATION IN MEDICAL SETTINGS SCALE (DMS)	
4	CAREGIVER PATIENT ACTIVATION MEASURE (CG-PAM)	
5	CAREGIVER REACTION ASSESSMENT	
6	PEARLIN MASTERY SCALE	

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Discrimination in Medical Settings Scale

In your experience as a caregiver for this patient, how often have you witnessed the patient experience the following in the his/her health care?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (Asked only of those answering "Sometimes" or more frequently to at least one question.): What do you think is the main reason for the patient's experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

RECOMMENDED OPTIONS
1. Ancestry or National Origins
2. Gender
3. Race
4. Age
5. Mental Illness
6. Religion
7. Weight
8. Some other Aspect of Physical Appearance
9. Sexual Orientation
10. Education or Income Level

Caregiver Activation Measure (CG-PAM)

Please indicate how much you agree or disagree with each statement as it applies to you personally as the caregiver/carer for _____. There are no right or wrong answers, just what is true for you as a caregiver/carer. If the statement does not apply to you, circle N/A

1.	I am responsible for seeing that this person's health is managed properly.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in this person's healthcare is one of the most important factors in determining her/his health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of this person's prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell when this person needs to get medical care and when I can handle the problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident I can tell a doctor or nurse the concerns that I have about this person's health even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can carry out medical treatments I need to do for this person at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand the nature and causes of this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	I know the different medical treatment options available for this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I am able to help this person maintain lifestyle changes, like healthy eating or exercising, for her/his condition.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can work out solutions when new situations or problems arise with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13.	I am confident I can help this person with lifestyle changes, like healthy eating and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Caregiver Reaction Assessment

Circle the number corresponding to your answer

Questions:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I feel privileged to care for ___.	1	2	3	4	5
2. Others have dumped caring for ___ onto me.	1	2	3	4	5
3. My financial resources are adequate to pay for things that are required for caregiving.	1	2	3	4	5
4. My activities are centered around care for ___.	1	2	3	4	5
5. Since caring for ___, it seems like I'm tired all of the time.	1	2	3	4	5
6. It is very difficult to get help from my family in taking care of ___.	1	2	3	4	5
7. I resent having to take care of ___.	1	2	3	4	5
8. I have to stop in the middle of work.	1	2	3	4	5
9. I really want to care for ___.	1	2	3	4	5
10. My health has gotten worse since I've been caring for ___.	1	2	3	4	5
11. I visit family and friends less since I have been caring for ___.	1	2	3	4	5
12. I will never be able to do enough caregiving to repay ___.	1	2	3	4	5
13. My family works together at caring for ___.	1	2	3	4	5
14. I have eliminated things from my schedule since caring for ___.	1	2	3	4	5
15. I have enough physical strength to care for ___.	1	2	3	4	5
16. Since caring for ___, I feel my family has abandonec me.	1	2	3	4	5
17. Caring for ___ makes me feel good.	1	2	3	4	5
18. The constant interruptions make it difficult to find time for relaxation.	1	2	3	4	5
19. I am healthy enough to care for ___.	1	2	3	4	5

20. Caring for ___ is important to me.	1	2	3	4	5
21. Caring for ___ has put a financial strain on the family.	1	2	3	4	5
22. My family (brothers, sisters, children) left me alone to care for ___.	1	2	3	4	5
23. I enjoy caring for ___.	1	2	3	4	5
24. It's difficult to pay for ___'s health needs and services.	1	2	3	4	5

Pearlin Mastery Scale

1. There is really no way I can solve some of the problems that I have	Strongly Disagree	Disagree	Agree	Strongly Agree
2. Sometimes I feel that I'm being pushed around in life	Strongly Disagree	Disagree	Agree	Strongly Agree
3. I have little control over the things that happen to me	Strongly Disagree	Disagree	Agree	Strongly Agree
4. I can do just about anything I really set my mind to	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I often feel helpless in dealing with the problems of life	Strongly Disagree	Disagree	Agree	Strongly Agree
6. What happens to me in the future mostly depends on me	Strongly Disagree	Disagree	Agree	Strongly Agree
7. There is little I can do to change many of the important things in my life	Strongly Disagree	Disagree	Agree	Strongly Agree

P. Caregiver 12 Week Questionnaire and Exit Feedback

CAREGIVER ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Time point: **12 Weeks**

	Caregiver-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TREATMENT SATISFACTION-PATIENT SATISFACTION (FACIT-TS-PS)	
4	DISCRIMINATION IN MEDICAL SETTINGS SCALE (DMS)	
5	CAREGIVER PATIENT ACTIVATION MEASURE (CG-PAM)	
6	CAREGIVER REACTION ASSESSMENT	
7	PEARLIN MASTERY SCALE	
8	PARTICIPANT FEEDBACK	

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

FACIT-TS-PS (Version 4)

These questions are about the quality of the health care services you are currently receiving. All of your responses will be kept confidential. Please mark one answer for each of the following questions.

	Physician Communication	No, not at all	Yes, but not as much as I wanted	Yes, almost as much as I wanted	Yes, and as much as I wanted
TS9	Did your doctor(s) give explanations that you could understand?	0	1	2	3
TS10	Did your doctor(s) explain the possible benefits of your treatment?	0	1	2	3
TS11	Did your doctor(s) explain the possible side effects or risks of your treatment?	0	1	2	3
TS12	Did you have an opportunity to ask questions?	0	1	2	3
TS13	Did you get to say the things that were important to you?	0	1	2	3
TS14	Did your doctor(s) seem to understand what was important to you?	0	1	2	3
TS15	Did your doctor(s) show genuine concern for you?	0	1	2	3

TS16	Did your doctor(s) seem to understand your needs?	0	1	2	3
TS18	Were you able to talk to your doctor(s) when you needed to?	0	1	2	3
TS27	Were you encouraged to participate in decisions about your health care?	0	1	2	3
TS28	Did you have enough time to make decisions about your health care?	0	1	2	3
TS30	Did your doctor(s) seem to respect your opinions?	0	1	2	3

	Confidence and Trust	**No, not at all**	**Yes, but not as much as I wanted**	**Yes, almost as much as I wanted**	**Yes, and as much as I wanted**
TS34	Did you feel that the treatment staff answered your questions honestly?	0	1	2	3
TS35	Did the treatment staff respect your privacy?	0	1	2	3
TS36	Did you have confidence in your doctor(s)?	0	1	2	3
TS37	Did you trust your doctor(s)' suggestions for treatment?	0	1	2	3

	Overall	**No**	**Maybe**	**Yes**
TS38	Would you recommend this clinic or office to others?	0	1	2
TS39	Would you choose this clinic or office again?	0	1	2

		Poor	**Fair**	**Good**	**Very Good**	**Excellent**
TS40	How do you rate the care you received?	0	1	2	3	4

Thank you! Do you have any comments?

_____

_____

_____

_____

Discrimination in Medical Settings Scale

In your experience as a caregiver for this patient, how often have you witnessed the patient experience the following in the his/her health care?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (Asked only of those answering "Sometimes" or more frequently to at least one question.): What do you think is the main reason for the patient's experiences? (CHECK MORE THAN ONE IF VOLUNTEERED).

RECOMMENDED OPTIONS
1. Ancestry or National Origins
2. Gender
3. Race
4. Age
5. Mental Illness
6. Religion
7. Weight
8. Some other Aspect of Physical Appearance
9. Sexual Orientation
10. Education or Income Level

Caregiver Activation Measure (CG-PAM)

Please indicate how much you agree or disagree with each statement as it applies to you personally as the caregiver/carer for _____. There are no right or wrong answers, just what is true for you as a caregiver/carer. If the statement does not apply to you, circle N/A

1.	I am responsible for seeing that this person's health is managed properly.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2.	Taking an active role in this person's healthcare is one of the most important factors in determining her/his health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3.	I am confident that I can take actions that will help prevent or minimize some symptoms or problems associated with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4.	I know what each of this person's prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5.	I am confident that I can tell when this person needs to get medical care and when I can handle the problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6.	I am confident I can tell a doctor or nurse the concerns that I have about this person's health even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7.	I am confident that I can carry out medical treatments I need to do for this person at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8.	I understand the nature and causes of this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9.	I know the different medical treatment options available for this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10.	I am able to help this person maintain lifestyle changes, like healthy eating or exercising, for her/his condition.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11.	I know how to prevent problems with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12.	I am confident I can work out solutions when new situations or problems arise with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13.	I am confident I can help this person with lifestyle changes, like healthy eating and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Caregiver Reaction Assessment

Circle the number corresponding to your answer

Questions:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I feel privileged to care for ___.	1	2	3	4	5
2. Others have dumped caring for ___ onto me.	1	2	3	4	5
3. My financial resources are adequate to pay for things that are required for caregiving.	1	2	3	4	5
4. My activities are centered around care for ___.	1	2	3	4	5
5. Since caring for ___, it seems like I'm tired all of the time.	1	2	3	4	5
6. It is very difficult to get help from my family in taking care of ___.	1	2	3	4	5
7. I resent having to take care of ___.	1	2	3	4	5
8. I have to stop in the middle of work.	1	2	3	4	5
9. I really want to care for ___.	1	2	3	4	5
10. My health has gotten worse since I've been caring for ___.	1	2	3	4	5
11. I visit family and friends less since I have been caring for ___.	1	2	3	4	5
12. I will never be able to do enough caregiving to repay ___.	1	2	3	4	5
13. My family works together at caring for ___.	1	2	3	4	5
14. I have eliminated things from my schedule since caring for ___.	1	2	3	4	5
15. I have enough physical strength to care for ___.	1	2	3	4	5
16. Since caring for ___, I feel my family has abandonec me.	1	2	3	4	5
17. Caring for ___ makes me feel good.	1	2	3	4	5
18. The constant interruptions make it difficult to find time for relaxation.	1	2	3	4	5
19. I am healthy enough to care for ___.	1	2	3	4	5

20. Caring for ___ is important to me.	1	2	3	4	5
21. Caring for ___ has put a financial strain on the family.	1	2	3	4	5
22. My family (brothers, sisters, children) left me alone to care for ___.	1	2	3	4	5
23. I enjoy caring for ___.	1	2	3	4	5
24. It's difficult to pay for ___'s health needs and services.	1	2	3	4	5

Pearlin Mastery Scale

1. There is really no way I can solve some of the problems that I have	Strongly Disagree	Disagree	Agree	Strongly Agree
2. Sometimes I feel that I'm being pushed around in life	Strongly Disagree	Disagree	Agree	Strongly Agree
3. I have little control over the things that happen to me	Strongly Disagree	Disagree	Agree	Strongly Agree
4. I can do just about anything I really set my mind to	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I often feel helpless in dealing with the problems of life	Strongly Disagree	Disagree	Agree	Strongly Agree
6. What happens to me in the future mostly depends on me	Strongly Disagree	Disagree	Agree	Strongly Agree
7. There is little I can do to change many of the important things in my life	Strongly Disagree	Disagree	Agree	Strongly Agree

CAREGIVER - 12-WEEK PARTICIPANT FEEDBACK

We are now interested to know about your satisfaction with different aspects of this intervention. There are no right or wrong answers. Your answers will be kept confidential and will not affect your participation in future research studies, or your access to care at MGH or affiliated sites. **As a reminder, you participated as a caregiver in a research study of an intervention that involved a psychiatrist (Dr. Irwin or Dr. Hirschberg) and a social work case manager (Amy Corveleyn) in the patient's cancer care team.**

1. From your perspective, how useful was the intervention **in the patient's cancer care?**

   Very useful Somewhat useful A little bit useful Not at all useful

2. How useful was the intervention **for you as a caregiver?**

   Very useful Somewhat useful A little bit useful Not at all useful

3. How useful were the following parts of the intervention?

Involving psychiatry early in the patient's cancer care	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with the psychiatrist **(Dr. Irwin/Dr. Hirschberg)** in person	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach the psychiatrist **(Dr. Irwin/Dr. Hirschberg)** by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach the case manager, Amy, by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Communicating with the patient's community mental health clinicians	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with the patient's cancer and psychiatry teams together	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Helping with barriers to the patient's care (e.g. rides to the hospital, insurance, housing)	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Addressing the patient's psychiatric symptoms and medications	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me

4. What do you think was the most useful part about the intervention **in the patient's cancer care**?

_____

_____

5. What do you think was the most useful part about the intervention **for you as a caregiver?**

_____

_____

6. What changes, if any, did you notice in your **relationship with the patient** because of the intervention?

_____

_____

7. What do you think could be **improved** about the intervention?

_____

_____

8. What else, if anything, would you like to add about the intervention that we did not discuss? _____

_____

_____

_____

Thank you for being a part of the Proactive Psychiatry Consultation for Patients with Cancer Study. Your feedback is valuable to us and we appreciate your responses.

Q. Clinician Administered Assessments

ASSESSMENT CHECKLIST

Date: _____
Study ID: _____ Timepoints: **Baseline, 6-week, 12-week**

	Clinician-Administered Measures	Date
1	BRIEF PSYCHIATRIC RATING SCALE (BPRS)	
2	CLINICAL GLOBAL IMPRESSION – SEVERITY (CGI-S)	
3	CLINICAL GLOBAL IMPRESSION – IMPROVEMENT (CGI-I)	
4	ASSESSMENT OF CAPACITY TO PARTICIPATE	

Baseline Assessments

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Please enter the score for the term that best describes the patient's condition

0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

Score	Condition
	1. SOMATIC CONCERN
	2. ANXIETY
	3. DEPRESSION
	4. SUICIDALITY
	5. GUILT
	6. HOSTILITY
	7. ELEVATED MOOD
	8. GRANDIOSITY
	9. SUSPICIOUSNESS

	10. HALLUCINATIONS
	11. UNUSUAL THOUGHT CONTENT
	12. BIZARRE BEHAVIOR
	13. SELF-NEGLECT
	14. DISORIENTATION
	15. CONCEPTUAL DISORGANIZATION
	16. BLUNTED AFFECT
	17. EMOTIONAL WITHDRAWAL
	18. MOTOR RETARDATION
	19. TENSION
	20. UNCOOPERATIVENESS

	21. EXCITEMENT
	22. DISTRACTABILITY
	23. MOTOR HYPERACTIVITY
	24. MANNERISMS AND POSTURING

CGI

SEVERITY OF ILLNESS

1. Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

- ☐ Not Assessed (0)
- ☐ Normal, not at all ill (1)
- ☐ Borderline mentally ill (2)
- ☐ Mildly ill (3)
- ☐ Moderately ill (4)
- ☐ Markedly ill (5)
- ☐ Severely ill (6)
- ☐ Among the most extremely ill patients (7)

6-week Interval Assessments

CGI

SEVERITY OF ILLNESS

1. Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

- ☐ Not Assessed (0)
- ☐ Normal, not at all ill (1)
- ☐ Borderline mentally ill (2)
- ☐ Mildly ill (3)
- ☐ Moderately ill (4)
- ☐ Markedly ill (5)
- ☐ Severely ill (6)
- ☐ Among the most extremely ill patients (7)

CGI
IMPROVEMENT OF ILLNESS

1. Compared to the patient's condition at admission to the project, this patient's condition is:

- ☐ Very much improved since the initiation of treatment (1)
- ☐ Much improved (2)
- ☐ Minimally improved (3)
- ☐ No change from baseline (the initiation of treatment) (4)
- ☐ Minimally worse (5)
- ☐ Much worse (6)
- ☐ Very much worse since the initiation of treatment (7)

12-week Post Intervention Assessments

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Please enter the score for the term that best describes the patient's condition

0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

Score	Condition
	1. SOMATIC CONCERN
	2. ANXIETY
	3. DEPRESSION
	4. SUICIDALITY
	5. GUILT
	6. HOSTILITY
	7. ELEVATED MOOD
	8. GRANDIOSITY
	9. SUSPICIOUSNESS

	10. HALLUCINATIONS
	11. UNUSUAL THOUGHT CONTENT
	12. BIZARRE BEHAVIOR
	13. SELF-NEGLECT
	14. DISORIENTATION
	15. CONCEPTUAL DISORGANIZATION
	16. BLUNTED AFFECT
	17. EMOTIONAL WITHDRAWAL
	18. MOTOR RETARDATION
	19. TENSION
	20. UNCOOPERATIVENESS

	21. EXCITEMENT
	22. DISTRACTABILITY
	23. MOTOR HYPERACTIVITY
	24. MANNERISMS AND POSTURING

CGI

SEVERITY OF ILLNESS

1. Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

- ☐ Not Assessed (0)
- ☐ Normal, not at all ill (1)
- ☐ Borderline mentally ill (2)
- ☐ Mildly ill (3)
- ☐ Moderately ill (4)
- ☐ Markedly ill (5)
- ☐ Severely ill (6)
- ☐ Among the most extremely ill patients (7)

CGI
IMPROVEMENT OF ILLNESS

1. Compared to the patient's condition at admission to the project, this patient's condition is:

- ☐ Very much improved since the initiation of treatment (1)
- ☐ Much improved (2)
- ☐ Minimally improved (3)
- ☐ No change from baseline (the initiation of treatment) (4)
- ☐ Minimally worse (5)
- ☐ Much worse (6)
- ☐ Very much worse since the initiation of treatment (7)

R. Oncology and Mental Health Clinician Email Consent

Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Dear [Clinician Name],

I am emailing about your patient [Patient Name], who recently completed participation in Dr. Kelly Irwin's open pilot study of proactive psychiatry consultation and case management for patients with serious mental illness. We would love your feedback on how useful the intervention has been for [Patient name] and for you, as a clinician.

> Can I schedule a 5-10 minute call at a time that is convenient for you? If preferred, you can complete the survey via email or in-person.

Your responses may be used for research purposes. All data will be kept confidential and accessible only to study staff. Responses will be aggregated and de-identified prior to publication.

Completion of the brief survey will count as your consent to participate in the study. Please feel free to contact the PI, Dr. Kelly Irwin, with any questions or concerns.

Thank you for your time,

[Study Staff]

S. Oncology Clinician Exit Survey

Proactive Psychiatry Consultation for Patients with Cancer Study
ONCOLOGY CLINICIANS

We are currently conducting a research study of an intervention involving proactive psychiatry consultation and a social work case manager for patients with serious mental illness and a recent cancer diagnosis. Your patient, XXXXXX XXXXX, participated in this intervention. We would like your feedback on the challenges and benefits of this intervention and how it can be most useful to you as an oncology clinician. You will not be compensated for participating in this study.

There are minimal risks involved with providing this feedback. However, it is possible that providing feedback may make you feel uncomfortable. The benefits of your participation are that researchers may better understand the challenges and benefits of this intervention for patients with serious mental illness and cancer. Your participation is voluntary and your responses will be kept confidential. We will not collect your name or other identifying information. You can withdraw from the study, stop the survey, or choose not to answer any questions. Neither your feedback nor your decision to participate will affect your employment or care at Massachusetts General Hospital. If you have questions about the study, you may contact Dr. Kelly Irwin at 617-643-4453 or kirwin1@partners.org.

Thank you very much for your time!

1. Please choose what best describes your job.

   ☐ Medical Oncologist
   ☐ Surgical Oncologist
   ☐ Radiation Oncologist
   ☐ Oncologist Nurse Practitioner

2. What year did you complete your professional training? _____

3. Gender: Please choose one answer.

   ☐ Male
   ☐ Female
   ☐ Other: please specify _____

4. Of the patients you currently care for, how many have **cancer** and **bipolar disorder**?

Approximate #: _____

5. Of the patients you currently care for, how many have **cancer** and **schizophrenia**?

   Approximate #: _____

6. Of the patients you currently care for, how many have **cancer** and **severe major depression (with prior psychiatric hospitalization or suicide attempt)**?

   Approximate #: _____

The following questions are specifically about your experience caring for your pt XXXX who participated in the intervention.

1. How useful was the intervention in the patient's cancer care?

   Very useful Somewhat useful A little bit useful Not at all useful

   What was most useful?

   _____

   _____

   What would you change to improve the intervention?

   _____

   _____

2. Did this patient receive the same regimen and intensity of cancer treatment as other patients who present with the same stage of disease?

   ☐ Yes
   ☐ No

   If not, how was the treatment different?

   _____

   _____

3. How much of the cancer treatment that you recommended at the time of cancer diagnosis did your patient receive?

   ☐ 100%
   ☐ Most
   ☐ Some
   ☐ A little bit

☐ None

4. Did this patient have a **delay** in starting cancer treatment?

☐ Yes
☐ No

5. Did this patient have a **deviation** from guideline-concordant treatment at the time of cancer diagnosis?

☐ Yes
☐ No

6. Did this patient have an **interruption** in cancer treatment received?

☐ Yes
☐ No

7. What impact did the intervention have on the cancer care for your patient?

Large positive impact	Small positive impact	No impact	Small negative impact	Large negative impact

7a) Did the intervention impact the **cancer treatment plan**?

☐ Yes
☐ No

If yes, how so?

_____

7b) Did the intervention impact your **relationship** with this patient?

☐ Yes
☐ No

If yes, how so?

_____

7c) Did the intervention impact your **communication** with the patient or caregiver?

☐ Yes
☐ No

If yes, how so?

_____

8. Did the intervention help you as the oncologist care for the patient?

☐ Yes
☐ No

If yes, how so?

_____

9. What else, if anything, would you like to add about the intervention that we have not discussed?

_____

_____

T. Mental Health Clinician Exit Survey

Proactive Psychiatry Consultation for Patients with Cancer Study
MENTAL HEALTH CLINICIANS

We are completing a research study of a care delivery model intervention for patients with serious mental illness and a recent cancer diagnosis which includes a psychiatry consultation and access to a social work case manager. Your patient, XXXXXX XXXXX, participated in this study. We would like your feedback on the challenges and benefits of this intervention, and ideas on how this intervention can be most useful to you. We estimate that participation will take 5-10 minutes. You will not be compensated for participating in this study.

There are minimal risks involved with providing feedback. However, it is possible that providing feedback may make you feel uncomfortable. The benefits of your participation are that researchers may better understand the challenges and benefits of psychiatry and social work interventions for patients with serious mental illness who have been recently diagnosed with cancer. Your participation is voluntary and your responses will be kept confidential. We will not collect your name or other identifying information about you. You can stop participating, choose not to answer any of the questions, or withdraw from the study at any time. Neither your feedback nor your decision to participate will affect your care or your patient's care at Massachusetts General Hospital. If you have questions about the study, you may contact Dr. Kelly Irwin at 617-643-4453 or kirwin1@partners.org.

Thank you very much for your time!

1. Please select what best describes your clinical discipline:

   - ☐ Licensed Mental Health Clinician
   - ☐ Social Work
   - ☐ Psychology
   - ☐ Psychiatry
   - ☐ Psychiatric Nurse Practitioner
   - ☐ Other: _____

2. What year did you complete your professional training? _____

3. Gender: Please choose one answer.

   - ☐ Male
   - ☐ Female

☐ Other: please specify _____

4. Where do you see patients clinically? Please check all that apply.

☐ A private office
☐ Community mental health clinic
☐ Academic hospital
☐ Other: _____

5. Of the patients you currently care for, how many have **cancer** and **bipolar disorder**?

Approximate # _____

6. Of the patients you currently care for, how many have **cancer** and **schizophrenia**?

Approximate # _____

7. Of the patients you currently care for, how many have **cancer** and **severe major depression** (with prior psychiatric hospitalization or suicide attempt)?

Approximate # _____

The following questions are specifically about your experience caring for your pt XXXX, who participated in the 12-week intervention which combined proactive psychiatry consultation and case management for patients with serious mental illness and cancer.

8. How useful was the intervention in the patient's cancer care?

Very useful Somewhat useful A little bit useful Not at all useful

What was most useful?

_____

_____

What would you change to improve the intervention?

_____

_____

9. How did the intervention impact the **coordination** of cancer and mental health care?

_____

_____

10. How did the intervention impact your **communication** with the oncology team?

_____

_____

11. What worked best to communicate with you? Please check all that apply.

- ☐ Phone
- ☐ Email
- ☐ Text

12. Have you seen XXXX since they completed the intervention?

- ☐ Yes
- ☐ No

If not, why?

_____

_____

13. What information, assistance or support would be helpful to you after your patient completes the intervention?

_____

_____

14. What else, if anything, would you like to add that we have not discussed?

_____

_____

_____

_____

Thank you for your participation in the study and for offering your feedback!

RANDOMIZED CONROLLED TRIAL

A. Clinician Fact Sheet

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

Proactive Psychiatry Consultation and Case Management for Patients with Serious Mental Illness and Cancer

WHY: Individuals with serious mental illness (SMI) die nearly 25 years younger than the general population and are significantly more likely to die from cancer.

- Diagnosed with more advanced stage cancer
- Less likely to receive recommended cancer treatment
- Collaborative care can improve cancer outcomes but hasn't been tested in patients with SMI

WHAT: Randomized controlled trial combining screening, proactive psychiatry consultation at cancer diagnosis, and case management at the MGH Cancer Center.

- Patient-centered care
- Collaborative care strengthening communication among providers
- Case manager linked to patient throughout cancer treatment

WHO: Patients with SMI and recent diagnosis of cancer.

- Diagnosis of psychotic disorder (schizophrenia, schizoaffective disorder), bipolar disorder, or major depressive disorder with prior psychiatric hospitalization
- Diagnosed with breast, lung, GI, or head and neck cancer that can potentially be treated with curative intent
- Within 8 weeks of initial oncology consultation at MGH
- Are ≥ 18 years of age
- Have verbal fluency in English

HOW: Enrollment

* **If you know of a patient who may be eligible for this study please contact:**
    - **Kelly Irwin, MD: kirwin1@partners.org, (617) 643-4453**
    - **Zoe Nelson: znelson@mgh.harvard.edu, (617) 726-2297**

* Dr. Irwin will meet with patients at their convenience to confirm eligibility, explain study procedures, and obtain consent.

Study Activities

* **If randomized to receive the intervention:**
    - Participants will complete a psychiatric assessment with Dr. Irwin focused on decreasing symptoms and identifying barriers to care. Participants will complete a brief questionnaire at enrollment, 6 weeks, 12 weeks, and 24 weeks.
    - Dr. Irwin will communicate recommendations to the participant's oncology team and SW and remain available for ongoing consultation.
    - A social work case manager will communicate directly with participants to promote self-management, coordinate care, bridge communication with providers and document in medical record.
* **If randomized to receive enhanced usual care**:
    - The treating oncologist will receive information about available mental health services at MGH
* **All study participants** can receive up to $50 for participation in the study.

Additional Questions

* If you have or encounter additional questions about this study, please contact Kelly Irwin and/or Zoe Nelson.

B. Patient Fact Sheet

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

HARVARD MEDICAL SCHOOL

Bridge: Early Psychiatry Consultation and Case Management Study for Patients with Cancer

Why participate in this study?

- We're conducting a study to understand if having a psychiatrist and case manager be part of your care team improves your cancer care.

Who can participate?

- Patients who have recently been diagnosed with cancer and are getting their care at the MGH Cancer Center and have a history of mental health concerns, including depression, bipolar disorder, and schizophrenia.

What does the study involve?

- You have an equal chance of either:
  1) Having a psychiatrist and case manager be part of your cancer care team
     OR
  2) Your oncologist being informed about available mental health supports
- You will be asked to complete 4 brief surveys over 24 weeks and be reimbursed $50.
- You may choose to identify a caregiver to participate in the study, but this is not required.
- Participation involves no additional cost.

Do I have to participate?

- Participation is completely voluntary and will not affect the care you receive at Massachusetts General Hospital or Department of Mental Health services.

What are the benefits of the study?

- Your oncologist will receive information about mental health supports.
- Your participation can help us learn how to provide better care for people with cancer and mental health concerns.

What are the risks of the study?

- This is a minimal risk study.
- You may experience distress when responding to certain survey questions. You do not have to answer any questions that you find upsetting, and you may stop participating in the study at any time.
- In every study, there is a risk for some loss of privacy regarding your health information. The study team will take measures to minimize this risk as much as possible.

Questions? Please contact Zoe Nelson at (617) 726-2297, znelson@mgh.harvard.edu, or Dr. Kelly Irwin at (617) 643-4453, kirwin1@partners.org

C. Patient Recruitment Letter

Date

Joan R, Patient
29 High Street
Boston MA

Dear Mr./Ms. Patient,

I am writing to tell you about a research study that is being conducted at the Massachusetts General Hospital (MGH) Cancer Center by Kelly Irwin, MD, MPH, and a team of MGH researchers and clinicians. You are receiving this letter because you have recently been diagnosed with lung, gastrointestinal, breast, or head and neck cancer and may receive cancer care at MGH. (Name of Dr/NP who gave permission to contact) believes you may be a good fit for this program and gave us permission to contact you.

The goal of this study is to understand if having a psychiatrist and case manager be part of your care team improves your cancer care.

If you join this research study, you have an equal chance of either:

- Your oncologist being told about available mental health supports
  OR
- Having a psychiatrist and case manager as part of your cancer care team.

It will take you about 3 months to complete this research study. You will be asked to complete a set of questionnaires with the help of a clinician at 3 points in time; at the first visit (30-45 minutes), at 6 weeks (10 minutes), 3 month follow-up (20 minutes), and 6 month follow-up (20 minutes). Questionnaires can be completed via email, phone, or in-person, whichever you prefer.

Please contact the principal investigator Dr. Kelly Irwin, at (617) 643-4453 if you would like to learn more about the study. Taking part in this research study is your choice and will not impact the care you receive at MGH. If you do not want to participate in the research study, please call us within one week at (617) 726-2297. If we do not hear from you, someone from the study team will call to see if you might want to hear more about the research study.

Attached is a fact sheet which will provide more information about the study. Thank you for thinking about being part of this research study.

Sincerely,

Oncologist/Cancer Clinic Tumor Site Study Liaison
Massachusetts General Hospital Cancer Center

Kelly Irwin, MD, MPH
(617) 643-4453

D. Caregiver Recruitment Letter

MASSACHUSETTS GENERAL HOSPITAL
CANCER CENTER

HARVARD MEDICAL SCHOOL

Date

Joan R, Caregiver
29 High Street
Boston MA

Dear Mr./Ms. Caregiver,

I am writing to tell you about a research study that is being conducted at the Massachusetts General Hospital (MGH) Cancer Center by Kelly Irwin, MD, MPH, and a team of MGH researchers and clinicians. You are receiving this letter because you have been identified as a caregiver for someone who has recently been diagnosed with lung, gastrointestinal, breast, or head and neck cancer and may receive cancer care or monitoring at MGH. (Name of Dr/NP who gave permission to contact) believes him/her may be a good candidate for this program and (patient name) gave us permission to contact you.

The goal of this study is to understand if having a psychiatrist and case manager be part of a patient's care team improves cancer care.

If you join this research study, you have an equal chance of either:

- (Patient name)'s oncologist being told about available mental health supports
  OR
- Having a psychiatrist and case manager as part of (patient name)'s cancer care team.

It will take you about 3 months to complete this research study. You will be asked to complete a set of questionnaires with the help of a clinician at 3 points in time; at the first visit (30-45 minutes), at 6 weeks (10 minutes), and 3 month follow-up (20 minutes). Questionnaires can be completed via email, phone, or in-person, whichever you prefer.

Please contact the principal investigator Dr. Kelly Irwin, at (617) 643-4453 if you would like to learn more about the study. Taking part in this research study is your choice and will not impact the care (patient name) receives at MGH. If you do not want to participate in the research study, please call us within one week at (617)726-2297. If we do not hear from you, someone from the study will be calling to see if you might want to hear more about the research study.

Attached is a fact sheet, which will provide more information about the study. Thank you for thinking about being part of this research study.

Sincerely,

Oncologist/Cancer Clinic Tumor Site Study Liaison
Massachusetts General Hospital Cancer Center

Kelly Irwin, MD, MPH
(617) 643-4453

E. Clinician Recruitment Email

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Dear Dr. _____,

Dr. Kelly Irwin is conducting a randomized controlled trial focused on patients with both cancer and serious mental illness (SMI) including schizophrenia, schizoaffective disorder, bipolar disorder, and major depressive disorder with prior hospitalization. The goal of the study is to pilot a randomized controlled trial to assess the acceptability and feasibility of an innovative model of care that incorporates proactive psychiatry consultation, collaborative care strengthening communication among providers, and engagement of a case manager at cancer diagnosis to optimize cancer care for patients with SMI. We are recruiting patients with SMI and a recent diagnosis of breast, lung, GI, or head and neck cancer (within 8 weeks of initial oncology consultation at the MGH Cancer Center). If you know of a patient who may be eligible for this study, please contact Dr. Irwin (kirwin1@partners.org, 617-643-4453) or Zoe Nelson (znelson@mgh.harvard.edu, 617-726-2297). Dr. Irwin will meet with patients at their convenience to confirm eligibility, explain study procedures, and obtain consent. If you have any additional questions about this study, please contact Dr. Irwin and/or Zoe Nelson.

Thank you,

F. Clinician Approval to Approach Email

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer
PI: Kelly E. Irwin, MD, MPH

Hello,

I am a research coordinator working with Dr. Kelly Irwin on a randomized controlled trial to investigate the effectiveness of proactive psychiatry consultation and case management for patients with serious mental illness and a recent cancer diagnosis.

Your patient(s) **[name] [MRN]** is (are) potentially eligible for the study and I would like to approach him/her/them during his/her/their next appointment or call him/her/them on the phone to discuss the study. Please let me know at your earliest convenience if I have your permission to approach this patient. If I do not hear from you, I will request your permission in person to approach this patient.

Study participation does not preclude you or the rest of the patient's care team for consulting psychiatry per your clinical judgment.

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

Thank you,
Zoe Nelson

G. Clinician Email (Sent at Patient Consent)

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer
PI: Kelly E. Irwin, MD, MPH

Dear Dr. _____,

Your patient XXXXX XXXXX has consented to Dr. Kelly Irwin's randomized controlled trial: BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer. XXXXX XXXXX has _____ (psychiatric diagnosis). This trial does not preclude you from referring XXXX XXXX to available mental health services. To consult psychiatric oncology, you can place a consult through EPIC or call 617-643-6833.

Thank you,

H. Response to Direct Referral to Principal Investigator

Dear Dr. _____,

Thank you for your referral. Dr. Irwin will only be able to see patients who are assigned to the intervention arm of the study. Please direct your referral to psychiatric oncology. To refer, please place a consult through EPIC or call 617-647-6833.

Thank you,

I. Telephone Script (Recruitment)

Proactive Psychiatry Consultation Telephone Script

Hi is this (patient name)? My name is _____ and I'm calling from Massachusetts General Hospital Cancer Center. I am calling about a letter that you may have received in the mail about a proactive psychiatry consultation program that you may be eligible for. Did you receive this letter?

NOT RECEIVED: I am happy to give you a brief overview if you have a couple of minutes. Would that be ok?

> YES: Great. This program tests a new model of collaborative care that includes meeting with a psychiatrist and a social worker, known as our case manager, for patients at the MGH Cancer Center. We want to understand whether this model of care helps patients get the best possible cancer care. As part of the study, you have an equal chance of your oncologist being informed about mental health supports, or being connected to a

psychiatrist and a case manager who will be a part of your cancer care team. The psychiatrist and case manager will follow you for 3 months. We will ask you to complete a brief questionnaire at 3 different times during the study which will be coordinated with other appointments whenever possible, and can be completed via phone, email, or in-person. Your participation is completely voluntary and will not impact the care you receive at MGH.

NO: Is there a better time for me to call you back?

YES RECEIVED: That's great to hear! Did you have a chance to look over it and think about if you might be interested in participating?

YES: Wonderful! Do you have any questions about the program?

NO: I am happy to give you a brief overview if you have a couple of minutes. Would that be ok?

YES: Great. This program tests a new model of collaborative care that includes proactive psychiatry consultation and a social work case manager for patients at the MGH Cancer Center. We want to understand whether this model of care helps patients in navigating cancer care. As part of the study, you have an equal chance of your oncologist being informed about mental health supports, or being connected to a psychiatrist and a case manager who will be a part of your cancer care team. It will take you about 3 months to complete the study, and we will ask you to complete a brief questionnaire at 3 different points of the study, and can be completed via email, phone, or in-person. Of course, participation is completely voluntary and will not impact the care you receive at MGH.

NO: Is there a better time for me to call you back?

PATIENT WANTS TO ENROLL: Great. The next step is to arrange a time for you to meet with the psychiatrist or case manager and learn more about the study. We will try to coordinate the meeting with an upcoming oncology appointment. The total visit should take about one hour to complete. (If they have an upcoming appointment): I noticed you have an appointment on _____ (specific day), are you able to have the study appointment at that time? If not, when are you able to come in for this visit?

PATIENT INELIGIBLE/WANTS TO ENROLL: Unfortunately, you're not eligible to participate in this study but we are happy to refer you to the oncology social worker.

PATIENT WANTS TO THINK ABOUT IT: Sure, I understand. Can I give you a call in the next week to see what you are thinking and answer any questions?

PATIENT REFUSES: No problem. You do not have to answer this question, but, if you are willing, may I ask why? Your response to this question will not affect your care in any way.

VOICEMAIL: Hello this message is for (patient name). Hi (patient name), my name is ____, and I'm calling from the MGH Cancer Center about a letter that you should have received in the mail about a program that you may be eligible for. Please give a call back at _____ and let me know a good time to contact you.

J. Patient Verbal Consent

Bridge: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Principal Investigator: Kelly Irwin, MD, MPH
Contact information: Call 617-643-4453

Purpose of the Research

It is challenging to cope with cancer. We are conducting a study to understand if having a psychiatrist and case manager as part of your cancer care team at the time of cancer diagnosis might improve your cancer care. Many people with illnesses like major depression, schizophrenia and bipolar disorder face barriers to receiving high quality cancer care. It can be difficult to get to appointments, have many different doctors, and experience depression or worry. Better communication between the patient, the oncology team, and mental health providers may improve care. As for all patients, it is important for people with mental illness to have access to high quality cancer treatment that is patient-centered and coordinated. Having a case manager and psychiatrist at the cancer center may help patients to receive the cancer care that they need.

Study Information

We are asking you to participate in this study because we think you may benefit from this intervention. This is a randomized research study, which means that study participants are assigned to a study group based on chance alone, like flipping a coin. If you choose to participate in this study, you will have an equal chance of being assigned to two options, either: One, you and your oncologist will be informed about mental health supports, or: Two, a psychiatrist and case manager will be a part of your cancer care team. If you are assigned to be connected to a psychiatrist and case manager, they will be available to you and communicate with your oncology team throughout your treatment. A case manager will help identify your needs, find resources, and communicate with the people who support you.

The study team will tell you which option you will receive *after* you agree to participate in the study. **All study participants** (regardless of which study option they are assigned) will complete a set of questionnaires (about 30-45 minutes) and have a study clinician review their mental health history and communicate it to their oncologist. At 6 weeks, we will ask all study participants to complete a second set of questionnaires (about 10 minutes), at 12 weeks, a third set of questionnaires (about 20 minutes), and a fourth set at the 24 week time point (about 10 minutes) with study staff.

These questionnaires can be completed over the phone, by email, or in-person, whichever is least burdensome. With your permission, we will audio record parts of these assessments and certain study team visits during study participation. These recordings will be used for data analysis purposes only. If you do not want to be recorded, you may still participate. We will also ask you to identify a caregiver who is part of your cancer care. This can be a family member, friend, or community-based staff member who comes to visits with you or talks with your doctors. If you choose to include a caregiver in the study, the caregiver will be informed of your mental health and cancer diagnosis with your permission. Choosing not to identify a caregiver will not prevent you from participating in this study.

Following the completion of this study, you may also be asked to participate in a 30-minute audio-recorded interview. You are free to decline. If you do participate, the hope is to better understand your experience with our study and how we might increase access to mental health and oncology care in other healthcare settings. If you are asked to participate in a 30-minute interview following the completion of the intervention, you will also be offered $30 in the form of cash or check to thank you for your time.

A description of this clinical trial will be available on http:www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Potential Risks and Discomforts

This study does not have any physical risks. You will not be injured or become physically sick because of participating in this study. Some of the items on the questionnaire may be upsetting. If any of the questions upset you, you can talk to your doctor or members of the study team**.** The research assistant and study clinician will be available to you throughout your participation in the study. You can also meet with our case manager or the principal investigator, a licensed psychiatrist, for additional support who can refer you to additional services as needed. If your responses indicate that you are in severe distress, a study clinician will call you to follow-up and assess your safety. At that point, you may be offered a referral to appropriate services, which you may accept or decline. Your healthcare team may be notified of this referral.

Your responses to the questionnaires will be written down on paper or completed online. Your responses will not become part of your medical record, and they will not be seen by your care providers. We will also look at relevant parts of your MGH medical record, and store relevant data from your medical history. We may request authorization to receive medical records and to share information/communicate with current providers for those who are not part of the MGH system. That data will be used only by study staff and will be protected by a password. Your identity will be kept confidential and we will be extremely careful to protect your privacy. If you receive the intervention, our psychiatrist and case manager will document their contacts with you in the medical record and share relevant recommendations with your oncology team. Taking part in this research study will not lead to added costs to you or your insurance company beyond usual care.

Benefits

All study participants will have access to an oncologist that is informed of available mental health supports at the cancer center. Additionally, participants who receive the intervention are linked to a psychiatrist and case manager as part of their cancer care team during cancer treatment. We will give you $20 after completing the first set of questionnaires, $10 after completing the third set of questionnaires, and $20 after completing the third set of questionnaires in the form of cash or check, to thank you for your time.

Confidentiality

There is little risk involved with study participation. We will be extremely careful to protect your privacy and health information by locking survey material and audio recorders in file cabinets and storing data and audio recordings on password protected computers. Only our study team can access this information. Your responses will be kept confidential. You can stop participating in the study at any time. If the results of this research study are published in a medical journal, they will not identify individual patients. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. For example, if we are concerned about your safety or the safety of others, we may need to discuss this information with your medical team. A Certificate of Confidentiality from the Department of Health and Human Services has been issued on this study as an additional protection of your privacy. Despite the study team's precautions, you and your family must also actively protect your own privacy.

Participation

Please note that participation in this study is completely voluntary and will not affect your medical care at the Massachusetts General Hospital or your access to Department of Mental Health services. You can stop participating in the research study at any time, and you can still get your medical care from your hospital or Investigator. We appreciate your time and consideration.

Contact Information

If you have questions about the study, please contact:

Research assistant: Zoe Nelson (617-726-2297), M-F 9am-5pm.
Principal investigator (licensed psychiatrist): Dr. Kelly Irwin (617-643-4453)

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

K. Caregiver Verbal Consent

Bridge: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Principal Investigator: Kelly Irwin, MD, MPH
Contact information: Call 617-643-4453

Purpose of the Research

It is challenging to cope with cancer. We are conducting a study to understand if having a psychiatrist and case manager as part of the cancer care team at the time of cancer diagnosis might improve patients' cancer care. Many people with illnesses like major depression, schizophrenia and bipolar disorder face barriers to receiving high quality cancer care. It can be difficult to get to appointments, have many different doctors, and experience depression or worry. Better communication between the patient, caregivers, the oncology team, and mental health providers may improve care. As for all patients, it is important for people with mental illness to have access to high

quality cancer treatment that is patient-centered and coordinated. We want to understand if is helpful for patients with mental illness to be connected to a case manager and psychiatrist at the cancer center.

Study Information

We are asking you to participate in this study because you are a caregiver for an individual who may benefit from this intervention. This is a randomized research study, which means that study participants are assigned to a study group based on chance alone, like flipping a coin. If the patient agrees to participate in this study, he or she has an equal chance of receiving to two options, either: One, his/her oncologist will be informed about mental health supports, or: Two, a psychiatrist and case manager will be a part of his/her cancer care team. If the patient is assigned to be connected to a psychiatrist and case manager, they will be available to him/her and you as a caregiver and communicate with the oncology team throughout cancer treatment. A case manager will help identify the patient's needs, find resources, and communicate with the people who support him/her, such as yourself.

The study team will tell you which option the patient will receive *after* he or she agrees to participate in the study. **All study participants** (both patients and caregivers), will complete a brief set of questionnaires by phone, email, or in-person, whichever is least burdensome, which will take about 30-45 minutes. In 6 weeks, we will ask you to complete a second set of questionnaires, which will take about 10 minutes. In three months, we will ask you to complete a third set of questionnaires with study staff, which will take about 20 minutes. These questionnaires can be completed over the phone, by email, or in-person, whichever is least burdensome. With your permission, we will audio record certain study team visits during study participation accessed only by study staff and used only for the study. If you do not want to be recorded, you may still participate.

Following the completion of this study, you may also be asked to participate in a 30-minute audio-recorded interview. You are free to decline. If you do participate, the hope is to better understand your experience with our study and how we might increase access to mental health and oncology care in other healthcare settings. If you are asked to participate in a 30-minute interview following the completion of the intervention, you will also be offered $30 in the form of cash or check to thank you for your time.

A description of this clinical trial will be available on http:www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Potential Risks and Discomforts

This study does not have any physical risks. You will not be injured or become physically sick because of participating in this study. Some of the items on the questionnaire may be upsetting. If any of the questions upset you, you can talk to members of the study team. The research assistant and study clinician will be available to you, and you can also meet with our case manager or the principal investigator, a licensed psychiatrist, for additional support who can refer you to additional services as needed. If your responses indicate that you are in severe distress, a study clinician will call you to follow-up and assess your safety. At that point, you may be offered a referral to appropriate services, which you may accept or decline. The patient's healthcare team may be notified of this referral. If a study clinician is not able to reach you, they may reach out to your emergency contact or a member of the patient's healthcare team.

Your responses to the questionnaires will be written down on paper or completed online. Your identity will be kept confidential and we will be extremely careful to protect your privacy. That data will be used only by study staff and will be protected by a password.

Benefits

We hope that participation will help us to understand the needs of caregivers for patients with cancer and mental illness and help us to support patients coping with these challenges and the network of people who support them. We will give you $25 after completing the first set of questionnaires and another $25 after completing the third set of questionnaires in the form of cash or check, to thank you for your time.

Confidentiality

There is little risk involved with study participation. We will be extremely careful to protect your privacy by locking survey material and audio recorders in file cabinets and storing data and recordings on password protected computers. Only our study team can access this information. Your responses will be kept confidential. If the results of this research study are published in a medical journal, they will not identify individuals. A Certificate of Confidentiality from the Department of Health and Human Services has been issued on this study as an additional protection of your privacy. Despite the study team's precautions, you and your family must also actively protect your own privacy.

Participation

Please note that participation in this study is completely voluntary. You can stop participating in the research study at any time, and leaving the research study will not affect the patient's medical care at Massachusetts General Hospital or the patient's access to Department of Mental Health services. You can still get your medical care from your hospital or Investigator. We appreciate your time and consideration.

Contact Information

If you have questions about the study, please contact:

Research assistant: Zoe Nelson (617-726-2297), M-F 9am-5pm.
Principal investigator (licensed psychiatrist): Dr. Kelly Irwin (617-643-4453)

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

L. **Participant Written Consent for Recordings**

Research Consent Form
Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 6.17.2019

Bridge: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Principal Investigator: Kelly Irwin, MD, MPH

Participant Written Consent for Recordings

INTRODUCTION AND KEY INFORMATION

With your permission, we will audio record parts of the study assessments and certain study team visits during study participation using hand-held audio recorders. These assessments may include clinical interviews, joint visits with your oncology team, and exit interviews. We will never record in public spaces, and the audio recorders will be locked in file cabinets. The recordings will be used for data analysis purposes only and will be stored on password protected Partners computers in a secure study team folder. The recordings will be labeled with a unique study ID number which will be assigned to you at the time of enrollment, and which only the study team will have access to. Your responses will be kept confidential. Identifiers such as name will only be used during the initial data retrieval process and can be destroyed once all data records have been obtained and data analysis completed.

If you do not want to be recorded, you may still participate in the study and your care will not be impacted. At the time of each assessment, we will verbally confirm your permission to record the interview before we begin. The recording of assessments is voluntary. It is your choice whether you allow your assessments and visits to be recorded or not. If you decide to allow the study team to record your assessments and visits, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

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Date Posted for Use:	TBD		

A. WHAT WILL HAPPEN IF I DECIDE I DO NOT WANT TO BE RECORDED ANYMORE DURING STUDY VISITS OR ASSESSMENTS?

You can choose to decline audio recordings in the research study at any time. Tell the research staff if you decide you no longer wish to be recorded. Declining the use of recorders will not affect your participation in the study or your medical care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

B. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,

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- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): National Cancer Institute
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

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Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. **For how long will protected health information about me be used or shared with others?**

   - There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. **Statement of privacy rights:**

   - You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"
   - You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

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C. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about allowing audio recordings in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to have my assessments and visits audio-recorded;
- I have been told that being recorded is optional and I can ask to not be recorded at any time

Signature of Participant
or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

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To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

☐ A copy of this signed consent form will be given to the participant or legally authorized representative.

☐ 1) The participant is an adult and provided consent to participate.

☐ 1a) Participant is physically unable to sign the consent form because:

☐ The participant is illiterate.

☐ The participant has a physical disability.

☐ Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ 2a) gave permission for the adult participant to participate

☐ 2b) did not give permission for the adult participant to participate

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M. Assessment of Capacity to Participate in Clinical Research

Proposed questions to assess capacity to participate in clinical research:

1) Do you want to participate in this research study?
2) What is the study about?
3) What benefits do you get from participating in this study?
4) Why do you want to participate?

In his/her answers to the above questions, the research subject has indicated that

- ❑ **He/she *communicates the choice* to participate in the proposed research study.**
  Participation is his/her choice. The participation is voluntary.

- ❑ **He/she has a *factual understanding* of the research study.**
  Aims Institutional affiliations of the researcher

  Methods Anticipated benefits

  Possible conflicts of interest Potential risks or discomfort it may entail

- ❑ **He/she has an *appreciation* of the significance of the facts about research participation.**
  This is a research study, not treatment. There might be no immediate benefit.

- ❑ **He/she is able to *reason* about research participation.**
  Cognitive limitations considered. Limitations due to psychosis considered.

  Limitations due to affective state considered.

SUMMARY STATEMENT

- ❑ **Informed consent obtained.**
- ❑ **Subject has capacity to provide informed consent to participate in research despite the following (potentially limiting) factors:**

_____

_____

_____

I, the undersigned representative of the Investigator and staff member of the research project attest that the afore signed individual showed understanding of the research project and what is involved in participating as evidenced by replies to queries on each section as the informed consent was explained. Further I attest that the individual agreed to participate voluntarily

_____ _____

Signature **Date**

N. Patient Baseline Questionnaire

PATIENT ASSESSMENT CHECKLIST

Date: _____

Study ID: _____ Time point: **Baseline**

	Patient-Reported Measures	Date
1	BACKGROUND INFORMATION	
2	PSYCH RESOURCE UTILIZATION QUESTIONNAIRE	
3	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
4	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
5	UCLA 3-ITEM LONELINESS SCALE	
6	PATIENT ACTIVATION MEASURE (PAM 10)	
7	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	
8	DISCRIMINATION IS MEDICAL SETTINGS SCALE (DMS)	
10	HEALTH LEADS SOCIAL NEED SCREENING TOOLKIT	
11	PARTICIPANT LOCATOR FORM	

Demographics

1. Gender: _____

Please check the appropriate box or boxes.

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

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

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

5. Current relationship status
   - ☐ Married or living with someone as if married
   - ☐ Non-cohabiting relationship
   - ☐ Single, never married
   - ☐ Divorced/Separated
   - ☐ Loss of long term partner/ Widowed

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

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

8. Do you currently have stable housing that you own, rent, or stay in as part of a household?
   - ☐ Yes
   - ☐ No

9. Please indicate who you live with (you may check more than one box)
   - ☐ By myself
   - ☐ Partner/Spouse
   - ☐ Roommate/Friend
   - ☐ Children under 18
   - ☐ Children over 18
   - ☐ Group home/assisted living/nursing home
   - ☐ Parent
   - ☐ Other (please specify) _____

10. Have you ever lacked stable housing in the past (not known where you would be sleeping night to night)?

- ☐ Yes
- ☐ No

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

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

12. Aside from mental health professionals, is there a medical health professional you see most often (a primary care provider)?

- ☐ Yes
- ☐ No

13. If yes, who is your primary care provider?

_____

14. When was your last visit to your primary care provider?

_____

Resource Utilization Questionnaire

1. Are you currently receiving any of the following mental health services at MGH? Please check all that apply:
   - ☐ No services at this time
   - ☐ Support Group
   - ☐ Social Worker
   - ☐ Psychologist
   - ☐ Psychiatrist
   - ☐ Other:_____

2. Are you currently receiving any of the following mental health services outside of MGH? Please check all that apply:
   - ☐ No services at this time
   - ☐ Support Group
   - ☐ Social Worker
   - ☐ Psychologist
   - ☐ Psychiatrist
   - ☐ Case manager
   - ☐ Day program
   - ☐ Visiting nurse (VNA)
   - ☐ Department of Mental Health (DMH) Services
   - ☐ Other:_____

3. Have you ever been hospitalized for mental illness (such as depression, anxiety, bipolar disorder, or schizophrenia)?
   - ☐ Yes
   - ☐ No

   3a. If yes, please list the number of hospitalizations:

   3b. Briefly, what was the reason for the hospitalization(s)?_____

3c. When was your last hospitalization? _____

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

UCLA 3-ITEM LONELINESS SCALE

INSTRUCTIONS: Please read each item below and circle one number in each row to indicate how often each statement is descriptive of you.

1 indicates “I hardly ever feel this way”
2 indicates “I sometimes feel this way”
3 indicates “I often feel this way”

	Hardly ever	**Some of the time**	**Often**
1. How often do you feel that you lack companionship?	1	2	3
2. How often to you feel left out?	1	2	3
3. How often do you feel isolated from others?	1	2	3

Patient Activation Measure (PAM 10)

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say.

If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of my prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I may need to do at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new problems arise with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

MDASI

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
1. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
2. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
3. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
4. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
5. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
6. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
7. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
8. Your problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
9. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
10. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
11. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
12. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
13. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items **in the last 24 hours**? Please select a number from 0 (symptoms have not interfered) to 10 (symptoms interfered completely) for each item.

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	**Interfered Completely** 10
14. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
15. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
16. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
17. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
18. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
19. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

Discrimination in Medical Settings Scale

In your prior experiences receiving health care, how often did the following experiences happen to you?

		Never	Rarely	Sometimes	Most of the time	Always
1	You are treated with less courtesy than other people.	1	2	3	4	5
2	You are treated with less respect than other people.	1	2	3	4	5
3	You receive poorer service than others.	1	2	3	4	5
4	A doctor or nurse acts as if he or she thinks you are not smart.	1	2	3	4	5
5	A doctor or nurse acts as if he or she is afraid of you.	1	2	3	4	5
6	A doctor or nurse acts as if he or she is better than you.	1	2	3	4	5
7	You feel like a doctor or nurse is not listening to what you were saying.	1	2	3	4	5

Follow-up Question (complete this section only if you answered "Sometimes" or more frequently to at least one question.): What do you think is the main reason for these experiences? (YOU MAY CHECK MORE THAN ONE).

RECOMMENDED OPTIONS
1. Your Ancestry or National Origins
2. Your Gender
3. Your Race
4. Your Age
5. Your Mental Illness
6. Your Religion
7. Your Weight
8. Some other Aspect of Your Physical Appearance
9. Your Sexual Orientation
10. Your Education or Income Level

Health Leads Social Need Screening Toolkit

Preferred Language:_____ Best time to call:_____

	Yes	No
1. In the last 12 months, did you ever **eat less than you felt you should** because there wasn't enough money or food?		
2. In the last 12 months, has your **utility company shut off your service** for not paying your bills?		
3. Are you worried that in the next 2 months, you **may not have stable housing?**		
4. Do problems getting **child care make it difficult for you to work** or study? (*leave blank if you do not have children*)		
5. In the last 12 months, have you needed to see a doctor, **but could not because of cost?**		
6. In the last 12 months, have you ever had to go without health care because you didn't have **a way to get there?**		
7. Do you ever need help **reading hospital materials?**		
8. Are you **afraid you might be hurt** in your apartment building or house?		
9. If you checked YES to any boxes above, **would you like to receive assistance** with any of these needs?		
10. **Are any of your needs urgent?** For example: I don't have food tonight, I don't have a place to sleep tonight		

PARTICIPANT LOCATOR FORM

Participant name: _____

Home address: _____
(Street) (Apt.)

_____
(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email: (will only be used if necessary): _____

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 phone: _____

Alternate phone: _____

O. Patient 6-Week Questionnaire

PATIENT ASSESSMENT CHECKLIST

Date: _____
Study ID: _____ Time point: **6 Weeks**

	Patient-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	PATIENT ACTIVATION MEASURE (PAM 10)	
4	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	

Caregiver Change

Do you have a different primary caregiver than you had when you completed the last survey?

- ☐ Yes
- ☐ No

If no, please skip to the next page.

If yes, please explain why: _____

When did this change occur? _____

Who is your new caregiver? _____

Please indicate your relationship with the new caregiver:

- ☐ Married or living as if married
- ☐ Non-cohabitating relationship
- ☐ Divorced/Separate
- ☐ Friend
- ☐ Family Member
    - ☐ Parent (mother or father)
    - ☐ Child (daughter or son)
    - ☐ Sibling (brother or sister)
    - ☐ Other relative
- ☐ The caregiver is a community mental health worker
- ☐ Other: _____

Do you live with the caregiver?

- ☐ Yes
- ☐ No

Caregiver contact information:

Home address: _____
(Street) (Apt.)

_____
(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email (will only be used if necessary): _____

Time Spent with Caregiver

We understand that time spent with your caregiver may change over time. Think about the past two weeks. Please estimate the number of hours per week (on average) that your caregiver provided direct care (in-person or virtual) to you:

- ☐ Less than 1 hour per week
- ☐ 1-2 hours per week
- ☐ 2-5 hours per week
- ☐ 5-10 hours per week
- ☐ 10-15 hours per week
- ☐ Over 15 hours per week

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Patient Activation Measure (PAM 10)

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say.

If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of my prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I may need to do at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new problems arise with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

MDASI

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
1. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
2. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
3. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
4. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
5. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
6. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
7. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
8. Your problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
9. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
10. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
11. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
12. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
13. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items **in the last 24 hours**? Please select a number from 0 (symptoms have not interfered) to 10 (symptoms interfered completely) for each item.

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	**Interfered Completely** 10
14. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
15. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
16. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
17. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
18. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
19. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

P. Patient 12 Week Questionnaire

PATIENT ASSESSMENT CHECKLIST

Date: _____
Study ID: _____ Time point: **12 Weeks**

	Patient-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	UCLA 3-ITEM LONELINESS SCALE	
4	PATIENT ACTIVATION MEASURE (PAM 10)	
5	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	
6	FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TREATMENT SATISFACTION-PATIENT SATISFACTION (FACIT-TS-PS)	
7	TRUST IN PHYSICIAN SCALE (TPS)	
8	PSYCH RESOURCE UTILIZATION QUESTIONNAIRE	

Caregiver Change

Do you have a different primary caregiver than you had when you completed the last survey?

- ☐ Yes
- ☐ No

If no, please skip to the next page.

If yes, please explain why: _____

When did this change occur? _____

Who is your new caregiver? _____

Please indicate your relationship with the new caregiver:

- ☐ Married or living as if married
- ☐ Non-cohabitating relationship
- ☐ Divorced/Separate
- ☐ Friend
- ☐ Family Member
    - ☐ Parent (mother or father)
    - ☐ Child (daughter or son)
    - ☐ Sibling (brother or sister)
    - ☐ Other relative
- ☐ The caregiver is a community mental health worker
- ☐ Other: _____

Do you live with the caregiver?

- ☐ Yes
- ☐ No

Caregiver contact information:

Home address: _____
(Street) (Apt.)

_____
(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email (will only be used if necessary): _____

Time Spent with Caregiver

We understand that time spent with your caregiver may change over time. Think about the past two weeks. Please estimate the number of hours per week (on average) that your caregiver provided direct care (in-person or virtual) to you:

- ☐ Less than 1 hour per week
- ☐ 1-2 hours per week
- ☐ 2-5 hours per week
- ☐ 5-10 hours per week
- ☐ 10-15 hours per week
- ☐ Over 15 hours per week

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

UCLA 3-ITEM LONELINESS SCALE

INSTRUCTIONS: Please read each item below and circle one number in each row to indicate how often each statement is descriptive of you.

1 indicates “I hardly ever feel this way”
2 indicates “I sometimes feel this way”
3 indicates “I often feel this way”

	Hardly ever	**Some of the time**	**Often**
1. How often do you feel that you lack companionship?	1	2	3
2. How often do you feel left out?	1	2	3
3. How often do you feel isolated from others?	1	2	3

Patient Activation Measure (PAM 10)

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say.

If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of my prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I may need to do at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new problems arise with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

MDASI

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
1. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
2. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
3. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
4. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
5. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
6. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
7. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
8. Your problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
9. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
10. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
11. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
12. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
13. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items **in the last 24 hours**? Please select a number from 0 (symptoms have not interfered) to 10 (symptoms interfered completely) for each item.

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	**Interfered Completely** 10
14. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
15. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
16. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
17. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
18. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
19. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

FACIT-TS-PS (Version 4)

These questions are about the quality of the cancer care services you are currently receiving. All of your responses will be kept confidential. Please mark one answer for each of the following questions.

Please list the name of your oncologist(s): _____

	Physician Communication	No, not at all	Yes, but not as much as I wanted	Yes, almost as much as I wanted	Yes, and as much as I wanted
TS9	Did your doctor(s) give explanations that you could understand?	0	1	2	3
TS10	Did your doctor(s) explain the possible benefits of your treatment?	0	1	2	3
TS11	Did your doctor(s) explain the possible side effects or risks of your treatment?	0	1	2	3
TS12	Did you have an opportunity to ask questions?	0	1	2	3
TS13	Did you get to say the things that were important to you?	0	1	2	3
TS14	Did your doctor(s) seem to understand what was important to you?	0	1	2	3
TS15	Did your doctor(s) show genuine concern for you?	0	1	2	3
TS16	Did your doctor(s) seem to understand your needs?	0	1	2	3
TS18	Were you able to talk to your doctor(s) when you needed to?	0	1	2	3

TS27	Were you encouraged to participate in decisions about your health care?	0	1	2	3
TS28	Did you have enough time to make decisions about your health care?	0	1	2	3
TS30	Did your doctor(s) seem to respect your opinions?	0	1	2	3

	Confidence and Trust	**No, not at all**	**Yes, but not as much as I wanted**	**Yes, almost as much as I wanted**	**Yes, and as much as I wanted**
TS34	Did you feel that the treatment staff answered your questions honestly?	0	1	2	3
TS35	Did the treatment staff respect your privacy?	0	1	2	3
TS36	Did you have confidence in your doctor(s)?	0	1	2	3
TS37	Did you trust your doctor(s)' suggestions for treatment?	0	1	2	3

	Overall	**No**	**Maybe**	**Yes**
TS38	Would you recommend this clinic or office to others?	0	1	2
TS39	Would you choose this clinic or office again?	0	1	2

Poor	**Fair**	**Good**	**Very Good**	**Excellent**

TS40	How do you rate the care you received?	0	1	2	3	4

Thank you! Do you have any comments?

_____

_____

_____

_____

_____

_____

_____

_____

Trust in Physician Scale (TPS)

Below are some statements referring to your cancer care doctors. Please rate how much you agree or disagree with each statement. Response choices vary from “strongly disagree” to “strongly agree”.

1. I doubt that my doctor really cares about me as a person	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. My doctor is usually considerate of my needs and puts them first	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I trust my doctor so much that I always try to follow his/her advice	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. If my doctor tells me something is so, then it must be true	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I sometimes distrust my doctor’s opinion and would like a second one	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I trust my doctor’s judgment about my medical care	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I feel my doctor does not do everything he/she should for my medical care	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I trust my doctor to put my medical needs above all other considerations when treating my medical problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. My doctor is a real expert in taking care of medical problems like mine	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I trust my doctor to tell me if a mistake was made about my treatment	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I sometimes worry that my doctor may not keep the information we discuss totally private	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Resource Utilization Questionnaire

Please answer the following questions if you have a psychiatrist, social worker, case manager, or therapist that you saw ***before*** your diagnosis of cancer.

1. How many times have you seen your psychiatrist since you learned of your cancer diagnosis?
   - ❑ I did not have a psychiatrist before my cancer diagnosis
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

2. How many times have you seen or talked with your therapist or social worker since you learned of your cancer diagnosis?
   - ❑ I did not have a therapist or social worker before my cancer diagnosis
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

3. Have you been hospitalized for mental illness (such as depression, anxiety, bipolar disorder, or schizophrenia) since you learned of your cancer diagnosis?

   - ❑ Yes
   - ❑ No

   3a. If yes, please list the number of hospitalizations: _____

   3b. Briefly, what was the reason for the hospitalization(s)?

   _____

   3c. When was your last hospitalization? _____

Q. Patient 12-week Exit Survey (Bridge arm only)

PATIENT -12-WEEK PARTICIPANT FEEDBACK

We are now interested to know about your satisfaction with different aspects of this intervention. There is no right or wrong answer. Your answers will be kept confidential and will not affect your participation in future research studies, or your access to care at MGH or affiliated sites. **As a reminder, you participated in a research study of an intervention that involved a psychiatrist (Dr. Irwin or Dr. Marouf) and a social work case manager (Amy Corveleyn) in your cancer care team.**

1. From your perspective, how useful was the intervention **in your cancer care?**

Very useful Somewhat useful A little bit useful Not at all useful

2. How useful were the following parts of the intervention?

Involving psychiatry early in your cancer care	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with your psychiatrist, **(Dr. Irwin/Dr. Marouf)** in person	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach your psychiatrist **(Dr. Irwin/Dr. Marouf)** by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach your case manager, Amy, by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Communicating with your community mental health clinicians	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with your cancer and psychiatry teams together	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Helping with barriers to your care (e.g. rides to the hospital, insurance, housing)	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Addressing your psychiatric symptoms and medications	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Involving your caregiver in your cancer care	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me

3. What did you think was the **most useful** part about the intervention?

_____

_____

4. What do you feel could be **improved** about the intervention?

_____

_____

5. What else, if anything, would you like to add about the intervention that we did not discuss? _____

_____

_____

Thank you for being a part of the Proactive Psychiatry Consultation for Patients with Cancer Study. Your feedback is valuable to us and we appreciate your responses.

R. Patient 24 Week Questionnaire

PATIENT ASSESSMENT CHECKLIST

Date: _____
Study ID: _____ Time point: **24 Weeks**

	Patient-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	UCLA 3-ITEM LONELINESS SCALE	
4	PATIENT ACTIVATION MEASURE (PAM 10)	
5	THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)	
6	PSYCH RESOURCE UTILIZATION QUESTIONNAIRE	

Caregiver Change

Do you have a different primary caregiver than you had when you completed the last survey?

- ☐ Yes
- ☐ No

If no, please skip to the next page.

If yes, please explain why: _____

When did this change occur? _____

Who is your new caregiver? _____

Please indicate your relationship with the new caregiver:

- ☐ Married or living as if married
- ☐ Non-cohabitating relationship
- ☐ Divorced/Separate
- ☐ Friend
- ☐ Family Member
    - ☐ Parent (mother or father)
    - ☐ Child (daughter or son)
    - ☐ Sibling (brother or sister)
    - ☐ Other relative
- ☐ The caregiver is a community mental health worker
- ☐ Other: _____

Do you live with the caregiver?

- ☐ Yes
- ☐ No

Caregiver contact information:

Home address: _____
(Street) (Apt.)

_____
(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email (will only be used if necessary): _____

Time Spent with Caregiver

We understand that time spent with your caregiver may change over time. Think about the past two weeks. Please estimate the number of hours per week (on average) that your caregiver provided direct care (in-person or virtual) to you:

- ☐ Less than 1 hour per week
- ☐ 1-2 hours per week
- ☐ 2-5 hours per week
- ☐ 5-10 hours per week
- ☐ 10-15 hours per week
- ☐ Over 15 hours per week

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

UCLA 3-ITEM LONELINESS SCALE

INSTRUCTIONS: Please read each item below and circle one number in each row to indicate how often each statement is descriptive of you.

1 indicates “I hardly ever feel this way”
2 indicates “I sometimes feel this way”
3 indicates “I often feel this way”

	Hardly ever	**Some of the time**	**Often**
1. How often do you feel that you lack companionship?	1	2	3
2. How often do you feel left out?	1	2	3
3. How often do you feel isolated from others?	1	2	3

Patient Activation Measure (PAM 10)

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think the doctor wants you to say.

If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of my prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I may need to do at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new problems arise with my health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

MDASI

Part I. How **severe** are your symptoms?

People with cancer frequently have symptoms that are caused by their disease or by their treatment. We ask you to rate how severe the following symptoms have been ***in the last 24 hours.*** Please fill in the circle below from 0 (symptom has not been present) to 10 (the symptoms was as bad as you can imagine it could be) for each item.

	Not Present 0	1	2	3	4	5	6	7	8	9	As Bad As You Can Imagine 10
1. Your **pain** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
2. Your **fatigue** (tiredness) at its WORST?	O	O	O	O	O	O	O	O	O	O	O
3. Your **nausea** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
4. Your **disturbed sleep** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
5. Your feelings of being **distressed (upset)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
6. Your **shortness of breath** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
7. Your problem with **remembering things** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
8. Your problem with **lack of appetite** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
9. Your feeling **drowsy (sleepy)** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
10. Your having a **dry mouth** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
11. Your feeling **sad** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
12. Your **vomiting** at its WORST?	O	O	O	O	O	O	O	O	O	O	O
13. Your **numbness or tingling** at its WORST?	O	O	O	O	O	O	O	O	O	O	O

Part II. How have your symptoms interfered with your life?

Symptoms frequently interfere with how we feel and function. How much have your symptoms interfered with the following items **in the last 24 hours**? Please select a number from 0 (symptoms have not interfered) to 10 (symptoms interfered completely) for each item.

	Did Not Interfere 0	1	2	3	4	5	6	7	8	9	**Interfered Completely** 10
14. **General activity?**	O	O	O	O	O	O	O	O	O	O	O
15. **Mood?**	O	O	O	O	O	O	O	O	O	O	O
16. **Work (including work around the house)?**	O	O	O	O	O	O	O	O	O	O	O
17. **Relations with other people?**	O	O	O	O	O	O	O	O	O	O	O
18. **Walking?**	O	O	O	O	O	O	O	O	O	O	O
19. **Enjoyment of life?**	O	O	O	O	O	O	O	O	O	O	O

Resource Utilization Questionnaire

Please answer the following questions if you have a psychiatrist, social worker, case manager, or therapist that you saw ***before*** your diagnosis of cancer.

1. How many times have you seen your psychiatrist since you learned of your cancer diagnosis?
   - ❑ I did not have a psychiatrist before my cancer diagnosis
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

2. How many times have you seen or talked with your therapist or social worker since you learned of your cancer diagnosis?
   - ❑ I did not have a therapist or social worker before my cancer diagnosis
   - ❑ Not at all
   - ❑ Once
   - ❑ 2-5 times
   - ❑ More than 5 times

3. Have you been hospitalized for mental illness (such as depression, anxiety, bipolar disorder, or schizophrenia) since you learned of your cancer diagnosis?

   - ❑ Yes
   - ❑ No

   3a. If yes, please list the number of hospitalizations: _____

   3b. Briefly, what was the reason for the hospitalization(s)?

   _____

   3c. When was your last hospitalization? _____

S. Caregiver Baseline Questionnaire

CAREGIVER ASSESSMENT CHECKLIST

Date: _____

Study ID: _____ Time point: **Baseline**

	Caregiver-Reported Measures	Date
1	BACKGROUND INFORMATION	
2	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
3	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
4	UCLA 3-ITEM LONELINESS SCALE	
5	CAREGIVER PATIENT ACTIVATION MEASURE (CG-PAM 10)	
6	CAREGIVER REACTION ASSESSMENT	
7	FAMCARE 2	
8	PEARLIN MASTERY SCALE	
9	PARTICIPANT LOCATOR FORM	

Demographics

Please check the appropriate box or boxes.

1. Date of Birth: _____

2. Gender: _____

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

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

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

6. Current relationship status
   - ☐ Married or living with someone as if married
   - ☐ Non-cohabiting relationship
   - ☐ Single, never married
   - ☐ Divorced/Separated
   - ☐ Loss of long term partner/ Widowed

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

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

9. Please indicate who you live with (you may check more than one box)
   - ☐ By myself
   - ☐ Partner/Spouse
   - ☐ Roommate/Friend
   - ☐ Children under 18
   - ☐ Children over 18
   - ☐ Group home/assisted living/nursing home
   - ☐ Parent
   - ☐ Other (please specify) _____

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

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

11. Please indicate your relationship with the patient:

- ☐ Married or living as if married
- ☐ Non-cohabitating relationship
- ☐ Divorced/Separate
- ☐ Friend
- ☐ Family Member
    - ☐ Parent (mother or father)
    - ☐ Child (daughter or son)
    - ☐ Sibling (brother or sister)
    - ☐ Other relative
- ☐ I work with the patient through community mental health
- ☐ Other: _____

12. Do you live with the patient?

- ☐ Yes
- ☐ No

13. Please estimate the number of hours per week (on average) you provide direct care for the patient:

- ☐ 1-2 hours per week
- ☐ 2-5 hours per week
- ☐ 5-10 hours per week
- ☐ 10-15 hours per week
- ☐ Over 15 hours per week

14. Aside from mental health professionals, is there a medical health professional you see most often (a primary care provider)?

- ☐ Yes
- ☐ No

14a. If yes, who is your primary care provider?

_____

14b. When was your last visit to your primary care provider?

_____

Subject ID_____
Date_____

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

Subject ID_____
Date_____

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

UCLA 3-ITEM LONELINESS SCALE

Subject ID_____
Date_____

INSTRUCTIONS: Please read each item below and circle one number in each row to indicate how often each statement is descriptive of you.

1 indicates “I hardly ever feel this way”
2 indicates “I sometimes feel this way”
3 indicates “I often feel this way”

	Hardly ever	**Some of the time**	**Often**
1. How often do you feel that you lack companionship?	1	2	3
2. How often do you feel left out?	1	2	3
3. How often do you feel isolated from others?	1	2	3

Subject ID_____
Date_____

Caregiver Activation Measure (CG-PAM 10)

Below are statements people sometimes make about caring for the health of someone else. Please indicate how much you agree or disagree with each statement as it applies to you personally as a caregiver. Circle the answer that is most true for you today. If the statement does not apply, select N/A.

1. When all is said and done, I am responsible for seeing that this person's health is managed properly.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in this person's health care is one of the most important factors in determining her/his health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of this person's prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell when this person needs to get medical care and when I can handle the problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident I can tell a doctor the concerns that I have about this person's health even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I need to do for this person at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am able to help this person maintain lifestyle changes (like eating right or exercising) for her/his condition.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new situations or problems arise with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident I can help this person with lifestyle changes, like diet and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Subject ID_____
Date_____

Caregiver Reaction Assessment

Circle the number corresponding to your answer

Questions:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I feel privileged to care for ___.	1	2	3	4	5
2. Others have dumped caring for ___ onto me.	1	2	3	4	5
3. My financial resources are adequate to pay for things that are required for caregiving.	1	2	3	4	5
4. My activities are centered around care for ___.	1	2	3	4	5
5. Since caring for ___, it seems like I'm tired all of the time.	1	2	3	4	5
6. It is very difficult to get help from my family in taking care of ___.	1	2	3	4	5
7. I resent having to take care of ___.	1	2	3	4	5
8. I have to stop in the middle of work.	1	2	3	4	5
9. I really want to care for ___.	1	2	3	4	5
10. My health has gotten worse since I've been caring for ___.	1	2	3	4	5
11. I visit family and friends less since I have been caring for ___.	1	2	3	4	5
12. I will never be able to do enough caregiving to repay ___.	1	2	3	4	5
13. My family works together at caring for ___.	1	2	3	4	5
14. I have eliminated things from my schedule since caring for ___.	1	2	3	4	5
15. I have enough physical strength to care for ___.	1	2	3	4	5
16. Since caring for ___, I feel my family has abandoned me.	1	2	3	4	5
17. Caring for ___ makes me feel good.	1	2	3	4	5
18. The constant interruptions make it difficult to find time for relaxation.	1	2	3	4	5
19. I am healthy enough to care for ___.	1	2	3	4	5
20. Caring for ___ is important to me.	1	2	3	4	5

21. Caring for ___ has put a financial strain on the family.	1	2	3	4	5
22. My family (brothers, sisters, children) left me alone to care for ___.	1	2	3	4	5
23. I enjoy caring for ___.	1	2	3	4	5
24. It's difficult to pay for ___'s health needs and services.	1	2	3	4	5

FAMCARE 2

Subject ID_____
Date_____

Think about the care that the patient has received. Please answer the questions below indicating how satisfied you are with the care received: very satisfied (VS), satisfied (S), undecided (U), dissatisfied (D), or very dissatisfied (VD). Please circle the letters below that best match your experience.

How satisfied are you with:

1. The patient's comfort	VS	S	U	D	VD
2. The way in which the patient's condition and likely progress have been explained by the team	VS	S	U	D	VD
3. Information given about the side effects of treatment	VS	S	U	D	VD
4. The way in which the team respects the patient's dignity	VS	S	U	D	VD
5. Meetings with the team to discuss the patient's condition and plan of care	VS	S	U	D	VD
6. Speed with which symptoms are treated	VS	S	U	D	VD
7. The team's attention to the patient's description of symptoms	VS	S	U	D	VD
8. The way in which the patient's needs for comfort are met	VS	S	U	D	VD
9. Availability of the team to the family	VS	S	U	D	VD
10. Emotional support provided to family members by the team	VS	S	U	D	VD
11. The practical assistance provided by the team (e.g. bathing, home care, respite)	VS	S	U	D	VD
12. The Doctor's attention to the patient's symptoms	VS	S	U	D	VD
13. The way the family is included in treatment and care decisions	VS	S	U	D	VD
14. Information given about how to manage the patient's symptoms (e.g. pain, constipation)	VS	S	U	D	VD
15. How effectively the team manages the patient's symptoms	VS	S	U	D	VD
16. The team's response to changes in the patient's care needs	VS	S	U	D	VD
17. Emotional support provided to the patient by the team	VS	S	U	D	VD

Pearlin Mastery Scale

Subject ID_____
Date_____

Please circle the answer that best matches your experience.

1. There is really no way I can solve some of the problems that I have	Strongly Disagree	Disagree	Agree	Strongly Agree
2. Sometimes I feel that I'm being pushed around in life	Strongly Disagree	Disagree	Agree	Strongly Agree
3. I have little control over the things that happen to me	Strongly Disagree	Disagree	Agree	Strongly Agree
4. I can do just about anything I really set my mind to	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I often feel helpless in dealing with the problems of life	Strongly Disagree	Disagree	Agree	Strongly Agree
6. What happens to me in the future mostly depends on me	Strongly Disagree	Disagree	Agree	Strongly Agree
7. There is little I can do to change many of the important things in my life	Strongly Disagree	Disagree	Agree	Strongly Agree

PARTICIPANT LOCATOR FORM

Participant name: _____

Home address: _____
(Street) (Apt.)

_____
(City, State, Zip)

Preferred phone: _____

Alternate phone: _____

Email (will only be used if necessary): _____

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 phone: _____

Alternate phone: _____

T. Caregiver 6-week Questionnaire

CAREGIVER ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Time point: **6 Weeks**

	Caregiver-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	CAREGIVER PATIENT ACTIVATION MEASURE (CG-PAM)	
4	CAREGIVER REACTION ASSESSMENT	
5	FAMCARE 2	
6	PEARLIN MASTERY SCALE	

Time Spent Caregiving

We understand that time spent caregiving may change over time. Think about the past two weeks. Please estimate the number of hours per week (on average) you provided direct care for the patient:

- ☐ Less than 1 hour per week
- ☐ 1-2 hours per week
- ☐ 2-5 hours per week

- ☐ 5-10 hours per week
- ☐ 10-15 hours per week
- ☐ Over 15 hours per week

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

	Not at all	Several days	More than half the days	Nearly every day

Subject ID_____
Date_____

1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Feeling nervous, anxious or on edge	0	1	2	3

2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Caregiver Activation Measure (CG-PAM 10)

Below are statements people sometimes make about caring for the health of someone else. Please indicate how much you agree or disagree with each statement as it applies to you personally as a caregiver. Circle the answer that is most true for you today. If the statement does not apply, select N/A.

1. When all is said and done, I am responsible for seeing that this person's health is managed properly.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in this person's health care is one of the most important factors in determining her/his health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of this person's prescribed	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

medications do.	
4. I am confident that I can tell when this person needs to get medical care and when I can handle the problem myself.	Disagree Strongly Disagree Agree Agree Strongly N/A
5. I am confident I can tell a doctor the concerns that I have about this person's health even when he or she does not ask.	Disagree Strongly Disagree Agree Agree Strongly N/A
6. I am confident that I can follow through on medical treatments I need to do for this person at home.	Disagree Strongly Disagree Agree Agree Strongly N/A
7. I am able to help this person maintain lifestyle changes (like eating right or exercising) for her/his condition.	Disagree Strongly Disagree Agree Agree Strongly N/A
8. I know how to prevent problems with this person's health.	Disagree Strongly Disagree Agree Agree Strongly N/A
9. I am confident I can figure out solutions when new situations or problems arise with this person's health.	Disagree Strongly Disagree Agree Agree Strongly N/A
10. I am confident I can help this person with lifestyle changes, like diet and exercise, even during times of stress.	Disagree Strongly Disagree Agree Agree Strongly N/A

Caregiver Reaction Assessment

Circle the number corresponding to your answer

Questions:	**Strongly disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly agree**
1. I feel privileged to care for ___.	1	2	3	4	5
2. Others have dumped caring for ___ onto me.	1	2	3	4	5
3. My financial resources are adequate to pay for things that are required for caregiving.	1	2	3	4	5
4. My activities are centered around care for ___.	1	2	3	4	5
5. Since caring for ___, it seems like I'm tired all of the time.	1	2	3	4	5
6. It is very difficult to get help from my family in taking care of ___.	1	2	3	4	5
7. I resent having to take care of ___.	1	2	3	4	5
8. I have to stop in the middle of work.	1	2	3	4	5
9. I really want to care for	1	2	3	4	5

21. Caring for ___ has put a financial strain on the family.	1	2	3	4	5
22. My family (brothers, sisters, children) left me alone to care for ___.	1	2	3	4	5
23. I enjoy caring for ___.	1	2	3	4	5
24. It's difficult to pay for ___'s health needs and services.	1	2	3	4	5

FAMCARE 2

Subject ID_____
Date_____

Think about the care that the patient has received. Please answer the questions below indicating how satisfied you are with the care received: very satisfied (VS), satisfied (S), undecided (U), dissatisfied (D), or very dissatisfied (VD). Please circle the letters below that best match your experience.

How satisfied are you with:

1. The patient's comfort	VS	S	U	D	VD
2. The way in which the patient's condition and likely progress have been explained by the team	VS	S	U	D	VD
3. Information given about the side effects of treatment	VS	S	U	D	VD
4. The way in which the team respects the patient's dignity	VS	S	U	D	VD
5. Meetings with the team to discuss the patient's condition and plan of care	VS	S	U	D	VD
6. Speed with which symptoms are treated	VS	S	U	D	VD
7. The team's attention to the patient's description of symptoms	VS	S	U	D	VD
8. The way in which the patient's needs for comfort are met	VS	S	U	D	VD
9. Availability of the team to the family	VS	S	U	D	VD
10. Emotional support provided to family members by the team	VS	S	U	D	VD
11. The practical assistance provided by the team (e.g. bathing, home care, respite)	VS	S	U	D	VD
12. The Doctor's attention to the patient's symptoms	VS	S	U	D	VD
13. The way the family is included in treatment and care decisions	VS	S	U	D	VD
14. Information given about how to manage the patient's symptoms (e.g. pain, constipation)	VS	S	U	D	VD
15. How effectively the team manages the patient's symptoms	VS	S	U	D	VD
16. The team's response to changes in the patient's care needs	VS	S	U	D	VD
17. Emotional support provided to the patient by the team	VS	S	U	D	VD

Pearlin Mastery Scale

Subject ID_____
Date_____

Please circle the answer that best matches your experience.

1. There is really no way I can solve some of the problems that I have	Strongly Disagree	Disagree	Agree	Strongly Agree
2. Sometimes I feel that I'm being pushed around in life	Strongly Disagree	Disagree	Agree	Strongly Agree
3. I have little control over the things that happen to me	Strongly Disagree	Disagree	Agree	Strongly Agree
4. I can do just about anything I really set my mind to	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I often feel helpless in dealing with the problems of life	Strongly Disagree	Disagree	Agree	Strongly Agree
6. What happens to me in the future mostly depends on me	Strongly Disagree	Disagree	Agree	Strongly Agree
7. There is little I can do to change many of the important things in my life	Strongly Disagree	Disagree	Agree	Strongly Agree

U. Caregiver 12-Week Questionnaire

CAREGIVER ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Time point: **12 Weeks**

	Caregiver-Reported Measures	Date
1	PATIENT HEALTH QUESTIONNAIRE (PHQ-9)	
2	GENERALIZED ANXIETY DISORDER 7-ITEM SCALE (GAD-7)	
3	UCLA 3-ITEM LONELINESS SCALE	
4	CAREGIVER PATIENT ACTIVATION MEASURE (CG-PAM)	
5	CAREGIVER REACTION ASSESSMENT	
6	FAMCARE 2	
7	PEARLIN MASTERY SCALE	

Time Spent Caregiving

We understand that time spent caregiving may change over time. Think about the past two weeks. Please estimate the number of hours per week (on average) you provided direct care for the patient:

☐ Less than 1 hour per week

☐ 1-2 hours per week

- ☐ 2-5 hours per week
- ☐ 5-10 hours per week
- ☐ 10-15 hours per week
- ☐ Over 15 hours per week

PHQ-9

INSTRUCTIONS: How often have you been bothered by any of the following problems, IN THE PAST WEEK? Please read each item and circle one number in each row to indicate your answer.

Subject ID_____
Date_____

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching tv	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead	0	1	2	3

GAD-7

Subject ID_____
Date_____

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

UCLA 3-ITEM LONELINESS SCALE

INSTRUCTIONS: Please read each item below and circle one number in each row to indicate how often each statement is descriptive of you.

1 indicates “I hardly ever feel this way”
2 indicates “I sometimes feel this way”
3 indicates “I often feel this way”

	Hardly ever	**Some of the time**	**Often**
1. How often do you feel that you lack companionship?	1	2	3
2. How often do you feel left out?	1	2	3
3. How often do you feel isolated from others?	1	2	3

Subject ID_____
Date_____

Caregiver Activation Measure (CG-PAM 10)

Below are statements people sometimes make about caring for the health of someone else. Please indicate how much you agree or disagree with each statement as it applies to you personally as a caregiver. Circle the answer that is most true for you today. If the statement does not apply, select N/A.

1. When all is said and done, I am responsible for seeing that this person's health is managed properly.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in this person's health care is one of the most important factors in determining her/his health and ability to function.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I know what each of this person's prescribed medications do.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I am confident that I can tell when this person needs to get medical care and when I can handle the problem myself.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident I can tell a doctor the concerns that I have about this person's health even when he or she does not ask.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can follow through on medical treatments I need to do for this person at home.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am able to help this person maintain lifestyle changes (like eating right or exercising) for her/his condition.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I know how to prevent problems with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I am confident I can figure out solutions when new situations or problems arise with this person's health.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I am confident I can help this person with lifestyle changes, like diet and exercise, even during times of stress.	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

Subject ID_____
Date_____

Caregiver Reaction Assessment

Circle the number corresponding to your answer

Questions:	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
1. I feel privileged to care for ___.	1	2	3	4	5
2. Others have dumped caring for ___ onto me.	1	2	3	4	5
3. My financial resources are adequate to pay for things that are required for caregiving.	1	2	3	4	5
4. My activities are centered around care for ___.	1	2	3	4	5
5. Since caring for ___, it seems like I'm tired all of the time.	1	2	3	4	5
6. It is very difficult to get help from my family in taking care of ___.	1	2	3	4	5
7. I resent having to take care of ___.	1	2	3	4	5
8. I have to stop in the middle of work.	1	2	3	4	5
9. I really want to care for ___.	1	2	3	4	5
10. My health has gotten worse since I've been caring for ___.	1	2	3	4	5
11. I visit family and friends less since I have been caring for ___.	1	2	3	4	5
12. I will never be able to do enough caregiving to repay ___.	1	2	3	4	5
13. My family works together at caring for ___.	1	2	3	4	5
14. I have eliminated things from my schedule since caring for ___.	1	2	3	4	5
15. I have enough physical strength to care for ___.	1	2	3	4	5
16. Since caring for ___, I feel my family has abandoned me.	1	2	3	4	5
17. Caring for ___ makes me feel good.	1	2	3	4	5
18. The constant interruptions make it difficult to find time for relaxation.	1	2	3	4	5
19. I am healthy enough to care for ___.	1	2	3	4	5
20. Caring for ___ is important to me.	1	2	3	4	5

21. Caring for ___ has put a financial strain on the family.	1	2	3	4	5
22. My family (brothers, sisters, children) left me alone to care for ___.	1	2	3	4	5
23. I enjoy caring for ___.	1	2	3	4	5
24. It's difficult to pay for ___'s health needs and services.	1	2	3	4	5

FAMCARE 2

Subject ID_____
Date_____

Think about the care that the patient has received. Please answer the questions below indicating how satisfied you are with the care received: very satisfied (VS), satisfied (S), undecided (U), dissatisfied (D), or very dissatisfied (VD). Please circle the letters below that best match your experience.

How satisfied are you with:

1. The patient's comfort	VS	S	U	D	VD
2. The way in which the patient's condition and likely progress have been explained by the team	VS	S	U	D	VD
3. Information given about the side effects of treatment	VS	S	U	D	VD
4. The way in which the team respects the patient's dignity	VS	S	U	D	VD
5. Meetings with the team to discuss the patient's condition and plan of care	VS	S	U	D	VD
6. Speed with which symptoms are treated	VS	S	U	D	VD
7. The team's attention to the patient's description of symptoms	VS	S	U	D	VD
8. The way in which the patient's needs for comfort are met	VS	S	U	D	VD
9. Availability of the team to the family	VS	S	U	D	VD
10. Emotional support provided to family members by the team	VS	S	U	D	VD
11. The practical assistance provided by the team (e.g. bathing, home care, respite)	VS	S	U	D	VD
12. The Doctor's attention to the patient's symptoms	VS	S	U	D	VD
13. The way the family is included in treatment and care decisions	VS	S	U	D	VD
14. Information given about how to manage the patient's symptoms (e.g. pain, constipation)	VS	S	U	D	VD
15. How effectively the team manages the patient's symptoms	VS	S	U	D	VD
16. The team's response to changes in the patient's care needs	VS	S	U	D	VD
17. Emotional support provided to the patient by the team	VS	S	U	D	VD

Pearlin Mastery Scale

Subject ID_____
Date_____

Please circle the answer that best matches your experience.

1. There is really no way I can solve some of the problems that I have	Strongly Disagree	Disagree	Agree	Strongly Agree
2. Sometimes I feel that I'm being pushed around in life	Strongly Disagree	Disagree	Agree	Strongly Agree
3. I have little control over the things that happen to me	Strongly Disagree	Disagree	Agree	Strongly Agree
4. I can do just about anything I really set my mind to	Strongly Disagree	Disagree	Agree	Strongly Agree
5. I often feel helpless in dealing with the problems of life	Strongly Disagree	Disagree	Agree	Strongly Agree
6. What happens to me in the future mostly depends on me	Strongly Disagree	Disagree	Agree	Strongly Agree
7. There is little I can do to change many of the important things in my life	Strongly Disagree	Disagree	Agree	Strongly Agree

V. Caregiver 12-week Exit Survey (Bridge arm only)

CAREGIVER - 12-WEEK PARTICIPANT FEEDBACK

We are now interested to know about your satisfaction with different aspects of this intervention. There are no right or wrong answers. Your answers will be kept confidential and will not affect your participation in future research studies, or your access to care at MGH or affiliated sites. **As a reminder, you participated as a caregiver in a**

research study of an intervention that involved a psychiatrist (Dr. Irwin or Dr. Marouf) and a social work case manager (Amy Corveleyn) in the patient's cancer care team.

1. From your perspective, how useful was the intervention **in the patient's cancer care?**

Very useful Somewhat useful A little bit useful Not at all useful

2. How useful was the intervention **for you as a caregiver?**

Very useful Somewhat useful A little bit useful Not at all useful

3. How useful were the following parts of the intervention?

Involving psychiatry early in the patient's cancer care	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with the psychiatrist **(Dr. Irwin/Dr. Marouf)** in person	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach the psychiatrist **(Dr. Irwin/Dr. Marouf)** by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Being able to reach the case manager, Amy, by phone or email	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Communicating with the patient's community mental health clinicians	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Meeting with the patient's cancer and psychiatry teams together	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Helping with barriers to the patient's care (e.g. rides to the hospital, insurance, housing)	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me
Addressing the patient's psychiatric symptoms and medications	Very useful	Somewhat useful	A little bit useful	Not at all useful	Don't know/ Does not apply to me

4. What do you think was the most useful part about the intervention **in the patient's cancer care**?

_____

_____

5. What do you think was the most useful part about the intervention **for you as a caregiver?**

_____

_____

6. What changes, if any, did you notice in your **relationship with the patient** because of the intervention?

_____

_____

7. What do you think could be **improved** about the intervention?

_____

_____

8. What else, if anything, would you like to add about the intervention that we did not discuss? _____

_____

_____

Thank you for being a part of the Proactive Psychiatry Consultation for Patients with Cancer Study. Your feedback is valuable to us and we appreciate your responses.

W. Clinician-Administered Assessments

ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Timepoints: **Baseline**

	Clinician-Administered Measures	Date
1	BRIEF PSYCHIATRIC RATING SCALE (BPRS)	
2	CLINICAL GLOBAL IMPRESSION – SEVERITY (CGI-S)	

Subject ID_____
Date_____

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Please enter the score for the term that best describes the patient's condition

0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

Score	Condition
	1. SOMATIC CONCERN
	2. ANXIETY
	3. DEPRESSION
	4. SUICIDALITY

	5. GUILT
	6. HOSTILITY
	7. ELEVATED MOOD
	8. GRANDIOSITY
	9. SUSPICIOUSNESS
	10. HALLUCINATIONS
	11. UNUSUAL THOUGHT CONTENT
	12. BIZARRE BEHAVIOR
	13. SELF-NEGLECT
	14. DISORIENTATION
	15. CONCEPTUAL DISORGANIZATION
	16. BLUNTED AFFECT
	17. EMOTIONAL WITHDRAWAL
	18. MOTOR RETARDATION
	19. TENSION
	20. UNCOOPERATIVENESS
	21. EXCITEMENT
	22. DISTRACTABILITY
	23. MOTOR HYPERACTIVITY
	24. MANNERISMS AND POSTURING

CGI -SEVERITY OF ILLNESS

1. Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

- ☐ Not Assessed (0)
- ☐ Normal, not at all ill (1)
- ☐ Borderline mentally ill (2)
- ☐ Mildly ill (3)
- ☐ Moderately ill (4)
- ☐ Markedly ill (5)
- ☐ Severely ill (6)

☐ Among the most extremely ill patients (7)

ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Timepoint: **6-week**

	Clinician-Administered Measures	Date
1	CLINICAL GLOBAL IMPRESSION – SEVERITY (CGI-S)	
2	CLINICAL GLOBAL IMPRESSION – IMPROVEMENT (CGI-I)	

NOTE: BRIDGE ARM ONLY

CGI -SEVERITY OF ILLNESS

1. Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

- ☐ Not Assessed (0)
- ☐ Normal, not at all ill (1)
- ☐ Borderline mentally ill (2)
- ☐ Mildly ill (3)
- ☐ Moderately ill (4)
- ☐ Markedly ill (5)
- ☐ Severely ill (6)
- ☐ Among the most extremely ill patients (7)

CGI - IMPROVEMENT OF ILLNESS

1. Compared to the patient's condition at admission to the project, this patient's condition is:

- ☐ Very much improved since the initiation of treatment (1)
- ☐ Much improved (2)
- ☐ Minimally improved (3)
- ☐ No change from baseline (the initiation of treatment) (4)
- ☐ Minimally worse (5)
- ☐ Much worse (6)
- ☐ Very much worse since the initiation of treatment (7)

ASSESSMENT CHECKLIST

Date: _____
Study ID: _____

Timepoint: **12-week and 24-week**

	Clinician-Administered Measures	Date
1	BRIEF PSYCHIATRIC RATING SCALE (BPRS)	
2	CLINICAL GLOBAL IMPRESSION – SEVERITY (CGI-S)	
3	CLINICAL GLOBAL IMPRESSION – IMPROVEMENT (CGI-I)	

Subject ID_____
Date_____

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Please enter the score for the term that best describes the patient's condition

0 = Not assessed, 1 = Not present, 2 = Very mild, 3 = Mild, 4 = Moderate, 5 = Moderately severe, 6 = Severe, 7 = Extremely severe

Score	Condition
	1. SOMATIC CONCERN
	2. ANXIETY
	3. DEPRESSION
	4. SUICIDALITY
	5. GUILT
	6. HOSTILITY
	7. ELEVATED MOOD
	8. GRANDIOSITY
	9. SUSPICIOUSNESS
	10. HALLUCINATIONS

	11. UNUSUAL THOUGHT CONTENT
	12. BIZARRE BEHAVIOR
	13. SELF-NEGLECT
	14. DISORIENTATION
	15. CONCEPTUAL DISORGANIZATION
	16. BLUNTED AFFECT
	17. EMOTIONAL WITHDRAWAL
	18. MOTOR RETARDATION
	19. TENSION
	20. UNCOOPERATIVENESS
	21. EXCITEMENT
	22. DISTRACTABILITY
	23. MOTOR HYPERACTIVITY
	24. MANNERISMS AND POSTURING

CGI -SEVERITY OF ILLNESS

1. Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?

- ☐ Not Assessed (0)
- ☐ Normal, not at all ill (1)
- ☐ Borderline mentally ill (2)
- ☐ Mildly ill (3)
- ☐ Moderately ill (4)
- ☐ Markedly ill (5)
- ☐ Severely ill (6)
- ☐ Among the most extremely ill patients (7)

CGI - IMPROVEMENT OF ILLNESS

1. Compared to the patient's condition at admission to the project, this patient's condition is:

- ☐ Very much improved since the initiation of treatment (1)
- ☐ Much improved (2)

☐ Minimally improved (3)

☐ No change from baseline (the initiation of treatment) (4)

☐ Minimally worse (5)

☐ Much worse (6)

☐ Very much worse since the initiation of treatment (7)

X. Oncology and Mental Health Clinician Email Consent

Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Dear [Clinician Name],

I am emailing about one of your patients who recently completed participation in Dr. Kelly Irwin's randomized controlled trial of proactive psychiatry consultation and case management for patients with serious mental illness. We would love (your feedback on how useful the intervention has been for your patient and for you, as a clinician) / (to learn about your experience caring for this patient during their cancer treatment).

> Can I schedule a 5-10 minute call at a time that is convenient for you? If preferred, you can complete the survey via email or in-person.

Your responses may be used for research purposes. All data will be kept confidential and accessible only to study staff. Responses will be aggregated and de-identified prior to publication.

Completion of the brief survey will count as your consent to participate in the study. Please feel free to contact the PI, Dr. Kelly Irwin, with any questions or concerns.

Thank you for your time,

[Study Staff]

Y. Oncology Clinician Exit Survey (EUC)

Oncology Clinician Exit Survey
Proactive Psychiatry Consultation for Patients with Cancer Study

We are currently conducting a research study of an intervention involving proactive psychiatry consultation and a social work case manager for patients with serious mental illness and a recent cancer diagnosis. Your patient, XXXXXX XXXXX, participated in this study. We would like to learn about your experience caring for this patient during their cancer treatment. You will not be compensated for participating in this study.

There are minimal risks involved with providing this feedback. However, it is possible that providing feedback may make you feel uncomfortable. The benefits of your participation are that researchers may better understand the challenges and benefits of this intervention for patients with serious mental illness and cancer. Your participation is voluntary and your responses will be kept confidential. We will not collect your name or other identifying information. With your permission, we will record your responses for our data analysis. You can withdraw from the study, stop the survey, or choose not to answer any questions. Neither your feedback nor your decision to participate will affect your employment or care at Massachusetts General Hospital. If you have questions about the study, you may contact Dr. Kelly Irwin at 617-643-4453 or kirwin1@partners.org.

Thank you very much for your time!

1. What year did you graduate from oncology fellowship/start work as an oncology NP? _____

2. Gender: _____

3. How many patients have you cared for with cancer *and* serious mental illness (such as schizophrenia, bipolar disorder, or severe major depression) since graduating from fellowship/completing training?
   - ☐ 1
   - ☐ 2-5
   - ☐ 5-10

☐ 10-20

☐ 20-50

☐ More than 50

The following questions are specifically about your experience caring for your pt XXXX who participated in the study.

4. Has he/she completed the recommended cancer treatment? Please check all that apply:

☐ Surgery
☐ Chemotherapy
☐ Radiation
☐ Endocrine therapy
☐ Targeted therapy
☐ Other:_____

Notes:_____

_____

Note: The study team will tailor this question to each clinician completing the exit survey based on their involvement in the cancer care of this patient.

Considering the cancer treatment that could have been completed up until this point (*from date of enrollment to 24 weeks*), how much of the recommended cancer treatment has been completed?

☐ All
☐ Most
☐ Some
☐ A little bit
☐ None

Please approximate the percentage: _____

5. Did this patient have a clinically significant disruption in cancer care at any of the following timepoints?
By disruption we mean: A delay to the initiation of treatment, a change from guideline-concordant treatment at the time of cancer diagnosis, or interruption in cancer treatment received?

Prior to enrollment in the trial (*insert the patient's date of enrollment*)?

☐ Yes
☐ No

While enrolled in the trial (*insert the patient's enrollment date – 24-week completion date*)?

☐ Yes
☐ No

After completion of the trial (*insert the patient's 24-week completion date)?*

☐ Yes
☐ No

a. If yes, did this patient have a **delay, change, or interruption** in their cancer treatment? Please check all that apply:

- ☐ Delay
- ☐ Change
- ☐ Interruption

From your perspective, what were the reasons for this **delay**?

_____

In particular, do you think that mental illness contributed to this delay?

- ☐ Yes
- ☐ No

If yes, how?

_____

From your perspective, what were the reasons for this **change**?

_____

In particular, do you think that mental illness contributed to this change?

- ☐ Yes
- ☐ No

If yes, how?

_____

From your perspective, what were the reasons for this **interruption**?

_____

In particular, do you think that mental illness contributed to this interruption?

- ☐ Yes
- ☐ No

If yes, how?

_____

6. Reflecting on everything that you have shared, do you think this patient received the same regimen and intensity of cancer treatment as other patients who present with the same stage of disease?

☐ Yes
☐ No

If not, how was the treatment different?

_____

Why was the treatment different?

_____

7. What else, if anything, would you like to add about the patient's treatment that we did not discuss?

_____

_____

8. Are there any other concerns about this patient's treatment or treatment potential?

_____

_____

Z. Oncology Clinician Exit Survey Bridge

Proactive Psychiatry Consultation for Patients with Cancer Study
ONCOLOGY CLINICIANS

Subject ID_____
Date_____

We are currently conducting a research study of an intervention involving proactive psychiatry consultation and a social work case manager for patients with serious mental illness and a recent cancer diagnosis. Your patient, XXXXXX XXXXX, participated in this intervention. We would like your feedback on the challenges and benefits of this intervention and how it can be most useful to you as an oncology clinician. You will not be compensated for participating in this study.

There are minimal risks involved with providing this feedback. However, it is possible that providing feedback may make you feel uncomfortable. The benefits of your participation are that researchers may better understand the challenges and benefits of this intervention for patients with serious mental illness and cancer. Your participation is voluntary and your responses will be kept confidential. We will not collect your name or other identifying information. With your permission, we will record your responses for our data analysis. You can withdraw from the study, stop the survey, or choose not to answer any questions. Neither your feedback nor your decision to participate will affect your employment or care at Massachusetts General Hospital. If you have questions about the study, you may contact Dr. Kelly Irwin at 617-643-4453 or kirwin1@partners.org.

Thank you very much for your time!

1. What year did you graduate from oncology fellowship/start work as an oncology NP? _____

2. Gender: _____

3. How many patients have you cared for with cancer *and* serious mental illness (such as schizophrenia, bipolar disorder, or severe major depression) since graduating from fellowship/completing training?

- ☐ 1
- ☐ 2-5
- ☐ 5-10
- ☐ 10-20
- ☐ 20-50
- ☐ More than 50

The following questions are specifically about your experience caring for your pt XXXX who participated in the intervention.

4. How useful was the intervention in the patient's cancer care?

Very useful Somewhat useful A little bit useful Not at all useful

What was most useful?

_____

_____

What would you change to improve the intervention?

_____

_____

5. Did you find the joint visit to be useful?

   Very useful Somewhat useful A little bit useful Not at all useful

   Please explain.

   _____

   _____

6. Has he/she completed their recommended cancer treatment? Please check all that apply:
   - ☐ Surgery
   - ☐ Chemotherapy
   - ☐ Radiation
   - ☐ Endocrine therapy
   - ☐ Targeted therapy
   - ☐ Other:_____

Notes:_____

_____

Note: The study team will tailor this question to each clinician completing the exit survey based on their involvement in the cancer care of this patient.

Considering the cancer treatment that could have been completed up until this point (*from date of enrollment to 24 weeks*), how much of the recommended cancer treatment has been completed?

- ☐ All
- ☐ Most
- ☐ Some
- ☐ A little bit
- ☐ None

Please approximate the percentage: _____

7. Did this patient have a clinically significant disruption in cancer care at any of the following timepoints?
   By disruption we mean: A delay to the initiation of treatment, a change from guideline-concordant treatment at the time of cancer diagnosis, or interruption in cancer treatment received?

Prior to enrollment in the trial (*insert the patient's date of enrollment*)?

- ☐ Yes
- ☐ No

While enrolled in the trial (*insert the patient's enrollment date – 24-week completion date*)?

- ☐ Yes
- ☐ No

After completion of the trial (*insert the patient's 24-week completion date)?*

- ☐ Yes
- ☐ No

a. If yes, did this patient have a **delay, change, or interruption** in their cancer treatment? Please check all that apply:

- ☐ Delay
- ☐ Change
- ☐ Interruption

From your perspective, what were the reasons for this **delay**?

_____

In particular, do you think that mental illness contributed to this delay?

- ☐ Yes
- ☐ No

If yes, how?

_____

From your perspective, what were the reasons for this **change**?

_____

In particular, do you think that mental illness contributed to this change?

- ☐ Yes
- ☐ No

If yes, how?

_____

From your perspective, what were the reasons for this **interruption**?

_____

In particular, do you think that mental illness contributed to this interruption?

- ☐ Yes
- ☐ No

If yes, how?

_____

8. What impact did the intervention have on the cancer care for your patient?

Large positive impact	Small positive impact	No impact	Small negative impact	Large negative impact

a) Did the intervention impact the **cancer treatment plan**?

☐ Yes
☐ No

If yes, how so?

_____

b) Did the intervention impact your **relationship** with this patient?

☐ Yes
☐ No

If yes, how so?

_____

c) Did the intervention impact your **communication** with the patient or caregiver?

☐ Yes
☐ No

If yes, how so?

_____

9. Did the intervention help you as the oncologist care for the patient?

☐ Yes
☐ No

If yes, how so?

_____

10. Reflecting on everything that you have shared, do you think this patient received the same regimen and intensity of cancer treatment as other patients who present with the same stage of disease?

☐ Yes
☐ No

If not, how was the treatment different?

_____

Why was the treatment different?

_____

11. What else, if anything, would you like to add about the intervention that we have not discussed?

_____

_____

12. Are there any other concerns about this patient's treatment or treatment potential?

_____

AA. Mental Health Clinician Exit Survey

Proactive Psychiatry Consultation for Patients with Cancer Study
MENTAL HEALTH CLINICIANS

We are completing a research study of a care delivery model intervention for patients with serious mental illness and a recent cancer diagnosis which includes a psychiatry consultation and access to a social work case manager. Your patient, XXXXXX XXXXX, participated in this study. We would like your feedback on the challenges and benefits of this intervention, and ideas on how this intervention can be most useful to you. We estimate that participation will take 5-10 minutes. You will not be compensated for participating in this study.

There are minimal risks involved with providing feedback. However, it is possible that providing feedback may make you feel uncomfortable. The benefits of your participation are that researchers may better understand the challenges and benefits of psychiatry and social work interventions for patients with serious mental illness who have been recently diagnosed with cancer. Your participation is voluntary and your responses will be kept confidential. We will not collect your name or other identifying information about you. With your permission, we will record your responses for our data analysis. You can stop participating, choose not to answer any of the questions, or withdraw from the study at any time. Neither

your feedback nor your decision to participate will affect your care or your patient's care at Massachusetts General Hospital. If you have questions about the study, you may contact Dr. Kelly Irwin at 617-643-4453 or kirwin1@partners.org.

Thank you very much for your time!

1. Please select your clinical discipline:

- ☐ Licensed Mental Health Clinician
- ☐ Social Work
- ☐ Psychology
- ☐ Psychiatry
- ☐ Psychiatric Nurse Practitioner
- ☐ Primary Care Provider
- ☐ Other: _____

2. What year did you receive your license/start practicing independently? _____

3. Gender: _____

4. How often do you see this patient? _____

5. Where do you see patients clinically? Please check all that apply.

- ☐ A private office
- ☐ Community mental health clinic
- ☐ Academic hospital
- ☐ Other: _____

6. Of the patients you currently care for, how many have **cancer** and **bipolar disorder**?

Approximate # _____

7. Of the patients you currently care for, how many have **cancer** and **schizophrenia**?

Approximate # _____

8. Of the patients you currently care for, how many have **cancer** and **severe major depression** (with prior psychiatric hospitalization or suicide attempt)?

Approximate # _____

Subject ID_____
Date_____

The following questions are specifically about your experience caring for your pt XXXX, who participated in the 12-week intervention which combined proactive psychiatry consultation and case management for patients with serious mental illness and cancer.

9. In your opinion, how useful was the intervention in the patient's cancer care?

Very useful Somewhat useful A little bit useful Not at all useful

What do you think was most useful?

_____

_____

What would you change to improve the intervention?

_____

_____

10. How did the intervention impact the **coordination** of cancer and mental health care?

_____

_____

11. How did the intervention impact your **communication** with the oncology team?

_____

_____

12. What worked best to communicate with you? Please check all that apply.

- ☐ Phone
- ☐ Email
- ☐ Text

13. Have you seen XXXX since they started the intervention?

- ☐ Yes
- ☐ No

If not, why?

_____

_____

14. What information, assistance or support would be helpful to you now that your patient completed the intervention?

_____

_____

15. What else, if anything, would you like to add that we have not discussed?

_____

_____

_____

_____

Thank you for your participation in the study and for offering your feedback!

BB. Caregiver Risk Assessment Semi-Structured Guide

Family Version
Date of Assessment:
Caregiver Name:
Patient's Name:
Contact information: (phone/email/text)
Best way to contact:

Relationship to patient:

Time spent with patient per week/month:

Where does the patient live? Do you live with the patient? Will that be consistent through treatment?:

Are you and/or the patient at risk for losing your housing?:

Is there someone you share caregiving responsibilities with? What is the best way to contact this person?:

Is there a health care proxy?:

Is there a court appointed guardian? What is the best way to contact this person?:

Who manages the patient's medications?:

What are your worries about the patient receiving treatment? How will the patient get to treatment?:

Do you have concerns about the patient's income/finances?:

Do you have any safety concerns for the patient?:

Patient Strengths:

Stressors/Barriers to caregiving:

Medical illness: Do you see a PCP? What other providers do you see? What for? What medications do you take?:

Mental illness: Do you see a mental health professional? What for?:

Are you concerned about being able to pay your monthly bills during this time?:

What are your worries about your own needs? Where do you receive support?:

What is your understanding of the patient's illness and treatment plan?:

What questions do you have for the oncology team?:

Resource needs:

Plan:

Impression:

Community Version

Date of Assessment:
Caregiver's Name:
Patient's Name:
Contact information: (phone/email/text)
Best way to contact:

Relationship to patient:

Time spent with patient per week/month:

Who covers you with this patient when you are out of the office? What is the best way to contact this person?:

How does caregiving fit with your current role?

Is there a health care proxy?:

Is there a court appointed guardian? What is the best way to contact this person?:

Who manages the patient's medications?:

What are your worries about the patient receiving treatment? How will the patient get to treatment?:

Where does the patient live? Will that be consistent through treatment?:

Do you have concerns about the patient's income/finances?:

Do you have any safety concerns for the patient?:

Patient Strengths:

Stressors/Barriers to caregiving:

What are your worries about your own needs? Where do you receive support?:

What is your understanding of the patient's illness and treatment plan?:

What questions do you have for the oncology team?:

Resource needs:

Plan:

Impression:

CC. Patient Initial Assessment Semi-Structured Guide

BRIDGE INITIAL ASSESSMENT: COLLABORATIVE CARE FOR MENTAL ILLNESS AND CANCER
Assessment date:
Best way to reach participant:
Oncology team:
Community mental health team:
PCP:
Collaborative Care team at MGH: Dr. Kelly Irwin, Amy Corveleyn LICSW
Caregiver: *include if consented/not consented*

ID/Reason for Referral (Summary):

Chief Complaint (participant's own words):

History of Present Illness:

Illness understanding:

Motivation for cancer treatment:

Cancer treatment goals (what do they hope treatment will achieve):

Potential barriers:

Strengths:

Past Psychiatric History:

Past Oncology History:

Additional Past Medical and Surgical History:

Social History:

Substance Use Hx:

Family Hx:

Spiritual Hx:

Data:

ROS:

PE:

Mental Status Exam:

Impression:

Recommendations:

DD. Psychosocial Resources Flyer

Mental Health Resources and Supportive Services

Psychiatric Oncology

Phone: 617-643-6833

Psychiatrists specializing in the care of oncology patients provide treatment for anxiety, depression and coping with persistent physical symptoms or emotional challenges surrounding cancer treatment.

Maxwell V. Blum Cancer Resource Program

The Maxwell V. Blum Cancer Resource Program offers a range of support resources around the Cancer Center. The program has an ongoing mission to make support services, as well as respite and community-building areas, more accessible to patients and families throughout the Cancer Center.
Phone: 617-724-1822

The Katherine A. Gallagher Integrative Therapies Program

The Katherine A. Gallagher Integrative Therapies Program offers free wellness services, such as acupuncture, art therapy and yoga, for patients with cancer and their loved ones. The programs can help you feel better throughout your cancer experience. Through a wide range of services, you can learn tips for coping with symptoms and stress. These services are designed to enhance quality of life and help manage a broad range of physical and emotional symptoms. Cancer patients and their families use these methods as tools in which they may maintain health and wellness throughout and beyond treatment.
Phone: 617-726-4178

Oncology Social Work

Oncology social workers are licensed mental health professionals who provide support for issues that affect you and your family during cancer diagnosis, treatment, and recovery. Each disease center has its own social workers with expertise in your specific disease.

The Oncology Resource Specialist (a member of the Oncology Social Work team) can answer questions about transportation options for cancer patients and local lodging for patients and their families during treatment. We offer a variety of cancer support groups, but if needed the resource specialist can investigate if there are any offered closer to your home. Contact the Oncology Resource Specialist at: (tel) 617-724-0295.

More Supportive Care Services

Chaplaincy
Phone: 617-726-2220
Support is available to persons of all faiths and to those with no religious affiliation.

Environmental Music Program
The Mass General Environmental Music Program brings live, high-quality music to public spaces in the hospital to create a calming and soothing environment for patients, families, and staff.

Education Workshops
Phone: 617-724-1822
Education workshops share the information that can help ease your fear and anxiety. They also let families and friends learn more about what their loved ones are going through. Topics include:

- Chemotherapy
- Radiation therapy
- Clinical trials
- Blood counts
- Nutrition
- Fatigue
- Radiology
- Exercising during treatment

Illuminations Program
Phone: 617-650-1143
Illuminations is a rotating art exhibit housed throughout the Mass General Cancer Center and many of its affiliate locations. The exhibit is intended to offer enlightenment and encouragement to patients,

families, staff, and friends of the Cancer Center as they receive care, provide care, or accompany loved ones.

Images Boutique

Phone: 617-726-3211

The oncology boutique carries a wide variety of specialized products and services, including wigs, hats, breast prostheses, mastectomy products and lymphedema sleeves. Patients can learn more about skin care and managing hair loss. Our specially trained staff will provide you with personalized advice and assistance, and will teach you ways to minimize and manage the changes in appearance resulting from cancer treatment. They will work with you to create a plan that will help you look and feel your best throughout and following treatment. The boutique is located in the Yawkey Center on the 9th floor. Ask the staff about the frequent shopping card, which offers additional savings at this boutique, along with other Mass General stores.

The Marjorie E. Korff Parenting At a Challenging Time (PACT) Program

Phone: 617-724-7272

This program provides individual support for cancer patients who have children in their lives. Working hand-in-hand with parents, PACT's child psychiatrists and child psychologists offer age-specific guidance for helping children cope with a parent's cancer.

Lifestyle Medicine Clinic

Phone: 617-724-4000

The Lifestyle Medicine Program provides personalized one-on-one consultations for any patient with cancer or a history of cancer who wants to improve their physical fitness, nutrition, quality of life or cancer prognosis.

The Network for Patients and Families

This peer support program matches patients and family members with volunteers who are experienced in living with a similar type of cancer.

Palliative Care Program (Outpatient Services)

Phone: 617-724-4000

Our palliative care specialists focus on improving the quality of life of people facing serious illness. From the time of diagnosis, we provide expert management of pain and other symptoms; guidance with difficult treatment choices; and emotional and spiritual support for you and your family. Talk with your doctor or nurse for a referral.

Support Groups

Phone: 617-724-1822

Groups led by oncology social workers provide patients, their family members and their friends the chance to share information, gain support and learn how others cope with cancer. Support workshops provide you with a comfortable place to share how you feel and learn how others cope with cancer. Topics include:

- Talking to your children about cancer
- Finding faith and hope
- Moving forward after cancer treatment

The Social Service Department at Massachusetts General Hospital offers many types of support groups, including groups for certain types of cancer, siblings of children with life threatening illnesses, and programs for parents of children with cancer.

Survivorship Program

Phone: 617-726-4920

Mass General has world class clinical programs aimed at overcoming challenges related to quality of life, cardiopulmonary fitness, neurologic complications of cancer therapy, sexual health, and many other issues that impact cancer survivors. Our survivorship program is helping to coordinate these activities across Mass General and ensure that all patients who can benefit have access to these services.

Howard Ulfelder, MD, Healing Garden

The Healing Garden is a year-round respite for Cancer Center patients, families and friends. This rooftop garden allows patients, families and visitors to enter into a landscaped setting for rest and solace. An enclosed, glazed pavilion provides shelter from the elements. Created as a serene respite for cancer patients and their families, the garden has extraordinary views of the Boston skyline and the Charles River Basin, generous seating, gentle water courses, and plentiful greenery year-round. The garden is accessible from the eighth floor in the Yawkey Center for Outpatient Care.

CANCER*Care*

CANCER*Care* offers counseling, support groups (via phone, online, and in person), education workshops, financial resources, and community programs for patients and caregivers. Learn more at: https://www.cancercare.org/

Project Bread

Project Bread is committed to preventing and ending hunger in Massachusetts. If you or your family is facing hunger right now, we want to help. Call our FoodSource Hotline at 1-800-645-8333 or visit http://www.projectbread.org/get-help/ to find resources that can make a real difference.

https://www.massgeneral.org/cancer/experience/

EE. Partners Rally Recruitment Advertisement

Rally at Partners Healthcare

Do you have a new cancer diagnosis and a history of major depression, bipolar or schizophrenia?

This PDF is intended for IRB review and includes information that may not appear to the public. A preview of what will appear on the Rally site is available at the link below.
https://rally.partners.org/preview/ujaN2N
Rally collects some information (e.g., gender eligibility and study activities) using structured fields. Options that were available but not selected appear in this document in light grey with a strikethrough

The Basics

Headline
Do you have a new cancer diagnosis and a history of major depression, bipolar or schizophrenia?

Summary
It is challenging to cope with cancer. The Bridge study aims to understand if it is helpful for patients with mental illness to be connected to a psychiatrist and case manager at the time of cancer diagnosis.

Project Title
Bridge: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Custom URL
https://rally.partners.org/study/bridge

Category
• Cancer
• Mental Health

Project Image

Project Website
(empty)

ClinicalTrials.gov Identifier
NCT03360695

Funding Source
NIH or Other Federal

At which institutions is the project being conducted?

Organization Name
Massachusetts General Hospital

Department
Cancer Center

IRB Organization
Dana Farber Cancer Institute

IRB Protocol Number
17396

Recruitment Start Date
12/11/2017
Recruitment End Date
05/15/2022

Team

Principal Investigator
Kelly E Irwin, MD, MPH
Email Address (for internal use only)
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6176434453
PI Organization
Massachusetts General Hospital

Project Contact
Catherine Pappano/Clinical Research Coordinator, cpappano@mgh.harvard.edu, 617-643-6087

Research

What are you studying?
It is challenging to cope with cancer. We want to understand if having a psychiatrist and case manager be part of your care team improves your cancer care.
Why is it important?
Many people with illnesses like major depression, schizophrenia and bipolar disorder face barriers to receiving high quality cancer care. It can be difficult to get to appointments, have many different doctors, and experience depression or worry. Better communication between the patient, the oncology team, and mental health providers may improve care. As for all patients, it is important for people with mental illness to have access to high quality cancer treatment that is patient-centered and coordinated. Having a case manager and psychiatrist at the cancer center who collaborates with the oncology team starting at cancer diagnosis may help patients to receive the cancer care that they need.
What do you hope to accomplish?
We hope to examine the potential benefits of involving a psychiatrist and case manager in cancer care, and how we may improve person centered care in the future. Your participation can help us learn how to provide better care for people with cancer and mental health concerns.
Clinical Trial Phase
This project does not study a drug or biologic product. Not applicable.

Eligibility

Who can participate?
Recent diagnosis of breast, lung, gastrointestinal or head and neck cancer. Receiving cancer treatment at MGH History of mental health concerns, including major depression, bipolar disorder, or schizophrenia spectrum disorder English speaker Over the age of 18
Who cannot participate?
Unwilling or unable to participate in the study Unable to speak or read English Recurrence of the same cancer type
Age

18 years or older

Gender

Male
Female
Transgender Female
Transgender Male
Gender-expansive

Participation Details

Estimated time commitment

5 hours over 24 weeks

What may participants be asked to do?

Participants will be asked to complete 4 brief surveys and clinical interviews over 24 weeks. Some participants will also have study visits with a psychiatrist and social worker. You may choose to identify a caregiver to participate in the study, but this is not required. Participation involves no extra costs. You have an equal chance of either: 1. Having a psychiatrist and case manager be part of your cancer care team OR 2. You and your oncologist being informed about available mental health supports

Does your project involve any of the following activities?

Survey
Office visit

Travel Requirements

No travel required

Benefits and Compensation

What will participants receive?

You may receive up to $50 for your participation in this study.

Select all that apply

Payment

Dollar Amount (up to)

$50.00

Preview URL

https://rally.partners.org/preview/ujaN2N

FF. Clinician Flyer

ENGAGE

TOGETHER WE WILL ENSURE THAT MENTAL HEALTH
IS NEVER A BARRIER TO CANCER CARE

BRIDGE: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

To advance equity, we need bridges

We are conducting a study to understand if having a psychiatrist and case manager as part of your care team improves your cancer care. We target patients who have recently been diagnosed with cancer and have a history of mental health concerns.

- ➔ Individuals with serious mental illness have worse cancer outcomes due to inequalities in cancer treatment.
- ➔ The Bridge trial utilizes a collaborative care model with a psychiatrist, case manager, and oncologist, which has been shown to improve cancer care.
- ➔ Randomized trials and community engagement are needed to advance equity in cancer care and research for people with SMIs.

We are currently enrolling patients who have been:

1) Previously diagnosed with schizophrenia, bipolar disorder, or depression.
2) **Recently** diagnosed with breast, GI, head & neck, or lung cancer

If you see a patient who may be eligible for the Bridge Trial, PLEASE CONTACT:
Maura Barry (617) 726-2297 or Dr. Kelly Irwin at: kirwin1@partners.org

MASSACHUSETTS GENERAL HOSPITAL CANCER CENTER

ENGAGE

engageinitiative.org

@EndTheInequity
@KellyIrwin_MD

Subject ID_____
Date_____

KK. **Qualitative Interview Guide: Persons with cancer and mental illness**

Section 1: INTRODUCTION

Hi, my name is _____ and I am a researcher calling from Massachusetts General Hospital. I'm calling to understand more about your experience with the Bridge study (talking with the psychiatrist *[give name]* and/or social worker Amy Corveleyn) when you were receiving cancer care.

As a reminder, we are interested in learning about the experience of people affected by cancer and mental health needs. We are hoping to find out about your experiences as a patient, your perspective about your care, and your thoughts about being connected to the Bridge mental health team at the cancer center.

We are interested in all of your ideas and appreciate you responding as honestly as you can. I'm interested in hearing all of your ideas- there is no right or wrong answer. If you don't want to answer a particular question, you can choose not to answer. You can stop the interview at any time.

This interview should last 30-40 minutes. Is it okay for me to record our conversation so that I can remember what you are sharing today? The only people who will look at your responses will be our trained research staff. If we use the information you share, such as for publication, we will do so in a way that you cannot be personally identified. After the interview, I will pay you $30 in cash or check, whichever your preference, to thank you for your time. *(State that you are turning on the recorder).*

Part A: **Introduction**

1) How are you doing today?

2) We sometimes use the word "caregiver" to describe family, friends, or community supports. Different people use different words to describe their role supporting or caring for others.
   Prompts:
   Is there someone you identify as a caregiver?
   Would you use the word caregiver? If not, what words do you prefer (e.g., loved one, family, staff)?
   Do you have a more than one caregiver?

Note: If a person prefers to use a word other than "caregiver" to describe themself, use that person's language throughout the interview.

3) If you have a support or caregiver* *(use person's language)*, what did they do as a caregiver* *(use person's language)* for you prior to the cancer diagnosis?
   Optional prompts:
   Related to mental health care?
   Related to medical care
   Related to other needs (transportation, food, housing, helping with medications)?

4) How did the pandemic affect the way you interacted with:
   Prompts:
   Caregivers (e.g., family, friends, community staff)?
   Mental health team?
   Primary care?
   Prompts:
   Positives?
   Negatives?

Part B: **Experience with cancer diagnosis and treatment**

Transition: Now, we would like to focus on the time of your diagnosis with cancer and the next 6 months when were you enrolled in the Bridge study from *(give patient's enrollment date)* to *(give patient's end of 24-week window date)*.

1) Looking back at the time of your cancer diagnosis and treatment, what was most challenging for you?
   Prompts:
   Related to cancer diagnosis?
   Mental health?
   Financial burden/resource needs?

***Note: The following question (#2) should only be asked to patient participants who identified a caregiver.**

2) How did your relationships with your caregiver* *(use person's language)* change during cancer care?
   Prompts:
   Changes in relationship/deepening of bond
   Time together
   Other?

Transition: Next, we would like to ask about your experiences related to participation in cancer care and communication with the oncology team.

1) How did the pandemic affect the way you were able to participate in cancer care?
   Prompts:
   Positives?
   Negatives?
   Optional Prompts:
   Delays in accessing cancer care?
   Delays in accessing mental health care?
   Having appointments in person?
   Having caregivers (use person's language) attend appointments with you?*
   Participating in video visits?
   Was that helpful? How so?
   Joining patient appointments by phone?
   Was that helpful? How so?
   Challenges with virtual care?

2) What was challenging about communicating with the oncology team (medical, radiation, surgical oncology team)?
Prompts:
Knowing who to contact?
Waiting for responses?
During transitions in care (from hospital to home or rehab)?

3) What worked well to communicate with the oncology team?
Prompts:
What strategy/strategies worked best?
What modality (e.g., phone, email, page, Patient Gateway)?

Part C: **Experience Collaborating with the Bridge Team at Mass General as a Caregiver *(use person's language)* During Cancer Care**

Transition: Next, I want to ask you about your experience in the Bridge study. Participants were able to meet with a psychiatrist and social worker *(names)* during the 24-week trial that was focused on the time period of cancer treatment. *(Provide dates of enrollment in the Bridge study).*

1) Thinking back, what do you remember about working with the Bridge team when you were diagnosed with cancer?
Prompts:

Social work?
Psychiatry?
Navigator?

2) How, if at all, did working with the Bridge team affect your cancer care?
Prompts:

Ability to get needed cancer care?

Your understanding of your cancer?

Decision-making about cancer treatment?

Ability to follow up with cancer care?

3) How was working with the Bridge team different from your previous experiences working with other providers or clinicians?
Prompts:

How was working with the psychiatrist different from your psychiatrist?
How was working with the social worker different from working with other social workers/therapists?
How was working with the navigator different than previous experiences?

How was it different than working with your psychiatrist, primary care doctor, or therapist?
Team from DMH or VNA?

4) Was it helpful for a psychiatrist to be involved in the Bridge study?
Prompts:

If helpful, how so?

If not, why not?

Optional prompts:

Expertise in mental illness/medical aspects of cancer care?

Expertise in psycho-oncology and serious mental illness?

Need for medication changes?

5) Did you have a joint visit with a member of the Bridge team and your oncology team?
Prompts:

If so, was that helpful? How so?

6) For many patients, the pandemic affected the way they interacted with their healthcare providers. How did the pandemic affect the way that you and your healthcare providers interacted?
Prompts:
Positives?
Negatives?

7) Did you see the Bridge team in person?
Prompt if yes:

How did that affect your relationship/rapport?

Prompt if no:

Was there a time that you think that would have been helpful? When?

8) What strategies worked best for you when meeting with/trying to each the Bridge team?
Prompts:

Phone visits?
Virtual/video visits?
Text between visits?
Email between visits?

Part D: **After Completion of the Study *(give date)***

Transition: Next, I want to ask you about after the Bridge study ended. As a reminder, you completed the study on *(give patient's 24-week end date)*.

****Note to interviewer: The following question (#1) should not be asked if the patient did not identify a caregiver.***

1) Currently, how would you describe your role or relationship with your caregiver* *(use person's language)*?
   Prompt:

   How has your relationship with your caregiver changed since completing the study?

2) After completing the study, what issues are most on your mind as someone who has experienced cancer and mental illness?
   Prompts:

   Worries about your health?

   Cancer recurrence?

   Mental health symptoms/relapse?

   Not being able to access care?

   Financial burden?

3) Do you continue to be in touch with the Bridge team?

4) How was the transition to community-based mental health care?
   Prompts:

   Psychiatry/NP? Therapy? Other supports?
   How to better support communication with oncology and mental health?
   Resources/information that would better support that transition?

Part E: **Patient Resource Interest**

Subject ID_____
Date_____

Introduction: Different patients have different needs and availability during cancer care that change over time.

1) What do you think would support other people who are experiencing mental illness and cancer?
   Prompts:

   During cancer care?

   After cancer treatment?

   Approaching end of life?

2) Would you be interested in:
   Individual support for people with mental illness/cancer?

   Referrals to recommended therapists?

   Group support with others experiencing mental illness/cancer?

   Link to others experiencing mental illness and cancer/peer supports?

   Participation in educational events?

   Assistance with resources/financial burden related to mental illness treatment/cancer care?

   Do you prefer in person, phone, or video-conferencing?

3) Is there anything that you would like to bring up that we did not address?

Conclusion: Thank you very much for your time and feedback.

LL. Qualitative Interview Guide: Caregivers of persons with cancer and mental illness

Section 1: INTRODUCTION

Hi, my name is _____ and I am a researcher calling from Massachusetts General Hospital. I'm calling to understand more about your experience with the Bridge study (talking with the psychiatrist *[give name]* and/or social worker Amy Corveleyn) when *(patient's name)* was receiving cancer care.

As a reminder, we are interested in learning about the experience of people who have been involved in helping to care for people affected by cancer and mental health needs. We are hoping to find out about your experiences as a caregiver, your perspective about the person's care, and your thoughts about being connected to the Bridge mental health team at the cancer center.

We are interested in all of your ideas and appreciate you responding as honestly as you can. I'm interested in hearing all of your ideas- there is no right or wrong answer. If you don't want to answer a particular question, you can choose not to answer. You can stop the interview at any time.

This interview should last 30-40 minutes. Is it okay for me to record our conversation so that I can remember what you are sharing today? The only people who will look at your responses will be our trained research staff. If we use the information you share, such as for publication, we will do so in a way that you cannot be personally identified. After the interview, I will pay you $30 in cash or check, whichever your preference, to thank you for your time. *(State that you are turning on the recorder).*

Section 2: CARING FOR *(identify specific patient)*
Part A: **Introduction**
Introduction: Thank you for making the time to talk today.

5) How are you doing today?

6) We sometimes use the word "caregiver" to describe family, friends, or community supports who care for individuals affected by cancer and mental health needs. Different people use different words to describe their role supporting or caring for others.
   Prompts:
   How would you describe your role or relationship with _____?
   Do you use the word caregiver?
   If not, what words do you relate to/prefer (e.g., loved one, staff)?

Note: If a person prefers to use a word other than "caregiver" to describe themself, use that person's language throughout the interview.

7) What were you doing as a caregiver* *(use person's language)* for _____ before his/her cancer diagnosis?
   Optional prompts
   Related to mental health care
   Related to other needs

Part B: **Caregiving During Cancer Care**

Transition: Now, we would like to focus on the time when _____ was diagnosed with cancer and enrolled in the Bridge study from *(give patient's enrollment date)* to *(give patient's end of 24-week window date)*.

1) Looking back at the time of _____'s cancer diagnosis and treatment:
   What were you doing as a caregiver for _____?
   Related to their cancer?
   Related to their mental health?
   Related to patient needs like food, or transportation

2) Were other caregivers involved in supporting _____?
   Positives of having multiple caregivers?
   Negatives?

3) How did your role as a caregiver* *(use person's language)* change after the person's cancer diagnosis? During the person's cancer care?
   Prompts:
   What contributed to changes in what you were doing as a caregiver?
   The patient's health needs (related to cancer, related to mental health?)
   The patient's financial resources/situation?
   Changes in your relationship?
   Caregiver (use person's language) needs*

Note: The following question (#4) should be asked to community caregivers only.

4) How did caregiving* *(use person's language)* for _____ affect your ability to do your job as community mental health staff?
   Prompts:
   What issues came up?
   How did transitions in staffing affect the person's care?

5) What parts of caregiving* *(use person's language)* for _____ during cancer were challenging?
   Prompts
   What was most challenging?
   Optional prompts:
   Limited time?
   Financial burden?
   Emotional burden?
   Balancing need to be a caregiver for others?
   How did this change during the pandemic?

6) What aspects of caring* *(use person's language)* for ____ were rewarding for you?

Prompts:
Spending time together?
Fulfillment from providing care/meeting needs?
Strengthening relationship/deepening bond?

7) For many caregivers* *(use person's language)*, the pandemic affected the way that they interacted with loved ones or people they care for. How did the pandemic affect the way you and ____ interacted?
Prompts:
Positives?
Negatives?

Transition: Next, we would like to ask about your experiences related to participation in _____'s cancer care and communication with the oncology team.

1) What was challenging about communicating with the oncology team (medical, radiation, surgical oncology team)?
Prompts:
Knowing who to contact?
Waiting for responses?
During transitions in care (from hospital to home or rehab)?

2) What worked well to communicate with the oncology team?
Prompts:
What strategy/strategies worked best?
What modality? (e.g. phone, email, page)

3) For many caregivers* *(use person's language)* and loved ones, the pandemic changed how they were able to participate in cancer care. How did the pandemic affect the way you were able to participate in cancer care?
Prompts:
Positives?
Negatives?

Optional Prompts:
Joining appointments in person?
Was that helpful? How so?
Visiting in person in the hospital?
Was that helpful? How so?
Participating in video visits?
Was that helpful? How so?
Joining patient appointments by phone?
Was that helpful? How so?

***Part C:* Experience Collaborating with the Bridge Team at Mass General as a Caregiver *(use person's language)* During Cancer Care**
Transition: Next, I want to ask you about your experience while ____ was involved in the Bridge study (and you may have been enrolled as a caregiver). Patients were able to meet with a psychiatrist and social

worker *(names)* for 24 weeks of their cancer treatment. We are interested in your perspective about working with the Bridge team and your experience as a caregiver* (*use person's language)*.

9) Thinking back, what do you remember about working with the Bridge team when ____ was diagnosed with cancer?
Prompts:

Who do you remember talking to/connecting with? (psychiatrist, social worker, navigator)?

10) What did you find most helpful about being connected to the Bridge team during the person's cancer care?
Prompts:

For the person/patient?

For you, as a caregiver(use person's language)?*

11) How, if at all, did working with the Bridge team affect the person's cancer care?
Prompts:

Ability to get needed cancer care?

The person's understanding of their cancer?

Decision-making about cancer treatment??

Ability to follow up with cancer care

12) How was working with the Bridge team different from your previous experiences working with ____'s clinicians?
Prompts:

Working with _____'s mental health clinicians? _____'s other doctors?

Your own experience with healthcare?

13) Was it helpful for a psychiatrist to be involved in the Bridge study?
Prompts:

If helpful, how so?

If not, why not?

Optional prompts:

Expertise in mental illness/medical aspects of cancer care?

Expertise in psycho-oncology and serious mental illness?

Need for medication changes?

14) As a caregiver, in what ways did you interact with the Bridge team during the study?
Part 1: Joint vs. Individual Visits

a) Did you meet together with the patient and Bridge team? Was that helpful? How so?
b) Did you talk separately with the social worker or psychiatrist? Was that helpful/how so?
c) Did you meet together with the oncology team, the patient, and Bridge teams? Was that helpful? How so? When?

15) Impact of the pandemic
The pandemic impacted how many caregivers were able to interact with mental health clinicians and virtual care rapidly expanded.
Positives?
Negatives?

16) Did you see the Bridge team in person?
Prompt: if yes: How did that affect your relationship/rapport?

Prompt if no: Was there a time that you think that would have been helpful? When?

17) What strategies worked best for you when meeting with/trying to reach the Bridge team?
Prompts:

Phone visits
Virtual/video visits
Text between visits
Email between visits

Part D:* After Completion of the Study *(give date)

Note to interviewer: Tailor this section based on patient's clinical course; will need to modify based on if patient died during the study.

Transition: Next, I want to ask you about after the Bridge study ended. As a reminder, _____ completed the study on *(give patient's 24-week end date)*.

***Note to interviewer: The following question (#1) should not be asked if the patient has died.**

5) Currently, how would you describe your role or relationship with _____?
   Prompts:

   Do you consider yourself a caregiver?

   How has your role as a caregiver changed since completing the study?

6) After completing the study, what issues are most on your mind as a caregiver for _____ with cancer and mental illness?
   Prompts:

   Worries about the patient's health?

   Cancer recurrence

   Mental health symptoms/relapse

   Not being able to access care

   Financial burden

   Your needs

   Your wellbeing and mental health

   Other caregiving responsibilities

   Financial burden

7) Do you continue to be in touch with the Bridge team?

8) How was the transition to community-based mental health care?
   Prompts:

   Psychiatry/NP? Therapy? Other supports?
   How to better support communication with oncology and mental health?
   Resources/information that would better support that transition?

Part E: **Caregiving Resource Interest**

Introduction: Different caregivers* *(use person's language)* have different needs and availability during cancer care that change over time.

4) What do you think would support other caregivers* *(use person's language)* for patients with mental illness and cancer?
   Prompts:

   During cancer care?

   After cancer treatment?

   Approaching end of life?

5) Would you be interested in:
   Individual support for caregivers?

   Referrals to recommended therapists?

   Group support with other caregivers?

   Link to other caregivers/peer supports?

   Participation in educational events?

   Assistance with resources/financial burden related to caregiving (use person's language) and access to care?*

   Do you prefer in person, phone, or video-conferencing?

6) Is there anything that you would like to bring up that we did not address?

Conclusion: Thank you very much for your time and feedback.

Section 3: DEMOGRAPHICS AND CAREGIVER* *(use person's language)* CHARACTERISTICS

Note: Ask only of caregivers* (use person's language) who were not enrolled in trial.

Introduction: For these questions, please provide responses based on the time when _____ was diagnosed with cancer and the following 6 months. As a reminder, _____ was enrolled in the trial from *(give enrollment date)* to *(give end of 24-week date)*.

1. Date of birth (mm/dd/yyyy): _____
2. Gender: _____
3. Ethnicity
   - ○ Hispanic or Latino
   - ○ Not Hispanic or Latino
4. Race (please check all that apply)
   - ☐ American Indian or Alaskan native
   - ☐ Asian
   - ☐ African American or Black
   - ☐ Native Hawaiian or other Pacific Islander
   - ☐ White
   - ☐ Other

4a. If other, please specify: _____

5. Religion
   - ○ Catholic Christian
   - ○ Other Christian (such as Protestant, Orthodox, etc.)
   - ○ Jewish
   - ○ Muslim
   - ○ Atheist
   - ○ None
   - ○ Other
6. What was your relationship status?
   - ○ Married or living with someone as if married
   - ○ Non-cohabitating relationship
   - ○ Single, never married
   - ○ Divorced/Separated
   - ○ Loss of long term partner/Widowed

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

8. What is your annual combined household income?
   - ○ Less than $25,000
   - ○ $25,000 – 50,000
   - ○ $100,000 - $150,000
   - ○ Greater than $150,000

9. Please indicate who you lived with (you may check more than one box)
   - ☐ By myself
   - ☐ Partner/Spouse
   - ☐ Roommate/Friend
   - ☐ Children under 18
   - ☐ Children over 18
   - ☐ Group home/assisted living/nursing home
   - ☐ Parent
   - ☐ Other

9a. If other, please specify: _____

9b. Did you experience a change in housing/living situation during the study? _____

10. Employment status during the study (please check all that apply):
   - ☐ Employed (full-time or part-time)
   - ☐ Caring for home or family (not currently employed and not looking for paid work)
   - ☐ Unemployed and looking for work
   - ☐ Unable to work due to illness or disability
   - ☐ Retired
   - ☐ Student
   - ☐ Other

10b. If other, please specify: _____

11. Do you have medical conditions (including mental health conditions such as depression, anxiety) that might require ongoing care?
    - o Yes
    - o No

11a. If so, what conditions? _____

12. What was your relationship with the patient during the study?
    - ☐ Married or living as if married
    - ☐ Partner/Non-cohabitating relationship
    - ☐ Divorced/Separarated
    - ☐ Friend
    - ☐ Family Member
    - ☐ Staff/provider: Worked with the patient through community mental health
    - ☐ Other

12a. If other, please specify: _____

12b. If staff/provider, please describe your role

13. Please estimate the number of hours per week (on average) you were involved as a caregiver for the patient during the Bridge study:
    - o 1-2 hours per week
    - o 2-5 hours per week
    - o 5-10 hours per week
    - o 10-15 hours per week
    - o Over 15 hours per week

14a. Did that amount of time spent caregiving* *(use person's language)* change during the study?

    - o Yes
    - o No

14. Were others involved in caregiving* *(use person's language)* for the patient?
    - o Yes
    - o No

15a. If so, who and in what roles?

    - o Family members: _____
    - o Friends: _____
    - o Mental health staff: _____

15. Do you continue to consider yourself a caregiver for _____?

Subject ID_____
Date_____

MM. **Qualitative Interview Guide: Mental health clinicians of persons with cancer and mental illness**

Section 1: INTRODUCTION

Hi, my name is _____and I am a researcher calling from Massachusetts General Hospital. I'm calling to understand more about your experience as a mental health clinician for _____ when receiving cancer care and your experience collaborating with the Bridge team (talking with the psychiatrist *[give name]* and/or social worker Amy Corveleyn).

As a reminder, we are interested in learning about your experiences as a mental health clinician working with patients with mental illness and cancer and your needs as a mental health clinician and how those needs have evolved during the pandemic. We are hoping to find out about your experiences as a caregiver, your perspective about the person's care, and your thoughts about being connected to the Bridge mental health team at the cancer center.

We are interested in all of your ideas and appreciate you responding as honestly as you can. I'm interested in hearing all of your ideas- there is no right or wrong answer. If you don't want to answer a particular question, you can choose not to answer. You can stop the interview at any time.

This interview should last about 30 minutes. Is it okay for me to record our conversation so that I can remember what you are sharing with me today? The only people who will look at your responses will be our trained research staff. If we use the information you share, such as for publication, we will do so in a way that you cannot be personally identified. I am interested in hearing all your ideas - there is no right or wrong answer. If you do not want to answer a particular question, you can choose not to answer. After the interview, I will pay you $30 in cash or check, whichever your preference, to thank you for your time. (*State that you are turning on the recorder).*

Section 2: CARING FOR *(identify specific patient)*

***Part A:* Before Enrollment in Bridge Collaborative Care Trial**

Introduction: Thank you for making the time to talk today.

1) Please describe your involvement in this person's mental health care before their cancer diagnosis.
   Prompts:

   How long had you been seeing ____?

Did you prescribe medications?
Did you provide therapy?

2) How did your role in _____'s mental health care change during the pandemic (before the cancer diagnos?
Prompts:

Positives?

Negatives?

See less often?

Not applicable

Part B: **During Cancer Care**

Transition: Next, we will focus on the time period after the person's cancer diagnosis.

1) How did the person's mental health care change after the cancer diagnosis?
Prompts:

Frequency of visits?

What aspects of caring for the patient were challenging?

What was rewarding?
How was the mental health care impacted by the pandemic?

Part C: The Bridge Collaborative Care Trial

Transition: Next, I want to ask you about the Bridge collaborative care study that_____ was involved in. During the study, patients had a proactive consultation with the Bridge team (a psychiatrist and social worker with expertise in serious mental illness and cancer) and collaboration with oncology over the next 24 weeks. I'm interested in your perspective as a mental health clinician about the person's cancer care and their involvement in the Bridge trial.

Do you remember communicating with a member of the Bridge team? A social worker or psychiatrist *(prompt with clinician names)?*

1) How did working with the Bridge team *(identify clinicians)* impact your access to information about cancer diagnosis, prognosis or treatment?

2) What the Bridge trial helpful for _____? How so?

3) Was the Bridge trial helpful for you, as a mental health clinician?
If so, what was most helpful?

Access to in person/more frequent visits?

Expertise in psycho-oncology care?

Direct communication with oncology team?

Collaboration with a social worker?

4) What was your experience communicating with the Bridge team? What worked best?
Prompts:

What was helpful?

Frequency of communication?

Mode of communication?

How could the communication be more helpful to you?
Frequency of communication?
Mode of communication?
Content
What is the best way to communicate about urgent needs?

Part C: **After Completion of the Bridge Collaborative Care Trial**

Transition: Next, I want to ask you about your experience after the study ended. We appreciate your feedback as we hope to learn how to better support patients and their mental health

clinicians throughout cancer care. As a reminder, _____ completed the study on *(give patient's 24-week end date)*.

1) Please tell us about the experience of your patient transitioning from the Bridge trial.
   Prompts:

   Has your role as a mental health clinician changed? If so, how?

   How frequently do you have visits with this patient?

2) What worried you about this patient returning to your practice?
   Prompts:

   Cancer of physical health needs

   Mental health needs
   Poverty related barriers with coming to care

3) Any challenges with the transition in mental health care?

4) Any challenges with cancer care?

5) Any ongoing worries or concerns?

6) Anything else you would like to add?

7) How could the Bridge team best support this transition in care?
   Prompt:

   Would it help to have the ability for ongoing consultation related to cancer

   care/psycho-oncology after completing the study for clinicians?

8) What could be improved to better support the transition in care to community mental health?
   Prompts:

   Clarifying roles?

   Prescribing medication?

   Giving the patient and/or caregiver a treatment summary?

Direct communication with the oncology team?

Transition: Understanding that we all have limited time and resources, we are interested in your guidance about how to be most helpful to mental health clinicians caring for patients with mental illness and cancer.

1) What challenges do you face with communication with medical providers when your patients have acute/serious medical needs?
   Prompts:

   Difficulty with communicating across systems? (HIPAA)
   Structure of clinic and schedule does not allow for care coordination
   Lack of shared medical record?
   Limited time?

2) How has your experience as a mental health clinician for patients with serious mental illness changed during the pandemic?
   Prompts:

   Transition to telehealth?

   What is working better regarding communication with other clinicians?

   What has been more challenging regarding communication with other clinicians?

      Culture of your work environment and how reimbursement works for care coordination?
      Burden on you as a clinician and acuity of patients you are seeing?
      Limited time

3) How is the care in the collaborative care trial different from other experiences coordinating with mental health clinicians?
   Prompts:

   Different from your practice?

   Is there a need for an intervention like the Bridge trial in the community?

   What other initiatives are happening in your setting related to telehealth/covid?

4) To what extent do you feel like you can try new things to change your practice?

5) Anything else you would like to share?

Conclusion: Thank you for your time and feedback.

Section 3: DEMOGRAPHIC QUESTIONS

1. Please select your clinical discipline:

- ○ Licensed Mental Health Clinician
- ○ Social Work
- ○ Psychology
- ○ Psychiatry
- ○ Psychiatric Nurse Practitioner
- ○ Primary Care Provider
- ○ Other: _____

3. What year did you receive your license/start practicing independently? _____

5. Gender: _____

4. In what setting do you see patients clinically now? Please check all that apply.

- ☐ A private office
- ☐ Community mental health clinic
- ☐ Academic hospital
- ☐ Other: _____

5. During the pandemic (March 2020 through August 2021), what proportion of your visits have occurred virtually (using phone or video-conferencing technology?

- ○ Less than 25%
- ○ 25-50%
- ○ 50-75%

- 75-95%
- Nearly all visits

6. What proportion of those virtual visits (those by phone and videoconferencing) were by phone?

- Less than 25%
- 25-50%
- 50-75%
- 75-100%

7. Going forward, what proportion of your patients do you anticipate seeing using phone or video-conferencing technology?

- Less than 25%
- 25-50%
- 50-75%
- 75-95%
- Nearly all visits

8. Approximately how many patients with cancer and serious mental illness (schizophrenia, bipolar disorder, and/or major depressive disorder with prior psychiatric hospitalization) have you cared for?

- <5
- 5-10
- 10-50
- >50

9. How prepared do you feel to care for patients with cancer and serious mental illness?

- Very prepared
- Somewhat prepared
- Somewhat unprepared
- Not at all prepared

JJ.Qualitative Interviews Verbal Consent

Bridge: Proactive Psychiatry Consultation and Case Management for Patients with Cancer

Principal Investigator: Kelly Irwin, MD, MPH

Contact information: Call 617-643-4453

Purpose of the Research

It can be challenging to cope with cancer, and many people with illnesses like major depression, schizophrenia, and bipolar disorder face barriers to receiving quality cancer care. You may have already participated in our randomized controlled trial as a patient, caregiver, or mental health clinician in which we investigated if having a psychiatrist and case manager as part of a patient's team at the time of cancer diagnosis might improve cancer care
We are reaching out now to better understand your experience and learn more about barriers and challenges to accessing mental health and cancer care for people, families and caregivers affected by mental health and cancer across healthcare settings.

Study Information

We are asking you to participate in this study because we think you may help us better understand how to increase access to mental health and cancer care. All participants will undergo one approximately 30-minute, semi-structured, qualitative interview with trained study staff. This interview can be completed over the phone, by video call, or in-person, whichever is least burdensome.

With your permission, we will audio record this interview. These recordings will be used for data analysis purposes only. If you do not want to be recorded, you may still participate.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Potential Risks and Discomforts

This study does not have any physical risks. You will not be injured or become physically sick because of participating in this study. Some of the interview questions may be upsetting. If any of the questions upset you, you can talk to your doctor or members of the study team**.** If your responses indicate that you are in severe distress, a study clinician will call you to follow-up and assess your safety. At that point, you may be offered a referral to appropriate services, which you may accept or decline.

If your responses to the interview are audio-recorded, that data will be used only by study staff and will be protected by a password. Your identity will be kept confidential and we will be extremely careful to protect your privacy. Taking part in this interview will not lead to any costs to you or your insurance company.

Benefits

All study participants will receive $30 in cash or check, whichever your preference, to thank you for your time completing the interview. Your participation may also help us understand how to better help people who have mental illness and cancer, as well as how to better help their caregivers.

Confidentiality

There is little risk involved with study participation. We will be extremely careful to protect your privacy and health information by locking survey material and audio recorders in file cabinets and storing data and audio recordings on password protected computers. Only our study team can access this information. Your responses will be kept confidential. You can stop participating in the study at any time. If the results of this research study are published in a medical journal, they will not identify individual participants.

A Certificate of Confidentiality from the Department of Health and Human Services has been issued on this study as an additional protection of your privacy. Despite the study team's precautions, you will also need to also actively protect your own privacy.

Participation

Please note that participation in this study is completely voluntary and will not affect your medical care or at the Massachusetts General Hospital or your access to Department of Mental Health services. You can stop participating in the research study at any time. We appreciate your time and consideration.

Contact Information

If you have questions about the study, please contact:

Research assistant: Zoe Nelson (617-726-2297), M-F 9am-5pm.

Principal investigator (licensed psychiatrist): Dr. Kelly Irwin (617-643-4453)

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

DELPHI CONSENSUS METHOD

A. Clinician Introductory Email

Dear (Insert Name),

Based on your expertise in [breast, thoracic, gastrointestinal, or head and neck] cancer, Dr. Kelly Irwin hopes you will consider participating as a member of a Delphi consensus panel. The aim of this consensus panel is to create metrics to identify changes in [breast, thoracic, gastrointestinal, or head and neck] cancer care that could impact cancer outcomes (e.g. deviations from stage-appropriate treatment) for underrepresented and underserved populations.

The Delphi method is an iterative, multistage survey technique, which is commonly used in health and social sciences to generate group consensus from a panel of expert opinions. For more information on the Delphi method, please refer to (Hasson F, Keeney S, & McKenna H. Research Guidelines for the Delphi survey technique. Journal of Advanced Nursing. 2000: 32(4), 1008-1015).

The study will consist of 4 rounds of questionnaires, over the course of several months. We expect each survey to take no longer than 20 minutes to complete, and you will be compensated $100 for completion of all 4 rounds of questionnaires. The data collected from this survey will directly impact future cancer care research, as well as inform Dr. Irwin's trial on facilitating appropriate and effective collaborate care among cancer patients with mental illness.

If you have any other questions or concerns please do not hesitate to reach out to us directly at (study email).

Sincerely,

____