Mindfulness and Cognitive Behavioral Therapy for Sleep in Cancer

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Purpose of the Study

In this study, we will develop and pilot test the MBTI+ protocol for one-on-one, home-based delivery to hematologic cancer patients (i.e., acute myeloid leukemia, acute lymphoblastic leukemia, Non-Hodgkin's lymphoma, multiple myeloma, myelodysplastic syndrome) reporting insomnia, fatigue, pain, and distress after any cycle of inpatient chemotherapy treatment.

Study Phase I (months 0-6) will use patient (3 patient focus groups, approx. 4 patients in each focus group) and provider (1 provider focus groups, approx. 6 providers in focus groups) focus groups to adapt MBTI+ for individual treatment and improved symptom management. Intervention timing, scaling, and content will be further refined through iterative patient testing (months 6-12; N=5). The specific aims and hypotheses are:

Aim 1: To develop and refine the MBTI+ protocol for individual, home-based delivery to hematologic cancer patients reporting insomnia, fatigue, pain, and distress following discharge from any cycle of inpatient chemotherapy treatment. Patient (3 patient focus groups, approx. 4 patients in each focus group) and provider (1 provider focus groups, approx. 6 providers in focus groups) focus groups, along with theory and expert opinion, will inform intervention adaptation. The MBTI+ protocol will be refined through an iterative patient testing process (N=5). Hypothesis: These activities will result in a manualized MBTI+ protocol including patient materials (i.e., study workbook, study folder) and a structured therapist manual (e.g., timing, scaling, content) that can be used to standardize the intervention.

Study Phase II (months 12-36) will be a single-arm pilot (N=30). Patient-reported outcomes will be assessed at baseline, post-treatment, and 1-month follow-up. The specific aims and hypotheses are:

Aim 2: To assess the feasibility, acceptability, and examine pre- to post-intervention outcomes of MBTI+ (N=30). Hypothesis 1: MBTI+ will be feasible (≥80% completed sessions; ≤20% attrition) and acceptable (80% of participants reporting intervention satisfaction on Client Satisfaction Questionnaire); Hypothesis 2: Participants will evidence improvement in the primary outcome of insomnia symptoms; Hypothesis 3: Participants will evidence improvement in secondary outcomes: fatigue, pain, distress (i.e., anxiety, depression, hyperarousal), mindfulness, and self-efficacy for symptom management.

Background & Significance

Survival rates for hematologic cancer have increased with improved treatment. Unlike other cancers, treatment for hematologic malignancy often involves a rigorous 4 to 6-week hospitalization for induction chemotherapy. Patients who return home after undergoing this intensive inpatient treatment are left with significant sleep disturbance and persistent problems with fatigue, pain, and distress during the day. Rumination (i.e., anxiety and depressive symptoms, hyperarousal) about sleep problems can result in unhelpful responses that further exacerbate insomnia symptoms (e.g., napping/ extended time in bed, avoidance, medication use). As sleep quality worsens, cancer patients are more likely to have significant daytime fatigue, pain, and distress that interferes with valued work and family-related activities. Moreover, chronic insomnia puts cancer patients at elevated risk for disease progression.

Treatment for insomnia in cancer is typically pharmacological, despite research suggesting 1) these interventions are suboptimal for cancer patients, and 2) that behavioral interventions for insomnia are efficacious and cost-effective. Although insomnia and persistent daytime fatigue, pain, and distress are experienced by many hematologic cancer patients after demanding inpatient treatment regimens, there is very little research on behavioral interventions for addressing these problems. Thus, there is a critical need for symptom management interventions that specifically target both nighttime sleep disturbance and daytime fatigue, pain and distress in hematologic cancer patients after discharge home from inpatient chemotherapy.

Mindfulness-Based Therapy for Insomnia (MBTI) is a new treatment for insomnia. Delivered in a group setting, this intervention combines sleep restriction and stimulus control with mindfulness principles (e.g., non-striving, letting go, beginner's mind) and exercises (e.g., body scan, sitting and walking meditations) to treat insomnia, reduce rumination, and promote positive responses to poor sleep (e.g., less time in bed, nurturing activities, less medication). MBTI could be particularly beneficial to hematologic cancer patients who are prone to experience both nighttime sleep disturbance and daytime fatigue, pain, and distress in the months following discharge from inpatient treatment. However, MBTI has only been tested in healthy outpatients with insomnia where it evidenced a large pre-post effect size on insomnia symptom severity.

If MBTI is to meet the unique needs of hematologic cancer patients who have returned home after inpatient chemotherapy, it needs to be adapted in several ways. First, because hematologic cancer patients are immunosuppressed, MBTI needs to be adapted so it can be delivered in a one-to-one rather than group format. Second, because hematologic cancer patients often experience significant problems with fatigue, pain, and distress during the day, an adapted MBTI protocol needs to provide systematic training in skills for coping with these bothersome symptoms. An MBTI protocol that is specifically adapted to hematologic cancer could reduce the burden of insomnia and daytime symptoms (i.e., fatigue, pain, and distress) experienced by hematologic cancer patients in the months after they have completed inpatient chemotherapy treatment.

The proposed, adapted MBTI+ intervention is designed to meet the unique symptom needs of hematologic cancer patients returning home after inpatient chemotherapy. This intervention aims to reduce both insomnia and symptoms of fatigue, pain, and distress. Insomnia is considered a 24-hour disorder, with daytime consequences of nighttime sleeplessness being cited as one of the most upsetting aspects of insomnia. The proposed MBTI+ intervention is innovative in that it integrates training in strategies to address sleep disturbance at night, with training in skills for managing daytime symptoms of daytime fatigue pain and distress. Although the proposed MBTI+ intervention could be beneficial and have implications for improving the health-related quality of life of hematologic cancer patients, to date, MBTI+ has not been adapted for, or tested with this understudied cancer population.

We seek to provide researchers with a better understanding of the feasibility, acceptability, and preliminary efficacy of an adapted MBTI+ protocol for insomnia and daytime fatigue, pain, and distress in patients with hematologic cancer. Given the novel application to this population, it is essential to adapt the protocol to be minimally burdensome (e.g., remote treatment, flexible session scheduling,

and well-received [i.e., high completed sessions, retention, and satisfaction]). If pre- to post-intervention reductions to insomnia symptoms are observed, this would provide support for a larger, more rigorous randomized efficacy trial. Findings could also encourage researchers to extend MBTI+ to other cancer and chronic illness populations reporting insomnia and daytime fatigue, pain, and distress. Finally, positive results could have implications for clinical practice. Patients with hematologic cancer returning home after inpatient chemotherapy might be screened for insomnia, fatigue, pain, and distress, and then offered timely intervention with our MBTI+ protocol. Delivery of this intervention may offset indirect costs associated with insomnia (i.e., physical and psychological comorbidities, health care use, decreased work performance). Future work could assess the cost-effectiveness of the MBTI+ intervention.

Design & Procedures

The proposed project will include two phases: 1) intervention adaptation (Phase I); and 2) assessing feasibility (i.e., ≥80% complete sessions; attrition ≤20%) and acceptability (i.e., 80% of participants reporting intervention satisfaction on the Client Satisfaction), and examining pre- to post-intervention outcomes in hematologic cancer patients (Phase II).

Phase I: Focus Groups

Study staff will conduct three focus groups comprised of 4 hematologic cancer patients, and one provider focus group comprised of 6 medical providers (e.g., hematology-oncologist, physician assistant etc.). Using a semi-structured format, participants will be asked to evaluate the MBTI+ protocol by reviewing session handouts outlining educational content and behavioral strategies to address symptoms of insomnia, fatigue, pain, and distress. After reviewing handouts, participants will be prompted with direct and open-ended questions such as “When you read this, what did you think about? What changes, if any, would you make?” Participants will also be asked about preferences for intervention structure (i.e., individual delivery, session length etc.) and delivery modality (i.e., in-person, telephone, or videoconference), and to describe potential barriers to attendance. Particular attention will be focused on adapting the intervention to be acceptable for hematologic cancer patients experiencing a high symptom burden. We expect qualitative data derived from focus groups to result in a manualized protocol including patient materials (i.e., study workbook, folder) and a therapist manual (e.g., timing, scaling, content) tailored to the unique needs of patients with hematologic cancer. Focus groups will range in length from 45-75 minutes. Patients will be compensated $30, while providers will be compensated with a $15 Starbucks gift card. Focus groups will be conducted at the Duke Cancer Institute (DCI) or the offices of the Pain Prevention and Treatment Research Program (approx. 1 mile from DCI). If necessary, focus groups may be conducted remotely via video-conferencing. All focus groups will be audio recorded and transcribed verbatim by F32-awardee, Hannah Fisher PhD, or other study personnel, for supervision and qualitative analysis. Focus group recordings will be stored on a secured drive behind the Duke firewall. These recordings will be destroyed upon study completion. Following the focus group, patients will complete an assessment of insomnia (Insomnia Severity Index), fatigue (Fatigue Symptom Inventory), pain (Brief Pain Inventory-Short Form), and distress (Hospital Anxiety and Depression Scale). Demographic and medical information will be completed via medical record review.

Phase I: User Testing and Phase II: Single Arm Pilot

Initial feasibility and acceptability of MBTI+ will be assessed with 5 hematologic cancer participants recruited for user testing. Participants will be asked to complete six, 60- to 75-minute intervention sessions with a study therapist. Interventions sessions will be done in-person or via a videoconferencing program (i.e., Zoom), depending on feedback given during focus groups. Participants will be asked to complete daily sleep diaries before each session, and at the beginning of each session participants will be asked several questions about any recent cancer treatments, use of sleep and/or pain medication, and coping skill use. The study sessions will be audio recorded by the therapist using the program Voice Recorder. A subset of these recordings will be reviewed by the study PI and research team to improve the intervention and ensure therapist fidelity to the intervention. Sessions recordings will be stored on a secured drive behind the Duke firewall. These recordings will be destroyed upon study completion. There are three assessments we will ask all participants to complete. They each take about 30-40 minutes and include questions about the participant and their background, their cancer symptoms (e.g., insomnia, fatigue, pain), and their emotions (e.g., symptoms of depression, anxiety, hyperarousal). Participants will also be asked to give feedback on the sessions and intervention content; feedback will be used to make the intervention better for other patients who receive it in the future. The first survey is completed at the start of the study. The second survey is about 7 weeks later and the final survey is about 11 weeks after the start of the study. Study staff will be blinded to outcome assessments, as these will be completed online (i.e., via Redcap). Participants will receive $40 for completing each of the three study assessments. Total compensation may be up to $120.

Selection of Subjects

Eligibility criteria for patients included in Phase I and Phase II include:

1) an initial or recurrent/relapse diagnosis of acute myeloid leukemia, acute lymphoblastic leukemia, Non-Hodgkin's lymphoma, multiple myeloma, myelodysplastic syndrome
2) within 8 weeks of discharge home after inpatient chemotherapy or CAR-T therapy
3) score of 8 or greater on the Insomnia Severity Index (ISI);
4) score of 5 or greater on the MD Anderson Symptom Inventory Scale for "worst" fatigue or pain or distress, and report that these symptoms interfered with at least two activities of living (i.e., general activity, mood, work) in the last week at 3 or greater on a 0="Did not interfere" to 10="Interfered completely" scale
5) ability to speak and read English, and hearing and vision that allows for completion of sessions and assessments;
6) age of 18 years or older.

Exclusion criteria for patients included Phase I and Phase II include:

1) reported or suspected cognitive impairment subsequently informed by a Folstein Mini-Mental Status Examination of <25
2) presence of a serious psychiatric (e.g., schizophrenia, suicidal intent) or medical condition (e.g., seizure disorder, narcolepsy) indicated by medical chart, treating oncologist or other medical provider that would contraindicate safe participation
3) expected survival of 6 months or less.

Eligibility criteria for providers included in Phase I include:
1) Healthcare professional (e.g., oncologist, physician assistant, nurse) working within the Division of Hematological Malignancies and Cellular Therapy at Duke University Medical Center

In order to assess eligibility, basic patient information will be gathered through the use of electronic medical record database information (i.e., DEDUCE and MaestroCare) under a Waiver of Consent and HIPAA authorization. This information will allow the study team to assess whether or not the patient meets study inclusion criteria (see above) and provide the study team with the patients' name, provider's name, mailing address, phone number, and medical record number.

Subject Recruitment and Compensation

Recruitment will take place through the Duke Cancer Institute (DCI). Research and clinical care providers at the DCI are in support of recruitment for this study, including Thomas LeBlanc, MD, hematology-oncologist, and Cheyenne Corbett, PhD, LMFT, Director of DCI Psychosocial Services and the Cancer Patient Support Program. Recruitment procedures will comply with HIPAA regulations.

Provider recruitment will be facilitated by Thomas LeBlanc, MD, a hematology-oncologist and member of this study's mentoring committee. Dr. LeBlanc will invite his colleagues within the Division of Hematological Malignancies and Cellular Therapy to participate in the provider focus group. Interested providers will be contacted by F32-awardee and study coordinator, Hannah Fisher, PhD. Dr. Fisher will also deliver a brief presentation about the study to providers within the Division of Hematological Malignancies and Cellular Therapy to advertise the study. Time, format, and location for this presentation will be coordinated with Dr. LeBlanc.

For patient recruitment, the proposed study will follow the same recruitment procedures used in numerous federally funded projects by our research team in the Duke Pain Prevention and Treatment Research Program (PPTRP).

Under a HIPAA waiver, potentially eligible patients will be identified via electronic medical record review. Potential participants will be emailed directly and/or mailed a letter signed by their treating oncologist and study PI informing them about the study. The email or letter will state that a member of the study team may approach them in clinic at their next appointment; patients wishing not to be approached can call a number to opt out of the study. All study team members who are involved in recruitment (Dr. Fisher) have completed the required DOCR Recruitment and Engagement training. Confirmation of training completion has been attached to this application. Hematology-oncology providers will be recruited for the focus group directly through Dr. Thomas LeBlanc. Using a script that is compliant with IRB policies, a member of the study team will describe the study purpose, procedures, risks and benefits, and provide potential participants with an opportunity to ask questions, as well as assess participants' eligibility. Informed consent will be documented by signature on forms approved by the IRB for eligible and interested participants. If a member of the study team is unable to make contact with the participant during a clinic appointment (e.g., due to time constraints, COVID-19 restrictions), the participant will be informed that a member of the study team would like to contact him/her by telephone. In these cases, the eligibility screening and informed consent procedures will occur remotely,

via phone and/or videoconferencing. Eligible and interested participants who consent by phone will either: 1) complete an eConsent form via Redcap; or 2) be mailed two written consent forms (one for the participant and one to be returned to the research team via mail). This will be based on participant preference and convenience.

For those who decline participation, information will immediately be deleted from our records including their address and telephone number. However, we will retain their name and MRN so that we do not contact a person who has already declined participation. This will allow us to respect the wishes of the patients who do not want to be involved. We will delete the patient's name and MRN upon completion of enrollment. We will retain demographic information and basic medical information on patients who decline in order to see if we are systematically under including certain subgroups of the study population, which would limit our ability to generalize findings. This information will always be kept separate from direct identifiers. If a patient is not eligible or if he/she decides he/she is not/no longer interested in participating, the patient will be provided with psychosocial resources offered through DCI, if needed. Participants will be told they can discontinue participation at any time with no impact to their medical care.

Additionally, Duke patients with hematologic cancer are able to contact the study staff if they are interested in participating in this study.

Participants will be compensated $30 for participating in the focus group. Providers who participate in the focus group will be compensated with a $15 Starbucks giftcard. Participants recruited into user testing or the single-arm pilot will be compensated $40 for completing each of the three study assessments (i.e., baseline, post-intervention, 1-month follow-up) for a maximum compensation of $120.

Demographic and Medical Variables Collected from Medical Record: These variables will be collected one time when a potential patient is identified for the study under a Waiver of HIPAA authorization. Demographic and medical variables will be collected from electronic medical records (via DEDUCE and Maestro Care) and include the patients' MRN, name, sex, age, marital status, education, race, address, telephone number, cancer type, date of diagnosis, cancer stage, and cancer treatments received. As noted previously, for those who decline, identifying information will immediately be deleted from our records including their address and telephone number. However, we will retain their name and MRN so that we do not contact a person who has already declined participation. We will delete the patient's name and MRN upon completion of enrollment. We will retain demographic information and basic medical information on patients who decline participation in order to see if we are systematically under including certain subgroups of the study population, which would limit our ability to generalize findings. This information will always be kept separate from direct identifiers.

Self-Report Measures. Participants will complete online assessments of primary and secondary outcome measures at all time points (i.e., baseline, post-intervention, 1-month follow-up). These measures have been extensively tested in cancer populations and demonstrate good reliability and validity evidence. We specifically selected measures that are brief to reduce participant burden. Our preliminary data suggests these assessments take a total of 30 minutes to complete.

Primary Outcome. Insomnia. Insomnia symptoms will be measured using the Insomnia Severity Index (ISI).33 The ISI consists of three items assessing difficulty falling asleep, staying asleep, and waking up too early in the past two weeks. The ISI uses a 5-point response scale, with options ranging from 0 (no difficulty) to 4 (very severe difficulty). The ISI also includes four items assessing satisfaction/dissatisfaction with sleep, how noticeably insomnia is impairing quality of life, distress regarding current sleep disturbance, and interference to daily functioning. The ISI has exhibited good reliability and validity in cancer populations and is recommended for studies targeting insomnia symptoms.

Secondary Outcomes. Sleep. Sleep will be assessed using the 9-item Whole Week Self-Assessment of Sleep Survey (SASS). This is a retrospective version of the Consensus Sleep Diary from Carney et al. (2012) and includes questions that assess average bedtime, risetime ,and sleep quality across the past week (Dietch, Sethi, Slavish, & Taylor, 2019). Fatigue. Fatigue (i.e., severity and interference) will be assessed using the Fatigue Symptom Inventory (FSI), which was developed for and validated in cancer patients. The FSI consists of four items assessing fatigue (worst, least, average, and current fatigue) and seven items assessing fatigue interference in the past week. The FSI includes an 11-point response scale, with options ranging from 0 (no fatigue or no interference) to 10 (fatigue as bad as you can imagine or completely interferences). The FSI is often used in cancer populations and has evidenced excellent reliability and validity. Pain. Pain (i.e., severity and interference) will be measured using the Brief Pain Inventory-Short Form (BPI-SF). The BPI-SF consists of four items assessing pain (worst, least, average, and current pain) and seven items assessing pain interference in the past week. The BPI-SF includes an 11-point response scale, with options ranging from 0 (no pain or no interference) to 10 (pain as bad as you can imagine or completely interferes). The BPI-SF has demonstrated good reliability and validity in prior studies investigating pain severity and interference in cancer patients. Distress. Anxiety and Depressive Symptoms. Anxiety and depressive symptoms will be measured using the 14-item Hospital Anxiety and Depression Scale (HADS). The HADS consists of two 7-item subscales assessing anxiety and depressive symptoms in the past week. Items are rated using an 4-point response scale. The HADS has demonstrated adequate reliability and validity in cancer populations. Hyperarousal. Hyperarousal will be measured using the 16-item Pre-Sleep Arousal Scale (PSAS), which assesses cognitive and somatic arousal before sleep in the past week. The PSAS uses a 5-point scale, with response items ranging from 1 (not at all) to 5 (extremely). The PSAS has demonstrated good reliability and validity in studies targeting insomnia symptoms, and has been used in cancer populations. Mindfulness. Mindfulness skills (e.g., observing, describing, etc.) will be measured using the 39-item Kentucky Inventory of Mindfulness Skills (KIMS). Response options range from 1 (never/very rarely true) to 5 (very often/always true). The KIMS has adequate reliability and validity in cancer samples, and has been used in studies exploring mindfulness-based interventions for insomnia. Self-efficacy for symptom management. Self-efficacy for symptom management will be measured using the Self-Efficacy for Management Chronic Disease scale. This 6-item scale will assess participants' confidence regarding management of symptoms, medication use, and doctor visits. Response options range from 1 (not at all confidence) to 10 (totally confident). An additional item will be added to assess self-efficacy for managing insomnia. This scale has been shown to have excellent validity and reliability in cancer populations.

Treatment Feasibility and Acceptability. Feasibility. Feasibility will be assessed by session attendance (≥80%) and attrition (≤ 20%). Acceptability. Satisfaction will be measured post-intervention using the Client Satisfaction Questionnaire 8-item version. The scale includes eight items assessing the participant's level of satisfaction with treatment, with response options ranging from 1 (quite dissatisfied) to 4 (very satisfied). Acceptability will be demonstrated by 80% of participants reporting intervention satisfaction on the Client Satisfaction Questionnaire. Engagement in the intervention will be assessed at the beginning of sessions 3 and 6, and post-intervention follow-up. The participant will be asked about his or her coping skills practice and completion of homework assignments from the previous time point. These data will be recorded by the study therapist in RedCap.

Demographics and Medical Information: At baseline, participants will report their education, household income, employment status, and history of comorbidities (e.g., hypertension, heart disease). At each assessment, participants will also be asked about their cancer treatments in the last 7 days (chemotherapy, radiation, surgery, hormone therapy, vaccine, pill anti-cancer drug) and how many days in the last 7 they have taken any type of pain and/or sleep medication.

Risk/Benefit Assessment

Risks:
In the proposed study, the risks to participants are minimal and primarily include psychological distress and breach of confidentiality. Participants will be asked about their thoughts and feelings about their cancer; thus, it is possible that they may experience distress. The psychological risk associated with answering questions and participating in the intervention is expected to be minimal. Although some participants may find certain questions or topics to be upsetting, heightened awareness of existing psychosocial and practical needs may be the first step in resolving these concerns. The recruitment letter clearly acknowledges the voluntary nature of participation and patients will have the ability to decline further contact from study personnel (i.e., to opt out). Participants will be fully informed about the study during the informed consent process and instructed to decline to answer any question or to discuss any issues they find troubling. If a participant reports significant distress during study participation, Dr. Somers (licensed clinical psychologists) will be consulted. If the participant requires additional treatment, appropriate referrals will be made. The study team has extensive experience conducting psychosocial intervention trials with cancer patients and have not encountered significant psychological distress caused by study participation. Moreover, cancer patients and their family caregivers often report benefits from participating in psychosocial research. Thus, the risk of psychological distress is modest and the safeguards should be adequate. Breach of confidentiality is another possible risk. This is clearly stated in the consent form. All efforts will be made to maintain confidentiality. Participants' data and research records will be carefully stored. All study personnel will be required to complete courses and ongoing training in protecting participant confidentiality.

The adapted MBTI intervention involves sleep consolidation and reconditioning exercises. Although unexpected, it is possible that these sleep strategies may result in increased daytime sleepiness, and some problems with mood and/or slowed thinking during treatment; however, these effects are primarily restricted to the early stages of treatment, when behavioral therapies are introduced, and improve over time, typically resolving by the end of treatment.

If patients are not interested in study participation but are interested in supportive services, they will be given information on the extensive, free resources available to them through the Duke Cancer Patient Support Program. These resources range from psychotherapy to financial and legal services. These resources will also be described to those who enroll in the study, regardless of their assigned study condition.

The risks to providers are minimal and primarily include psychological distress and breach of confidentiality. Providers will be asked to evaluate the MBTI+ protocol by reviewing session handouts outlining educational content and behavioral strategies to address cancer symptoms (e.g., insomnia, fatigue, pain, and distress). Providers will also be asked about preferences for intervention structure (i.e., individual delivery, session length etc.) and delivery modality (i.e., in-person, telephone, or videoconference), and to describe potential barriers to attendance. These questions are unlikely to cause psychological distress, however, providers will be reminded that they can decline to answer any question or to discuss any issues they find troubling. Breach of confidentiality is another possible risk. This is clearly stated in the consent form. All efforts will be made to maintain confidentiality. Participants' data and research records will be carefully stored. All study personnel will be required to complete courses and ongoing training in protecting participant confidentiality.

Benefits:
There are numerous potential benefits of the proposed research. Providers and hematologic cancer patients who participate in the focus group may learn about skills that can help reduce nighttime sleep disturbances and daytime symptoms of fatigue, pain, and psychological stress. Participants who participate in user testing or the single-arm pilot will receive a mindfulness and cognitive-behavioral intervention at no cost. As demonstrated in prior mindfulness and behavioral symptom management studies, the proposed intervention may lead to improvements in patients' nighttime sleep and daytime symptoms of fatigue, pain, and distress. Furthermore, information learned from this study may benefit other patients with cancer in the future. Lessons learned will provide a foundation for subsequent larger, methodologically rigorous, randomized efficacy trials of adapted MBTI. This research program could also serve an heuristic purpose in encouraging researchers to extend adapted MBTI to other cancer and chronic illness populations reporting insomnia and daytime fatigue, pain, and distress. Future work might examine the effects of adapted MBTI on neuroendocrine and immune markers that are linked to sleep and have implications for cancer progression

Data Analysis & Statistical Considerations

Sample size and statistical power: Part 1 of Phase I will include three focus groups comprised of 4 patients and one provider focus group comprised of 6 medical providers. User testing (Part 2, Phase I) will involve 5 patients. This sample size is based on our prior work using focus groups in the hematology-oncology setting.27 Research suggests that 2-3 focus groups are sufficient to reveal 80% of themes.70 If the intervention content is not significantly altered during user testing, these participants will be combined with those from Phase II for an intent-to-treat sample of 35 participants.

Analytic Plan

Aim 1: Focus groups with hematologic cancer patients and their providers will be transcribed verbatim and analyzed using Atlas.ti. An initial coding scheme will be developed based on a review of literature, our research goals, and prior work, as well as themes that emerged during focus groups. The codes will be applied to the transcripts in Atlas.ti. Two independent individuals, including Dr. Fisher, will code each transcript to ensure similar understanding of the codes and consistency in judgement.72 As part of the training plan, Dr. Fisher will complete several workshops on analyzing qualitative data. Additionally, the study sponsors and the mentoring team have extensive experience with qualitative analyses, and access to a shared resource of qualitative experts to assist with these analyses and any challenges that may arise.

Aim 2: Feasibility (i.e., ≥80% of sessions completed; attrition ≤ 20%) and acceptability (i.e., 80% of participants reporting intervention satisfaction on the Client Satisfaction Questionnaire, participant completion of homework assignments) data will be examined using descriptive statistics (mean, median, standard deviation, percent etc.). Paired sample t-tests will be run to quantify the degree of change over time for all primary and secondary outcomes. Effect sizes will be computed using Cohen's d. Unconditional latent growth models will be used to assess main time effects across baseline, post-treatment, and 1-month follow-up. Time will be coded as the number of months since the baseline assessment. Determination of linear versus quadratic change will be made by comparing the relative fit of the two models using the Bayesian Information Criterion, as recommended. Control variables and their interactions with time will be included in the conditional models. Analyses will be conducted on an intent-to-treat basis to make use of all available data (N=35).

Data & Safety Monitoring

The proposed study carries minimal risk. The protocol does not use an investigational drug, procedure, or device. Data obtained from participants will include information from medical chart review, patient and provider focus groups, and self-report inventories. The study team considers the management of participant information and data as a key priority. Best practices for confidentiality and data management will be observed.