MSK PROTOCOL COVER SHEET

Pilot Trial of Telehealth Music Therapy for Cognitive Dysfunction in Hematologic Cancer Survivors (PRELUDE)

Principal Investigator/Department: Kevin Liou, MD/Medicine

MT = music therapy

TAME = therapist attention-music education

WLC = wait-list control

CRCD = cancer-related cognitive dysfunction

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1.0 PROTOCOL SUMMARY AND/OR SCHEMA

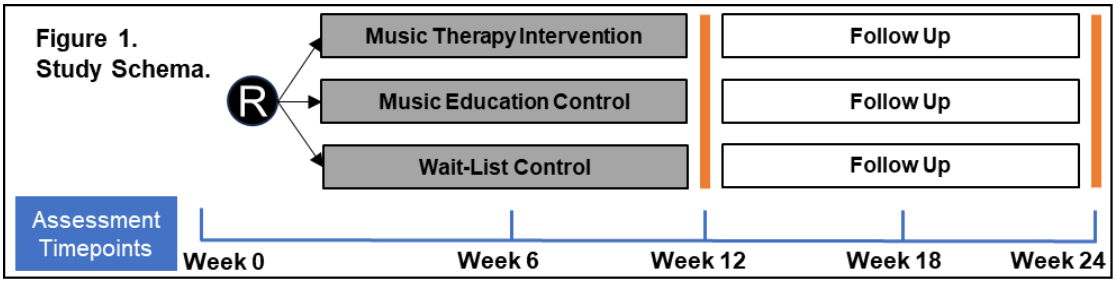
Over 30% of hematologic cancer survivors experience cancer-related cognitive dysfunction (CRCD).[1-4] Characterized by problems with attention, memory, and/or executive function,[5] CRCD disrupts daily activities, worsens quality of life,[6] and is associated with worse median survival in hematologic cancer survivors.[1] Despite these devastating consequences, existing CRCD treatments are limited.[7,8]

Music therapy (MT) is an evidence-based intervention, in which board-certified therapists engage patients in tailored music experiences to achieve therapeutic goals.[9] These experiences range from receptive activities (e.g., guided music listening) to more active engagement (e.g., playing instruments). While MT is recommended for psychological distress in clinical guidelines from the National Comprehensive Cancer Network (NCCN),[10] American Society of Clinical Oncology (ASCO),[11,12] and Society for Integrative Oncology (SIO),[12-14] its role in treating CRCD is not well-studied. In non-cancer populations, musical training has been shown to improve cognitive performance, even in people without musical backgrounds.[15-20] However, no studies have applied this promising research to investigate MT for CRCD in hematologic cancer survivors, highlighting an untapped scientific opportunity.

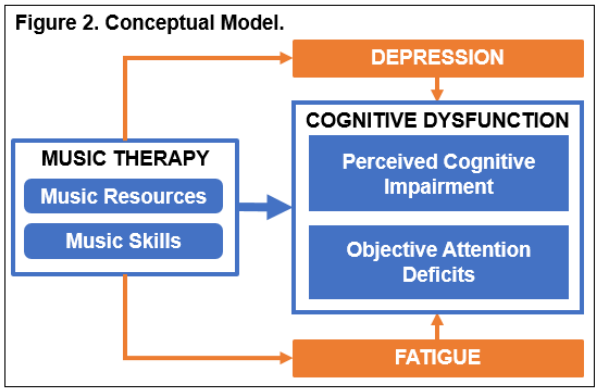
In our ongoing randomized clinical trial comparing MT versus cognitive behavioral therapy for anxiety in cancer survivors,[21] 60 (62.5%) of the 96 survivors randomized to MT reported a FACT-Cog perceived cognitive impairment (PCI) subscale score of <54, indicating clinically significant CRCD.[22] *Among these 60 MT recipient (including 16.7% with hematologic malignancies), the FACT-Cog PCI score improved by 7.9 from baseline to week 8 (end of MT treatment) and further improved by 8.9 from baseline to week 26, exceeding the minimum clinically important difference (MCID) of 7.4 at both timepoints*.[23] These preliminary findings provide proof-of-concept that MT can produce clinically meaningful and durable improvements in CRCD among cancer survivors.

Building on this work, we assembled a multi-disciplinary team to propose the Pilot Trial of Telehealth Music Therapy for Cognitive Dysfunction in Hematologic Cancer Survivors (PRELUDE). The overarching goal is to determine the feasibility of studying MT for CRCD and establish the groundwork for a well-powered efficacy trial with the potential to improve the standard of care for CRCD in hematologic cancer survivors.

We will conduct a pilot RCT randomizing N=60 to MT, therapist attention-music education (TAME) control, or wait list control (WLC) in a 1:1:1 ratio (Figure 1).



The ORBIT model of behavioral intervention development posits that feasibility testing should precede efficacy testing to enhance methodological rigor.[24] Thus, the primary aim is to determine feasibility. The secondary aim is to explore within-group changes in CRCD and co-morbid symptoms, as informed by our conceptual model (Figure 2).



2.0 OBJECTIVES AND SCIENTIFIC AIMS

- **Primary Aim: To determine the feasibility of studying a telehealth-based MT intervention for CRCD in hematologic cancer survivors.** We will randomize 60 survivors of hematologic cancers (lymphoma, leukemia, myeloma) to 12 weeks of a weekly 1-hour telehealth MT intervention, a therapist attention-music education (TAME) control, or a waitlist control (WLC) group in a 1:1:1 ratio, with assessments at baseline, Week 12 (end of treatment), and Week 24. We will assess *a priori* quantitative benchmarks (i.e., treatment adherence) to determine the feasibility of conducting an efficacy trial. We will also collect descriptive statistics on recruitment/enrollment, fidelity of treatment delivery, and assessment completion rates to inform future trial design.

- **Secondary Aim: To explore the preliminary effects of a telehealth-based MT intervention, as well as its TAME and WLC comparators, on CRCD and co-morbid symptoms.** We will administer validated, patient-reported outcomes for CRCD and co-morbid symptoms (anxiety, depression, fatigue), as well as an objective neurocognitive battery. We

will examine within-group changes in these outcomes to inform the design of a rigorous efficacy trial.

Tertiary Aim (exploratory): we will explore: 1) associations between co-morbid symptoms (HADS, BFI) and CRCD (FACT-Cog, HVLT-R, ANT); and 2) improvement in objective attention (HVLT-R Trial 1, ANT variables) as a predictor of treatment response (≥FACT-Cog MCID value).

3.0 BACKGROUND AND RATIONALE

3.1 Cancer-Related Cognitive Dysfunction: A Prevalent, Debilitating Condition with Limited Treatments.

Characterized by problems with attention, memory, or executive function,[5] CRCD affects 35-70% of hematologic cancer survivors,[1-4] resulting in difficulties with work responsibilities and other daily activities.[6] *CRCD is one of the top two unmet needs for which hematologic cancer survivors are seeking help*.[25] CRCD is also associated with worse median survival in this population, highlighting its importance for long-term cancer-related outcomes.[1]

Unfortunately, existing CRCD treatments are limited. Medications, such as modafinil,[26-28] donepezil,[29] methylphenidate,[30] memantine,[31] and gingko biloba[32] have shown poor or mixed results.[5,7] Polypharmacy is also a growing concern in cancer survivors,[33-35] with 64% already taking five or more medications.[36] The NCCN recommends medications as a last line option for CRCD.[37] Non-pharmacologic interventions, such as cognitive rehabilitation,[38-42] physical activity,[43-47] yoga,[48-50] qi gong,[51] and mindfulness techniques,[52,53] have shown more promise, but most studies were conducted in breast cancer and require further investigation in larger trials with rigorous controls to determine efficacy.[8]

These treatment challenges are further complicated by the *entanglement of CRCD with co-morbid symptoms*, particularly anxiety, depression, and fatigue.[54-57] These symptoms are not only prevalent in hematologic cancer survivors[25,58,59] but are also known to impair cognitive function.[60-65] If inadequately addressed, these co-morbid symptoms could exacerbate CRCD and impede treatment efforts. Furthermore, high symptom burden is a well-documented barrier to engaging in non-pharmacological interventions.[66,67] Despite the cognitive benefits of exercise and cognitive rehabilitation, 75% of cancer survivors do not meet physical activity guidelines,[68] and 73% of survivors are unable to complete a cognitive rehabilitation program in the recommended timeframe.[69] *These challenges highlight the need for other accessible, non-pharmacological CRCD interventions with the capacity to jointly target co-morbid symptoms and spark motivation and engagement among survivors.*

3.2 Music Therapy: A Promising Therapy for CRCD and Co-Morbid Symptoms.

Music therapy (MT) is an evidence-based intervention, in which board-certified music therapists guide patients through personalized experiences with music to achieve therapeutic

goals. These experiences range from receptive activities, such as guided music listening, to more active forms of musical engagement, such playing an instrument.[9]

MT has a growing evidence base for cancer symptom management.[70-72] In a recent Cochrane review on MT in oncology (81 studies, N=5576 patients), MT demonstrated benefits for *anxiety* (mean -7.7 units on Spielberger State Anxiety Inventory, 95% CI - 10.0 to - 5.4), *depression* (standardized mean difference [SMD] -0.4, 95% CI -0.7 to -0.2), and *fatigue* (SMD -0.3, 95% CI -0.5 to -0.1).[73] MT is also recommended for psychological distress in cancer care guidelines,[10-14] including a recent joint guideline from ASCO and SIO.[12] *This literature suggests MT could improve CRCD indirectly by reducing co-morbid anxiety, depression, and fatigue, which are known to impair cognitive functioning*.[60-65] While the direct effects of MT on CRCD has not been studied, substantial research exists on the cognitive benefits of music in non-cancer populations.[18,20] Listening to some forms of background music enhances attention on certain tasks.[74-76] Furthermore, music training is associated with structural and functional changes in brain regions responsible for attention, memory, learning, executive functioning, motor coordination, and visuo-auditory processing.[16] In a randomized clinical trial of 31 musically naïve older adults without cancer, individualized piano instruction improved objective cognitive performance on the Trail Making and Digit Symbol tests, which measure attention and other cognitive functions.[17] *These findings align with observed cognitive benefits in other music training interventions*[15,18-20,77-79] *and suggest that MT with music training components could directly improve CRCD*. Despite these promising findings, no studies have applied this research to investigate MT for CRCD in hematologic cancer survivors, highlighting an untapped scientific opportunity.

Up to 90% of people with cancer routinely turn to music for self-care.[80-83] This near-universal appeal of music could be explained by the effects of music on the brain's reward centers underlying pleasure and motivation.[84,85] The reward-inducing aspects of music represent a distinct advantage of MT that may help cancer patients overcome the burden of initiating and adhering to non-pharmacological CRCD interventions.

3.3. Digital Transformation as a Powerful Catalyst for Music Therapy.

MT was historically an in-person service; however, during the pandemic, the American Music Therapy Association disseminated guidelines to help the MT workforce pivot to telehealth.[86,87] As a result, the percentage of MT services delivered remotely increased from 2.6% pre-pandemic to 46% during the pandemic.[88] Many MT practices continue to maintain online platforms,[89,90] including in oncology settings.[91] While key disparities in digital access remain,[92] the digital transformation of MT offers promising avenues to reduce treatment barriers.

Paralleling the shift of MT to telehealth, music consumption has migrated from physical assets (e.g., records, CDs) to online streaming platforms (e.g., Amazon Music),[93] enabling on-demand access to millions of songs.[94] Nearly 80% of music listeners now stream music online.[93] This shift has not only democratized access to music as a wellness resource, but also equipped music therapists with more tools than ever before to help patients engage with

music in their daily lives. Importantly, MT is widely available at 74% of NCI-designated Comprehensive Cancer Centers,[95] and the MT workforce has doubled in the past decade,[88,96] highlighting the scalability of MT.

3.4. Summary of Significance.

CRCD is prevalent, debilitating, and associated with worse median survival in hematologic cancer survivors.[1-4] Existing CRCD treatments are limited and not well-studied in hematologic cancer survivors.[37] *The PRELUDE study is the first randomized controlled trial (RCT) to investigate a telehealth-based MT intervention for CRCD in hematologic cancer survivors.* Our innovative approach tackles key limitations of existing CRCD treatments. First, our MT intervention targets CRCD both directly and indirectly by reducing anxiety, depression, or fatigue. Given that these co-morbid symptoms impair cognition function,[60-65] addressing them jointly with CRCD has the potential to further improve cognitive outcomes. Second, in contrast to the burdensome nature of other non-pharmacological interventions, our MT intervention is designed to spark joy through a personalized approach featuring music that resonates with each individual.[84,85] Leveraging the reward-inducing properties of music will motivate patients to adhere to our MT intervention and enhance cognitive benefits. Lastly, our study capitalizes on key trends in telehealth[97,98] and music streaming[94] to increase accessibility and reduce treatment barriers. *If feasibility is demonstrated, the PRELUDE study will establish the groundwork for an efficacy trial with potential to improve standard of care for CRCD in hematologic cancer survivors.*

4.0 OVERVIEW OF STUDY DESIGN/INTERVENTION

4.1 Design

Study Design. We will conduct a pilot RCT randomizing N=60 to MT, TAME control, or WLC in a 1:1:1 ratio (Figure 2). The ORBIT model of behavioral intervention development posits that feasibility testing should precede efficacy testing to enhance methodological rigor.[24] Thus, the primary aim is to determine feasibility. The secondary aim is to explore within-group changes in CRCD and co-morbid symptoms, as informed by our conceptual model (Figure 1).

- Population: Hematologic cancer survivors with cancer-related cognitive dysfunction (CRCD).
- Intervention: Music therapy intervention with therapeutic music lessons as the active component.
- Comparators: Therapist attention-music education and waitlist controls.
- Outcome: Subjective and objective CRCD.
- Time: 24 weeks.

5.0 THERAPEUTIC/DIAGNOSTIC AGENTS & NON-THERAPEUTIC ASSESSMENTS

MT and TAME control are non-pharmacological interventions that do not involve the use of any therapeutic agents or devices. Non-therapeutic assessments are outlined below. Participants will receive $20 gift cards after the completion of assessments at each of timepoints (baseline and weeks 6, 12, 18, and 24) for a total of up to $100.

Patient-Reported Outcomes (PROs)

We will assess subjective CRCD using FACT-Cog PCI subscale,[99,100] which has demonstrated reliability (Cronbach's α 0.94)[23] and is considered an ecologically valid CRCD measure.[101] We will assess anxiety and depression with Hospital Anxiety and Depression Scale (HADS). Its reliability and validity is established in cancer patients with Cronbach's α of 0.83 (anxiety) and 0.79 (depression).[102,103] We will assess fatigue using Brief Fatigue Inventory (BFI), a reliable measure validated in cancer populations with Cronbach's α of 0.96.[104] To assess feasibility and gain insight into preferred methods of completing assessments, we will allow patients to complete these on REDCap,[105] by phone, or using texts. If patients opt to receive study-specific text communications, they may receive text messages with reminders about surveys, direct links to REDCap to complete the surveys, or prompts to complete surveys by text. Text-based communications will be delivered using the secure, HIPAA-compliant Mosio texting platform developed specifically for clinical research. PROs will be assessed at weeks 0, 6, 12, 18, and 24 and will take participants approximately 10-15 minutes to complete (Table 2).

Objective Neurocognitive Testing

Given the discrepancies between subjective and objective CRCD measures,[106] we will remotely administer CogSuite, an objective neurocognitive battery on weeks 0, 12, and 24 (+/- 2 week window) to gain a better understanding of potential MT effects (Appendix B). The Attention Network Task (ANT) will serve as the primary measure of attention.[110] In the ANT, participants try to determine, as quickly and accurately as possible, the correct direction of an arrow on a screen in conditions involving correct or incorrect cues. ANT assesses reaction times, global accuracy, and intra-individual variability in these measures, with higher variability reflecting more attentional deficits. Detection of intra-individual variability and subtle attentional sub-processes are unique ANT features that provide more insight into our primary target of attention, which is not well-captured with traditional list-learning tasks. The other CogSuite tests will measure executive function, working memory, verbal fluency, and processing speed, all of which will provide a broader context for interpreting the ANT results. CogSuite has been studied and validated in cancer populations.[110,112] The neurocognitive testing takes approximately 1 hour to complete.

Covariates

At week 0, we will assess socio-demographic (age, sex, race, ethnicity, education)[113] by self-report and clinical characteristics (cancer type, stage, treatment, years since diagnosis) by chart abstraction. We will administer Barcelona Music Reward Questionnaire (Cronbach's α=0.92) at week 0 to assess pleasure associated with music, which may affect responses to MT or TAME.[114] We will track use of sedative, stimulant, or anticholinergic medications, as well as other CRCD interventions, using one-week diaries (treatment name/dose/frequency)

at weeks 0, 12, and 24 (+/- 2 week window) in Appendix F. The patient can choose any 7 consecutive days within the week window for each visit. The diary takes approximately 2 minutes to complete daily. Finally, patients in the MT and TAME groups will complete a Treatment Credibility Scale at Week 6 to assess their views towards the interventions and success of masking to treatment assignment; the scale takes less than 2 minutes to complete

6.0 CRITERIA FOR PARTICIPANT ELIGIBILITY

6.1 Participant Inclusion Criteria

- English-proficient, aged 18 or older
- Diagnosis of lymphoma, leukemia, or myeloma
- Stable oncologic disease or no evidence of disease as indicated in the medical chart or by the oncology team
- Score of <54 on the FACT-Cog PCI subscale
- Minimum life expectancy of one year as per clinician assessment
- Patient should be able to understand and complete all study assessments on their own.
- Eligible patient should be able to understand informed consent and provide signed informed consent in English.

6.2 Participant Exclusion Criteria

- Less than 3 months since completion of surgery, radiation, induction chemotherapy (for newly diagnosed or relapsed disease), transplantation, or immunotherapy (e.g., CAR T-Cell, bispecific antibodies)
    - If there is a defined treatment period, the patient must be at least 3 months from treatment completion
    - If the patient is on continuous therapy, patient must have completed at least 6 months of the therapy
    - Maintenance therapies are allowed
- Received music therapy (MT) in the past year
- Current music training, >6 months of music training in the past 10 years, or plan to initiate music training during the study
- No access to an internet-connected device
- Active suicidal ideation, bipolar, schizophrenia, or substance abuse
- BOMC score ≥10 (indicative of dementia)
- Uncorrectable visual, auditory, or motor impairments

- Initiation or altered dose of sedative, stimulant, or anti-cholinergic medications in the past month or plan to initiate these medications during the study, as these are known to impact cognitive function
- Initiation of any other interventions for CRCD (e.g., cognitive rehabilitation) in the past month or plan to initiate these interventions during the study, as these are known to impact cognitive function

7.0 RECRUITMENT PLAN

We plan to recruit patients at Memorial Sloan Kettering Cancer Center (MSK) and all OneMSK locations. Each year, over 1,000 hematologic cancer patients' complete treatment and transition to survivorship care at MSK. Around 30% of survivors experience CRCD,[1-4] leaving 300 potential participants. Of these, we anticipate 20% will be willing to participate, based on our ongoing MT trial.[21] These conservative estimates yield 60 survivors will be potentially eligible and interested each year, which supports our accrual target, N=60.

Population-based methods: We will review the clinic appointment lists of clinicians to identify hematologic survivors who meet basic eligibility criteria. We will also query patient databases to identify survivors who meet basic eligibility criteria. We will then distribute a recruitment message to these potentially eligible patients. The recruitment message will introduce the study and provide instructions for interested patients to contact the study team if they are interested in learning more. The message will also provide patients with an opt-out instructions if they do not wish to participate or be contacted further about the study. The recruitment message will be disseminated via physical mail, phone call, text-based communication, or patient portal. There is growing research that multi-channel distribution of study-related information (particularly text-based communications) is critical to promote greater inclusion in clinical research and reach under-served populations who may not otherwise learn about research opportunities through traditional methods. All text-based communications will be delivered using the secure, HIPAA-compliant Mosio texting platform, which was developed specifically for clinical research, with an option for opting out of receiving future text messages.

Clinician referrals: The study team will educate clinical stakeholders about the study protocol and provide information about eligibility criteria to facilitate study referrals.

Public and community outreach: We will disseminate study information on clinicaltrials.gov, as well as MSK's websites and social media channels. In the future we may also use brochures at clinics or community sites to increase recruitment if needed. Permission from all sites will be obtained before posting in any location. We will also hold engagement events with MSK's community partners, including but not limited to Red Door Community.

Potential research subjects will be identified by a member of the patient's treatment team, the protocol investigator, or research team at Memorial Sloan Kettering (MSK). If the investigator is a member of the treatment team, they will screen their patient's medical records for suitable research study participants and discuss the study and their potential for enrolling in the research study. Potential participants contacted by their treating physician will

be referred to the investigator/research staff of the study. The principal investigator may also screen the medical records of patients with whom they do not have a treatment relationship for the limited purpose of identifying patients who would be eligible to enroll in the study and to record appropriate contact information in order to approach these patients regarding the possibility of enrolling in the study.

During the initial conversation between the investigator/research staff and the patient, the patient may be asked to provide certain health information that is necessary to the recruitment and enrollment process. The investigator/research staff may also review portions of their medical records at MSK in order to further assess eligibility. They will use the information provided by the patient and/or medical record to confirm that the patient is eligible and to contact the patient regarding study enrollment. If the patient turns out to be ineligible for the research study, the research staff will destroy all information collected on the patient during the initial conversation and medical records review, except for any information that must be maintained for screening log purposes.

In most cases, the initial contact with the prospective subject will be conducted either by the treatment team, investigator or the research staff working in consultation with the treatment team. The recruitment process outlined presents no more than minimal risk to the privacy of the patients who are screened and minimal PHI will be maintained as part of a screening log. For these reasons, a (partial) limited waiver of authorization for the purposes of (1) reviewing medical records to identify potential research subjects and obtain information relevant to the enrollment process; (2) conversing with patients regarding possible enrollment; (3) handling of PHI contained within those records and provided by the potential subjects; and (4) maintaining information in a screening log of patients approached (if applicable) is being requested.

All applicable protected health identifiers (PHI) to be collected for the purposes of recruitment will be marked with an “X”:

Names	X
Medical Record Numbers (MRN)	X
Dates (all elements of dates [except year] for dates related to an individual, including: birth date, admission date, discharge date, date of death, all ages over 89, and all elements of data [including year] indicative of such age)	X
Any other unique identifying numbers, characteristics, or codes (e.g., Pathology Session Numbers)	X

If any of the following identifiers are selected, a reason must be included in the last row.

Vehicle identifiers and serial numbers (license plates)	☐
Device identifiers and serial numbers	☐
Web universal resource locators (URLs)	☐
Biometric identifiers, including finger- and voiceprints	☐
Full-face photographic images and anything comparable	☐

All geographic subdivisions smaller than a state, including: street address, city, county precinct, zip codes and their equivalent geocodes, except the initial three digits of a zip	☐
Telephone and/or fax numbers	X
E-mail addresses	X
Social Security Numbers	☐
Health plan beneficiary numbers	☐
Account numbers	☐
Certificate/license numbers	☐
Internet Protocol (IP) address numbers	☐
Reason for request: We will request phone numbers and email addresses in order for us to make initial contact with participants and assess their interest in participating in the study. Enabling multiple channels for communication has been shown to facilitate recruitment and offer more convenience for potential participants. We will not make more than 3 attempts at establishing initial contact.	

Study Procedures. All interested, potentially eligible patients will undergo a phone screening with a clinical research coordinator (CRC). The CRC will introduce the study, perform basic eligibility screening and conduct the consent discussion. They will meet with patients to confirm eligibility criteria, explain study procedures, and perform informed consent. Once consented, participants will first complete baseline assessments and then undergo randomization (1:1:1 to MT:TAME:WLC) using a secure computer system with full allocation concealment and randomly permuted blocks of random length.

7.1 Research Participant Registration

We will confirm eligibility as defined in the section entitled Inclusion/Exclusion Criteria. We will obtain informed consent by following procedures defined in section entitled Informed Consent Procedures. During the registration process, registering individuals will be required to complete a protocol-specific Eligibility Checklist. The individual signing the Eligibility Checklist is confirming whether the participant is eligible to enroll in the study. Study staff are responsible for ensuring that all institutional requirements necessary to enroll a participant to the study have been completed. See related Clinical Research Policy and Procedure #401 (Protocol Participant Registration).

7.2 Randomization

During the RCT, randomization will occur after baseline assessments. Randomization will be implemented via MSK's Clinical Research Database (CRDB), a secure system that ensures that treatment allocation cannot be guessed before or modified after a patient is registered on trial, allowing for full allocation concealment. Randomization will be 1:1:1 (MT:TAME:waitlist control) using randomly permuted blocks of random length stratified by stem-cell transplantation (yes/no).

7.2.1 Blinding

The CRC responsible for scheduling the treatments will be unblinded, but the CRC responsible for administering neurocognitive assessments will be blinded. The music

therapists will be unblinded because they are administering the treatments. The WLC patients will also be unblinded, as they will be aware that they are receiving usual care; however, we will attempt to blind the MT and TAME patients with regards to their assignment to the treatment group with the purported active "ingredient" – therapeutic music lessons. The PI and biostatistician will be unblinded to allow them to audit treatment fidelity and monitor treatment effects for the purpose of guiding intervention development and ensuring patient safety. The unblinded status of research staff will be fully disclosed in any reporting of study findings.

8.0 INFORMED CONSENT PROCEDURES

Scenario 1: standard written consent scenario

The consent form/research authorization meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of this Center. The consent form will include the following:

1. The nature, objectives, potential risks, and benefits of the intended study.
2. The length of study, what it entails, and the likely follow-up required.
3. Alternatives to the proposed study. (This will include available standard and investigational therapies. In addition, patients will be offered an option of supportive care for therapeutic studies.)
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.
6. How the participants' data will be protected, who will have access to their PHI, and what data will be disclosed for research purposes

Prior to inclusion in the study and before protocol-specified procedures are carried out, the consenting professionals will explain the details of the protocol as outlined in the consent and research authorization to the participants/LARs. The participant/LAR will also be informed that they are free to withdraw from the study at any time. The consent discussion may occur in person or remotely via teleconference, telephone, or videoconference.

All participants/LARs must sign an IRB/PB-approved consent form/research authorization indicating their consent to participate. Each participant/LAR and consenting professional will sign and date the consent form. The participant/LAR must receive a copy of the signed informed consent form.

Scenario 2: documentation of consent waived (e.g.,, verbal consent, only consenting professional signs)

The verbal informed consent/research authorization meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of this Center. The consent/research authorization script will include the following:

1. The nature, objectives, potential risks, and benefits of the intended study.
2. The length of study, what it entails, and the likely follow-up required.
3. Alternatives to the proposed study.
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.
6. How the participants' data will be protected, who will have access to their PHI, and what data will be disclosed for research purposes.

Prior to inclusion in the study and before protocol-specified procedures are carried out, consenting professionals will explain the details of the protocol to participants/LARs. Participants/LARs will also be informed that they are free to withdraw from the study at any time. The consent discussion may occur in person or remotely via teleconference, telephone, or videoconference.

The consenting professional must sign an IRB/PB-approved consent /research authorization script to document the consent discussion and the participant's agreement.

In following the Code of Federal Regulations Title 45, Part 46, Subpart A, the IRB is waiving the requirement for an investigator to obtain a signed consent form from the participant as the research:

- presents no more than minimal risk of harm to participants, and
- involves no procedures for which written consent is normally required outside of the research context.

In following the Code of Federal Regulations Title 45, Part 164, Subpart E, IRB/PB is waiving the requirement for the investigator to obtain signed research authorization from the participant as:

- the use or disclosure of the PHI involves no more than minimal risk to the privacy of the individuals, based on the following elements:
    - An adequate plan to protect identifiers from improper use and disclosure;
    - An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research (unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law); and
    - Adequate written assurances that the PHI will not be reused or re-disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use of disclosure of PHI would be permitted by HIPAA.
- The research could not be practicably conducted without access to and use of the PHI.
- The research could not practicably be conducted without the waiver.

9.0 PRE-TREATMENT/INTERVENTION

9.1. Initial Screening

All potential participants will undergo an initial screening with a CRC over the telephone or Zoom. At this initial contact, research staff will explain the study goals and procedures and the CRC will ensure that participants meet basic eligibility criteria. If participants are potentially eligible, they will be scheduled for a baseline eligibility visit.

9.2. Baseline Visit

Interested and potentially eligible patients will be seen by a clinician (physician, nurse/nurse practitioner, physician assistant, or Integrative Medicine clinician) during a baseline visit to confirm eligibility. This visit can be virtual or over the phone. If deemed eligible, study staff will explain the study and review the written or verbal informed consent with the patient. After informed consent is obtained, patients will complete baseline assessments within two weeks from enrollment. After baseline assessments are completed, patients will undergo randomization, stratified by stem-cell transplantation (yes/no). Please refer to Table 2 for additional details on the assessments collected at the baseline visit.

10.0 TREATMENT/INTERVENTION PLAN

10.1. Music Therapy Intervention. Therapeutic music lessons are the core component of the MT intervention. Other components include guided music listening to help participants use music as a tool for regulating mood, energy, and attention, as well as music-centered discussions to help participants discover songs with personal meaning that they will enjoy learning to play.

Table 1. Overview of MT Intervention.

Session	Primary Session Topic
1	Introduction to Music Therapy
2	Music Listening as a Resource: Mood
3	Music Listening as a Resource: Energy
4	Music Listening as a Resource: Attention
5	Identifying a Song with Personal Meaning
6	Music Training: Rhythm
7	Music Training: Musical Notations
8	Music Training: Keyboard Technique
9	Music Training: Melody, Part 1
10	Music Training: Melody, Part 2
11	Music Training: Performing the Personal Song
12	Applying Music for Cognitive Health in Daily Life

Patients will receive 12, weekly 60-minute MT sessions (+/- 1 week) with homework in-between sessions to reinforce in-session concepts, practice musical skills, and serve as transitions to subsequent sessions (Table 1).

In the first session, patients will be introduced to Playground Sessions, a keyboard training app designed for music novices. The therapist will help patients get set up on the app and assign a course of study. The first 4 sessions will also involve guided music listening to introduce music as a tool for regulating mood, energy, and attention. These sessions will also feature music-centered discussions, during which the participant will explore music preferences and identify a personal song that sparks joy and carries special meaning. The remaining sessions will be dedicated to learning and practicing the musical concepts/techniques necessary to play the personal song on the keyboard. The therapist will modify the song as needed to ensure an appropriate difficulty level. The focus is on the music training process, not the end-result. Playground Sessions will also be used to facilitate home practice. All MT sessions will

be delivered via Zoom's HIPAA-compliant videoconferencing software. Zoom has superior audiovisual quality with less latency compared to other platforms. It also has features (e.g., turn on original sound) that facilitate music-based interactions. Our group has extensive experience delivering MT via Zoom.[21,115] Participants will receive a portable keyboard with compatibility with Playground Sessions. A keyboard was chosen over other instruments because it has fewer physical and technical demands for musical novices.[17] Patients will also receive a subscription to Playground Sessions. Therapists will track session attendance and review completion of homework assignments. As part of the homework patients will practice piano skills and music exploration exercises through the Playground Sessions app for at least 10 minutes per day. The patient will be assigned these modules in the playground sessions app, and will be reminded at the end of each telehealth session.

10.2. Therapist-Attention Music Education (TAME) Control. Given that listening to music has been associated with improved mood, energy, and arousal,[116-119] we will include a therapist attention-music education (TAME) control to isolate the non-specific effects of therapist attention and music listening while removing core components of the MT intervention, i.e. therapeutic music lessons. Patients will receive 12, weekly 60-minute TAME sessions (+/- 1 week) with homework in-between sessions to reinforce in-session concepts and serve as transitions to subsequent sessions. The TAME control group will involve board-certified music therapists guiding participants through music listening exercises. These music listening exercises will serve as prompts for deeper discussions about the songs, as well as education about music history and other music concepts. However, these music listening exercises will not involve any keyboard training or any other aspects of therapeutic music lessons. The TAME group will receive a 6-month Amazon Music subscription to facilitate the music listening activities. Amazon Music has provided 30 1-year Amazon Music Unlimited subscriptions for patients randomized to the TAME control group, free of cost. As part of the homework patients will listen to suggested songs in the designated genre for at least 10 minutes per day. The patient will be informed of suggested songs to listen to at the end of each telehealth session.

Instructions for the patient to receive Amazon Music Unlimited subscriptions Is provided in appendix G.

10.3. Interventionist Training and Treatment Fidelity. All MT and TAME interventionists will be board-certified music therapists with >3 years of experience. The lead music therapist will train interventionists and provide monthly supervision. All MT sessions will be recorded and stored on encrypted MSK servers. To monitor treatment fidelity, we will review all session recordings for the first two participants of each interventionist, using treatment fidelity checklists outlining core intervention components. Therapists who fail to adhere to ≥80% of checklist items will be retrained. If a therapist adheres to ≥80%, then fidelity monitoring will be reduced to 2 randomly selected session recordings per participant. All protocol deviations will be discussed during monthly supervision meetings.

10.4. Waitlist Control. The WLC will control for regression to the mean, Hawthorn effect, natural variability of cognition over time, and potential learned practice effects from

memory/learning measures.[111] During the study, the WLC group will receive usual care from healthcare providers and complete the same assessments as the other groups. The WLC will have the option of receiving either 12 sessions of MT or 12 sessions of TAME intervention when the study concludes after the 24-week waiting period. The WLC participants will choose which intervention (MT or TAME) they wish to receive.

11.0 EVALUATION DURING TREATMENT/INTERVENTION

11.1 Feasibility Outcomes

Limited research has been conducted in hematologic cancer survivors (population) to evaluate MT (intervention) for CRCD (assessment). Thus, guided by methodological experts, we will focus on three aspects of feasibility.

Population/Enrollment: We will track the proportion of screened eligible patients who agree to enroll and undergo randomization, as this will help inform recruitment strategies in future trials.

Intervention Completion and Fidelity: We will track the proportion of participants who complete ≥9 of 12 sessions (over 12 weeks). We will also track the proportion of MT and TAME sessions delivered with no deviations from the treatment fidelity checklist. During each treatment visit, therapists are required to document their delivery of the intervention. During the fidelity checks, this documentation will be checked against a treatment fidelity checklist. This information will be leveraged to develop strategies to improve treatment adherence among future study participants and to improve the fidelity of intervention delivery among future study therapists.

Assessment Completion: We will track the proportion of participants who complete the CRCD assessments (FACT-Cog and objective neurocognitive battery) at baseline and at one or more follow-up assessment times. Deviations are not required for missed assessments during a timepoint as long as at least one is completed. This information will help us to understand what an acceptable assessment burden is for our target population.

Table 2: Schedule of Assessments

	Initial Screening	Baseline (Week 0) (+/- 1 week)	Week 6 (+/- 1 week)	Week 12 (+/- 1 week)	Week 18 (+/- 1 week)	Week 24 (+/- 1 week)
Confirm basic eligibility (in person, over the phone, or via videoconferencing)	X					
Confirm eligibility (in person, over the phone, or via videoconferencing)		X				
PROs						
FACT-Cog PCI		X	X	X	X	X
Hospital Anxiety and Depression Scale (HADS)		X	X	X	X	X
Brief Fatigue Inventory (BFI)		X	X	X	X	X
Neurocognitive testing						
Attention Network Task (ANT) and CogSuite		X		X		X
Covariates						
Demographics		X				
Clinical characteristics		X				
Barcelona Music Reward Questionnaire		X				
Treatment diaries		X		X		X
Treatment credibility scale			X (MT and TAME only)			

12.0 CRITERIA FOR REMOVAL FROM STUDY

Any subjects experiencing a serious adverse event (SAE) that is thought to be related to the study intervention will be removed from receiving further treatments. Patients also will be removed from receiving further treatment if they miss multiple visits without notification of study staff, or if discontinuation from the treatment is deemed by the PI to be in their best interest. Subjects discontinued from the treatment aspects of the clinical trial will be scheduled for the Week 12 and 24 neurocognitive evaluations and given appropriate treatment referrals. For the Week 6, 12, 18, and 24 visits, subjects will receive all assessments that were scheduled for these study visits. Any subject withdrawing their consent to participate in the study or their authorization to use their protected health

information will be withdrawn from the study. Subjects will be informed during the consent discussion that treatment may be discontinued due to: 1) Intolerable side effects (side effects felt by the patient, therapist, or physician to be of greater severity than the potential benefit from treatment); or 2) failure to attend 2 consecutive MT or TAME visits without notification of study staff. If patients fail to attend sessions with notification, every effort will be made to reschedule the patient such that they can receive the maximum number of treatments. Reasons for subject discontinuation from the clinical trial will be documented on the Study Termination Form, along with any referrals that are made. We will make every effort to continue to collect data on every subject for the entire study duration regardless of whether or not the subject continues to adhere to the study interventions, assuming the subject has not withdrawn their authorization to obtain such information.

Subjects who experience a disease relapse or recurrence will be given the option to continue the study. If the subject wishes to continue participate, they will be allowed to do so; in these situation, we will make a note of their disease relapse/recurrence so that this change in status can be accounted for in the analyses. Subjects who experience a disease relapse or recurrence will only be removed from the study if: 1) they do not wish to continue participation; or 2) if the PI or oncology team deems it is not safe for the participant to continue the study in light of their change in disease status.

13.0 CRITERIA FOR OUTCOME ASSESSMENT AND ENDPOINT EVALUABILITY

13.1 Criteria for Therapeutic Response/Outcome Assessment

Since feasibility is the primary aim of this study, we did not specify criteria for determining therapeutic response.

13.2 Criteria for Study Endpoint Evaluability

We will follow intention-to-treat (ITT) principles, with all patients analyzed in their randomized groups, irrespective of actual treatment received or number of study assessments completed.

Each patient will be randomized after completing the baseline assessments; therefore, all randomized patients will have baseline data and be evaluable for CRCD and co-morbid symptom endpoints. Any participant who does not have baseline data within 4 weeks of enrollment will be removed from the study, and they will not count towards the accrual target of N=60.

14.0 BIOSTATISTICS

14.1 Populations for Analyses

The analysis populations for the feasibility endpoints differ by endpoint and include all screened eligible patients (enrollment rate), all patients randomized to the MT and TAME arms (intervention completion rate and intervention fidelity), and all randomized patients (assessment completion rate).

All randomized patients will have baseline data and be evaluable for CRCD and co-morbid symptom endpoints.

14.2. Statistical Analyses

Primary Aim: To determine the feasibility of studying a telehealth-based MT intervention for CRCD in hematologic cancer survivors.

The sample size of N=60 was informed by budgetary constraints, the funding timeframe for the award supporting the trial, guidelines proposed by methodological experts for feasibility and pilot trials, as well as our experience from previous pilot trials on how many subjects are needed to provide sufficient information for evaluating and refining study procedures.

The top reason for null trials of behavioral interventions is the inability of study participants to adhere to the behavioral intervention; as treatment adherence rates approach 50%, the ability to distinguish between the behavioral intervention and control conditions is diminished substantially.[120] Therefore, in a feasibility study, it is critical to first establish that participants can adhere to the behavioral intervention at rates above 50% (ideally closer to 80%) before proceeding to larger efficacy trials.

For each study participant, feasibility will be defined as the completion of 9 or more sessions out of the planned 12 weekly sessions of music therapy. Feasibility cutoff for the study, specific to the MT arm, will be set at 15 or more completions out of the expected 20 patients randomized to the MT arm to reject the null feasibility of 50% in favor of an alternative of 80%, at a two-sided type-I error of 0.02 and a type-II error of 0.20.

Additionally, descriptive statistics will be sought to characterize study benchmarks across the three treatment arms, as described in section 11.1 (e.g., enrollment rate, number of sessions completed, and completion of assessments). The assessment completion rate is defined as the observed proportion of patients who complete the baseline (week 0) CRCD assessments (FACT-Cog and objective neurocognitive battery) and at least one follow-up pain assessment (week 6, week 12, week 18, and/or week 24). The results for participants with disease relapse/recurrent will be summarized separately. The descriptive statistics are collected to help guide a future study, for example, to trim the number of assessments to help with assessment completion.

Secondary Aim: To explore the preliminary effects of a telehealth-based MT intervention, as well as its TAME and WLC comparators, on CRCD and co-morbid symptoms.

We will calculate within-group change scores for subjective CRCD (FACT-Cog total and subscale scores), co-morbid symptoms (HADS, BFI), and objective CRCD (ANT [reaction

time, global accuracy, coefficient of variation]) from baseline to weeks 12 and 24. Confidence intervals (95%) will be sought to estimate the difference in these change scores between the MT group and the TAME and WLC groups. No inferential statistics are planned, because the intent for calculating these estimates are to check for appropriate potency of the intervention (e.g., within-group change score ≥MCID value) and inertness of the comparators (<MCID).[121] Informed by our conceptual model, we will also explore: 1) associations between co-morbid symptoms (HADS, BFI) and CRCD (FACT-Cog, ANT); and 2) improvement in objective attention (HVLT-R Trial 1, ANT variables) as a predictor of treatment response (≥FACT-Cog MCID value).[23]

Data from week 6 will be used primarily for estimating the potential early effects of the 12-week intervention. Data from weeks 18 will be used primarily for estimating the potential durability of treatment effects. This information will allow us to better understand how the intervention is working and whether the current treatment schedule is appropriate. Furthermore, these additional timepoints (weeks 6 and 18) will allow us to explore what an acceptable assessment burden is for a future trial (which may require these additional timepoints for longitudinal modeling of outcomes). We may also consider using these timepoints for estimating treatment effects if participants do not complete the week 12 or 14 assessments.

Tertiary Aim (exploratory): we will explore: 1) associations between co-morbid symptoms (HADS, BFI) and CRCD (FACT-Cog, HVLT-R, ANT); and 2) improvement in objective attention (ANT variables) as a predictor of treatment response (≥FACT-Cog MCID value).

Associations between continuous variables will be estimated, along with their confidence intervals, using Pearson or Spearman correlation coeffects as appropriate. Point-biserial correlation will be used to estimate the associations between continuous (e.g., changes in attention performance) and dichotomous variables (e.g., treatment response).

15.0 TOXICITIES/RISKS/SIDE EFFECTS

MT and TAME are non-pharmacological interventions. All potential risks that might occur as a result of participation will be detailed in an informed consent form and will also be fully discussed with each patient prior to enrollment. We will also explain to each patient that in the unlikely event of an injury directly resulting from the research procedures, every effort will be made to make the facilities and professional skills of MSK available to them.

Physical Risks: MT and TAME are not associated with any physical risks.

Psychological Risks: During MT and TAME sessions, cancer survivors may experience psychological discomfort when thinking about their experiences with cancer and how it has affected their lives. In addition, study assessments will consist of questions related to sociodemographics, medical history (including cancer type and treatment), anxiety, depression, fatigue, insomnia, pain, cognitive difficulties, and health-related quality of life. It is possible that participants may feel uncomfortable with some of these questions. Although

there is the potential for psychological distress while completing study questionnaires or neurocognitive testing, this has been found to be a rare event in our previous and ongoing studies. CTCAE Version 5.0 will be utilized for side effect evaluation.

Financial and Legal Risks: There are no financial or legal risks to the study participants. All research interventions and evaluations are provided free of charge to study participants.

Privacy and/or Confidentiality Risks: There is a small risk of loss of privacy or confidentiality as someone could get access to the personal information in the study participants' study records.

CTCAE Version 5.0 will be utilized for toxicity evaluation. AEs will be assessed at all study timepoints (weeks 0, 6, 12, 18, and 24). In the MT and TAME control groups, AEs will also be assessed at each treatment session. AEs will be documented in RedCap until participants are taken off study.

15.1 Serious Adverse Event (SAE) Reporting

An adverse event is considered serious if it results in ANY of the following outcomes:

- Death
- A life-threatening adverse event
- An adverse event that results in inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- Important Medical Events (IME) that may not result in death, be life threatening, or require hospitalization may be considered serious when, based upon medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition

Note: Hospital admission for a planned procedure/disease treatment is not considered an SAE.

SAE reporting is required as soon as the participant starts investigational treatment/intervention. SAE reporting is required for 30 days after the participant's last investigational treatment/intervention. Any event that occurs after the 30-day period that is unexpected and at least possibly related to protocol treatment must be reported.

Please note: Any SAE that occurs prior to the start of investigational treatment/intervention and is related to a screening test or procedure (e.g., a screening biopsy) must be reported.

All SAEs must be submitted in PIMS. If an SAE requires submission to the HRPP Office per IRB SOP RR-408 'Reporting of Serious Adverse Events', the SAE report must be submitted

within 5 calendar days of the event. All other SAEs must be submitted within 30 calendar days of the event.

The report should contain the following information:

- The date the adverse event occurred
- The adverse event
- The grade of the event
- Relationship of the adverse event to the treatment(s)
- If the AE was expected
- Detailed text that includes the following
    - An explanation of how the AE was handled
    - A description of the participant's condition
    - Indication if the participant remains on the study
- If an amendment will need to be made to the protocol and/or consent form
- If the SAE is an Unanticipated Problem

16.0 PROTECTION OF HUMAN PARTICIPANTS

16.1 Privacy

MSK's Privacy Office may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. The use and disclosure of protected health information will be limited to the individuals/entities described in the Research Authorization form. A Research Authorization form must be approved by the IRB and Privacy Board (IRB/PB).

The consent indicates that individualized, de-identified information collected for the purposes of this study may be shared with other qualified researchers. Only researchers who have received approval from MSK will be allowed to access this information, which will not include protected health information such as the participant's name, except for dates. It is also stated in the Research Authorization that their research data may be shared with others at the time of study publication.

16.2 Data Management

The CRC assigned to this study will be responsible for project compliance, data collection, abstraction and entry, data reporting, regulatory and quality control monitoring, problem identification, and prioritization. Coordination of the study team activities will be the responsibility of our Clinical Research Supervisor (CRS) and/or Clinical Research Manager (CRM). The CRS and CRM will work with the CRC on problem resolution, organization, and quality control. The PI will hold weekly meetings with the research staff to review study progress and to manage any issues that arise. For any communication with participants, all security precautions will be taken. The data collected for this study will be entered secure databases (i.e. CRDB, Excel, or REDCap [Research Electronic Data Capture], based on the

database functionality. A minimal dataset will be entered into CRDB, and a study tracker will be in Excel. To reduce burden, we will administer all assessments remotely. Participants will be asked to complete patient reported outcomes assessments online using REDCap. If they prefer, patients will have the option to complete the measures via pencil and paper or over the phone with a CRC to reduce participant burden and ensure timely completion. To minimize missing data,[122] we will perform ongoing data verification and send proactive reminders to preemptively manage missing data. Using similar approaches, our recent behavioral intervention trial had <10% missing data.[123]

REDCap is a data management software system supported by the Clinical Research Administration (CRA) at MSK. Members of the CRA supporting the REDCap software will have access to REDCap projects hosted by MSK"s servers for the purpose of ensuring the proper functioning of the database and the overall software system. REDCap is a tool for the creation of customized, secure data management systems including web-based data entry forms, reporting tools, and a full array of security features including user- and group-based privileges with a full audit trail of data manipulation an export procedures. REDCap is maintained on MSK-owned servers that are kept in a locked server room with appropriate environmental modifications (e.g. proper ventilation, power redundancy and fault tolerance arrangement) and backed up nightly with some back-up tapes stored off-site. The MSK Information Systems group is responsible for applying all operating system patches and security updates to the REDCap servers. All connections to REDCap utilize encrypted (SSLbased) connections. Nationally, the REDCap software is developed, enhanced, and supported through a multi-institutional consortium led by Vanderbilt University.

Source documentation will be available to support the computerized patient data. The confidentiality of patient information will be carefully protected. Following data entry by Integrative Medicine Service research staff, data will be maintained in a secure location in the Integrative Medicine offices.

Final data sets for publication are required to be locked and stored centrally for potential future access requests from outside entities.

16.3 Quality Assurance

Monthly registration reports will be generated to monitor patient accruals and completeness of registration data. Routine data quality reports will be generated to assess missing data and inconsistencies. Accrual rates and extent and accuracy of evaluations and follow-up will be monitored periodically throughout the study period and potential problems will be brought to the attention of the study team for discussion and action. Random-sample data quality and protocol compliance audits will be conducted by the study team at a minimum of two times per year and more frequently if indicated.

16.4 Data and Safety Monitoring

The Data and Safety Monitoring Plan utilized for this study aligns with the MSK DSM Plan where applicable.

The Data and Safety Monitoring (DSM) Plans at Memorial Sloan Kettering were approved by the National Cancer Institute in August 2018. The plans address the new policies set forth by

the NCI in the document entitled "Policy of the National Cancer Institute for Data and Safety Monitoring of Clinical Trials."

There are several different mechanisms by which clinical studies are monitored for data safety and quality. At a departmental/PI level, there exist procedures for quality control by the research team(s). Institutional processes in place for quality assurance include protocol monitoring, compliance and data verification audits, staff education on clinical research QA, and three institutional committees that are responsible for monitoring the activities of our clinical trials programs.

The committees: the *Data and Safety Monitoring Committee (DSMC)*, the *Data and Safety Monitoring Board (DSMB)*, and the *Pediatric Data and Safety Monitoring Committee (PDSMC)* are managed by the Protocol Review Core and report to the Deputy Physician-in-Chief of Clinical Research.

The DSMB monitors phase III and select non phase III randomized trials and the DSMC monitors non-phase III studies. The DSMB/C have oversight for the following:

- MSK Investigator-Initiated Trials (IITs; MSK as sponsor)
- External studies where MSK is the data coordinating center
- Low risk studies identified as requiring DSMB/C review

The PDSMC has oversight for studies under the following programs:

- Pediatric Precision Oncology Consortium (PPOC)
- MSK Kids
- MSK Adolescent and Young Adult Cancers

All committee monitoring is conducted in accordance with the MSK DSM Plans and committee-specific SOPs.

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18.0 APPENDICES

Appendix A: PROs

Appendix B: Neurocognitive Assessments

Appendix C: MT Protocol

Appendix D: TAME Protocol

Appendix E: Recruitment Letter

Appendix F: Covariates

Appendix G: Amazon Music Redemption Instructions