PROTOCOL TITLE: **A feasibility study of Chaplain-delivered compassion meditation for patients receiving stem cell transplantation.**

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
3	01/20/2022	We will access patients' information from the electronic medical record to determine eligibility and to get patients' contact information.

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1. Study Summary

Study Title	**A feasibility study of Chaplain-delivered compassion meditation for patients receiving stem cell transplantation.**
Study Design	**The study will be an open-pilot trial of chaplain-delivered CCSH to examine chaplain fidelity to CCSH.**
Primary Objective	**To examine the adoption, extent of implementation, and fidelity of chaplain-delivered CCSH.**
Secondary Objective(s)	**The second goal is to make refinements as necessary.**
Research Intervention(s)/Interactions	**Compassion Centered Spiritual Health (CCSH)**
Study Population	**The study participants for this aim will be (1) Chaplains who have already completed the formal educational course as part of their residency training and willingly volunteer to participate. There will be no exclusion criteria and no consequence to the chaplains for refusing to volunteer. (2) The patients they see during consultation are also part of the study population.**
Sample Size	**6-8 chaplains** **50 stem cell patients**
Study Duration for individual participants	**8 months**
Study Specific Abbreviations/ Definitions	**Compassion Centered Spiritual Health (CCSH)** **Hematopoietic stem cell transplant (HSCT)**
Funding Source (if any)	**NIH- 5TK01AT010488** **EPEX#- 62568**

2. Objectives

To examine the feasibility, adoption, extent of implementation, and fidelity of chaplain-delivered CCSH.

3. Background

Based on a wealth of research demonstrating the associations between physical health and psychosocial well-being, modern health care in the United States is characterized by an increasingly patient-centered model of care that places a premium on the holistic treatment of the patient as a physical, psychosocial, and spiritual whole. Hospital chaplains play a vital role in delivering emotional and spiritual care to a broad range of both religious and non-religious patients for a wide variety of stressors, and extensive research indicates that spiritual consults impact patient outcomes and satisfaction. However, there is remarkably little research on the "active ingredients" of chaplaincy spiritual care, and a subsequent lack of standardization and best-practice guidelines informing chaplain training and chaplain spiritual consulting. CCSH ® (Compassion-Centered Spiritual Health) is a secularized compassion meditation program adapted from the Tibetan Buddhist mind training (*lojong*) tradition, and it may be an ideal addendum to both chaplain training programs and to the spiritual care consults provided by Emory University hospital chaplains to approximately 100,000 patients each year.

Importance of integrative treatment for depression and quality of life (QOL) in cancer. In 2016, more than 15.5 million Americans were cancer survivors, and that number is projected to grow to more than 20 million in 2026.[1] Epidemiological studies find that survivors of almost all types of cancer have significantly poorer mental health[2] and health-related QOL[3] than people without cancer. At one year after diagnosis, the prevalence of depression in cancer survivors is estimated to range between 8-24% compared to the 4-7% in the general population.[4-6] The rates of depression among cancer patients actively undergoing treatment is higher, closer to 32%,[7-9] and an astounding 73% of cancer patients with depression do not receive any treatment for this very debilitating symptom.[10] Both depression and QOL levels during and after cancer treatment predict mortality, independent of, and sometimes better than,[11] clinical variables of disease.[12,13] Effective evidence-based interventions to improve psychosocial well-being and long-term QOL for cancer survivors are imperative to advancing cancer care.[14-16]

Hematopoietic stem cell transplant (HSCT) is among the most physically and mentally arduous cancer treatments. Due to chemotherapy-induced toxicity and early post-transplant medical complications, HSCT patients experience a multitude of acute physical symptoms that negatively impact their QOL and psychosocial well-being.[17-19] This array of symptoms occurs concomitant with requisite physical isolation, as the average hospitalization for transplantation is 2-3 weeks.[20] While rates of emotional distress and physical limitations are acutely elevated in the 100 days following transplant,[21,22] the majority of survivors don't regain high levels of

physical function until nearly 5 years out of treatment.[23] Moreover, socio-emotional symptoms are difficult to remediate, and long-term medical uncertainty and fear of relapse leave the majority of survivors with lingering emotional distress[23,24] and restricted social function.[21,25] Of note, the deleterious psychosocial symptoms that accompany HSCT also affect mortality, likely due, in part, to elevated levels of beta-adrenergically induced pro-inflammatory processing that is seen with depression,[26,27] fatigue,[28,29] and with reduced QOL for patients with blood cancers.[30] Depressed HSCT patients have a three-fold increased risk of dying within 1 year after transplantation,[31] and a recent clinical trial found that administration of a serotonin reuptake inhibitor (sertraline) reduced engraftment time for patients with depression and/or anxiety.[32] Together, these findings suggest that intervening on the emotional and social symptoms during HSCT may reduce depression and improve QOL, which is so critical for well-being and survival.

Compassion meditation can be an eminently feasible adjunctive intervention for depression and QOL. The Society for Integrative Oncology highly recommends (grade A) meditation as an adjunctive intervention for anxiety and depression and for improving QOL for patients during and after cancer treatment.[33,34] Mindfulness-based approaches have received the most research attention and appear to be particularly promising, with a 0.44 (*Hedges' g*) effect on symptoms of depression for adult cancer patients and survivors, estimated from 22 randomized controlled trials (n = 1,403).[35] A small but emerging body of research indicates that compassion-based compassion practices reduce anxiety and depressive rumination among cancer survivors.[36-39] Our ultimate goal in this research is to test whether **CCSH** (Compassion-Centered Spiritual Health) a *secular* meditation program that includes mindfulness and compassion practices, can be delivered at the bedside by chaplains to reduce depression and increase QOL. Previous work from our group and others has found that CCSH is beneficial: CCSH increases hope[40] and reduces symptoms of depression in healthy populations[41,42] and attenuates the pro-inflammatory response to psychosocial stress.[43,44] In breast cancer survivors, CCSH reduced depression and psychological stress associated with the fear of cancer recurrence.[37,38]

Scientific Premise: CCSH is a secularized, research-based mindfulness and compassion meditation program designed to expand and strengthen compassion for self and others. Practices include training in attentional stability and increased emotional awareness, as well as targeted reflections to appreciate one's relationship with self and others. By centering the mind, controlling debilitating ruminative thoughts, and cultivating personal resiliency and an inclusive and more accurate understanding of others, CCSH reduces the sympathetic response to psychosocial stress and thus reduces beta-adrenergic induction of inflammatory processing.[43,44]

In advance of implementation and evaluation of CCSH, here we will conduct a pre-implementation study to evaluate the **feasibility** of chaplain-delivered CCSH for patients receiving stem cell transplantation. Systematic investigation of the fidelity of program implementation (FOI) of chaplain-delivered CCSH is required to establish methodological rigor. 1) Incorporating evidence-based interventions requires *rigorous evaluation of whether the*

intervention is being implemented as intended, and whether its implementation varies depending on individual- or system-level factors. 2) Assessing FOI of chaplain-delivered CCSH will be essential for *program improvement and refinement.* 3) Quantifying FOI will be necessary for future studies evaluating the impact of CCSH on patient outcomes, as fidelity to intervention delivery directly informs conclusions that can be made about the effectiveness of the intervention *[i.e., Does chaplain-delivered CCSH reduce depression?]*. In general, counseling programs delivered with high fidelity report better outcomes than those of programs implemented with lower fidelity.[45] 4) Quantifying FOI will be imperative for any future mechanistic study aiming to identify the core components, or "active ingredients", of CCSH that improve outcomes (*i.e. How does chaplain-delivered CCSH reduce depression?*).

4. Study Endpoints

The primary endpoints for this feasibility study are measuring **fidelity to intervention delivery**. As a secondary outcome, we will measure number of sessions completed. We will use an iterative theoretical framework for FOI proposed for mindfulness and yoga interventions[46] to refine the fidelity coding manual.

5. Study Intervention/Design

This will be an open-pilot trial of chaplain-delivered CCSH to examine chaplain fidelity to CCSH.

6. Procedures Involved

Chaplains will be asked to volunteer to participate and be consented according to standard IRB-approved protocols. We will enroll a convenience sample of 6-8 chaplains who have already completed the formal CCSH educational course.

Jennifer (PI) will work with collaborators and CCSH experts to identify the core components of chaplain-delivered CCSH and to develop an objective fidelity-coding manual that we will use to evaluate the fidelity of chaplain-delivered CCSH for patients during HSCT. We will utilize FOI theoretical frameworks to identify structural components (the content that is delivered) and process components (the manner in which chaplains implement content).[47]

1. Chaplains will deliver between four and eight 30-minute sessions (2-4/week) of CCSH to up to 50 adult patients with multiple myeloma or lymphoma during their admission for HSCT. CCSH sessions will be delivered in the patient's room. The number of sessions between four and eight will be determined based on patient availability, interest, and feasibility. Based on the interviews with staff, we will work within the cancer unit's workflow to minimize any interference with medical care. Before the chaplain completes each session, we will administer the (<1 min) NCNN Distress Thermometer, a single-item distress thermometer that compares favorably with longer measures used to screen for distress.

2. Chaplains will complete a post-visit fidelity checklist after each session to report which of the key intervention activities were completed.

3. To rigorously assess fidelity, the study team will collect audio recordings of all CCSH sessions. All sessions will be transcribed verbatim, and two CCSH experts will independently evaluate the extent to which chaplain residents deliver CCSH with fidelity in a random subset of 50% of the sessions. The audio transcripts will be secured on a password-protected Emory server for one year after transcription and will then be destroyed.

4. After the chaplain completes each session, we will administer the (<1 min) NCNN Distress Thermometer, a single-item distress thermometer that compares favorably with longer measures used to screen for distress. We will also administer the (4 min) **Scottish Patient Reported Outcome Measure (PROM)**[48]. The PROM is an 18-item Likert-scale that assesses how a hospitalized patient felt about the Pastoral Care visit both during the consult and after it. Here, we will use the subscale that asks patients how they felt after the chaplain's visit (5 items).

There will be no need for deception during the study.

CCSH: Chaplain-delivered CCSH (description summarized and abridged from 109-page intervention manual):
STAGE 1 Prepare the Care Responder (CR): Before engaging with the Care seeker (CS), if at all possible, the CR sets aside time to attune to their own motivation, attentional stability, and emotional state, using compassion training practice (CCSH) to do the following:
- Connect with a personally nurturing moment
- Stabilize attention/ ground in the body/ witness the nature of mental experience
- Connect with the changing nature of suffering
- Connect with the determination to emerge from internal sources of suffering
- See others as the same as myself, fundamentally, in their desire to be free from distress or harm
- Attune to the reality of interdependence and the affective response of gratitude
- Generate warm-hearted attitude/altruistic love and the intent to share this inclusively
- Deepen the intent to help all others be well and free from distress and discomfort
- Set the intention to stay mindful

STAGE 2 Attune to Relationship with CS: Attune to self, attune to other, and discern sources of distress.
- Communicate the role of the CR through the introduction, right away, so there is not confusion about the purpose of the consultation
- Recall that caring for physical needs/immediate needs is sometimes primary
- Identify, if any, faith tradition or belief system
- Gauge trust, while also building trust
- Sustain empathic balance
- Sustain humility
- Discern sources of distress: Examples: (CCSH module VI) Feeling unheard, disrespected, disconnected, or disparaged; (CCSH module F) Overwhelming anxiety or fear (open to connection); (CCSH module I) Overwhelming anxiety or fear (resistant to connection); (CCSH

module II) Over-identification with thoughts; fixation on one aspect of situation; (CCSH module III-a) Overly harsh self-judgment or self-criticism; toxic shame; (CCSH module III-b) Exaggerated expectations of being free from difficult emotions; (CCSH module III-c) Unrealistic expectations of predicting or controlling outcomes; (CCSH module III-d) Suffering is due to automatic or habitual mental interpretations of events; (CCSH module IV) Harsh blame or objectification of others V-a Feelings of isolation or disconnection, abandonment; (CCSH module V-b) Forgotten agency to hold another (or a group of others) with tenderness; (CCSH module VI) Disconnection from a sense of meaning or purpose in life

STAGE 3 Access Compassion: Seeks to build on the CS's own capacity to find and promote warm-heartedness, resilience, and wellbeing. The fundamental outcome of the Access Compassion stage is that the CS experiences heightened warmheartedness (tenderness, affection) – for self, or for others – which allows them to generate and sustain compassion in the face of difficult situations, struggles, and suffering.

There are several types of cultivation that are constructive, and they are related to the foundational practice and the 6 modules of CCSH as follows, and as illustrated in the simplified diagram above.

NURTURING MOMENT

Foundational Practice: Resting in a Moment of Nurturance

GROUNDING I. Stabilizing Attention / Clarifying Attention

PRESENT MOMENT ATTUNMENT

II. Resting the Mind in its Natural State

BROADENING PERSPECTIVES (CULTIVATING SKILLS AND PERSPECTIVES)

III. Cultivating Self-Compassion

IV. Developing Impartiality toward Others

V. Attuning to Interdependence; Cultivating Gratitude and Affection

VI. Empathetic Concern and Engaged Compassion

STAGE 4 Entrust the Care Seeker: As we prepare to bring closure to the visit, we are continuing to utilize the skills of attunement to the relationship in Stage 3. The CR is attuning to the desire to provide some relief from suffering for the CS while also sustaining the insight that the CS has many internal resources which they may have touched on together during the visit. The CR can also attune to the aspiration to have realistic expectations of what can occur in this closure moment. We aspire to "entrust" the CS with the tools they have begun to access during the conversation. By this, we mean that we give over agency to the CS to enact their own process of accessing compassion and wellbeing.

Training Certification for chaplains to deliver CCSH:

Pre-requisite: Master's level Theological degree and at least two units of CPE.

I. Engaged in the process of ACPE education (or) certified as an Educator with ACPE (or) in the process of certification (or) previously certified with one of its Strategic Partners.

II. Intensive 4-week CBCT course/CBCT Foundations course

III. Intensive 1-day course in CCSH delivery following intervention manual

IV. 4-hour in person follow-up training

V. Weekly follow-up group call booster sessions with practical reflections (2 months)

Certification is analogous to Standard (Level 1) CBCT Teacher certification
Pre-requisite: Complete CBCT Foundations course, 1 year meditation practice,7-day retreat
I. Retreat: CBCT Immersion (4 days)
II. Retreat: Teaching Workshop (3 days)
III. Practicum: 8-week seminar, online with weekly meetings, readings, class planning, teaching
IV. Practicum: Final Workshop (2.5 days)
V. Supervised Co-Teaching (8-10 week course)

The study participants who are patients will be experiencing a medical procedure that will be stressful in nature, but the research study is not inherently stressful. On the contrary, the ultimate goal of this program of research is to alleviate some of the stress the patients are experiencing.

7. Study Timelines

Individual subject participation: approximately 8 months

Chaplain study participants will deliver between four and eight 30-minute sessions (2-4/week) of CCSH to 30-50 adult patients with multiple myeloma or lymphoma during their admission for autologous HSCT. We expect recruitment will take up to 8 months.

8. Inclusion and Exclusion Criteria

Inclusion criteria**:**
Patient Inclusion: 1) within 6 weeks of scheduled HSCT, 2) > 18 years of age, 3) speak and read English

Chaplain Inclusion: Emory Healthcare Chaplain

Exclusion Criteria:
Chaplains: There will be no exclusion criteria and no consequence to the chaplains for refusing to volunteer

Patient exclusion criteria**:** Neurologic or cognitive problems that preclude chaplain-delivered CCSH.

9. Population

We are not recruiting or enrolling participants from any vulnerable or special populations.

Results of the research will be disseminated in peer reviewed journals and presentations. We will share the findings with study participants upon request.

10. Local Number of Participants

This is not a multi-site study.

We will enroll a convenience sample of 6-8 chaplains. The 2018 entering class of chaplain residents is 47% male, and 88% non-white. We expect to enroll 50% women, and 50% non-white chaplains.

Chaplains will deliver eight 30-minute sessions (4/week) of CCSH up to 50 adult patients with multiple myeloma or lymphoma during their admission for autologous HSCT. Based on a previous pilot study of yoga with hospitalized HSCT patients[49], we anticipate that 37% of the patients will be men, and 44% will be non-white.

11. Recruitment Methods

Chaplains will be asked to volunteer to participate via an in-person presentation of the research aims and be consented according to standard IRB-approved protocols. We will enroll a convenience sample of 6-8 chaplains who have already completed the formal educational course as part of their residency training and willingly volunteer to participate. There will be no exclusion criteria and no consequence to the chaplains for refusing to volunteer.

Adult patients hospitalized for HSCT will be recruited by the study team on Emory campus to receive CCSH. Potential participants will be identified via:

1. Collaboration with clinic staff – Our study team will receive an email from the clinic staff each time a new patient is identified. We will use the patients' electronic medical record prior to their hospitalization in order to determine eligibility and to gather the contact information of those patients. Identifiers will be recorded to track contact. Identifiers include: patient name, email, address, and phone number. The study team will email new patients prior to hospitalization with a description of the study, the consent form, and a link to provide indication of interest and consent via Qualtrics.

2. In-person recruitment by the research team.

Patient eligibility will be determined by direct communication between the patient and the study team. Cognitive capacity will be determined if the person is confused, disoriented, unable to make a decision, unable to answer questions, or based on information obtained from family or other caregivers.

12. Withdrawal of Participants

The researchers will stop participation without participant consent if:

- They believe it is in the patient's best interest.
- The patient objects to any future changes that may be made in the study plan.
- The patient is no longer able or willing to receive CCSH.

Participants are free to withdraw from the research at any time. If a participant requests withdrawal, the study team will request permission to use the acquired data and ask the reason for withdrawal.

13. Risk to Participants

Hematopoietic stem cell transplant (HSCT) is among the most physically and mentally arduous cancer treatments and patients experience a multitude of acute physical symptoms that negatively impact their QOL and psychosocial well-being.[17-19] We do not have any reason to believe that CCSH will increase patients' physical, psychological, social, legal, or economic risks. Patients may become upset during the CCSH interventions due to the nature of their treatment, diagnosis, and any emotional discomfort associated with thinking about their disease. However, CCSH has been widely used in usual care in the hospital for 12 months and the chaplains are trained in delivering this type of 'talking therapy'. CCSH is widely associated with low levels of distress.

Risks to confidentiality: The questionnaires that subjects will fill out as part of this study will contain personal information, and participants will have private pieces of audio recorded. We acknowledge that it could be embarrassing if this information were to become public or fall into the hands of someone not associated with the study. We will take the following steps to prevent this from happening: All information obtained from patients will be kept strictly confidential and will be de-identified and stored by a randomly assigned study number, such that these data will be anonymous at all times during data entry and analysis. The key used to link the study number with subject identification will be stored in a password protected, secure database accessible only to study researchers. The key will only be used in the case of study personnel needing to identify a subject and not for data analysis. In addition, all data, including personal identifiers (i.e., name, address, email contact details), will be maintained in secure password-protected electronic files stored on a secure computer system that can only be accessed by study researchers. Emory Spiritual Health supervisors and others in the spiritual health department (other than members of the research team) will not have access to the key nor will they receive any study data.

14. Potential Benefits to Participants

Hematopoietic stem cell transplant (HSCT) is associated with an array of negative symptoms that affect long-term QOL, and these symptoms occur during a requisite period of

hospitalization and physical isolation, as the average hospitalization for transplantation is 2-3 weeks.[20] Intervening on the emotional and social symptoms during HSCT may reduce depression and improve QOL, which is so critical for well-being and survival.
Previous research from our group found that a single session of chaplain-delivered CCSH reduced depression and anxiety among hospitalized inpatients (paper in progress). Patients in this study may directly benefit from CCSH. Moreover, this feasibility study will establish the manualized protocol and intervention delivery process that can be further evaluated in future research.

15. Compensation to Participants
There is no financial compensation for participation.

16. Data Analysis, Management and Confidentiality

Statistical analysis

Measuring and evaluating retention: Based on a large randomized trial of exercise and stress management programs for patients receiving blood and marrow transplant[50], we expect that:

- Benchmark 1: 29 (97%) patients enrolled in the study will complete at least one session of chaplain-delivered CCSH, based on the fact that 3% of patients enrolled in the larger trial did not receive an intervention).
- Benchmark 2: We will lose 7 patients throughout the trial and thus have complete data from 23 patients (78.8%), based on the Day 100 completion percentage from the trial cited above (78.8%).

We believe this is a conservative estimate because the 78.8% Day 100 completion rate reported in the previous study is approximately 2.5 month past our final time point for this aim.

Measuring and evaluating adherence: While chaplains will intend to deliver 8 sessions of CCSH during HSCT, we may find that patients are too sick to receive all 8 sessions or that they drop out of the study prior to the completion of all 8. We may also find that chaplains do not deliver the intervention with fidelity during all 8 sessions. Adherence will be evaluated as the percent of sessions completed by patients and characterized as “low” (< 70%), “moderate” (70-80%) and “high” (> 80%) adherence.

- Benchmark 1: We expect that all chaplain residents will achieve high levels of adherence.
- Benchmark 2: We expect that 23 patients will begin the intervention, complete at least one session of CCSH and remain in the study until the end of HSCT (see retention benchmarks below), completing at least 75% (6 out of 8) CCSH sessions.

Data collection: We will collect audio recordings from all CCSH sessions conducted with enrolled participants. All sessions will be transcribed verbatim, and two CCSH experts will independently evaluate fidelity of implementation (FOI) in a random subset of 50% of the sessions. From the transcripts, coders will quantify 4 dimensions of fidelity according to a recent guide for FOI in meditation studies[46]:

1) Accuracy (sometimes referred to as *adherence* but called *accuracy* here to avoid confusion with overall adherence): the extent to which the core elements of CCSH were implemented as intended. Accuracy will be evaluated as the percent of session components implemented by chaplains and characterized as "low" (< 70%), "moderate" (70-80%) and "high" (> 80%) accuracy.

2) Dosage: quantified as the amount (percentage) of CBCT that patients receive. We will also characterize the modal number of sessions received as well as the range of sessions completed by all patients. From the range, we will create categories of "low", "medium", and "high" dosage that we will use as categorical groups in future studies.

3) Quality: extent to which the chaplain delivered the content as intended. We will generate average competency ratings for each chaplain as well as overall average quality ratings.

4) Responsiveness: the extent to which patients were engaged in each session, operationalized as "maximally," "moderately", or "minimally" enthusiastic and attentive during each. We will quantify the average patient engagement for all sessions, as well as the average responsiveness for each session (i.e., 1^{st} – 8^{th}).

In addition, I will quantify Accuracy, Dosage, and Responsiveness from chaplain checklists that chaplains complete after each session.

- Benchmark 1: We will be able to quantify FOI for all chaplain sessions and generate an average FOI for each chaplain
- Benchmark 2: We expect all chaplains will deliver CCSH with high levels of fidelity.

Audio files will be stored for one year after transcription is complete. All other data will be stored for at least 5 years as de-identified data and secured on a password protected Emory server. Only the IRB-approved study team will have access to the data. The PI (Mascaro) will be responsible for storage and maintenance and destruction of the data.

17. Provisions to Monitor the Data to Ensure the Safety of Participants

We do not believe the research involves more than minimal risk to participants. We will closely monitor all subjects' responses and record conventional serious adverse events (SAEs) and unexpected and expected adverse events (AEs). For the purposes of study reporting, an SAE is any of the following events: 1. Death within 30 days of CCSH, 2. Suicidal ideation at any time during the study. When any of these events occur, the PI will report these events to the

granting agency (NIH NCCIH). These events will also be reported to the IRB per local reporting requirements
The PI has identified 3 independent scientists who are not related to the study who will serve on the Data and Safety Monitoring Committee (DSMC) for the conduct of this study. Prior to recruitment, the DSMC will review the protocol and monitoring plans. Following this, the DSMC will mainly monitor for adequate recruitment milestones and for the occurrence of adverse events related to participation in the study.

Safety Review Plan Study progress and safety will be reviewed monthly and more frequently if needed. The PI will submit progress reports, including patient recruitment, retention/attrition, and AEs to the DSMC semi-annually. On an annual basis the DSMC will review pertinent aspects of the study to assess subject safety, compliance with the protocol, data collection, and risk-benefit ratio. The PI will generate an Annual Report that will include (1) a list and summary of AEs; (2) whether AE rates are consistent with pre-study assumptions; (3) reason for dropouts from the study; (4) whether all participants met entry criteria; (5) whether continuation of the study is justified on the basis of that additional data are needed to accomplish the aims of the study; and (6) conditions whereby the study might be terminated prematurely. This report will be sent to the DSMC, Emory's IRB, and to the funder (NIH NCCIH).

This study will be stopped prior to its completion if: (1) the intervention is associated with adverse effects that call into question the safety of the intervention; (2) difficulty in study recruitment or retention that will significantly impact the ability to evaluate the study endpoints; (3) any new information becomes available during the trial that necessitates stopping the trial; or (4) other situations occur that might warrant stopping the trial.

18. Provisions to Protect the Privacy Interest of Participants
Emory will keep any research records private to the extent that this is required by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

19. Economic Burden to Participants
Study participants will not incur or be responsible for costs because of participation in this research.

20. Informed Consent

Yes, informed consent will be obtained from both chaplains and patients. Chaplains will be asked to volunteer to participate and will be consented according to standard IRB-approved protocols. To avoid any sense of coercion, all chaplains will be contacted by researchers in private and they will be informed that their participation status will be unknown to all supervisors.

For patients: To avoid any sense of coercion of the potential participant by the patient's physician, an investigator/research assistant will be the recruiter for the study. The physician or nurses may refer a patient who satisfies the inclusion criteria to the recruiter, but he or she will not be the recruiter for the study. All recruited patients engage in a detailed informed consent before the study, prior to becoming a participant.

To minimize burden on the patients and to reduce exposure to study staff, we will conduct informed consent online using a waiver of documented consent.

Non-English-Speaking Participants

N/A: all participants will be English-speaking because CCSH is delivered in English.

Participants who are not yet adults (infants, children, teenagers)
N/A: we are not recruiting non-adults

Cognitively Impaired Adults
Patient ability to consent will be determined by direct communication between the patient and the study team. Cognitive capacity will be determined if the person is confused, disoriented, unable to make a decision, unable to answer questions, or based on information obtained from family or other caregivers.

Adults Unable to Consent
N/A: we will not obtain assent.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)
N/A: we will not use a waiver or alteration of the consent process.

21. HIPAA
We will not be recording identifiers from the medical record.

22. Setting

The setting will be at Winship Cancer Institute at Emory Hospital.

23. Resources Available

It is expected that enrollment will take place from November 2021 through July 2022.

To recruit patients for this study, we will engage with referring physicians in Emory's Bone Marrow and Stem Cell Transplant Center. We will arrange to give a presentation at the Emory Huddle and/or the center's grand rounds so that providers and staff are familiar with the study.

Lost to follow-up: The funder (NCCIH) considers lost to follow-up as a research subject who was participating in the study at a certain point in time and subsequently missed two consecutive study visits and is unresponsive to study contact or is no longer participating in study activities.

We base our calculations on a large randomized trial of exercise and stress management programs for patients receiving blood and marrow transplant[50], in which the 120-day lost-to-follow-up was 30.8%. Of 711 consented and randomized, the researchers received final surveys from 492 patients (69.2%): 5 (0.7%) did not undergo HCT, 21 (3.0%) did not receive the intervention, 37 (5.2%) died before Day 100, and 48 (6.8%) died between Day 100 and day 180.

Based on these data, we expect that 97% patients enrolled in the study will complete at least one session of CCSH (based on the fact that 3% of patients enrolled in the larger trial withdrew prior to receiving an intervention). Based on the Day 100 completion percentage from that trial (78.8%), we expect that we will have complete data from 78.8% of enrolled patients. However, this is a conservative estimate, given that the 78.8% Day 100 completion rate reported in the previous study is approximately 2.5 month past our final time point for this aim.

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