Sleep Treatment Education Program for Young Adult Cancer Survivors (STEP-YA): An Online Educational Intervention for Insomnia

Protocol and Analysis Plan

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PI: Christopher Recklitis, PhD, MPH

Dana Farber Cancer Institute

TABLE OF CONTENTS

APPENDICES

1.0 INTRODUCTION

1.1 Background

Young adult cancer survivors (YACS) are particularly vulnerable to treatment late-effects including insomnia.[1-8] Insomnia is often viewed "as a temporary reaction to the cancer diagnosis or treatment,"[9] with few long-term consequences, but insomnia frequently develops into a debilitating chronic condition. As many as 1 in 4 YACS experience significant insomnia even many years after cancer treatment.[5-7, 10] Chronic insomnia is associated with significant health problems, including heart disease, obesity, hypertension, diabetes, depression, and anxiety.[11-20] Because of their cancer treatments, YACS are already vulnerable to many of these health conditions, making access to effective insomnia treatment critically important to their overall health.[21-23]

Cognitive-behavioral therapy for insomnia (CBTI) is a well-established and empirically supported treatment. Multiple randomized trials have demonstrated it is the most effective long-term insomnia treatment, even compared to pharmacotherapy.[24-26] A review of CBTI for cancer survivors similarly concluded it "provides significant, lasting improvement."[27] Unfortunately, despite compelling evidence, this empirically validated treatment is largely unavailable to the growing population of YACS who need it.[28, 29] To make CBTI widely available to YACS, several barriers need to be resolved, including the shortage of trained CBTI providers,[30, 31] the high burden of standard CBTI regimens,[32 33] and the lack of CBTI interventions specifically targeting the needs of YACS. Moreover, as the ongoing COVID-19 pandemic presents considerable health risk for cancer survivors,[34] it is imperative CBTI be delivered using methods that minimize risk of exposure.

To address these challenges and deliver effective insomnia treatment to YACS, we have developed the **S**leep **T**reatment **E**ducation **P**rogram for **Y**oung **A**dult Cancer Survivors **(STEP-YA),** a brief low-intensity intervention presenting essential elements of CBTI in an online educational format. Delivered in a 90-minute, 1 on 1, instructor-led session, STEP-YA educates YACS about causes of insomnia after cancer, including developmental, social, and health factors affecting YACS, and introduces them to CBTI principles and methods. Following a self-management approach, the instructor provides guided behavioral planning encouraging survivors to develop an individualized sleep action plan they will implement after the session. STEP-YA

targets YACS' specific needs and experiences and supports their autonomy by helping them make informed choices to manage their own insomnia.[35]

STEP-YA builds on our previous work successfully developing novel CBTI interventions for cancer survivors, including brief educational interventions, synchronous and asynchronous online interventions, and targeted interventions for YACS.[36-39] Based on results showing low-intensity CBTI interventions are potent enough to significantly improve insomnia in cancer survivors, we have developed STEP-YA to meet the needs of the majority of YACS with insomnia for whom standard CBTI is not appealing, not available, or not needed. Guided by the ORBIT model[40, 41] for development and early testing of behavioral interventions, we now plan this Phase I/II optimization trial (cites) to refine and preliminarily test the STEP-YA intervention.

1.2 Overview

This study will evaluate STEP-YA in an RCT of 74 off-treatment YACS (ages 20-39). As individualized coaching is an effective component of behavioral interventions for cancer survivors and other populations,[42-44] we are interested in evaluating their utility for supporting STEP-YA outcomes. Study participants will be assigned (1:1) to receive the STEP-YA intervention either, 1) alone (non-coaching condition), or 2) with the addition of 2 remote coaching sessions (coaching condition). STEP-YA sessions will be delivered online using the Zoom platform, which is currently in use at DFCI for virtual patient visits and education programs. Participants will complete measures of insomnia and mood at baseline and again at 4- and 8-weeks post-baseline. A repeated-measures design, with each subject acting as their own control, enables the trial to efficiently evaluate potential efficacy of STEP-YA (phase IIa "proof of concept" objective). Randomization to a coaching condition makes it possible to the evaluate utility of remote coaching to improve STEP-YA outcomes (phase Ib objective). As coaching sessions add significantly to costs and complexity, a goal of this study is to determine if they have potential to augment STEP-YA effects before including them in any future Phase III efficacy trials of STEP-YA.

2.0 AIMS

1. To test the hypothesis that STEP-YA improves insomnia symptoms (primary outcome) and mood (secondary outcome) in young adult cancer survivors.
2. To determine if improvement in these outcomes are superior in the coaching condition compared to the non-coaching condition.

A secondary aim will be to explore participant factors associated with clinically significant response to the STEP-YA intervention.

3.0 PATIENT SELECTION

3.1 Eligibility Criteria

To be determined by patient self-report from eligibility screening with potential participants. (See Appendix A for eligibility screening materials). Participants must be screened for eligibility ≤2 weeks prior to study enrollment. Participants who are screened earlier must be rescreened within this period. ISI scores are valid for 4 weeks, only rescreen with ISI if > 4 weeks since initial screening.

- Age 20-39
- History of a cancer diagnosis (except non-melanoma skin cancer) ≥ 1 year prior
- No active cancer therapy (excluding chemoprevention) in the past four months, and no further therapy planned
- Significant insomnia as evidenced by an Insomnia Severity Index score ≥12
- Able to read and write in English

3.2 Exclusion Criteria

- Survivors who report ever being diagnosed with Bipolar Disorder.
- Survivors who report ever being diagnosed with a Seizure Disorder or have experienced a seizure in the past 12 months.

- Intention to adjust (decrease or increase) use of any prescribed or over-the-counter medications taken to decrease insomnia during the study period.
- Survivors who report being diagnosed with sleep apnea who are not receiving recommended medical treatment for their sleep apnea (as assessed by screening questions, see Appendix A).
- Survivors who report suspected sleep apnea who have not completed an evaluation by a sleep specialist (as assessed by screening questions, see Appendix A).
- Survivors who report their usual bedtime does not fall between 5:00 pm and 5:00 am.
- Employment that involves irregular sleep patterns, such as shift-work or frequent long-distance travel across time zones, or employment in a position that could impact public safety (such as air traffic-controller, operating heavy machinery)
- Any impairment (e.g., hearing, visual, cognitive) that interferes with the ability to complete all study procedures independently.
- Prior participation in a research study which provided an educational or behavioral intervention for insomnia
- Prior participation in a behavioral treatment or patient education program for insomnia delivered at the Dana-Farber Cancer Institute, or at Boston Children's Hospital.
- Participation in behavioral or educational interventions for insomnia in the 2 years prior to enrollment. This includes in-person as well as synchronous and asynchronous online insomnia programs, but not independent use of books, workbooks or other written self-help materials addressing insomnia.

4.0 RECRUITMENT

This study will follow procedures currently in place for other survivorship interventions which recruit from multiple clinics at DFCI (17-515, 17-402) in order to identify potentially eligible survivors for recruitment purposes. Recruitment procedures for this study are identical to Dr. Recklitis' recently approved study testing a version of the Sleep Treatment Education Program

for older survivors (DFCI 20-516). All procedures have been developed in consultation with the disease centers and have proven to be effective and non-burdensome for clinicians and patients, while ensuring that only survivors appropriate for recruitment are approached.

Dr. Recklitis will work with each participating clinic's leadership to determine how each clinic wishes to make their patients aware of the study, and develop specific procedures for each clinic or disease center. As in our past studies, the survivorship research coordinator will typically function in the same manner as the clinic's research coordinators, working with the clinicians to determine appropriate patients and timing for providing study information to potential participants. Additionally, each clinic will determine an appropriate clinician or clinicians to co-sign the recruitment letter/email, as seen in the recruitment materials provided in Appendix A.

After getting permission to approach potential subjects from their medical provider, subjects will be approached, screened for eligibility, and recruited by a member of the study staff. Recruitment materials and a study information sheet can be found in Appendix A. While this could occur in person at a scheduled clinic visit, as survivorship visits are frequently conducted as telehealth visits, it is anticipated that some survivors will be contacted by telephone, videoconference, email, or mail. Templates for all of these recruitment methods can be found in Appendix A.

Eligible survivors will also be identified from Project REACH (DFCI 07-134; Dr. Recklitis, PI), a cohort study of survivors followed at DFCI. Project REACH participants complete annual surveys of physical and emotional health and have consented to these surveys being used to determine eligibility for other survivorship studies.

To identify eligible participants, we will work directly with the administrative and clinical staff in participating clinics and programs, and we will also use administrative data sources including EPIC, OncDRS, and CORIS. We are requesting a Waiver of Authorization to identify eligible participants. Subjects will be screened in person, by telephone, or videoconference using the eligibility screen, including the ISI scale (see Appendix A).

Potential subjects may also be referred by a Dana-Farber clinician or self-refer to the study. To ensure that potentially interested YACS are aware of the study, investigators will collaborate with survivorship education and support programs both affiliated with DFCI, and those in the community. Specifically, these programs will be asked to inform their members about the study;

a brief advertisement suitable for use in patient newsletters, advocacy group newsletters or websites can be found in Appendix A. Similarly, as social media has been found to be a highly successful recruitment tool for YA cancer survivors, we will utilize social media popular with this cohort (e.g. Reddit, Facebook, Twitter, IG); a sample social media post can be found in Appendix A. A study website (STEPforSleep.com) will contain IRB-approved information about the study including contact information for the study team, the study information sheet, a link to the study on Clinical Trials.gov, and the video advertisement (see Appendix A). The study will also have a Facebook page, as well as Instagram and Twitter accounts which will direct potential subjects to the study web site. To promote the study to potentially interested cancer survivors, study staff will periodically post on these sites (see Appendix A for sample posts).

5.0 STUDY DESIGN AND METHODS

5.1 Study Design

This study is a randomized controlled trial of 74 young adult cancer survivors with clinically significant symptoms of insomnia, randomized to the STEP-YA intervention with or without 2 remote coaching sessions. All participants will take part in a single STEP-YA session, during which they will complete baseline measures prior to receiving the STEP-YA intervention. Following the intervention session, they will be randomized to the coaching or non-coaching conditions. Participants will complete follow-up measures 4 and 8 weeks post-baseline.

5.2 Methods

S*ee section 5.5 for descriptions of all study measures. Copies of the assessments can be found in Appendix B, and participant correspondence in Appendix C.*

Informed Consent: We are requesting a Waiver of Documentation of Informed Consent for this study, as it is a minimal risk study involving no procedures (questionnaires and educational session) for which signed consent is generally required outside of the research context. The intervention sessions in this study are similar to educational sessions currently conducted through the Blum Center at DFCI, and for which no signed consent is required. A similar online intervention currently being conducted by Dr. Recklitis (17-515) was granted a waiver of documentation of consent, and we propose to utilize those approved consent procedures for this

study. Potential participants will be provided with a study information sheet which contains all the elements of informed consent (See Appendix A), and will have a consent conversation with a member of the study staff in which they can ask questions about the study or study procedures before providing verbal consent. As it is anticipated that many off-treatment survivors will not have in person clinic visits at DFCI for the foreseeable future, it is expected that most of these consent conversations will take place by telephone or videoconference, although they could be in person if requested.

Intervention session: After expressing interest, participants will be scheduled for an individual videoconference intervention session. The intervention session consists of the following components:

1) Informed Consent: Study staff will review the study procedures and the Study Information Sheet with the participant and answer any questions they may have. They will then obtain verbal consent. (Verbal consent procedures can be found in Appendix C)

2) Baseline measures: Study staff guide participants in completing baseline measures including insomnia and mood using the Qualtrics web-based survey platform.[45] Participants enter data directly into the system, and the study staff do not collect data from participants.

3) Intervention Delivery. After completing baseline measures, the participant will immediately receive the STEP-YA intervention session via videoconference. (See section 5.3 for a description of the STEP-YA intervention). During the session, both the participant and the interventionist will be blinded to whether the participant has been randomized to receive the coaching sessions.

4) Randomization: After completing the session, randomization will be performed using Sealed Envelope, a commercially available online software application for randomising patients into clinical trials. Participants will be randomized (1:1) to either: **1)** STEP-YA alone (non-coaching condition) or **2)** STEP-YA with the addition of 2 remote coaching sessions (coaching condition). Participants will then be informed of whether they were randomized to receive the coaching sessions, and will schedule their first telephone call (first coaching session for those in the coaching condition or 4-week follow-up for those in the non-coaching condition). Additionally, participants will be asked to provide preferences for all future contact and correspondence (i.e., phone, email, send secure, text, mail) and

these preferences and addresses/phone numbers will be recorded in the participant's record.

5) Session evaluation: Participants will receive a link to a questionnaire on which they will report on ease of use and acceptability, satisfaction, and credibility of the session. To promote completion of the questionnaire, participants will be encouraged to complete it while still in the Zoom session, but can choose to complete it at a later time. Participants will receive a $10 gift card upon completion of this evaluation.

Coaching Sessions: Participants randomized to the coaching condition will receive 2 individualized remote coaching sessions 1, and again 2 weeks following their STEP-YA session. (See section 5.4 below for a description of the coaching sessions and timing).

Post-intervention Follow-up: At 4- and 8-weeks post-baseline, study staff will recontact participants by telephone at previously scheduled times, ask them to enter follow-up data directly into Qualtrics, and provide technical assistance if needed. Participants who cannot complete the full assessment at that time due to time constraints will be asked to complete the 7-item ISI (primary outcome measure) verbally and their responses will be collected; they will then be asked to complete the full questionnaire at their earliest convenience. Participants will receive emailed reminders in advance of each phone call. At the 4-week call, participants will schedule a phone call for the 8-week assessment.

Incentive: Participants will receive a $25 Amazon gift card upon completion of each follow-up assessment.

Optional 16-week ISI: At the time of their 8-week follow-up phone call, participants will be asked if they would be willing to complete an additional sleep checklist two months later. Participants who agree will receive a Qualtrics link to the 7-item ISI 8 weeks later by email. This would take approximately 1-2 minutes to complete, and participants will not receive an incentive for this optional checklist. The link would be sent again a week later for non-responders, but participants will receive no additional reminders.

5.3 STEP-YA Intervention

STEP-YA is delivered in a single 90-minute synchronous videoconference session using HIPAA compliant Zoom technology[46-48] licensed to our cancer center. Interventionists with graduate level training in psychology, social work, or closely aligned discipline (e.g., human development,

nursing) will be trained and supervised by psychologists with CBTI expertise to deliver the STEP-YA intervention following a structured outline. The interventionist will deliver STEP-YA in a 1 on 1 session using a slide deck of 47 slides and following a structured outline. During the session, the participant is able to see and hear the presenter, view the presentation slides, and ask questions. To support participants in developing and implementing their sleep action plan, take-home materials including a copy of the presentation slides and sleep action plan template are provided by email. The presentation begins with educational information on the problem of insomnia after cancer and the 3-P model before presenting specific suggestions for improving sleep in YACS. These suggestions are based on CBTI components of sleep hygiene, stimulus control, and cognitive restructuring.[27, 32, 49-51] To aid comprehension, this material is presented in four sections addressing 1. Lifestyle issues, (e.g., benefits of exercise and limiting alcohol), 2. Sleep environment (e.g., importance of a dark, quiet bedroom; avoiding bed for non-sleep activities), 3. Sleep timing (e.g., regular wake time, avoiding napping) and 4. Managing expectations and challenges (e.g., sleep worry, physical symptoms, social pressures). For each suggestion, an underlying rationale and potential benefit are presented. Both the look and content of the STEP-YA material are targeted to appeal to YACS. For example, text describing the benefits of exercise are accompanied by photos of young adults engaged in traditional and contemporary exercises, (e.g., yoga, spin class, cross-fit), and the description of the effects of caffeine includes photos of products YACS commonly consume (e.g., energy drinks, green tea, sodas, coffee drinks). In section 4, examples of the social, developmental and health challenges that YACS may encounter are noted, along with suggestions for managing them. These include living spaces shared with roommates or parents, social pressures, “fear of missing out,” and tendency toward a delayed sleep phase common in young adults, as well as physical health symptoms such as pain, or hot flashes. At the conclusion of each section (e.g., lifestyle), the participant is asked to review the suggestions in the section and complete their sleep action plan template to record their current sleep practices and behavioral changes they intend to make. Action plans of this kind are central to self-management education[35] and have been shown to increase successful behavior change.[52, 53] To close the session, the presenter offers examples of STEP-YA suggestions implemented in a daily routine, and asks the participant to review and revise their sleep action plan, including anticipating challenges and planning strategies to manage them.

5.4 Behavioral Coaching

Participants randomized to the coaching condition will receive 2 individualized remote coaching sessions 1, and again 2 weeks following their STEP-YA session. Optimal timing for coaching sessions is 7 and 14 days after the STEP-YA session, but may be scheduled between 5-23 days after the STEP-YA session with at least 5 days between coaching sessions. Paraprofessional coaches trained and supervised by psychologists with CBTI expertise will follow a structured outline adapted from a previous self-management intervention at our center.[54] In the sessions, designed to last approximately 30 minutes, coaches ask participants to review their progress and challenges implementing their sleep action plan. Coaches offer support and encouragement and may refer participants to the take-home materials to help answer questions and reinforce program goals and suggestions. Following, principles of self-care management and previous coaching interventions sucesssful with cancer survivors,[44, 55-58] coaching sessions are not prescriptive, but support YACS to use self-management skills including decision-making, goal-setting, self-assessment, and problem solving to help them implement their individual sleep action plan. Administrative data on coaching session duration, and sessions missed, interrupted, or rescheduled will be collected.

5.5 Study Measures

All measures were previously used with cancer survivors on DFCI 15-336. Measures can be found in Appendix B. Measures are given at all timepoints unless otherwise noted.

The Insomnia Severity Index (ISI)[59]: The 7-item ISI is the most commonly used measure in insomnia research and has been validated in cancer populations.[60] It has demonstrated adequate internal consistency, and is sensitive to detect changes in perceived sleep difficulties with treatment.

Profile of Mood States – Short Form (POMS-SF)[61]: The Profile of Mood States-Short Form is a commonly used measure of psychological distress that has been validated in cancer populations.[62] It is a 35-item measure which assesses the mood states of participants, and provides multiple scales including an overall Total Mood Disturbance (TMD) score used here.

Physical Health: Physical health will be assessed with one item from the commonly-used SF-12[63] asking respondents to rate their overall health. Pain will be measured with the commonly used Pain Thermometer[64] on which participants rate their pain on a scale of 1-10, and a single item asking participants to rate whether they feel "in pain" on a five-point scale.

Sleep Treatment Change: Participants will be asked to report any changes made in sleep behaviors during the study period including those not specifically recommended by the study interventions (e.g., new sleep medications, new non-study meditation class). This measure is only completed at post-intervention timepoints.

Demographics and Medical History: Demographic information, medical information (e.g., cancer diagnosis and treatment, recent psychiatric treatment), and insomnia history (e.g., insomnia duration, burden, past treatments) will be collected by direct patient report. The 5-item Morningness-Eveningness Questionnaire (Reduced)[65] will also be included to identify participants' circadian tendencies. This measure is only given at baseline.

Intervention Evaluations: Participants will complete evaluations at several timepoints. 1) At the end of the intervention session, participants will report on ease of use and acceptability using checklist items adapted from the Telehealth Usability Questionnaire[66] and satisfaction will be assessed with checklist items adapted from Dr. Recklitis's previous survivorship education trials. 2) Participants who are randomized to the coaching condition will complete a brief satisfaction evaluation of the coaching sessions after the second coaching phone call. 3) All participants will complete a brief questionnaire to provide their feedback about the intervention and how it could be improved at the 8-week post-intervention timepoint.

Steps to insure complete data: Participants will complete baseline measures online using Qualtrics at the intervention session prior to randomization to insure completeness. Following procedures found to be effective in Dr. Recklitis' DFCI protocols 17-515, 15-336 and 14-583, the study also makes use of scheduled telephone appointments to insure timely completion of the follow-up assessments. In previous intervention studies, telephone appointments have been highly effective for encouraging survivors to complete assessments; we have achieved 100% complete data for primary endpoints and 95% complete data overall using this method.

5.6 OnCore Registration

As per DF/HCC SOP REGIST-101A, with the approval of the Director of the Office of Data Quality, retrospective registration will be utilized for this minimal risk study.

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

Registration requires a signed informed consent document and a completed eligibility checklist according to DF/HCC SOP REGIST-104.

6.0 RISKS AND ADVERSE REACTIONS AND THEIR MANAGEMENT

Potential for some participants to experience increased daytime fatigue from the study intervention

The primary risk of this minimal risk study for participants is a brief (1-2 week) period of daytime fatigue, which is the result of sleep scheduling (i.e., reducing daytime sleep). Consequently, participants may experience some physical and mental side effects associated with sleepiness. However, these side effects should be similar to the effects of sleepiness they have previously experienced due to their insomnia. In order to address and mitigate this risk, the STEP-YA intervention provides information about anticipating and planning management strategies to cope with increased symptoms of fatigue that may occur. In particular, instructions will be provided to maintain personal safety by avoiding driving at times when participants are likely to become sleepy, and taking appropriate steps if they become sleepy while driving. Specifically, participants are instructed that they should immediately pull over to a safe area, stop driving and sleep if they become fatigued while driving. Additionally, participants will be provided with the contact information of the PI, Dr. Christopher Recklitis, a licensed psychologist with extensive clinical experience with cancer survivors and insomnia treatment. Participants who have any concerns about the study are encouraged to contact him for assistance.

Privacy and Confidentiality

We have taken steps to protect the privacy of participants during all aspects of intervention delivery and data collection.

The Zoom videoconferencing technology which will be used to conduct eligibility screening conversations and deliver the online intervention is fully HIPAA compliant. The platform is licensed to our cancer center, and is currently used for telehealth visits, research visits, educational webinars, and study meetings. As of June 2020, Zoom is encrypted using AES 256-bit GCM encryption standard, the strongest and most robust encryption standard that is currently commercially available. For additional security, our institution has locked the password function so that passwords are required for all Zoom meetings. A new individual password is created for each session, which is then embedded into the link sent to the participant. This enables the participant to access the session securely without having to enter a password, while ensuring that only the participant has access to the meeting. Once the participant enters the meeting, the meeting will be locked which provides further protection against any other person entering the meeting either accidentally or intentionally.

The Qualtrics web-based survey platform that will be used to collect study data remotely has been used successfully by Dr. Recklitis for other online intervention studies, including a recently completed study for young adult cancer survivors (DFCI protocol 17-515). The Qualtrics platform is available through the Harvard Medical School which provides access to a licensed version to all HMS faculty and staff as well as affiliated institutions. Qualtrics is the leading global provider of data collection and analysis for academic research, serving over 5,000 customers in 75 countries. The Qualtrics platform can deliver web and mobile surveys, embed videos in a larger survey, send email and mobile reminders, and automate the data collection procedures. Qualtrics provides secure collection of survey data using encrypted data transfer and complies with HIPAA protections for privacy of patient information. In our application for this study, the Qualtrics program will identify participants only by study ID, and will contain no identifiers. Participants will access the Qualtrics platform through a unique link connected only to their study ID, and email addresses will not be stored in Qualtrics, so that no protected health information is stored on the Qualtrics platform.

We will use standard IRB-approved and HIPAA compliant measures to maintain patient confidentiality, privacy and data security. Data privacy and security procedures will include: a) training staff on data sensitivity and protocols for safeguarding confidentiality; b) storing and processing sensitive hardcopy in a secured, centralized location; c) securing sensitive hardcopy in locked files when not in use; d) removing names, addresses, and other direct identifiers from

hardcopy and computer readable data after they are not necessary for patient tracking and then using encrypted codes for subsequent identification of subjects; e) destroying all identifiable linkages to data after data accuracy has been verified and final analyses have been completed; f) using restricted logon identification and password protection computer protocols for all computerized entry, retrieval, and analysis.

7.0 STATISTICAL ANALYSIS

Primary Aims:

1. To test the hypothesis that STEP-YA improves insomnia symptoms (primary outcome) and mood (secondary outcome) in young adult cancer survivors.

2. To determine if improvement in these outcomes are superior in the coaching condition compared to the non-coaching condition. This is a randomized 2-arm trial evaluating the STEP-YA intervention when delivered with and without supplementary remote coaching session. Immediately after completing baseline assessment subjects will be randomized (1:1 by the Sealed Envelope system) to receive the STEP-YA intervention either, 1) alone (**Non-Coaching condition**), or 2) with the addition of 2 remote coaching sessions delivered in the two weeks following the intervention session. (**Coaching condition**). Randomization, with block size of 4, will be stratified by age category (20-29 years vs. 30-39 years). Primary endpoint is change in Insomnia Severity Index score from baseline to 8-weeks post-intervention. Secondary endpoint is change in mood symptoms on the Profile of Mood States-Short Form from baseline to 8-weeks post-intervention. Primary and secondary endpoints are change at 8 weeks; data collected at 4-week post-assessment will be analyzed using similar methods for descriptive and exploratory purposes.

Data analysis for this study will follow methods used for our recently completed clinical trial of in-person insomnia interventions delivered to cancer survivors (1R03CA201459). Change scores will be treated as continuous variables and primary analyses will compare the arms using 2-way analysis of variance with one between-subjects factor (Coaching vs. Non-Coaching) and one within-subjects factor (time). Cohen's d will be used to quantify within-group effect sizes and Hedges' g adjustment will estimate between-group effect sizes. Aim 1 will be addressed using a

within-subjects analysis including all participants to determine if the STEP-YA intervention is associated with significant changes in outcome measures over time. Aim 2 will be addressed with an analysis that includes both the within – and between-subjects factors as well as an interaction term to determine if the effect of the intervention differs between Coaching and non-Coaching groups (i.e. significant interaction term).

Sample Size/Power: To meet our aims we require 64 participants with evaluable data but will enroll 74 as a hedge against attrition. Our prior single-session educational interventions have demonstrated large effects of $d \geq 1.00$; the study is conservatively powered to detect an effect size of .52 (Primary Aim). With sample size of 64 (32 per arm), the study will have 80% power to detect an effect of this size within each arm (α=0.05). To compare the relative improvement in the primary endpoint between arms, N=64 subjects will have 80% power to detect a difference of d=0.62 between arms (α=0.05, one-sided).

Secondary Aim*: Explore participant variables associated with clinically significant response to the STEP-YA intervention.* Logistic regression will be used to identify demographic and sleep factors (e.g., age, severity of insomnia symptoms) associated with a reduction of ISI scores ≥ 6 points at 8 weeks. Variables identified in univariate analysis ($p<.10$) will be entered into a multivariable model estimating STEP-YA response from baseline variables. Analyses will explore these relationships separately in the two study arms; Pooled analyses including participants across arms will be conducted if univariate analyses indicate relationship of predictors and outcome are consistent.

Missing Data: Participants will be randomized after completing a baseline so complete baseline data are assured. Primary analysis will be an intent-to-treat analysis of randomized subjects. Based on experience using similar data collection methods, we anticipate minimal missing data (<10%). If needed, we will use multiple imputation to account for missing data. Potential factors in the imputation model include baseline sleep and mood variables. Sensitivity analysis will be used to evaluate the potential impact of imputation on results.

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