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Promoting Follow-Up Care Self-Management for Adolescent and Young Adult (AYA) Childhood Cancer Survivors

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LIST OF ABBREVIATIONS

AYA	Adolescent and Young Adult
CINJ	Cancer Institute of New Jersey
LITE	Long-term, Information, Treatment effects, and Evaluation program
IRB	Institutional Review Board
NCI	National Cancer Institute
NIH	National Institutes of Health
PI	Principal Investigator
CCSS	Childhood Cancer Survivor Study

1. Purpose/Specific Objectives

Childhood cancer survivors are a growing population in the US (currently over 379,000).[6] Unfortunately, these survivors are at risk for adverse health late effects from treatment such as cardiovascular disease and premature mortality.[7-10] Survivors require lifelong follow-up care to identify, monitor, and treat medical and psychosocial late effects stemming from their cancer, its treatment, and lifestyle factors.[11] However, over 70% of childhood cancer survivors do not obtain specific risk-based follow-up care.[12] Adolescent and young adult (AYA) survivors of pediatric cancers are particularly vulnerable to lapses in follow-up care due to ineffective transitions from parent-guided management to self-management of care.[11,13]

The transition from parent-guided management to self-management of long-term follow-up care involves assuming primary responsibility for tasks such as managing health records, making appointments, filling and taking prescriptions, and understanding late effects monitoring and cancer screening needs. It occurs during a critical developmental period when AYAs may be unaware or fail to recognize their health risks and need for regular follow-up.[11] Barriers to successful transition include survivors' lack of knowledge of their diagnosis and treatment, cancer-related anxiety and other emotional concerns, and failure or inability to assume personal responsibility for health.[13-15]

A survivor-focused intervention is likely to have the greatest impact on health outcomes because giving AYA survivors the knowledge, skills, support, and self-efficacy to manage their follow-up care will apply to any setting (i.e., cancer center or community-based primary care). This project takes an innovative approach to improving AYA survivors' self-management of long-term follow-up care through adaptation of an evidence-based problem-solving skills training (PSST) intervention and the addition of peer mentors to facilitate completion of the intervention. PSST has been shown to improve problem-solving skills in other cancer contexts,[3-5] and we will adapt the content of the program to address the needs of AYA cancer survivors using patient, parent, and provider input. We anticipate that the adapted program will focus on improving disease knowledge, health motivation, problem-solving skills, stress management, and communication with caregivers and providers, all of which are important constructs to promote transition readiness as outlined in the Social-Ecological Model of AYA Readiness for Transition (SMART).[1] Peer mentors have been suggested as an innovative approach to support healthcare transitions,[6] and many AYA survivors express a supportive care need to connect with other young adult survivors and seek advice from others who "get it."[7,8]

The goal of this project is to develop and evaluate a peer mentoring self-management intervention to improve self-management skills for AYA survivors. We will evaluate feasibility (i.e., enrollment, retention, satisfaction with the program) and preliminary efficacy (i.e., changes in survivors' healthcare self-management skills, readiness to transition, and cancer-related anxiety). In Phase 1, we will use AYA survivor, parent, and provider interviews to adapt an evidence-based problem-solving skills training program to promote AYA self-management of care. We will recruit and train peer mentors to implement the PSST intervention. In Phase 2, we will conduct a pilot test of the program with 40 young adult survivors ages 18-25 years transitioning to self-management of follow-up care. Based on feedback collected in Phase 2, we will refine the online modules and conduct usability testing of the new modules in Phase 3A. We will then evaluate the feasibility and preliminary efficacy of the self-management + peer mentoring intervention in a randomized two-arm trial comparing the intervention to usual care (Phase 3B).

1.1 Objectives/Hypotheses

Aim 1: Develop the self-management + peer mentoring to improve AYA self-management of long-term follow-up care.
Qualitative research with AYA cancer survivors, parents, and healthcare providers will be conducted to adapt an evidence-based problem-solving skills training (PSST) program to address the needs of AYA survivors.

Aim 2: Evaluate the feasibility of the self-management + peer mentoring program.
We will examine feasibility through study enrollment rates, retention rates, adherence to the intervention, reasons for study drop out, and patient and mentor satisfaction with the program.
Hypothesis 1: Based on literature, we expect enrollment >50% of eligible patients and retention >80%.
Hypothesis 2: We expect patients enrolled in the mentor program to complete >75% of intervention sessions

Aim 3: Assess preliminary outcomes of the peer mentoring program.
Hypothesis 3 (Phase 2): Participants in the mentor group will demonstrate improvement in self-management skills, transition readiness, and anxiety.
Hypothesis 4 (Phase 3): Participants in the self-management + peer mentor intervention will demonstrate greater improvement in transition readiness than participants in the usual care group.
Hypothesis 5 (Phase 3): Participants in the self-management + peer mentor intervention will participate in survivorship and preventive healthcare at greater rate than participants in the usual care group.

2. Background and Significance

The transition to adult self-management of health care is often ineffectively managed by AYAs.
Ineffective transition to adult self-management of care results in inadequate follow-up care and potential health problems. Although it is recommended that childhood cancer survivors obtain long-term follow-up care tailored to address the risks of their cancer, treatment, and lifestyle (called "risk-based follow-up care"), over 70% of young adult childhood cancer survivors do not obtain such care.[9,10] Results from the largest cohort study of childhood cancer survivors, the Childhood Cancer Survivor Study (CCSS), show that even survivors at greatest risk for late effects demonstrate low rates of cancer screening.[2,10,11] The transition to adulthood is a particularly challenging time when many AYAs are lost to follow-up.[12,13] This is both a personal medical risk because late effects may go undetected or be misdiagnosed or mistreated, and a societal risk because lack of monitoring can lead to increased healthcare utilization and costs that may have been preventable. Barriers to adult-oriented health care transition for AYA survivors

include survivor-related factors, such as inadequate knowledge of their cancer history and treatment, complex medical conditions, anxiety, and difficulty assuming personal responsibility for health.[7,8,12,14,15] These survivor-related factors call for a survivor-focused intervention.

Theoretically-driven interventions to improve self-management of care are needed.
Although there is attention to AYA transition in the literature, a lack of transition-related theoretical frameworks has hindered the development and evaluation of targeted interventions to promote self-management of care.[1] The Social-Ecological Model of AYA Readiness for Transition (SMART)[1] proposes that there are modifiable factors that interact to promote AYA readiness for transition (Figure 1). Transition readiness refers to the capacity of the AYA and his/her support network to prepare for and complete the process of moving to adult-oriented care.[1] Factors related to transition readiness include knowledge of health history, risks, and needs; self-management skills and self-efficacy for managing care; beliefs and expectations regarding the transition process or adult-oriented care (such as belief that adult provider will not understand patient's needs); goals related to health transition; relationships with parents and providers; and psychosocial functioning of patients, parents, and providers (such as anxiety about the transition process or future health).[1] Problem-solving skills training (PSST) is a generic, cognitive-behavioral intervention that can be readily adapted to target these constructs. For example, PSST can be used to help AYAs set transition and self-management goals, explore beliefs/expectations related to the goals or barriers to such goals, manage stress, and promote self-efficacy by breaking down large goals into small, achievable steps. We chose PSST as an intervention because it empowers individuals to improve self-management skills, which include maintaining health records, making appointments, filling and taking prescriptions, and understanding health risks and monitoring needs. PSST also has a strong evidence base and has been shown to be effective for increasing problem-solving skills for parents who are managing a child's cancer treatment.[3-5] We will use Phase 1 of this project to explore strategies for adapting PSST to address many of the modifiable components of the SMART model, including knowledge and communication with parents and providers.

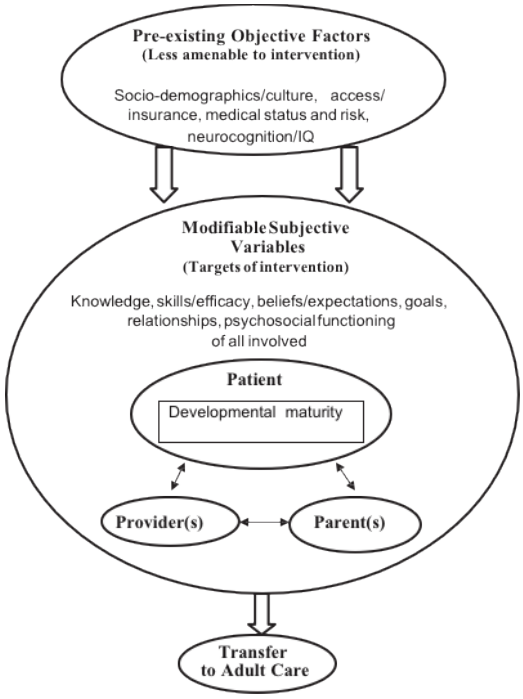

Figure 1. SMART model[1,2]

Peer mentoring meets a unique need for AYA childhood cancer survivors.
Qualitative and quantitative studies suggest that AYA survivors want to discuss their medical care needs with other AYA survivors.[7,8,16,17] Although peer mentoring has been recommended as an innovative approach to facilitate health care transitions for AYAs,[6] the only published intervention utilizing this approach for survivors is a peer-delivered counseling intervention for smoking cessation among adult childhood cancer survivors from the CCSS.[18] Childhood cancer survivors who received the peer-delivered telephone counseling intervention were twice as likely

to quit smoking as survivors who received the self-help print intervention, providing evidence of effectiveness of peer-to-peer programs for health behavior change in this population.[18]

Peer mentoring programs delivered using technology can be implemented across a variety of settings.

The Adolescent and Young Adult Oncology Progress Review Group (AYAO PRG) recommended the development of standardized peer-to-peer programs as a strategy for supporting the psychosocial needs of AYA cancer patients and survivors.[19] The AYAO PRG suggested that efficacious programs be disseminated by partnering with cancer centers, oncology professional societies, and community-based support groups that work with AYA survivors. By partnering with various organizations, peer mentoring programs can be initiated and maintained with minimal health care system support. Peer-to-peer programs are also likely to be relatively low cost, as demonstrated by the peer counseling smoking cessation intervention for childhood cancer survivors, which has recently been translated to a web-based intervention.[18,20] The use of technology to deliver skills-building modules and peer mentoring aligns with AYAs' preferences for technology, with 85% of young adults 18-29 owning smartphones.[21] It also sets up the program for dissemination. Finally, since many childhood cancer survivors participate in volunteer activities and informal peer-to-peer outreach is commonly offered to cancer patients,[18] sustaining a peer-to-peer program on a large scale is plausible.

3. Research Design and Methods

This research will be conducted in three phases. In Phase 1, we will use provider, survivor, and caregiver interviews to adapt PSST to focus on AYA self-management of care and develop the intervention. In Phase 2, we will conduct a single arm pilot test of the program with 40 young adult survivors ages 18-25 years and 20 peer mentors. Based on feedback collected in Phase 2, we will refine the online modules and conduct usability testing of the new modules in Phase 3A. We will then evaluate the feasibility and preliminary efficacy of the self-management + peer mentoring intervention in a randomized two-arm trial comparing the intervention to usual care (Phase 3B). The biostatistician will determine a randomization scheme using an undisclosed block size. The scheme will be uploaded to DatStat for automatic assignments. For a backup, randomization assignments will be provided to PI in sealed envelopes as well.

3.1. Duration of Study

Phase 1: Participants will be asked to complete a one-time interview lasting approximately 60 minutes.

Phase 2: Participants will be asked to complete the intervention over a period of 6 weeks. Participants will be asked to complete 6-week online self-management educational modules and 6 weekly peer mentor calls to facilitate engagement with the online modules and offer specialized support.

Phase 3A: Usability sessions will last approximately 1-hour. Given that usability testing is iterative and design changes are made in response to participant feedback, we will ask some participants if they are willing to review the product another time after changes are made, up to a total of five times. Each session is voluntary and conducted in a way to minimize participant burden.

Phase 3B: Participants assigned to the intervention will be asked to complete it over a period of approximately 8 weeks (which includes 6 peer mentor calls and five corresponding online modules). All participants will be asked to complete surveys at four time points: baseline, immediate post-intervention (~8 weeks after baseline), 3-month follow-up (~5 months after baseline), and 9-month follow-up (~12 months after baseline).

3.2 Study Sites

Phase 1& 3a: Interviews will be conducted at the Rutgers Cancer Institute of New Jersey or via phone.
Phase 2&3b: Peer mentors will be trained at the Rutgers Cancer Institute of New Jersey or via phone or online webinars. Participants will receive intervention materials online, via email, or via text messaging.

3.3 Sample Size Justification

Phase 1: Total sample size is 24-28, including 10 AYA survivors, 10 parents of AYA survivors, and 4-8 physicians who work with AYA survivors. Qualitative data will be analyzed on a continuing basis. Pooling data across participants, we expect 24-28 interviews will be adequate to achieve data saturation (that is, no new themes emerge from additional participants).
Phase 2: 40 AYA survivors and 20 peer mentors will be recruited for the pilot trial to evaluate feasibility (primary objective) and preliminary outcomes (secondary objective). As this is a feasibility study, we recognize we are underpowered to detect small or medium effects. Published data suggest 5-9% of survivors are African American or Hispanic;[22] data from the NJSCR show greater diversity, with 11.6% of patients diagnosed with cancer at age 10-19 during the period of 2008-2012 reporting as African American, 19% reporting as Hispanic, and 5.7% as Asian American/Pacific Islander. We will oversample these groups.
Phase 3A: Up to 20 AYA survivors will be recruited for usability testing of the online intervention. Given the preliminary work conducted in Phase 2, we expect 12-20 sessions will achieve data saturation (i.e., no new issues emerge according to pre-specified stopping criteria).[23] Usability testing is designed to be iterative in that changes can be made to the site after a small number of participants. Therefore, participants who agree may be asked to complete multiple usability sessions over the course of a few months to provide additional feedback on changes or new features added. Thus we expect about 12 to 20 participants will be needed to achieve data saturation.
Phase 3B: Total sample size is 50 AYA survivors. We chose the sample size and decision rules so that the probability of declaring feasibility would be approximately 5% under unacceptable rates of acceptance/completion and exceed 95% under acceptable rates. If true acceptance and completion rates were 41% and 70%, respectively, which we consider too low to move to an efficacy trial, then the probability of declaring feasibility would be 5%.

Table 1. Feasibility decision rules.

Feasibility	Unacceptable Rate	Acceptable Rate	Decision rule for claiming Feasibility	Prob. Declare Feasible under Unacceptable Rates	Prob. Declare Feasible under Acceptable Rates
Acceptance	41%	50%	If 50 recruited by the 100th eligible	5%	97%
Retent	70%	80%	40 people complete	5%	94%

ion			the follow-up		

Sample size was based on the primary feasibility aim, but we also calculated detectable group difference in the primary outcome of the RTQ Adolescent Responsibility total score at the 6-week post-intervention time. Based on survey data,[24] we expect AYA survivors to score an average of 2.57 (*SD* = 0.83) at baseline. Using an independent t-test assuming the control group remains at baseline levels and two-sided alpha of .05, we have 80% power to detect a group difference of 0.66 in the outcome. This would represent the intervention group increasing from "sometimes" to "often" being responsible, which we consider clinically meaningful.

Up to 20 mentors will participate. Mentors will be matched 1:1 with AYA survivors; each mentor may agree to work with up to 5 individuals. As in Phase 2, we expect that several mentors will choose to mentor more than one individual, so a sample size of up to 20 is reasonable.

3.4 Subject Selection and Enrollment Considerations

3.5.1 Inclusion Criteria

Phase 1:
Patient eligibility includes:
(1) age 18-25
(2) at least 1.5 years from treatment (which is a typical time for preparation to transfer to long-term follow-up care)

Parent eligibility includes:
(1) caregiver of a pediatric cancer survivor age 18-25 who was primary caregiver at diagnosis
(2) patient is at least 1.5 years from treatment

Provider eligibility:
(1) health professional who works with childhood cancer survivors ages 18 to 25

Phase 2:
Peer mentor eligibility includes:
(1) age 21-29
(2) at least 1.5 years from treatment
(3) self-reported primary responsibility for care and "complete readiness" using the Readiness for Transition Questionnaire[25]

Patient eligibility includes:
(1) age 18-25
(2) at least 1.5 years from treatment
(3) currently does not independently self-manage follow-up care according to self-report (i.e., reports low readiness to assume total responsibility for care [score of 1 or 2

out of 4 on overall readiness item OR scores <3 on any of the 10-item responsibility scale) using the Readiness for Transition Questionnaire[25])

Phase 3A:
AYA survivor eligibility includes:
(1) age 18-29
(2) at least 2 years from treatment for any pediatric cancer diagnosed at age 0-19

Phase 3B:
Peer mentor eligibility includes:
(1) age 21-29
(2) at least 2 years from treatment
(3) self-reported primary responsibility for care and "complete readiness" to assume responsibility for care or high scores (3 or 4) on all items from the Readiness for Transition Questionnaire[25]

Patient eligibility includes:
(1) age 18-25
(2) at least 2 years from treatment for any pediatric cancer diagnosed at age 0-19
(3) currently does not independently self-manage follow-up care according to self-report (i.e., reports parent is primarily responsible or low readiness to assume total responsibility for care [score of 1 or 2 out of 4 on overall readiness item OR scores <3 on two or more items of the 10-item responsibility scale) using the Readiness for Transition Questionnaire[25])

3.5.2 Exclusion Criteria

Phase 1:
Patient exclusion criteria includes:
(1) physician- or self-reported cognitive delay or impairment that would prevent self-management of healthcare

Parent exclusion criteria includes:
(1) patient has physician- or caregiver-reported cognitive delay or impairment that would prevent self-management of healthcare

No provider exclusion criteria

Phase 2:
Patient exclusion criteria includes:
(1) physician- or self-reported cognitive delay or impairment that would prevent self-management of healthcare
(2) patients with cancer diagnoses that are not typically considered pediatric cancer, including basal and squamous cell skin cancer, breast, colorectal, lung, melanoma, merkel cell skin cancer, ovarian, testicular, kidney cancer diagnosed at age >17, and nasopharyngeal diagnosed at age > 17.

Phase 3A/3B:

Patient exclusion criteria includes:

(1) physician- or self-reported cognitive delay or impairment that would prevent self-management of healthcare
(2) patients with cancer diagnoses that are not typically considered pediatric cancer, including basal and squamous cell skin cancer, breast, colorectal, lung, melanoma, merkel cell skin cancer, ovarian, testicular, kidney cancer diagnosed at age >17, and nasopharyngeal diagnosed at age > 17.
(3) Non-English speaker

3.5.3 Subject Recruitment

Phase 1: We will recruit 10 AYA survivors of childhood cancers and 10 caregivers through the Rutgers Cancer Institute Long-Term Information Treatment-Effects Evaluation (LITE) program. Invitational letters from Dr. Masterson, the Director of the LITE program, will be sent to patients on the CINJ LITE mailing list. Flyers will be posted and handed out in clinic. Potentially eligible participants will be approached at routine LITE clinic visits to describe the study, answer any questions, and assess interest in participating. If a parent does not accompany an AYA survivor to the LITE visit, we will ask interested AYA survivors to share a flyer with their parent(s). AYAs and parents do not have to be dyads to enroll in the study. We will also recruit 4-8 healthcare providers (e.g., physicians, nurse practitioners, social workers, psychologists) who regularly work with AYA pediatric cancer survivors. These providers will be recruited through the Rutgers Cancer Institute of New Jersey as well as through the AYA and Survivorship Working Groups of the Children's Oncology Group because they will have greater expertise and experience with AYA survivors than community providers.

Phase 2: Peer mentors will be recruited via advertisements in the CINJ LITE clinic and newsletter, AYA cancer support groups, and online forums/social media, such as stupidcancer.org. Following the Children's Oncology Group's approach to recruiting patient advocates, potential mentors will complete an application including two letters of recommendation. The PI or study staff will interview candidates to evaluate interpersonal skills, level of commitment to the program, and counseling or related experience. Participants for the randomized trial will be recruited using the New Jersey State Cancer Registry (NJSCR). All participant information and surveillance data from the NJSCR is collected and maintained by the NJSCR following Standard Operating Procedures (see IRB#Pro20140000992 NJSCR SEER Data Repository). Patient contact procedures, tracking, and data release also follows NJSCR Standard Operating Procedures. Per Standard Operating Procedures, NJSCR staff will contact the physician of record for eligible cases to notify the physician about the study and that staff will be contacting the patient. An introductory letter and flyer will be mailed to potential participants. NJSCR staff will make follow-up phone calls to provide additional information and, for patients who express interest in participating, to obtain permission to send their contact information to Dr. Devine's study staff, who will then contact the patient for further details and discussion of consent.

Phase 3A: AYA survivors will be recruited during routine CINJ LITE clinic visits, via advertisements in the CINJ LITE clinic and newsletter, mailing a recruitment flyer to

CINJ LITE clinic patients, and via online forums/social media, such as Twitter and Facebook (wording of advertisements are submitted for approval as recruitment materials prior to use). At LITE visits, the PI or trained study staff will approach potentially eligible patients to provide a brief description of the study, answer any questions, and, if interested, obtain consent and schedule a feasibility session. For potential participants mailed a recruitment flyer, trained study staff will make follow-up phone calls to provide study information, answer any questions, and, if interested, obtain consent and schedule a feasibility session.

Phase 3B: As done in Phase 2, peer mentors will be recruited via advertisements in the CINJ LITE clinic and newsletter, AYA cancer support groups, and online forums/social media, such as stupidcancer.org. Following the Children's Oncology Group's approach to recruiting patient advocates, potential mentors will complete an application including two references or a letter of recommendation. The PI or study staff will interview candidates to evaluate interpersonal skills, level of commitment to the program, and counseling or related experience. Participants for the randomized trial will be recruited using the New Jersey State Cancer Registry (NJSCR). All participant information and surveillance data from the NJSCR is collected and maintained by the NJSCR following Standard Operating Procedures (see IRB#Pro20140000992 NJSCR SEER Data Repository). Patient contact procedures, tracking, and data release also follows NJSCR Standard Operating Procedures. Per Standard Operating Procedures, NJSCR staff will contact the physician of record for eligible cases to notify the physician about the study and that staff will be contacting the patient. An introductory letter and flyer will be mailed to potential participants. NJSCR staff will make follow-up phone calls to provide additional information and, for patients who express interest in participating, to obtain permission to send their contact information to Dr. Devine's study staff, who will then contact the patient for further details and discussion of consent. NJSCR staff will send second mailings to participants who they are unable to reach via phone, with an informational sheet and an option for participants to respond via mail. At the end of the study NJSCR will provide investigators with aggregate de-identified data (i.e., age, gender, time since diagnosis, etc.) on refusers, so that a comparison can be made between "refusers" and the "acceptors."

To maximize the enrollment, we will also recruit mentors and participants during routine CINJ LITE clinic visits or by mail. We will include an approved study recruitment flyer and study staff will follow-up with a phone call to answer any questions and, if interested, initiate the consent process.

3.5.4 Consent Procedures

Phase 1 and 2: The study will be explained to the potential participant by the Principal Investigator or trained study staff via phone. The PI or study staff will review essential elements of consent and answer any questions. Interested and eligible participants will be emailed a link to an online consent form prior to starting the program. To consent, potential participants will be instructed to click "submit the form" button in order to consent.

Phase 3A: The study will be explained to the potential participant by the Principal Investigator or trained study staff in person or on the phone. All subjects will receive a

copy (paper or electronic) of the consent form. To document the process of the consent, we will complete "documentation of Consent Process" form to document that 1) study subjects were provided with a copy of the Consent Forms, 2) all essential elements of informed consent were discussed with subjects, 3) subjects were given adequate time to read and discuss the study with study staff, and 4) all questions asked by the subjects about the study were answered.
Phase 3B: As done in Phase 2, the study will be explained to the potential participant by the Principal Investigator or trained study staff via phone. The PI or study staff will review essential elements of consent and answer any questions. Interested and eligible participants will be emailed a link to an online consent form prior to starting the program. To consent, potential participants will be instructed to click "submit the form" button in order to consent. Since consent forms will be completed online, we are requesting a waiver of documentation of consent.

3.5.5 Subject Costs and Compensation

Phase 1: Participants who drive to the Rutgers Cancer Institute of New Jersey to complete an interview will incur parking costs. Participants will be given $25 for completion of an interview.
Phase 2: Peer mentors will be asked to travel to the Rutgers Cancer Institute of New Jersey for training; they will be compensated $100 for their time and travel. Peer mentors and participants will be asked to use their personal phone for communication via phone and text, which may incur costs depending on the participants' phone plan. Peer mentors will be compensated $100 per participant mentored to cover costs and effort. Participants will receive $25 per assessment completed (for a total of $50).
Phase 3A: There are no anticipated costs of completing usability testing. Participants will receive $25 gift card for each usability session completed, up to 5 sessions.
Phase 3B: Similar to Phase 2, peer mentors will be asked to travel to the Rutgers Cancer Institute of New Jersey for in-person training or attend via videoconference/webinar. They will be compensated $75 for their time/travel. Peer mentors and participants will be asked to use their personal phone for communication via phone and text, which may incur costs depending on the participants' phone plan. Peer mentors will be compensated $75 per participant mentored to cover costs and effort. Participants will receive $50 per assessment completed (for a total of $200).

4. Study Variables

4.1 Independent Variables or Interventions

Phase 1: Semi-structured interview guides will be used to conduct interviews. The goal of the interviews is to understand patient, parent, and provider perspectives on the challenges faced by AYAs in managing their health care and on how PSST materials can be adapted to address the challenges of self-management of care.
Phase 2: Independent variables include demographics (age, gender, socioeconomic status, education, employment status, living at home or independently) and cancer diagnosis and treatment history (i.e., diagnosis, time since treatment completion, types of treatment received). Diagnosis and date of diagnosis will be obtained from NJSCR records and the remaining information from self-report.

Phase 3A: Demographics (age, gender, socioeconomic status, education, employment status, living at home or independently) and cancer diagnosis and treatment history (i.e., diagnosis, time since treatment completion, types of treatment received) will be collected by self-report.
Phase 3B: Same as Phase 2.

Phase 2: Peer Mentoring Intervention. Based on initial interviews and feedback on the PSST intervention, we identified five major themes to be addressed in our program. The intervention will include two components: (1) online self-management educational modules using the Rutgers Canvas online course platform and (2) weekly video-conference calls on Doxy.me between the peer mentor and participant. Table 1 shows the content of the five online modules based on preliminary work. Participants are expected to complete one module per week in addition to a call with their mentors. Each module takes approximately 30 minutes to complete and ends with a personalized assignment for the participant to complete on his/her own (e.g., obtain survivorship care plan, make an appointment, practice communication skills).

Participants will be matched with a peer mentor of the same sex and cancer type to the extent possible.[26,27] The objectives of the first mentor call are to build rapport, exchange stories regarding current long-term follow-up care, and identify the participant's self-management strengths, weaknesses, and goals. During this call, the mentor will explain that the mentee is expected to complete one online module per week prior to their next scheduled mentor call (one a week for six weeks). The dose was chosen based on other peer mentoring programs that employed weekly Skype calls.[26,27] Weekly video-conference calls will be made on HIPAA compliant Doxy.me (https://doxy.me/) that implements security and encryption protocols to assure that data integrity and privacy is maintained. In addition to weekly calls, the mentor will encourage the participant to work through the assignment and modules via a weekly text message (using TigerText,[28] a HIPAA-compliant program) to offer encouragement, support, and relevant resources. Mentor-mentee calls will be recorded and text messages will be archived for supervision and content analysis.

Given that AYAs are high consumers of technology[21] and tend to have many different educational, work, and social scheduling demands, we believe using online educational modules and technology to connect the peer mentor and participants will be the most efficient delivery system for this group. To capitalize on AYAs' regular use of technology, peers will provide support and facilitate completion of educational modules via 6 weekly phone calls and secure text messaging. We will utilize the TigerText service that will allow for secure messaging between participants and peer mentors, as well as between the study personnel, peer mentors, and participants.

Table 2. Content of self-management modules

Module	Proposed Content	Transition Readiness Construct
1	**Understanding Treatment History and Survivorship Care Plan** • Name diagnosis, treatments received, risks for late health effects • Obtain (if needed) and store Survivorship Care Plan • Identify necessary health screenings and frequency	Knowledge Goals/motivation
2	**Managing Your Health Care** • Review self-management tasks (e.g., make appointments, obtain screenings) • Establish and maintain relationship with primary care doctor • Logistics of insurance and healthcare tasks • Identify barriers to obtaining care and problem solve	Self-Management Skills Self-efficacy Relationships/communication Goals/motivation

	• Review motivation and confidence to assume responsibility for care	
3	**Negotiating Family Involvement in Your Care** • Discuss challenges of parents who do not relinquish control & communication skills • Discuss supportive ways to include family	Relationships/communication
4	**Dealing with Emotions about Your Health and Follow-Up Care** • Coping with uncertainty of future health • Communicating with providers & families about adult-oriented healthcare	Self-Management Skills Relationships/communication
5	**Staying Healthy in the Context of Life Transitions** • Recognize that health must be maintained in the context of other important life transitions (e.g., education, career, relationships) • Skills & resources for healthy diet, exercise, sexual health/fertility, education, career • Identify value in prioritizing health	Goals/motivation Self-Management Skills Self-efficacy

Peer Mentor Training. Peer mentors will attend a one-day training workshop conducted by the PI and study staff (similar to other peer mentor programs[26,29]). Peer mentors will be given the Peer Mentor Handbook, a manual adapted from the National Mentoring Research Center, which details their roles, responsibilities, and an outline for each mentor call. Presentations, interactive discussions, and role plays will be used to teach mentors how to facilitate their mentee's use of the online self-management modules, and how to provide informational and emotional support to their mentees. Ethical issues, including confidentiality and setting boundaries with peers, will be discussed. Peer mentors will also be instructed in how to securely transfer audio recordings of their calls with mentees and destroy the original file from their devices. In addition to the in-person training, we will email these instructions. Peer mentors will have regular weekly phone supervision with the PI or trained study staff once assigned mentees to review mentoring calls and discuss any challenges experienced. During this supervision call, the PI or research staff will verbally confirm that peer mentors have destroyed any transferred audio recordings for the study.

Phase 3B: Self-Management + Peer Mentoring Intervention. The intervention content is the same as described in Phase 2. There are a few minor differences: (1) the online modules will be hosted on its own website instead of Canvas; this website will be built in Phase 3A using Radiant Creative Group, LLC, an experienced technology development firm that has a strong history of collaboration with Dr. Devine and other Rutgers Cancer Institute of New Jersey investigators; (2) TigerText is now called TigerConnect and has expanded its services to include secure videoconferencing; therefore, doxy.me will no longer be used; and (3) peer mentor training can be completed either in-person or via videoconference to minimize peer mentor burden.

Phase 3B: Usual Care Comparison. The Usual Care group will complete surveys only. To select an appropriate comparison, we reviewed the literature of advantages/disadvantages of different designs.[30-33] This study can be characterized as a phase IIb feasibility pilot focused on feasibility and acceptability, as well as detecting a clinically significant signal over noise.[32] A usual care comparison group is recommended for initial evaluations of such interventions,[30] as it maximizes statistical power and protects against falsely concluding that the intervention lacks efficacy. We will offer access to the online educational modules upon completion of all study procedures to the interested subjects in the usual care comparison group.

4.1.1 Drug or Device Interventions

N/A

4.2 Dependent Variables or Outcome Measures

Phase 1: The primary outcome measure is qualitative interview data. Interviews will be transcribed for analysis (see Data Handling and Statistical Analysis section for details). Participants will also be asked to complete the questionnaires selected for Phase 2 and provide feedback to the study staff regarding how well the questionnaires capture self-management of survivorship care.

Phase 2: The following standardize measures will be administered at baseline and immediately post-intervention (~6 weeks), except where noted:

Transition readiness. The Readiness for Transition Questionnaire – Survivor Version (RTQ)[25] is a 22-item scale evaluating transition readiness for cancer survivors. Respondents are asked to rate the degree to which they are responsible for various aspects of their health care, such as knowing their survivorship care plan, scheduling visits, and filling prescriptions. They are separately asked to rate the degree to which their parents are responsible for managing the same aspects of their care. Two questions ask about the survivors' overall perception of their readiness to transfer to an adult-approach to health care. The RTQ has demonstrated adequate reliability.[25]

The Transition Readiness Inventory (TRI), developed using the SMART framework,[34] is a comprehensive measure of multiple components of transition readiness. While the RTQ focuses on responsibility for behaviors, the TRI focuses on behaviors *and knowledge, attitudes, and beliefs*. Specifically, the TRI yields a total score and provides scales for the following targets of our intervention: knowledge, self-management skills, self-efficacy for managing care, goals/motivation, and communication with family and providers around survivorship care. The TRI has shown adequate reliability and content validity,[34,35]and evidence of predictive validity of engagement in adult healthcare.[35] We will utilize the total TRI score.

Negative Affect. PROMIS Depression and PROMIS Anxiety measures are validated 8-item measures of depressive symptoms and anxiety. We will examine cancer-related anxiety using the Fear of Recurrence Scale,[36] which has been used with young adult survivors of childhood cancers.[37] Finally, we will adapt items to examine anxiety related to healthcare transition and cancer late effects. We will also use the Cancer Related Worry Scale to assess participants' concerns related to their cancer past and future.

Impact of Cancer. Three subscales from the Impact of Cancer – Childhood Cancer Survivors Scale[38] will evaluate perceptions of impact on body and health, memory and thinking, and personal growth. Participants will be asked to complete all three subscales; mentors will be asked to complete body and health and personal growth only to evaluate if mentoring has positive effects on these outcomes.

Perseverance. The Short GRIT Scale[39] is an 8-item measure of perseverance for long-term goals. We will examine the total score as a correlate of transition readiness and adherence to follow-up care.

Barriers to follow-up care & adherence. We will evaluate insurance status, current provider, and other barriers to care with the Follow-Up Care Use and Health Outcomes of Cancer Survivors (FOCUS) measure. Participants will report on appointments, cancer screenings, and other adherence markers.

Treatment Integrity. Peer mentors will record their video/phone conversations with participants for supervision with the PI. Additionally, 10% of tapes will be randomly selected for treatment integrity review using a checklist of the core components of each session.

Mentor/Participant Alliance. A brief measure of personality (Ten Item Personality Inventory[40]) will be administered to participants and mentors at baseline only to examine whether personality matching relates to perceived relationship alliance. A brief measure of the alliance between the mentor and participant (Working Alliance Inventory – Short Form[41]) will be completed by mentors and participants at post-intervention only.

Satisfaction with Intervention. At the 6 week post-intervention assessment, participants will be asked to complete a survey regarding their satisfaction with the intervention received and recommendations for improvement. For the intervention group receiving the online modules and peer mentor, items from a standardized set of internet-based intervention evaluation tools will be used - Internet Intervention Utility Questionnaire, Impact Questionnaire, and Adherence Questionnaire.[42,43] The Utility Questionnaire measures perceived usefulness, enjoyment, and ease of use. The Impact Questionnaire measures perceived effectiveness in improving targeted skills. The Adherence Questionnaire measures barriers to engagement. Objective user data (i.e., log-ins, posts, modules completed) will be obtained unobtrusively from Canvas. Peer mentors will be given an interview (i.e., Peer Mentor Interview) at the end of the program to assess their thoughts about the program (what went well, did not work well, etc.) The participants will also be asked to do a brief (~20 minute) phone exit interview with the PI or the study staff to gather qualitative feedback on how to improve the program in the future (see Participant Exit Interview Guide).

Phase 3A: The primary outcome measure is qualitative interview data and participant report on a brief standardized internet-based intervention evaluation tool, the Visual Aesthetics of Websites Inventory. Notes will be taken during usability sessions.

Phase 3B: Feasibility outcomes include treatment fidelity, satisfaction, acceptability, usability/engagement with the online modules, and acceptance/engagement with the peer mentor. These will be measured via survey and objective user analytics for the online modules. Behavioral outcomes include transition readiness, fear of recurrence, barriers to follow-up care, adherence to follow-up care, adherence to general healthcare practice recommendations, self-efficacy (i.e., general, survivorship care specific, health insurance, communication, managing emotions), perceived emotional and informational support, perceived stigma/shame associated with cancer survivorship, healthcare utilization behaviors, and health behaviors (i.e., tobacco, alcohol, exercise, sedentary). The survey consists of validated measures of each construct or items drawn from validated instruments including the BRFSS 2018[40], NHANES 2013-2014[41], HINTS[44], and CCSS[45]. The table below indicates the items and time points for administration.
At the last follow-up, we will also ask participants to sign medical record release forms to share medical information from their cancer-related physician(s) and primary care physician(s) to verify healthcare utilization during the study period. These forms will be available to participants either via regular mail, along with a postage-paid return envelope, and/or a link to the electronic copy of the form, requesting an electronic signature, hosted by the HIPAA compliant Qualtrics data collection tool.

Once the Medical Record Release form is completed, signed and returned along with the contact information of the doctors visited in the last 12 months, we will verify the contact information provided by the patient for completeness against publicly available data on the web. We will then mail, email, and/or fax the request for information to the doctor (depending on the contact information available) along with a cover letter and a copy of the signed medical record release form for the patient. We will follow-up with up to three phone calls or emails to the doctor/doctor's office if we do not receive a response to our request. We will request the following information: survivorship care plan/treatment summary (if available), dates and types of visits in the past 12 month (i.e., preventive care, survivorship care, or sick visit) and dates and types of medical screening tests/labs completed in the past 12 months.

	Time Point			
Measure	Baseline	Post-Intervention (~8 weeks)	Follow-Up (~5 months)	Follow-Up2 (~12 months)
Readiness for Transition Questionnaire – Survivor Version (RTQ)	x	x	x	x
Transition Readiness Inventory (TRI)	x	x	x	
Fear of Recurrence Scale[36]	x	x	x	
Perceived public stigma and internalized shame[47]	x	x	x	
Self-efficacy (general, cancer-survivorship, health insurance, communication)	x	x	x	x
Follow-Up Care Use and Health Outcomes of Cancer Survivors (FOCUS)	x		x	x
Healthcare Practices (i.e., general physical exam, immunizations, dentist, cancer screenings)	x		x	x
Health behaviors (i.e., tobacco, alcohol, exercise, sedentary)	x	x	x	
PROMIS -Self-Efficacy for Managing Chronic Conditions-Managing Emotions -Information Support -Emotional Support	x	x	x	X (Information & Emotional Support only)
Chronic Disease Self-Efficacy: Communicate with physician scale[42]	x	x	x	x
Working Alliance Inventory – Short Form[41]		x		
Internet Intervention Utility Questionnaire, Impact Questionnaire, and Adherence Questionnaire.[42,43] &		x		

Treatment Evaluation Inventory-Short Form				

Mentors will be asked to complete a brief self-efficacy survey at time of training (Mentor Survey 1), a brief evaluation of the training (Mentor Training Evaluation), and a survey including program evaluation ratings when they have completed mentoring their last mentee (Mentor Survey 2). After completing the final call with each mentee, they will be asked to complete the Working Alliance Inventory – Short Form[41] regarding their relationship with the mentee.

4.3 Risk of Harm

Phase 1: Risks are considered minimal and include breach of confidentiality. Every effort will be made to ensure confidentiality of data.
Phase 2: Risks are considered minimal and include breach of confidentiality. Every effort will be made to ensure confidentiality of data. Peer mentors will be instructed in the importance of maintaining confidentiality and supervised by the PI. Surveys will ask about self-management skills, transition readiness, anxiety, barriers to care, and adherence to follow-up recommendations. Although discomfort related to such questions is unlikely, participants can choose not to answer any question for any reason and may withdraw at any time.
Phase 3A: (same as Phase 1) Risks are considered minimal and include breach of confidentiality. Every effort will be made to ensure confidentiality of data.
Phase 3B: (same as Phase 2) Risks are considered minimal and include breach of confidentiality. Every effort will be made to ensure confidentiality of data. Peer mentors will be instructed in the importance of maintaining confidentiality and supervised by the PI. Surveys will ask about self-management skills, transition readiness, fear of recurrence, self-efficacy, barriers to care, adherence to follow-up recommendations, and health behaviors. Although discomfort related to such questions is unlikely, participants can choose not to answer any question for any reason and may withdraw at any time.

4.4 Potential for Benefit

Phase 1: There is no direct benefit to participants.
Phase 2: There may or may not be a direct benefit to participants. All participants will receive information regarding self-management that may be useful to participants but the study will evaluate the feasibility of implementing the interventions as well as participant-reported satisfaction and relevant quality of life outcomes.
Phase 3A: There is no direct benefit to participants.
Phase 3B: There may or may not be a direct benefit to participants, as we do not yet know if the intervention is better than usual care.

5. Data Handling and Statistical Analysis

Phase 1 (Aim 1):
Data Management: Digital recordings will be transferred off of the recorders to the PI's secure shared drive as soon as possible following the interview and then erased from the recorder. Transcription will be completed as soon as possible, removing any identifiable information. All transcriptions will be labeled with a subject number rather than any identifiable information. Digital recordings will be deleted after they are described and checked for accuracy. Paper questionnaires will be labeled with an ID number and stored separately from consent forms in a

locked cabinet in the PI's locked office. The key linking subject names and subject numbers will be stored electronically on the PI's password-protected CINJ internal shared drive and destroyed at the end of the study.
Data Analysis: Qualitative data will be analyzed using content analysis, following the framework approach described by Pope and colleagues.[44] Specifically, themes will be identified based on the a priori theoretical framework (SMART model). Data will be constantly compared to evaluate fit to the model and new themes that emerge from participants' data will be added to the model. An index of themes will be created and applied systematically to the data using NVivo, a qualitative data analysis software. Data analysis will continue until theme saturation occurred (that is, no new themes emerge from additional participants). Participant feedback on questionnaires will be used to determine if any changes are needed to the outcome measures for Phase 2 of the study.

Phase 2 (Aims 2 & 3):
Data Management: The Rutgers Cancer Institute of New Jersey has a contract and Business Associate Agreement with TigerText to supply HIPAA-compliant secure messaging services and archiving of messages. TigerText will be used for secure text messaging with participants and between mentors/mentees. TigerText uses AES-256/SSL encryption and exercises a number of physical, technical, and administrative safeguards to protect all messages and data. At the application layer, TigerText uses Secure Socket Layers (SSL) to encrypt all communication between the web browser and the data center, and a processing pipeline that ensures performance and data privacy between customer accounts. TigerText partners with Sonian to archive the messages between participants, which will be used for supervision of mentors and for content analysis to determine how mentors and mentees communicated during the study. The archived message data will be accessed and downloaded by the PI or project coordinator using the secure TigerText web portal and stored electronically on the PI's password-protected CINJ internal shared drive. These data will be labeled with an ID number rather than participant name or other identifier. All interactions in the TigerText system are included in the audit logs to ensure that administrators are properly using the web portal and it's services.

Databases for participant recruitment and tracking and participant survey data will be developed in collaboration with the CINJ Population Science Research Support Core using HIPAA-compliant DatStat software. The Core provides access to the DatStat software, facilitates initial study setup, and assists in the event of any technical problem in using the DatStat software. Approval for use of this software in research studies has been provided by the Rutgers Biomedical and Health Sciences Institutional Review Board (IRB). (The approval process included: obtaining a Technology Professional Service Agreement and a Business Associate Agreement from DatStat; the approval of a Security Questionnaire from the Rutgers Office of Information Technology; and the completion of a Security Risk and Assessment Tool by the Rutgers CINJ Office of Information Technology.) The software allows for research study personnel to be assigned data access and privileges specific to their role on the study. Study team members are given access to the minimum amount of data needed to perform their role on the study.

Online surveys will be completed by participants using a secure website (hosted on DatStat servers). DatStat secure servers are registered with site certificates provided by AddTrust that

provide for advanced encryption over the wire. As each user moves through the survey form, his/her responses are encrypted while in-transit between the browser and DatStat's server using SSL (Secure Sockets Layer) and 40, 56, or 128-bit Public Key Encryption. All servers used for data collection are highly fault-tolerant and equipped with redundant, hot-pluggable power supplies, redundant network interfaces, and RAID 5 hot-swappable disk storage. All primary servers are plugged into a monitored, uninterruptible power supply (UPS). DatStat servers are stored in a locked server cabinet/rack, which are housed in a state-of-the-art, well-ventilated data center. Physical access to servers and data backup is restricted to a minimal number of information technology professionals. The servers are secured with physical and firewall security.

Participants will complete surveys online or via paper (depending on participants' choice). Paper surveys will be identified using only a subject number and will be entered into the database by study staff and kept in a locked filing cabinet accessible only be authorized study staff. We will keep a separate electronic key linking codes and subject names on the PI's department drive. This key will be destroyed at the end of the study. De-identified data will be kept indefinitely. Audio files of video/phone calls between peer mentors and mentees will be recorded using the peer mentor's handheld audio recorder. The peer mentor will then use Rutgers Large File Transfer Service (LiFT) to securely upload the files for the study team to review. This service allows both internal and external users to upload files securely with their email and password. The peer mentors will be instructed to destroy the files after they have successfully uploaded files to Rutgers LiFT for study team to review. Peer mentors will receive training on how to securely transfer the files and delete the files from their devices during the mandatory in-person peer mentor training. The study team will download the files via the secure LiFT service and store them on the Rutgers secure shared drive accessed via a password-protected computer. For participant exit interviews, study staff will record the interview, transfer to the secure shared drive (access limited to pertinent research team members). Recordings will be transcribed as soon as possible, removing any identifying information from the written document. Recordings will be destroyed upon completion of the study procedures.

Data Analysis: We will examine feasibility through study enrollment rates, retention rates, reasons for study drop out, adherence to the intervention, and patient and mentor satisfaction with the program. Descriptive analyses (frequencies, means) will be used to evaluate our hypotheses regarding expected enrollment (>50%), retention (>75%), and completion of intervention sessions (>75%). We based these predictions using the literature describing barriers to recruiting AYA participants[45] and the team's collective experience in intervention development and implementation.

To assess the preliminary outcomes of the peer mentor self-management program, we will evaluate whether participants in the program demonstrate improvement in transition readiness and the impact of cancer, and reductions in symptoms of depression and anxiety. We will also explore adherence outcomes. We will compare scores on outcome measures at the end of 6-week assessment using dependent/paired t-tests. Since the primary purpose of this project is to evaluate feasibility, we recognize that we do not have adequate power to detect small to medium statistical effects. Exit interviews will be reviewed to identify strengths of the intervention, weaknesses of the intervention, and ideas to improve the intervention.

Phase 3A:
Data Management: Usability testing notes will be labeled with an ID number without any identifying data. The Visual Aesthetics of Websites Inventory will only be labeled with an ID number. The key linking subject names and subject numbers will be stored electronically on the PI's password-protected CINJ internal shared drive and destroyed at the end of the study.

Data Analysis: The research team will discuss user experience difficulties with the design team for changes during the iterative cycles of usability testing. Given the preliminary work already conducted, we expect 12-20 sessions will achieve data saturation (i.e., no new issues emerge according to pre-specified stopping criteria). Responses to the Visual Aesthetics of Websites Inventory will be summarized with descriptive statistics (e.g., means, frequencies of responses).

Phase 3B:
Data Management: The same procedures used in Phase 2 will be used in Phase 3B, with the exception that TigerConnect (previously called TigerText) will be used for secure messaging as well as secure videoconferencing (instead of doxy.me). Additionally, TigerConnect now allows for secure file transfer so that peer mentors can securely transfer audio recordings to the study team either via Rutgers LiFT or TigerConnect. For participants who consent to be contacted for future studies, the study team will store their contact information separately from research records on the PI's secure One Drive, with access granted only to the PI, study coordinator, and limited authorized research staff. We will store this information for up to 10 years from date of consent.

We will utilize HIPAA compliant Qualtrics survey tool to request the name and contact information of the physician they have seen in the past 12 months to understand their health care utilization during the study period and to obtain their electronic signature on the Release of Medical Record form. Any paper copies will be kept in a locked filing cabinet in the PI's office.

Data Analysis: We will examine feasibility through study enrollment rates, retention rates, usability/engagement with online modules and peer mentor, barriers to engagement, and reasons for study drop out. Descriptive analyses (frequencies, means, confidence intervals) will be used to evaluate hypotheses regarding enrollment (>50%), retention (>80% complete all surveys), and intervention completion (>75% modules/mentor calls). Multilevel modeling (MLM) will be used to examine differences between the intervention and usual care groups over time on transition readiness (RTQ Adolescent Responsibility and TRI total scores). Our primary analysis will consider both time and treatment to be categorical with an interaction between the two. The interaction will be assessed to determine whether change in transition readiness differs between the two groups. The MLM approach assumes any missing observations are missing at random but includes all observed data. Exploratory analyses of additional outcomes (e.g., self-efficacy, adherence to medical appointments and screenings, and health behaviors) will use the identity link or the logit link as appropriate for continuous or binary outcomes.

6. Data and Safety Monitoring

Phase 1 & 2: This study is minimal risk. The PI and co-investigators will monitor for adverse events and report any events according to RBHS IRB guidelines.

Phase 3A & 3B: This study is minimal risk. The PI will convene a Data and Safety Monitoring Board (DSMB) composed of the biostatistician and a behavioral scientist and clinician who are not associated with the study. The committee will be responsible for oversight of patient safety and will meet yearly to review patient safety and trial progress. This review will include for each arm of the study: the number of patients enrolled, withdrawals, serious adverse events both expected and unexpected, and responses observed. All unexpected and/or serious adverse events (AEs) occurring during the active portion of the intervention or up to 30 days after the last peer mentor call, will be reported to the Rutgers Cancer Institute of New Jersey Office of Human Research Services and the Rutgers Biomedical Sciences Institutional Review Board (IRB) in accordance with IRB policy. The PI and study staff will continuously monitor for any potential AEs. Peer mentors will be instructed in how to assess and report adverse events during the mentor training and study staff will explicitly ask about adverse events during regular supervision sessions with each mentor. The research team will review and discuss via a teleconference any serious adverse events to ensure protections to the participants and security of the data, and discuss any modifications needed. If modifications are needed, they will be implemented immediately following standard IRB procedures. The Rutgers Cancer Institute of New Jersey Scientific Review Board and the IRB will review this Data and Safety Monitoring Plan and the study protocol prior to initiation of the study. A report with recommendations from the DSMB will be submitted annually to the IRB with the continuing review for the study.

7. Reporting Results

7.1 Individual Results
N/A

7.2 Aggregate Results
Aggregate results will be reported in scientific publications. Plain language summaries will also be made available at the end of the study. After participants complete the final assessment, we will have a separate form that they can voluntarily complete with preferred contact information (i.e., mail, email) to receive a summary of aggregate results. This information will be stored confidentially until the summary is provided, at which time the contact information will be destroyed.

7.3 Professional Reporting
It is expected that the results of this research will be submitted for publication in a timely manner following the conclusion of the study. The PI and all co-authors must review any abstract or manuscript prior to submission.

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