

# Examples of Funded Grants in Healthcare Delivery Research

## Overview

The National Cancer Institute (NCI) frequently receives requests for examples of funded grant applications. Several investigators and their organizations agreed to let the Healthcare Delivery Research Program (HDRP) post excerpts of their healthcare delivery research grant applications online.

## About

We are grateful to the investigators and their institutions for allowing us to provide this important resource to the community. We only include a copy of the SF 424 R&R Face Page, Project Summary/Abstract (Description), Project Narrative, Specific Aims, and Research Strategy; we do not include other SF 424 (R&R) forms or requisite information found in the full grant application (e.g., performance sites, key personnel, biographical sketches). To maintain confidentiality, we have redacted some information from these documents (e.g., budgets, social security numbers, home addresses, introduction to revised application).

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## SF 424 R&R Face Page

**PI:** Devine, Katie A

**Grant Number:** 1 R21 CA222936-01A1

**Title:** Improving Transition Readiness in Adolescent and Young Adult (AYA) Survivors of Childhood Cancer

**FOA:** PAR16-278

**FOA Title:** STIMULATING INNOVATIONS IN BEHAVIORAL INTERVENTION RESEARCH FOR CANCER PREVENTION AND CONTROL (R21)

**Organization:** RBHS -CANCER INSTITUTE OF NEW JERSEY

**Department:** Rutgers Cancer Institute of NJ

**Senior/Key Personnel:** Katie Devine

**Organization:** Rutgers, The State University of New Jersey

**Role Category:** PD/PI

## **Project Summary/Abstract**

Adolescent and young adult (AYA) survivors of pediatric cancers require lifelong “risk-based” follow-up care tailored to their treatment exposures, including routine medical appointments, monitoring for late effects, and regular cancer screenings. In addition to normal developmental tasks of pursuing higher education, initiating careers, living independently, and forming intimate relationships, AYA survivors must also assume primary responsibility for the management of their long-term follow-up care. This transition from parent-guided management to self-management of medical care can be challenging for the AYA and his or her family, resulting in lapses in care and potentially preventable health problems. Only a minority of young adult cancer survivors obtain risk-based follow-up care; one major contributor to non-adherence is a lack of preparation or low “transition readiness” to transfer to adult-oriented care.

The goal of this project is to pilot test a self-management + peer mentoring intervention to improve AYA cancer survivor transition readiness. Based on the Social-Ecological Model of AYA Readiness for Transition and interviews with AYA cancer survivors, parents, and providers, we created the content for the self-management intervention that focuses on overcoming survivor barriers to self-management such as lack of knowledge, low self-efficacy, and poor communication skills. Peer mentors are a novel component of the intervention and serve to provide credible specialized information, empathy, and advice, capitalizing on shared experience and meeting a psychosocial need for AYA survivors. We conducted a small pilot with AYA survivors to gain feedback on the content and infrastructure of the peer mentor component. AYA survivors found the content, online delivery, and peer mentor contact acceptable, but highlighted a need for engaging online tools. This project will utilize AYA survivor input to build the online intervention with interactive tools such as personalized feedback, animated videos, and games to encourage engagement with the intervention. Then we will conduct a randomized pilot test of the intervention to evaluate feasibility, acceptance, and preliminary effects on AYA transition readiness.

## **Project Narrative**

A lack of preparation to transition from pediatric to adult-oriented healthcare can result in lapses in care and adverse health effects for adolescent and young adult (AYA) cancer survivors who are at-risk for negative health effects due to their cancer treatment history. The proposed innovative intervention is highly responsive to NCI's call for behavioral interventions to improve cancer-related health behaviors across the cancer continuum. This project is intended to empower AYA cancer survivors to become strong advocates of lifelong follow-up care, leading to increased adherence to survivorship medical recommendations and reductions in healthcare costs through prevention or early detection of late effects for survivors of childhood cancers.

## Specific Aims

Childhood cancer survivors are a growing population (>379,000 in the US)<sup>3</sup> who are at risk for adverse late health effects from treatment. Between 67-95% of childhood cancer survivors develop chronic health conditions such as cardiovascular disease.<sup>4-6</sup> Survivors require lifelong “risk-based” follow-up care based on the treatment they received to identify and treat late health effects.<sup>7</sup> Unfortunately, less than 1 in 5 adult survivors of childhood cancer obtain risk-based follow-up care.<sup>8</sup> The transition from pediatric to adult follow-up care is a critical period when many survivors are lost to follow-up.<sup>9</sup> One reason for this loss to follow-up is a lack of preparation or low “transition readiness” for adult-oriented healthcare, which relies on the young adult to assume responsibility for medical decision-making (vs. parent responsibility).<sup>10</sup> Transition readiness is defined as having the skills, motivation, and resources to move from pediatric-oriented to adult-oriented care.<sup>11</sup> This transition involves shifting from parent-management of care to young adult self-management of care, and may also involve changing physical location and providers of care. Transition readiness has been linked to engagement in adult-oriented care.<sup>12</sup> However, very few medical centers have programs to prepare adolescent and young adult (AYA) survivors for successful transfer to adult care. Further, this transition in responsibility for care occurs within the broader developmental transition from adolescence to young adulthood, which is characterized by exploration and striving for autonomy in multiple life domains (e.g., education, career, intimate relationships).<sup>13</sup> These competing developmental tasks often take priority over healthcare transition.<sup>10</sup>

To address this important unmet need among childhood cancer survivors, we developed the *content* of “Managing Your Health,” a self-management skills + peer mentoring intervention that focuses on overcoming survivor barriers to self-management of care. The intervention is guided by the Social-Ecological Model of AYA Readiness for Transition,<sup>1</sup> and it is informed by a series of interviews with AYA cancer survivors, parents, and providers. It consists of two components: (1) online educational modules to improve self-management skills and (2) a peer mentor to provide support and facilitate engagement with the modules. We focus on improving survivors’ transition readiness so they have the skills, motivation, and resources to navigate the healthcare system and overcome barriers to obtaining care. Key barriers addressed by the self-management modules include: lack of knowledge of treatment history and late effect risks, lack of self-management skills for handling healthcare logistics, low self-efficacy for managing care, concern about impersonal relationships with adult (vs. pediatric) providers, and poor communication about medical care with parents and providers.<sup>9,10,14,15</sup> The use of peer mentoring with other AYA cancer survivors is a novel intervention component designed to provide support regarding emotional and practical barriers to transition and to facilitate AYA survivors’ engagement with the online modules. Because of their shared cancer experience, peer mentors can validate AYAs’ concerns about healthcare self-management and address emotional and practical barriers to transition. AYA survivors prioritize opportunities to interact with other AYA survivors<sup>16</sup> and information from trusted peers with similar health experiences may be perceived as more credible,<sup>17</sup> offering an advantage over provider-delivered interventions.

To fill this gap in transitional care, we conducted a series of small studies with AYA survivors to develop and evaluate the basic content of the five self-guided self-management modules and infrastructure of the peer component. The next step is to add interactive components to increase usability and engagement with the material. The goal of this project is to evaluate the feasibility of the “Managing Your Health” intervention. We will use AYA survivor interviews and usability testing to develop interactive tools to create more engaging self-management modules. We will then conduct a randomized controlled pilot test of the intervention versus usual care with 50 AYA survivors ages 18-25 years who have low transition readiness.

### **Primary Aim: Evaluate the feasibility of intervention.**

We will examine feasibility through study enrollment rates, reasons for refusal, retention rates, usability of and engagement with the intervention components, and reasons for study drop out.

*Hypothesis 1:* Based on literature, we expect >50% enrollment of eligible patients and  $\geq$ 80% retention.

*Hypothesis 2:* Participants will complete >75% of online modules and >75% of scheduled contacts with mentor.

### **Secondary Aim: Assess preliminary efficacy of the intervention.**

*Hypothesis 3:* Participants in the self-management + peer mentor intervention will demonstrate greater improvement in transition readiness than participants in the usual care group.

The proposed research seeks to address gaps in the long-term healthcare of pediatric cancer survivors by evaluating an innovative theory-based intervention to improve transition readiness of AYA survivors. Results of the proposed research will provide evidence of feasibility and yield an intervention that will be ready for efficacy testing in a large randomized trial.

## A. SIGNIFICANCE

### A.1. The transition to adult self-management of health is critical but often poorly planned.

AYA cancer survivors are expected to assume primary responsibility for their healthcare when they reach adulthood. Poor readiness to transition to adult self-management of care can lead to inadequate follow-up care or disengagement from care.<sup>18</sup> Given that 67-95% of survivors of childhood cancer develop a chronic health condition by age 45,<sup>5,6</sup> lapses in care present both a personal and societal risk. The personal risk is that late effects are undetected, misdiagnosed, or mistreated. The societal risk is that a lack of monitoring leads to increased preventable healthcare costs. Unfortunately only a minority (<18%) of adult childhood cancer survivors obtain risk-based follow-up care.<sup>8</sup> Current guidelines recommend at least an annual surveillance visit in addition to general preventive health behaviors.<sup>19</sup> Results from the Childhood Cancer Survivor Study and our prior work show that even survivors at greatest risk for late effects demonstrate low rates of cancer screening and follow-up.<sup>2,8,20,21</sup> The transition to adulthood is a particularly challenging time when AYAs are lost to follow-up due to competing developmental demands that take priority (e.g., moving out of parents' home, pursuing a career).<sup>7,22</sup> Although there has been attention to medical models of transition care for AYA survivors,<sup>10</sup> very few pediatric cancer centers have transition programs to prepare AYAs to move to adult-oriented healthcare.<sup>9,18,23</sup>

### A.2. Improving transition readiness can improve engagement in adult healthcare.

Transition readiness is defined as having the skills, motivation, and resources to move from pediatric-oriented to adult-oriented care.<sup>11</sup> Survivor-related barriers to transition readiness include inadequate knowledge of cancer treatment and late effect risks, lack of self-management skills, low self-efficacy for managing care, concern about impersonal relationships with adult (vs. pediatric) providers, poor communication with parents and providers, and lower perceived priority of health compared with competing developmental pursuits (e.g., education, career).<sup>10,14,16,22</sup> Transition readiness is a critical precursor to adult self-management of care,<sup>18</sup> and adult self-management improves health status and reduces healthcare utilization.<sup>24</sup> To date, little work has evaluated transition readiness as a predictor of adult adherence and outcomes in AYA survivors. One study linked components of transition readiness, including survivor motivation, comfort speaking with providers about health concerns, and parental support in healthcare decision-making, to AYA survivor engagement in adult-oriented care.<sup>12</sup> A growing body of research in other populations has generally shown positive associations between transition readiness and adherence to adult care and better health outcomes.<sup>25-32</sup>

### A.3. Theoretically-driven interventions to improve AYA transition readiness are needed.

Until recently, the lack of transition-related theoretical frameworks hindered the development of theory-based interventions to improve transition readiness.<sup>1</sup> However, the recent Social-Ecological Model of AYA Readiness for Transition (SMART; Figure 1)<sup>1</sup> outlines modifiable treatment targets: knowledge of health history and future risks; self-management skills and self-efficacy for managing care; beliefs and expectations regarding adult-oriented care (e.g., belief that adult providers will not understand unique AYA survivors' needs); health transition goals; relationships/communication with parents and providers; and psychosocial functioning of patients, parents, and providers.<sup>1</sup> To date, research has primarily focused on defining and measuring transition readiness;<sup>33</sup> the proposed project will be one of the first to apply transition theory to intervention development. Published survivor-focused interventions have been education-based, using in-person speaker series<sup>34</sup> and/or one-day conferences<sup>35</sup> to improve knowledge. Although important, knowledge is only one aspect of transition readiness. The proposed intervention will target multiple aspects of transition readiness to prepare AYA survivors for adult-oriented healthcare.

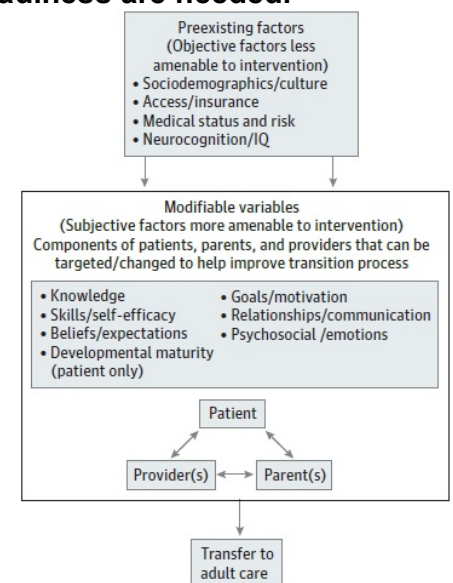


Figure 1. SMART conceptual

### A.4. Peer mentors offer specialized support that addresses an unmet need for AYA survivors.

Providing skills to manage their health is necessary for an effective transition to adult-oriented care, but

does not address a common unmet need of AYA survivors to connect with other AYA survivors. Our preliminary work and other studies show that AYA survivors have an unmet need to discuss their healthcare with other AYA survivors who “get it,” as healthy peers do not share the same healthcare demands.<sup>9,16,36</sup> This aligns with functional specificity theory of social networks, which proposes that individuals receive specific types of support (e.g., informational, emotional, logistical) from different people or ties in their network.<sup>37</sup> Social network ties who have direct personal experience with a life event or “experiential similarity” are more likely to offer specialized health-related informational support (e.g., symptom management tips) and emotional support (e.g., empathy).<sup>38</sup> Because of their experiential similarity, peer survivors can offer informational and emotional support, serve as role models, and provide advice as AYAs take greater responsibility for managing their healthcare.<sup>39</sup> AYA survivors prioritize information from other AYA survivors<sup>16</sup> and such information is likely to be perceived as more credible,<sup>17</sup> giving peer mentoring an advantage over provider-delivered interventions. Peer mentoring using weekly video calls improved self-management skills for adolescents with other chronic conditions,<sup>40,41</sup> but has not yet been tested for AYA survivors. The only published peer-delivered intervention for survivors focused on smoking cessation. It was effective, suggesting peer-to-peer interventions can change health behaviors in this population.<sup>42</sup>

#### **A.5. Internet interventions are particularly relevant for AYA and overcome barriers to engaging AYA.**

AYA survivors are digital natives and express a desire for Internet interventions that offer trustworthy information, psychological support, and peer support.<sup>43-45</sup> Delivery via the Internet overcomes geographical barriers to participation common among AYA survivors.<sup>46</sup> The small but growing body of research using Internet interventions has demonstrated feasibility and acceptability among AYA survivors,<sup>47-49</sup> but more work is needed regarding the efficacy of these interventions. Studies with other populations suggest that interfaces that are efficient (i.e., easy to understand and use) and those that increase user engagement are more effective.<sup>50,51</sup> Elements that increase engagement include prompts, gamification, and tailoring of content.<sup>52-54</sup>

#### **A.6. Summary of Scientific Premise.**

In summary, there is strong evidence demonstrating that the transition to adult-oriented healthcare is critical but there are few formal transition programs available, and no theoretically driven survivor-focused interventions.<sup>1,9,10,18</sup> Current survivor-focused interventions have focused on knowledge and required in-person attendance, limiting the reach of such interventions. The use of engaging online delivery and a peer mentor to improve self-management of care shows promise for this population.

## **B. INNOVATION**

This study of a novel intervention will advance AYA survivorship care research in the following ways:

1. **Theoretical Approach:** The application of the SMART theory<sup>1</sup> to guide intervention development moves the field from measure development to intervention. The use of theory also shifts current research from single component interventions (i.e., in-person speakers or conferences targeting knowledge improvement) to interventions that target multiple components of healthcare self-management for this unique age group.
2. **Intervention Approach:** The use of peer mentors meets the unique social needs of AYA survivors<sup>16,36</sup> and capitalizes on the “experiential similarity” of peers to provide specialized health-related informational and emotional support unlikely to be offered by family and friends in the survivors’ social network.<sup>55</sup> The use of technology overcomes logistical barriers of in-person interventions and can be scaled for dissemination.
3. **Addresses unmet need among AYA survivors:** There are no efficacious interventions for AYA survivors transitioning to adult healthcare. AYA survivors have unique psychological and social needs<sup>10</sup> and must navigate survivorship care in the midst of normative life transitions. This calls for an intervention developed specifically for this population, accounting for the developmental transitions occurring in multiple domains.

## **C. APPROACH**

**C.1. Preliminary Studies.** The study team has expertise in AYA survivorship and transition (Devine<sup>21,45,56</sup>), interventions for cancer survivors and caregivers (Manne<sup>57-59</sup>), AYA medical follow-up care (Masterson), social networks/peer health-related support (Gage Bouchard<sup>38,60,61</sup>), eHealth (Palermo), and statistics (Ohman-



Strickland). This proposal builds from a series of preliminary studies to identify AYA survivors' unmet needs, illuminate intervention topics relevant to the SMART theoretical model, identify optimal delivery approaches, and demonstrate feasibility of the peer mentorship model and online modules. First, we conducted a qualitative study of barriers and facilitators to risk-based follow-up care with 19 AYA survivors of pediatric cancer (recruited locally and using Twitter and stupidcancer.org) to identify unmet needs to target. We found that poor knowledge, a lack of preparation to take charge of their health, and difficulty negotiating parental involvement in care were barriers to transition to adult-oriented care. One third of the sample spontaneously suggested that it would be helpful to seek advice from a peer who had successfully navigated the transition. These findings demonstrated a need for skills-based self-management interventions that incorporate peer social support.

Next, we conducted interviews with 10 AYA survivors, parents, and providers (recruited locally) regarding specific components of a self-management + peer mentoring intervention to improve transition readiness. Survivors expressed preference for talking with a peer mentor via videoconference or phone and text message rather than social media. Informed by the SMART model and these initial interviews, we developed the basic content of the intervention (in PowerPoint) to address five major themes from preliminary work and the literature<sup>7</sup> (see Table 1). Initial feedback from 4 AYA survivors indicated that online delivery was preferred and content was relevant, but lacked engaging interactive elements. Participants suggested videos, narrated presentations, and tailored feedback, in line with the broader literature on user engagement.<sup>52-54</sup>

Since the last submission, we conducted a small pilot of the intervention, which has allowed us to reduce the amount of development work in this proposal. The intervention modules were built in Powerpoint and delivered via Canvas, an online learning system; participants connected with a peer mentor using HIPAA-compliant text-messaging (TigerText) and videoconferencing (Doxy.me). We trained 10 peer mentors and enrolled 19 participants (6 completed, 10 in progress, 3 dropped). Participants' overall satisfaction and satisfaction with the modules were high (4.7 and 3.8 out of 5). Qualitative feedback indicated module content was relevant and guided peer mentor discussions. Based on participant and mentor feedback, we added new information to modules (e.g., communicating with significant others, support resources) and obtained design ideas (e.g., videos, quizzes). In sum, we have evidence of interest in a self-management + peer mentoring intervention, relevance of the content, and feasibility of the infrastructure of the peer mentoring and modules, but need to enhance interactive components to improve usability and engagement with the online materials.

## **C.2. Research Design and Methods**

**C.2.1. Overall Study Design.** Usability testing will occur in months 1-9. We will recruit 50 AYA survivors and 10 mentors to participate in the pilot in months 10-18. Participants will complete surveys at baseline, post-intervention (~6 weeks), and follow-up (~4.5 months). Data collection and analyses will occur in months 11-24.

### **C.2.2. Phase 1: Usability Testing of Self-Management + Peer Mentoring Intervention**

In preliminary work we developed useful *content* of the self-management educational modules but identified a need for a more user-friendly and engaging website. The first phase will build a more engaging mobile responsive website with AYA survivor stakeholder input, following processes of user-centered design.

**Patient Eligibility & Recruitment.** We will recruit up to 20 AYA survivors of childhood cancers through the New Jersey State Cancer Registry (NJSCR) using the same eligibility criteria as the pilot trial (see C.2.3).

**Usability Testing.** ITX Corporation, an experienced technology firm with whom Dr. Devine has worked (K07174728), will create wireframes or mock-ups of the mobile-responsive website based on functionality requirements defined in preliminary work. We chose responsive web design to optimize viewing on any device and provide flexibility with future technology developments. AYA survivors will complete 1-hour long usability sessions where they are asked to move through standardized features of the site, commenting on any difficulties they encounter. Research staff will record each session, observe participants completing tasks, including time to complete tasks and errors.<sup>62</sup> At the end of the session, staff will use a semi-structured interview to solicit additional feedback on layout, navigation, and expectations for use of the site. AYA survivors will also provide standard ratings of acceptability (e.g., attractiveness) and usability (e.g., ease of use).<sup>63</sup> Usability tests are completed using a rapid iterative procedure, in which design changes are identified and made after receipt of a small group of user feedback (~2-4 people) and

the revised interface tested in the next cycle until no major issues are found. The research team and user design/interaction experts from ITX will discuss conflicting suggestions to form a consensus on proposed changes. We have planned for up to 3 iterative design changes. We also build resources into Phase 2 for maintenance and upgrades.

**Proposed Analyses/Intervention Refinement.** Notes will be taken and comments transcribed for qualitative analysis. The research team will discuss user experience difficulties with the ITX design team for changes during the iterative cycles of usability testing. Comments on intervention materials will be analyzed using content analysis, guided by our theoretical framework.<sup>64</sup> Using NVivo qualitative analysis software, Dr. Devine and the research assistant will independently identify themes regarding intervention content and bring to the research team for discussion of refinement. 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).<sup>65</sup> We will field-test the live website to identify any technical issues prior to moving to the pilot RCT.

### **C.2.3. Phase 2: Pilot RCT of Self-Management + Peer Mentoring Program vs. Usual Care**

**AYA Survivor Eligibility & Recruitment.** AYA survivors will be recruited through the New Jersey State Cancer Registry. Eligibility includes: (1) age 18-25, (2) at least 2 years from treatment completion (the typical time for transfer to long-term follow-up care), (3) no documented or self-reported cognitive delay to prevent self-management of healthcare, and (4) low self-reported transition readiness as indicated by report of *not at all ready* or *somewhat ready* (vs. *mostly* or *completely ready*) to assume complete responsibility for healthcare on the Readiness for Transition Questionnaire overall readiness item.<sup>66</sup> A screener identifies patients in need of intervention.<sup>67</sup> Recent survey studies show 61-67% of AYA survivors will meet the low readiness criteria.<sup>66,68</sup>

**Procedures for AYA Survivors.** After informed consent, participants will complete an online baseline survey using DatStat, a HIPAA-compliant electronic data capture system. Next, participants will be randomly assigned to the intervention or usual care group. Dr. Ohman-Strickland will determine a randomization scheme using an undisclosed varying block size of 4 to 6 to ensure balance in sample size between groups.<sup>69</sup> We will not stratify randomization by any variable, as there is no evidence to suggest that any variable would influence response to intervention. Research staff will notify survivors of assignment via phone and/or email. All participants will be asked to complete a post-intervention survey at 6 weeks and a follow-up survey 3 months after that (~4.5 months after baseline). Participants will receive \$25 for completion of each survey.

**Self-Management + Peer Mentoring Intervention.** The “Managing Your Health” intervention consists of: (1) online self-management educational modules and (2) weekly peer mentor calls to facilitate engagement with the modules and offer specialized support. Table 1 shows the content of the calls and online modules based on preliminary work. Phase 1 of this project will build the website and add engagement tools, including tailored feedback on transition readiness, personalized assignments, animated videos, and interactive games. Each module takes 20-30 minutes to complete and ends with a personalized assignment for the participant to complete (e.g., obtain survivorship care plan, make appointment, practice communication skills).

Participants will be matched with a peer mentor of the same sex and cancer type to the extent possible.<sup>40,41</sup> Peer mentors will introduce themselves via secure text-message (TigerText<sup>70</sup>) prior to the initial videoconference (using HIPAA-compliant Doxy.me<sup>71</sup>). The first call is to build rapport, exchange survivor stories regarding follow-up care, and identify the participant’s self-management strengths, weaknesses, and goals. Mentor-participant pairs then complete five additional weekly calls, each aligned with one module, which the mentee is expected to complete prior to their scheduled call. The dose was chosen based on other peer mentoring programs that employed weekly videocalls.<sup>40,41</sup> Prompts to complete modules will be generated if there is no user activity within five days of the previous log-in. In addition to weekly calls, the mentor will offer support and relevant resources through weekly secure text message. Mentor-mentee calls will be recorded and text messages will be archived for fidelity checks, supervision, and content analysis.

**Table 1. Theoretically informed content of self-management modules**

Call	Module	Proposed Content	Transition Readiness Construct
1	N/A	<b>Getting to Know Each Other</b> – rapport building, exchanging survivor stories	N/A
2	1	<b>Understanding Treatment History and Survivorship Care Plan</b> <ul style="list-style-type: none"> <li>Name diagnosis, treatments received, risks for late health effects</li> <li>Obtain (if needed) Survivorship Care Plan; Identify necessary health screenings</li> </ul>	Knowledge Goals/motivation
3	2	<b>Managing Your Health Care</b> <ul style="list-style-type: none"> <li>Review self-management tasks (e.g., make appointments, obtain screenings)</li> <li>Logistics of insurance and healthcare tasks, problem-solving barriers to care</li> </ul>	Self-Management Skills Self-efficacy Goals/motivation
4	3	<b>Negotiating Family Involvement in Your Care</b> <ul style="list-style-type: none"> <li>Challenges of parents who do not relinquish control; communication skills</li> <li>Discuss supportive ways to include family &amp; significant others</li> </ul>	Relationships/communication
5	4	<b>Dealing with Emotions about Your Health and Follow-Up Care</b> <ul style="list-style-type: none"> <li>Coping with uncertainty of future health</li> <li>Communicating with providers &amp; families about adult-oriented healthcare</li> </ul>	Self-Management Skills Relationships/communication
6	5	<b>Staying Healthy in the Context of Life Transitions</b> <ul style="list-style-type: none"> <li>Maintaining health in midst of other transitions (education, career, relationships)</li> <li>Skills &amp; resources for healthy diet, exercise, stress management, sexual health</li> </ul>	Goals/motivation Self-Management Skills Self-efficacy

**Peer Mentor Recruitment, Training, and Supervision.** Peer mentors will be recruited in year 1 via advertisements at the Rutgers Cancer Institute of New Jersey and online via AYA cancer forums and social media, such as Twitter and stupidcancer.org (used in preliminary interview study). Following guidelines from the National Mentoring Research Center<sup>72</sup> and the Children’s Oncology Group (personal communication with Patient Advocacy Committee Chair), potential mentors will complete an application with one letter of recommendation. The PI or study staff will interview candidates to assess interpersonal communication skills, level of commitment, and related experience. Peer mentor eligibility is (1) age 21-29, (2) at least 2 years from treatment, and (3) self-reported primary responsibility using the Readiness for Transition Questionnaire overall readiness question (maximum score of 4, *completely ready*).<sup>66</sup> We successfully used this method in the pilot and will recruit 10 peer mentors (assigned 2-3 mentees each).

Peer mentors will attend a one-day training workshop conducted by the PI and study staff (similar to other peer mentor programs<sup>41,73</sup>). Peer mentors will be given the Peer Mentor Handbook, a manual detailing their roles, responsibilities, and the outline for each mentor call (developed in preliminary work). Presentations, interactive discussions, and role plays are used to teach mentors how to provide informational and emotional support to their mentees. Ethical issues, including confidentiality and setting boundaries with peers, are discussed. Peer mentors will have regular weekly supervision with the PI or trained study staff once assigned mentees. Peer mentors will record phone/video calls with their mentees and all secure text messages exchanged between participants will be archived for use in fidelity checks, supervision, and content analysis. Peer mentors will be compensated \$75 for time and travel to the training workshop and per mentee completed.

**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.<sup>74-77</sup> 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.<sup>76</sup> A usual care comparison group is recommended for initial evaluations of such interventions,<sup>74</sup> as it maximizes statistical power and protects against falsely concluding that the intervention lacks efficacy. We considered an attention condition (e.g., nonspecific peer support), but because our intervention targets skills and adherence outcomes, not psychological outcomes, we would not expect attention to change behavior.<sup>77</sup> Further, nonspecific peer support would be difficult to implement with a credible expectancy for participant benefit if peers are limited in discussion topics to avoid contamination of groups. If the intervention demonstrates a clinically significant signal, a larger future trial can determine if comparable outcomes could be achieved with a less intensive or less expensive intervention.<sup>75</sup> The few published studies evaluating transition interventions have used non-randomized designs or usual care comparisons.<sup>25,27,29,30</sup>

**C.2.4. Feasibility Measures.**

*Treatment Fidelity.* Mentor-participant weekly calls will be recorded and text messages will be archived via administrative aspects of TigerText; these will be used for weekly supervision with the PI or trained research staff. Additionally, 20% of interactions will be randomly selected for treatment fidelity

checklist review.

*Usability/Engagement with Self-Management Modules.* Participants will complete three standard measures of internet-based interventions immediately post-intervention:<sup>63,78</sup> 1) Utility Questionnaire (perceived enjoyment, ease of use); 2) Impact Questionnaire (perceived effectiveness in improving skills); 3) Adherence Questionnaire (barriers to engagement). Objective user data (i.e., log-ins, session duration, modules completed, assignments completed, and use of interactive components) will be obtained unobtrusively.

*Acceptance/Engagement with Peer Mentor.* Acceptance will be evaluated by mentors' and participants' report on perceived alliance with each other using the Working Alliance Inventory – Short Form,<sup>79</sup> a validated measure of the quality and strength of the relationship immediately post-intervention. Engagement will be measured via number of contacts (video/phone calls, text), length of video/phone calls, and content discussed.

### **C.2.5. Outcome Measures.**

Demographic/medical history will be gathered at baseline. Transition readiness will be assessed at baseline, immediate post-intervention (6 weeks), and 3-months post-intervention (~4.5 months):

*Transition Readiness.* There is no gold standard measure assessing transition readiness.<sup>33</sup> Therefore, we will use two complementary measures of transition readiness. The Readiness for Transition Questionnaire – Survivor Version (RTQ)<sup>66</sup> assesses the degree to which survivors are *responsible for 10 healthcare behaviors*, including knowing their survivorship care plan, scheduling annual visits, scheduling specialist appointments, taking and filling medications (if prescribed), explaining medical history to others, knowing insurance coverage, attending appointments, communicating with providers, and calling providers, on a scale from 1 (*not responsible at all*) to 4 (*almost always responsible*). The RTQ yields a total Adolescent Responsibility score and has demonstrated good reliability ( $\alpha = .89$ ) and construct validity.<sup>66,68</sup> The RTQ also has one item evaluating “overall readiness to assume complete responsibility for healthcare” with response options of *Not at all ready, somewhat ready, mostly ready, or completely ready*. This item correlates highly with total Adolescent Responsibility ( $r = .63$ )<sup>68</sup> and will be used as a screener (see C.2.4. eligibility).

The Transition Readiness Inventory (TRI), developed using the SMART framework,<sup>80</sup> is a comprehensive measure of multiple components of transition readiness. The TRI differs from the RTQ in its focus on behaviors *and knowledge, attitudes, and beliefs*. Specifically, the TRI yields a total score and provides scales for these 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 good reliability ( $\alpha = .86$ ) and content validity,<sup>80,81</sup> as well as predictive validity with engagement in adult healthcare among AYA survivors.<sup>12</sup> We will use the total TRI score.

*Follow-up Care Adherence (exploratory outcome).* At baseline and 3-months post-intervention, participants will report on cancer-specific and general medical appointments, cancer screenings, and detection of new comorbidities using the Follow-Up Care Use Among Survivors (FOCUS) survey developed by NCI.<sup>82</sup> Items are generally considered separately and traditional psychometrics (e.g., reliability) are not relevant.

### **C.2.6. Proposed Analyses.**

**Aim 1:** 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 ( $\geq 80\%$  complete all surveys), and intervention completion (>75% modules/mentor calls).

**Aim 2:** 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., adherence and comorbidity detection) will use the identity link or the logit link as appropriate for continuous or binary outcomes.

**Sample Size and Power.** 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 2. 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%
Retention	70%	80%	40 people complete the follow-up	5%	94%

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,<sup>68</sup> 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.

**C.3. Sex as biological variable.** We attend to sex by: 1) recruiting both sexes, 2) matching peer mentors and participants by sex, and 3) exploring any differences in outcomes by sex.

**C.4. Design Considerations, Potential Problems, & Alternative Strategies.**

*Design Considerations.* We chose AYA survivors ages 18-25 given legal responsibility for healthcare at age 18. The survivor-focused intervention includes skills to communicate effectively with parents and providers to address provider and system level barriers to transition readiness.<sup>83</sup> We set the “dose” of one weekly call based on peer mentoring interventions in other populations.<sup>41</sup> We chose in-person training for peer mentors now but future iterations could use technology to reach mentors in widespread geographic locations. With any technology, there is a risk of becoming outdated prior to wide dissemination; we mitigate this risk by using a mobile responsive website that optimizes delivery across devices and allocate some resources for upgrades.

*Potential Problems & Alternative Strategies.* Recruitment of AYAs can be challenging,<sup>46</sup> but the New Jersey State Cancer Registry has a large database (>1000 AYA survivors) and the team has experience and resources, including staff to make calls during evening and weekend hours.<sup>84</sup> We demonstrated initial success in our small pilot for this revision. Web, phone, and text delivery provide flexibility for participating. If we are not meeting recruitment goals, we will expand recruitment to online (e.g., stupidcancer.org) and local sites from which we have successfully recruited in prior studies (e.g., Rutgers, Hackensack University Medical Center).

**C.5. Scientific Rigor.** We are taking steps to ensure a robust and reproducible approach: 1) random assignment, 2) validated measures, 3) objective engagement data through website monitoring, 4) a peer mentor manual with guidelines for weekly contacts, 5) treatment fidelity checklists for peer contacts, 6) use of online modules to deliver content uniformly, and 7) adherence to CONSORT guidelines in reporting results.<sup>85</sup>

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