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A digital, coach-assisted intervention to address the psychosocial needs of young adult cancer survivors: randomized controlled trial protocol and intervention adaptation process

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Abstract

Background: Given the increasing number of young adult cancer survivors and the impacts of cancer on various life domains, interventions addressing the psychosocial needs of young adult survivors are crucial. However, such intervention research is limited, and the existing literature has often: 1) overlooked young adult survivors' psychosocial needs; 2) targeted depression, anxiety,

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or fear of recurrence – rather than positive outcomes like well-being; and 3) failed to consider scalable approaches, like digital health.

Methods: This paper documents the development and refinement of an 8-week digital, coach-assisted intervention targeting hope among young adult cancer survivors (ages 18-39, within 3 years of treatment completion) and presents the protocol of the 2-arm RCT (comparing intervention vs. attention control). The intervention builds upon a 2017-2018 pilot trial (n=56); intervention refinements were based on subsequent semi-structured interviews among young adult survivors (n=23).

Results: The pending trial design involves an increased sample size (n=150) to increase power and diversified recruitment efforts (i.e., clinic-based, social media, community-based organizations, etc.) to facilitate intervention reach, accessibility, and scalability. The intervention was enhanced by integrating highly relevant theoretical and therapeutic frameworks, specifically the concept of hope and Acceptance and Commitment Therapy, as well as updating intervention delivery technology. Intervention outcomes include feasibility and acceptability at end-of-treatment and preliminary efficacy on hope (primary outcome) and quality of life measures (secondary outcomes) at end-of-treatment and 16-week follow-up.

Conclusions: This paper may facilitate discussion regarding approaches for addressing the significant psychosocial challenges faced by young adult survivors and catalyze dissemination of trial results.

Keywords

cancer survivorship; young adult cancer survivors; quality of life; health promotion; positive psychology; hope; acceptance and commitment therapy

INTRODUCTION

In the U.S., ~80,000 young adults (YAs) ages 20-39 are diagnosed with cancer annually [1]. Given advancements in cancer treatment, YAs have 5-year survival rates greater than 80% and an estimated life expectancy of 39-53 years [1]; however, their survivorship journey entails managing the physical and mental health, social, educational, occupational, and financial consequences of cancer diagnosis and treatment [2-6]. Unfortunately, for YAs, this occurs during a pivotal period for developing coping strategies and resilience, and for establishing one’s future [7]. Thus, for this population, more comprehensive, longer-term, integrated approaches addressing a range of psychosocial needs are particularly important for enhancing quality of life across the lifespan [8].

Despite the need for such approaches, there are significant gaps in YA survivorship intervention research [8]. First, historically much of the research has focused on the physical needs of cancer survivors and, perhaps relatedly, has defined the target populations by cancer site. While some more recent research has focused on psychosocial needs among survivors [9-11], a 2017 systematic review identified only 17 studies testing psychological or health promotion interventions for adolescent and YA survivors. Only 10 of these studies were randomized controlled trials (RCTs), 2 of which focused on individuals diagnosed in young adulthood, and none of which were psychological interventions for individuals diagnosed in young adulthood [12]. Another limitation is that research on psychosocial interventions for cancer survivors has often targeted depression, anxiety, emotional distress, negative affect, or fear of cancer recurrence as outcomes – rather than positive outcomes, such as well-being [11, 12].

To address these gaps, identifying and leveraging appropriate theoretical frameworks and therapeutic approaches is crucial. The field of positive psychology offers a range of theories and constructs that may inform interventions for YA survivors [13]. One highly relevant construct is hope [14-16], which is conceptualized as a cognitive skillset for effectively setting and pursuing goals [17, 18], The 3 core components of hope are: 1) establishing values-based, meaningful goals across several life domains; 2) developing several strategies to reach established goals and overcome challenges (i.e., pathways thinking); and 3) maintaining motivation (i.e., agency) [17, 18]. This cognitive set (i.e., identifying goals, addressing/overcoming barriers/challenges, maintaining motivation) can be applied to a broad range of areas, including physical, mental, academic, career, social, reproductive, spiritual, and other areas of well-being. Research has shown that hope is associated with enhanced mental health and quality of life in the general population [19-21] and in cancer survivors [3, 16, 21-27], life meaning among cancer survivors [28-30], and coping with illness, cancer, and pain [16, 23, 27, 31-37]. Further, hope-based interventions, which focus on bolstering individual strengths and resilience in goal pursuits [38, 39], have been shown effective in improving coping, hope, life meaning, and self-esteem in general populations [38, 39], as well as hope, quality of life, and mental health in YA cancer survivors [14].

A related beneficial approach for YA survivors is Acceptance and Commitment Therapy (ACT). ACT addresses goals, values, barriers, and cognition through acceptance, mindfulness, commitment, and behavior changes [40-42]. Although limited, research has shown ACT to improve various outcomes, including fear of cancer recurrence, anxiety, depression, emotional distress, and quality of life [9-11]. For example, in a 3-arm pilot RCT addressing fear of cancer recurrence among breast cancer survivors, ACT demonstrated greater acceptability and improvements in mental and physical quality of life, cognitive flexibility, and a reduction in avoidant coping skills, relative to survivorship education and enhanced usual care [43]. A 2022 meta-analysis study of 77 studies examining ACT processes among cancer survivors indicated that higher scores on flexible processes (acceptance, present moment awareness, self-compassion) and lower scores on inflexible processes (experiential avoidance, cognitive fusion) were associated with lower distress [11]. Despite the promise of ACT for cancer survivors, its utility for YA survivors and for those who are further along in their survivorship journey has yet to be explored.

Notably, there is relatively little research testing scalable, high-reach psychosocial survivorship interventions. The majority of survivorship intervention research has involved face-to-face sessions delivered by clinical psychologists, psychiatrists, and social workers in clinic- or hospital-based settings, supplemented with intervention booster sessions via phone or internet [9, 12]. While the rigor of these approaches is commendable, their scalability may be limited given the intensive resources involved for both: 1) the health system, which faces limitations regarding skilled personnel and mechanisms to sustain financial support to deliver such interventions; and 2) YAs, who are navigating several life demands during their survivorship period (e.g., re-engaging with family and occupational goals) [44, 45].

Digital health approaches may provide one underutilized scalable avenue, particularly suitable for YAs. A 2021 systematic review examining systematic reviews of telemedicine interventions for cancer survivors [46] indicated their feasibility and acceptability (i.e., easy use, usefulness, improved patient experience) and generally high retention rates (60%-95%), satisfaction (70%-85%), and adherence (70%-100%), although adherence was lower for longer interventions. Moreover, this systematic review identified 29 reviews (including 139 primary studies), 23 of which included interventions with psychosocial outcomes. Notably, there was only 1 review of survivorship interventions for adolescent and YA survivors [47], which included only 4 studies testing interventions addressing psychosocial outcomes (typically as secondary outcomes) [47].

Furthermore, health coaching may be a valuable strategy in the context of cancer survivorship interventions, particularly those focused on psychosocial well-being [48]. Health coaching incorporates evidence-based interventions and techniques from behavioral medicine literature (e.g., positive psychology, health psychology) to address health promotion, prevention, early intervention, treatment, and management of chronic conditions [48]. Health coaching interventions have shown positive effects on a range of patient physiological, behavioral, psychological, and social outcomes [49], as well as healthcare system and provider outcomes (e.g., provider job satisfaction, patient satisfaction with services/outcomes) [48], suggesting the appropriateness of this underused strategy for cancer survivorship interventions.

This manuscript documents the development and refinement of a digital health intervention with health coaching that targets hope among YA survivors (ages 18-39) of any cancer and within 3 years of completing primary cancer treatment. Specifically, this paper presents: 1) the objectives, design, and protocol of the pending trial, and 2) preliminary work that provides the basis for and informs this study. The goals of this paper are to: 1) synthesize and contribute to the literature regarding psychosocial interventions for YA cancer survivors; and 2) catalyze the dissemination of the pending trial's results.

METHODS

Study Objectives and Design

The pending RCT aims to test acceptability, feasibility, and preliminary efficacy of an enhanced version of our previously developed intervention for YA cancer survivors [14]. The evaluation of the enhanced intervention, called Achieving Wellness After Reaching the End of Treatment – or AWARE – involves a 2-arm RCT (compared to an attention control [AC]) among YA survivors (n=150; ages 18-39 within 3 years of completing primary treatment) recruited through a diversity of channels in order to examine feasibility and inform future studies assessing implementation, dissemination, and scale-up. This study is approved by the George Washington University Institutional Review Board (NCR224269) and registered with clinicaltrials.gov (NCT05905250).

Preliminary Intervention Description and Outcomes

In 2017-2018, our team developed and tested an 8-week app-based intervention with interactive phone-based coaching (vs. AC focused on finances) via an RCT among YA cancer survivors recruited from 2 cancer centers (n=56; ages 18-39, within 2 years of completing primary treatment; average age=32.55, SD=5.45; 75.0% female, 80.4% White, 28.6% breast cancer, 16.1% melanoma, 12.5% leukemia/lymphoma) [14]. (See Table 1 for an overview of the pilot trial design and intervention components.) The app delivered: 1) weekly educational videos; 2) weekly homework activities for applying the educational content; and 3) a component for monitoring of daily mood and health behaviors, which participants could customize to fit their health behavior goals (e.g., substance use, physical activity). Additionally, coaches (Masters-level staff and Master's students trained/supervised by a licensed clinical psychologist) called each participant weekly for coaching sessions, which involved discussing the previous week's content and homework, psychoeducation regarding a new hope-related skill, ways of applying skills, and the next week's homework [14].

The intervention demonstrated feasibility (95% retention), high engagement in intervention components (of 8 weeks, average number of completions: coaching sessions M=6.16, SD=2.83; videos M=6.79, SD=2.00; homework M=4.50, SD=2.31), and high satisfaction (3.14 on 0-4 scale; 88.9% would recommend to peers), and intervention (vs. control) participants rated educational video content as more relevant and reported greater likelihood of talking positively about the program [14]. Furthermore, at 6-month follow-up (FU), intervention participants reported greater increases in hope [14]. Despite these positive outcomes, results indicated areas for improvement, for example, to increase overall satisfaction (M=3.14, SD=1.17), content relevance (M=3.14, SD=1.00 of 0=not at all to 4=very satisfied/relevant), and engagement in homework activities (M=4.50, SD=2.31 of 8 completed) [14].

Participant Eligibility, Recruitment and Randomization

Eligibility.—Inclusion criteria for the pending trial include: 18-39 years old, within 3 years of completing primary treatment or on maintenance chemotherapy (continuous first remission), English-speaking, and smartphone access. Exclusion criteria include: cancer recurrence since treatment completion, diagnosis of central nervous system cancer (to ensure requisite mental/emotional functioning), in hospice, and prior diagnoses of alcohol/drug dependency, psychosis, bipolar disorder, or major depressive disorder.

Sample Size.

The target sample size is n=150 (with representation of each sex [≥35%] and racial/ethnic minorities [≥35%]), which allows detection of differences across conditions in key measures of feasibility (i.e., retention, adherence) and acceptability (e.g., satisfaction) at end-of-treatment (EOT), as well as preliminary efficacy on hope and quality of life at FU. This calculation assumes 80% power and alpha=. 10 (given the nature of this pilot trial, the relatively small sample size per condition and potential attrition, and uncertainty about intervention engagement and, relatedly, magnitude of effects [50]), as well as pre-post correlations of .50 for efficacy outcomes for future analysis of covariance. (With 15%

attrition to FU, n=127 allows detection of an effect size of ~0.32, sufficient to detect the modest effects documented in the previous pilot study [14]).

Recruitment and Randomization.—To expand reach and inform future studies assessing intervention implementation, dissemination, and scale-up, we diversified our recruitment strategies to include not only clinics, but also survivorship groups, non-profit organizations, and social media. Regarding the latter, we partnered with a third-party vendor, BuildClinical, for online participant recruitment, particularly via social media (e.g., Facebook, Instagram). BuildClinical uses data mining and machine learning to identify potential participants; those who click on ads (e.g., “Remote Cancer Survivor Research Study”) are sent to a webpage describing study procedures, risks, benefits, and compensation. Interested and potentially eligible participants authorize BuildClinical to provide their contact information to the study team. The study team then contacts potential participants via email, text, and/or phone to obtain consent, confirm eligibility, and administer the web-based baseline survey. After completing the baseline survey, participants are randomized to intervention or AC (using a pre-determined blocked random number sequence). Participant randomization is stratified by biological sex (due to the different cancer types by biological sex, e.g., breast, testicular, and relatedly different treatment protocols and implications) and age (18-29, 30-39, given likely developmental differences in emerging versus later young adulthood).

Formative Research to Identify Intervention Adaptations

In preparation for this intervention trial, we conducted formative work involving semi-structured video interviews with YA cancer survivors (n=23) [51] to inform intervention refinements, specifically to ensure content relevance and acceptable delivery. The first section of the interview guide included questions regarding their lived experiences, using hope theory as a lens to understand their hope-related cognitive processes. Specifically, we asked about disruptions they experienced across important life domains (e.g., plans and goals they had) and strategies they used to reorient to or reconsider their goals, overcome barriers and challenges, and cope through difficult periods/experiences. Results from this portion of the interview have been previously detailed [51], but in summary, key opportunities for improvement included increased focus on navigating cancer’s impacts on various life domains, particularly mental health and social relationships, for example, navigating new roles (e.g., accepting and/or asking for support) and effectively seeking understanding and validation of one’s cancer-related experiences and longer-term survivorship-related challenges [51]. The language used by participants often reflected concepts like “meaning”, “values”, “purpose”, “challenges”, “acceptance”, and “being present”, which reflected the relevance of the ACT approach [40], which explicitly addresses these concepts and aligns with hope theory.

The second section assessed factors related to intervention delivery to ensure alignment with participants’ preferences. Of the 21 participants who engaged in questions regarding intervention delivery, the majority indicated that 8 weeks was the ideal length of the program (n=15; with others indicating longer), they would spend ≤30 minutes per week on sessions (n=15), and weekly coaching sessions were preferable (others suggested every 2 weeks), with most (n=13) suggesting coaching sessions lasting ≤30 minutes and all preferring coaching primarily via zoom and/or phone. Additionally, the majority indicated they were likely/very likely to complete homework activities (n=14) and track their behaviors (e.g., physical activity) and/or mood (n=13). One of the most frequent suggestions for intervention enhancement was to provide a set of resources related to various life domains (e.g., mental health, social, reproductive) and positive psychology (e.g., meditation).

Intervention and Attention Control (AC) Condition Descriptions

An AC was chosen as our comparative behavioral intervention; thus, the intervention and AC are designed to be parallel in terms of intervention platform and delivery; duration; and length and mode of educational content, coaching, and activities. The interface for the 2 digital programs was designed to be accessible on a mobile smart-device or online via computer. Participants in both groups are invited via email/text to access one of the 2 programs. As in the pilot trial [14] and as suggested/endorsed in our formative research [51], the program is designed for 8 weekly sessions consisting of: 1) educational content via ~5 minute audio-recordings (and associated transcripts); and 2) “reflections” (i.e., homework) to apply content to daily life. See Table 2 for an overview of session topics for the intervention and AC.

Each participant is assigned a coach trained and supervised by a licensed clinical psychologist (CJB). Participants use a function in the digital platform to schedule coaching sessions. As in our prior trial [14] and supported in our formative work [51], each coaching session is designed to last ~30 minutes, with 3 ~10-minute segments regarding: 1) the previous week’s content and reflections; 2) psychoeducation on a new skill; and 3) applying program content to daily life. Recommended processes are used to ensure coaching protocol fidelity (i.e., tracking logs, review of audio-recorded coaching calls [25%] using a fidelity checklist, regularly-occurring supervision) [52].

Responding to our formative research findings [51], the program includes a “resources” component (i.e., page with links to websites regarding various survivorship needs, listed by life domains, e.g., financial, reproductive, mental health) and “wellness monitoring” (i.e., opportunity to track happiness, motivation, physical activity, and use of alcohol, tobacco, and cannabis). Additionally, the digital program is designed to send email and/or text notifications to participants when a new session is available (prompting them to complete the session and schedule a coaching call) and provides up to 2 prompts each week to encourage completion of weekly sessions and notify them of scheduled coaching calls.

Intervention Condition Topics/Content.—In our pilot trial, session topics included: hope and relevance to cancer survivorship; effective goal-setting and goal re-evaluation; interactions between thoughts, emotions, and goal pursuits; effectively managing thoughts and emotions; and addressing barriers to goals (Table 1) [14]. As suggested by formative research results [51]. the intervention was revised to more explicitly describe how hope’s cognitive processes apply to goals and addressing disruptions across various life domains, for example, intrapersonal (e.g., cancer self-identity) and interpersonal challenges (e.g., navigating new roles, seeking understanding/validation), and to integrate meaning, values, purpose, mindfulness, and acceptance (borrowing from ACT [40, 53]) as it relates to these processes.

As shown in Tables 1 and 2, the newly-adapted sessions address: 1) processing the cancer experience and its impact; 2) the connection between values, self-identity, and goals; 3) the concept of hope (i.e., pursuing specific, meaningful, adaptive, realistic, and time-limited goals; pathways thinking; motivation); 4) applying values and goals in relationships; 5) willingness and acceptance (i.e., engaging with and learning from distressing thoughts); 6) effectively navigating unhelpful thoughts (i.e., cognitive fusion vs. defusion); 7) being present in the moment, mindfulness, and its utility; and 8) program summary and navigating the road ahead.

Attention Control (AC) Condition Topics/Content.—We revised the AC content from its focus on finances in our pilot trial [14] to nutrition. This decision was made because of the increasing acknowledgment of the relevance and salience of financial toxicity experienced among cancer survivors [54] and because a financial management intervention would, in essence, apply hope-related cognitive processes (e.g., goal-setting, planning) to that topic. To better align with the purpose of an AC (i.e., not to include active intervention elements [55]), we chose an AC focused on the generally well-established evidence regarding nutrition and cancer [56], which is also better suited for a health education AC. We identified an existing 6-session podcast with 3-5 minute audio-recordings addressing various nutrition-related topics for cancer survivors from reputable sources (e.g., cancer centers) and supplemented with introduction and summary sessions to total 8 sessions; see Table 1 for specific topics.

Data Collection

Data collection involves ~20-minute web-based surveys (via REDCap) at baseline, EOT (8 weeks post-baseline, to assess immediate effects), and FU (16 weeks post-baseline, to assess longer-term effects), with $50 Amazon e-gift codes for completing each survey.

Primary Outcomes: Feasibility and Acceptability.—Feasibility measures include: 1) accrual (recruitment of n=150); 2) retention at EOT and FU; and 3) adherence, assessed via electronically captured program data regarding the number of weekly sessions viewed and reflections completed, and coach logs of coaching sessions completed [14, 57]. Coaching protocol fidelity measures are drawn from recommended procedures (e.g., tracking logs, review of audio-recorded coaching calls [25%] using a fidelity checklist, regularly-occurring supervision) [52].

Acceptability measures include participant reports of whether they would recommend the program to friends who are cancer survivors (yes/no) and their overall satisfaction with the program and the helpfulness of each component (i.e., session content, reflections, coaching, wellness monitoring, resources) (0=not at all to 4=very) [14, 57]. Additionally, open-ended questions assess what participants found to be the most relevant or important aspects of the program, what they would change about the program, and what they would like to see added to the program. Program usability is assessed using an adapted and abbreviated version of the System Usability Scale [58].

We will use the following benchmarks for feasibility and acceptability: <50%: failure of the current intervention design; 50-74%: major revisions required; and ≥75%: no/minor revisions needed for a confirmatory trial. That is, key indicators of intervention feasibility and acceptability are ≥75%: recruitment of intended sample characteristics (i.e., ≥26% racial/ethnic minority and men), retention at EOT and FU, adherence to weekly sessions, indicating that they would recommend the program to friends who are cancer survivors, and indicating 3=somewhat or 4=very satisfied with the program and helpfulness of each component.

Preliminary Efficacy Outcome: Hope.—At baseline, EOT, and FU, the Adult Hope Scale is administered. This psychometrically-sound measure includes 4 agency items (e.g., “I energetically pursue my goals”), 4 pathways items (e.g., “I can think of many ways to get out of a jam”), and 4 distracter items (assessed on a scale of 1=definitely false to 8=definitely true) [18], yielding scores ranging from 8 to 64 (4 to 32 for each subscale; higher scores indicate higher hope). In our prior study, Cronbach’s alpha for the total scale, agency subscale, and pathways subscale were .95, .91, and .89, respectively [14].

Exploratory Secondary Outcomes: Quality of Life.—Baseline, EOT, and FU surveys include: 1) the 43-item Patient Reported Outcome Measurement Information System (PROMIS) Global Health Scale V1.2 [59]; and 2) Functional Assessment of Cancer Therapy – General (FACT-G) [60] for cancer-specific factors.

Covariates: Sociodemographic and Health Characteristics.—At baseline, participants report sociodemographic characteristics (e.g., age, sex, gender identity, sexual orientation, race, ethnicity, educational background, employment status, relationship status, household composition), cancer diagnosis/treatment factors (e.g., site and stage at diagnosis, treatments, date of diagnosis and treatment completion), and comorbidities (e.g., hypertension, diabetes). They also report on health behaviors (e.g., alcohol, tobacco, and cannabis use; physical activity; nutrition; sleep) at baseline, EOT, and FU.

Data Analysis

The clinical trial follows CONSORT guidelines. We will conduct descriptive analyses to characterize measures of feasibility and acceptability, and then bivariate and multivariable analyses (as possible/appropriate) to compare metrics of feasibility and acceptability of the intervention vs. AC. To examine preliminary efficacy on hope and quality of life, we will assess the respective changes through ANCOVA using the intent-to-treat principle. Exploratory moderation and mediation analyses will examine: 1) levels of engagement (number of sessions and coaching calls completed) by covariates (e.g., sex, gender, age group) to determine subgroup differences in intervention feasibility and acceptability; and 2) the extent to which engagement (e.g., sessions and/or coaching calls completed) impacted intervention effects.

DISCUSSION

This paper details the development and refinement of a digital psychosocial intervention targeting hope among YA cancer survivors (ages 18-39) and presents the protocol for the

RCT to test the intervention. In doing so, we hope to advance the discussion regarding interventions addressing the psychosocial needs of YA survivors and expedite dissemination of intervention trial outcomes. Given the increasing number of YA survivors [1] and the impacts of cancer across various aspects of life, particularly among YAs [2-6, 8], there is a pressing need for interventions addressing YA survivors' psychosocial concerns in order to enhance quality of life across the lifespan [7].

This pending trial responds to several gaps in the existing literature regarding approaches for addressing the psychosocial needs of YAs [8], including: 1) limited attention to the common and pressing psychosocial needs among YAs with different cancer diagnosis and during their longer-term survivorship journey [12]; 2) existing interventions largely targeting depression, anxiety, or fear of cancer recurrence as outcomes – rather than well-being or other positive outcomes [11, 12]; and 3) limited use of scalable approaches, like digital health [9, 12, 46] and health coaching [48]. The current intervention addresses these gaps by using a novel therapeutic approach integrating the concept of hope [14-16, 61] and ACT [40-42], and by leveraging a digital health program with video/audio-based coaching delivered by psychologist-supervised Master's level and Master's student coaches.

This trial advances our prior pilot trial [14] by using a more rigorous RCT with a larger sample, diversifying the recruitment channels to include digital media to increase reach and accessibility among YA survivors, updating the technological approach for intervention delivery and its components to facilitate usability and scalability, and enhancing the intervention content to be more responsive to the psychosocial needs of YA survivors. Regarding this latter point, intervention revisions responded to key findings in our formative research, specifically to enhance content related to helping YAs navigate the impacts of cancer across various life domains and using a more comprehensive framework to address values, meaning, acceptance, and being present, as well as additional focus on the mental and social impacts, for example, navigating new roles and seeking validation of their longer-term survivorship-related needs [51]. The integration of ACT [40] with the concept of hope [14-16, 61] provided an intuitive, seamless approach to respond to these suggested enhancements.

Given the limited literature regarding comprehensive, scalable interventions for addressing the psychosocial needs among YA cancer survivors, this trial marks an important step forward in promoting discussion regarding how to best address the significant psychosocial challenges faced among YAs and serves to catalyze the dissemination of trial results. These results will advance the knowledge base regarding theoretical, therapeutic, and delivery approaches that may be most effective, accessible, and scalable for addressing this population's needs.

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ABBREVIATIONS

AC	attention control
ACT	Acceptance and Commitment Therapy
ANCOVA	analysis of covariance
AWARE	Achieving Wellness After Reaching End of Treatment
EOT	end of treatment
FU	follow-up
RCT	randomized controlled trial
YA	young adult

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Table 1.

Overview of the Previous Pilot Trial and the Current Pilot Trial

Week	Previous Pilot Trial	Current Pilot Trial	Rationale for change
Design	Pilot RCT	Pilot RCT	--
Recruitment & Setting	Recruited via 2 large NCI-designated cancer centers; identified via medical record review Described to participants as a trial examining intervention strategies to promote well-being	Recruit via clinics, survivorship groups, non-profit organizations, and social media Described to participants as a trial examining intervention strategies to promote well-being	To enhance reach and scalability
Sample Size	N=56 total (intervention n=38; control n=18)	N=150 total (n=75 per condition)	To increase power to estimate feasibility and acceptability, as well as effect size on hope and quality of life for fully powered RCT
Eligibility Criteria	Inclusion criteria: • 18–39 years old • English-speaking • Within 2 years of cancer treatment completion • Functioning smartphone Exclusion criteria: • Diagnosis of a central nervous system cancer • Cancer recurrence since treatment completion • In hospice • Diagnosis of alcohol/drug dependency, psychosis, bipolar disorder, or major depressive disorder	Inclusion criteria: • 18–39 years old • English-speaking • Within 3 years of cancer treatment completion • Functioning smartphone Exclusion criteria: • Diagnosis of a central nervous system cancer • Cancer recurrence since treatment completion • In hospice • Diagnosis of alcohol/drug dependency, psychosis, bipolar disorder, or major depressive disorder	To provide intervention to a broader population for whom it may be relevant
Program Components	8-week intervention Weekly phone-based coaching sessions Digital platform with: • Educational video segments (~5 mins) • Homework • Behavior tracking	8-week intervention Weekly Zoom-based coaching sessions Digital platform with: • Educational audio segments (~5 mins); transcripts • Reflections (previously homework) • Wellness monitoring (previously behavior tracking) • Resources	To align with the current (e.g., post COVID-19 pandemic) technology and communication environment To respond to reactions to intervention terms and components indicated by participants in the formative research
Attention Control (AC) Condition	Financial management	Nutrition	To ensure the AC does not include intervention elements (e.g., hope-related cognitive processes applied to financial planning); nutrition is relevant and appropriate for a health education

Week	Previous Pilot Trial	Current Pilot Trial	Rationale for change
Intervention Content	**1** Hope: Goals, Willpower, and Waypower **2** Get and Stay Motivated **3** Setting Good Goals **4** Addressing Cognitive Distortions **5** Waypower: How to Reach Goals **6** Physical Willpower: Health Matters **7** Dealing with Roadblocks **8** Staying on Track	**1** You, Your Cancer Survivorship, and the Road Ahead **2** Connection Between Values, Self-Identity, and Goals **3** Pursuing Values-Based Goals: The Concept of Hope **4** Applying Values and Goals in Relationships **5** Willingly Experiencing Uncomfortable Thoughts **6** Navigating Distressing Thoughts and Emotions **7** Mindfulness and Being Present **8** Planning for the Road Ahead	To respond to the needs of the target population, based on the formative research
Assessments	Baseline End-of-treatment (8 weeks) Follow-up (6 months)	Baseline End-of-treatment (8 weeks) Follow-up (4 months)	To obtain outcomes post-intervention while maintaining within the timeline of the grant funding period
Primary Outcome(s)	Feasibility Acceptability	Feasibility Acceptability	--
Secondary Outcome(s)	Efficacy: **1** Hope: Adult Hope Scale **2** Quality of life: RAND Medical Outcome Study 36-Item Short Form, Functional Assessment of Cancer Therapy – General (FACT-G)	Efficacy: **1** Hope: Adult Hope Scale **2** Quality of life: Patient Reported Outcome Measurement Information System (PROMIS) Global Health Scale V1.2. Functional Assessment of Cancer Therapy – General (FACT-G)	To align measures with current state of the science regarding quality of life measures

Notes: Underlined content indicates differences.

Table 2.

Intervention (AWARE) Condition and Attention Control (AC) Condition Weekly Session Overview

Week	*AWARE*	*AC* *
1	*You, Your Cancer Survivorship, and the Road Ahead:* program introduction; session overview; exploring cancer experience and its impact. *Reflection*: Week 1: Explore self-identity – irrespective of and considering your cancer experience	*Introduction*
2	*Connection Between Values, Self-Identity, and Goals:* understanding and identifying personal values and their impact on self-identity and life purpose; cancer's impact on self-identity and values. *Reflection*: Values clarification, values hierarchy	*Fruits, Vegetables and Proteins*
3	*Pursuing Values-Based Goals: The Concept of Hope:* connecting values and goals; pursuing specific, meaningful, adaptive, realistic, and time-limited goals. *Reflection*: Setting SMART (specific, meaningful, adaptable, realistic, time-framed) goals	*Whole Grains*
4	*Applying Values and Goals in Relationships:* the role of values and goals in relationships; impact of cancer on relationships; using values to reevaluate bonds. *Reflection*: Examining relationships and reflected values (i.e., do others reflect your values, do you reflect your values)	*Sugar*
5	*Willingly Experiencing Uncomfortable Thoughts:* managing distressing thoughts; why people try to control thoughts; the benefits of accepting and processing uncomfortable thoughts and feelings. *Reflection*: Practicing willingness and acceptance, learning from uncomfortable thoughts, defusion	*Phytonutrients and Antioxidants*
6	*Effectively Navigating Distressing Thoughts and Emotions:* identifying and reframing unhelpful thoughts; cognitive distortions; cognitive reframing. *Reflection*: Identifying and reframing cognitive distortions	*Organic Foods*
7	*Mindfulness and Being Present:* overview of mindfulness; benefits of using mindfulness in daily life; how mindfulness can be a useful guide to goals and values. *Reflection*: Mindfulness practice	*Alkaline Diet*
8	*Planning for the Road Ahead:* program summary; personal reflection; strategies for incorporating concepts moving forward. *Reflection*: Overcoming FEAR (Fusion, Excessive goals, Avoidance, Remoteness of values) and embracing DARE (Defusion, Acceptance, Realistic goals, Embracing values)	*Program Summary*

Notes: * Weekly reflections prompted participants to reflect on how they might integrate what they learned into their day-to-day dietary and nutritional routine.