STUDY PROTOCOL (including Statistical Analysis Plan and Informed Consent):
An mHealth Positive Psychology Intervention to Reduce Cancer Burden in Young Adult Cancer Survivors
Protocol Number: NCR224269
National Clinical Trial (NCT) Identified Number: NCT05905250
Principal Investigator: Carla J Berg, PhD, MBA, LP, George Washington University
Co-investigator: Hannah Arem, PhD, Medstar Research Institute
Study site: George Washington University
Funded by: US National Institutes of Health/National Cancer Institute (R21CA261884)
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List of Abbreviations:

AC: Attention control
AWARE: Achieving Wellness After Reaching the End of Treatment
EOT: End-of-treatment
FU: Follow-up
GW: George Washington University
IRB: Institutional Review Board
QOL: Quality of life
RCT: Randomized controlled trial
YA: Young adult

Principal Investigator, Research Team, and Study Site:

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Study site: George Washington University

Research Synopsis:

Study Title: An mHealth Positive Psychology Intervention to Reduce Cancer Burden in Young Adult Cancer Survivors
Clinical Phase: Phase I
Protocol Number: NCR224269
National Clinical Trial (NCT) Identified Number: NCT05905250
Funded by: US National Institutes of Health/National Cancer Institute (R21CA261884)
Study Population: This study focuses on young adult (YA) cancer survivors, targeting ~150 participants total enrolled. Inclusion criteria included: 18-39 years old, within 3 years of completing primary treatment or on maintenance chemotherapy, English-speaking, US resident, and smartphone access. Exclusion criteria were: cancer recurrence since treatment completion, central nervous system cancer diagnosis (to ensure requisite cognitive functioning), in hospice, and prior diagnoses of alcohol/drug dependency, psychosis, bipolar disorder, or major depressive disorder.
Study Design: 2-arm randomized controlled trial (RCT) assessing the feasibility, acceptability, and preliminary efficacy of 'Achieving Wellness After Reaching the End of Treatment' – or AWARE – a digital intervention with health coaching that targets hope, compared to an attention control (AC; randomized at a 1:1 ratio), among 155 YA cancer survivors.
Sample Size: 155 participants
Study Duration: Participants are involved in an 8-week digital, coach-assisted intervention and asked to complete assessments at baseline and 2- and 4-month follow-up.
Primary Objective: Assess the feasibility and acceptability of AWARE vs. AC
Secondary Objectives: Assess the preliminary efficacy of AWARE vs. AC

Background and Significance:

Addressing the needs of young adult (YA) cancer survivors (ages 18-39) is crucial, given the ~80,000 US YAs diagnosed annually,[1] their high survival rates,[1] and the multiple challenges (e.g., physical, emotional, social, occupational, financial) they face post-treatment within this pivotal developmental period.[2-4] Thus, research is needed to develop effective interventions addressing YA survivors' psychosocial needs and quality of life (QOL) during the survivorship journey.[5]

Historically, YA survivorship intervention research has largely focused on physical needs and, perhaps relatedly, defined target populations by cancer site. More recently, research has focused on psychosocial needs of cancer survivors, including pediatric, adolescent, and YA (AYA) survivors.[6-9] A 2022 meta-analysis identified 61 psychosocial, behavioral, and supportive interventions for pediatric and AYA survivors (1987-2020)[10] and documented moderate effects for certain outcomes (i.e., physical symptoms, mental health, social, general QOL) but not others (i.e., cognitive, academic, cancer-related knowledge). This study identified 16 trials focused on AYAs; only 5 had a mean age >18 and only one had a sample size >100.[10] Moreover, findings indicated that interventions for AYA (vs. pediatric) survivors were less effective.[10]

Notably, psychosocial interventions for cancer survivors have often targeted mental health outcomes (e.g., depression, anxiety) rather than positive outcomes.[8,10,11] Interventions targeting positive outcomes for YA survivors may draw from positive psychology.[12] Hope, which can be defined in several ways, is a particularly relevant construct.[9,13] One well-published definition, developed by Snyder et al.,[14,15] suggests that hope involves cognitive skills to: 1) establish values-based, meaningful goals across

several life domains (e.g., physical, mental, academic, career, social); 2) develop several strategies to reach goals and overcome challenges (i.e., pathways thinking); and 3) maintain motivation (i.e., agency).[14,15] Snyder's hope scale assesses individuals' self-reports of their pathways thinking (e.g., ability to strategize and navigate challenges) and agency (e.g., self-efficacy, motivation).[14,15] Hope is associated with several positive outcomes (e.g., mental health, QOL, life meaning, coping with illness/pain) in the general population, cancer survivors, and other subpopulations,[3,16-18] and hope-based interventions have shown effectiveness in improving these outcomes in general populations[19,20] and YA cancer survivors.[13] Acceptance and Commitment Therapy (ACT) aligns with hope, as ACT applies acceptance, mindfulness, commitment, and behavior change to hope-related constructs (e.g., goals, barriers, values)[21] and can improve various outcomes (e.g., mental health, fear of recurrence) among cancer survivors.[6-8]

Also important, most survivorship interventions have been intensive[22,23] and delivered in-person by licensed mental health specialists in healthcare settings.[6,11,23] These rigorous approaches are commendable but limit scalability due to the intensive healthcare resources required and engagement barriers among YA survivors who are navigating several life demands.[2-4] These limitations could be addressed by using health coaching and digital health. Health coaching incorporates evidence-based psychological interventions and has shown positive effects on various physiological, behavioral, psychological, and social outcomes,[24] as well as healthcare system outcomes (e.g., patient satisfaction).[25] Regarding digital approaches, a 2021 systematic review examining 29 systematic reviews of telemedicine interventions for cancer survivors (including 139 primary studies) indicated generally high feasibility, acceptability, adherence, and satisfaction;[26] however, of the 23 reviews including interventions with psychosocial outcomes, only one review included survivorship interventions for AYA survivors and only 4 studies in that review involved interventions addressing psychosocial outcomes (typically as secondary outcomes).[27]

In summary, it is crucial to address YA survivors' psychosocial needs. Under-tapped opportunities to address these needs include focusing on positive outcomes, like hope, and leveraging scalable strategies like health coaching and digital approaches.

Objectives:

Primary Objectives: This 2-arm RCT addresses the primary objective of testing the feasibility and acceptability of AWARE (a digital intervention with health coaching that targets hope) compared to an AC among 155 YA cancer survivors.[28]

Secondary Objectives: This 2-arm RCT addresses the secondary objective of testing the preliminary efficacy of AWARE (vs. an AC) in enhancing hope and QOL among 155 YA cancer survivors.[28]

Study Design/Methodology:

Figure 1 provides an overview of this 2-arm RCT, involving a behavioral intervention (AWARE) and an AC. A total of 155 YA cancer survivors were enrolled in the study and randomized to AWARE (n=78) vs. AC (n=77). Participants were recruited, screened for eligibility, consented, and asked to complete the baseline survey. Both AWARE and the AC involved an 8-week intervention and control for non-specific intervention components. After the 8-week interventions, participants were immediately asked to complete the end-of-treatment (EOT; 8-week/2-month) follow-up assessment. At 16-weeks post-baseline, participants were asked to complete the final follow-up (FU; 16-week/4-month) assessment.

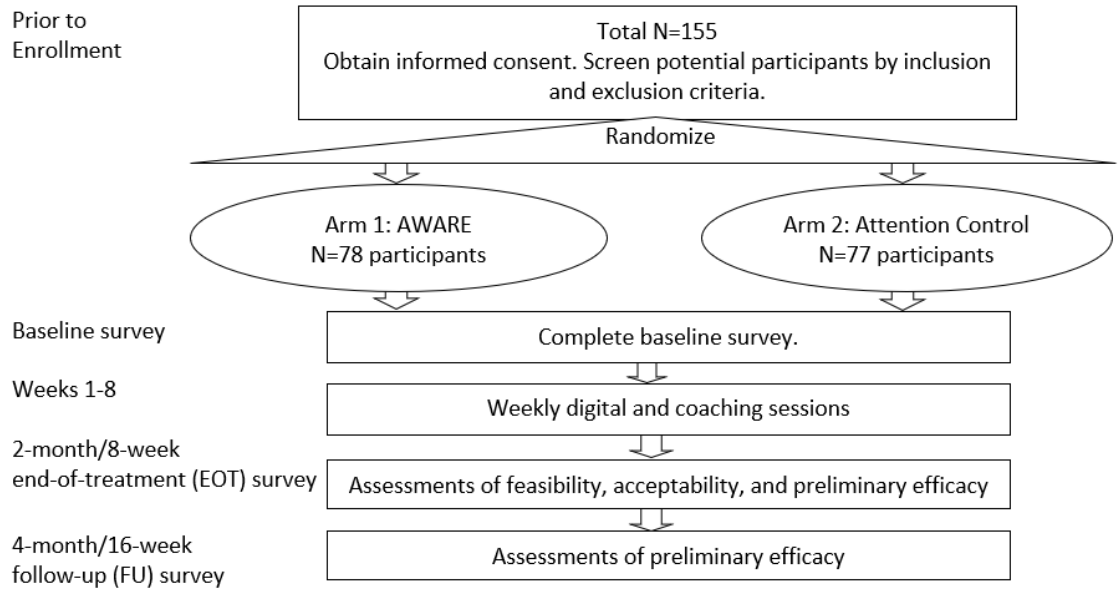

Figure 1. Study Overview

Study Population:

This study focuses on YA cancer survivors, targeting ~150 participants total randomized to AWARE vs. AC (1:1 randomization).

Inclusion Criteria: Inclusion criteria included: 18-39 years old, within 3 years of completing primary treatment or on maintenance chemotherapy, English-speaking, US resident, and smartphone access.

Exclusion Criteria: Exclusion criteria were: cancer recurrence since treatment completion, central nervous system cancer diagnosis (to ensure requisite cognitive functioning), in hospice, and prior diagnoses of alcohol/drug dependency, psychosis, bipolar disorder, or major depressive disorder.

Study Interventions:

Program Elements Consistent Across Conditions: AWARE was compared to an AC, designed to be parallel in terms of intervention platform (accessible on smart-device or computer), delivery (i.e., contact frequency), duration (i.e., number of weeks, session length), and certain components. Each involved 8 weekly sessions consisting of: 1) educational content via ~5-minute audio-recordings (and associated transcripts); 2) "reflections" (i.e., homework) to apply content to daily life; and 3) coaching sessions (which could be scheduled via the digital platform or during coaching calls) lasting ~15-30 minutes focused on the previous week's content and reflections, education on new skills, and application to daily life. Coaches were trained and supervised by a licensed clinical psychologist, and recommended processes were used to ensure fidelity (i.e., tracking, audio-recorded session review, fidelity checklists, regular supervision).[29] Both programs also included a "resources" page with links to websites regarding various survivorship needs across life domains (e.g., financial, reproductive, mental health) and "wellness monitoring" (i.e., tracking happiness, motivation, sleep, physical activity, substance use). Additionally, the digital program sent email/text notifications for new sessions and coaching calls (up to 2 reminders/week).

Intervention (AWARE) Condition: AWARE aims to respond to cancer-related goal disruptions,[30] which particularly impact YA survivors,[2-4] by enhancing goal-oriented thinking. Specifically, AWARE integrates elements from ACT[21] and involves: 1) reassessing and reestablishing short- and long-term values-based, meaningful goals; 2) enhancing pathways thinking, including problem-solving skills, recognizing challenges, and reacting with flexibility; and 3) enhancing agency, for example, by promoting coping skills and effectively processing difficult thoughts and emotions in order to maintain motivation and self-efficacy. We hypothesized that AWARE will increase hope (i.e., goal-reorientation, pathways thinking, and agency), which may ultimately promote QOL.[31] The first 4 AWARE sessions focused mainly on goals: (1) considering the cancer experience and its impact on identity and goals; (2) exploring values, self-identity, and goals; (3) reassessing and reestablishing short- and long-term values-based, meaningful goals across life domains; and (4) applying values and goals in relationships. The subsequent 3 sessions focus on pathways and agency: (5) experiencing and processing uncomfortable thoughts; (6) effectively navigating distressing thoughts and emotions; and (7) the utility of mindfulness and perspective when assessing goals and challenges. The final session (8) provided a program summary, opportunity for reflection, and strategies for ongoing application of program-related skills.

Attention Control (AC) Condition. The AC focused on nutrition and cancer,[32] which is well-suited for an AC as it has participant relevance but is unrelated to efficacy outcome (hope). The AC involved an existing 6-session podcast with 3- to 5-minute audio-recordings addressing various nutrition-related topics for cancer survivors from reputable sources (e.g., cancer centers), supplemented with introduction and summary sessions to total 8 sessions.

Study Schedule and Timeline:

Participants were recruited in February–September 2024, with final data collection in February 2025. Participants are involved in an 8-week digital, coach-assisted intervention and asked to complete assessments at baseline and 2- and 4-month follow-up.

Survey data collection involved ~20-minute web-based assessments (via REDCap) at baseline, end-of-treatment (EOT; 8 weeks post-baseline), and follow-up (FU; 16 weeks post-baseline), with $50 Amazon e-gift codes for completing each survey (up to $150 total).

Feasibility and acceptability. Feasibility measures include: 1) accrual (recruitment of n=150); 2) retention at EOT and FU; and 3) program engagement, assessed via electronically captured program data regarding the number of weekly sessions viewed and reflections completed, and coach logs of coaching sessions completed.[13]

Acceptability measures include whether participants would recommend the program to friends who are cancer survivors (yes/no), as well as overall program satisfaction and helpfulness of each component (i.e., weekly educational recordings/transcripts, reflections, coaching, wellness monitoring, resources; 1=not at all to 5=very).[13] We also asked about program frequency and length (about right, too frequent/long, not enough). We also assessed online program usability (i.e., program was easy to use, various functions were well integrated; 1=strongly disagree to 5=strongly agree; Cronbach's alpha=.90) and quality of coach interactions (i.e., my coach: was helpful, was friendly and warm towards me, showed genuine care about me and my experiences, listened to what I was saying, seemed to understand my thoughts/feelings, made me feel free to express myself, was not critical/judgmental; 1=strongly disagree to 5=strongly agree; Cronbach's alpha=.91). Additionally, we asked participants about alternative coaching channels (e.g., phone, text, email, opt-in for coaching only), barriers to coaching and overall program engagement (providing checklists of potential barriers and open-text fields for each), the program's most relevant or important aspects (open-ended), and potential

changes/additions (open-ended).[33]

We pre-defined benchmarks for feasibility and acceptability: ≥75% completion/positive suggested no/minor revisions needed, 50-74% completion/positive required major revisions, and <50% suggested intervention failure.

Preliminary efficacy outcomes. Hope (primary efficacy outcome) was assessed using the Adult Hope Scale, which includes 4 agency items (e.g., "I energetically pursue my goals") and 4 pathways items (e.g., "I can think of many ways to get out of a jam") with responses (1=definitely false to 8=definitely true) yielding total scores of 8-64 and subscale scores of 4-32 (Cronbach's alpha=.90, .81, and .87).[15]

We used 2 measures of QOL (secondary efficacy outcome). To assess cancer-specific QOL, we administered the Functional Assessment of Cancer Therapy – General (FACT-G),[34] which includes subscales with 7 items each for physical, functional, and social well-being and 6-items for emotional well-being (Cronbach's alphas=.83, .83, .82, and .75). We also administered the 43-item Patient Reported Outcome Measurement Information System (PROMIS) Global Health Scale V2.0,[35] including subscales with 6 items each for physical functioning, fatigue, sleep disturbance, pain interference, ability to participate in social roles/activities, anxiety, and depression (Cronbach's alphas=.90, .94, .91, .96, .95, .93, and .93), and one item for pain intensity.

Covariates. Participants reported sociodemographic characteristics (e.g., age, sex, sexual orientation, ethnicity, race, education level, employment status, relationship status, parental status, health insurance) and cancer diagnosis/treatment factors (e.g., site and stage at diagnosis, treatments, date of diagnosis and treatment completion).

Statistical Analysis Plan:

Sample Size Determination: Assuming 80% power for sample size calculations, we targeted a sample size of n=~150 to detect differences across conditions in key measures of feasibility and acceptability. Tests of efficacy in this pilot were secondary;[36] nonetheless, this sample size is sufficient to detect medium effects on hope (and secondary outcomes (based on the prior one-arm trial[13]), estimating ≥85% retention.

Data Analysis: Survey data were analyzed descriptively using SPSS V.27 with an alpha of .05. First, descriptive analyses characterized participants, and bivariate analyses (t-tests and ANOVAs for continuous variables, Chi-square tests for categorical) examined sociodemographics, health-related factors, and primary and secondary outcomes in relation to condition to determine any baseline differences.

Then, bivariate analyses assessed feasibility and acceptability outcomes. Next, responses to open-ended survey questions regarding acceptability were thematically analyzed using inductive analysis. Two coders reviewed responses and determined primary and secondary themes, which were then applied to an initial subset of surveys. The coders compared their codes to identify and resolve any discrepancies and clarify or revise themes and subthemes. After establishing high overall agreement (Kappa's>90%), the 2 coders independently coded the remainder of survey responses. Themes were organized into overarching domains alongside representative quotes.

We then assessed preliminary efficacy. Matched pairs t-tests assessed differences in hope and QOL measures from baseline to EOT and to FU among AWARE and AC participants, respectively. Preliminary bivariate analyses (Pearson correlations for continuous variables, t-tests and ANOVAs for categorical) explored factors associated with our outcome of interest (to identify potentially confounding variables to control for in multivariable analyses). Finally, we conducted multivariable

linear regression using block entry: 1) condition only; 2) condition and key sociodemographics (age, sex, education) and cancer-related factors (i.e., cancer stage, treatments, time since treatment completion); and 3) baseline outcome measures. There were minimal differences across the 3 models with regard to intervention effects; thus, we presented block 2, as baseline randomization yielded no differences by condition in hope or QOL outcomes, and hope and QOL scores over time were highly correlated with their respective baseline scores. We also explored program engagement levels in relation to changes in the primary hope outcome and interactions between baseline hope and condition on hope effects.

Informed Consent Process:

In February–September 2024, participants were recruited via BuildClinical, a third-party clinical trial recruiting system that helps investigators more efficiently recruit participants for clinical trials. BuildClinical uses machine learning and data mining procedures to recruit the target population from a variety of internet sources (e.g., Instagram, Facebook, Google). Ad content and placement targeted YA survivors, with specific considerations for men and diverse racial/ethnic minority groups. Individuals who clicked on ads were sent to a webpage describing the study. Interested and potentially eligible participants authorized BuildClinical to provide their contact information to the study team, who then contacted them via email, text, and/or phone to obtain consent, confirm eligibility, and administer the web-based baseline survey. After completing the baseline survey, participants were randomized to AWARE or AC (using a pre-determined blocked random number sequence). Participant randomization was stratified by sex (due to different cancer types by sex) and age (18-29, 30-39, given potential developmental differences).

Privacy and Confidentiality:

To minimize risks to confidentiality, study data are protected with all appropriate physical and operational security protections. All data files use encryption and strong password protection. Access to data is on a role-based standard; only those study staff who require access to identifying data to complete their study-related roles are allowed access. REDCap, the electronic platform for self-interview, is HIPPA compliant. We also remind participants before each survey begins to only take the survey in a private area, where he/she will not be observed.

We also developed procedures to minimize indirect disclosure of participation in this study. For each mode of contact information, we asked specifically whether anyone else potentially has access to that mode of communication, and if it was acceptable to leave a non-specific message about participation in a health study. No study-related messages were ever mention the nature of the research study. Additionally, all scripts for email, text message, and telephone contact with participants were reviewed and approved by the GW IRB before being used for contact with participants. All study staff were trained in security and confidentiality procedures.

All researchers involved were required to be trained in the importance of patient confidentiality and de-identification of data as well as HIPAA and Good Clinical Practice requirements. Staff were trained through GW HIPAA training protocol offered via www.CITIprogram.org. Study staff were trained upon confidentiality standards and proper interviewing/coaching techniques. Staff training is comprehensive and will surround not only confidentiality but respect for persons, safety, the intervention, testing, and all related components of the study. The MPIs oversaw and ensured ongoing respect for participants and their data throughout the study.

Risk/Benefit:

Risk to Participants: The potential risks to participants are minimal. Some participants may be uncomfortable answering personal questions. Participants will be told that they have the right to refuse to answer sensitive questions. It is also possible for someone participating in online data collection could be identified as a research participant, but this is uncommon.[37] There is some risk that those completing surveys via smartphones could be observed if they complete the surveys in public or that data could be at risk during transmission.

Benefits to Participants: The potential benefits from participation in this intervention include improvement in hope, psychosocial distress, and QOL. For control participants, benefits relate to the contributed knowledge from the study results, as well as increased knowledge of financial management.

Furthermore, knowledge gained from this project will be used to design a more detailed phone-based hope intervention for YA cancer survivors completing treatment and undergoing major life transitions. In view of the potential information to be gained, and how it will ultimately be able to contribute to new approaches to providing care to this survivor population, the minimal risks do not outweigh the potential for benefit.

Data Safety Monitoring & Adverse Event Reporting:

The safety of our study participants is paramount. The following mechanisms were put in place throughout the study.

Potential Adverse Events Resulting from Participation: Adverse events include potential violation of confidentiality; possible discomfort or embarrassment in disclosing sensitive information; possible dissatisfaction with the intervention programs or study activities; possible embarrassment or fear in discussing experiences with cancer.

Procedures to Safeguard Against Adverse Events: The Institutional Review Board (IRB) at GW reviewed the protocol and all study materials, including consent documents and recruitment materials before the study begins. Quality control procedures include creation of a manual of operations and tracking procedures, and maintenance of personal identifiers in locked files and in keyword-protected computer files. Data is shared only among the research team and contains only study identification numbers, without identifying information.

Informed consent: All participants will be required to complete informed consent prior to participation. The potential participants are informed about the voluntary nature of the study and their rights to refuse or withdraw without consequence. Dr. Berg and the study coordinator trained in human subjects protection are available throughout the study to address participant concerns about study procedures. If either PI determines that potential participants exhibit comprehension difficulties, extra guidance will be provided to make sure they feel fully informed about the study. Participants will be encouraged to call the PI and/or the GW IRB for questions or clarification.

Confidentiality safeguards. All participants were assigned a study ID used on any communication. Codes linking the study ID to participant identities remain in a secured server; no identifying information are maintained in the participant file. Individual data and names are never attached in any way. Data were collected by trained, NIH/HIPAA certified project personnel. Data were entered into a computerized data base (REDCap) with assigned codes/id numbers only. Computers are maintained in a locked area. Only research team members have access to the computerized or stored data.

Dissatisfaction safeguards. Participants were encouraged to discuss with the PI any possible dissatisfaction with the intervention or assessment activities.

Data and Safety Monitoring Plan. The monitoring plan addresses: safety of participants, reporting of adverse events, validity and integrity of the data, enrollment rate relative to expectation, retention of participants and adherence to protocol, and data completeness.

Data. All quantitative data were entered into REDCap (research electronic data capture). The monitoring of the progress of the clinical trial and the safety of participants were performed by the study team and Data and Safety Monitoring Board. A four-person board of individuals not involved in the study (including those with expertise in adolescent or young adult oncology, qualitative data collection, epidemiology, and biostatistics) was created to monitor for data integrity and safety, and met quarterly.

Safety. The PIs are responsible for following adverse event reporting requirements as outlined below. These responsibilities include: a) reviewing the accuracy and completeness of all adverse events reported; b) compliance with IRB policies for reporting adverse events and/or serious adverse events; and c) closely monitoring research participants at each point of contact for any new adverse events or serious adverse events. A serious adverse event is any untoward medical occurrence that: results in death; is life-threatening; requires in-patient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability or incapacity; is a congenital anomaly/birth defect; an event that requires intervention to prevent permanent impairment or damage; or important medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events when, based upon appropriate medical judgment, they might jeopardize the subject and might require medical or surgical intervention to prevent one of the outcomes listed above.

The grading of adverse events used the scale below: 0=no adverse event or within normal limits; 1=mild adverse event; 2=moderate adverse event; 3=severe adverse event resulting in hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect; 4=life-threatening or disabling adverse event; and 5=fatal adverse event.

Although this study is of low to moderate risk and no serious adverse events were expected, we ensured that all adverse events are reported and properly addressed. 1) Serious unanticipated events were to be reported within 24 hours to the GW IRB. 2) An adverse event report including a description of the event, when the event occurred, and when and how the event was reported, was to be generated for each event. 3) The study PIs were to conduct a review of all adverse events upon completion of every study subject. They were to evaluate the frequency and severity of the adverse event(s) and, in conjunction with the DSMB and the IRB at GWU, were to determine if modifications to the protocol or consent forms are required. 4) A report to the IRB was to be made at a minimum of once every 6 months, including when re-approval for the protocol is sought. The IRB was to evaluate whether the study should continue unchanged, require modification, continue, or close to enrollment. If increased frequency of serious adverse events were detected and reported, an ad hoc safety review was to be convened to determine whether and how to modify, continue, or terminate enrollment.

In this study, no adverse events were reported.

Conflict of Interest:

The investigators declare no conflicts of interest.

Publication and Presentation Plans:

Study findings have been disseminated via peer-reviewed journal articles and scientific conferences.

Peer-reviewed Journal Articles (published, in press, under review):

1. McCready, D.M., Arem, H., Duarte, D.A., Dennis, K., Ball, N., Cafferty, L.A., Hinds, P., Howlader, A., & Berg, C.J. (2024). A digital, coach-assisted intervention to address the psychosocial needs of young adult cancer survivors: randomized controlled trial protocol and intervention adaptation process. *Contemporary Clinical Trials, 141*, 107545.
2. Arem, H., Duarte, D.A., White, B., Vinson, K., Hinds, P., Ball, N., Dennis, K., McCready, D.M., Cafferty, L.A., & Berg, C.J. (2024). Young adult cancer survivors' perspectives on cancer's impact on different life areas post-treatment: A qualitative study. *Journal of Adolescent and Young Adult Oncology, 13*(5), 748-759.
3. Schubel, L.C., McCready, D.M., LoParco, C.R., Arem, H., & Berg, C.J. (2025). Cannabis use among adolescents and young adults with cancer: A scoping review. *Journal of Cancer Education*, doi: 10.1007/s13187-025-02693-0. Online ahead of print.
4. McCready, D.M., Schubel, L., Arem, H., LoParco, C.R., Howlader, A., Shajan, S., Bhanot, P., & Berg, C.J. (In press). Cannabis use for medical or non-medical purposes in a sample of young adult cancer survivors in the United States. *Cannabis*.
5. Dennis, K., Arem, H., McCready, D.M., Howlader, A., Shajan, S., Bhanot, P., Shaffer, L., Schubel, L., & Berg, C.J. (Under review). Interpersonal impacts of cancer diagnosis and treatment: A mixed methods study among young adult cancer survivors.
6. Berg, C.J., McCready, D.M., Hinds, P.S., Lyon, M.E., Dennis, K., Howlader, A., Bhanot, P., Shajan, S., Chalasani, P., Chitalia, A., & Arem, H. (Under review). Outcomes of a randomized controlled trial testing the feasibility, acceptability and preliminary efficacy of a digital, coach-assisted intervention to enhance hope and quality of life among young adult cancer survivors.

Presentations at Scientific Conferences:

1. McCready, D.M., Schubel, L., Arem, H., LoParco, C.R., Howlader, A., Shajan, S., Bhanot, P., & Berg, C.J. (2025, November). *Cannabis use for medical or non-medical purposes in a sample of young adult cancer survivors in the United States*. Presentation at the Annual Meeting of the American Public Health Association, Washington, DC.
2. McCready, D.M., Arem, H., Lyon, M.E., Dennis, K., Howlader, A., Bhanot, P., Shajan, S., Chalasani, P., Chitalia, A., & Berg, C.J. (2025, November). *Outcomes of a randomized controlled trial testing the feasibility, acceptability and preliminary efficacy of a digital, coach-assisted intervention to enhance hope and quality of life among young adult cancer survivors.* Presentation at the Annual Meeting of the American Public Health Association, Washington, DC.
3. Arem, H., Duarte, D.A., White, B., Vinson, K., Hinds, P., Ball, N., Dennis, K., McCready, D., Cafferty, L.A., & Berg, C.J. (2024, September). *Young adult cancer survivors' perspectives on cancer's impact on different life areas post-treatment and hopes for the future: A qualitative study*. Presentation at International Psycho-Oncology Society, Maastricht, The Netherlands.
4. Schubel, L., Arem, H., McCready, D.M., Shajan, S., Dopke, C., Bhanot, P., Howlader, A., Hinds, P.S., Levine, J., Lyon, M.E., Chalasani, P., & Berg, C.J. (2025, November). *Profiles of quality of life and psychological characteristics among US young adult cancer survivors*. Presentation at the Annual Meeting of the American Public Health Association, Washington, DC.

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Informed Statement of Consent:

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON, DC

Study Assigned Consent Version #/Date:GW OHR Document Revision Date: 04Jan2019

Informed Consent for Participation in a Research Study

Title of Study: An mHealth Positive Psychology Intervention to Reduce Cancer Burden in Young Adult Cancer Survivors – Part 3
IRB #: NCR224269
Principal Investigator Name: Dr. Carla Berg
Version Date: 1/12/2024

You are invited to participate in a research study under the direction of Dr. Carla Berg, Professor of Prevention and Community Health, George Washington University (GWU), in collaboration with Medstar Health Research Institute, and paid for by the National Institutes of Health. Taking part in this research is entirely voluntary. Further information regarding this study may be obtained by contacting Dr. Carla Berg, the Principal Investigator of this study, at telephone number (202) 994-0168 or by email at bergresearch@gwu.edu.

The purpose of this study is to inform interventions that can help young adult cancer survivors reconsider their life goals and quality of life after cancer diagnosis and treatment. If you agree to participate, you will be asked to complete a survey, with follow-up surveys 8 weeks later and 4 months later. After you complete the first survey, you will be randomly assigned to one of 2 Smartphone app-based programs that would provide information, activities, and a phone-based coach on a weekly basis.

What are the reasons you might choose to volunteer for this study? You may choose to volunteer for this study to provide insight into how young adult cancer survivors think about their life goals and quality of life after cancer diagnosis and treatment and what supports might be helpful in that process. While we cannot promise any benefits to you or others from your taking part in this research, the benefits to science and humankind that might result from this study is informing interventions to support young adult cancer survivors. For participating in this study, you will receive $50 in the form of an Amazon e-gift card for completing **each** online survey – one at the beginning of the study (after completing the consent form), one 8 weeks later, and one 4 months after enrollment – for a total of $150 if all 3 surveys are completed. There are no costs associated with participating in this study.

What are the reasons you might not choose to volunteer for this study? You may choose not to volunteer for this study due to possible loss of privacy or confidentiality; however, this risk is minimal as we have put in place safeguards to ensure that your information remains protected. Your identity as a participant will not be revealed in any way by the Principal Investigator or core research team personnel. If results of this research study are reported in journals or at scientific meetings, the people who participate in this study will not be named or identified. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. In addition, you might choose not to volunteer as you may feel emotionally or psychologically distressed or anxious when responding to questions or engaging in activities that relate to your experiences as a cancer survivor or your mental health.

If you choose to take part in this study, you will be sent to a brief online survey, which you can complete on your own time. You will have roughly 2 weeks to complete the survey and will be emailed to let you know the final deadline for completion before the opportunity expires. Upon completing the survey, you will be notified by email, phone, and/or text message regarding which intervention group you have been assigned to receive. The intervention group you get assigned to will be chosen by chance, like flipping a coin. Neither you nor the study staff will choose what program you are enrolled in. You will have an equal chance of being in each program. You will not be told which program you are in; however, the people conducting the research will know.

All participants will receive information regarding goals they may want to set, delivered on a weekly basis via a Smartphone app for approximately 8 weeks. The information sent via text or app will take about 10-20 minutes to review, and you will have the opportunity to schedule a call with a coach each week to expand on the session and how you might apply it to your life. The length of the coaching call is up to you, but typically should not exceed 30 minutes each week. The coaches who will deliver the intervention in both conditions are qualified research personnel, trained and supervised by a licensed clinical psychologist. The activities of both conditions are similar; however, the exact focus of the content and discussion will be different in terms of the types of goals you might focus on.

All participants will be asked to participate in online surveys 8 weeks after study enrollment and 4 months after study enrollment; you will be notified of these surveys via email, phone, and/or text message. You may refuse to answer any of the survey or interview questions, take a break, and/or leave the study at any point. We encourage participants to be in a private space, given the sensitive nature of the questions being asked during the surveys.

There is no cost to you for receiving the intervention. There is no cost for accessing the app, you will be provided with information regarding how access and download the app (and troubleshoot if needed), and no separate terms of service agreement is required. No 3rd party will be able to access or use your information from the app in any way.

Possible risks or discomforts you could experience during this study include psychological stress and anxiety associated with questions or activities related to your experiences as a cancer survivor, your mental health, and questions about alcohol consumption and marijuana use. We will provide a list of mental health resources to all participants to ensure participants have access to resources/supports available to them.

There is also a small chance that someone not on our research team could find out that you took part in the study or somehow connect your name with the information we collect about you. However, steps are being taken to reduce this risk. Any potential loss of confidentiality will be minimized by storing any data with identifying information in a secure portal, and password protecting any electronic files that contain identifying information. Through the use of an identification key, we will be able to link the collected data to your identity. The information that has your personally identifiable information will be kept separately from the rest of your data. The data collected will remain the property of the study staff but will not be used for any other purposes beyond dissemination via publications and presentations. The records of this study will be kept private. In any published articles or presentations, we will not include any information that will make it possible to identify you as a subject.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate

to withhold that information. The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

The Office of Human Research of George Washington University, at telephone number (202) 994-2715 or by email ohrirb@gwu.edu, can provide further information about your rights as a research participant.

To ensure confidentiality, your signature is not required. If you agree to participate in the study, you can click the link indicating your consent to participate, which will lead you to the initial online survey.

Your willingness to participate in this research study is implied if you proceed.
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