

# **Development of an mHealth Alcohol Reduction Intervention for Adolescent and Young Adult Cancer Survivors**

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## ***Table of Contents***

---

<b>Original Manuscript.....</b>	<b>5</b>
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Preprint  
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# Development of an mHealth Alcohol Reduction Intervention for Adolescent and Young Adult Cancer Survivors

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## Abstract

**Background:** Adolescent and young adult survivors of cancer (AYAs, aged 15-39) frequently engage in hazardous alcohol use, which can have multiple mental and physical health effects.

**Objective:** The aim of this study was to adapt and refine an existing motivational interviewing-based mHealth alcohol reduction intervention, called Tracking and Reducing Alcohol Consumption (TRAC), for post-treatment AYAs.

**Methods:** This was a two-phase, mixed methods study consisting of key informant interviews with post-treatment AYAs aged 18-39, oncology and psycho-oncology providers, and community advocates (n=15) to inform the adaptation of TRAC. After qualitative analysis of interview findings led to the development of the new TRAC-AYA intervention, 4 AYAs completed an open trial of the 4-week intervention and provided feedback on content and protocols through a qualitative exit interview. Descriptive statistics were used to provide data on intervention feasibility and adherence.

**Results:** Key informant interviews revealed a need for the intervention to address cancer-specific alcohol use triggers such as scan-related anxiety, financial toxicity, and reproductive health concerns. TRAC-AYA was well-received by open trial participants—enrollment and retention were above target rates (67% and 75%, respectively) and 100% of participants completed at least 3/4 intervention sessions. Participants reported high satisfaction with TRAC-AYA content and its impact on their drinking.

**Conclusions:** Post-treatment AYAs have unique triggers for alcohol use, which should be considered in the development of alcohol reduction interventions for this population. TRAC-AYA represents a potentially valuable tool in addressing high rates of hazardous alcohol use among this population and warrants further evaluation in larger randomized trials. Clinical Trial: ClinicalTrials.gov NCT05087875

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## Original Manuscript

## Original Paper

Authors: Haney, Kimberly<sup>1</sup>; Borger, Tia<sup>2</sup>; Bursac, Vilma<sup>1</sup>; Sorge, Caryn<sup>3</sup>; Shelton, Brent<sup>4</sup>; Salsman John<sup>5</sup>; McLouth, Laurie<sup>1</sup>; Lauckner, Carolyn<sup>1</sup>

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**Conclusions:** Post-treatment AYAs have unique triggers for alcohol use, which should be considered in the development of alcohol reduction interventions for this population. TRAC-AYA represents a potentially valuable tool in addressing high rates of hazardous alcohol use among this population and warrants further evaluation in larger randomized trials.

**Trial Registration:** ClinicalTrials.gov NCT05087875

### Keywords

alcohol use; young adults; cancer survivors; mobile health; mobile phone; mHealth; motivational interviewing

## Introduction

### Background

Each year in the U.S., nearly 90,000 people aged 15-39 (adolescents and young adults; AYAs) are diagnosed with cancer.[1] Five-year survival for AYAs is over 80%; most will live an additional 36-59 years after diagnosis,[1] highlighting the critical importance of maximizing their physical and mental health to support quality of life and avoid premature mortality. Unfortunately, AYA cancer survivors report poorer physical and mental health compared to their unaffected peers and have greater than two-fold risk of dying from non-cancer-related causes, such as cardiovascular disease.[2-5] Hazardous alcohol use (i.e., heavy or binge drinking) is one modifiable factor that may contribute to AYA cancer survivors' physical and mental health. Over 50% of AYA cancer survivors exceed moderate drinking recommendations,[6] and 36-45% of survivors report engaging in binge drinking, defined as consuming 5 or more drinks (for males) or 4 or more drinks (for females) in a two-hour period.[6,7] Given known health risks of hazardous alcohol use in the general population (e.g., increased risk of heart and liver disease, stroke, depression, and anxiety, reduced fertility), as well as in cancer survivors specifically (e.g., increased risk of certain cancer incidence, recurrence, and even pre-mature mortality),[2-5] helping AYA cancer survivors reduce hazardous drinking should be a key component of survivorship care.

Unfortunately, few interventions have been developed and tested to address risky alcohol use among cancer survivors, let alone among AYA cancer survivors.[8] Few have leveraged mHealth or similar technology-based interventions that may significantly increase reach not only among AYA cancer survivors who show near ubiquitous use of smartphones[9], but also among those living in rural and underserved areas who have limited access to mental health providers[10] and may experience stigma when seeking help.[11,12] Finally, no interventions have been developed to address the potentially distinct needs of AYA cancer survivors who, by virtue of their developmental and life stage, may face additional social pressure to drink and may experience unique stressors that may trigger drinking, such as mental health concerns stemming from their cancer experience [13].

### Objectives

The purpose of this study was to adapt an existing, efficacious mHealth intervention that targeted hazardous alcohol use among people living with HIV[14] for posttreatment AYA cancer survivors. We focused on the posttreatment period to ensure survivors had experienced sufficient time to establish more routine drinking patterns, as well as to avoid the likelihood that active cancer treatment side effects may be impacting drinking levels[15,16]. Additionally, we specifically queried rural AYA cancer survivor experiences and needs to ensure the resulting intervention would reach this underserved, vulnerable population.

### Methods

#### Overall Study Design

This was a two-phase, mixed methods study comprised of 1) key informant interviews to adapt content and delivery of an existing mHealth intervention (Tracking and Reducing Alcohol Consumption; TRAC), originally developed for people living with HIV/AIDS; and 2) an open pilot trial to identify whether refinements were needed to the adapted intervention (TRAC-AYA) and its associated pilot randomized controlled trial study

protocol. This study was approved by the University of Kentucky Institutional Review Board (67410).

## Phase I Methods – Adapting an Existing Intervention (TRAC)

### *Description of Existing Intervention (Tracking and Reducing Alcohol Consumption; TRAC)*

The original TRAC intervention focused on increasing motivation to reduce hazardous drinking and awareness of drinking behaviors, identifying triggers for drinking, and building skills to reduce alcohol use [14]. Over an 8-week period, 8, 30-minute sessions were conducted remotely via video chat or telephone call with a trained interventionist (see Table 1 for session content of the original TRAC intervention). Throughout the intervention period, participants completed twice-daily self-monitoring of alcohol use via mobile surveys and a BACtrack Mobile Breathalyzer, which uses law enforcement-grade sensors to determine breath alcohol concentration (BrAC). The study interventionist discussed the prior weeks' alcohol use as reported via these self-monitoring tasks during weekly intervention sessions.

Table 1. Original TRAC intervention (pre-interviews)

	Session emphasis	Session content
<b>Session 1</b>		
	Developing a Change Plan	<ol style="list-style-type: none"> <li>1. Increasing Motivation</li> <li>2. Developing a Change Plan</li> <li>3. Self-monitoring and phone training</li> </ol>
<b>Session 2</b>		
	Triggers for Drinking Alcohol	<ol style="list-style-type: none"> <li>1. Urges and cravings</li> <li>2. Emotional triggers</li> <li>3. Situational and Environmental triggers</li> <li>4. Social triggers</li> </ol>
<b>Session 3</b>		
	Skill Building: Distraction	<ol style="list-style-type: none"> <li>1. Breathing awareness</li> <li>2. Personal distraction techniques</li> </ol>
<b>Session 4</b>		
	Skill Building: Managing Urges and Cravings	<ol style="list-style-type: none"> <li>1. Delay before acting</li> <li>2. Negative consequences of drinking</li> <li>3. Positive consequences of not drinking</li> </ol>
<b>Session 5</b>		
	Skill Building: Managing Emotional Triggers	<ol style="list-style-type: none"> <li>1. Improve the moment</li> <li>2. Do something relaxing</li> </ol>
<b>Session 6</b>		
	Skill Building: Managing Social Triggers	<ol style="list-style-type: none"> <li>1. Drink refusal</li> <li>2. Seek social support</li> <li>3. Seek spiritual support</li> </ol>
<b>Session 7</b>		
	Skill Building: Managing Situation and Environmental Triggers	<ol style="list-style-type: none"> <li>1. Consuming alternate food or drink</li> <li>2. Engaging in alternate behavior</li> <li>3. Avoiding the situation or environment</li> </ol>
<b>Session 8</b>		
	Looking Ahead	<ol style="list-style-type: none"> <li>1. Summative self-assessment</li> </ol>



	2. Planning for the future
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## Participants

Key informant interview participants (n=15) represented AYA cancer survivors, providers, and community advocates. Recruitment was accomplished via convenience sampling. We utilized the University of Kentucky Markey Cancer Center Community Impact Office to identify community advocates, used professional networks to identify oncology and psycho-oncology providers, and reviewed clinic schedules at the University of Kentucky Markey Cancer Center to identify potentially eligible survivors. We also contacted survivors who recently completed a related survey who had indicated interest in participating in follow-up research. Survivors (n=7) were eligible if they were between the ages of 18 and 39, had been diagnosed with cancer between the ages of 15 and 39, and were residents of a rural area (determined by the zip code of their primary residence). Oncology providers (n=3) included physicians, nurses, nurse practitioners, or physician assistants who had been in practice for at least 6 months and saw at least 25% AYA cancer patients in their practice. Psycho-oncology providers (n=3) included social workers, psychologists, or other mental health providers who treated AYA cancer patients and had been in practice for at least 6 months. Community advocates (n=2) included partners from the Kentucky Cancer Consortium and the Kentucky American Cancer Society. Individuals who were unable to speak English were excluded from the key informant interviews. All participants provided documentation of informed consent via REDCap (Research Electronic Data Capture; Vanderbilt University)[17,18] prior to beginning the interview. Key informants received \$40 as compensation for their participation.

## Interview Protocol

Key informant interviews lasted between 45-60 minutes and were conducted through videoconferencing, by phone, or in-person using a semi-structured interview guide developed by the principal investigators. All interviews were audio-recorded and transcribed verbatim. The semi-structured interview guides elicited feedback on the relevance, appropriateness, acceptability, and feasibility of TRAC content and delivery. See Table 2 for example interview inquiries. The study coordinator provided reference materials to the participants prior to the interview, including a diagram of the study steps and components and excerpts from the participant manual. Individuals from all three participant groups were generally asked the same questions, though there were some differences. Oncology and psycho-oncology providers were asked questions about their approaches to assessing and counseling on alcohol use in their practice. Survivors were asked whether they had received any information or recommendations from their providers about maintaining a healthy lifestyle post-treatment, what those recommendations were, and if they had been told about alcohol's relationship to cancer recurrence or development of other cancers. In addition to the interview, key informants also completed a brief demographic questionnaire that collected information on gender, race/ethnicity, and education and income level.

Table 2. Key Informant Interview Domains

	Example interview inquiries
Content and Components	<ul style="list-style-type: none"> <li>Overall concept of intervention for AYAs <ul style="list-style-type: none"> <li><i>Do you think that adolescent and young adult cancer survivors would be interested in participating in a program like this?</i></li> </ul> </li> <li>Adding information on alcohol and cancer survivorship for motivation to change</li> </ul>

	<ul style="list-style-type: none"> <li>o <i>How helpful do you think the information is about the relationship between alcohol and cancer, if at all?</i></li> <li>• Unique stressors AYAs face that are relevant to alcohol urges/cravings, drink refusal skills               <ul style="list-style-type: none"> <li>o <i>Are there unique stressors or circumstances faced by this population that could impact drinking?</i></li> </ul> </li> <li>• Breathing/stress reduction techniques               <ul style="list-style-type: none"> <li>o <i>Do you think the breathing exercise is a useful skill to cover in the first session?</i></li> </ul> </li> <li>• Use of breathalyzers, frequency               <ul style="list-style-type: none"> <li>o <i>How do you think survivors will feel about using mobile breathalyzers to track alcohol use?</i></li> </ul> </li> </ul>
Delivery	<ul style="list-style-type: none"> <li>• Number of sessions, session length               <ul style="list-style-type: none"> <li>o <i>What do you think about this 8-session schedule?</i></li> </ul> </li> <li>• Smartphones: Pros and Cons               <ul style="list-style-type: none"> <li>o <i>What do you see as the pros and cons of using phones for delivery?</i></li> </ul> </li> <li>• Interventionist characteristics               <ul style="list-style-type: none"> <li>o <i>Who do you think would be the best type of person to deliver these counseling sessions?</i></li> </ul> </li> <li>• Strategies for retention, adherence               <ul style="list-style-type: none"> <li>o <i>What ideas do you have for helping to keep survivors engaged in the program and attending sessions?</i></li> </ul> </li> </ul>

## Analysis

Interview transcripts were analyzed using a thematic approach. Analysis steps involved: 1) reading and discussing two randomly selected interviews, 2) identifying key concepts as preliminary codes, 3) creating a draft codebook with operational definitions for each code, 4) double-coding the initial two randomly selected interviews by line-by-line coding (i.e., independent coding by TB and KH, with discrepancies rectified to achieve a final set of agreed upon codes for each interview), 5) finalizing the codebook, 6) revising the initial two previously coded interviews to reflect the final codebook, 7) double-coding all remaining interviews, and 8) analyzing all coded interviews in NVivo ([www.lumivero.com](http://www.lumivero.com)) [19]. Single coding occurred when independent coders reached  $\geq 80\%$  agreement. Half of all interviews were double-coded as a fidelity check. In total, two separate codebooks were created (survivor and provider/advocate).

## Phase II Methods – Open Pilot Trial of Adapted TRAC-AYA Intervention

### Participants

To test and further refine the TRAC-AYA intervention and procedures, we completed an open pilot trial with four survivors. Survivors who participated in the open trial (n=4) were recruited from University of Kentucky Markey Cancer Center clinics. We used medical records to pre-screen AYA cancer survivors with upcoming appointments to determine if they met the following inclusion criteria: 1) were diagnosed with cancer between the ages of 15 and 39, 2) were between the ages of 18 and 39 at the time of enrollment, 3) were 1-10 years post-treatment (not including hormonal therapies), and 4) reported hazardous alcohol use in the previous 3 months. Hazardous alcohol use was operationalized based on

definitions provided by the National Institute on Alcohol Abuse and Alcoholism[20]; individuals were eligible if they met one or more of these criteria: 1) exceeding moderate daily drinking levels (more than 1 drink per day for women; more than 2 drinks/day for men) at least 3 times in the past 3 months, 2) engaging in heavy weekly drinking (more than 7 drinks per week for women, more than 14 drinks per week for men) at least once in the past 3 months, 3) engaging in binge drinking (more than 3 drinks per sitting for women, more than 4 drinks per sitting for men) at least once in the past 3 months, or 4) meeting hazardous drinking criteria on the AUDIT-C questionnaire (a score of 3 or higher for women, 4 or higher for men), which has demonstrated reliability and validity among multiple studies and populations[21]. Individuals whose screening survey results indicated signs of alcohol dependence, operationalized as an AUDIT score of 20 or higher[22], were excluded from participation and referred to specialized treatment, as the investigators determined that a remote intervention would not be sufficient to meet their needs and they may be in danger of experiencing alcohol withdrawal. Individuals who did not speak English were also excluded. Participants who were eligible and interested provided consent via REDCap, completed baseline assessment, and were randomized to either the control group or the TRAC-AYA Intervention group. Participants in the open pilot trial received up to \$215 as compensation for their participation in the study.

### ***Intervention Conditions***

Participants assigned to the TRAC-AYA intervention condition (n=2) attended weekly sessions with the study interventionist to discuss their alcohol use and goals for reducing consumption (see Results section for information on TRAC-AYA content developed based on Phase 1 interview findings). These sessions were completed via phone call or videoconference, according to participant preference. Upon group assignment, participants were given a workbook that included reference materials and worksheets that could be used during their sessions. The study interventionist was trained in the intervention materials by the principal investigators, held a master's-level degree in counseling, completed additional training on motivational interviewing for addiction, and had direct clinical and research experience.

Throughout the study period, participants also completed daily self-monitoring of alcohol use via mobile surveys in the morning (completed between 6am and 12pm according to participant preference), within which they could also report on other health metrics (e.g., sleep, mood). Each night between 5 and 11 PM they also completed a breathalyzer reading and submitted a screenshot of their results via REDCap. Weekly summary reports of alcohol use were sent electronically via REDCap to participants, with information about the number of monitoring tasks they had completed, their highest breathalyzer reading for the week, and the highest number of drinks reported. The interventionist reviewed responses and breathalyzer readings from the previous week and discussed these with participants at the beginning of each intervention session.

Participants assigned to the control condition (n=2) completed daily alcohol self-monitoring as described above, and were provided with educational materials regarding alcohol use and its health effects.

### ***Assessments***

To elicit participant feedback on the feasibility and appropriateness of the intervention content and study procedures, after each TRAC -AYA intervention session, participants received a brief REDCap survey asking them to rate their experience on a scale of 1-10 (10 being the best) and to provide their open-ended feedback. At the conclusion of the open trial, all participants completed a qualitative exit interview lasting

between 15-20 minutes with the study coordinator. These interviews elicited feedback on the helpfulness, acceptability, and feasibility of the TRAC-AYA intervention (see Table 3 for interview prompts). All participants also provided demographic information.

Table 3. Exit Interview Domains.

	Example interview inquiries
Intervention Content	<ul style="list-style-type: none"> <li>Initial reaction to TRAC-AYA               <ul style="list-style-type: none"> <li><i>Tell me about your initial reaction to the TRAC-AYA program once you learned about what it would involve.</i></li> </ul> </li> <li>Most useful topics for decreasing drinking               <ul style="list-style-type: none"> <li><i>What topics or techniques were the most useful in terms of helping you decrease your drinking?</i></li> </ul> </li> <li>Least useful topics for decreasing drinking               <ul style="list-style-type: none"> <li><i>What topics or techniques were the least useful in terms of helping you decrease your drinking?</i></li> </ul> </li> <li>Biggest benefit and most challenging part of completing TRAC-AYA               <ul style="list-style-type: none"> <li><i>What was the most challenging part of participating in this program? What was the biggest benefit?</i></li> </ul> </li> <li>Topics covered in the intervention               <ul style="list-style-type: none"> <li><i>What topics would you like to see added to the sessions that were not covered?</i></li> </ul> </li> </ul>
Delivery	<ul style="list-style-type: none"> <li>Attitudes about completing the program via phone/video call               <ul style="list-style-type: none"> <li><i>How did you feel about having these sessions done over the phone?</i></li> </ul> </li> <li>Daily surveys and use of breathalyzers, frequency               <ul style="list-style-type: none"> <li><i>How was your experience with using the breathalyzer? How was your experience with the daily mobile survey? How do you feel about the number of times you were asked to complete the monitoring tasks?</i></li> </ul> </li> <li>Strategies for retention, adherence               <ul style="list-style-type: none"> <li><i>Is there anything we could have done to better encourage you to complete the monitoring tasks? Do you have any suggestions for keeping participants in the program engaged?</i></li> </ul> </li> </ul>

## Analysis

Descriptive statistics were used to examine the rates of enrollment and adherence to both daily monitoring tasks and intervention session attendance, as well as acceptability of the intervention. A thematic analysis approach, as described for the Phase 1 interviews, was used to analyze exit interview responses. Two exit interviews were double coded to ensure  $\geq 80\%$  agreement between coders, and the final two interviews were single coded. One codebook was created for exit interviews.

## Results

### Phase I Results – Key Informant Interviews

#### Participants

Participants included seven AYA cancer survivors (M age = 24.1 yrs; 71.4% female; 100% white), three oncologists (M years in practice = 16 yrs; 66.7% female; 66.7% white), three psycho-oncology providers (M years in practice = 16.6 yrs; 100% female, 100% white), and two community advocates (M age = 45 yrs; 50% female; 50% white). The following sections describe key themes obtained from their responses.

#### Theme 1: Time Commitment and Requirements of Intervention

The time commitment required of participants in the intervention was a concern for key informants, with survivors describing the original 8-week TRAC program as “a lot for a working person” and “kind of overwhelming.” Participants from all four groups recommended flexible approaches to the intervention to help reduce the time burden. These approaches included changing the delivery format based on personal preference, i.e., allowing participants to choose 8, 30-minute sessions or 6, 40-minute sessions based on what fit best in their schedules.

Participants also expressed concern about adherence to twice-daily surveys for the full 8-week period, with one participant stating they “wonder about compliance with daily surveys, that would be one thing that might be hard for people for 8 weeks.” Participants offered ideas to better encourage completion of these daily monitoring tasks, including monetary compensation, prize drawings, and the ability to track other health behaviors relevant to survivors.

### ***Theme 2: Information on Cancer Survivorship/Cancer Recurrence and Alcohol Use***

Both the oncology and psycho-oncology provider groups had strong recommendations surrounding the intervention content, specifically content about survivorship and recurrence in the context of survivors' alcohol use. Participants from these groups suggested providing “more context about the relationship between alcohol and the cancers listed in the intervention manual.” One psycho-oncology provider suggested adding information about “specific health issues related to cancer, and how alcohol might impact those issues as well,” (e.g., worsened mental health as a result of cancer diagnosis and treatment, conditions caused by drug side effects). However, participants noted the need to be mindful of the wording used when discussing alcohol use and cancer to avoid triggering feelings of guilt or shame, saying “you need to make it non-judgmental right from the get go,” and “I think helping them understand how drinking can be problematic without making them feel guilty or stigmatized.”

### ***Theme 3: Inclusion of Cancer-Specific Triggers***

All four groups remarked on the need to expand on the types of alcohol use triggers discussed in TRAC as there are unique circumstances and stressors which impact the lives of cancer survivors. One survivor participant stated “there’s a potential for medical triggers—like having to go back to the doctor.” Another participant echoed this sentiment, saying “There would be a benefit of including some potential triggers related to their cancer survivorship status, like, drinking to manage anxiety about follow up scans.” Other suggestions included discussing the financial burden that many survivors face due to cancer treatment, and including information relating to reproductive health concerns or fertility, with participants from multiple groups stating that these could be triggers for AYAs.

### ***Theme 4: Hesitation toward Mobile Breathalyzers***

The use of breathalyzers was an area of concern for interviewees, with many suggesting that intervention participants may find them off-putting. One survivor remarked “The shame associated with it, ‘I’m going to be judged because I drank a six-pack,’” and another stated “It’s almost downgrading...they might feel bad about themselves when they do it.” Another survivor suggested that they would not complete a breathalyzer reading if they have been drinking because they would not want to see that recorded— “I wouldn’t be against it, but I wouldn’t actually use it. I’ve had too much to drink...do I really want that being recorded?” Others expressed concerns about the data obtained from breathalyzers—

whether participants would complete the readings if they have been drinking, or if participants would fabricate data to avoid feelings of judgment. One provider participant stated that “[relying] on them to be able to give you that data when they’re impaired is probably wishful thinking.” Informants recommended using neutral, non-stigmatizing language when discussing the monitoring procedures with participants. A participant from the community advocate group emphasized this, saying “It will be important that they feel respected, valued, and safe to be willing to be that vulnerable.”

## **Intervention Adaptations**

Significant changes were made to the TRAC intervention based on feedback from the key informant interviews. The most notable changes involved 1) reducing the length of the intervention from 8 sessions to 4 sessions to accommodate the busy schedules of AYAs and 2) adding new content to address cancer-specific triggers among AYA cancer survivors. A key part of reducing the number of intervention sessions involves allowing survivors to choose which topics were most relevant to them for discussion, which also allows the intervention to feel more tailored to their needs and experiences. In the new TRAC-AYA intervention, participants are asked to describe the context of their typical drinking experiences, and the counselor works with them to determine if they are most often drinking due to social/situational or emotional triggers. They then focus specifically on those kinds of triggers during the intervention (vs. covering all types of triggers, as done in the original TRAC intervention). Additionally, participants can choose to discuss financial or fertility/reproductive health concerns during the session on cancer-specific triggers.

A brief orientation session with the study coordinator was also added to enrollment procedures so that the interventionist did not need to spend time discussing the self-monitoring tasks or overall study procedures. This orientation session lasts between 15-20 minutes and includes a review of study protocols, training on the mobile breathalyzers and self-monitoring procedures, and scheduling future study tasks. Importantly, the study coordinator emphasizes the confidentiality of breathalyzer results and addresses any participant concerns about the breathalyzer during this session. See Table 4 for a detailed description of the intervention content changes.

Table 4. Adapted TRAC-AYA Intervention

	Session emphasis	Session content
<b>Session 1</b>		
	Understanding your drinking and reasons for change	<ol style="list-style-type: none"> <li>1. Education on alcohol and cancer survivorship</li> <li>2. Review current drinking behaviors, when/why they drink</li> <li>3. Identify reasons for changing drinking behaviors (change plan)</li> <li>4. Skill: Breathing awareness, deep breathing</li> </ol>
<b>Session 2</b>		
	Managing your biggest trigger for drinking	<ol style="list-style-type: none"> <li>1. Managing emotional OR situational/social triggers</li> <li>2. Skill: Riding the wave for urges and cravings</li> <li>3. Suggested activities to do instead of drinking</li> </ol>
<b>Session 3</b>		
	Understanding and managing cancer-specific triggers	<ol style="list-style-type: none"> <li>1. Fear of recurrence/Surveillance</li> <li>2. Financial concerns</li> <li>3. Reproductive health worries</li> </ol>

<b>Session 4</b>		
	Looking ahead	<ol style="list-style-type: none"> <li>1. Summative self-assessment</li> <li>2. Planning for the future</li> <li>3. Finding resources in your community</li> </ol>

As an added measure to reduce study burden for this population, we reduced the number of required self-monitoring tasks; in the original TRAC intervention, participants completed both a breathalyzer reading and mobile survey twice each day (four tasks total). For TRAC-AYA, it was determined that we would ask participants to complete one morning survey and one evening breathalyzer reading (two tasks total).

Based on suggestions received from key informants to bolster participant engagement over the full study period, we also added the option to track more health behaviors and outcomes through daily surveys (e.g., mood, sleep quality, physical activity). It was determined that participants would be allowed to track up to three of these additional health metrics, and would receive a weekly report of their responses.

## **Phase II Results – Open Pilot Trial of TRAC-AYA**

### ***Participants***

Four AYA survivors participated in the open pilot. The average age for participants was 25 years (range: 22-31). Most participants were male (75%), and all were white, non-Hispanic. Regarding cancer type, two participants had been diagnosed with Leukemia, one had been diagnosed with Non-Hodgkin Lymphoma, and one had had brain cancer. The average age at diagnosis was 16.5 years (range: 15-17). Three participants were 1-5 years post-treatment, and 1 participant was 10 or more years post-treatment.

### ***Intervention Feasibility, Adherence, and Acceptability***

Our target for enrollment was that at least 60% of eligible participants approached chose to enroll, and in the open pilot this enrollment rate was 67%. Retention, defined as the number of participants who completed the post-survey/the number of participants randomized, was 75%, while our target was at least 60%.

Adherence to the intervention and daily self-monitoring was very high. Intervention adherence, defined as completing at least 3 of the 4 sessions, was 100% (target: at least 70%). All participants completed 100% of the daily surveys, and the overall breathalyzer completion rate was 97.3%.

Overall, participants assigned to the intervention condition offered high ratings with regard to their experiences with the interventionist and the sessions. Completion rate for post-session acceptability surveys was 88%. One participant rated Session 1 a 9/10, and the average ratings from both participants for Sessions 2, 3, and 4 were 7, 8, and 8.5, respectively. Comments from participants included “it was a great session, worked thru [sic] triggers and how to help with them,” and “I feel like it was beneficial.”

### ***Exit Interviews***

All four participants enrolled in the open pilot trial completed exit interviews. Overall, participants reported positive experiences with the trial and satisfaction with its impact on their drinking behaviors. Identified themes from these interviews are described below.

### ***Theme 1: Satisfaction with the Intervention***

Participants who completed the intervention reported satisfaction with the program and its impact on their alcohol use, as well as their understanding of their personal triggers.

One participant spoke at length about managing their triggers and their improved ability to cope: "I think the biggest thing was that normally when I'm under a lot of stress, I'll drink normally by myself. But even with all the stress that I've been under in this month, I never did it once." Another participant noted that being in the study allowed them a greater awareness of their drinking habits, and how this helped them to reduce the amount they drank: "I thought it was useful because it kind of just helps you put in perspective about if you are drinking and how much you're drinking."

### ***Theme 2: Ease of Completing Monitoring Tasks***

None of the four participants reported that the daily monitoring tasks were inconvenient or generally unacceptable. All participants noted that the daily monitoring tasks were easy, including use of the mobile breathalyzer— "It was actually really easy. Wasn't hard to use," and "It was pretty straightforward, I didn't have any problems with doing it." One participant did remark that the number of reminders received to complete the monitoring tasks was "irritating," however the remaining participants believed the amount and frequency of monitoring tasks to be acceptable.

### ***Theme 3: Workbook Improvements***

All participants expressed a desire to see more information and resources added to the accompanying workbook, especially materials relating to cancer recurrence and coping with stress. One participant said "I think everyone's different, but if you're more worried about your cancer coming back, maybe give some more resources for that," and another recommended including suggestions for ways of dealing with stress outside of drinking: "Having people realize that they don't have to turn to that option, and you could give other coping mechanisms or other ways to find that high that people get, like exercise." Participants also recommended having an electronic version of the workbook available, so it can be accessed from anywhere.

### ***Theme 4: Convenience of a Phone-Based Program***

All participants expressed satisfaction with the intervention's delivery, specifically with the high degree of convenience. One participant remarked "I feel like it's much easier to do it, especially like very remote, doing it all on a phone app." Another participant credited the convenience of accessing the program with an impact on their drinking behavior: "I thought it was more helpful, just with the convenience of it."

## **Discussion**

Participants in the key informant interviews provided many suggestions for adapting TRAC content to better suit the AYA survivor population. A number of changes were made to the intervention based on these suggestions, including to the structure of the intervention itself. TRAC (8 sessions) became TRAC-AYA (4 sessions)—collapsing the three sessions devoted to the types of potential triggers into one, and adding a separate session focusing solely on triggers specific to cancer survivorship. Assessments were reduced by half—originally, participants would complete a total of 4 monitoring tasks each day. The revised procedures saw this changed to 2 tasks each day, completed at a time of the participant's choosing, and allowed participants the option to track additional health metrics. These changes were made to better accommodate life circumstances of AYAs, many of whom are already struggling to cope with challenges relating to their education, career and employment, and intimate or familial relationships[23,24].

Information relating to financial concerns of survivors was added to the intervention,



and a new measure of financial toxicity was added to the baseline and follow-up assessments. Financial toxicity, which can be described as the issues that arise in patients' physical and mental health due to the costs of medical care, can have a significant impact on the lives of AYA survivors—data show that AYAs see higher medical costs than their unaffected peers[25], and, depending on the type of cancer and treatments received, survivors may face challenges in entering or returning to work[26]. Prior research suggests that financial concerns and survivors' mental health are closely related[27]. We also added content related to fertility and reproductive health concerns, which was discussed as a potential trigger by key informants and has been shown to be a common stressor for AYA survivors. A qualitative study showed that survivors felt as though fertility was an afterthought in their cancer care, and wanted more information about reproductive health[28]. Another demonstrated the gaps in survivors' knowledge about their own fertility and reproductive health[29], which, when left unaddressed, can be distressing for survivors. Finally, we also added content on cancer-related worry and fear of recurrence. These sources of stress have been found to have a negative impact on survivors' overall quality of life[30], and survivors who report having a fear of recurrence and/or worry surrounding medical appointments or scans—"scanxiety"—report increased psychological distress[31,32]. Given the impact of these topics of AYAs' mental health, it is not surprising that key informants suggested that they may also impact drinking.

Participants who completed the open trial of the TRAC-AYA intervention reported satisfaction with the intervention and its impact on their alcohol use and understanding of their personal triggers. All participants reported that the daily monitoring tasks (i.e., morning surveys and evening breathalyzers) were easy to complete, as evidenced by high adherence rates. These monitoring adherence rates are higher than in prior studies of the TRAC program, which only saw adherence rates of 62% for breathalyzer readings and 80% for daily surveys[33], and 76% for breathalyzer readings and 73% for daily surveys[14]. This suggests a benefit to reducing participant burden in terms of increasing participant engagement.

## Limitations

This study is limited by its lack of racial or ethnic diversity among participants and its small sample size, though a large sample was not the purpose of this current study. Of the 15 key informants who participated in interviews, the overwhelming majority were white, non-Hispanic, and of the 4 participants in the open pilot trial, 3 were male and all 4 were white, non-Hispanic. Additional tailoring to the TRAC-AYA intervention may be needed to adapt to the specific needs of additional populations not represented in the key informant interviews.

## Conclusions

Key informant interviews with stakeholders pointed to the need for addressing cancer-specific triggers when targeting alcohol use among AYA cancer survivors. They also highlighted the need for accommodating the busy schedules of the AYA population, many of whom are in school, working full-time, and/or have caregiving responsibilities. The adapted TRAC-AYA intervention, after undergoing a small open pilot trial that demonstrated high adherence and acceptability, is now being tested via an ongoing pilot randomized controlled trial with a nationwide sample (ClinicalTrials.gov NCT05087875). If shown to be feasible, TRAC-AYA has potential to provide an accessible, scalable intervention approach for addressing alcohol use among the vulnerable population of AYAs.

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## Conflicts of Interest

The authors declare no conflicts of interest.

## Abbreviations

AUDIT: Alcohol Use Disorders Identification Test

AUDIT-C: Alcohol Use Disorders Identification Test – Concise

AYA: Adolescent and young adult

BrAC: Breath alcohol concentration

REDCap: Research Electronic Data Capture

TRAC: Tracking and Reducing Alcohol Consumption

TRAC-AYA: Tracking and Reducing Alcohol Consumption – Adolescent and Young Adult

## References

1. Miller KD, Fidler-Benaoudia M, Keegan TH, Hipps HS, Jemal A, Siegel RL. Cancer statistics for adolescents and young adults, 2020. *CA Cancer J Clin*. 2020;70:443-459. doi:10.3322/caac.21637
2. Suh E, Stratton KL, Leisenring WM, Nathan PC, Ford JS, Freyer DR, et al. Late mortality and chronic health conditions in long-term survivors of early-adolescent and young adult cancers: a retrospective cohort analysis from the childhood cancer survivor study. *Lancet Oncol*. 2020;21(3):421-435. doi:10.1016/S1470-2045(19)30800-9
3. De R, Zabih V, Kurdyak P, Sutradhar R, Nathan PC, McBride ML, et al. Psychiatric disorders in adolescent and young adult-onset cancer survivors: a systematic review and meta-analysis. *J Adolesc Young Adult Oncol*. 2020 Feb;9(1):12-22. doi:10.1089/jayao.2019.0097
4. Burkhart M, Sanford S, Dinner S, Sharp L, Kinahan K. Future health of AYA survivors. *Pediatr Blood Cancer*. 2019;66(2):e27516. doi:10.1002/pbc.27516
5. Stoneham SJ. AYA survivorship: the next challenge. *Cancer*. 2020;126(10):2116-2119. doi:10.1002/cncr.32774
6. Sanford NN, Sher DJ, Xu X, Ahn C, D'Amico AV, Aizer AA. Alcohol use among patients with cancer and survivors in the United States, 2000-2017. *J Natl Compr Canc Netw*. 2020;18(1):69-79. doi:10.6004/jnccn.2019.7341
7. Asvat Y, King AC, Smith LJ, Lin X, Hedeker D, Henderson TO. Substance use behaviors in adolescent and young adult cancer patients: associations with mental and physical health. *Psychooncology*. 2020;29(6):1068-1076. doi:10.1002/pon.5378
8. Barnett M, McDonnell G, DeRosa A, Schuler T, Philip E, Peterson L, et al. Psychosocial outcomes and interventions among cancer survivors diagnosed during adolescence and young adulthood (AYA): a systematic review. *J Cancer Surviv*. 2016 Oct;10(5):814-31. doi:10.1007/s11764-016-0527-6

9. Perrin A, Atske S; About three-in-ten U.S. adults say they are 'almost constantly' online. Pew Research Center. Published March 26, 2021. Accessed February 14, 2024. <https://www.pewresearch.org/short-reads/2021/03/26/about-three-in-ten-u-s-adults-say-they-are-almost-constantly-online/>
10. HSPA Find. Health Resources and Service Organization (US). Updated October 10, 2023. Accessed February 14, 2024. <https://data.hrsa.gov/tools/shortage-area/hpsa-find>
11. Browne T, Priester MA, Clone S, Iachini A, Dehart D, Hock R. Barriers and facilitators to substance use treatment in the rural South: a qualitative study. *J Rural Health*. 2016;32(1):92-101. doi:10.1111/jrh.12129
12. Andrykowski MA, Burris JL. Use of formal and informal mental health resources by cancer survivors: differences between rural and nonrural survivors and a preliminary test of the theory of planned behavior. *Psychooncology*. 2010 Nov;19(11):1148-1155. doi:10.1002/pon.1669
13. Milam J, Slaughter R, Meeske K, Ritt-Olson A, Sherman-Bien S, Freyer DR. Substance use among adolescent and young adult cancer survivors. *Psychooncology*. 2016 Nov;25(11):1357-1362. doi:10.1002/pon.3958
14. Taylor E, Patel D, Marconi V, Whitmire A, Hansen N, Kershaw T, et al. Pilot trial of a smartphone-based intervention to reduce alcohol consumption among veterans with HIV. *Mil Behav Health*. 2023 Jun;11(1-2):66-77. doi:10.1080/21635781.2023.2221465
15. Shi M, Luo C, Oduyale OK, Zong X, LoConte NK, Cao Y. Alcohol consumption among adults with a cancer diagnosis in the all of us research program. *JAMA Netw Open*. 2023 Aug;6(8):e2328328. doi:10.1001/jamanetworkopen.2023.28328
16. Pinto BM, Trunzo JJ. Health behaviors during and after a cancer diagnosis. *Cancer*. 2005 Dec;104 (11 Suppl):2614-23. doi:10.1002/cncr.21248
17. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) – a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform*. 2009 Apr;42(2):377-81. doi:10.1016/j.jbi.2008.08.010
18. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, et al. The REDCap consortium: building an international community of software platform partners. *J Biomed Inform*. 2019 Jul;95:103208. doi:10.1016/j.jbi.2019.103208
19. NVivo R1/2020 [Computer software]. Version 1.7.1. Denver, CO: [www.lumivero.com](http://www.lumivero.com); 2022.
20. Alcohol's effects on health: research-based information on drinking and its impact. National Institute on Alcohol Abuse and Alcoholism. Updated 2023. Accessed February 14, 2024. <https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking>
21. Bush K, Kivlahan DR, McDonnell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (AQUIP). Alcohol Use Disorders Identification Test. *Arch Intern Med*. 1998 Sep;158(16):1789-95. doi:10.1001/archinte.158.16.1789
22. Daeppen, J. B., Yersin, B., Landry, U., Pécoud, A., & Decrey, H. (2000). Reliability and validity of the Alcohol Use Disorders Identification Test (AUDIT) imbedded within a general health risk screening questionnaire: results of a survey in 332 primary care patients. *Alcohol Clin Exp Res*. 2000 May;24(5):659-665.
23. Patterson P, McDonald FEJ, Zebrack B, Medlow S. Emerging issues among adolescent and young adult cancer survivors. *Semin Oncol Nurs*. 2015 Feb;31(1):53-9. doi:10.1016/j.soncn.2014.11.006
24. Dyson GJ, Thompson K, Palmer S, Thomas DM, Schofield P. The relationship between

- unmet needs and distress amongst young people with cancer. *Support Care Cancer*. 2012 Jan;20(1):75-85. doi:10.1007/s00520-010-1059-7
25. Guy Jr GP, Yabroff KR, Ekwueme DU, Wilder Smith A, Dowling EC, Rechis R, et al. Estimating the health and economic burden of cancer among those diagnosed as adolescents and young adults. *Health Aff (Millwood)*. 2014 Jun;33(6):1024-31. doi:10.1377/hlthaff.2013.1425
26. Guy Jr GP, Ekwueme DU, Yabroff KR, Dowling EC, Li C, Rodriguez JL, et al. Economic burden of cancer survivorship among adults in the United States. *J Clin Oncol*. 2013 Oct;31(30):3749-57. doi:10.1200/JCO.2013.49.1241
27. Abdelhadi OA, Pollack BH, Joseph JG, Keegan THM. Psychological distress and associated additional medical expenditures in adolescent and young adult cancer survivors. *Cancer*. 2022 Apr;128(7):1523-1531. doi:10.1002.cncr.34064
28. Penrose R, Beatty L, Mattiske J, Koczwara B. Fertility and cancer—a qualitative study of Australian cancer survivors. *Support Care Cancer*. 2012 Jun;20(6):1259-65. doi:10.1007/s00520-011-1212-y
29. Zebrack BJ, Casillas J, Nohr L, Adams H, Zeltzer LK. Fertility issues for young adult survivors of childhood cancer. *Psychooncology*. 2004 Oct;13(10):689-99. doi:10.1002/pon.784
30. Quinn GP, Concalves V, Sehovic I, Bowman ML, Reed DR. Quality of life in adolescent and young adult cancer patients: a systematic review of the literature. *Patient Relat Outcome Meas*. 2015 Feb;17(6):19-51. doi:10.2147/PROM.S51658
31. Barnett M, McDonnell G, DeRosa A, Schuler T, Philip E, Peterson L, et al. Psychosocial outcomes and interventions among cancer survivors diagnosed during adolescence and young adulthood (AYA): a systematic review. *J Cancer Surviv*. 2016 Oct;10(5):814-31. doi:10.1007/s11764-016-0527-6
32. Richter D, Koehler M, Friedrich M, Hilgendorf I, Mehnert A, Weißflog G. Psychosocial interventions for adolescents and young adult cancer patients: a systematic review and meta-analysis. *Crit Rev Oncol Hematol*. 2015 Sep;95(3):370-86. doi:10.1016/j.critrevonc.2015.04.003
33. Lauckner C, Taylor E, Patel D, Whitmire A. The feasibility of using smartphones and mobile breathalyzers to monitor alcohol consumption among people living with HIV/AIDS. *Addict Sci Clin Pract*. 2019 Nov;14(1):1-11. doi:10.1186/s13722-019-0174-0