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Evaluating an engaging and coach-assisted online cognitive behavioral therapy for depression among adolescent and young adult cancer survivors: A pilot feasibility trial

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ABSTRACT

Objectives: Technology-assisted Cognitive Behavioral Therapy (tCBT) has significant potentials to provide engaging and accessible depression treatment for adolescents and young adults (AYAs) coping with cancer. This study evaluated the feasibility and preliminary efficacy of an engaging and tailorable tCBT – Mind Your Total Health (MYTH) – for AYA cancer survivors' depression.

Methods: Seventeen AYAs diagnosed with cancer were randomly assigned to either the intervention (MYTH) or control group. The intervention group (n=10) received eight weekly 30-35 minutes coach-assisted tCBT (MYTH), while the control group (n=7) received active control, BeatingtheBlues (BtB).

Results: Eight out of ten participants in the MYTH group completed at least six out of eight sessions, suggesting strong feasibility (80% completion rate) among AYAs with cancer. Efficacy outcomes indicated that participants in the MYTH group reported significant pre- and post-treatment reduction in depression, $t(9) = 5.25, p < 0.001$, and anxiety, $t(9) = 5.07, p < 0.001$. Notably, participants in the MYTH group reported significantly lower post-treatment depression than participants in the BtB group, $t(15) = 2.40, p < 0.05$. The between-group difference reflected a significant between-group treatment effect size, $d = 1.12, p < 0.05$.

Discussion: This engaging, tailorable, and coach-assisted tCBT intervention is promising in alleviating depression and anxiety among AYA cancer survivors. Future research needs to include larger sample size and a more diverse patient population.

KEYWORDS:

Adolescent and young adult; cancer; depression; randomized controlled trial; technology-assisted

Introduction

Adolescents and young adults (AYA) diagnosed with cancer are an age-defined population (15–39 years old), constituting approximately 20% of the global cancer prevalence for all ages in 2017.¹ In the United States there were about 90,000 newly diagnosed AYA cancer patients and over 650,000 AYAs cancer survivors in 2020.² The National Cancer Institute considers someone to be a cancer survivor from the time of their diagnosis until the end of life, which includes both patients receiving active treatment and those post-treatment survivors.³ The AYA cancer survivor population has gained global attention due to its lowest rate of improvement in 5-year survival rates when compared to pediatric and older adult populations.⁴ While the gap in survival has narrowed over the past decade,⁵ AYAs with cancer experience more severe mental health challenges than other age groups due, to a large extent, their unique psychosocial and developmental needs.⁶ In addition to the common psychosocial issues confronting cancer survivors of all ages, AYAs with cancer face age-specific challenges, including developing sexuality, oncofertility, and the transition into adulthood, to name a few.^{7,8} Specifically, studies consistently show that approximately 30% of AYAs with cancer meet criteria for clinical depression, a rate significantly higher than other age groups with cancer and almost three times higher than the general population rates among individuals without cancer.^{9–11} If not adequately treated, depression among AYAs with cancer may lead to limited treatment adherence, social isolation, compromised quality of life, and increased suicide risk.^{12,13} Therefore, it is critical to treat depression and its associated life disruptions among AYAs with cancer.

Cognitive-behavioral therapy (CBT) is a gold standard psychological depression treatment approach that has received overwhelming research support for its effectiveness.¹⁴ Over 500 systematic reviews of CBT were published as of 2018, with most of these reviews targeting depressive outcomes.¹⁵ Specifically for individuals diagnosed with cancer, numerous review studies support CBT's effectiveness in treating depression among cancer populations.^{16–19} With significant advancements in technology, technology-assisted CBTs (tCBT) have received increasing research support for depression treatment. For example, a recently published meta-analysis of 39 clinical trials of tCBT revealed a large and statistically significant treatment effect for depression, ($d=0.9$, $p<0.01$).²⁰ Several randomized controlled trials offer preliminary evidence supporting tCBT for depression among individuals diagnosed with cancer.^{21,22}

In addition to the accumulating evidence supporting its effectiveness, the availability of tCBT is critical for reducing mental health treatment access disparities for depressed individuals, including those diagnosed with cancer.²³ For example, McCarthy et al.²⁴ reported a feasibility trial of tCBT

for rural breast cancer survivors. The study reported that evidence-based treatments are often unavailable in rural areas where healthcare services are limited. Even in urban cancer centers, CBT providers are scarce, and the waitlist for treatment is often long. tCBT significantly reduces CBT providers' time commitment and can be flexibly delivered at locations where a patient feels comfortable and safe.²⁵ As a result, tCBTs have significant potential to alleviate access barriers that contribute to mental health disparities among patients with depression, including those diagnosed with cancer.

Although promising overall, the research literature repeatedly documents several weaknesses of existing tCBT interventions. First, treatment adherence is often low among tCBTs and is significantly lower than face-to-face CBT treatments.²⁶ Specifically, a meta-analysis of CBT adherence revealed that the percentage of treatment completers was significantly higher in face-to-face CBT (84.7%) than in guided internet-based CBT (65.1%, $p < .001$).²⁷ Second, most existing tCBT options are academically-oriented and text-heavy,²⁸ thus contributing to low patient engagement and a high dropout rate.²⁵ Treatment engagement is a critical factor that impacts treatment effectiveness, particularly among AYAs diagnosed with cancer.^{29,30} Notably, a meta-analysis of technology-assisted psychological interventions for young cancer patients found that technology-assisted interventions are only effective for pediatric cancer patients but not for AYAs diagnosed with cancer.³¹ A salient factor contributing to the reported low treatment efficacy for AYA cancer patients is poor engagement. Zhang et al.³² suggest that an important factor when developing a technology-assisted treatment for AYAs diagnosed with cancer is to design the intervention to enhance engagement while maintaining intervention fidelity for optimal treatment outcomes. Consistent across the general and cancer-specific literature, adding a human coach in tCBT platforms enhances engagement to some extent, and subsequently leads to improved treatment outcomes.³³⁻³⁵ However, to our knowledge, none of the existing tCBTs offer platform-based engagement elements to improve treatment adherence, which remains a gap in the literature.

Finally, high dropout rates and low engagement of existing tCBTs, also likely relate to a lack of treatment tailoring and customization for specific client groups, settings, and contexts. In fact, most, if not all, of the currently available tCBTs are *not* customizable.³⁶ This is of concern, given literature consistently suggesting that treatment tailoring and customization is associated with increased engagement and improved treatment outcomes. Without customization, a range of patient populations receive the same tCBT without the necessary tailoring of content to meet patient-specific needs.³⁶ For example, to our knowledge, none of the existing tCBT

treatment options has content specifically customized to meet the unique developmental and medical needs of AYAs diagnosed with cancer. This would likely lead to AYA cancer survivors finding these available platforms less relevant due to their perception of these options being designed for older people or for people without cancer.^{37–39} Consequently, they are likely to disengage in these treatment options due to boredom or low relevance. Implementing technology-assisted CBT with limited support from a human clinician, as is sometimes done, may provide tailoring to a certain extent.⁴⁰ However, the lack of platform-based customization poses significant challenges for tCBT implementation and treatment uptake.^{41,42}

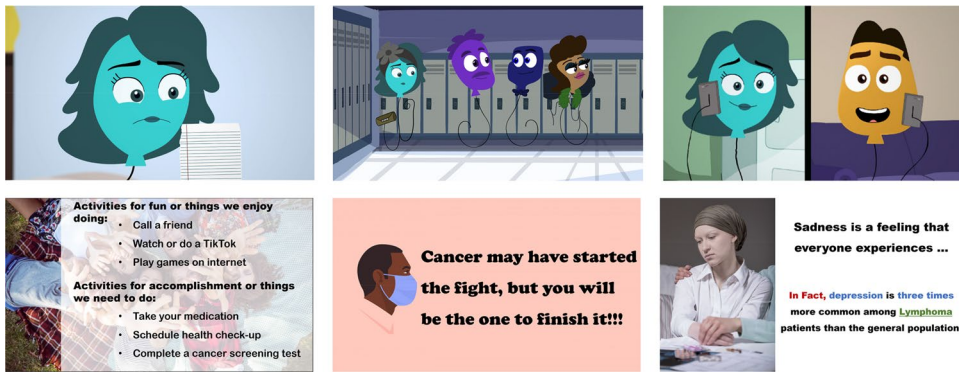
Age-appropriate, entertaining, engaging and customizable tCBT are essential to enhance patient adherence and innovative platforms are essential for depression treatment in AYAs with cancer. The intervention evaluated in this study, Mind Your Total Health (MYTH), is a tCBT solution that meets these requirements.

Mind your total health (MYTH)

MYTH is an 8-session tCBT specifically targeting depression among AYAs with cancer, intentionally tailored based on its parent program EntertainMeWell (EMW)^{25,43} MYTH engages users through a character-driven, animated storyline. Users follow the main character, Billi, across eight MYTH sessions as she shares about her previous experiences living with depression and how she used core CBT concepts and strategies to overcome her low mood. As Billi's story unfolds, users learn CBT techniques from Billi, and follow her improvement after taking action (behavioral activation), identifying and evaluating her negative thoughts (cognitive restructuring), and working to overcome setbacks (problem-solving).

Each MYTH session includes a combination of psychoeducational content delivered via video and text (including examples, vignettes) and an “episode” of the character-driven video storyline (Figure 1A–C). In addition to teaching and reinforcing core CBT content each session, a central feature of MYTH is to entertain users to enhance treatment engagement and adherence. Each “episode” of the character-driven storyline ends with a “cliffhanger” to persuade the user to return for the subsequent episode. For example, after Billi's high school sweetheart Johnny does not show up to their date and does not respond to Billi's text messages, session 6 ends with a cliffhanger where Billi receives a call from Johnny the next day but hesitates to answer the call. Users must return and engage with session 7 to find out what happens and if Billi answers Johnny's call.

EntertainMeWell, MYTH's parent program, was intentionally designed to support treatment tailoring and customization. Therefore, MYTH was



Figures 1. (A–C) examples of character-driven storyline teaching CBT. (A). Billi uses activity planner to schedule goals and activities for herself. (B) Billi uses CBT to motivate herself to attend her high school reunion. (C). Billi teaches how interacting with friends alleviates depression. (D–F) Examples of treatment tailoring for AYAs diagnosed with cancer. (D) An activity planning panel with young adults in the background. (E) A cancer-specific quote next to a modernistic portrait of a young adult. (F) A panel normalizing depression for *lymphoma* patients. (condition specific).

tailored through a community-engaged process to include customized content. This enabled the program to be flexibly and easily modified at low-cost for the esthetics and psychosocial needs that are unique to AYA cancer patients. Based on feedback from AYAs diagnosed with cancer, two overall principles for tailoring EntertainMeWell for AYAs diagnosed with cancer were identified, resulting in MYTH. These principles are: 1. adjusting the program esthetic and content to be developmentally appealing and relevant to AYAs; and 2. adjusting/adding CBT related therapeutic content to be medically relevant to cancer treatment, survivorship, and side- and late-effects. For example, as shown in Figure 1D, when Billi introduces pleasurable activities and activities for accomplishment as part of behavioral activation, MYTH intentionally added taking medication and health checkups as activities for accomplishment to directly connect behavioral activation with cancer-related needs. Similarly, when psycho-educating about the negative impact of life stressors on individuals' mood, MYTH intentionally includes the risk of reproductive health and financial burden as examples, integrating AYA cancer survivors' unique psychosocial needs into treatment content. Given the ease of tailoring, MYTH administrators can modify weekly activities to better fit AYAs' developmental stage and their cancer management. Visual assets inclusive of AYA cancer patients' racial/ethnic backgrounds and different diagnoses, can also be easily adjusted using MYTH's customization functions. As demonstrated in Figures 1E-F, MYTH contains cancer-specific motivational quotes and psychoeducational content specifically tailored for AYAs with comorbid depression and cancer.

In addition to platform-based customization, MYTH utilizes a brief, coach-assisted approach to further tailor each week's content specifically

for cancer survivors (Figure 2). For example, a common negative thought among younger cancer patients is that “*Now that I have cancer, I will never be healthy again.*” During weekly, brief coach-led content, a trained clinician will first normalize this thought by acknowledging the fact that cancer and its treatment does impact an individual’s health status in both the short and long term. However, the coach will also work with the patient to “talk back” to the negative thought by expressing that, though not guaranteed, many cancer survivors have a healthy post cancer life with effective survivorship care, including regular cancer surveillance, proactive disease management, and a healthy lifestyle. To our knowledge, MYTH is the only tCBT platform available that targets the comorbidity of cancer and depression among AYAs.

Including a brief check-in from a human coach after each session is consistent with literature suggesting human support and attention maximizes both tCBT engagement and outcomes. Although using a brief check-in

Sessions	Billi led core content	Coach-led content*
1. Low mood and CBT (introduction and goal setting)	<ol style="list-style-type: none"> 1. What is depression 2. What is CBT and how it works 3. Setting goals for the program 	<ol style="list-style-type: none"> 1. Depression and cancer 2. Reviewing goals and connecting the goals with cancer care
2. The importance of taking action (behavioral activation)	<ol style="list-style-type: none"> 1. The relationship between low mood and low levels of activities 2. The importance of taking action 3. Tips and examples of taking action 	<ol style="list-style-type: none"> 1. What does take action mean when you have cancer 2. Including your cancer care into weekly schedule
3. Tools for taking action (behavioral activation)	<ol style="list-style-type: none"> 1. Tips for choosing activities 2. Planning participant’s own activities 3. Setting activity goals 	<ol style="list-style-type: none"> 1. Planning activities consistent with patients’ cancer care 2. Reviewing activity goals
4. Identifying negative thoughts (behavioral activation) (cognitive restructuring)	<ol style="list-style-type: none"> 1. Common negative thoughts 2. Negative thoughts and low mood 3. Psychoeducation about thought tracker 	<ol style="list-style-type: none"> 1. Negative yet normal thoughts among individuals with cancer 2. A preview about talking back to negative thoughts (next week)
5. Talking back to negative thoughts (behavioral activation) (cognitive restructuring)	<ol style="list-style-type: none"> 1. Thinking it through and talking back to negative thoughts 2. Talking back to negative thoughts and be more active 	<ol style="list-style-type: none"> 1. Although some negative thoughts are normal, but you can still talk back to them 2. Be physically and socially active as an individual with cancer
6. Beliefs and our moods (cognitive restructuring) (identifying and modifying faulty beliefs)	<ol style="list-style-type: none"> 1. The connection between negative thoughts and low mood 2. Common faulty beliefs that drive our thinking errors 3. Identifying and challenging faulty beliefs 	<ol style="list-style-type: none"> 1. Common faulty beliefs among individuals with cancer 2. Challenging common faulty beliefs among individuals with cancer
7. Overcoming setbacks (problem-solving)	<ol style="list-style-type: none"> 1. Setbacks are normal and can bring up negative thoughts 2. Use problem-solving to work through setbacks 	<ol style="list-style-type: none"> 1. Setbacks are common during your cancer journey, but you can do it! 2. Some cancer-specific problem-solving techniques, e.g., talk with your cancer care team, or talk to your peers
8. Putting it all together	<ol style="list-style-type: none"> 1. Overall session review and reflection 2. Reinforcing some skills learned 3. Reviewing five steps to problem-solving 	<ol style="list-style-type: none"> 1. Congratulate the patients for completing the journey 2. Reviewing some key skills learned

* The coach will do a weekly mood and safety check-in with the patients

Figure 2. Brief session outline of Mind Your Total Health (MYTH).

model with human support has cost and human resource implications, this study included brief human support for the following reasons. First, having a trained study coach to check in with AYAs diagnosed with cancer maximized patient safety by monitoring this high risk patient population for depressive symptoms. Second, while MYTH contains platform-based tailoring for the unique developmental and medical needs of AYAs diagnosed with cancer, it does not currently allow for precision tailoring to patient-specific needs that vary across individuals. Including a coach permits personalized evaluation of concerns and needs unique to the AYA population. Finally, all coach-assisted sessions were intentionally designed to be brief, only lasting between 10 to 15 minutes. This format promotes treatment adherence without adding prohibitive clinician burden that would significantly compromise future dissemination.

The present study

MYTH contains core CBT elements for depression treatment, including behavioral activation, cognitive restructuring, and problem-solving, which reflects MYTH's high CBT treatment fidelity.^{14,25} Additionally, MYTH extends one step further from other tCBT platforms by offering a fun and engaging treatment experience and customized content specifically for AYAs with cancer. Therefore, this present study explores the feasibility, acceptability, and efficacy of MYTH for addressing depression among AYA cancer survivors when compared to an active control condition, BeatingTheBlues (BtB). Our primary hypothesis is that MYTH is a feasible tCBT treatment for AYA cancer survivors with depression. In addition, we further explore 1. MYTH's acceptability among AYA cancer survivors; 2. MYTH's efficacy for AYA cancer survivors' depressive symptoms (versus BtB); and 3. MYTH's efficacy for AYA cancer survivors' anxiety (versus BtB). Although MYTH is designed to treat depression, we also included anxiety as an exploratory outcome because 1. depression and anxiety often co-occur among AYAs diagnosed with cancer¹⁸ and 2. studies have reported that CBT for depression often improves comorbid anxiety.⁴⁴ We do not hold additional hypotheses for exploratory aims, as the hypothesis testing approach is not appropriate for feasibility trials.⁴⁵

Methods

This study is a small-scale, pilot randomized controlled trial using a pre-test-post-test design to assess the feasibility of MYTH to treat AYA cancer survivors' depression compared to an active treatment condition. All participants across treatment conditions completed baseline and

post-intervention assessment immediately after treatment completion. The Medical Institutional Review Board at the University of Michigan approved the study.

Setting, eligibility criteria, and recruitment procedures

This study recruited participants through several methods. First, we used clinic-based recruitment at Michigan Medicine via physician referrals or patient self-referral. Second, we disseminated study flyers electronically through a community partner, a local Cancer Support Community, and relevant social media, like Twitter. This multi-faceted recruitment strategy allowed us to be inclusive of AYA cancer survivors from comprehensive cancer centers and local communities. Participants were eligible for this study if they: 1. were between 15–26 years of age; 2. had a current cancer diagnosis; and 3. experienced at least moderate depressive symptoms as evidenced by a score > 9 Patient Health Questionnaire 9 (PHQ-9). This study defines an individual as a cancer survivor from the time of diagnosis until the end of life, consistent with the National Cancer Institute (NCI) definition.³ Specifically in this study, AYAs currently receiving active/curative treatment or those who were within 5 years of their cancer treatment were eligible to participate. Although the AYA population has been broadly defined as young people between 15–39 years old in the cancer field, this study focused on those between 15–26 years old because emerging adulthood (15–26 yrs) and young adulthood (27–39 yrs) cancer survivors have distinct psychosocial needs.⁴⁶ Participants were not eligible for this study if they: 1. were currently receiving end-of-life care; or 2. presented with acute mental health conditions, including active psychosis or suicidal ideation with imminent risk.

Randomization and blinding

Consented eligible participants were randomly assigned to either the MYTH (treatment) or BeatingTheBlues (BtB, active control) condition. A computer random number generator created a list of random non-repetitive integer numbers ranging from 1 to 100, and the numbers were assigned to participants as they entered the study. Participants receiving an odd number were assigned to the MYTH treatment condition, whereas participants receiving an even number were assigned to the BtB active control condition. A designated, trained research staff blind to participants' treatment condition completed all baseline and post-treatment assessments. Study coaches, trained research staff providing

regular phone-based human support to participants (see protocol below), were assigned to only one treatment condition, MYTH or BtB, and were blinded to the nature of the condition they were not assigned to support.

MYTH treatment protocol

Participants assigned to MYTH, described above, received 8 sessions of tCBT weekly, with each session lasting between 25 to 30 minutes. Participants were asked to complete the 8 sessions within 8 weeks but were allowed up to 10 weeks to complete the MYTH program. MYTH follows the gold-standard CBT treatment approaches and includes the following session-by-session core components: Session 1: introduction and goal setting; Sessions 2 and 3: behavioral activation; Sessions 4 to 6: cognitive restructuring, identifying and modifying faulty beliefs, and behavioral action; and Sessions 7 and 8: problem-solving and session wrap up. After MYTH participants completed each session, a trained study coach reached out to participants through telephone or secure, web-based videoconference platforms (like Zoom or Google Meet) for a brief check-in call (10–15 mins). The trained study coach connected each session's content to individual participants' cancer diagnosis and care management. Notably, study coaches were instructed *not* to provide additional therapy but to reinforce the MYTH platform content and encourage participants to complete homework. Study coaches also conducted weekly mood and safety check-ins with participants. [Figure 2](#) presents a detailed program flow.

BeatingTheBlues as active control

BeatingTheBlues (BtB, www.beatingtheblues.co.uk) is a research-supported, computer-based CBT program for depression.^{47,48} Similar to the MYTH program, BtB has 8 sessions and includes core CBT components, including cognitive restructuring, behavioral activation, and problem-solving.⁴⁸ BtB was not designed for customization and cannot be changed without substantial cost, time, and effort. Therefore, BtB did not include any customizations to address the unique needs of AYAs with cancer. BtB program frequency and intensity mimics MYTH in that participants were instructed to complete one session per week but were allowed up to 10 weeks to complete all sessions. A trained study coach followed the same protocol as in the MYTH group when conducting brief check-in calls (10-15 mins.) with BtB participants after completion of each session.

Although MYTH and BtB share similar session structures and both contain core CBT elements for treating depression, the depression-focused elements of the MYTH program and the BtB program are not identical especially in content delivery. First, each BtB session contains 3 to 4 modules using examples and narratives from experts and role-played patients, whereas MYTH sessions are not divided by modules but instead, follow Billi's character-driven storyline. Second, each BtB session has projects for users to complete during the week ahead, whereas, in MYTH, Billi invites the users to personalize the goals and plans for their weekly homework. Finally, BtB introduces cognitive restructuring first, followed by behavioral activation and problem solving, whereas MYTH focuses on behavioral activation first, then introduces cognitive restructuring and problem solving.

Training of research staff and study coaches

Five graduate-level social work interns were selected and trained as study research staff ($n = 1$) and study coaches ($n = 4$). All research staff members were in the advanced year of their Masters of Social Work program and had received basic training in CBT, meaning they have at least taken an introductory mental health course that teaches CBT. The study research staff received two half-day trainings on all assessment materials, study procedures, and safety protocols. The research staff completed three mock assessments and were evaluated by the study PI as satisfactory. Four study coaches completed three half-day trainings on the treatment platforms they would be supporting (MYTH ($n = 2$) and BTB ($n = 2$)), study procedure, and safety protocols. Study coaches were trained separately for their group-specific follow-up check-in call protocols and were instructed not to communicate with other coaches about their assignment. All study coaches completed 5 mock follow-up check-in calls per person and were evaluated as satisfactory before starting clinical contact with participants. All study coaches received ongoing weekly supervision from the study PI.

Data collection and outcome measures

Participants completed two assessments, one at baseline and one immediately after treatment completion. Background and clinical information, including age, gender, race, cancer diagnosis, and current treatment stage, were collected, in addition to measures of feasibility, mental health symptoms, and acceptability, described below.

Primary outcome

Feasibility of MYTH was measured by the percentage of participants who completed at least 6 out of 8 MYTH sessions.

Secondary outcomes

The exploratory *efficacy outcome for depression* was measured by the Patient Health Questionnaire, 9 (PHQ-9).⁴⁹ Participants responded to a list of 9 questions asking how frequently they experienced depressive symptoms over the last two weeks using a 4-point Likert scale ranging from “0 = not at all” to “3 = nearly every day”, with a higher score indicating greater severity of depressive symptoms. The nine questions included in the PHQ-9 closely align with core diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual of Mental Disorders, 5th edition, DSM-5.⁵⁰ The PHQ-9 is one of the best-researched, most widely used depression assessment tools with satisfactory psychometric properties.^{51,52} This study reported satisfactory internal reliability with a Cronbach’s alpha of 0.88.

The exploratory *efficacy outcome for anxiety* was measured by the Generalized Anxiety Disorder-7-(GAD-7).⁵³ Participants responded to a list of 7 questions asking how frequently they experienced symptoms of anxiety over the last two weeks using a 4-point Likert scale, ranging from “0 = not at all” to “3 = nearly every day”, with a higher score indicating greater anxiety. GAD-7 questions align with core diagnostic criteria of generalized anxiety disorder in the DSM-5.⁵⁴ This study reported satisfactory internal reliability with a Cronbach’s alpha of 0.83.

Acceptability of MYTH was measured by the Acceptability of Intervention Measure, AIM.⁵⁵ AIM is a psychometrically validated measure assessing intervention acceptability. Participants responded to four questions using a 5-point Likert scale, from “1 = completely disagree” to “5 = completely agree”, with a higher score indicating stronger acceptability. The 4 questions are (THE INTERVENTION): 1. seems fitting; 2. seems suitable; 3. seems applicable; and 4. seems like a good match. This study reported satisfactory internal reliability with a Cronbach’s alpha of 0.93.

Sample size justification and statistical analysis

We planned the study sample size based on published methodological guidelines, suggesting that a minimum of 10 participants per group is sufficient for feasibility trials.^{45,56} For data analysis, we first conducted descriptive statistics of participants’ baseline demographic and clinical characteristics. We then conducted descriptive statistics of treatment completion, including the

percentage of participants completing at least 6 out of 8 MYTH or BtB (feasibility), and perceived treatment acceptability (measured by AIM).

Treatment effect was first analyzed using within-group paired sample's t-test to characterize the before- and after-treatment progress. In addition, we calculated the between-group difference in the change score, calculated by post-treatment mean score minusing baseline mean score, for the PHQ-9 and GAD-7 using independent sample's t-test. For both within- and between-group treatment effect, we also calculated small sample size corrected Hedges' g, following procedures outlined by Cooper and colleagues.⁵⁷ Analyses for treatment effect used an intent-to-treat framework, meaning all participants who were randomized are included in data analysis.^{58,59} We conservatively imputed a participant's post-treatment score using their baseline score for those who did not complete the post-treatment assessment for missing values. Sensitivity analysis using each group's post-treatment mean score for missing data imputation resulted in the same finding. Therefore, we report findings based on the conservative missing data imputation.

Results

Recruitment, enrollment, and retention

Over 8 months (Sep. 2020 to April 2021), the research team contacted 49 potentially eligible participants. Twenty of these individuals were not interested in the study for reasons including being self-identified as not depressed and not in need for treatment at the time (n=4), not interested due to over-exposure to computer screens during the COVID-19 pandemic (n=11), prefer to wait for in-person approach (n=2), and reasons not specified (n=3). In addition, twelve potential participants did not meet study inclusion criteria (9 participants had a PHQ-9 score ≤ 9 ; 2 participants were receiving end-of-life care; and 1 participant had a history of suicide attempt over the past 2 months). Seventeen participants consented to participate in the study, met all eligibility requirements, and were randomly assigned to a treatment condition. During the trial, two participants from MYTH and two participants from BtB did not complete the post-treatment assessment for reasons listed in [Figure 3](#) and described in the results section in detail. [Figure 3](#) presents the CONSORT flowchart of recruitment, treatment assignment, and retention.

Baseline characteristics

[Table 1](#) presents descriptive statistics of participants' baseline demographic and clinical characteristics. Participants' (N=17) average age was 20.24 years

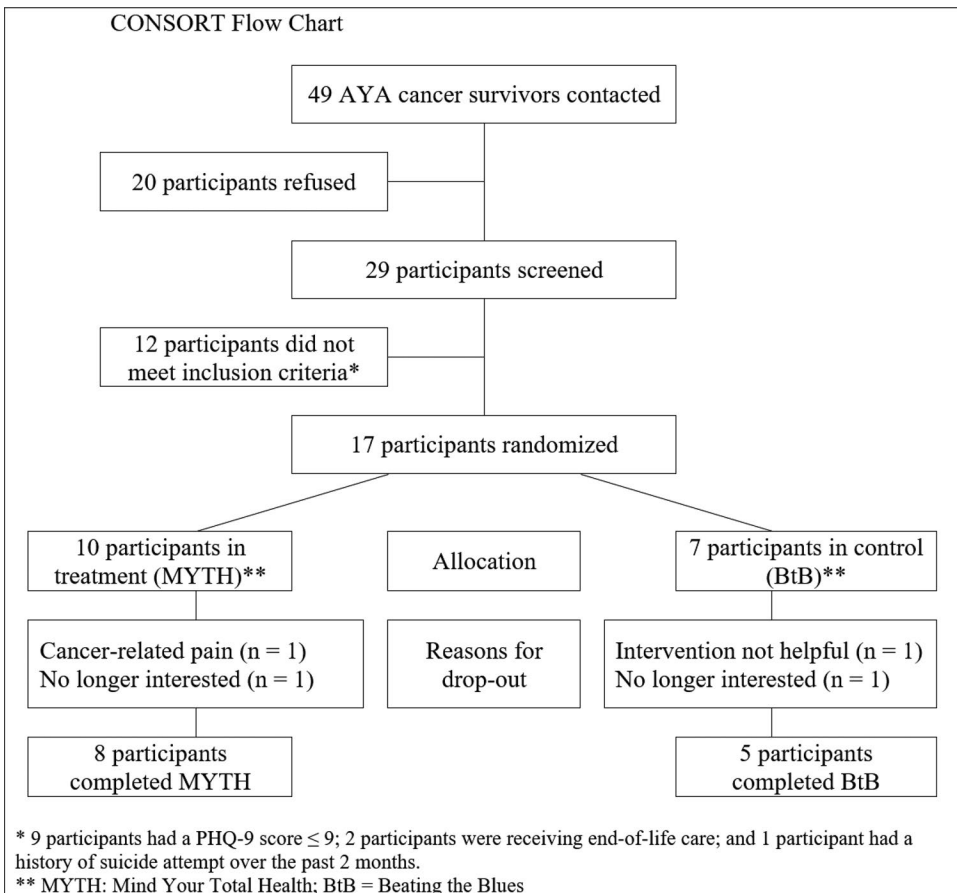


Figure 3. CONSORT flow chart. *9 participants had a PHQ-9 score ≤ 9 ; 2 participants were receiving end-of-life care; and 1 participant had a history of suicide attempt over the past 2 months. **MYTH: Mind Your Total Health; BtB=Beating the Blues.

old ($SD=2.17$) and the majority identified as female ($n=12$, 70.6%). Over half of the participants identified as non-Hispanic White ($n=11$, 64.7%), whereas a little more than one-third of participants identified as being a member of a racial/ethnic minority group (1 non-Hispanic Black, 3 non-Hispanic Asian, and 2 multi-racial participants). Ten participants (58.8%) were receiving active cancer treatment, and seven were post-treatment cancer survivors. The majority of participants were diagnosed with Acute Lymphoblastic Leukemia ($n=6$) or Hodgkin's Lymphoma ($n=4$). Other diagnoses included sarcoma ($n=3$), giant cell tumor ($n=1$), Acute Myeloid Leukemia ($n=1$) and osteosarcoma ($n=1$). Participants' baseline PHQ-9 scores averaged at 15.12 ($SD=1.32$), indicating moderately severe depressive symptoms. Participants' baseline GAD-7 scores averaged at 12.88 ($SD=2.57$), indicating moderate anxiety. Between-group analyses (not presented) indicate no significant difference in baseline demographic and

Table 1. Participants' demographic and baseline characteristics ($N=17$).

	Mean/SD	n(%)
Age	20.24/2.17	
Sex (female)		12(70.6)
Race		
Non-Hispanic White		11(64.7)
Non-Hispanic Black		1(5.9)
Non-Hispanic Asian		3(17.6)
Multi-racial background		2(11.8)
Treatment Stage		
Active treatment		10(58.8)
Post-treatment survivor		7(41.2)
Recruitment Setting		
Clinic recruited participants		6(35.3)
Community recruited participants		11(64.7)
Cancer Diagnosis		
Acute Lymphoblastic Leukemia		6(35.3)
Hodgkin's Lymphoma		4(23.5)
Sarcoma		3(17.6)
Burkitt Leukemia		1(5.9)
Giant Cell Tumor		1(5.9)
Acute Myeloid Leukemia		1(5.9)
Osteosarcoma		1(5.9)
Depression (PHQ-9 score)	15.12/1.32	
Anxiety (GAD-7 score)	12.88/2.57	

clinical characteristics between participants randomly assigned to MYTH versus BtB, or between completers versus non-completers.

MYTH feasibility

During the study period, 10 participants were enrolled in the study and randomly assigned to the MYTH treatment condition. Two participants dropped out of the MYTH condition before completing at least 6 sessions, suggesting strong feasibility (80% completion rate) of MYTH among AYAs with cancer. One participant dropped out due to increased pain caused by cancer treatment, and the other participant dropped out because they were “no longer interested in the study.” Among the eight participants who completed MYTH, six completed all eight sessions within 10 weeks, and two participants completed six out of eight sessions within 10 weeks.

Seven participants were enrolled in the study and randomly assigned to the BtB active control condition. In the BtB condition, five of the seven participants completed at least 6 out of 8 sessions, resulting in a 71.4% completion rate. Both participants who dropped out reported “the intervention not helpful” and they were “no longer interested in the study” after completing the first 2 sessions and dropped out of the study.

Table 2. Exploratory analysis of treatment effect and effect sizes.

	Within-group effect ^a			Within-group effect			Between-group effect ^b	
	MYTH (n = 10)			BeatingTheBlues (n = 7)			t(df)	D
	T ₁ M/SD	T ₂ M/SD	t(df)	T ₁ M/SD	T ₂ M/SD	t(df)		
Depression	15.10/1.37	11.50/1.78	5.25(9)***	15.14/1.35	13.39/1.29	2.78(6)**	0.98*	2.40(15)*
Anxiety	12.90/2.96	10.90/2.28	5.07(9)***	12.86/2.12	11.68/1.37	2.20(6)	0.79	0.80(15)

*** $p < 0.001$, ** $p < 0.01$, * $p < 0.05$.

^aT₁M/SD = baseline mean score / standard deviation; T₂M/SD = post-treatment mean score / standard deviation; t(df) = paired sample's t-test and degrees of freedom; g = within-group small sample size corrected Hedges' g.

^bt(df) = independent sample's t-test and degrees of freedom of the post-treatment mean scores between MYTH and BeatingTheBlues; d = between-group small sample size corrected Hedges' g.

Exploratory analysis of treatment effect and effect sizes

Table 2 presents results of the within- and between-group treatment effect of MYTH (versus BtB). Participants reported significant within-group improvement in depression before and after treatment in both MYTH, $t(9) = 5.25$, $p < 0.001$, and BtB, $t(6) = 2.78$, $p < 0.01$. The before and after treatment improvements were clinically meaningful evidenced by statistically significant treatment effects, $g = 1.59$, 95% CI 0.64–2.51, $p < 0.01$, and $g = 0.98$, 95% CI 0.08–1.84, $p < 0.05$, for MYTH and BtB, respectively. Finally, MYTH participants reported significantly lower post-treatment depressive symptoms than BtB participants, $t(15) = 2.40$, $p < 0.05$. The difference was clinically meaningful evidenced by a statistically significant treatment effect, $d = 1.12$, 95% CI 0.11–2.11, $p < 0.05$.

For the anxiety outcome, MYTH participants reported significant within-group improvement before and after treatment, $t(9) = 5.07$, $p < 0.001$. The improvement was clinically meaningful with a statistically significant treatment effect, $g = 1.54$, 95% CI 0.60–2.44, $p < 0.05$. The within-group improvement for anxiety was statistically *non-significant* among BtB participants, $t(6) = 2.20$, $p = 0.07$. The between-group post-treatment anxiety was statistically *non-significant* between MYTH and BtB participants, $t(15) = 0.80$, $p = 0.44$.

MYTH acceptability

MYTH participants reported an average post-treatment AIM score of 4.69 ($SD = 0.44$) out of 5 (versus a mean score of 4.25 in the BtB group), indicating strong acceptability of MYTH among AYAs diagnosed with cancer. The AIM score difference was *not* statistically significant.

Discussion

Depression is a salient factor impacting cancer care and quality of life for AYAs diagnosed with and treated for cancer. Building on an accumulating body of research on tCBT as a promising strategy to deliver research-supported and accessible depression treatment to AYA cancer survivors, this study contributes to the literature by evaluating a novel tCBT solution that addresses known weaknesses of existing tCBTs, including minimal engagement and tailoring to meet age-specific developmental needs. The study's primary finding provided compelling evidence of MYTH's feasibility as a tCBT for depression among AYAs with cancer. The 20% dropout rate among participants randomly assigned to the MYTH treatment condition was lower than commonly reported tCBT dropout rates ranging from 74%

(with no clinician involvement) to 38% (with coach support).⁶⁰ It is also important to note that one MYTH participant dropped out due to increased pain from cancer treatment *but not* because of the participant's dissatisfaction with the program. Despite the enhanced dropout risk among AYAs with cancer due to treatment-related pain, fatigue and other side-effects, MYTH still reported a lower dropout rate than other tCBTs, with documented dropout rates of 38% or higher.⁶⁰ This finding is consistent with MYTH's core innovation of using entertaining elements and population-specific tailoring to enhance treatment engagement.²⁵

This study revealed an average AIM score of 4.69 (out of 5) among participants randomly assigned to the MYTH treatment condition, which further underscores the significance of entertainment and targeted tailoring when delivering tCBT for depression to AYAs with cancer. Several tCBT studies reported that adolescents or young adults are generally interested in trying various platforms, but many discontinued early in treatment citing lack of interest, engagement, and perceived utility.⁶¹⁻⁶³ The high acceptability score of MYTH is likely due to the enhanced engagement and tailoring (for utility), which directly targets known risk factors for dropout. It is also reasonable to believe that MYTH's strong acceptability contributed to its low dropout rate, especially considering 6 out of 8 participants who did not drop out completed all 8 sessions.

The promising findings of MYTH's feasibility and acceptability call for future efforts to evaluate MYTH's effectiveness among younger (15 to 25 years old) as compared to older AYAs (26 to 39 years old) diagnosed with cancer. The parent program of MYTH, EntertainMeWell, was originally designed for the general adult population (without cancer) living with depression, and preliminary data has supported the program's acceptability among a middle-aged adult population.⁴³ In this study, however, the mean age of AYA cancer survivors was 20.24 years old. Therefore, it is important to evaluate MYTH among those who are 26 years or older in the future to confirm its feasibility and acceptability across the AYA age spectrum.

Though exploratory in nature, we were not surprised to find that participants from both MYTH and BtB reported statistically significant and clinically meaningful before and after treatment improvement scores in depression. As indicated earlier, MYTH contains core components of CBT, including behavioral activation, cognitive restructuring, and problem-solving, ensuring its fidelity to the best depression treatment guidelines. Additionally, when compared with BtB, a research-supported tCBT for depression, MYTH has an even greater focus on user entertainment/engagement and platform-based tailoring. These unique features may be key contributors to the finding that MYTH participants reported significantly lower post-treatment

depressive symptom scores than their BtB counterparts. Consistent with the psychotherapy and psycho-oncology literature,^{36,64,65} treatment engagement is one of the most important factors influencing treatment efficacy and should be a top priority for future research. The promising, though preliminary, finding of MYTH outperforming BtB adds to this important research direction by focusing on delivering an engaging and tailorable tCBT platform to AYAs diagnosed with cancer.

Interestingly, MYTH also improved participants' anxiety, whereas anxiety change was *not* statistically significant among BtB participants. Although both MYTH and BtB were developed to target depression, both programs are likely to result in some benefit to comorbid anxiety, as evidenced by lower GAD-7 scores at post-treatment when compared to baseline. It is important to reiterate that this feasibility trial was not sufficiently powered to detect statistical significance for efficacy endpoints, which is most likely the reason for the non-significant treatment effect for anxiety among BtB participants. Despite the power limitations, MYTH's significant treatment effect on anxiety further strengthened our confidence in its positive preliminary effect on both depression and anxiety among AYAs diagnosed with cancer.

A few limitations of this study must be noted. Given the nature and scope of this study, we had a small sample size; therefore we had a high risk of experiencing Type II error. Second, this study's small sample size prevented us from conducting additional exploratory analyses, such as Analysis of Covariance controlling for key participants' demographic and clinical characteristics. Third, almost two-thirds of the study participants were non-Hispanic White, which limited the implications of our preliminary findings to minority AYAs diagnosed with cancer. Fourth, this pilot feasibility adopted a set of broad set of inclusion criteria, including AYA cancer survivors of all cancer diagnoses, and those who were receiving active treatment with curative intent or within 5 years of post-treatment survivorship phase. Therefore, we were unable to determine if there were differences in feasibility and acceptability across cancer diagnosis and treatment stages, which should be considered in future research. Finally, the main character in the current version of MYTH, Billi, is identified as female. It is important to consider and develop characters who have diverse identities and positionalities, including gender identities, in future iterations of MYTH for depression among AYAs diagnosed with cancer.

Implications for psychosocial providers

Notwithstanding these limitations, this pilot feasibility trial highlights the importance and significant potential to offer an engaging and tailorable tCBT for depression among AYAs diagnosed with cancer. As the number

of AYA cancer survivors continues to grow both in the United States and internationally, it is essential to provide this population with research-supported and accessible depression treatment. Results suggest that MYTH is feasible and acceptable for treating depression among AYAs diagnosed with cancer, a population that has unique support needs and worse outcomes than their pediatric or older adult counterparts. Though exploratory, results also suggest MYTH is likely efficacious for treating AYA cancer survivors' depression. MYTH's key innovations of user engagement and tailorability have major implications for psychosocial oncology providers when treating depression among AYAs diagnosed with cancer.

Findings of this pilot study emphasize the benefits of providing an entertaining, engaging, customized, and age-appropriate technology-assisted depression treatment option for AYAs diagnosed with cancer as a complement to other more traditional treatment options. For psychosocial oncology providers, especially oncology social workers, when considering alternative depression treatment options for AYAs, it is important to account for the accessibility, level of treatment engagement, relevance to co-occurring cancer and depression diagnoses, and age appropriateness, to maximize potential treatment outcomes. As a promising tCBT platform for AYA cancer survivors with depression, future research testing MYTH with larger sample sizes and sufficient power to assess treatment efficacy is warranted.

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