

Using a Heuristic Tool to Improve Symptom Self-Management in Adolescents and Young Adults with Cancer: Protocol for a Randomized Controlled Trial

Suzanne Ameringer, Grace Hodges, R. K. Elswick Jr, Lauri Linder, Catherine Fiona Macpherson, Kristin Stegenga

Submitted to: JMIR Research Protocols
on: April 28, 2025

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Abstract

Background: Adolescents and young adults (AYAs) with cancer experience multiple distressing symptoms during treatment, yet few developmental relevant resources have been developed to help them self-manage their symptoms. Empowering patients to have a more active role in self-management during cancer treatment may lessen their symptom severity and distress.

Objective: This project will test an intervention designed to improve symptom self-management, the Computerized Symptom Capture Tool (C-SCAT) by helping AYAs understand their unique symptom experience and discuss it with their health care providers.

Methods: We are conducting a multi-site, two-group randomized control trial (RCT) to evaluate the effects of the C-SCAT for improving symptom self-management versus usual care in 126 AYAs who are within the first three months of a diagnosis of cancer and who are receiving chemotherapy. Participants are randomly assigned to either the C-SCAT intervention group or usual care group. The primary aim is to determine the effects of the C-SCAT versus usual care on the primary outcomes of self-efficacy for symptom management and symptom self-management behaviors. The secondary aim is to examine the effects of the C-SCAT versus usual care on distal outcomes including symptoms and quality of life. Participants complete measures of self-efficacy for symptom management, symptom self-management behaviors, symptom severity and distress, quality of life social function, and quality of life satisfaction of social function at baseline, immediately post intervention, and at follow-up one month later.

Results: Recruitment started on January 4, 2024, at the first site, and all sites were open by May 1, 2024. To date, we have enrolled 35 (28%) out of 126 participants and anticipate the final participant will complete the study by December 2026. Linear mixed effects models will be used to test for group differences across time for the primary and secondary aims.

Conclusions: This RCT is evaluating an innovative, point-of-care intervention designed to be used at a clinic visit with the provider to improve symptom self-management for AYAs with cancer. Designing behavioral intervention studies that that accrue and retain AYAs can be challenging. Other researchers who engage with this population may find this protocol useful. Clinical Trial: ClinicalTrials.gov NCT05958316

<https://clinicaltrials.gov/study/NCT05958316>

(JMIR Preprints 28/04/2025:76667)

DOI: <https://doi.org/10.2196/preprints.76667>

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Original Manuscript

Original Paper

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Conclusion: This RCT is evaluating an innovative, point-of-care intervention designed to be used at a clinic visit with the provider to improve symptom self-management for AYAs with cancer. Designing behavioral intervention studies that accrue and retain AYAs can be challenging. Other researchers who engage with this population may find this protocol useful.

Trial Registration: Trial Registration: ClinicalTrials.gov NCT05958316

Keywords: Randomized clinical trial; cancer; adolescents and young adults; digital health; symptom management

Introduction

Background

Approximately 90,000 adolescents and young adults (AYAs) are diagnosed with cancer yearly in the U.S [1]. As a distinct subset of patients with cancer, AYAs are underserved, understudied, and at risk for inferior outcomes, both physical and psychosocial, compared to younger children and older adults [2]. The epidemiology of AYA cancers, the physical and psychosocial effects of the requisite treatments, and characteristics of the AYA's developmental stage combine to create a distinctive cancer experience, including multiple distressing interrelated symptoms [3-5].

Undermanaged, persistent, and/or recurrent symptoms negatively affect quality of life, function, health care costs, morbidity, and survival [6]. Specifically, AYAs report a decline in both mental and physical aspects of quality of life with as few as three symptoms [7]. Symptoms can interfere with the AYA's ability to attend school, participate in sports, and develop and maintain romantic relationships [8]. AYAs with cancer desire personalized symptom management information [9] but communicating their symptom experience to health care providers (HCPs) can be difficult for multiple reasons. These include the AYA's lack of familiarity with the health care environment, inexperience talking about symptoms, a lack of systematic symptom assessment in many clinical settings, and the HCP's focus on issues other than those important to the AYA [10]. One critical aspect of obtaining relief from symptoms is to enhance an individual's ability to self-manage symptoms.

Self-management is defined as the process by which individuals use knowledge, beliefs, skills and abilities to achieve health-related outcomes [11]. A distinct component of self-management is symptom self-management, defined as "a dynamic, self-directed process of implementing behaviors that recognize, prevent, relieve, or decrease the timing, intensity, distress, concurrence, and unpleasant quality of symptoms to achieve optimal performance outcomes." [12, p. E18] Developing self-management abilities in general, and symptom self-management abilities specifically, may be

challenging for AYAs with cancer because they may be gaining autonomy but often still somewhat dependent on parents/guardian, emotionally or physically unprepared for or incapable of executing responsibilities they need to assume, and/or novices at dealing with chronic illness, monitoring symptoms, and interacting with HCPs [13]. While effective interventions exist for AYAs to improve self- management of other chronic diseases such as asthma and diabetes [14], nearly none exist for AYAs with cancer. Two aspects that are critical to improving symptom self-management are having self-efficacy to manage symptoms and engaging in effective symptom self-management behaviors.

The concept of self-efficacy is described as the confidence a person has in their abilities to successfully engage in a behavior [15] and is essential to self-management [16]. Self- efficacy for symptom self-management is defined as the individual's belief in their "ability to implement behaviors to prevent, recognize, and relieve symptoms" [17 p. E274], In AYAs with cancer, evidence suggests that increased self-efficacy is associated with improved symptom self-management behaviors, in particular improved nutrition and physical activity [18,19]. Among adults with cancer, self-efficacy is a key predictor of symptom self-management behaviors and associated with decreased symptom severity/distress, improved psychosocial function, and greater quality of life [20-24]. Targeting self-efficacy has been shown to be effective; however, interventions to increase AYAs' self-efficacy for symptom self-management are lacking.

Symptom self-management behaviors are those actions that individuals initiate to alleviate symptoms [12]. Mastering effective symptom self-management behaviors can be particularly challenging as AYAs transition from having their parents manage their healthcare to managing it on their own [25]. Studies addressing symptom self-management behaviors among AYAs receiving cancer treatment are largely cross-sectional and descriptive; however, they provide important insights into the strategies AYAs use. AYAs may initiate symptom self-management behaviors to target an individual symptom, such as taking an anti-emetic medication to manage nausea, or to target more than one symptom, such as allowing for rest periods to self-manage fatigue, and pain

[5,26]. AYAs have revealed their rationales for engaging in certain symptom self-management behaviors, which have included enduring a given symptom for the sake of avoiding another. For example, AYAs may opt to omit opioid analgesics to avoid side effects of nausea and vomiting [5,27]. Symptom self-management behaviors may also be influenced by the AYA's own role-related responsibilities, for example, AYAs who are parenting may select or even forgo given symptom self-management strategies in deference to priorities for their children [28].

Collectively, these studies indicate efforts that AYAs initiate to self-manage their symptoms. More significantly, they reveal challenges that AYAs face when deciding how to optimally manage their symptoms, and therefore, a person-centered approach to support symptom self-management is vital.

To address this need, we developed and pilot tested the Computerized Symptom Capture Tool (C-SCAT), an innovative, inductive, heuristics-based symptom self-management intervention delivered via a tablet computer [29]. Heuristics are conscious or unconscious "mental models" used in decision-making and problem-solving. A heuristic approach is proposed to assist individuals to become more aware of their symptoms and the need to engage in symptom self-management behaviors. The C-SCAT is designed to target key processes of symptom self-management, including self-efficacy, self-regulation, and communication with providers to enhance symptom self-management behaviors.

Theoretical Framework

The Individual and Family Self-Management Theory [11], which acknowledges the complex process of changing health behaviors to self-manage symptoms related to an illness such as cancer was used to develop the C-SCAT intervention. The theory proposes that context and process factors influence proximal and distal health outcomes. Individual contextual factors may add risk or protection to engagement in self-management, and process factors facilitate change in health behaviors. Interventions to improve symptom self-management can target context and/or process factors.

The context factors include gender, race, ethnicity, and family structure. The process factors are self-efficacy for symptom management, self-regulation, and negotiated collaboration. As mentioned above, symptom self-efficacy is defined as the individual's belief in their ability to manage their symptoms. Self-regulation is a process that leads to self-management behaviors through self-monitoring, decision-making, and reflective thinking [11,30]. Negotiated collaboration is defined as perceived communication and collaboration with HCPs regarding symptom management. The proximal outcome, symptom self-management behaviors, are those activities used to prevent, monitor, manage, and communicate symptoms [31]. The distal outcomes are symptom severity and distress and quality of life-social health.

The C-SCAT intervention targets process and proximal outcome factors. For this study, the primary outcomes are self-efficacy for symptom self-management and engagement in symptom self-management behaviors. The secondary outcomes are symptom severity, symptom distress, social function, and satisfaction with social function.

Aims/Hypotheses

This randomized controlled trial is testing a heuristics-based intervention designed to enhance symptom self-management in AYAs with cancer. Primary aim 1 is to determine the effects of the C-SCAT versus usual care on the primary outcomes of self-efficacy for symptom management and symptom self-management behaviors immediately post intervention (Time 1) and at follow-up one month later (Time 2). Aim 1 hypotheses are that AYAs using the C-SCAT will have higher self-efficacy for symptom self-management and higher scores on symptom self-management behaviors compared to AYAs receiving usual care. Primary aim 2 is to examine the effects of the C-SCAT versus usual care on secondary outcomes (symptom severity, symptom distress, social function, and satisfaction with social function) immediately post intervention (Time 1) and at follow-up one month later (Time 2). Aim 2 hypotheses are that AYAs using the C-SCAT will have lower symptom distress and symptom severity, and higher social function and satisfaction with social function compared to

AYAs receiving usual care.

Methods

Ethical Considerations

This study has been approved by Advarra which serves as the single institutional review board of record and has received administrative approval from the institutional review boards at each study site. The informed consent process is conducted by study staff and includes verbally reviewing the consent form, answering questions, and obtaining signatures from the participant and one parent/legal authorized representative of participants who are minors. Obtaining informed consent/assent and parental permission occurs in-person in a private setting in the inpatient or outpatient oncology setting. Assent is documented by the participant who is less than 18 years of age signing the informed consent/permission/assent form. A re-consent process will occur for participants who are minors at enrollment but become adults during the study period are re-consented as adults.

Written informed consent/assent and parental permission as appropriate are obtained before completing baseline measures. After the informed consent process is complete, participants are considered enrolled and assigned a study identification number linked to their survey responses and intervention visits. Participants are compensated with a \$25 prepaid gift card after completing each of the first and second data collection visits, and a \$30 prepaid gift card after completing the third data collection visit, for a total of \$80.

Recruitment

At each of the sites, recruitment occurs in both inpatient and outpatient oncology settings. Potential participants are approached in person. Sites using Epic are also able to provide a recruitment message through the electronic medical record.

Screening

At each site, oncology clinic schedules are reviewed at least weekly to identify potential participants. In addition, hospital staff in inpatient and outpatient oncology settings are asked to identify

potentially eligible participants. A screening form is completed prior to enrollment to determine eligibility.

Trial Design

This study employs a multi-site two-group randomized control trial design to evaluate the effects of the C-SCAT for improving symptom self-management versus usual care in AYAs who are within the first three months of a diagnosis of cancer and who are receiving cancer treatment. For this study, cancer treatment is defined as a prescribed infusion (e.g., chemotherapy, immunotherapy). Data collection occurs at 3 timepoints (Times 0, 1, and 2). Time 0 (baseline, followed by randomization) occurs at or near the enrollment visit. The C-SCAT intervention period is approximately 12 weeks, depending on the participant's treatment schedule. Time 1 (post-intervention) occurs approximately 2 weeks (± 7 days) after completion of the intervention. Time 2 (follow-up) occurs approximately 4 weeks (± 7 days) after Time 0 as seen in Figure 1.

Participants and Setting

Recruitment and enrollment are conducted by trained study staff and take place at four institutions from the Northwest, Intermountain West, Midwest, and Southeast regions of the US. Participants are AYAs with cancer who are in active treatment. The inclusion criteria are: 1) ages 15 to 29 years, 2) has received at least one cycle of cancer treatment and is within 3 months of receiving that first cycle of treatment, 3) receiving regularly scheduled cancer treatment and will be receiving at least three more cycles, 4) reports at least one symptom related to cancer and/or its treatment, and 5) able to speak, read, and write English as required for completion of the C-SCAT and study measures. The exclusion criterion is cognitive and/or physical inability to complete study measures.

Randomization

Participants are randomized to either the C-SCAT intervention or usual care control group. Study staff and participants are not blinded to treatment allocation due to the nature of the intervention. Using stratified randomization (a separate randomization at each clinical site), participants are

randomized to the C-SCAT group or to the usual care control group. Within each clinical site, a block randomization schema is generated with randomly selected block sizes of 2, 4, and 6. Stratified and block randomization with randomly selected block sizes are preferred in unblinded studies because they make it very difficult, if not impossible, for people enrolling participants to know what group assignment is next [32]. The biostatistician/PI generates the various randomization schemas by clinical site and the data manager uploads them into Research Electronic Data Capture allowing study staff at all sites to instantaneously receive the group assignment via computer.

Study Intervention

The C-SCAT is a symptom heuristic tool that is delivered via a tablet computer and was developed based on a symptom cluster heuristics interview guide created by Dr. Nancy Woods and colleagues [33]. The tool engages the AYA to create a graphical image of the symptoms they experienced during the past week, designating relationships among symptoms and identifying priority symptoms. It can be completed just prior to an HCP visit to assist the AYA to understand their symptom experience and communicate it effectively to the HCP to facilitate symptom self-management. The C-SCAT uses a heuristics approach to promote AYA's self-awareness of their symptoms, specifically to help them visualize the 'big picture' of their unique symptom experience. The heuristics approach of the C-SCAT is proposed to assist AYAs to become more aware of their symptoms and of the need to engage in symptom self-management behaviors.

The C-SCAT includes the 32 symptoms from the Memorial Symptom Assessment Scale [34]. Users select symptoms they have experienced over the past week, rate each symptom's severity and distress, and name a perceived cause (Figure 2). They then identify temporal and causal relationships between symptoms using lines and arrows, designate groups, i.e., "clusters" of symptoms, and give a name to each cluster (Figure 3). Users can designate up to three priority symptoms (symptoms most important to them). They are asked the reason for a symptom's designation as a priority symptom and what they do to alleviate that symptom (Figure 4). Next, they are asked to designate a priority

cluster and finally, to confirm whether the image accurately reflects their symptom experience (Figure 5). Then, at the clinic visit, the AYA shares the visual image with the HCP, and more importantly, their priority symptoms, which can facilitate the symptom discussion.

As a person-centered intervention, the C-SCAT targets three key symptom self-management processes: 1) self-efficacy for symptom management, 2) self-regulation, and 3) negotiated collaboration. Self-efficacy for symptom management is enhanced by using the C-SCAT because creating the image facilitates individuals' interpretation of their symptoms.

Description of the C-SCAT Intervention Group

Participants assigned to the C-SCAT intervention group complete the C-SCAT on a tablet computer in addition to their institution's usual care and processes for assessing symptoms prior to three of their scheduled clinic visits with their healthcare providers (HCPs) for their cancer treatment. Depending on the individual's treatment protocol, treatments are typically every 2 to 4 weeks. Prior to the AYA's first encounter with the HCP, study staff provide a short interactive practice session on how to use the C-SCAT that includes: 1) an introduction to the C-SCAT as a tool that can be used to create a graphical image of the AYA's symptom experience that can be printed out and shared with the HCP, 2) a video that demonstrates how to complete the C-SCAT and how it can be used in an encounter with the HCP, 3) a practice session to ensure that the AYA is proficient and comfortable with using the C-SCAT, and 4) a question/answer period. The AYA then completes the C-SCAT, and the resulting image is printed out and given to the AYA to share with the HCP at this first encounter. Prior to the subsequent two encounters with the HCP, AYAs are asked if they would like another practice session with the C-SCAT. Study staff give supply providers with a document which describes an image created in the C-SCAT.

Description of the Usual Care Control Group

Participants assigned to the usual care control group receive care based on the institution's usual approach to assessing symptoms during the HCP encounter. To provide attention control to the usual

care control group and help prevent disproportional attrition from that group, study staff make contact with usual care control group participants three times during the intervention period (same as the intervention group) during scheduled clinic visits and communicate the following: 1) express appreciation for ongoing study participation; 2) ask how everything is going with their treatment; 3) ask if anything has changed with their treatment plan since the last study visit; and 4) confirm continued willingness to participate in the study.

Intervention Fidelity/Training of Study Staff

Intervention fidelity is guided by recommendations from the National Institute of Health Behavior Change Consortium [35], with attention to design, training, delivery, receipt, and enactment. Study staff at each site are involved in recruitment, retention, and data collection. Training addresses protection of human subjects, research compliance, study methods, data entry/management, roles/responsibilities, training on the C-SCAT intervention, and attention to the usual care control group. All staff complete required human subjects and other relevant training at initiation of the project and throughout as appropriate.

To ensure that the intervention is delivered as intended within and across sites, we developed a standard operating procedure manual with core procedures for all sites and specific considerations within sites and ensure training of the study staff to procedures and interventions through review of the manual, didactic sessions, and demonstrations. To maintain consistency of training, study procedures based on the manual are regularly reviewed with the study staff. The project coordinator monitors intervention delivery and receipt by routine random checking for any differences in study logs, completion of C-SCAT, and completeness of measures. Retraining is instituted as needed. The research team holds twice monthly meetings (and ad hoc as needed) with study staff to discuss any issues with study procedures. To confirm intervention enactment, at the beginning of each intervention visit, study staff ask the participant what questions they have on how to complete the C-SCAT, and whether they want another practice session. These processes will ensure consistency of

intervention delivery and integrity of data collection.

Outcome Measures

Primary Outcome Measures

Self-efficacy is measured with the PROMIS Self-efficacy of Symptom Management Scale (PROMIS S-E), a domain-based 28-item scale. Items assess the person's current level of confidence to manage/control symptoms, manage symptoms in different settings, and keep symptoms from interfering with work, sleep, relationships, or recreational activities [36]. Response options are on a 5-point Likert scale (1=*I am not confident at all*; 5=*I am very confident*). Scores are summed across items and can range from 28 to 140, and higher scores indicate greater self-efficacy. Cronbach's alpha in our previous study with AYAs was 0.94 [37].

Symptom self-management is measured with the Symptom Self-management Behaviors Tool (SSMBT) [38]. The SSMBT contains 12 items with two subscales: Manage Symptoms (8 items) that address behaviors related to managing their symptoms and Talk to Healthcare Provider (4 items) that address behaviors related to communicating with their HCP about their symptoms. Response options are on a 5-point Likert scale (0=*never*; 4=*always*). Scores are summed across all items. Higher scores indicate higher engagement in symptom self-management behaviors.

Secondary Outcome Measures

Symptom severity and distress in the past week are assessed using the Memorial Symptom Assessment Scale [34]. Participants rate the severity on a 4-point Likert scale (1=*slightly*; 4=*very severe*), and the distress on a 5-point Likert scale (0=*none*; 4=*very much*).

Two aspects of social function are assessed: quality of life related to social function, and satisfaction with social function. Quality of life related to social function is assessed with the PROMIS SF v2.0 Ability to Participate in Social Roles and Activities. It contains 8 items, is scored on a 5-point Likert response scale (5=*never*; 1=*always*), and has strong evidence of reliability and validity in clinical populations, including individuals with cancer [39]. Satisfaction with social

function is assessed with the PROMIS SF v2.0 Satisfaction with Social Roles and Activities. It contains eight items, is scored on a 5-point Likert response scale (1=*not at all*; 5=*very much*), and has been validated in adults ≥ 18 years⁴⁰ and used in young adults with cerebral palsy [41].

Descriptive Measures

Self-reported demographic data are collected with the Biomedical Research Informatics Computing System, National Institute of Nursing Research [42] demographic form including education, primary caregiver, employment, marital status, household member count. Additional items assess household income, number of children, people living with the AYA, and living arrangement changes during treatment. Self-reported race and ethnicity are also being collected. Clinical and other descriptive variables are collected by study staff from the participant's electronic health record and include age, sex, cancer diagnosis, time since diagnosis, chemotherapy protocol start date, treatment protocol, co-morbid conditions, and insurance type, and zip code.

Intervention Acceptability

Participants in the intervention group are asked to complete the C-SCAT Intervention Acceptability Survey. This 7-item survey assesses the acceptability of the intervention (Table 1).

Table 1. Study variables and measures by timepoint.

Variable	Measures	Time 0	Time 1	Time 2
Self-efficacy for symptom management	PROMIS ^a Self-efficacy for symptom management	ü	ü	ü
Symptom self-management behaviors	Symptom Self-management Behaviors Tool	ü	ü	ü
Symptom severity and distress	Memorial Symptom Assessment Scale	ü	ü	ü
Social function	PROMIS Ability to Participate in Social Roles and Activities	ü	ü	ü
Satisfaction with social function	PROMIS Satisfaction with Social Roles and Activities	ü	ü	ü
Demographics	BRICS NINR ^b Demographics form and Electronic Health Record	ü		
Intervention Acceptability	C-SCAT ^c Intervention Acceptability Questionnaire (Intervention group only)			ü

^aPROMIS Patient-Reported Outcomes Measurement Information System

^bBRICS NINRB Biomedical Research Informatics Computing System National Institute of Nursing Research

^cC-SCAT Computerized Symptom Capture Tool

Safety

Data Safety Monitoring

This study carries less than minimal risk to participants. Because this study is a multi-site clinical trial and involves adolescents ages 15 and older, we utilize a Safety Monitoring Committee to assess safety of the study and monitor the data. The Safety Monitoring Committee consists of two members who have areas of expertise in adolescents and young adults with cancer and biostatistics.

Monitoring Participant Safety

The research team uses a clearly defined protocol to monitor participant safety. Participant safety is monitored monthly and with each occurrence of a potential safety issue. The principal investigator, in collaboration with co-investigators/site principal investigators, is responsible for monitoring the safety of participants at each site.

Data Analysis Plan

This study is a 2 group (C-SCAT vs. control), longitudinal randomized multi-center, (5 sites) clinical trial with data collected at 3 time points (Times 0, 1, and 2). Two primary variables are being evaluated for group differences in Aim 1: Symptom self-efficacy as measured by the PROMIS Self-Efficacy of Symptom Management Scale (PROMIS S-E) and self-management behaviors as measured by the Symptom Self-Management Behavior Tool (SSMBT). The secondary outcomes in Aim 2 are symptom severity, symptom distress, social function, and satisfaction with social function. The plan is to enroll 126 adolescents and young adults with cancer in active treatment from 5 sites.

Sample Size and Power

A mixed effects linear model is planned to test for group differences across time for Aims 1 and 2. The co-primary outcome variables from Aim 1 are the PROMIS S-E and the SSMBT. From the outset, we planned to take a more conservative approach to the power analysis due in part to the

limited number of SSMBT samples observed from only one site. Thus, for both primary variables, power was estimated using a 20% inflated variance estimate and using a target power of 90% (as opposed to the usual 10% inflated variance and 80% power). A 20% inflated estimate of the residual standard error was estimated as 12.73 for PROMIS S-E and 6.35 for SSMBT. Assuming the smallest clinically significant difference between the groups of 10 for PROMIS S-E and 4.8 for SSMBT, a Bonferroni adjusted alpha of $\alpha = 0.05/2 = 0.025$ and a power of 90%, PASS [43] software estimated the total sample size to be 77 for PROMIS S-E and 83 for SSMBT. However, the proposed model will have effects for Time (0, 1 & 2), Group (C-SCAT vs. usual care), Time by Group interaction, Site (1, 2, 3, 4, & 5), Site by Group interaction, and Population (adolescent vs. young adult). Accounting for the 16 degrees of freedom necessary to fit these model effects, the total sample size will be $83 + 16 = 99$. Allowing for an attrition as high as 20%, the final sample size will be 126 AYAs or approximately 25 per site. Recruitment in our preliminary multi-site studies demonstrated that this sample size is feasible within the proposed time period of the project.

Descriptive statistics will be computed for demographic and all outcome variables. All data will be examined graphically to determine the distributional properties. In cases of non-normally distributed data, transformations may be used for analyses.

Aims

Aim 1 is to determine the effects of the C-SCAT versus usual care on the primary outcomes of self-efficacy for symptom management and symptom self-management behaviors immediately post intervention (Time 1) and at follow-up one month later (Time 2). Self-efficacy for symptom management and symptom self-management behaviors will be assessed at Times 0, 1, and 2 and will be compared between the C-SCAT intervention group and the usual care control group. We anticipate using a linear mixed effects model to test the effect of the C-SCAT versus usual care. The general form of the mixed linear model [44-46] is given by: $\mathbf{y} = \mathbf{XB} + \mathbf{ZU} + \mathbf{e}$, where $\mathbf{y}$ is the observed data vector (PROMIS S-E & SSMBT), $\mathbf{X}$ is a known design matrix, $\mathbf{B}$ is a vector of

unknown fixed effects, $\mathbf{Z}$ is a known design matrix, $\mathbf{U}$ is a vector of unknown random effects, and $\mathbf{e}$ is a vector of unknown random errors. This model will include a random effect for Participant (represented by $\mathbf{ZU}$ in the equation), and fixed effects for Group (C-SCAT & usual care control group), Time (0, 1 & 2), Group by Time interaction, Site (1, 2, 3, 4, & 5), Group by Site interaction and Population (adolescent & young adult) (represented by $\mathbf{XB}$ in the equation). The model is flexible enough to accommodate the potential cofactors of Race (Black, White, etc.), Ethnicity (Hispanic, non-Hispanic), and Gender (male & female). The first step in testing Aim 1, will be to test each of the primary variables (PROMIS S-E & SSMBT) using a contrast on the group by time interaction to specifically test for an immediate effect of C-SCAT versus the usual care control group at Time 1. A Bonferroni correction ($\alpha = 0.05/2 = 0.025$) is planned to adjust for testing each of the 2 primary variables. All other tests, e.g., testing for a sustained effect at Time 2, are considered supportive and will be testing with an $\alpha = 0.05$. Modeling assumptions such as normality and homoscedasticity will be checked for each model. In the case of positively skewed data, a transformation (such as a log-transformation) will be used to normalize the data. It is anticipated that all analyses will be performed using JMP®[47] and SAS/STAT® [47] software, specifically PROC MIXED.

Aim 2 is to examine the effects of the C-SCAT versus usual care on secondary outcomes (symptom severity, symptom distress, quality of life related to social function, and satisfaction with social function) immediately post intervention (Time 1) and at follow-up one month later (Time 2). The mixed effects linear model presented in the Aim 1 analysis plan is anticipated to be sufficient for the analysis of the secondary outcomes in Aim 2. The secondary outcomes are considered supportive of the tests of an immediate effect (Aim 1) and will be testing with an $\alpha = 0.05$.

Missing data

In addition to strategies to prevent missing data, such as completion checks after study visits and reminders, we will monitor for patterns of missing data when data are merged on a quarterly

schedule and determine reasons for missing data. We will use mean imputation for any missing data within a scale. Following an intention to treat principle, participants with any post intervention data will be included in the analysis.

Results

Recruitment began at the first site on January 4, 2024. All sites were open to recruitment by May 1, 2024. As of April 8, 2025, we have enrolled 35 (28%) of the goal of 126 participants. We anticipate that the study will close to recruitment on August 31, 2026, and the final participant complete the study by December 2026. We anticipate publishing results in 2027.

Discussion

We describe the protocol of a randomized controlled trial that is testing the effectiveness of the C-SCAT intervention designed to improve symptom self-management by helping AYAs to understand their unique symptom experience and discuss it with their HCPs. The intervention aims to increase self-efficacy for managing symptoms and engagement in effective symptom self-management behaviors. Empowering patients to adopt a more active role in self-management during cancer treatment may lessen their symptom severity and distress.

The main limitations of this study center around reaching recruitment goals. Recruitment and retention are well-recognized challenges in any RCT with multiple data collection timepoints. However, beyond that, the nature of this study population poses additional challenges. Cancer in AYAs is fortunately considered rare but this limits the number of eligible patients available. Recruiting minors (individuals less than 18 years of age) adds an extra layer of complexity to the consent process as both a parent/legally authorized representative and the eligible minor patient must be interested in study participation, the parent/legally authorized representative must give permission, and the patient must give assent. Sometimes the parent/legally authorized representative is interested but the patient feels too ill or feels that the burden of participation is excessive. Sometimes the patient is interested but the parent/legally authorized representative feels that the

burden of participation may be excessive and wishes to protect the patient from that. Some potential participants may decline study participation because they do not perceive potential personal benefit even if randomized to the intervention arm as they feel that their symptom experience is being well-managed and/or communication with their providers is already good. Alternatively, some potential participants may decline study participation because they feel too unwell from their symptom experience, or most commonly, express a sense of being overwhelmed, of 'having a lot going on' living a life that now includes cancer and cancer treatment. We aim to minimize recruitment challenges through our team's expertise and experience with conducting several previous studies with this AYA population. In addition, we are recruiting from major cancer centers that have large catchment areas. To aid retention, both groups (C-SCAT and usual care control group) participants receive personal contact with a study team member at least three times during the intervention period.

In conclusion, because undermanaged symptoms reduce quality of life and increase symptom severity and distress, effective person-centered symptom self-management is imperative for AYAs with cancer. A major barrier, however, is a lack of effective symptom self-management interventions that are tailored to this population. The proposed study addresses this gap by testing an intervention designed to improve symptom self-management behaviors in AYAs with cancer who are in active treatment. If shown to be effective, the C-SCAT could be incorporated into clinical settings at the point of care and potentially into the electronic health record as an efficient, low-cost approach to improve symptom self-management.

Acknowledgments

We are grateful to Dr. Deborah McGuire for her guidance and expertise with developing the study. Funding for the study was provided by NIH NCI R01CA286799. The content is solely the responsibility of the authors.

Conflicts of Interest

None declared

Abbreviations

AYAs: adolescent and young adults

C-SCAT: Computerized Symptom Capture Tool

HCPs: health care providers

PROMIS S-E: PROMIS Self-efficacy of Symptom Management Scale

SSMBT: Symptom Self-management Behavior Tool



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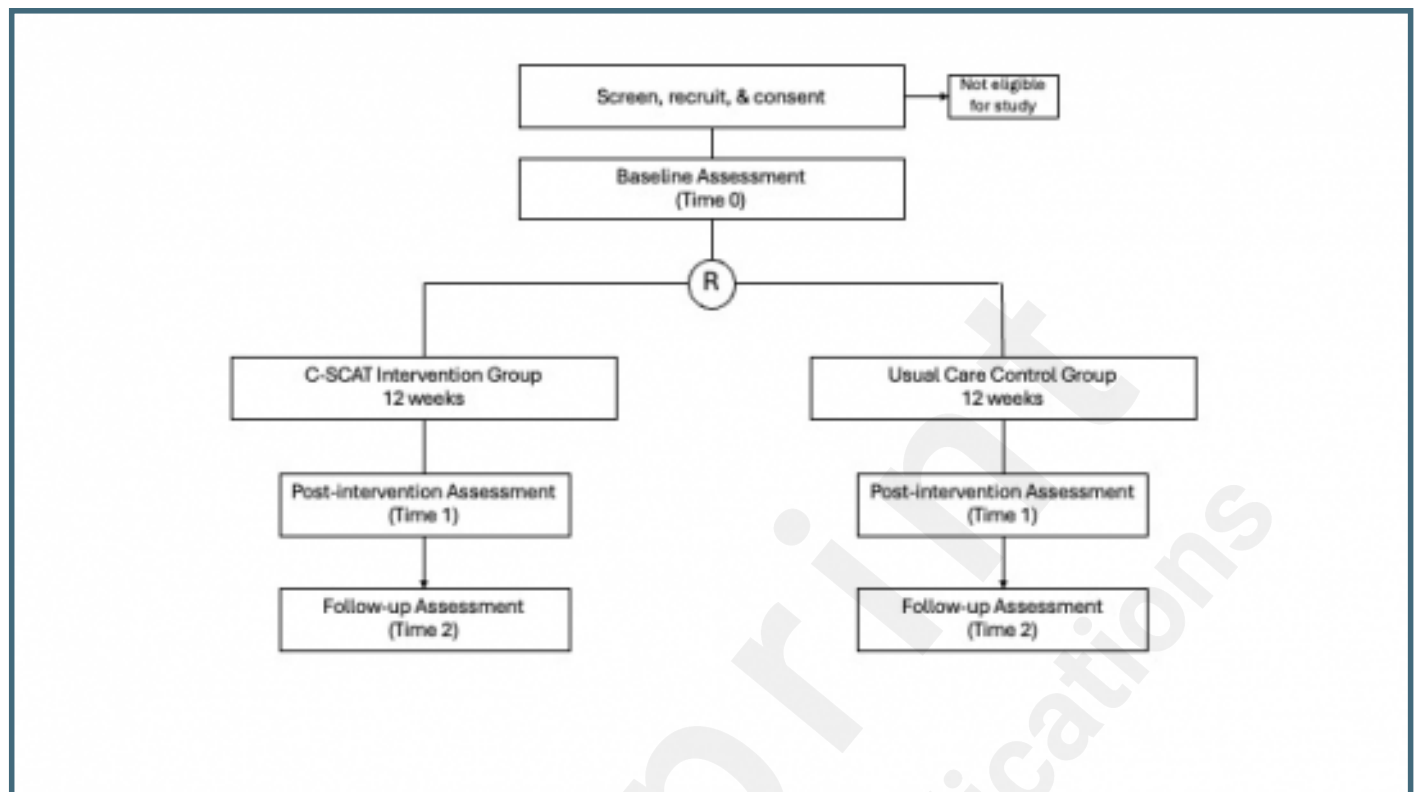
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Supplementary Files

Figures

Study schema.



C-SCAT screen depicting selection of a symptom and corresponding questions about the symptoms.

Participant #SD2C

Symptom Selection and Details

Please drag the symptoms you have experienced in the past week into the main portion of the screen. You may then answer some questions about that symptom.

Double tap a symptom to change your answers.

Once completed, click "Continue" to continue to the next section.

Based on the severity of the Symptoms chosen, the color of the symptom card will change in tone.

- Very Severe
- Severe
- Moderate
- Slight

Vomiting

How severe was it usually?

- ☐ Slight
- ☐ Moderate
- ☐ Severe
- ☐ Very Severe

How much did it distress or bother you?

- ☐ Not at all
- ☐ A little bit
- ☐ Somewhat
- ☐ Quite a bit
- ☐ Very Much

How many days have you had this symptom in the past week?

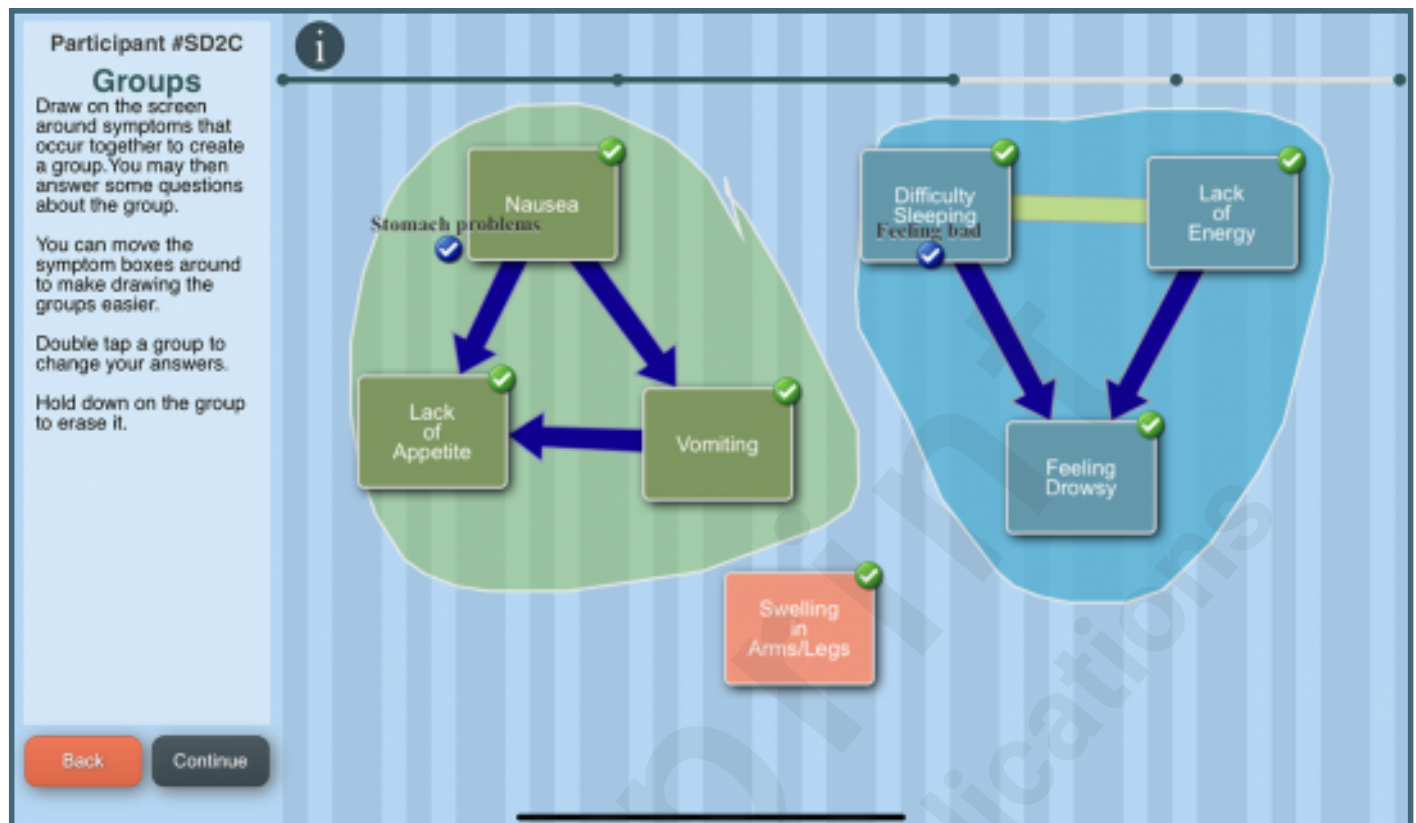
Cancel Save

Start Over

SKIN Changes Sweating in Hands/Feet

Feeling Drowsy

C-SCAT screen depicting selection of group/s of symptoms that occur together.



C-SCAT screen depicting priority symptoms the participant has chosen and the corresponding questions about the priority symptom.

Participant #SD2C

Symptom Priority

Tap on the symptoms that are most important to you. You may choose up to 3.

Stomach

Lack of Appetite

Lack of Energy

Fatigue

Priority Symptom

?

What makes this a priority symptom?

Causes the others

What do you do to make it better?

Meds and not eat

Cancel Save

Back

C-SCAT screen depicting the final image the participant created of their symptoms for their review.

