Name	Rachel Webster
Institution	St. Jude Children's Research Hospital
Address	262 Danny Thomas Place, MS 740 Memphis, United States, 38105 United States
Phone Number	9015957946
Alternate Phone Number	
Email Address	Rachel.Webster@stjdue.org

Requirements to submit AOI (all answers must be "yes" to proceed)

A comprehensive review of previously published data has been completed	Yes
The specific aims are clear and focused	Yes
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.	Yes
The investigator agrees to develop an initial draft of the concept proposal within 6 weeks of approval of the AOI and to finalize the concept proposal within 6 months	Yes

Project Title Mindfulness to Improve Psychological Stress and Cardiac Health in Adult Survivors of Pediatric Leukemia and Lymphoma

Planned research population (eligibility criteria)

Survivors 1) who are ≥18 years of age; 2) have a history of leukemia or lymphoma; 3) were diagnosed prior to 24 years of age; 4) are at least 3 months post treatment completion; 4) are experiencing elevated psychological stress scores at screening entry (total score > 14, indicating moderate stress on perceived stress scale)61; 5) speak and read English or Spanish Exclusion criteria: Survivors 1) who engage in mindful stress-reduction practices >2x per week (e.g., tai chi, meditation); 2) are taking psychiatric medications or

Proposed specific aims

Aim 1: Examine the efficacy of a 30-day, mHealth-delivered, mindfulness program (mindfulness program) on symptoms of psychological stress in survivors of leukemia and lymphoma. Hypothesis 1. Survivors randomized to the mindfulness program will report significantly fewer symptoms of psychological stress at the post-intervention and 3-month follow-up compared to survivors randomized to an attention control arm.

Aim 2: Evaluate the impact of the mindfulness program on changes in blood serum biomarkers of cardiac health (systemic inflammation, oxidative stress, cardiovascular function) and digital biomarkers of ANS activation (electrodermal activity, skin conductance, pulse rate variability). Hypothesis 2. Survivors randomized to the mindfulness program will evidence improved blood serum biomarkers of cardiovascular health at the 30-day and 3-month follow-up and digital biomarkers of ANS activation at the 30-day follow-up.

Aim 3: Analyze the effect of the mindfulness program on global psychological burden (depression, anxiety, sleep disturbance, perceived cognitive functioning, pain, fatigue). Hypothesis 3. Survivors randomized to the mindfulness program will report lower levels of symptom burden at the 30-day and 3-month follow-up compared to survivors randomized to an attention control arm.

Exploratory Aims: (1) Explore the impact of social determinants of health (e.g., SES, neighborhood deprivation, race/ethnicity) on intervention engagement and response. (2): Explore associations between changes in psychological distress, psychological burden, and biomarkers of cardiovascular health from baseline to 30-day and 3-month post-intervention follow-up and moderating role of intervention engagement, coping efficacy, and dispositional mindfulness.

Will the project require non-CCSS funding to complete?

Yes

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?

NCI; Submission Feb 2025; if awarded funds potentially available fall 2025

Does this project require contact of CCSS study subjects for:

Additional self-reported information	Yes
Biological samples	Yes
Medical record data	Yes

If yes to any of the above, please briefly describe.

Participants will complete self-report PROs pre and post a 30 day mindfulness intervention, we will seek to collect blood serum via ExamOne

What CCSS Working Group(s) would likely be involved? (Select all that apply)

	Primary	Secondary
Second Malignancy		
Chronic Disease		✓

	Primary	Secondary
Psychology/Neuropsychology	✓	
Genetics		
Cancer Control		
Epidemiology/Biostatistics		

Outcomes or Correlative Factors

	Primary	Secondary	Correlative Factors
Late Mortality			
Second Malignancy			

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco		✓	
Alcohol		✓	
Physical Activity		✓	
Medical Screening			
Other			

If other, please specify

Psychosocial

	Primary	Secondary	Correlative Factors
Insurance			✓
Marriage			✓
Education			✓
Employment			✓
Other			

If other, please specify

psychological stress (primary outcome); patient reported outcomes (sleep, depression, pain, etc)

Medical Conditions

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech			
Hormonal Systems			
Heart and Vascular		✓	
Respiratory			
Digestive			
Surgical Procedures			
Brain and Nervous System			
Other			

If other, please specify

Medications

Describe medications

medications associated with cardiovascular or psychological functioning will be assessed

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18			
SF-36			
CCSS-NCQ			
PTS			
PTG			
Other			

If other, please specify

Other

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring			
Family History			

	Primary	Secondary	Correlative Factors
Chronic Conditions (CTCAE v3)		✓	
Health Status			

Demographic

	Primary	Secondary	Correlative Factors
Age			✓
Race			✓
Sex			✓
Other			

If other, please specify

Cancer Treatment

	Correlative Factors
Chemotherapy	
Radiation Therapy	
Surgery	

Anticipated Sources of Statistical Support

CCSS Statistical Center	No
Local Institutional Statistician	Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.

Will this project utilize CCSS biologic samples?

No

If yes, which of the following?

If other, please explain

Other General Comments

Agree

I agree to share this information with St. Jude

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