Name Tara Henderson

Contact Information

Institution University of Chicago

Address 4941 S. Kimbark Ave.
Chicago, Illinois, 60637
United States

Phone Number 7735737690

Alternate Phone Number 7737026808

Email Address thenderson@uchicago.edu

Project Requirements and Description

Requirements to submit AOI

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 The SPRINT Study (SMN Screening and Prevention INTervention): A Bundled Intervention Study

Planned research population (eligibility criteria)

Randomized control trial of adult CCSS participants exposed to radiotherapy for their primary cancer.

Proposed specific aims

We propose a 3-arm randomized Hybrid Type1 Effectiveness-Implementation trial to evaluate the effectiveness of an mHealth application alone and the combination of mHealth and remote patient navigation (guided by the Economic Behavioral Theory of Nudging) to increase the completion rates of recommended

screenings and preventive measures (breast cancer and colorectal cancer screenings, yearly dermatological exam, and HPV vaccination) among high-risk childhood cancer survivors and simultaneously assess the implementation strategies for future adaptation and scalability. This project will have three aims:

Aim 1 (Primary Aim): Examine the effectiveness of a digital mHealth application alone ('Patient Activation' or PA) and a digital mHealth application plus remote patient navigation (PA + PN) in increasing the completion rates of recommended breast cancer and colorectal cancer screenings, a yearly dermatological exam, and HPV vaccination within 12 months, in comparison to usual care (C), which involves only a survivorship care plan (SCP) and screening recommendations.

Aim 2: Evaluate the moderator effects of social determinants of health (SDOH), such as employment status, education attainment, access to care, and neighborhood environment (measured by Area Deprivation Index), which may strengthen or weaken the effectiveness of the proposed intervention.

Aim 3: Use the Consolidated Framework for Implementation Research (CFIR) to assess the implementation strategies and process, identify facilitators and barriers to uptake of the recommended screening and prevention measures, and conduct a cost-effectiveness analysis on the PA and PA + PN components to inform future adaptation and scalability.

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?

R01 Submission February 2024 (may be a bit later as PI has continuous submission)

Does this project require contact of CCSS study subjects for:

Additional self-reported information	Yes
Biological samples	No
Medical record data	Yes

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

Contact for intervention, baseline and follow-up surveys

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

Second Malignancy	Secondary
Chronic Disease	
Psychology/Neuropsychology	
Genetics	
Cancer Control	Primary
Epidemiology/Biostatistics	

Outcomes or Correlative Factors

Late Mortality	
Second Malignancy	

Health Behaviors

Tobacco	
Alcohol	
Physical Activity	Correlative Factors
Medical Screening	Primary
Other	

If other, please specify

Psychosocial

Insurance	Correlative Factors
Marriage	Correlative Factors
Education	Correlative Factors
Employment	Correlative Factors
Other	

If other, please specify

Medical Conditions

Hearing/Vision/Speech	
Hormonal Systems	
Heart and Vascular	
Respiratory	
Digestive	
Surgical Procedures	
Brain and Nervous System	
Other	

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

BSI-18	
SF-36	
CCSS-NCQ	
PTS	
PTG	
Other	

If other, please specify

Other

Pregnancy and Offspring	
Family History	
Chronic Conditions (CTCAE v3)	Correlative Factors
Health Status	

Demographic

Age	Correlative Factors
Race	Correlative Factors
Sex	Correlative Factors
Other	

If other, please specify

Cancer Treatment

Chemotherapy	Correlative Factors
Radiation Therapy	Correlative Factors
Surgery	

Anticipated Sources of Statistical Support

CCSS Statistical Center	Yes
Local Institutional Statistician	Yes

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

Chaya Moskowitz, Memorial Sloan Kettering Cancer Center

Will this project utilize CCSS biologic samples? No

If yes, which of the following?

If other, please explain

Other General Comments

We will be in contact with CCSS Statisticians to develop frequency tables, sample size and power calculations to finalize aims and move forward 3-page proposal.

Agree I agree to share this information with St. Jude

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