

Section: Contact Information

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Section: Project Requirements and Description

Group: Requirements to submit AOI

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 : **Assessing the Effect of Virtual Navigation Interventions to Improve Health Insurance Literacy and Decrease Financial Burden: A CCSS Randomized Trial**

Planned research population (eligibility criteria) :

LTFU participants from the original and expansion cohort.

Proposed specific aims :

Childhood cancer survivors develop acute and chronic health problems at over 3-times the rate of their siblings. These survivors often face continued health care challenges and require ongoing care to monitor and treat long-term effects of their cancer and treatment. Given their ongoing health care needs, obtaining and utilizing health insurance coverage is vital to ensure adherence to needed survivorship care.

Unfortunately, childhood cancer survivors have reported higher rates of underinsurance, unmet health care needs, and burdensome costs. Many survivors may find themselves underinsured, either by having unmet health care needs due to cost or having high out-of-pocket (OOP) health care costs. Insured survivors may still lack access to desired specialist providers, tests, and screenings due to cost or other insurance restrictions. High-deductible health plans are being increasingly offered by employers and to enrollees in health insurance exchanges. These plans pose a risk of unmet health care need and financial burden for enrollees with chronic conditions such as childhood cancer survivors.

Health care reform under the Patient Protection and Affordable Care Act (ACA) offers considerable opportunities for childhood cancer survivors to obtain coverage and improve access to needed care. In the general population, many people have low understanding of available insurance benefits and resources and have limited health insurance literacy (i.e. perceived knowledge, ability, and confidence to make informed decisions about choosing and using health insurance). Lack of understanding about

which services are covered or require out-of-pocket costs may lead to avoidance of services that are in fact exempt from cost-sharing. The research team's previous research demonstrated that 1) many childhood cancer survivors lack of awareness about health care reform and policies and, compared to siblings, 2) were at risk for being underinsured, and experienced significant financial burden. Thus, even with coverage protections from the ACA, barriers to obtaining and utilizing health insurance coverage and accessing needed health care remain for childhood survivors. For this vulnerable population, barriers to follow-up care (e.g. access and adherence) include being underinsured, low health insurance literacy, and cost concerns related to follow-up care. Interventions are needed to support childhood cancer survivors to address these barriers. We developed a 4-session video-based, synchronous virtual health insurance navigation intervention (Health Insurance Navigation Tools; HINT) for pediatric, adolescent and young adult survivors who are in the Childhood Cancer Survivor Study (CCSS) cohort. Results of a pilot randomized trial support the feasibility, acceptability, and preliminary efficacy of HINT with a live, synchronous navigator. The synchronous and remotely delivered intervention provides opportunities for personalized and supportive intervention, an asynchronous version of this intervention may be more cost-effective and scalable. Thus, we propose to conduct a 3-arm randomized clinical trial to assess two virtual health insurance navigation interventions: HINT-S (live, synchronous navigator) and HINT-A (recorded, asynchronous navigator compared to enhanced usual care (health insurance booklet) with participants via the CCSS patient portal. The sample size is TBD.

The aims are as follows:

Aim 1: To determine the effectiveness of two virtually-delivered patient navigation interventions on improving childhood survivors' health care access and utilization. Primary outcome: health insurance literacy (understanding of health insurance terms and confidence). Secondary outcomes: financial burden (worry about medical costs, unmet healthcare needs related to medical costs, and financial consequences of medical expenses) and emotional distress at 6-month follow-up.

H1a. We hypothesize that survivors randomized to HINT-S will have significantly higher health insurance literacy and lower financial burden and emotional distress compared to survivors randomized to enhanced usual care.

H1b. We hypothesize that survivors randomized to HINT-A will have significantly higher health insurance literacy and lower financial burden and emotional distress compared to survivors randomized to enhanced usual care. Secondary: familiarity with healthcare reform policies.

H1c exploratory. To explore the relative differences in effect size improvements in health insurance literacy and decreases in financial burden and emotional distress between HINT-A and HINT-S.

Aim 2. To explore social determinants and cancer history factors associated with intervention effects: sociodemographic (health insurance type, sex, age, gender identity, zip code (neighborhood deprivation index), state Medicaid expansion status); financial (OOPS costs, problems due to medical expenses); and cancer history (cancer diagnosis, age at diagnosis) in Aim 1.

Aim 3. To apply mixed methods (exit interviews, treatment delivery documentation and surveys) to explore implementation of the two virtual interventions (reach (navigator recruitment video), relevance, intervention utilization, scalability (cost) and sustainability).

Aim 4: To explore intervention effects at 12-month follow-up on healthcare cost (out-of-pocket costs) and healthcare utilization (e.g., primary care visit in the past year, recommended screening).

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? :
7/31/21 submission to: RFA-CA-20-027

Group: Does this project require contact of CCSS study subjects for:

Additional self-reported information : **Yes**

Biological samples : **No**

Medical record data : **No**

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

As in our American Cancer Society funded study for this project, we would like to use CCSS data on sociodemographic and medical history information.

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

Second Malignancy :

Chronic Disease :

Psychology / Neuropsychology : **Secondary**

Genetics :

Cancer Control : **Primary**

Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy : **Correlative Factors**

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol :

Physical activity :

Medical screening : **Secondary**

Other :

If other, please specify :

Group: Psychosocial

Insurance : **Primary**

Marriage : **Correlative Factors**

Education : **Correlative Factors**

Employment : **Correlative Factors**

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :

Hormonal systems :

Heart and vascular :

Respiratory :

Digestive :
Surgical procedures :
Brain and nervous system :
Other :
If other, please specify :

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

BSI-18 : **Correlative Factors**

SF-36 : **Correlative Factors**

CCSS-NCQ :

PTS :

PTG : **Correlative Factors**

Other :

If other, please specify :

Group: Other

Pregnancy and offspring :

Family history :

Chronic conditions (CTCAE v3) : **Correlative Factors**

Health status : **Correlative Factors**

Group: Demographic

Age : **Correlative Factors**

Race : **Correlative Factors**

Sex : **Correlative Factors**

Other :

If other, please specify :

Group: Cancer treatment

Chemotherapy : **Correlative Factors**

Radiation therapy : **Correlative Factors**

Surgery : **Correlative Factors**

Section: Anticipated Sources of Statistical Support

CCSS Statistical Center : **Yes**

Local institutional statistician :

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

Wendy Leisenring has agreed to serve as the statistician for this study.

Will this project utilize CCSS biologic samples? : **No**

If yes, which of the following? :

If other, please explain :

Section: Other General Comments

Other General Comments :

I agree to share this information with St. Jude : **Yes**