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Contact Information

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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 Evaluating the Need for Dyadic Intervention Adaptation in the Health Insurance Navigation Tools Intervention (HINT)

Planned research population (eligibility criteria)

CCSS participants who took part in the ancillary study (HINT); who are 1) 18 years or older at time of enrollment, 2) able to give informed consent, and 3) have access to a smartphone, iPad, computer, or tablet with internet access. An additional criteria is 4) having access to the patient portal. Participants from the HINT pilot trial will not be eligible.

Proposed specific aims

Aim 1: Examine sociodemographic and clinical factors that are associated with endorsement of caregiver involvement in HINT. We will retrospectively analyze 12-month follow-up surveys of current HINT participants to evaluate their responses to questions about caregiver involvement in HINT.
H1: Survivors who are younger, married/partnered, and who are not their own insurance policy holder, will be more likely than older, single, policy holders to endorse caregiver involvement.
H2: Survivors who report neurocognitive impairment and those with severe chronic diseases will be more likely than survivors without these conditions to endorse caregiver involvement.
H3: Participants who engaged in HINT-S and HINT-A will be more likely to desire caregiver involvement than those randomized to usual care.

Aim 2: Explore survivor preferences for caregiver involvement in future dyadic implementation of the HINT intervention. Through purposive sampling, we will interview participants from each arm of the HINT intervention to explore:
RQ 1. Among caregivers who wanted caregiver involvement, what educational content, modes of delivery (i.e., HINT-S, HINT-A, usual care), and dyadic features are preferred by survivors for engaging in HINT with a caregiver?
RQ 2. Among caregivers who did not want caregiver involvement, what do they perceive as the barriers and limitations to caregiver involvement and how might those be overcome?

Aim 3: Contextualize the survey findings through integration of the interview feedback about the content, modes of delivery, and dyadic features required for caregiver involvement and generate potential solutions to barriers and limitations of a dyadic rollout of HINT.

Will the project require non-CCSS funding to complete?

No

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

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.

A subset of HINT participants will be contacted for qualitative interviews for Aim 2.

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

	Primary	Secondary
Second Malignancy		
Chronic Disease		
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

Insurance policy holder status (yes/no) - collected in HINT

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

N/A

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			
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	Yes
Local Institutional Statistician	Yes

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

Dr. Warner will conduct the analyses with support from Heydon Kaddas, MPH who has performed earlier HINT related analyses with Dr. Anne Kirchhoff.

Will this project utilize CCSS biologic samples? No

If yes, which of the following?

If other, please explain

Other General Comments

This explanatory sequential mixed methods study will occur cross-sectionally, with a secondary data analysis of HINT 12 month survey responses and iterative semi-structured interviews with HINT participants. The only additional CCSS data required are: CCSS NCQ and CTCAE. All other required data are collected as part of the HINT ancillary study.

Agree I agree to share this information with St. Jude

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