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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 Survivors engaged in Time-Restricted Eating After Therapy (STREAT) Study

Planned research population (eligibility criteria)

Eligibility survivors will include individuals with:
1) Prior treatment with abdominal radiation or TBI during childhood;
2) Attained age of 18 years or older
3) BMI≥25 kg/m2 (based on per self-reported height, weight);
4) Not currently fasting >10 consecutive hours per night on a consistent basis;
5) Not pregnant;
6) No history of an eating disorder
Participants also must be English - or Spanish-speaking and have internet access (can be via smartphone or computer). If neither device is available, the study can loan participants a Wi-Fi enabled device.

Proposed specific aims

Aim 1. Determine whether time-restricted eating (TRE) is superior to usual care in reducing weight, waist circumference and % body fat among at-risk overweight/obese survivors previously exposed to abdominal or total body irradiation.

Aim 2. Investigate whether TRE compared to usual care improves circulating biomarkers of glucose control, metabolic inflammation, and oxidative stress. In the same cohort, we will measure biomarkers of glucose control (glucose, insulin, HOMA-IR), adipokines (leptin, adiponectin, PAI-1) and inflammation (hs-CRP, IL-6, TNF-α) among survivors at baseline, 6-months, and 12-months.

Aim 3. Assess moderating and mediating factors (from baseline and 12-month surveys) that are associated with (a) TRE adherence and (b) weight loss. At 6- and 12- months post-intervention, we will measure biopsychosocial factors associated with adherence (defined as 5/7 days per week that the participant did not eat for $\geq$14 hours) and weight change.

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 5, 2023

Does this project require contact of CCSS study subjects for:

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

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

We will enroll participants in a remotely-delivered 12 month intervention

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

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

Outcomes or Correlative Factors

Late Mortality	
Second Malignancy	

Health Behaviors

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

If other, please specify

Weight

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	Secondary
Heart and Vascular	Secondary
Respiratory	
Digestive	
Surgical Procedures	
Brain and Nervous System	
Other	

If other, please specify

Changes in glucose control, blood pressure, inflammation post-intervention

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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)	
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	Correlative Factors

Anticipated Sources of Statistical Support

CCSS Statistical Center	
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

Participants will consent to a 12-month intervention; outcomes will be assessed with a Withings Wifi-enabled Body+ scale and blood draw (either via remote phelebotomy service or dried blood spots).
Drs. Kevin Oeffinger and Eric Chow are co-investigators on this projects and aims have been discussed with them; additional co-investigators to be determined.
I have also communicated study intent via email with Drs. Paul Nathan and Claire Snyder.

Agree I agree to share this information with St. Jude

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