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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 A Feasibility Study of the Remote Exercise Intervention on Neurocognitive Function and Gut Microbiome Among Adult Childhood Brain Tumor Survivors

Planned research population (eligibility criteria)

This study will recruit 30 adult childhood brain tumor survivors from the CCSS cohort, via collaboration with the CCSS Psychology/Neuropsychology Committee (primary, Drs. Tara Brinkman and Kevin Krull) and Cancer Control Committee (Drs. Paul Nathan & Claire Snyder). Inclusion criteria: 1) Adult childhood brain tumor survivors (age ≥ 18 years) from the CCSS cohort; 2) reported cognitive impairment as screened by the CCSS Neurocognitive Questionnaire; 3) currently engaging in < 150 minutes of physical activity per week assessed with the Godin Leisure-Time Physical Activity Questionnaire; 4) able to provide informed consent;

and 5) willing to use smartphone-based applications (app). Exclusion criteria include those with a history of 1) Gastrointestinal disorders (e.g., IBD) or recurrent disease requiring re-irradiation of the brain; 2) self-reported moderate to severe traumatic brain injury; 3) developmental disorders (e.g., Autism) or major psychotic illness (e.g., schizophrenia) based on self-report to avoid the confounding impact of behavioral and cognitive difficulties related to these disorders. Individuals with major depression and anxiety disorders will not be excluded unless their condition interferes with their ability to participate.

Proposed specific aims

Aim 1: Determine the feasibility and acceptability of a 12-week remote exercise intervention among adult childhood brain tumor survivors. Feasibility will be determined by rates of recruitment, retention, questionnaires and biological sample completion. Acceptability of the intervention will include satisfaction, adherence, perceived usefulness, and attrition.

Aim 2: Estimate the impact of the remote exercise intervention on neurocognitive function (primary) and functional outcomes (e.g., sleep, ADL, IADL and QOL) (secondary) as compared to attention control.
Aim 3: Examine the change of the gut microbiome in response to the intervention compared to attention control.

Exploratory Aim: Explore the potential mediating role of the gut microbiome and functional outcomes (e.g., sleep) in the relationship between the exercise level and neurocognitive outcomes.

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?

We will pursue a potential R21 submission in Feb 2023. Dr. Maria (MD Anderson) and I will pursue other internal and external grant, such as ACS and Rally Foundation for this proposal.

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.

Remote assessment of neurocognitive function, stool samples for the gut microbiome

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

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

Outcomes or Correlative Factors

Late Mortality	
Second Malignancy	

Health Behaviors

Tobacco	
Alcohol	
Physical Activity	Primary
Medical Screening	
Other	Primary

If other, please specify

Sleep

Psychosocial

Insurance	
Marriage	
Education	Correlative Factors
Employment	
Other	

If other, please specify

Medical Conditions

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

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

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

If other, please specify

Other

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

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	Yes
Local Institutional Statistician	No

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

Will this project utilize CCSS biologic samples? Yes

If yes, which of the following? Other requiring collection of samples

If other, please explain

Stool and blood spot

Other General Comments

Agree I agree to share this information with St. Jude

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