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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

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Project Title: EQUAL: Exercise and QUality diet After Leukemia
Planned research population (eligibility criteria): We propose the dissemination of a diet and physical activity intervention to 200 obese ALL survivors, stratified by gender and history of cranial radiotherapy (CRT). Subjects will be randomized to the standard intervention (proven effective in a landmark study) or the intervention supplemented with survivor-specific diet and physical activity materials.
Proposed specific aims: Specific Aim 1: Determine the efficacy of survivorship-specific supplemental materials, when included with a diet and physical activity intervention, on weight loss among a nationwide sample of obese leukemia survivors. Hypothesis 1: Obese leukemia survivors in the supplemental materials group will lose, on average, 2.75kg more than those who receive the standard diet and physical activity invervention. Specific Aim 2: Calculate cost effectiveness of a remotely-delivered diet and physical activity intervention if supplemented with survivorship-specific materials. Hypothesis 2: The addition of survivorship-specific materials will be cost effective. Secondary Aims: 1. Examine the effect of the diet and activity intervention on neurocognitive function. 2. Measure changes in gut microbiota and test their relevance to metabolic improvement in the setting of weight loss. 3. Identify barriers and facilitators to achieving weight loss in this population.
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?: Application for NIH R01-level funding is planned for October, 2013.

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.: Survivors will require questionnaires, anthropometrics (BMI, waist circumference) and metabolic testing (fasting blood work) at baseline, 3 months, 6 months, 12 months, and 24 months. A subgroup of survivors will donate a stool sample at these time points. All participants will report diet and physical activity in an ongoing manner.

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

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

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as outcome (primary or secondary) or correlative factors. (Check all that apply)

Late mortality:
Second Malignancy:

Health Behaviors

Tobacco:
Alcohol:
Physical activity: Secondary
Medical screening:
Other:
If other, please specify:

Psychosocial

Insurance:
Marriage:
Education:
Employment:
Other:
If other, please specify:

Medical conditions

Hearing/Vision/Speech:
Hormonal systems: Primary
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system: Secondary
Other:
If other, please specify: Body mass index and insulin resistance will be measured. Neurocognitive function will be tested.

Medications

Describe medications:

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

Chronic conditions (CTCAE v3):
Health status:

Demographic

Age: Correlative Factors
Race: Correlative Factors
Sex: Correlative Factors
Others:
If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy: Correlative Factors
Surgery:

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.:
Dr. Chaya Moskowitz, PhD in the Department of Epidemiology and Biostatistics at MSKCC.
Will this project utilize CCSS biologic samples?: No

If yes, which of the following?

Buccal cell DNA:
Peripheral blood:
Lymphoblastoid cell lines:
Second malignancy pathology samples:
Other requiring collection of samples:
If other, please explain:

Other general comments: