COG-ALTE2031: StepByStep: A Randomized Trial of a Mobile Health and Social Media Physical Activity Intervention among Adolescent and Young Adult Childhood Cancer Survivors

FAST FACTS
Eligibility Reviewed and Verified By
_____ MD/DO/RN/LPN/CRA Date _____
_____ MD/DO/RN/LPN/CRA Date _____
Consent Version Dated_____

PATIENT ELIGIBILITY:
Important note: The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient's medical research record which will serve as the source document for verification at the time of audit.

___1. Timing
All eligibility criteria (see Section 3.2) must be confirmed before study enrollment via CTSU OPEN. The Baseline Evaluation **must occur within 7 days before enrollment or up to 6 calendar months after enrollment.** Participating Site staff are asked to submit an Evaluation Plan at least 2 weeks prior to each of the 3 evaluation time points to establish the location of all evaluation components. (See Section 4.1.2.) The lead time allows the Coordinating Center to ship required study materials to the Participating Site if the decision is to proceed with in-person evaluation during a clinic visit. Alternatively, the Coordinating Center will ship the study materials directly to the participant if the decision is to proceed with a remote evaluation.

___2. Randomization
Randomization will take place after a patient is enrolled via CTSU OPEN and the Baseline Study Evaluation is completed. Randomization will be conducted by the Data Coordinating Center. The group will be randomly assigned based on the statistical design of the trial. Participating Site staff will be blinded to randomization. Results of randomization will be communicated directly to participants by the Coordinating Center independent of Participating Site staff. Participants will be instructed not to discuss their randomization with Participating Site staff or on any other online AYA cancer survivor social media forums. Participating Site staff are requested not to ask participants about their randomization.

___3. Age
Patient must be ≥15 years and < 21 years at the time of enrollment.

___4. Diagnosis
First diagnosis of malignant neoplasm (ICD-O behavior code of "3") in first and continuous remission at the time of enrollment.

___5. Prior Therapy Modalities
Curative cancer treatment must have included chemotherapy and/or radiation.
Note: *COG therapeutic trial participation is not required.*

___6. Timing
All cancer treatment must have been completed within 3-36 calendar months prior to enrollment.

___7. Life Expectancy
Patients must have a life expectancy of > 1 year.

___8. Physical Activity
Self-report of < 420 minutes of moderate-to-vigorous physical activity per week as assessed via the study-specific Physical Activity Worksheet.
Note: *See the COG Study Web Page for the Godin-Shephard Leisure-Time Physical Activity Questionnaire or link to online calculator.*

___9. Performance Status
- Ambulatory and no known medical contraindications to increasing physical activity.
- No known significant physical or cognitive impairment that would prevent use of the electronic devices used for the protocol intervention (e.g. Fitbit, smartphone, tablet, or computer).

___10. Language

___11. Able to read and write English.

___12. Regulatory Requirements
- All patients and/or their parents or legal guardians must sign a written informed consent.

Note: *Informed consent may be obtained electronically/online if allowed by local site policy and IRB/REB of record*.

Assent of children age 15 and older is a necessary condition for proceeding with the research.

EXCLUSION CRITERIA:

___1. Pregnancy
Post-menarchal female patients who are pregnant or planning to become pregnant in the next year are excluded.
Note: *Pregnancy status can be established by clinical history with patient. Post-menarchal female patients are eligible as long as they agree to use an effective contraceptive method (including abstinence) during study participation*.

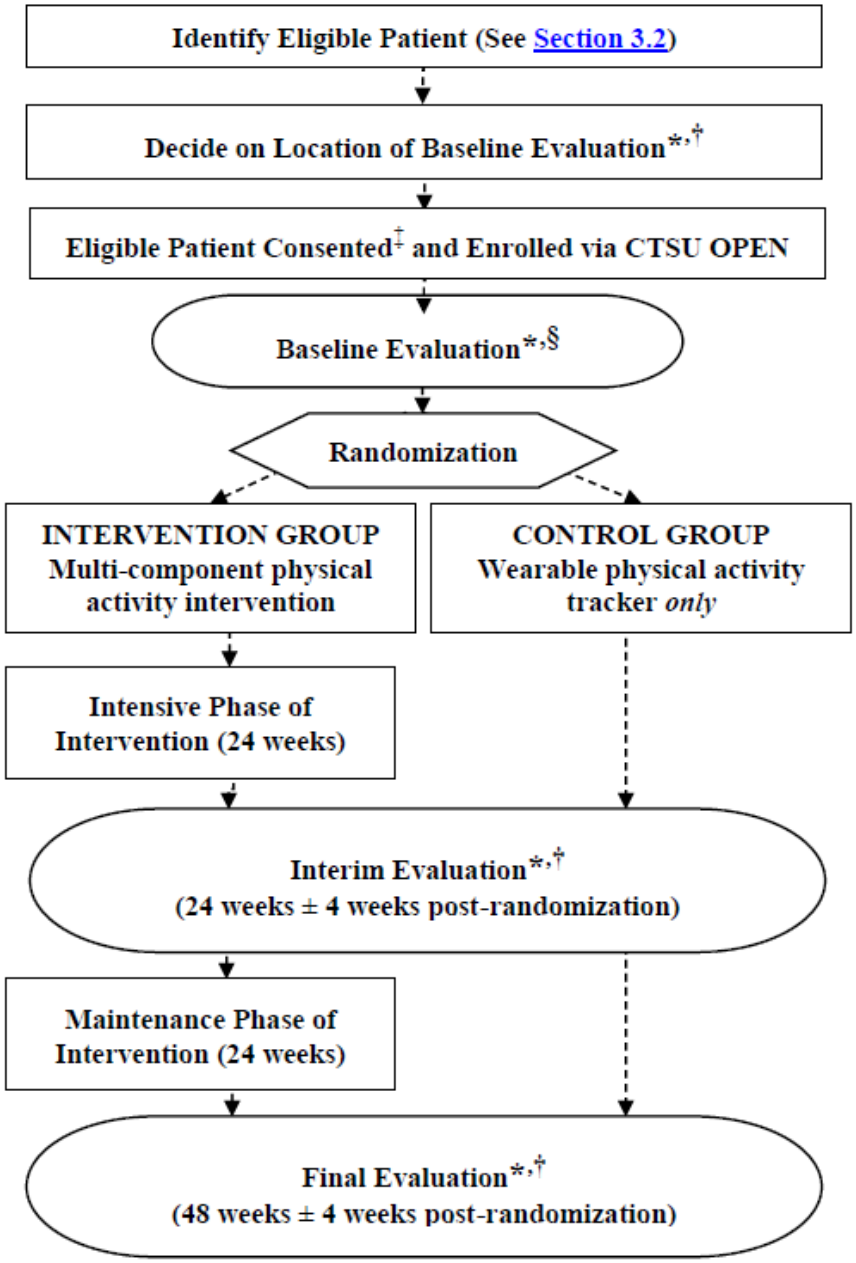
___2. Stem Cell Transplant
Patients with previous Hematopoietic Stem Cell Transplant (HSCT) are excluded.

TOXICITIES AND DOSAGE MODIFICATIONS:
n/a

SPECIMEN REQUIREMENTS:
Dried blood spot sampling required at baseline evaluation and at final evaluation.

TREATMENT PLAN:

Experimental Design Schema



*The Coordinating Center is responsible for Patient Questionnaires and Research Grade Accelerometers. Other evaluation components (Anthropometrics, 2-Minute Step Test, Dried Blood Spot Sampling) may be administered *either* **1)** in person by Participating Site staff during clinic visit, *or* **2)** remotely by phone/video by Coordinating Center. (Section 4.0).

† Participating Site staff submit an Evaluation Plan to the Coordinating Center in advance of each of the 3 time points (Section 4.1.2).

‡ Participating Sites may consider online/electronic consent if permitted by site policy and IRB/REB of record.

§ Baseline Evaluation must occur within **7 days before or up to 6 calendar months after OPEN enrollment**.