

COG ALTE 2321

Walking Juntos: Developing and Testing a Culturally-Tailored 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 _____

TIMING:

All eligibility criteria (see [Section 3.2](#)) must be confirmed before study enrollment via CTSU OPEN.

For participants in **Stage 1 and Stage 2**, the **Participant Contact Form** should be completed at the time of consent and checked for completeness and accuracy immediately upon receipt. **Sites are asked to submit the Participant Contact Form to the Coordinating Center as soon as possible no later than 3 business days after obtaining consent.** Since this study utilizes a remote intervention and (in most cases) evaluation, study procedures will not proceed until the Participant Contact Form is received by the Coordinating Center (See [Section 4.1.4](#).)

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

- ___ 2. Diagnosis
First diagnosis of malignant neoplasm (ICD-O behavior code of “3”) in first and continuous remission at the time of enrollment.

- ___ 3. Prior Cancer Therapy Modalities
Curative cancer treatment must have included chemotherapy (including cellular therapy) and/or radiation (including radioactive iodine).

Note: Certain stem cell transplant procedures are excluded. See Section 3.2.9.

- ___ 4. Timing
Completed all chemotherapy and/or radiation therapy in the last 3–36 months. This includes completion of all oral (e.g., tyrosine kinase inhibitors) and/or maintenance chemotherapy.

- ___ 5. Physical Activity
Self-report of < 420 minutes of moderate-to-vigorous physical activity per week as assessed and documented via the study-specific Physical Activity Worksheet.

Note: See the Case Report Forms packet on the COG Study Web Page for the study specific Physical Activity Worksheet.

___ 6. 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).

___ 7. Language

Able to read and write Spanish or English.

___ 8. Ethnicity

Self-identify as Hispanic, Latino/Latina/Latinx

The CIRB has determined that assent of children age ___ and older is a necessary condition for proceeding with the research.

Note: This trial has a protocol supplied wallet card that is required to be provided to the patient. See Appendix [1](#).

EXCLUSION CRITERIA

___ 1. Stem Cell Transplant

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

Note: *Patients with previous autologous HSCT, chimeric antigen receptor T-cell (CAR T-cell) therapy, and other cellular cancer therapies can participate as long as all other eligibility criteria are satisfied.*

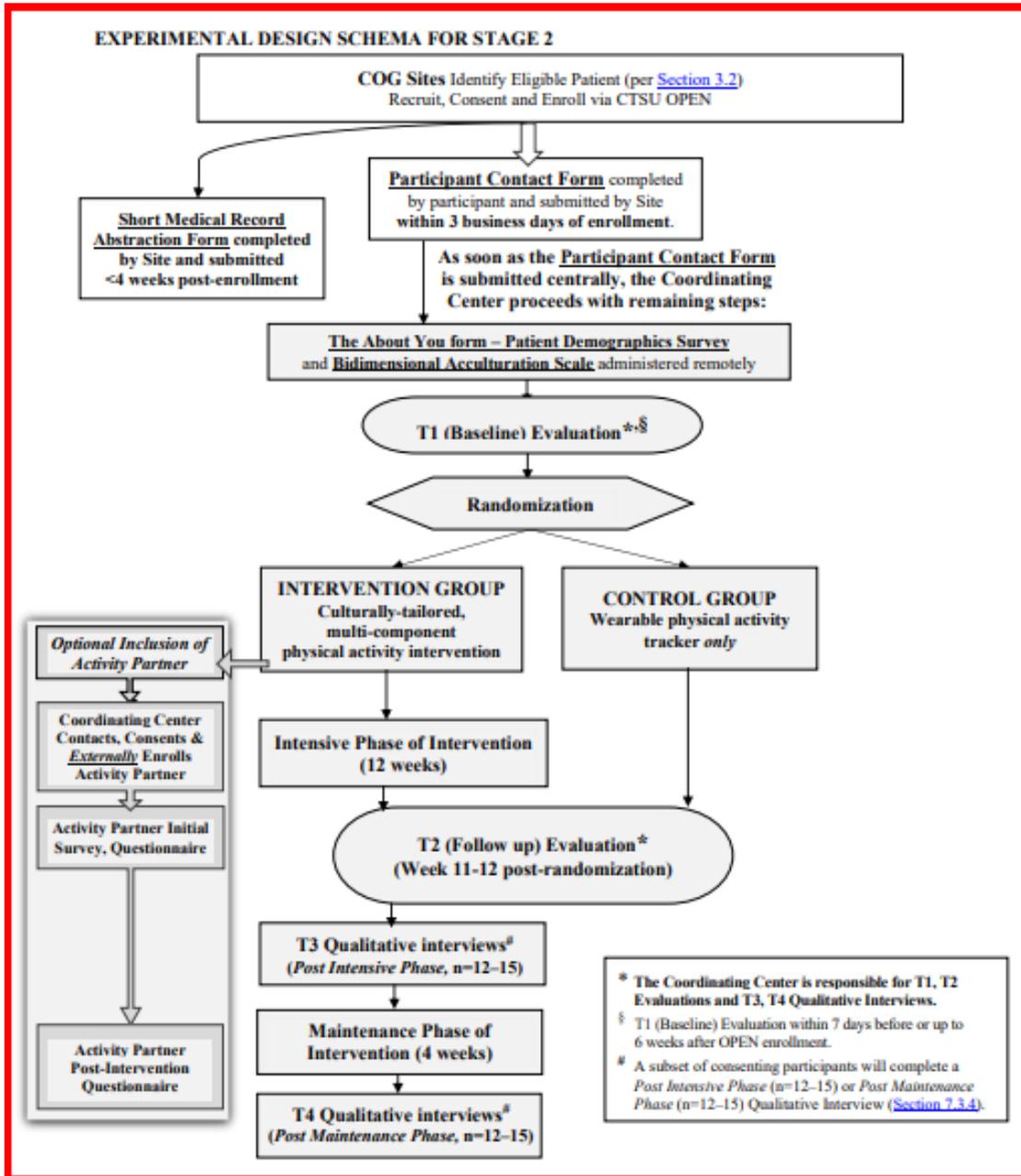
___ 2. Pregnancy

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.*

___ 3. Participation in Previous Study Stage

Participants who were enrolled in ALTE2031 (Step by Step) cannot enroll in ALTE2321. Participants who were enrolled in ALTE2321 Stage 1 (cultural tailoring) cannot enroll to participate in Stage 2 (RCT).



SPECIMEN REQUIREMENTS: None