

# **HABITS Protocol**

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**Protocol title:** Making Healthy Habits Stick: Extended Contact Interventions to Promote Long Term Physical Activity in African American Cancer Survivors

**Protocol acronym:** HABITS

**Protocol acronym definition:** Healthy Activity for Black Women cancer survivors Instilled Through Time and Support

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## **OVERVIEW AND AIMS**

Disparities in cancer survivorship are persistent and pervasive. Lack of regular physical activity (PA) intensifies health disparities suffered by African-American (AA) cancer survivors, e.g., their greater risk of obesity, medical comorbidities, second primary cancers, poor quality of life and compromised physical functioning. Yet, insufficient PA is more prevalent among AA cancer survivors and 76% do not meet PA guidelines. Efforts to increase PA longer term in cancer survivors have been modestly successful. The extant literature and our own preliminary data in cancer survivors show that PA adoption is often followed by an attenuation of PA over time. These findings have led to a recent shift in thinking, specifically that the social cognitive theory constructs (e.g., self-efficacy), important for PA adoption play less of a role in PA maintenance. Additional theoretical constructs (i.e., habit and identity) may be the key constructs necessary for long term behavior change. Conceivably, lack of success in promoting PA maintenance may also be due to few studies examining how well health behavior change interventions work in the broader societal context. For example, for AAs, discrimination is a potent social determinant of health. Discrimination is prevalent (reported by 82% of AA breast cancer survivors), disproportionate (AAs are more likely to report discrimination-related stress compared to other racial and ethnic groups), and stressful (stress, in general, impedes PA). Despite this evidence, the effect of discrimination on PA intervention outcomes is unknown. Thus, to advance PA maintenance science with a focus on a vulnerable population, investigators propose testing two potentially translatable PA maintenance promotion interventions (Short Message Service [SMS] and peer coach) in 260 physically inactive AA women cancer survivors.

### *Aim 1:*

Determine effects of both PA maintenance interventions (SMS, peer coach) compared to usual care (written materials) using a 2 x 2 randomized factorial experimental design (that allows simultaneous evaluation of both interventions). Individual effects of each intervention will be evaluated estimating the main effects; the interaction will estimate if the effect of either intervention differs in the presence of the other. Our primary outcome is weekly minutes of accelerometer moderate-to-vigorous PA assessed at 15 months (12 months after randomization; primary time point, to assess long term maintenance of PA). **Hypothesis 1:** Compared with usual care, both interventions will result in significantly greater PA at 15 months with intervention effects being larger in the presence of the other intervention.

### *Aim 2:*

Identify theory-based mediators of intervention effects on PA at 15 months. Using a causal inference approach, we will test mediators of PA maintenance promotion interventions compared to usual care on accelerometer moderate-to-vigorous PA at month 15. We will also explore mediators of lapses/relapses. **Hypothesis 2:** M-PAC constructs (i.e., identity, habit) will mediate intervention effects on PA at month 15 while M-PAC constructs focused on behavioral regulation (i.e., planning, self-monitoring) will mediate lapses and relapses.

### *Aim 3:*

Determine whether the level of discrimination experienced by AA women cancer survivors moderates the relationship between the PA maintenance interventions and PA at month 15. **Hypothesis 3:** Higher levels of discrimination will attenuate the effectiveness of the SMS intervention but not the peer coach intervention.

## **Research Procedures**

### *Overview:*

All study appointments will be conducted via telephone or video platform. Participants will be in the study for up to 17 months. The study has several segments with assessments at baseline (M0), 3 months (M3), 9 months (M9), and month 15 (M15).

- Adoption segment = complete 3-month intervention focused on PA adoption with assessments pre (M0) and post-adoption intervention (M3)
- Maintenance intervention segment = randomization, complete maintenance study condition, and complete a mini-survey check-in at M6 and full assessment M9.
- No intervention segment = no active intervention; mini-survey check-in at M12 and full assessment M15

### *Adoption (3-month) intervention:*

This social cognitive theory based intervention includes:

- Bi-weekly discussion groups via video platform - These discussion groups will be led by a trained health educator. Adapted BEAT Cancer (or Find your BEAT) program materials will be used.
- Individual exercise counseling sessions (weekly for weeks 1 – 6; bi-weekly for weeks 7 – 12) – These sessions will be done by an exercise physiologist using video conference and facilitated by a study-provided fitness bracelet. The physiologist will assist the participant in a gradual exercise progression with the goal of 150 weekly minutes of moderate intensity PA. Final counseling session includes a transition to the maintenance intervention segment.

### *Randomization:*

Concealed until participant completes the M3 assessment. Revealed in the order in which participants complete M3 assessment. Implemented by trained staff using written protocol

### *Maintenance (6-month) study group allocations:*

- Usual care: Participants will receive written materials dealing with PA lapses/relapses but no other intervention contact.

- SMS (text messaging): In addition to written materials on dealing with PA lapses/relapses, this group will also receive personalized, adaptive text messages that encourage ongoing PA maintenance. Automatic messages will be sent 9 times during the intervention, tapering from every other week in the early weeks to every 4 weeks by the end of the 6-month maintenance intervention. Participants can also request on demand text messaging as needed.
- Peer coach: In addition to written materials on dealing with PA lapses/relapses, this group will also receive telephone or videoconference peer coach sessions that assist with overcoming exercise barriers. Scheduled peer coach sessions occur 9 times during the intervention, tapering from every other week in the early weeks to every 4 weeks by the end of the 6-month maintenance intervention. Participants can also request additional peer coach sessions if needed.
- SMS and peer coach intervention: In addition to written materials on dealing with PA lapses/relapses, this group will receive both the SMS and the peer coach intervention.

#### *Mini-survey check-ins (M6 and M12):*

The check-ins will include a brief telephone interview asking about PA lapses/relapses, behavior theory constructs, and adverse events.

#### *Assessments (M0, M3, M9, and M15):*

The regular study assessments will include:

- Electronic survey (demographics, medical history, fatigue/energy level, exercise behavior and related constructs, quality of life, social support, race-related stressors)
- Accelerometer (waist-worn for 7 days)

#### *Adverse events:*

Adverse events in this study will be identified spontaneously or non-spontaneously. A description of each method of reporting follows.

- Any staff member or investigator can spontaneously identify an adverse event. The most likely way in which an adverse event is spontaneously identified would be when the participant reports an event to the study staff during contact time. Spontaneously identified adverse events may also take place during one of the testing visits.
- Non-spontaneous adverse events will be obtained by research staff using a structured interview at each assessment time-point.

Adverse events will be regularly reviewed by the study PIs, reported to the IRB of record according the IRB policies and procedures, and provided to the DSMB for oversight. The PIs will remain blinded to the study group allocation of the participants.