

Recruiting participants to a randomized controlled trial of a diet and physical activity intervention among Latina breast cancer survivors

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BACKGROUND

- Cancer survivors are recommended to eat a diet high in fruits and vegetables (F/V) (≥5 servings/day) and low in energy dense foods, and to engage in regular moderate-to-vigorous physical activity (MVPA) (150 minutes/week).
- Most Latina breast cancer (BC) survivors do not meet diet and PA recommendations and many lack the knowledge/skills needed to sustain diet and PA changes.

METHODS

- The *Mi Vida Saludable* (My Healthy Life) study is a randomized, controlled, 2x2 factorial trial testing the effects of a behavioral, in-person and electronic health (eHealth) communication program on changing diet and PA behaviors among Latina BC survivors (R01CA186080, PI: H Greenlee).
- The primary aims of the trial are to test the effects of the intervention on changing daily intake of F/V and MVPA from baseline to 12 months.
- Potential participants were identified via several recruitment methods: Columbia University Breast Oncology Clinic, Columbia University Medical Center database, community outreach, partnerships with local medical institutions, and breast cancer awareness events.

| | | In-person diet & physical activity classes | |
|------------------------------------|-----|--|--|
| | | Yes | No |
| Motivational eHealth communication | Yes | Arm A: In-person classes x 4 weeks + eHealth communication x 12 months | Arm B: eHealth communication x 12 months |
| | No | Arm C: In-person classes x 4 weeks | Arm D: Control group |

Figure 1. Randomization schema. Participants are randomized to four arms (target enrollment n=200). All participants receive a Fitbit, 30-minute health coaching session, and printed materials.

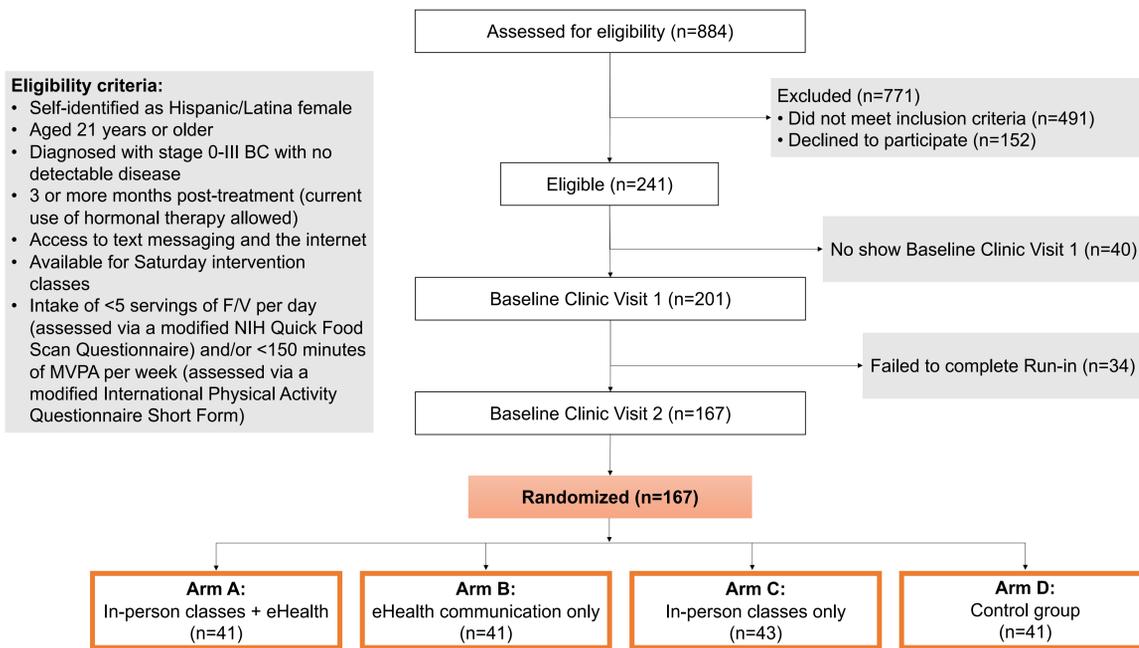


Figure 2. CONSORT (Consolidated Standards of Reporting Trials) Flow Diagram.

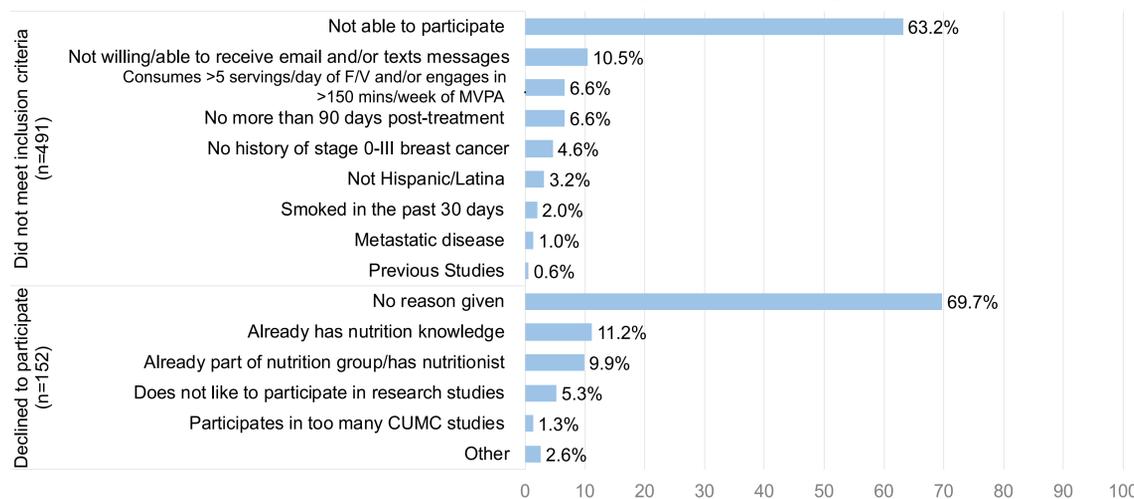


Figure 3. Reasons for exclusion from study (n=771).

RESULTS (n=167)

56.3

Average age
Range (34-81)

5.5

Years since diagnosis
Range (0-20)

53.3%

In food assistance programs

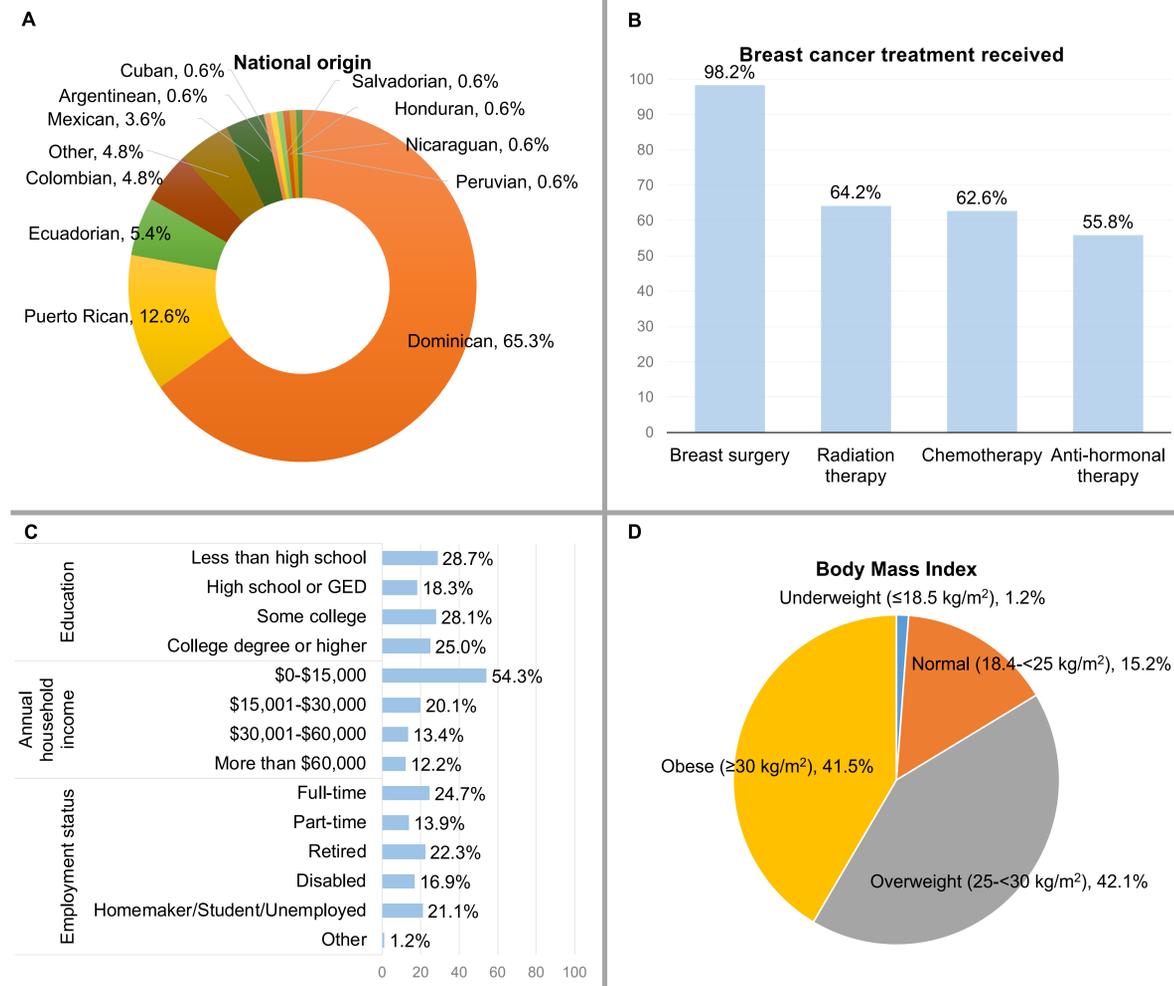


Figure 4. Self-reported data and measured characteristics (n=167). Panel A: Nationalities identified, Panel B: Therapies received, Panel C: Socioeconomic status measures, Panel D: Body mass index weight status from measured anthropometrics.

SUMMARY

- Participants were enrolled between July 2016 and March 2019.
- Of 884 women screened, 27% were eligible.
 - Primary reasons for ineligibility were not being able to participate due to work/life responsibilities (26%) or health reasons (12%), not being willing to participate (23%), or not being able to receive email/text messages (8%).
- A total of 167 women were randomized into the study, representing more than 11 Latin American nationalities.
- Women were, on average, 56.3 years old, 54% reported college education or higher, and 56% had an annual income of \$15,000 or less. Average time since BC diagnosis was 5.5 years.
- The study met its accrual goal and successfully recruited and enrolled a diverse group of Latina breast cancer survivors primarily via medical records and physician referrals.
- If effective, the *Mi Vida Saludable* program will provide BC survivors and cancer centers with scalable tools to promote sustained lifestyle behavior change.



Mi Vida Saludable



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