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# Assessing the utility of a telephonically delivered psychoeducational intervention to improve health-related quality of life in African American breast cancer survivors: a pilot trial

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## Background

There is an urgent need for interventions to enhance the health-related quality of life (HRQOL) of African American breast cancer survivors (AABCS), who bear a disproportionate burden of cancer with some of the worst survival and survivorship outcomes [1,2]. The objective of this pilot trial was to determine the utility of telephonic-based psychoeducational intervention sessions, guided by a culturally informed breast cancer survivorship booklet, to improve HRQOL outcomes among AABCS.

## Methods

### Recruitment and participants

Participants were recruited from hospital cancer registries and breast cancer survivor support groups, via mailed letters and flyers providing general study details and staff contact information. Study staff then contacted potential participants by phone to assess study eligibility and obtain verbal consent. All participants gave written informed consent. Participants were disease-free women aged  $\geq 18$  years who were within 1–6 years after a stage 0–III breast cancer diagnosis and self-identified as African American. A detailed description of study recruitment and enrollment is presented elsewhere [3].

### Procedure

This pilot trial was grounded in the Contextual Model of HRQOL that emphasizes responsiveness to cultural and socio-ecological considerations [4] and the cognitive–

behavioral framework [5], which focuses on goal-oriented, solution-focused adaptive skills. Institutional Review Board approval was obtained prior to study implementation. Computer-generated randomization to the intervention or control condition used a 1:1 allocation scheme. Participants completed the study questionnaire at baseline and 4–6 months after randomization. Participants eligible for randomization to the pilot study were those who endorsed burden, defined as two or more negative responses (i.e., ‘quite a bit’ or ‘very much’ on negatively worded items and ‘not at all’ or ‘a little bit’ on positively worded items) within each subscale of the Functional Assessment of Cancer Therapy-General (FACT-G) [6] (i.e., physical, social/family, emotional, and functional well-being) at baseline. Participants were compensated with a US\$20 and a US\$25 gift card upon completion of each questionnaire, respectively.

All participants received the 85-page survivorship booklet *Embracing Hope*, which was developed by Dr. Ashing and her team and informed by publications of the National Cancer Institute, American Cancer Society, *Living Beyond Breast Cancer*, Dr. Ashing’s previous work, and the multicultural and clinical psychology literature. *Embracing Hope* contains clinically relevant details about breast cancer (e.g., staging and treatment), culturally relevant information on the psychosocial impact of cancer, and low-cost treatment, surveillance, and psychosocial resources. Intervention group participants received eight bi-weekly 40- to 50-minute telephonic sessions guided by the domains of *Embracing Hope*: (1) Basic Breast Cancer Information; (2) Managing Medical and Physical Issues, Follow-up Care, and Cancer Resources; (3) Coping, Problem Solving, and Medical Communication Skills;

(4) Balancing Emotions and Stress Management; (5) Family and Social Concerns; (6) Sexual Health Concerns, and (7) Financial Issues and Employment Concerns.

Clinically trained research assistants with at least a bachelor's degree in the social sciences (i.e., psychology and social work) and  $\geq 3$  years of experience working with underserved communities were trained to deliver the intervention. Ongoing supervision and training ensured adherence to the intervention manual (based on Embracing Hope) and addressed ethical and cultural issues and any study or survivor concerns. Intervention fidelity was monitored during the supervision and by random review of session audio-recordings. Our previous study using the same framework and approach in Latina breast cancer survivors describes the intervention protocol in detail [7].

## Measures

Participants completed comprehensive self-report questionnaires, including standard and new measures developed from and used in the principal investigator's previous research with breast cancer survivors. HRQOL was measured using the FACT-G, which generates subscale scores that are aggregated to compute an overall score. The instrument had good internal consistency in this study ( $\alpha=0.82$ ). Demographic and medical characteristics were self-reported by participants within the questionnaires.

## Statistical analysis

Chi-square analyses and independent *t*-tests compared baseline demographic and clinical characteristics, and independent *t*-tests examined differences in mean HRQOL scores between study conditions. Paired sample *t*-tests assessed changes in mean HRQOL scores across time points. Simple regression analysis evaluated whether there was a significant effect of the intervention on HRQOL. Analyses were conducted using SPSS v.21 with a  $p < 0.05$  criterion of significance for a two-sided test.

## Results

A total of 123 AABCS were enrolled and assessed for study eligibility. About 35% ( $n=40$ ) reported moderate to severe HRQOL concerns based on the FACT-G and were eligible for trial assignment to either the telephone intervention or control group (booklet only). Because of one woman being lost to follow-up, 39 AABCS completed the trial: 20 in the intervention group and 19 in the control group.

### Participant characteristics

Participants' ages ranged from 31 to 89 years ( $M=55.5$ ,  $SD=13.1$ ). Most had at least a high school education (95%) and household incomes below US\$45,000 (61%),

and 33% were in a committed relationship. Participants reported lumpectomy (69%), mastectomy (33%), chemotherapy (69%), radiation (62%), and hormone therapy (64%). The mean number of comorbidities was 2.1. Demographic and medical characteristics did not significantly differ between the intervention and control groups. There were no significant correlations between participant characteristics and HRQOL at baseline or follow-up.

## Trial analyses

At baseline, there was no significant difference in overall HRQOL between the control ( $M=53.16$ ,  $SD=2.7$ ) and intervention ( $M=54.65$ ,  $SD=5.7$ ) groups ( $p > 0.05$ ). However, control group participants ( $M=56.42$ ,  $SD=11.1$ ) reported lower physical well-being than intervention group participants at ( $M=65.50$ ,  $SD=16.2$ ) ( $p=0.049$ ).

At follow-up, intervention group participants ( $M=58.20$ ,  $SD=7.5$ ) reported significantly greater overall HRQOL than control group participants ( $M=53.89$ ,  $SD=3.2$ ) ( $p=0.028$ ). Paired sample *t*-tests showed that overall HRQOL significantly increased from baseline ( $M=54.65$ ,  $SD=5.7$ ) to follow-up ( $M=58.20$ ,  $SD=7.5$ ) in the intervention group ( $p=0.049$ ). Intervention participants also showed significant increases in physical ( $p < 0.041$ ) and emotional ( $p < 0.003$ ) well-being from baseline to follow-up. In addition to having statistical significance, these changes constituted clinically significant increases in overall HRQOL (+4 points), physical well-being (+7 points), and emotional well-being (+12.55 points), based on a meaningful change scale found in published data on clinical significance of the FACT-G [8]. For control group participants, overall HRQOL was unchanged from baseline ( $M=53.16$ ,  $SD=2.6$ ) to follow-up ( $M=53.89$ ,  $SD=3.2$ ) ( $p > 0.05$ ). In the control group, there was no change in any HRQOL domain or in overall HRQOL from baseline to follow-up.

Results of the regression analysis demonstrated that the telephone intervention had a significant effect on HRQOL ( $b=4.31$ ,  $t=2.28$ ,  $F(1, 37)=5.20$ ,  $p < 0.028$ ).

## Discussion

This pilot trial assessed the utility of a culturally responsive, problem-focused, psychoeducational telephonic intervention delivered to AABCS. The results showed significant improvements in physical, emotional, and overall HRQOL among participants as a result of the intervention. However, the small sample size may limit the power to detect an intervention effect, as well as the generalizability of the findings. Thus, an implementation and dissemination study is needed to test the effectiveness of this intervention with a large population.

Psychosocial interventions targeting African American cancer survivors should incorporate relevant sociocultural

components, including the use of terminology and concepts that are familiar within the culture and community-based resources to address contextual burdens [9]. Anecdotal data based on the supervision of sessions and the review of session recordings suggest that the interventionists' authentic responsiveness to the survivors' day-to-day experiences and cultural milieu may have facilitated trust and interpersonal connection, which are essential for providing quality psycho-oncology and supportive care. Furthermore, ethnic minority patients tend to prefer empowerment-based guidance over traditional didactic approaches [10]. Our African American interventionists were able to employ an important role model and mentorship approach in delivering the intervention.

This psychoeducational trial emphasized patient-centered and culturally sensitive support provided by

well-trained and supervised interventionists. Patient responsiveness was demonstrated by the interventionists' tailoring the order of the session domains and addressing the individual needs of each participant. Implementation and dissemination science can facilitate translation of this type of intervention into broader application to reduce HRQOL disparities and bring relief to the increasingly diverse cancer survivor population.

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### Conflict of interest

The authors have declared no conflict of interest.

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