Title: Improving Uptake of Genetic Cancer Risk Assessment in African American Women – Video

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Study Overview

Genetic counseling and testing (GCT) provides invaluable information for women who are at risk of hereditary breast and/or ovarian cancer (HBOC). Black women underutilize GCT compared to White women. This study conducted an RCT to test the efficacy of a culturally-tailored theory-based video intervention aimed to address key psychosocial factors (emotions, ambivalence) to improve the uptake of genetic counseling in Black women at increased risk of HBOC. Findings from this study may offer an opportunity to engage at-risk Black women regarding genetic counseling through a multi-center trial and ultimately address the disparity in genetic counseling uptake that exists between Black and White women.

Detailed Description

Breast cancer (BC) is the most frequently diagnosed cancer in African American women (hereafter referred to as "Black"), and their cancer mortality is higher than other racial/ethnic groups in the United States (US). Compared to non-Hispanic Whites, Black women are diagnosed younger and with more advanced breast cancer. When diagnosed with BC, Black women present more often with triple-negative breast cancer (TNBC), an aggressive disease defined by the absence of estrogen and progesterone receptors and human epidermal growth factor (HER)-2 expression. TNBC has been associated with pathogenic BRCA1 variants. Racial disparities also exist for women with ovarian cancer, the most lethal of the gynecologic cancers. Among women with advanced ovarian cancers, up to 21% are associated with inherited pathogenic mutations, the most common of which is BRCA1. Women who carry a pathogenic BRCA variant (PV) have a lifetime breast cancer risk of 55-70% and a lifetime ovarian cancer risk of up to 44%. The National Comprehensive Cancer Network (NCCN) recommends referral for Hereditary Breast and Ovarian Cancer (HBOC) genetic counseling and testing (GCT) for women at risk of carrying a BRCA PV. GCT provides women with the information needed to make informed decisions to reduce their cancer risk, yet Black women are less likely to use GCT than Whites. There is a dearth of interventions to address this issue and produced results are mixed and modest. Awareness of a positive result can inform treatment decisions for cancer patients and risk management in survivors or women unaffected by cancer.

Reasons for the lower uptake of GCT in Black women are multi-factorial and include access, knowledge, psycho-social factors, and may vary by cancer status (affected versus unaffected). There are substantial scientific gaps regarding effective interventions to address the sub-optimal uptake of GCT in Black women. To be effective, GCT interventions should be anchored within the needs and cultural values of their audience. While improving knowledge about GCT and one's individual risks is important, interventions that only address knowledge may not enhance uptake, as risk information evokes emotional reactions that are often stronger predictors of behaviors than cognitive factors.

Notably, this team has identified factors that contribute to Black women's uptake of GCT. In preliminary studies, researchers found that self-efficacy in making decisions about GCT and medical mistrust were associated with GCT uptake. Low knowledge among Black BC survivors at risk of HBOC has also been found. Anticipated negative emotions to GCT have been associated with lower uptake. Similar studies suggest that Black women report emotions related to fear of being singled out and the fear of being hopeless. Because most interventions have

focused solely on knowledge or access, the proposed study makes a considerable shift in the field by additionally targeting emotions and ambivalence and developing a media-based risk communication tool.

Guided by two evidenced-based theories and preliminary data, this was a two-phased mixed methods study. In Phase I (months 1-7), formative research and preliminary data were used to develop the script for the GCT video. The script was reviewed by GCT experts (n=4) and piloted in two focus groups (n=16), followed by a staged reading to make final refinements. In Phase II (months 8-24), a two-arm randomized trial (RCT) to compare GCT uptake and psycho-social outcomes between 50 at-risk Black women receiving printed Susan G. Komen developed GCT literature (control group) (n=25) or a tailored YouTube video intervention (n=25) was be conducted. All women were referred to an appointment scheduler who assisted them with making an appointment with a genetic counselor. Participants completed a baseline survey and follow-up assessment. The primary outcome was genetic counseling uptake, and receipt testing at 3 months was explored. Specific aims are to:

Aim 1. Develop a YouTube video using formative data for Black women at risk for HBOC.

Aim 2. Evaluate the efficacy of the intervention by comparing outcomes between women in the YouTube intervention arm vs. the control group arm. H.2.1. Women in the intervention group (vs. control group) had higher genetic counseling uptake. H.2.2. Women in the intervention group (vs. control group) was report higher knowledge, higher self-efficacy, higher endorsement of positive attitudes, and positive anticipated emotions about GCT. H.2.3. Most women (≥75%) were satisfied with the experimental intervention.

Enhancing GCT in at-risk populations is a national priority. Given trends toward panel testing and other genomic advances, there is potential for existing disparities to widen. Findings inform new strategies for behavioral interventions for Black women and a larger trial. If successful, the intervention could be easily disseminated, broadening its reach to affected and unaffected women.

This study meets the Healthy People 2020 goals to enhance GRCA in at-risk populations, and the national priorities to increase diversity in genetics research participation and incorporate emotions into cancer research. Findings informed new strategies for behavioral interventions targeting African Americans in a larger trial.

Participation Criteria

Inclusion Criteria:

- Must be at least 18 years of age
- Must be at high risk for hereditary breast or ovarian cancer
- Must identify as Black/African American
- Must be a woman
- Referred to a genetic counselor for the purpose of being at high risk of carrying a hereditary breast and/or ovarian cancer mutation

Genetic Counselors:

- Must be at least 18 years of age
- Must be qualified
- Must be approved by the PI

Exclusion Criteria:

- Under the age of 18
- Race other than Black/African American
- Do not have a high risk for hereditary breast or ovarian cancer

Genetic Counselors:

- Under 18
- Not qualified
- Not approved by the PI

Participant Group/Arm	**Intervention/Treatment**
No Intervention: Fact Sheet Arm Komen print materials about genetic counseling and testing will be given to women.	
Active Comparator: YouTube Video Arm Participants in this arm was receive the culturally tailored video either via a YouTube link or a DVD.	Behavioral: YouTube Video Arm • Participants (n=25) watched a 20-minute YouTube video that described the genetic counseling and testing process and risk/benefit information in a culturally relevant format. Participants completed pre and post-assessments. After the session, participants interested in pursuing genetic counseling and testing services were referred to a patient navigator who navigated participants to identify no-cost or low-cost services.

What is the study measuring?

Outcome Measure	Measure Description
Rate of genetic counseling and testing uptake.	Our primary outcome was for participants to receive genetic testing and counseling. Investigators were able to see if a participant had scheduled a genetic testing appointment within the VCU Health appointment system.

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Knowledge Scale - Genetic counseling and testing knowledge.	The investigators tested general knowledge about hereditary breast and ovarian cancer	Within one hour before the intervention and within one hour post-intervention.
Self-efficacy Scale	The investigators tested self-efficacy in genetic counseling services.	Within one hour before the intervention and within one hour post-intervention.
Emotional Ambivalence Scale	The investigators tested the emotional ambivalence about participating in genetic counseling services.	Within one hour before the intervention and within one hour post-intervention.