Understanding Cancer Genetic Risk Assessment Motivations in a Remote Tailored Risk Communication and Navigation Intervention Randomized Controlled Trial Among Ethnically and Geographically Diverse Cancer Survivors

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Background	Purpose	Theoretical Frameworl	k	
 Pathogenic variants in cancer predisposition genes account for up to 20% of all cancers. For 20 years, national guidelines have recommended that women diagnosed with ovarian, fallopian, and/peritoneal cancer undergo cancer genetic risk assessment (CGRA) 	The Genetic Risk Assessment for Cancer Education and Empowerment (GRACE) Project sought to close this translational gap with a superiority trial that included the following arms: Tailored Counseling and Navigation (TCN); Targeted Print; and Usual Care.	 GRACE leveraged theoretical constructs drawn from: 1. Extended Parallel Process Model: Posits risk 	Extended Paralle Process Model Threat = Perceived Susceptibil Perceived Severity: P	el () ility: HBOC risk Potential HBOC harm
(genetic testing and/or genetic counseling) to determine their hereditary breast and/or ovarian cancer (HBOC) risk.	Project	threat and efficacy appraisals.	Response = Response Efficacy: U Self-Efficacy: Confide	tility of CGRA nce in obtaining CGRA

Yet less than one-half of women eligible for guidelinebased CGRA access it.

Underserved women from rural areas and racial/ethnic minorities are even less likely to access CGRA.

Hypotheses



Intent-to-Treat Analysis

- Theoretical variables mediated CGRA intentions from the baseline to one-month follow-up.
- Participants randomized to TCN would experience greater improvements in theorized mediators than brochure-only vs. usual care arms.
- Theoretical targets would vary race, place of residence, health literacy, and family history of breast and ovarian cancer.
- CGRA Intentions was a binary (yes/no) item: "How likely do you think it is that you will undergo cancer genetic risk assessment for hereditary breast and ovarian cancer within the next 6 months?"



- **Biostatisticians were ANALYTICAL STEPS** blinded to study arm assignment. . SUMMARY STATISTICS Summary statistics, Pearson correlations, . PEARSON CORRELATION and Cronbach's alphas **COEFFICIENT & CRONBACH'S ALPHA** MEASURES calculated. • Mixed model analysis **B. MIXED MODEL ANALYSIS: BETWEEN GROUP MEDIATION** conducted to discern
- pre-to-post differences in CGRA intentions and theorized mediators.
- Subanalysis assessed across sociodemographic factors.
- Šidák multiple

2. Health Action Process Approach: Facilitated creation of an action plan bridging CGRA intentions and uptake.

Health Action Process Approach

Tailored planning and support constructs bridge intentions and CGRA uptake.

Discussion: Implications

- To our knowledge, GRACE marks the first study to test a theoretically-grounded, population-level, remote risk communication intervention to increase CGRA uptake among breast and ovarian cancer survivors at increased risk for HBOC.
- Findings support use of TCN to increase CGRA intentions among breast and ovarian cancer survivors at increased risk for HBOC, including underserved Hispanic women and those with low health literacy.
- TCN's health coaches served as trusted informational resources for participants, and were well-positioned to encourage CGRA.
- TCN's impact varied by race, residence, health literacy level, and family history of breast and ovarian cancer.
- **GRACE was bolstered by a diverse sample** though small subgroup sample sizes limited our ability to discern between-group differences in our theorized mediator variables and subgroup analysis.
- Future directions include assessing how CGRA intentions vary by levels of provider communication and social support, and tailoring
 GRACE for different subpopulations, e.g. Blacks and rural dwellers.



comparison correction mitigated chances of Type 1 error.

7. SUBGROUP ANALYSIS

6. MODERATION ANALYSIS

. MIXED MODEL ANALYSIS:

WITHIN GROUP MEDIATION

5. MULTI-MEDIATION ANALYSIS

Nethods • **Traceback** – leveraging state cancer registries (NM, CO, and NJ) to identify breast and ovarian cancer survivors – was used to identify potential GRACE participants.

- Women who met eligibility requirements consented, completed a baseline survey, and were randomized to 1 of 3 study arms: TCN, Targeted Brochure-Only, or Usual Care.
- TCN participants received a tailored, psychoeducational, decision coaching and navigation session delivered by a health coach trained in motivational interviewing.

Eligibility Poquiromonto	GRACE STUDY FLOW Project		GRACE TAILORED COUNSELING AND NAVIGATION INTERVENTION STEPS									
Meet National Guidelines for CGRA		 Declined baseline survey (n=148) Direct refusal (n=58) 							READINES	S RULERS		
Resident of NM, CO, or NJ ≥ 21 years old Biologically female	Eligible for Baseline Survey (n=821)	 Implicit refusal (n=86) Eound ineligible during baseline (n=3) 	STEP 1	STEP 2	STEP 3	STEP 4		How Important Is It for You to Get Cancer Get	etic Risk Assesment in the Next 6 Months?	How Ready Are You to Get Cancer Ge	netic Risk Assessment in the Next 6	Months?
 Speaks English or Spanish Not in hospice 	Completed Baseline Survey (n=674)	 Found ineligible after baseline (n=6) 		* 1° **				NOT AT ALL IMPORTANT	VERY IMPORTANT 6 7 8 9 10	NOT AT ALL READY	6 7 8 9	10 Y READY
								What are you important reasons for getting cancer genetic	risk assessment?	People who are People wh not at all/a little ready somehwa	to are People who are tready very ready	
	Randomization (n=668)		Built rapport/	Provided overview of	Explored issues of	Discussed response		2.		Sometimes use these steps sometime Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specialis Image: Sometime specis Image: Sometim	s use these steps sometimes use these c cancer education t provide a referral cer risk specialist Image: Advancement of the steps	ucation referral cialist
		↓	trust.	HBOC, assessing	eliciting change talk	e efficacy of CGRA;		2		☑ Make a list of pros and cons, and discuss with friends/family ☑ Search f	or ansers to relevant s Whake an appointme with a cancer risk s	nt to meet becialist
Assigned to Usual Care (n=223)	Assigned to Targeted Print Brochure (n=225)	Assigned to Tailored Counseling and Navigation (n=220)		knowledge.	and mitigating fear. of HBOC.	their thoughts		J.		☐ Find out more about CGRA ☐ Talk to sa already	omeone who has had CGRA	ime off a, etc.)
• Withdrew/Lost to Follow-Up (n=0)	 Withdrew/Lost Prior to Intervention (n=0) 	 Withdrew/lost prior to intervention (n=9) 				about it.		CTED C	CTED 7			CTED O
 Found ineligible (n=0) 	 Found ineligible prior to intervention (n=1) 	 Found ineligible prior to intervention (n=0) 					STEP 5	STEP 6	STEP 7	51	EP 8	STEP 9
• Usual care (n=223)	 Mailed TP (n=224) 	Received TCN (n=211)										
		↓	7				////—((o))——			R		N
 Withdrew (n=1) 	 Withdrew (n=0) 	• Withdrew (n= 4)										
 Found ineligible (n=1) 	 Found ineligible (n=0) 	 Found ineligible (n=2) 					Guided participant in	Helped participant se	Coach reviewed the	session Action	Plan Er	llow up call tool
		,	_				exploring their perceptions	implementation	with participant, no	ting that a Remin	ider Card pl	ace 7 wks after t
1-Month Assessment	1-Month Assessment	1-Month Assessment					of self-efficacy to obtain	intentions to access	summary letter wor	uld be sent t	o participant co	aching session t
 Completed (n=207) 	Completed (n=207)	Completed (n=184)					CGRA.	CONA III HEAL O HIOS.	Darticipant then on	tod in Jourt of coach	ing session. re	ceipt of the Actio
 Missed time point (n=7) 	 Missed time point (n=7) 	 Missed time point (n=15) 					answer what they felt, in		having a copy of th	e letter sent	PI	an Reminder Car
 Lost to follow up (n=4) 	 Lost to follow up (n=5) 	 Lost to follow up (n=4) 					the next 6 mos., was:		to their provider; w	ere notified Reminder	ar	ia to determine iditional navigati
 Found ineligible (n=3) 	 Found ineligible (n=5) 	 Found ineligible (n=2) 					1) The importance of obtaining CGRA: and		Card would be mail	ed in 6 wks;	as	sistance was
Analyzed (n=219)	Analyzed (n=219)	Analyzed (n=216)					2) Their readiness to make a CGRA appointment.		and were schedule follow-up call for 7	a for a wks later.	Te	quireu.

Results

- **Demographic variables were balanced across study arms** and limited correlation between Pearson correlation coefficients. Cronbach's alphas showed acceptable internal consistency.⁺
- TCN improved CGRA intentions vs. brochure-only (0.64, p<0.001, CI 0.32, 0.97) and usual care (0.69, p<0.001, CI 0.37, 1.02).
- Within group mediation indicated that theoretical targets, perceived risk (0.77, p<0.05, CI 0.11, 1.44) and self-efficacy (0.67, p<0.05, CI 0.05, 1.28) mediated CGRA intentions in the TCN arm. Multi-mediation analysis indicated that indirect effects of perceived risk and self-efficacy contributed >15% to direct effects of TCN on CGRA intentions.
- **Subgroup analysis**: Greater pre-to-post improvements in CGRA intentions within the TCN arm for non-Hispanic whites, Hispanics, urban dwellers, and those with low health literacy and no family history of breast or ovarian cancer. Perceived self-efficacy improved in TCN participants with no family history of breast or ovarian cancer.



SELECTED SOCIODEMOGRAPHIC CHARACTERISTICS OF PARTICIPANTS BY STUDY ARM

	All (N=654), n (%)	Usual Care (N=219), n (%)	Brochure-Only (N=219), n (%)	TCN (N=216), n (%)	p-value
Age (Mean, SD)	61.1 (10.2)	61.0 (9.9)	61.1 (10.1)	61.2 (10.7)	0.9920
Self-Reported Race/Ethnicity Hispanic	165 (26.7)	57 (27.4)	48 (23.4)	60 (29.3)	0.4324
Non-Hispanic White	389 (62.9)	134 (64.4)	133 (64.9)	122 (59.5)	
Non-Hispanic Black	39 (6.3)	9 (4.3)	17 (8.3)	13 (6.3)	
Non-Hispanic Asian	25 (4.0)	8 (3.8)	7 (3.4)	10 (4.9)	
Other	36	11	14	11	
lealthy Literacy Level Adequate (<9)	42 (6.5)	10 (4.6)	15 (6.9)	17 (7.9)	0.3607
Marginal/Inadequate (>=9)	608 (93.5)	207 (95.4)	203 (93.1)	198 (92.1)	
Missing	4	2	1	1	
Rural vs. Urban Residence Urban	539 (82.7)	189 (87.1)	177 (80.8)	173 (80.1)	0.1058
Rural	113 (17.3)	28 (12.9)	42 (19.2)	43 (19.9)	
Missing	2	2			
• of 1 st (FDR) & 2nd Degree Relatives (SDR) w/ Breast/Ovarian Cancer 0 FDR and 0 SDR	420 (64.4)	136 (62.7)	145 (66.2)	139 (64.4)	0.8375
1 FDR or 1 SDR	131 (20.1)	49 (22.6)	40 (18.3)	42 (19.4)	
2 or more FDR/SDR	101 (15.5)	32 (14.7)	34 (15.5)	35 (16.2)	

SIGNIFICANT THEORIZED MEDIATORS: PRE-TO-POST DIFFERENCES WITHIN TAILORED NAVIGATION ARM (WITHIN-GROUP), BASELINE TO ONE-MONTH FOLLOW-UP

Study Arms	Outcome	Mean Difference	95% CI
TCN	Perceived Susceptibility	0.773*	(0.109, 1.437)
TCN	Self-Efficacy	0.666*	(0.049, 1.283)