Participation in a Cervical Cancer Clinical Trial by Women of Mexican Origin in the Texas-Mexico Border

Thelma Carrillo, M.P.H. [4]; Tara Perkins, B.A. [3]; Jane Montealegre, Ph.D. [2]; Christina Gutierrez, M.S. [1]; Carlotto Fisher, M.D. [1] ;

Felipe González Castro, Ph.D. [3]; Michele Follen, M.D., Ph.D. [4] ; Zuber Mulla, Ph.D. [1]

[1] Texas Tech University H.S.C., El Paso, TX; [2] Baylor College of Medicine, Houston, TX; [3] University of Texas at El Paso, El Paso, TX; [4] Brookdale Hospital and Medical Center , Brooklyn, NY.

Introduction

- In 2014, it is estimated that 12,360 new cases of cervical cancer and 4,020 deaths due to cervical cancer occurred worldwide. [1] In the U.S., cervical cancer mortality is highest among minority women, specifically African American and Hispanic women, with respective mortality rates of 3.9 and 2.6 per 100,000 versus 2.1 per 100,000 in white women. [2]. In Texas, Hispanic women have the highest cancer mortality rates among Hispanic women in the nation, with mortality rate of 3.4 per 100,000 [2].
- Research among vulnerable populations who are at an increased risk of disease and death is imperative to address and reduce health and social disparities.
- However, underrepresentation of ethnic minorities, the poor, and under-/uninsured in cancer clinical trials is a significant problem. [4]
- Participation in clinical trials is important because it is an opportunity to understand the barriers experienced by different populations in receiving adequate healthcare and in finding solutions to address these issues.
- Furthermore, participation in follow-up studies is important because health outcomes often occur over extended periods of time. Having the ability to re-contact participants allows researchers to gain a longer term perspective on health behaviors and outcomes.

Research Question

What factors predict intent to participate in future studies among Hispanic women who participated in a previous clinical trial?

Materials and Methods

- This multisite clinical trial is being conducted in El Paso, Texas, Brooklyn, New York and Vancouver, Canada. The data presented here was collected among participants enrolled in El Paso, Texas.
- Patients presenting to the colposcopy clinic for a diagnosis of an abnormal Pap result or for treatment for cervical neoplasia were approached if they met the eligibility criteria of the parent study: (>18 years of age , not pregnant, without a history of a hysterectomy.
- Participation was voluntary and written informed consent was obtained from all patients after a ten minute verbal explanation.
- Participants answered a survey regarding demographics and health history. Following their participation in the clinical trial, they were asked about factors that motivated them to participate in the trial and if they would be willing to be contacted to participate in future studies.
- Logistic regression was used to evaluate factors associated with intent to participate in follow-up studies. Measures included participants' age, country of birth, marital status, language, acculturation, and education.
- Between December 2012 and December 2014, 470 participants participated in the trial. Participants are diverse in terms of age, education, country of birth, marital status, language preference, and acculturation (Table 1).

Results

Table 1. Characteristics† of 306 Mexican-American Women. Results are Presented by Willingness to Participate in Future Studies.

Variable	Willing to participate N=250 Number (%)	Not willing to participate N=56 Number (%)	P
Average age (years) ± SD‡	35.2 ± 10.6	30.2 ± 8.3	0.0002
Education level			0.41
Less than high school	76 (30.4)	13 (23.2)	
High school graduate	54 (21.6)	16 (28.6)	
Some college or college graduate	120 (48.0)	27 (48.2)	
Country of birth			0.25
Mexico	133 (53.2)	25 (44.6)	
Other	117 (46.8)	31 (55.4)	
Married or living with partner	73 (29.2)	18 (32.1)	0.66
Language of the questionnaire			0.15
English	130 (52.0)	35 (62.5)	
Spanish	120 (48.0)	21 (37.5)	
Marín Short Acculturation Scale for Hispanics (SASH)			0.14
More acculturated*	107 (42.8)	30 (53.6)	
Less acculturated	143 (57.2)	26 (46.4)	

† Results are presented as number (%) unless otherwise stated.
‡ SD, standard deviation.
* Defined as an average score of >2.99 on the shortened version of the SASH.

Table 2. Adjusted† Odds Ratios (OR) for Agreeing to Participate in Future Studies (Yes vs. No) in 306 Mexican-American Women.

Variable	OR	95% Confidence Interval	P
Age in years (for each 10 year increase)	1.85	1.24-2.74	0.002
Educational level			
Less than high school	0.71	0.30-1.68	0.43
High school graduate	0.57	0.27-1.23	0.15
Some college or college graduate	1	(Referent)	-
Born in Mexico (vs. other country)	0.91	0.42-1.96	0.81
Married/living with partner (vs. other status)	0.70	0.36-1.36	0.30
More acculturated (vs. less acculturate)	0.67	0.31-1.44	0.30

† Each OR is adjusted for the remaining variables found in the table.

Table 3 Reasons for Participation in Trial

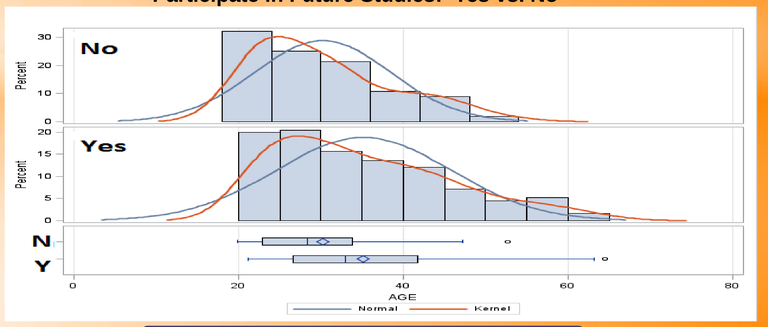
	Number of Responses*
Help others	69
To improve technology	44
Interesting research	10
Increase scientific knowledge	10
For my health	9
Other	8
Don't know	7

*Responses are not mutually exclusive.

Conclusions

- Recruitment into a clinical trial to improve the diagnostic technology for cervical cancer of a patient population at high risk of developing cervical cancer due to their socio-demographic characteristics has been highly successful. Despite the additional time requirement for the provision of socio-demographic , behavioral and biological data that participation entailed, the majority of patients have agreed to participate in the trial.
- Older participants were significantly more likely to consent to be contacted for future studies. This may be explained by the Erikson's Theory of Generativity that states that in middle adulthood (40–65 years old) people often feel the need to give back to the world and offer their wisdom to others. We were able to see this quality in patients who participated in the trial. As shown in Table 3, one of the main reasons for participation in the trial was to "Help others."
- Our results are limited due to the fact that participants in this study were already taking part in a current research project when consenting to be contacted for future research studies. However, a subset of women who refused to take part in the clinical trial were also willing to be contacted in the future (data not shown).
- Future research should investigate strategies to make clinical trials more attractive to the younger Hispanic women. This is imperative in order to ensure that clinical trials represent all segments of the population.

Figure 1. Distribution of the Subject's Age by Willingness to Participate in Future Studies: Yes vs. No



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