A Clinical Trials Education Program for Hispanic Americans

Georgia Robins Sadler, Vanessa L. Malcarne, Rina S. Fox, Alma I. Behar, Carolina A. Talavera, Natalia A. Ramirez-Sanchez

No Conflict of Interest

- NCI grants
  - 5R25CA130869
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  - P30CA23100 CURE Supplement
  - U54CA132379/U54CA132384
Reducing Hispanic Americans’ Cancer Disparities Via Clinical Trials Representation

- Multiple factors contribute to slow participant accrual
  - Differential access to health care and health education
  - Socioeconomic and linguistic barriers
  - Cultural differences in health attitudes, responsibilities, & practices
  - Unique environmental and social forces at play
- NCI’s CTs Education Series for HAs (CTES) in Spanish
  - Original program too complex
  - Fotonovelas
    - Insufficient content
    - Insufficient call to action

Hispanic Clinical Trials Project Goals

- A single Hispanic Americans’ CTs promotion program
- Capacity for
  - Cultural alignment with diverse HA community
  - Alignment with diverse Spanish dialects
  - Branding by other cancer institutions
Overview of Work Accomplished

- Established Community-Campus Partnership
- Community needs assessment for CTs
- Created CTs program for HA women with community input
- Pilot tested and refined CT program
- Randomized controlled trial with HA women
- Expanded program to include HA males – this presentation

Defined & Validated Outcome Measures

<table>
<thead>
<tr>
<th>Program Should</th>
<th>Outcome Measures</th>
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<tbody>
<tr>
<td>Change Knowledge</td>
<td>Pre/Post Knowledge Questionnaire</td>
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<tr>
<td>Change Attitudes</td>
<td>Pre/Post Benefits and Barriers to Clinical Trials Participation Scale</td>
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<td>Change Behaviors</td>
<td>Pre-study participation in CTs</td>
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<td>Post-study response to invitation to join CTs Ambassador Program</td>
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<td>Post-study response to invitation mailed months later to join CTs Sleep Study by unknown colleagues</td>
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<td>Interaction with Mediators &amp; Moderators</td>
<td>Locus of health control, depression, fatalism, subjective social status, etc</td>
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Randomized Controlled Trial to Test HA CT Program

- Baseline Surveys
- Randomized to
  - Clinical Trials Education for HAs
  - Neighborhood Watch Program
- Immediate post-intervention surveys
- Invitations to join another research study at two weeks and three months post-intervention

Randomized Controlled Trial to Test HAs CTs Program

- Stratified randomization assigned 400 participants to
  - Intervention condition ($n = 202$) or
  - Control condition ($n = 198$)
- Groups matched on
  - Gender
  - English vs. Spanish language preference
Sample Description

- 43.5 = average age of participants
- Just under 50% was employed for waged
- Half sample had household income < $20,000
- 40% married
- 60% had > high school diploma or GED
- 2/3 had no prior research participation experience
- 3/4 had children
- 1/3 had no health insurance
- Almost all born in United States or Mexico
- Most self-identified race as White/Caucasian

Analytic Plan

- Descriptive statistics run for key variables
  - Socio-demographic variables
  - Baseline levels of cognitive and affective outcomes
- Chi-square analyses for categorical variables
- Independent samples t-test for continuous variables
Both Groups Comparable at Baseline

- Sociodemographic characteristics
  - Age, gender, language preference, employment status, income, marital status, education, religious preference, race, years spent in US, past research participation, insurance coverage, parental status, Hispanic subgroup self-identification
- Levels of perceived barriers of clinical trials participation
- Levels of perceived benefits of clinical trials participation
- Clinical trials knowledge

Pre-Test to Post-Test Knowledge & Attitudes Outcomes

- Analyses
  - Within subjects variables (pre-test to post-test)
  - Between subjects variables (experimental and control groups)
  - Analyses by gender and language preference
Changes in Perceived Barriers

- Positive changes in three of four **perceived barriers** to clinical trials participation
  - No benefit for me
  - No support from my community
  - Lack knowledge of clinical trials
  - Mistrust of researchers—NO CHANGE

Changes in Perceived Benefits and Knowledge

- Positive changes in both **perceived benefits** to clinical trials participation
  - Benefit for me
  - Benefit for others
  - Gain in **clinical trials knowledge**
Gender and Language Preference

- Men and women benefitted equally
- Interaction for language preference
  - English language participants significant changes for
    - Perceived benefits to me
    - Clinical trials knowledge
  - Spanish language participants no significant changes for
    - Perceived benefits to me
    - Clinical trials knowledge

Two Week and Three Month Outcomes

- No statistically significant differences between groups at two weeks or three months
- Three month study trended toward significance
  - Experimental group (71%)
  - Control group (62%)
  - Unexpected high rate of return of completed study for both arms with a single invitation
Discussion

- Intervention triggered increased knowledge
- Intervention triggered change in five attitudes expected to change
- Unexpected high rate of completed research participation in two week & three month study by both groups

Ideas for Future Research Studies

- Exploration of why people in both study groups were so willing to join additional studies?
  - Preselected for willingness to participate?
  - The “Nice Researcher” trust factor?
  - The gained familiarity with the research experience?
- Exploration participants with Spanish language preference did not experience equivalent gain in increased perceived benefit to me and knowledge.
Questions?

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