

# Addressing Health Disparities through the Use of Community-Embedded Research Ambassadors to Diversify Clinical Research Participation

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## BACKGROUND

Despite making up a substantial part of the U.S. population (30%), and bearing the greatest burden of chronic disease, racial and ethnic minorities constitute less than 18% of clinical trial participants.<sup>1,2</sup> Low accrual rates are likely influenced by a limited focus on these populations; for example, data show that only 1% of the 10,000 National Cancer Institute sponsored clinical trials have focused on racial and ethnic minorities.<sup>3</sup> This lack of focus is reflected in accrual rates in nationwide cancer clinical trials, where Hispanic accrual rates were between 2-4% for all phase II or phase III cancer clinical trials published in 2012.<sup>4</sup> By contrast, of 40,835 participants in clinical trials in the U.S. from 2015-2016, 81% were White.<sup>5</sup>

These low accrual rates may contribute to preventable disparities in treatment outcomes and survival rates, and limit the generalizability of research findings.<sup>2,6,7</sup> As such, it is important to address the barriers to participation and embrace practices that show potential in increasing accrual rates. Among researchers, a lack of knowledge about the cultural differences between ethnic minorities coupled with personal bias can lead to ineffective communication and less effort to recruit racial and ethnic minorities for clinical trial participation.<sup>1,6</sup> Cited barriers among participants include: a lack of knowledge and misconceptions of research, mistrust and fear, and fewer available resources to access research opportunities (e.g. transportation, free time, access to care or health insurance).<sup>1,6,8,9</sup>

Given these obstacles, new approaches have been developed to reach underrepresented populations in clinical research. The current study serves as such an example with a focus on conducting culturally-competent outreach in Latino communities to promote participation in clinical research. The ultimate goal of this program is to reduce health disparities among Latinos in Southern California through the integration of Latinos in clinical research

## METHODS

### Promotora Model

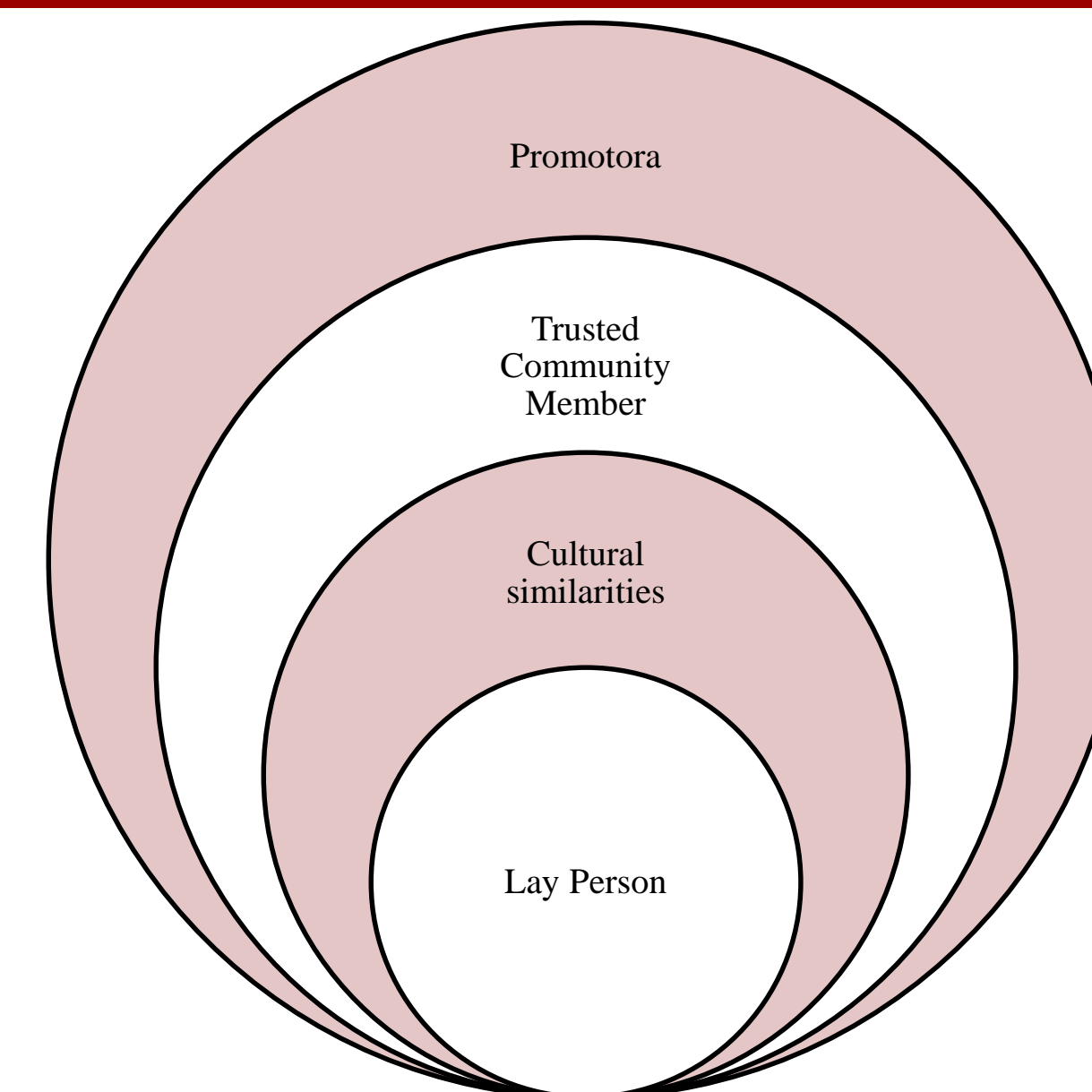
The Research Ambassador Program (RAP) was designed for underserved and underrepresented communities, particularly mono-lingual Spanish-speaking Latinos. Using a community and data-driven approach, RAP was designed as an educational program to be delivered by *promotoras de salud*, Latina community health workers who are defined as highly trained community leaders. *Promotoras* have been a part of a variety of health promotion programs in the United States, and have been successful in changing community knowledge and behaviors around different health issues.<sup>10-12</sup>

### Workshop

The RAP curriculum was developed in partnership with several community engagement programs in Southern California to develop a "Research 101" curriculum that could be taught in community settings. Based on literature reviews and formative research, we identified the primary areas of focus for the curriculum with the primary objectives of: 1) addressing myths and fears about research; 2) increasing scientific literacy about how clinical research is conducted; and 3) informing potential participants of their rights as a research participant. The resulting curriculum was adapted into a more succinct and digestible format for a workshop presentation. In this study, *Promotoras*, conducted outreach in schools, churches, and community centers in identified zip codes of South Los Angeles to recruit participants and schedule RAP workshops. Once a location for the workshop was identified, *promotoras* arranged for a pretest administration with interested participants. A week following the pretest, the workshop was provided. All Workshops were conducted in Spanish and lasted an hour and half, including the administration of the posttest.

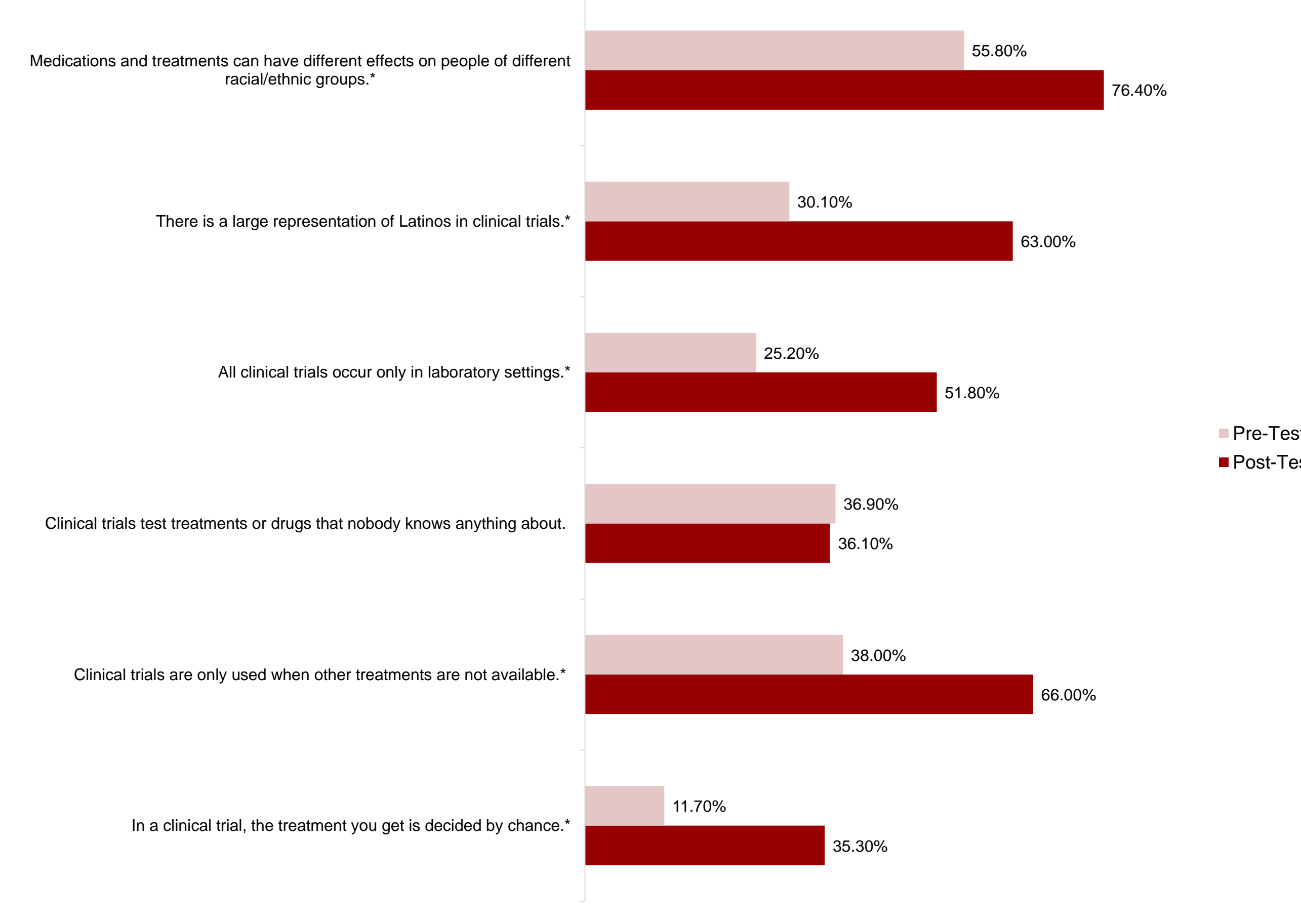
### Analysis

The current study used a pre-post intervention design; participants at identified workshop locations were enrolled in pre- and post-workshop periods. Data were collected from March 2017 to August 2017 a total of 274 individuals completed the pretest and a total of 18 workshops were conducted with 314 individuals who then completed the post test. It was not required that individuals attending the workshops complete the pretest the week before. Therefore, persons completing the post-workshop assessment were not always the same persons who completed the pre-workshop assessment, and persons were not individually identified from pre- to post-assessment.



## RESULTS

Figure 1. Pre and Post Test Results (% Correct) for Clinical Trials.



\* p < 0.0001

Table 2. Pre and Post Test Summary Score for Clinical Trials Knowledge.

Summary Measure	Pre Mean (SE)	Post Mean (SE)	Difference Mean (SE)	p-value
Clinical Trials Knowledge	12.6 (0.2)	15.2 (0.2)	2.6 (0.3)	<0.0001

Table 3. Multivariable Regression Model: Correlates of Clinical Trial Participation (Summary Continuous Measure)

	Regression Coefficient: Beta (SE)	p-value
b. Education (per year)	0.37 (0.12)	0.003
a. Language (compared to Spanish)		
I. English	3.3 (1.1)	0.002
II. Other	0.9 (2.5)	0.72
a. Post workshop (compared to Pre)	1.3 (0.6)	0.04

## CONCLUSION

Limited minority participation in clinical research has been identified as a barrier to advancing medical discoveries and addressing health disparities amongst Latinos, African American and Asian/Pacific Islander populations. Among the most important reasons for increasing the proportion of racial/ethnic minorities in clinical trials is to ensure that discoveries, treatments, interventions, and prevention strategies are relevant to those populations. While new treatments are constantly being developed, much of the work that has been done cannot be directly generalized to minorities because they are not represented in the trial sample.

Our findings suggest that the use of *promotoras de salud* as Research Ambassadors can increase community knowledge about and intent to participate in clinical research. Our next steps include adapting the curriculum for African American communities to be delivered by community health workers or similar cultural brokers. The RAP workshops appear to be successful in addressing some of the most prominent barriers to minority participation in research. The diversification of clinical trials is imperative to determine to what extent treatments and interventions are effective in diverse populations. More targeted and tailored approaches that address the barriers to research participation are needed in order to address the many health disparities that continue to exist among our most vulnerable communities.

## REFERENCES

- George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *American Journal of Public Health*. 2014;104(2):e16-e31.
- Hamel LM, Penner LA, Albrecht TL, Heath E, Gwede CK, Egly S. Barriers to clinical trial enrollment in racial and ethnic minority patients with cancer. *Cancer control : journal of the Moffitt Cancer Center*. 2016;23(4):327-337.
- Arevalo M, Heredia NI, Krasny S, et al. Mexican-American perspectives on participation in clinical trials: A qualitative study. *Contemporary Clinical Trials Communications*. 2016;4:52-57.
- Parra A, Karnad AB, Thompson IM. Hispanic accrual on randomized cancer clinical trials: A call to arms. *Journal of Clinical Oncology*. 2014;32(18):1871-1873.
- Food and Drug Administration (FDA). *Global participation in clinical trials report*. 2015.
- Fisher JA, Kalbaugh CA. Challenging assumptions about minority participation in US clinical research. *American Journal of Public Health*. 2011;101(12):2217-2222.
- Ogedegbe G, Shah NR, Phillips C, et al. Comparative effectiveness of angiotensin-converting enzyme inhibitor-based treatment on cardiovascular outcomes in hypertensive Blacks versus Whites. *Journal of the American College of Cardiology*. 2015;66(11):1224-1233.
- Ceballos RM, Knerr S, Scott MA, et al. Latino beliefs about biomedical research participation: A qualitative study on the U.S.-Mexico border. *Journal of Empirical Research on Human Research Ethics*. 2014;9(4):10-21.
- Zamora I, Williams ME, Higareda M, Wheeler BY, Levitt P. Brief Report: Recruitment and retention of minority children for autism research. *Journal of autism and developmental disorders*. 2016;46(2):698-703.
- Nuño T, Martinez ME, Harris R, Garcia F. A Promotora-administered group education intervention to promote breast and cervical cancer screening in a rural community along the U.S.-Mexico border: a randomized controlled trial. *Cancer Causes & Control*. 2011;22(3):367-374.
- Phillis-Tsimikas A, Fortmann A, Lleva-Ocana L, Walker C, Gallo LC. Peer-Led Diabetes Education Programs in High-Risk Mexican Americans Improve Glycemic Control Compared With Standard Approaches A Project Dulce promotora randomized trial. *Diabetes Care*. 2011;34(9):1926-1931.
- Welsh AL, Sauaia A, Jacobellis J, Min SJ, Byers T. The effect of two church-based interventions on breast cancer screening rates among Medicaid-insured Latinas. *Preventing Chronic Disease*. 2005;2(4):A07.

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