

Barriers to Recruitment for a THC Study - in progress

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INTRODUCTION

Current medical clinical investigations in the United States require heterogeneity in subjects willing to participate to ensure that therapies benefit all diverse peoples. Obtaining a group of differentiable subjects can be difficult, given the history of human research in this country. In an early study, African Americans were shown not to trust the medical system due to previous unethical experimentation on their community, such as Tuskegee Syphilis Study in the 1930s (1996, Harris, Yvonne, et al). This was an abusive investigation conducted on nearly 400 African American men with syphilis, conducted by the United States Public Health Service. It was deemed a major violation of ethical standards because when treatment for syphilis became known, it was withheld from these men for many years. A later project demonstrated that 'Awareness of Tuskegee' was a stand-alone category that extended into many other areas of medical decision-making among the Black community resulting in hesitancy to participate in clinical research (2010, Scharff *et al*).

A recent study indicated that despite FDA initiatives, African Americans are still underrepresented in pharmacologic trials (2022, Green, Trivedi, *et al*). To date, there appears to be no research which explores hesitation to volunteer as a subject in a study focused on THC. This current ongoing investigation seeks to investigate among patients of the PCOM Healthcare Centers specific barriers to participation in studies using FDA-approved delta-9-tetrahydrocannabinol (THC; dronabinol), a DEA Schedule III drug. The goal is to survey 100 participants to elucidate reasons for skepticism and refusal to participate in a clinical trial of THC designed to reduce chronic neuropathic pain.

HYPOTHESIS

It is predicted that there will be a higher rate of declination to participate in the study by minority patients. It is also predicted that those who are in a minority group with interest in proceeding will express some reluctance due to mistrust in the intentions of our research.

EXPERIMENTAL DESIGN

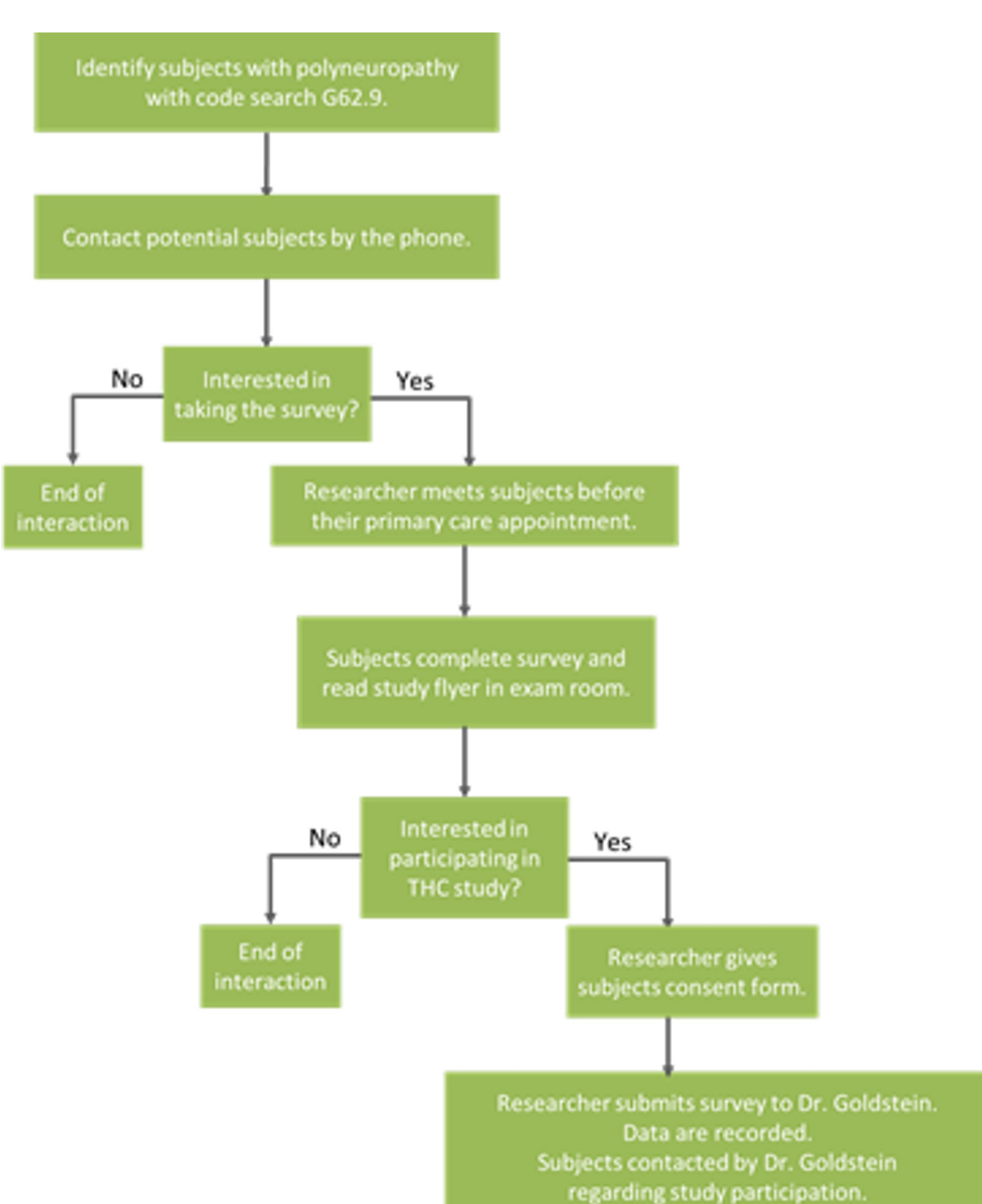


Figure 1. Participation of survey and THC Study after Contact.

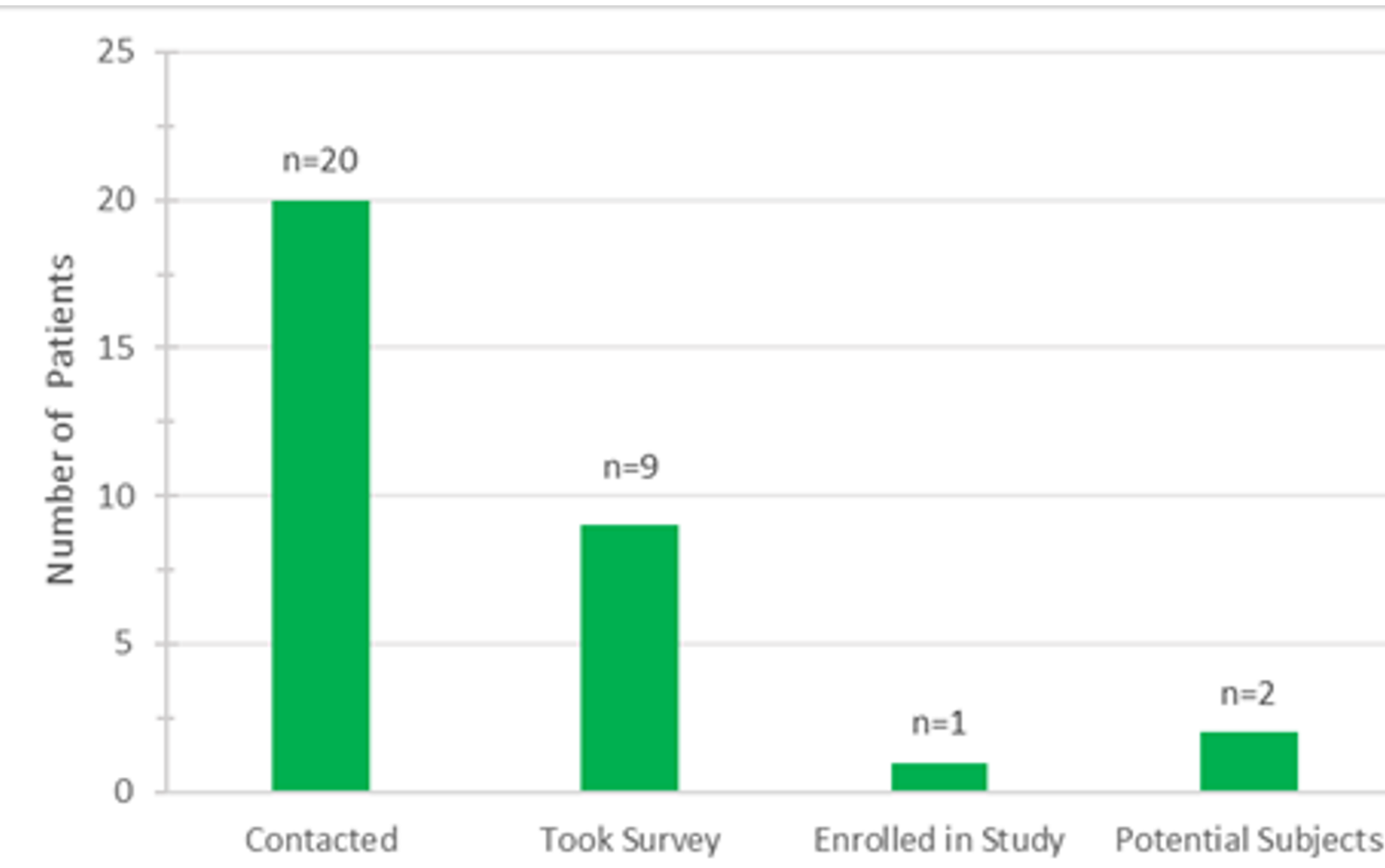


Figure 2. Ethnicity of survey participants.

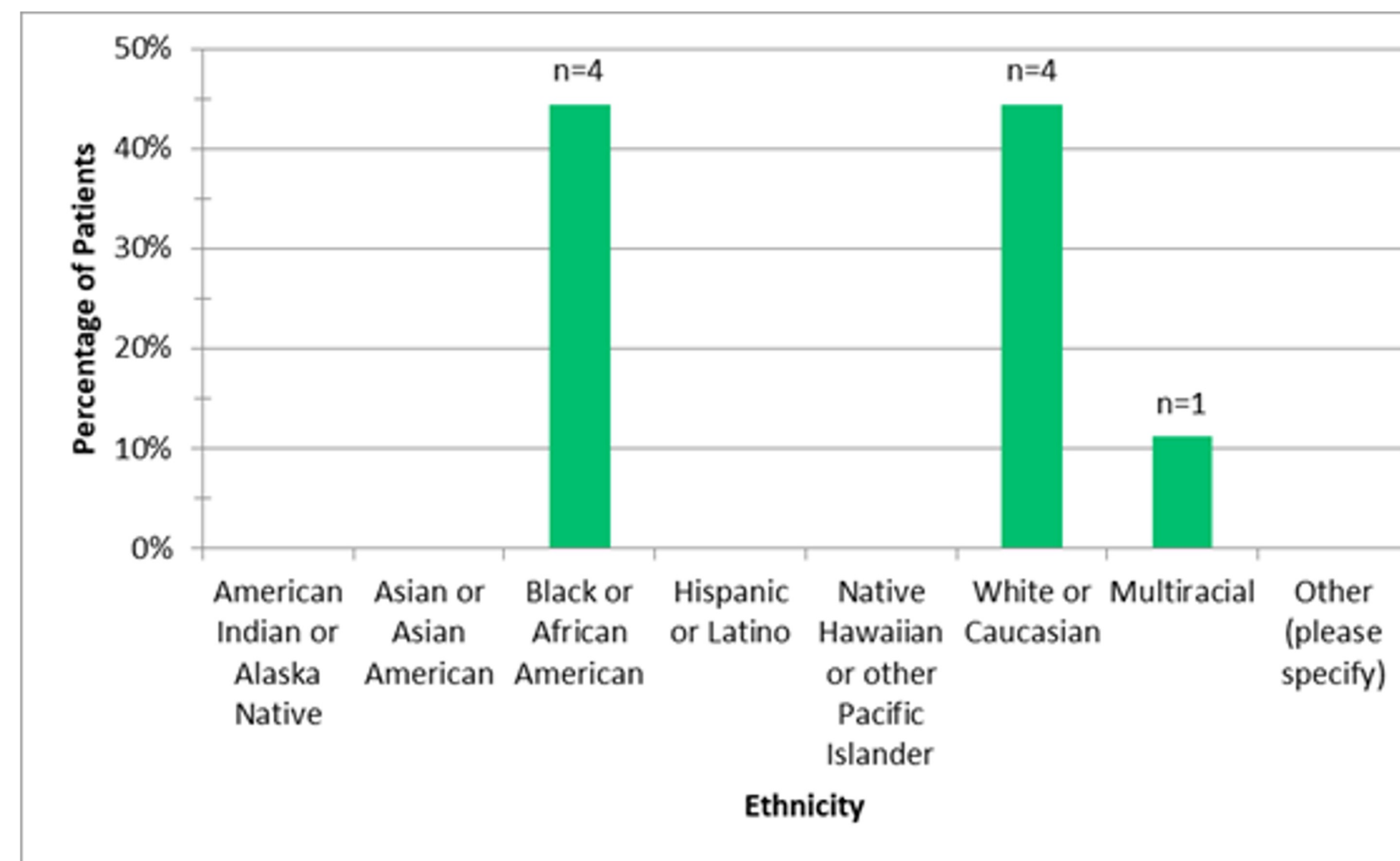


Figure 3. Response to "Do you think marijuana should be used to decrease pain?" by ethnicity

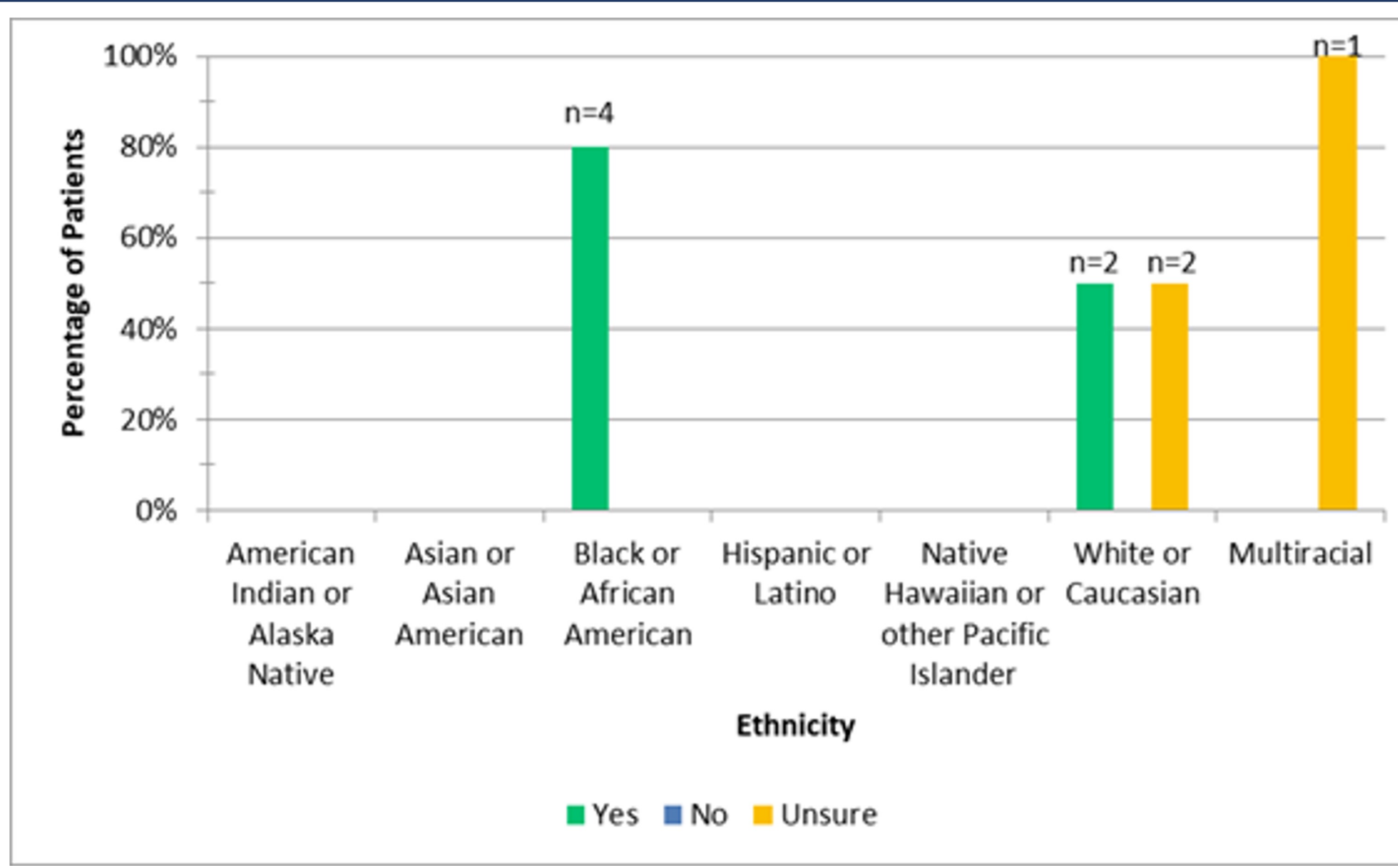


Figure 4. Responses to "Do you have any concerns about joining the study?" by ethnicity

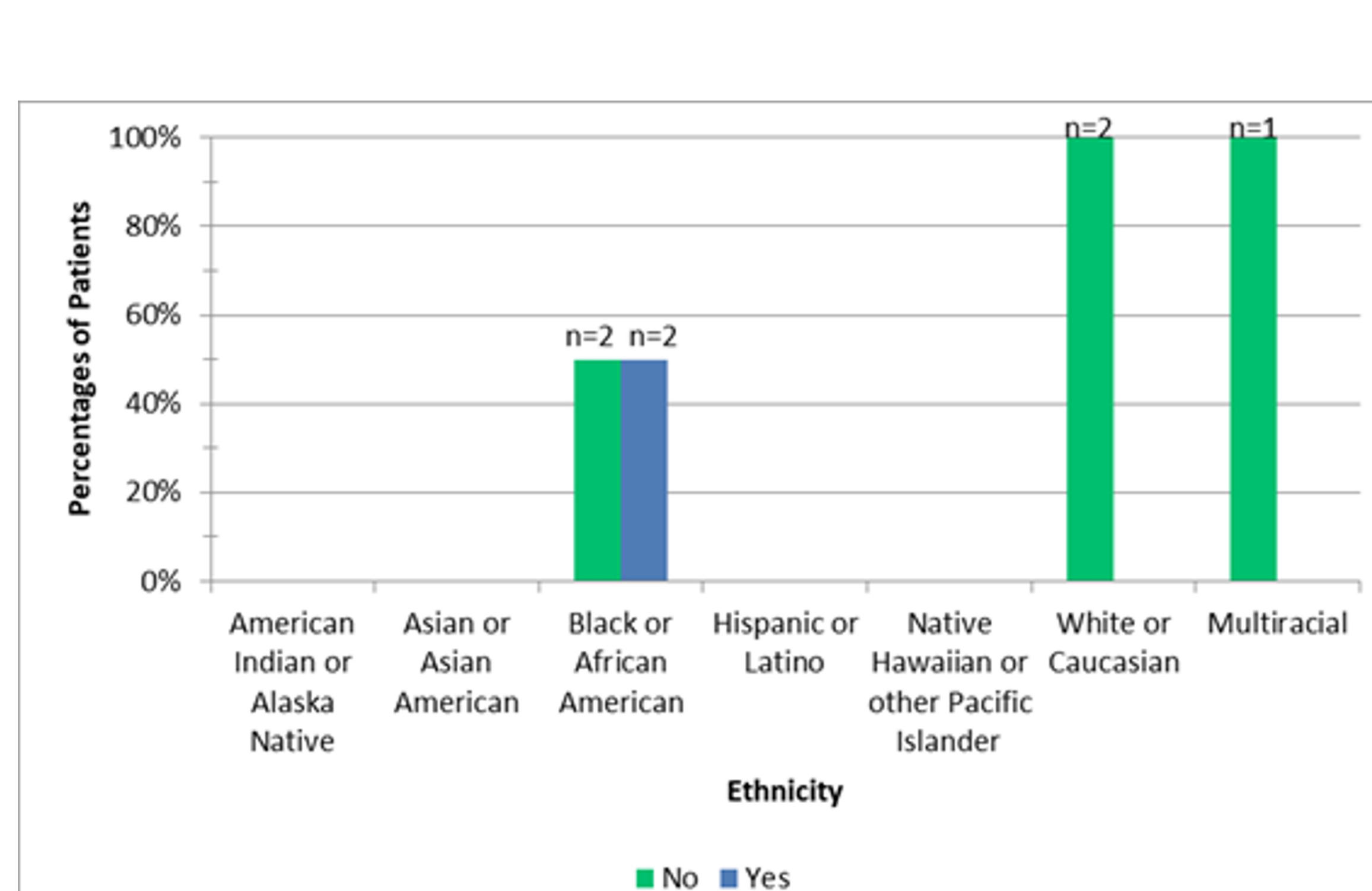
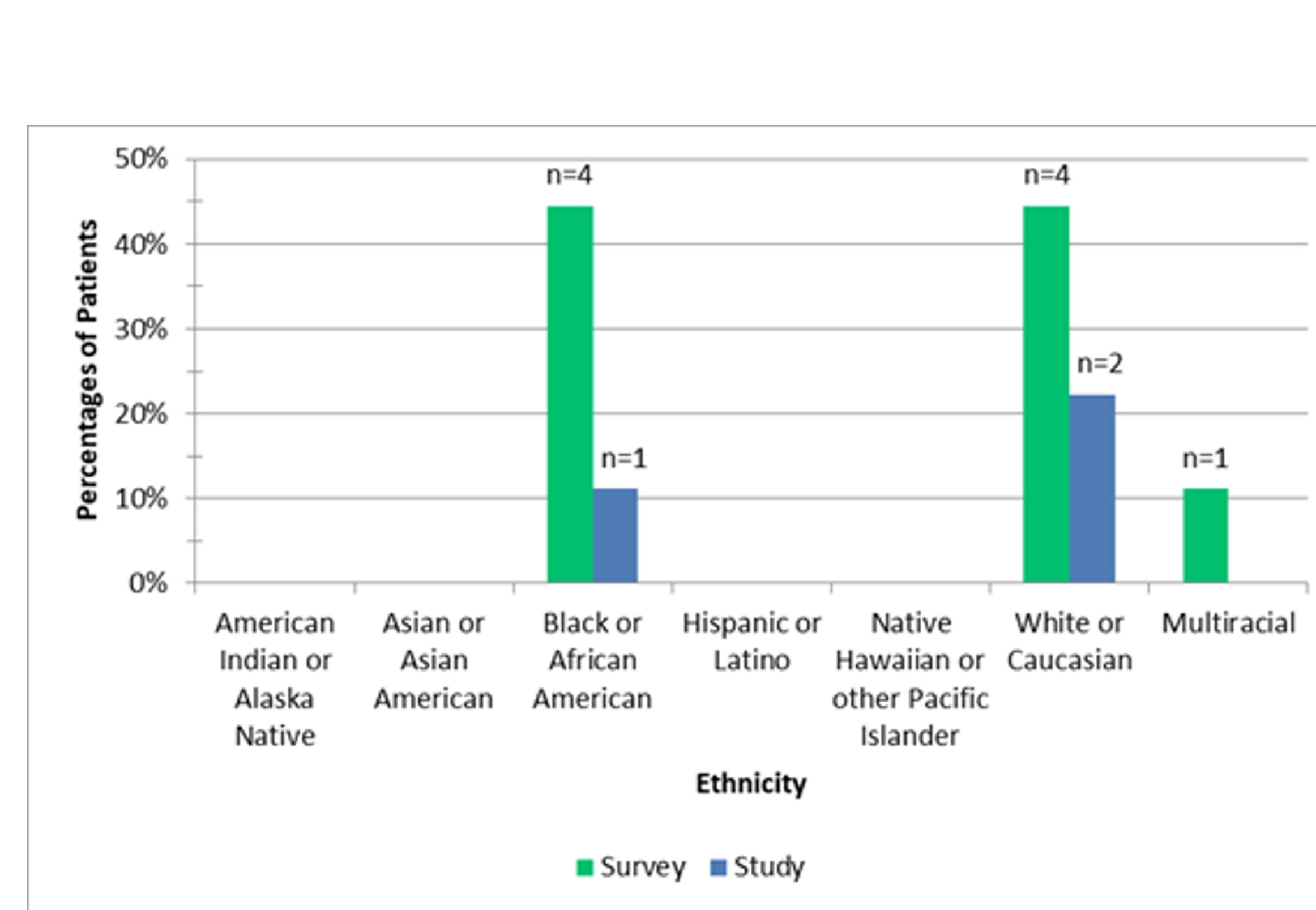


Figure 5. Ethnicity of THC survey and study participants.



Objectives

Primary:

To understand why some chronic neuropathic pain patients in primary care settings may be reluctant while others are willing to participate in a clinical research study for chronic pain.

Secondary:

To determine recruitment barriers for a THC Clinical study based on participant population;

To determine bias in which participating subjects differ from non-respondents in meaningful ways.

CONCLUSION

- Of the nine patients surveyed to date, 56% (5) were males, 44% (4) were females. Age range was from 25 to over 75 years-old; 44% (4) of patients were between 56 - 66.
- An equal number of survey participants identified as Black/African American (4) or White/Caucasian (4). One subject identified as multiracial.
- A greater percentage of Black/African American patients answered 'Yes' to the question "Do you think marijuana should be used to decrease pain?" than White/Caucasian participants.
- No White/Caucasian participant expressed concerns in joining the clinical THC study, while half of Black/African American participants did.
- One Black/African American participant who took the survey elected to join the clinical study; two White/Caucasian participants did.

ACKNOWLEDGMENTS

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REFERENCES

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