

**CARDIOCARE QUEST: A CO-CREATED GAME FOR IMPROVING HYPERTENSION TREATMENT
COMPLIANCE IN ARIZONA**

April 14, 2024

Study Protocol and Statistical Analysis Plan

Study Protocol:

Study Population

The study will enroll a total of 60 participants across three aims:

Aim 1. Employ Research through Design (RtD) methodologies to co-create culturally grounded design problem statements prioritizing healthcare access disparities among Navaho Nation Indigenous populations.

Aim 2. Employ thematic analysis of codesigned minigame prototypes using (and contributing to) an emerging serious game theory.

Aim 3. Determine the impact of *CardioCare Quest*'s telehealth interventions through a mixed methods approach.

Sample Size Determination

We performed a power analysis using a t-test for one sample to make sure the study is sufficiently powered to detect significant differences. The parameters for this analysis were carefully chosen based on relevant published data [1]. Specifically, we focused on hypertension prevalence in Navaho populations in Arizona.

Statistical Analysis Plan:

The following parameters were used for the power analysis:

Test Type: Two-tailed t-test for means from one sample.

Effect Size: 0.62, based on differences observed in previous studies.

Alpha Level (Error Probability): 0.05, which is the standard threshold for statistical significance.

Power: 0.90, indicating a 90% probability of detecting a true effect if it exists.

We determined that a sample size of 30 participants per group (totalling 60 participants) is sufficient, using the above parameters. This sample size is expected to provide statistically significant results, ensuring that the study can robustly test the hypotheses and draw meaningful conclusions about the differences in hypertension prevalence and characteristics among the targeted populations.

Justification of Sample Size

The choice of an effect size of 0.62 is justified by its relevance to the expected differences in hypertension prevalence and characteristics between the populations being studied. The high power of 0.90 ensures that the study has a strong likelihood of detecting true differences of hypertension prevalence and minimizing the risk of Type II errors. The use of a two-tailed test reflects the bidirectional nature of our hypotheses, accommodating the possibility of differences in either direction.

In summary, the proposed statistical design, including the determination of sample size, is based on rigorous power analysis and is designed to yield reliable and valid results, contributing valuable insights into the prevalence and characteristics of hypertension among Navaho populations.

References

[1] Harmon, M.E., Campen, M.J., Miller, C., Shuey, C., Cajero, M., Lucas, S., Pacheco, B., Erdei, E., Ramone, S., Nez, T. and Lewis, J. 2016. Associations of Circulating Oxidized LDL and Conventional Biomarkers of Cardiovascular Disease in a Cross-Sectional Study of the Navajo Population. *PloS One*. 11, 3 (2016), e0143102. DOI:<https://doi.org/10.1371/journal.pone.0143102>.