Sample size for the effect of a firefighter helmet-mounted device on the length of fire incidents in the US: cross-sectional study

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From: Felipe Figueiredo **To:** Mike Ralston

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- CI: confidence interval
- FD: fire department
- SD: standard deviation

2 CONTEXT

2.1 Objectives

To determine the minimum sample size required to detect a correlation between the proportion of firefighters in fire departments that use the helmet-mounted device under investigation and the length of fire incidents.

2.2 Hypotheses

The length of fire incidents is correlated with the usage of the helmet-mounted device under investigation.

3 DATA

3.1 Raw data

Upon study start the raw data will be collected in a raw table, that will be processed before analysis. The raw dataset to be collected will have 3 variables.

This dataset will include the measurements of average length of time for fire incidents and the proportion of usage of the device in each FD. Table 1 shows the structure of the raw dataset.

Table 1 *Raw dataset structure.*

id	usage	fire
1		
2		
3		
…		
N		

Each row represents all information collected from each FD, and each department included will require a unique study ID. The study outcome (fire in Table 1, defined in section 4.4) should be recorded in minutes. The exposure (usage in Table 1, defined in section 4.3) should be recorded either as a proportion (between 0 and 1) or a percentage (between 0 and 100), as long as all records reflect the same coding choice.

3.2 Analytical dataset

After the cleaning process 3 variables will be included in the analysis. The total number of observations excluded due to incompleteness and exclusion criteria will be reported in the analysis.

All variables in the analytical set will be labeled according to the raw data provided and values will be labeled according to the data dictionary for the preparation of production-quality results tables and figures.

4 STUDY PARAMETERS

4.1 Study design

Cross-sectional study, with the fire departments as the unit of measurement.

4.2 Inclusion and exclusion criteria

N/A

4.3 Exposures

Proportion of the time firefighters use the helmet-mounted device in the FD during an incident.

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Fire fighting
2. (Specific measurement) Length of fire incident
3. (Specific metric) End value
4. (Method of aggregation) Mean

Primary outcome

Average length of fire incidents put out by the FD.

4.5 Covariates

N/A

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The typical profile of the fire departments will be described as mean (SD) or as counts and proportions (%), as appropriate. The distributions of departments' characteristics will be summarized in tables and visualized in exploratory plots.

5.1.2 Inferential analyses

The Pearson correlation coefficient between the usage of the helmet-mounted device and the average length of fire incidents will be estimated. The CI and associated p-value will be reported together with the correlation estimate.

5.1.3 Statistical modeling

N/A

5.1.4 Missing data

No missing data imputation will be performed. All evaluations will be performed as complete case analyses. Missing data counts and proportions will be reported in tables.

5.2 Significance and Confidence Intervals

All analyses will be performed using the significance level of 5%. All significance hypothesis tests and confidence intervals computed will be two-tailed.

5.3 Study size and Power

This study aims to detect a correlation between usage of the device and the length of fire incidents, with 80% statistical power and 5% significance. Here we evaluate a number of target correlations, with effect sizes ranging from very small to moderate (Cohen, 1988).

Table 2 *Effect sizes (r) and the number of FD (n) required to achieve 80% statistical power.*

effect	r	n
very small	0.05	3137
small	0.10	782
small	0.15	346
small	0.20	194
small	0.25	123
moderate	0.30	85
moderate	0.35	61
moderate	0.40	46

Table 2 shows the minimum sample sizes required to achieve 80% power given various effect sizes. A study sized to collect data from 194 FD would be sufficiently powered to detect a correlation higher than 0.2 or lower than -0.2.

Conversely, if data from 80 FD are available, such a study would be suitable to detect a correlation stronger than 0.31 with 80% power, in any direction (Figure 1).

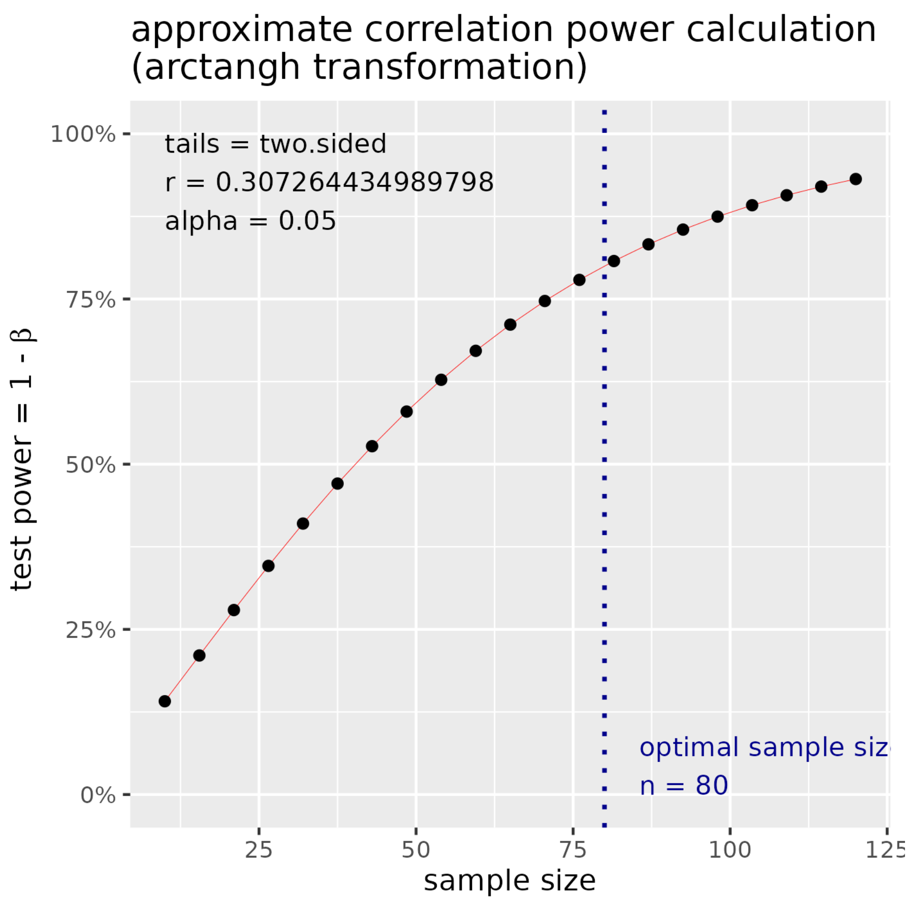

Figure 1 *Minimum effect size detectable with 80% power on a sample of 100 FD.*

5.4 Statistical packages

This analysis will be performed using statistical software R version 4.3.0.

6 OBSERVATIONS AND LIMITATIONS

Assumptions and simplifications

By taking averages and calculating the correlation on FD there is the implicit assumption that all FD are similar or comparable to one another. This simplification is required to allow for the methods chosen for the analysis, and thus the sample size calculation.

To provide a better estimate of an effect of the helmet-mounted device on the length of fire incidents one could use data from individual firefighters, grouped into their FD of allocation. This implies nesting individuals into their respective FD and possibly grouping those into a geographical stratum like county, state, or both. This hierarchical structure can only be represented under a mixed-effects modeling approach for analysis, but there are no sample size calculation formulae for these types of models. A substantially different technique would be required to calculate a suitable sample size under this analysis methodology, that involves the creation of simulated datasets that mimic what real world data would look like.

Recommended reporting guideline

The adoption of the EQUATOR network (http://www.equator-network.org/) reporting guidelines have seen increasing adoption by scientific journals. All observational studies are recommended to be reported following the STROBE guideline (von Elm et al, 2014).

7 REFERENCES

- Cohen, J. (1988). Statistical power analysis for the behavioral sciences (2nd Ed.). New York: Routledge.
- Zarin DA, et al. The ClinicalTrials.gov results database – update and key issues. N Engl J Med 2011;364:852-60 (https://doi.org/10.1056/NEJMsa1012065).
- Gamble C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA. 2017;318(23):2337–2343 (https://doi.org/10.1001/jama.2017.18556).
- von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Int J Surg. 2014 Dec;12(12):1495-9 (https://doi.org/10.1016/j.ijsu.2014.07.013).

8 APPENDIX

This document was elaborated following recommendations on the structure for Statistical Analysis Plans (Gamble, 2017) for better transparency and clarity.

8.1 Availability

All documents from this consultation were included in the consultant's Portfolio.

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2023-024-MR/