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# Sample size calculation for prevalence of sleep disturbance in competitive senior level judo athletes in Canada

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## Document version

Version	Alterations
01	Initial version

## 1 ABBREVIATIONS

- CI: confidence interval
- PSQI: Pittsburgh Sleep Quality Index

## 2 CONTEXT

### 2.1 Objectives

Calculate the minimum sample size to be able to detect the prevalence of sleep disturbance as measured by the Pittsburgh Sleep Quality Index in competitive senior level judo athletes in Canada.

### 2.2 Hypotheses

It is hypothesized that the prevalence of sleep disorders is high in competitive senior level judo athletes in Canada leading to psychological distress, on the order of 20%.

## 3 DATA

No data analysis is planned at this stage.

### 3.1 Raw data

N/A

### 3.2 Analytical dataset

N/A

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## 4 STUDY PARAMETERS

### 4.1 Study design

This is a single-arm cross-sectional study.

### 4.2 Inclusion and exclusion criteria

Competitive senior level judo athletes aged 18+ years old will be included.

### 4.3 Exposures

As this is a single-arm study, no exposures were defined for the prevalence calculation.

### 4.4 Outcomes

**Specification of outcome measures** (Zarin, 2011):

1. (Domain) Sleep quality
2. (Specific measurement) Pittsburgh Sleep Quality Index
3. (Specific metric) End value
4. (Method of aggregation) Proportion of participants with PSQI > 5

#### Primary outcome

Proportion of study participants with PSQI > 5.

### 4.5 Covariates

N/A

## 5 STATISTICAL METHODS

### 5.1 Statistical analyses

No data analysis is planned at this stage.

#### 5.1.1 Descriptive analyses

N/A

#### 5.1.2 Inferential analyses

N/A

### 5.1.3 Statistical modeling

N/A

### 5.1.4 Missing data

N/A

## 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

The sample size calculation was done using the method described in Humphry (2004), which adjusts for imperfect diagnostic sensitivity and specificity. The parameters used in the calculation are shown in Table 1. The target population accounted for 3839 senior competitive judo athletes in November, 2022. Considering the hypothesized 20% true population prevalence the tolerance of 50% around this hypothesized value which would give a 95% CI of 10% to 30%.

**Table 1** Parameters for sample size calculation.

Parameter	Value
Target population size (chosen)	3839
True population prevalence (assumed)	20%
Tolerance (chosen)	50%
Diagnostic sensitivity (chosen)	89.6%
Diagnostic specificity (chosen)	86.5%

Assuming a sensitivity of 89.6% and a specificity of 86.5%, the sample size calculated of 136 is sufficient to detect a prevalence of 20% in the target population, within the specified tolerance.

## 5.4 Statistical packages

This analysis was performed using statistical software R version 4.2.1. The methods for the sample size calculated were implemented in the epiR package version 2.0.53.

## 6 OBSERVATIONS AND LIMITATIONS

### 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

- Humphry RW, Cameron A, Gunn GJ. A practical approach to calculate sample size for herd prevalence surveys. *Prev Vet Med.* 2004 Oct 14;65(3-4):173-88. (<https://doi.org/10.1016/j.prevetmed.2004.07.003>).
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- 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-2022-036-TV/>