Analytical Plan for Impact of traffic infractions on the incidence of vehicle accidents in young adults with ADHD: cohort study

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Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- ADHD:
- CI: confidence interval
- IRR: incidence rate ratio
- LNCG:
- SD: standard deviation

2 CONTEXT

2.1 Objectives

To determine whether traffic infractions predict higher incidence rate of traffic accidents in young adults with ADHD, compared to LNCG young adults.

2.2 Hypotheses

- The incidence rate of traffic accidents of ADHD participants is different than the LNCG group;
- The incidence rate of traffic accidents is associated with traffic infractions.

3 DATA

3.1 Raw data

The original data base had 245 variables collected on 4565 observations.

3.2 Analytical dataset

After the cleaning process 21 variables were included in the analysis. The total number of observations excluded due to incompleteness and exclusion criteria will be reported in the analysis. Table 1 shows the structure of the analytical dataset.

Table 1 *Analytical dataset structure after variable selection and cleaning.*

ID	STATUS	ASS	outcome	EXP	AGE	SEXMF	A1	B1	C1	D1	E1	F1	G1	H1	I1	J1	K1	L1	X1	Y1
1																				
2																				
3																				
…																				
N																				

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

4 STUDY PARAMETERS

4.1 Study design

This is a retrospective longitudinal analysis on data collected for a prospective cohort study.

4.2 Inclusion and exclusion criteria

Only data from assessment points 144, 168 and 192 will be used in the analysis.

4.3 Exposures

ADHD Status.

4.4 Outcomes

Specification of outcome measures (Zarin, 2011):

1. (Domain) Driving behavior
2. (Specific measurement) Vehicle accidents
3. (Specific metric) End-value
4. (Method of aggregation) Incidence rate

Primary outcome

Incidence rate of vehicle accidents, defined as the number of cases over the driving experience, in years.

4.5 Covariates

1. Assessment Point
2. Subject Age
3. Gender
4. Driving without a seatbelt
5. Driving without expired tags or registration
6. Driving without a valid license
7. Driving without insurance
8. Illegally parking
9. Illegally turning
10. Speeding
11. Failing to stop to sign or signal
12. Fail to yield right-of-way
13. Tailgating
14. Reckless driving
15. DUI – Alcohol
16. DUI – Other substances
17. Using cellphone while driving

5 STATISTICAL METHODS

5.1 Statistical analyses

5.1.1 Descriptive analyses

The epidemiological profile of the study participants will be described. Demographic and clinical variables will be described as mean (SD) or as counts and proportions (%), as appropriate. The distributions of participants' characteristics will be summarized in tables and visualized in exploratory plots.

5.1.2 Inferential analyses

All inferential analyses will be performed in the statistical models (described in the next section).

5.1.3 Statistical modeling

The aim of this analysis is to assess the effect of the exposure on the number of vehicle accidents, tracking characteristics of individual participants across a number of assessment points. A multiple mixed-effect Poisson regression will be fitted to regress the IRR (defined in Section 4.4) of the exposure ADHD over the unexposed LNCG, controlling for the covariates defined in section 4.5. The natural log of the driving experience will be used as the offset of the Poisson model, so that the IRR can be calculated as the number of cases over the driving experience. To ensure no negative values are passed to the log transformation, a single constant will be added to all values, which will be chosen below the minimum value observed. The participant ID will be used as a random intercept to account for the incidence rates' trajectories of individuals over the study period. This modeling approach is able to track the both the status and characteristics of individuals over the repeated measurements that were done during the study period.

The modeling strategy planned is to reduce the model complexity until a suitable set of predictors is found that produces model convergence, starting with all covariates available. In the first step a full model including all covariates will be fitted, and estimates' significance will be evaluated. Next steps will start with only the predictors that are significantly associated with the outcome, and continue by testing adding one predictor at each further step, and checking if the added predictor is significantly associated with the outcome or should be dropped. This procedure will be repeated until a model is achieved with only significant predictors included. All models attempted will control for age, sex and assessment point. We do not plan to use stepwise selection to specify the final model.

The IRR estimates will be reported based on the final model, and the initial full model will be included in the Appendix of the report.

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

N/A

5.4 Statistical packages

This analysis will be performed using statistical software R version 4.2.3.

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

- **SAR-2023-015-RQ-v01** – Impact of traffic infractions on the incidence of vehicle accidents in young adults with ADHD: cohort study
- 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 Associated analyses

This analysis is part of a larger project and is supported by other analyses, linked below.

Effect of ADHD on the incidence of driving infractions and accidents in young adults: cohort study

https://philsf-biostat.github.io/SAR-2023-014-RQ/

8.2 Availability

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

The portfolio is available at:

https://philsf-biostat.github.io/SAR-2023-015-RQ/