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

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

Document version

Version	Alterations
01	Initial version

1 ABBREVIATIONS

- ADHD:
- CI: confidence interval
- LNCG:
- OR: odds ratio
- SD: standard deviation

2 CONTEXT

2.1 Objectives

To describe the impact of ADHD with the incidence of various driving infractions and accidents in young adults.

2.2 Hypotheses

The incidence odds of the ADHD young adults is different from the incidence odds of the LNCG young adults.

3 DATA

3.1 Raw data

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

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3.2 Analytical dataset

After the cleaning process 23 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 Analytical dataset structure after variable selection and cleaning.

ID	STATUS	ASS	SEXMF	AGE	HI_16E	HI_18A	HI_25	SM_4C	A1	E1	F1	G1	H1	I1	J1	K1	L1	X1	Y1	V2A	HEV	EXP	
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) Infractions or accidents
3. (Specific metric) End-value
4. (Method of aggregation) Odds

Primary outcome

Odds of various driving infractions or accidents.

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1. Driving without a seatbelt
2. Illegally parking
3. Illegally turning
4. Speeding
5. Failing to stop to sign or signal
6. Fail to yield right-of-way
7. Tailgating
8. Reckless driving
9. DUI – Alcohol
10. DUI – Other substances
11. Using cellphone while driving
12. I was NOT a driver in an accident in the past 2 years

4.5 Covariates

1. Gender
2. Driving Experience
1. Assessment Point
2. Generalized Anxiety Disorder Status
3. Major Depressive Disorder Status
4. ADHD Medication Status
5. Marijuana Use
6. Heavy alcohol user

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 a number of binary outcomes, tracking both outcomes and characteristics of individual participants across a

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number of assessment points. Multiple mixed-effect logistic regressions will be fitted to regress each outcome in Section 4.4 on the exposure ADHD, controlling for the covariates defined in section 4.5. The participant ID will be used as a random intercept to account for the odds' 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 variables is found that produces convergence on all models, starting with all covariates considered relevant from the literature. In order to keep the largest feasible set of covariates the categorical variables with the most amount of levels will be considered for dropping before, since these contain the largest numbers of parameters for estimation. We do not plan to apply stepwise selection to the models. The resulting set of variables will be applied to all models in the analysis, accounting for all outcomes in section 4.4.

The reporting of the incidence OR will focus on the effect of the exposure coefficients, and a comprehensive list of all models' coefficients will be reported 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-2023-014-RQ-v01** – Effect of ADHD on the incidence of driving infractions and accidents in young adults: 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.

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

<https://philsf-biostat.github.io/SAR-2023-015-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-2023-014-RQ/>