

Observational studies guidelines

[TITLE] The authors should indicate the study's design with a commonly used term in the title or the abstract

Authors:

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ABSTRACT [Maximum Length 300 Words]

Background

- Describe the study design, including whether it is a cohort study, case-control study, or cross-sectional study. Clearly state the specific objective or hypothesis that your study aimed to address.

Methods

- Provide a detailed description of the setting, including follow-up dates or the dates when the outcome events occurred or were observed.
- Specify any relevant time points or ranges on other time scales related to the outcomes, such as prevalence at age 18 or a time frame like 1998-2007.

Participants

For a Cohort Study:

- Please provide the key eligibility criteria for participants.
- Describe the primary sources and methods used to select participants.
- Briefly outline the methods employed for follow-up.

For matched studies;

- Please describe the matching criteria used.
- Provide the number of exposed participants and unexposed participants.

For a Case-Control Study:

- Specify the major eligibility criteria for cases and controls.
- Describe the primary sources and methods used for identifying cases and selecting controls.

For matched studies;

- Specify the matching criteria applied.
- Indicate the number of controls per case for matched studies;

For a Cross-Sectional Study:

- Provide the eligibility criteria for participants.
- Outline the major sources and methods employed for participant selection.

Variables

- Provide a clear and concise definition of the primary outcome for this report.

Statistical Methods

- Explain the statistical methods utilized in this analysis, including any techniques employed to mitigate confounding factors.

Results

- Provide the number of participants at the start and conclusion of the study
- Present the estimated associations, and if applicable, consider converting relative risk estimates into absolute risk for a specific relevant time frame.
- Include suitable measures of variability and uncertainty, such as odds ratios with confidence intervals

Conclusion

- Provide a general interpretation of the study results.

INTRODUCTION

- Elaborate on the scientific background and rationale that underpin the investigation being presented.
- Clearly articulate the specific objectives of the study, which may include any hypotheses that were predetermined.

METHODS

- Present essential elements of the study design at the beginning of the section.
- Provide a comprehensive description of the setting, including details about locations and pertinent dates such as recruitment periods, exposure periods, follow-up, and data collection.

Participants

For a Cohort Study:

- Provide the eligibility criteria for participants.
- Describe the sources and methods used to select participants.
- Explain the methods employed for follow-up.

For a Case-Control Study:

- Specify the eligibility criteria for cases and controls.
- Describe the sources and methods used to identify cases and select controls.
- Provide the rationale for choosing specific cases and controls.

For a Cross-Sectional Study:

- Provide the eligibility criteria for participants.
- Describe the sources and methods employed for participant selection.

For Matched Studies in Cohort and Case-Control Studies:

- Describe the matching criteria used.
- Provide the number of exposed and unexposed participants (Cohort Study) or controls per case (Case-Control Study)

Variables

- Provide clear definitions for all outcomes, exposures, predictors, potential confounders, and effect modifiers. If applicable, include diagnostic criteria.

Data sources / Measurement

- For each variable of interest, specify the sources of data and provide a detailed description of the methods used for assessment or measurement. If there are multiple groups, please also describe the comparability of the assessment methods.

Bias

- Explain any steps taken to mitigate potential sources of bias.

Study Size

- Provide an explanation of the rationale behind determining the study size.

Quantitative Variables

- Detail how quantitative variables were managed in the analyses. If relevant, discuss the chosen groupings and the reasoning behind their selection.

Statistical Methods

- Provide a comprehensive description of all statistical methods employed, including those used for confounding control.
- Detail any methods used for subgroup and interaction analysis.
- Explain the strategies used to address missing data.
- Cohort study: If applicable, describe how loss to follow-up was managed.
- Case-control study: If applicable, explain the approach used for matching cases and controls.
- Cross-sectional study: If applicable, discuss analytical methods considering the sampling strategy.
- Describe any sensitivity analyses conducted.

RESULTS

Participants

- Present the counts of individuals at various stages of the study, including the numbers who were potentially eligible, examined for eligibility, confirmed as eligible, included in the study, those who completed follow-up, and those analyzed.
- Provide explanations for non-participation at each stage.
- It is advisable to consider utilizing a flow diagram to visually depict the progression of participants through the study.

Descriptive Data

- Provide a comprehensive description of the characteristics of study participants, including demographic, clinical, and social factors, as well as details regarding exposures and potential confounders.
- Indicate the number of participants with missing data for each variable of interest.
- For cohort studies, summarize the follow-up time, including average and total duration.

Outcome Data

Cohort Study:

- Report the numbers of outcome events or provide summary measures over time.

Case-Control Study:

- Report the numbers within each exposure category or provide summary measures of exposure.

Cross-Sectional Study:

- Report the numbers of outcome events or provide summary measures.

Main Results

- Present unadjusted estimates and, if applicable, confounder-adjusted estimates, along with their precision, such as the 95% confidence interval. Clearly specify which confounders were adjusted for and provide the rationale for their inclusion.
- When continuous variables have been categorized, report the category boundaries.
- If relevant, consider converting estimates of relative risk into absolute risk for a meaningful time period.

Other Analyses

- Include a description of any additional analyses conducted, such as subgroup and interaction analyses, as well as sensitivity analyses.

DISCUSSION

- Provide a concise summary of the main findings, aligning them with the study's objectives.
- Engage in a thorough discussion of the study's limitations, acknowledging potential sources of bias and imprecision. Consider both the direction and magnitude of potential bias.
- Present an overall interpretation of the results, while maintaining a cautious approach. Take into account the study's objectives, limitations, the possibility of multiple analyses, findings from similar studies, and any other relevant evidence.

- Explore the applicability of the study's results to a broader context and discuss their generalizability or external validity.

Other

- Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.

Last Checks

- The resolution of the images used should be of high quality.
- Consent should be obtained from the patient for the use of images, and the source should be accurately referenced.
- The references used should not be older than 7 years.
- The tables used should be clear and informative.