# Interesting Title Including Study Design: Some Subtitle

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# Additional information

We have no known conflict of interest to disclose.

Acknowledgments

Something.

#### **Abstract**

**Background** The first sentence orients the reader by introducing the broader field in which the particular research is situated.

**Objectives** What is missing in the literature (ie, the specific gap) and why that matters.

**Methods** Describe the novel method or approach that you used to fill the gap or question.

**Results** Executive summary of the results.

**Discussion** Interpret the results to answer the question that was posed at the end of the context section.

*Keywords*—something

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• Place all in-text citations immediately after the information cited, using superscript numbers. Place citation numbers outside periods and commas but inside colons and semicolons.

#### 1 Introduction

# 5 1.1 Background

- Explain the scientific background and rationale for the investigation being reported.
- 7 Progressively more specific paragraphs that culminate in a clear exposition of what is lacking
- 8 in the literature. The introduction should not contain a broad literature review beyond the
- 9 motivation of the paper.

# o 1.2 Objectives

State specific objectives, including any prespecified hypotheses. The last paragraph compactly summarizes the results, which fill the gap just established and only briefly previews the conclusion of the paper, if at all.

# 14 **2 Methods**

# 15 2.1 Study design

#### 16 2.2 Setting

Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.

# 19 2.3 Participants

Give the eligibility criteria, and the sources and methods of selection of participants.

Describe methods of follow-up.

#### 22 2.4 Variables

Clearly define all outcomes, exposures, predictors, potential confounders, and effect

modifiers. Give diagnostic criteria, if applicable.

#### 25 **2.5 Data sources**

For each variable of interest, give sources of data and details of methods of assessment (measurement).

#### 28 2.6 Bias

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Describe any efforts to address potential sources of bias.

# 30 2.7 Study size

Explain how the study size was arrived at.

#### 2.8 Quantitative variables

Explain how quantitative variables were handled in the analyses.

#### 34 2.9 Statistical methods

Describe all statistical methods, including those used to control for confounding. De-

scribe any methods used to examine subgroups and interactions. Explain how missing data

were addressed. If applicable, explain how loss to follow-up was addressed. Describe any sensi-

38 tivity analyses.

3 Results

The first results paragraph is special in that it typically summarizes the overall approach to the problem outlined in the introduction, along with any key innovative methods that were developed.

# 43 3.1 Participants

Report numbers of individuals at each stage of study–eg, numbers potentially eligible,
examined for eligibility, confirmed eligible, included in the study, completing follow-up, and
analysed. Give reasons for non-participation at each stage. Consider use of a flow diagram.

# 47 3.2 Descriptive data

Give characteristics of study participants (eg, demographic, clinical, social) and information on exposures and potential confounders. Indicate number of participants with missing data for each variable of interest. Summarise follow-up time (eg, average and total amount).

#### 51 3.3 Outcome data

Report numbers of outcome events or summary measures over time.

# 3.4 Main results

52

Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included. Report category boundaries when continuous variables were categorized. If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.

# 59 3.5 Other analyses

Report other analyses done-eg, analyses of subgroups and interactions, and sensitivity analyses.

# 62 4 Discussion

# 3 4.1 Key results

Summarise key results with reference to study objectives. Explain how the results have filled the gap that was identified in the introduction. Describe how the paper advances the field by providing new opportunities.

# 57 4.2 Strenghts and limitations

Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.

# 70 4.3 Interpretation

Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.

# 73 4.4 Generalisability

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Discuss the generalisability (external validity) of the study result.

# 5 Funding

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.

6 Acknowledgments

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79 References

80	7	<b>Tables</b>

• One table per page.

8 Figures

• Maximum width of 7.5 inches.

# 9 Supplemental material

# 9.1 Supplemental tables

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• One table per page.

# 9.2 Supplemental figures

• Maximum width of 7.5 inches.