TEMPLATE FOR A CASE-CONTROL STUDY PROTOCOL

TITLE

The title should clearly reflect the study design with a commonly used term.

INTRODUCTION

The introduction should comprise of the scientific background and an explanation of the study rationale. The introduction might cover (but not limited to) the following aspects of the study:

-description of the condition

-description of the exposure variables

-description of the outcome variables

-description of any other pertinent variables

-any applicable biological pathways

-why is the study necessary

OBJECTIVES

Describe the primary and secondary objectives that the study intends to achieve. The components of a crisp objective might include the study participants, condition and outcome.

HYPOTHESIS

This section could also include the study hypothesis that are more specific than objectives and are amenable to explicit statistical evaluation.

METHODS

STUDY DESIGN:

This section describes the design and the key elements of the study.

PARTICIPANTS:

This section describes the eligibility criteria (inclusion/exclusion) used to select the participants. Also add details pertaining to the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. For matched studies, give matching criteria and the number of controls per case.

STUDY SETTINGS:

This section should include information on the settings and locations (for e.g. primary, secondary, or tertiary health care or from the community?). Also include the country, city if applicable, and immediate environment (for example, community, office practice, hospital clinic, or inpatient unit). Also describe relevant dates, including periods of recruitment, exposure, follow-up, and data collection.

VARIABLES:

This section describes how the study authors intends to define and measure the study variables. Define the variables of interest (including, but not limited to, exposure and outcome variables) in context to study objectives. Clearly define all predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.

DATA SOURCES AND MEASUREMENTS:

For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Variables for exposed and unexposed groups should be defined separately.

MEASURES TO MINIMISE BIAS:

Describe any measures that will be taken to minimise bias in the study. Some of the design-specific bias to tackle might include: similarity in baseline outcome measurements, similarity in baseline characteristics, incomplete outcome data, protection against contamination and selective reporting.

SAMPLE SIZE:

This section describes how the sample size will be determined. The elements of sample size calculation include consideration of the alpha error, beta error, clinically meaningful difference, variability or standard deviation, a safety margin and the dropout rate.

STATISTICAL METHODS:

This section should include details pertaining to:

-data collection methods: details on the methods for collection of data and appropriate tool descriptions (questionnaire etc.)

-data analysis methods: Statistical methods to be used to compare groups exposure and outcome variables. This section should also include statistical measures to be used to control for confounding, examining subgroups and interactions, addressing missing data, explaining how matching of cases and controls will be addressed and any potential sensitivity analysis planned.

REFERENCES

Annotated bibliography.