**TEMPLATE FOR A PRE-POST 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 intervention/variables*

*-how the intervention might work/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, intervention and outcome.*

**HYPOTHESIS**

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

**OPERATIONAL DEFINITIONS**

*Define the variables of interest (including, but not limited to, exposure and outcome variables) in context to study objectives. This section describes how the study authors intends to define and measure the study variables.*

**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 recruitment at both pre- and post- intervention.*

***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.*

***INTERVENTION(S):***

*This section includes detailed description of the interventions with sufficient details to allow replication, including how and when they were actually administered.*

***OUTCOME(S):***

*This section should include all the pre-specified primary and secondary outcome measures. Each outcome must be clearly defined including the details pertaining to how and when they will be assessed.*

***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 for primary and secondary outcome*

**REFERENCES**

Annotated bibliography.