

## Statistical Analysis Plan Template

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### 1. Review of statistical design

Insert relevant summary from the trial protocol including:

- Primary and secondary hypotheses
- Sample size evaluation
- Analysis plan (primary and secondary as stated in the protocol)

Note: this can be a direct copy of the relevant parts of the protocol. The purpose is to establish that the analysis plan follows exactly from the trial design.

### 2. Analysis Plan

#### 2.1 Preliminary evaluation of data:

**Purpose:** To identify issues that will affect our approach to the primary analysis. Specifically:

- To summarize the amount of missing data for key variables.
- To summarize time between baseline and follow-up key measurements.
- To examine the distributional characteristics of key variables in order to detect potential data entry/reduction errors.

**Methods:** (Combined intervention groups). Relevant approaches may include:

- Tabulation of descriptive statistics for key variables (including missing observations).
- Histograms, quantile plots of baseline levels and follow-up measures and changes in those measures.

#### 2.2 Description of study process

**Purpose:** To compare how the study unfolded with the pre-trial plan in order to determine if changes in the pre-trial analysis plans are warranted.

**Methods/Approach:**

- Study flow figure (see CONSORT statement)
- Number screened; number enrolled
- Subjects randomized (number to each group)
- Retention by group
- Final completion rates
- Number of subjects in analysis data sets

#### 2.3 Description of participant

**Purpose:**

**Methods/Approach:** Construct "table 1" describing the baseline characteristics of each intervention group including:

- Demographic characteristics (e.g., age, sex, socioeconomic status)
- Baseline exposure characteristics (e.g., smoke exposure)
- Baseline disease characteristics
- Baseline values of primary and/or secondary outcome variables (note, this may be a separate table)

#### 2.4 Primary analysis/results

**Purpose:** Primary results for the intention to treat (ITT) analysis.

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**N Colangelo**



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