

Statistical Analysis Plan Template

John M. Kibeleon, PhD

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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