Statistical analysis plan outline

Version _____ Date _____ Approved by _____. Date this plan before outcome analyses begin.

1. Administrative information

Title, version number and date, link to the protocol or ethics approval, who wrote and who approved the plan, and a version history.

2. Background and objectives

The research questions and hypotheses exactly as they will be tested, each numbered so analyses can refer back to them.

3. Study design

Design (for example cross-sectional survey, cohort, randomised trial), setting, timing of measurements, and any randomisation or blinding.

4. Sample size

The target sample and how it was justified (power calculation with the effect size, alpha, power and its source; or a precision or feasibility rationale).

5. Variables and outcomes

Each outcome and predictor with its definition, measurement instrument, scoring, level of measurement and time point. Name one primary outcome where your design has one.

6. Analysis populations

Who is included in which analysis (for trials, for example, intention-to-treat and per-protocol), and the eligibility rules applied before analysis.

7. Data management and cleaning

Range and consistency checks, handling of outliers (rule decided in advance), derived variables, and the software and version you will use.

8. Missing data

How much you expect, how you will describe it, the assumed mechanism, and the main approach (for example complete-case or multiple imputation) with a sensitivity analysis.

9. Descriptive statistics

Which summaries for which variables (mean and SD, median and IQR, counts and percentages), and the planned baseline or sample table.

10. Primary analysis

For each hypothesis: the test or model, covariates and why, the effect measure with its confidence interval, and the significance level, sided-ness included.

11. Assumption checks and fallbacks

Each assumption of the planned test, how it will be checked (plot or test), and what you will do if it is not met, decided now.

12. Secondary and exploratory analyses

Listed separately and labelled as such, so they are not mistaken for confirmatory tests.

13. Multiplicity

How you will handle multiple outcomes, groups or time points (for example a correction method, a hierarchy, or stating that results are exploratory).

14. Sensitivity and subgroup analyses

Which ones, why, and how subgroup effects will be tested (an interaction term, not separate p-values per subgroup).

15. Reporting

Planned tables and figures, decimal places, and the reporting guideline you will follow (for example CONSORT or STROBE).

16. Deviations log

A dated record of every change after the plan was fixed, with the reason and whether it was made before or after seeing outcome data.

Hypothesis-to-test table

Hypothesis	Outcome and predictor(s)	Planned test / model	Assumptions and how checked	Fallback if not met

Deviations log

Date	What changed	Why	Outcome data seen? (Y/N)

Adapted and simplified from Gamble C, et al. JAMA 2017;318(23):2337-2343. For regulated clinical trials use the full guideline.

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