# STATISTICAL ANALYSIS PLAN FOR RANDOMISED TRIALS

*This template is recommended by IGL for pre-specifying the details of the statistical analysis that will be used to assess the outcomes from randomised trials. Using a pre-specified statistical analysis plan adds greatly to the credibility of the findings of a trial, by demonstrating that the researcher has not engaged (even unconsciously) in* [*specification search*](https://www.aeaweb.org/articles?id=10.1257/jel.20171350)*. The statistical analysis plan will also enable the evaluator or researcher to carry out key analysis rapidly once the outcome data becomes available, so that the key findings from the trial can be made available in a timely fashion.*

*The statistical analysis plan should be completed and registered online* ***before the collection of outcome data takes place****. Preparing the statistical analysis plan provides an opportunity to revise the outcome measures that were defined in the trial protocol, based on learning about the measurement approaches from the baseline data and/or on changes in the project team’s expectations of the outcomes that may be affected by the treatment(s). It is important to* ***review the outcome measures with the project implementation or delivery team*** *before completing the statistical analysis plan, so that any changes in expectations about the most appropriate outcome measures are reflected in this plan.*

*Sections 4, 6 and 7 of this template include recommendations on approaches that are suitable for the majority of trials supported by IGL. These recommendations are in line with the guidance set out in IGL’s* [*Quantitative analysis guide*](https://www.innovationgrowthlab.org/quantitative-analysis-guide)*. However, since trials vary in their design and context, there may be good reasons for diverging from these recommendations in particular cases.*

**1. INTRODUCTION**

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| **1.1 Project title** | *Descriptive title identifying the study design, population and intervention.* |
| **1.2 Trial protocol** | *Reference to version number and date of trial protocol (include a link if trial protocol is available online)* |
| **1.3 Trial registration** | *Link to trial registration (e.g. on* [*https://www.socialscienceregistry.org/*](https://www.socialscienceregistry.org/)*)* |
| **1.4 Author(s) of statistical analysis plan** | *Name and affiliation of the author(s) of this document* |

**2. DOCUMENT HISTORY**

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| **Version number** | **Date** | **Significant changes made** |
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**3. LOGIC MODEL**

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| **Has the project’s logic model (setting out the underlying logic or theory of change and a set of assumptions about how an intervention works) changed since the trial protocol was completed?** If yes, insert an updated version of the logic model and a brief description of the changes below. | *Yes/No* |
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**4. PRELIMINARY CHECKS**

Describe the checks that will be carried out before beginning data analysis. This will normally include a check that the treatment and control groups are balanced in their baseline (pre-intervention) characteristics, as a confirmation that the randomisation worked as expected and that there has not been significant attrition bias.

In most cases it is also useful to revise the power calculations set out in the trial protocol, to establish the minimum detectable effect size that can be estimated from the data available. If the minimum detectable effect size is larger than the minimum policy-relevant effect size, the findings of the trial may not be useful for informing future policy decisions: if so, a change in evaluation approach may be required.

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|  | **Default approach (IGL recommendation)** | **Approach to be used** |
| **Balance checks** | *Produce a table showing the means of the baseline characteristics in each of the treatment and control groups.*  *Carry out an F-test for joint significance of these characteristics in predicting treatment status. (*[*More information here*](https://mattblackwell.org/files/teaching/ftests.pdf)*.)*  *Carry out the steps above twice: once for the sample as originally randomised, and once for the sample as analysed.* |  |
| **Power calculations** | *Revise the power calculations set out in the trial protocol, calculating the ex-post minimum detectable effect size with the sample available for analysis and with estimates of the standard deviations and (if relevant) intra-cluster correlations from the baseline data or from the control group in the final dataset. (*[*More information here.*](https://blogs.worldbank.org/impactevaluations/why-ex-post-power-using-estimated-effect-sizes-bad-ex-post-mde-not)*)* |  |

**5. CONSTRUCTION OF KEY VARIABLES**

5.1 OUTCOME MEASURES

For each of the primary and secondary outcome measures, describe exactly how the measures will be constructed from the raw data. Enough detail should be included to allow your analysis to be replicated exactly. Annexing a file with the code that will be used to do this in your statistical software is ideal.

In the right-hand column, note any changes in the outcome measures that have been made since the trial protocol was finalised. This may include changes in the definition of the outcome measures or in whether each are to be considered as primary or secondary measures.

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| **Primary or secondary outcome?** | **Description of variable** | **Detailed definition** (referring to question numbers from survey instruments, if applicable) | **Any significant changes made since the trial protocol** |
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5.2 CONTROL VARIABLES

Describe the construction of each of the variables that will be used as control variables/covariates in your main analysis, if any.

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| **Description of variable** | **Detailed definition** (referring to question numbers from survey instruments, if applicable) |
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**6. DATA CLEANING**

Describe any steps that you intend to take to prepare the data for analysis, including whether any observations will be excluded from the analysis and how you will deal with missing data.

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|  | **Default approach (IGL recommendation)** | **Primary approach to be used** | **Any alternative approaches to be used as robustness checks** |
| **Handling of missing data in outcome measures** | *Either exclude observations with missing values from the analysis (if there is limited missing data or evidence that it is missing at random)*  *or calculate Manski bounds (if the outcome measure is binary or discrete and attrition is low).* |  |  |
| **Handling of missing data in covariates** | *If less than 10% of observations have missing data, replace with the unconditional mean of the variable in the non-missing observations. Otherwise, replace the missing values with zero and create an additional variable indicating missingness, to be included as an additional covariate.* |  |  |
| **Criteria to be used to exclude observations from the analysis** | *None* |  |  |
| **Any additional data cleaning** | *None* |  |  |

**7. MAIN ANALYSIS**

Describe in detail how you will carry out the main analysis of outcomes in your trial.

The information below should apply to the analysis of both primary and secondary outcome measures. If a different approach is being used for the analysis of secondary outcomes, then this should be noted.

|  | **Default approach (IGL recommendation)** | **Primary approach to be used** | **Any alternative approaches to be used as robustness checks** |
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| **Type of treatment effect to be estimated** (estimand) | *Intention to treat (ITT)* |  |  |
| **Treatment groups to be compared** | *If the trial has two arms: treatment group against control group.*  *If the trial has more than two arms, specify which comparisons you expect to have sufficient statistical power for, and adjust for multiple comparisons in your inference (see below).* |  |  |
| **Type of statistical test** | *First step: unadjusted t-test (for continuous variables) or chi-squared test (for binary variables)*  *Second step: estimate linear regression/linear probability model using ordinary least squares (for continuous or binary variables)* |  |  |
| **Covariates** | *First step: no covariate adjustment*  *Second step: adjust for (i) stratification variables, (ii) baseline values of outcome variables, (iii) any other variables that are strongly predictive of the outcome in the baseline data.* |  |  |
| **Weighting of observations** | *Weight observations equally unless there is a reason for an alternative weighting.* |  |  |
| **Accounting for clustering in sampling or random- isation** | *(Applies only if using a clustered design.) If there are at least 50 clusters, calculate cluster-robust standard errors. If there are fewer than 50 clusters, calculate randomisation inference-based standard errors, or use a cluster-aggregated approach.* |  |  |
| **Subgroup analysis** | *None, or (if statistical power allows) only carry out subgroup analysis among groups that were used for stratification.* |  |  |
| **Correction for multiple comparisons** | *(Applies if there is more than one primary outcome measure, or more than two trial arms, or if any subgroup analysis is being carried out.) Calculate the family-wise error rate, using Bonferroni correction or an alternative method.* |  |  |
| **Statistics to be reported** | *Point estimates, 95% confidence intervals and continuous p-values* |  |  |

**8. SUPPLEMENTARY ANALYSIS**

Describe any additional analysis that you are planning to carry out with the trial data. This may include:

* Estimation of alternative types of treatment effect (e.g. estimate of the local average treatment effect, LATE, among those who complied with the treatment)
* Estimation of treatment effects on additional outcome measures
* Estimation of treatment effects among additional subgroups

Evaluators are free to conduct any additional exploratory analysis once the data is available. However, specifying in advance the analysis that will be carried out adds credibility to the findings, by reducing the potential for specification search.

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| **Type of analysis** | **Details** |
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