# YEF statistical analysis plan

**This template should be used to complete Statistical Analysis Plans (SAPs) for all trials ideally within three months from randomisation.** The SAP should be written for a statistician or analyst to be able to carry out the analysis without prior knowledge of the trial, in order to increase transparency, minimise bias and ensure continuity if there are any key changes in the evaluation team composition during the trial. The SAP will be reviewed by a member of the YEF Evaluation Team and by a member of the YEF SAP review panel and will be published online. The SAP should be read in conjunction with the protocol and it should not duplicate extensive content included in the protocol. The protocol and SAP template are based on the CONSORT-SPI extension and where appropriate a reference to the relevant CONSORT item from 1 to 26 is provided in brackets.[[1]](#footnote-1) It is the responsibility of the evaluator to ensure the SAP and the protocol are fully aligned and kept up-to-date with all changes being discussed with the YEF.

This template should be used in conjunction with the revised [YEF Statistical Analysis Guidance (DATE)](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Writing_a_Protocol_or_SAP/EEF_statistical_analysis_guidance_2018.pdf) and revised [YEF Report Template (DATE)](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Writing_a_Research_Report/EEF_evaluation_report_template_2019.docx).

**Any guidance notes (in italics) can be deleted on completion and replaced with the actual text which should not be in italics and instead in justified black Calibri font size 12 with 10pt spacing before and after and multiple 1.15 line spacing.**

|  |  |
| --- | --- |
| Project title[[2]](#footnote-2) | *e.g. The STAR programme to reduce drug use, a two-armed cluster randomised controlled trial.* |
| Developer (Institution) | *e.g. University of Greenwich* |
| Evaluator (Institution) | *e.g. Justice Research Foundation* |
| Principal investigator(s) | *e.g. Amitha Vikram* |
| SAP author(s) | *e.g. Amitha Vikram, Dr Simon Economou* |
| Trial design | *e.g. two-armed cluster randomised controlled trial with random allocation at the school level* |
| Trial type | Efficacy/ effectiveness |
| Evaluation setting | e.g. family; school |
| Target group | *e.g. 10 to 12 year olds at risk of exclusion* |
| Number of participants | *e.g. 10 schools, 100 pupils* |
| Primary outcome and data source | *e.g. exclusions (NPD)* |
| Secondary outcome and data source | *e.g. SDQ (self-report and teacher surveys)* |

# SAP version history

|  |  |  |
| --- | --- | --- |
| Version | Date | Changes made and reason for revision |
| 1.2 [*latest*] |  |  |
| 1.1 |  |  |
| 1.0 [*original*] |  | *[leave blank for the original version]* |

*Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).*

# Table of contents

* *Please insert (with section links, if possible).*

# Introduction

* *Brief description of the intervention and trial design, clarifying the purpose of the analyses to be performed (CONSORT 1b). (Please do not duplicate extensive content from the protocol.)*

# Design overview

Please ensure all details are in line with the latest version of the protocol.

|  |  |  |
| --- | --- | --- |
| **Trial design, including number of arms** | | *e.g. Two-arm, cluster randomised* |
| **Unit of randomisation** | | *e.g. Individual participant, setting* |
| **Stratification variables**  (if applicable) | | *e.g. Geographic area* |
| **Primary outcome** | variable | *e.g. Arrests* |
| measure (instrument, scale, source) | *e.g. N arrests within a two-year period, Policy National Computer (PNC)* |
| **Secondary outcome(s)** | variable(s) | *e.g. Self-regulation* |
| measure(s)  (instrument, scale, source) | *e.g. ELS Self-Regulation Scale, 0-5, survey of parents at end of first year* |
| **Baseline for primary outcome** | **variable** | *e.g. Arrests* |
| measure (instrument, scale, source) | *e.g. N arrests within a two-year period, Policy National Computer (PNC)* |
| **Baseline for secondary outcome** | **variable** | *e.g. Self-regulation* |
| measure (instrument, scale, source) | *e.g. ELS Self-Regulation Scale, 0-5, survey prior to randomisation* |

# Sample size calculations overview

Please ensure all details are in line with the latest version of the protocol.

|  | | **Protocol** | **Randomisation** |
| --- | --- | --- | --- |
| **Minimum Detectable Effect Size (MDES)** | |  |  |
| **Pre-test/ post-test correlations** | level 1 (participant) |  |  |
| level 2 (cluster) |  |  |
| **Intracluster correlations (ICCs)** | level 1 (participant) |  |  |
| level 3 (cluster) |  |  |
| **Alpha[[3]](#footnote-3)** | | 0.05 | 0.05 |
| **Power** | | 0.8 | 0.8 |
| **One-sided or two-sided?** | |  |  |
| **Average cluster size** | |  |  |
| **Number of clusters[[4]](#footnote-4)** | intervention |  |  |
| control |  |  |
| **total** |  |  |
| **Number of participants** | intervention |  |  |
| control |  |  |
| **total** |  |  |

* *Explain how the sample size was determined, whether it was determined a priori or due to practical constraints. Detail any sample size calculations that are being used (or Minimum Detectable Effect Size – MDES – if applicable), including assumptions, the reasons or sources for these assumptions (e.g., ICC, pre-post- test correlation) and any practical restrictions (e.g., the capacity of the developer) (CONSORT 7a).*
* *Evaluators may present more than one MDES scenario to demonstrate sensitivity to different assumptions but should indicate which is the main scenario being used to design the trial.*
* *Specify what is the primary population of interest. Where there are different participant groups (e.g. a programme that is delivered to all pupils in a school, but the primary population is those at risk of exclusion).*
* *Specify the software used for MDES calculation.*
* *Include an updated section with the actual sample size and MDES at randomisation using the same assumptions used at the protocol stage (see table above).*
* *Where an a priori sample size calculation was not performed, authors should not present a post hoc calculation, but rather the genuine reason for the sample size (e.g. limitations in time or delivery capacity) and the actual power to detect an effect for each result.*

# Analysis

* *Describe your statistical approach in detail to enable potential replication, ensuring you follow the latest Statistical Analysis Guidance.*
* *Provide full justification for all choices and assumptions made.*
* *Specify the chosen analysis model in full, including level(s) of analysis, covariate(s) (including any stratifiers used in the randomisation) and their source measures (instruments, scales, datasets), making sure, if relevant, that the clustered (nested) nature of the data is explicitly accounted for. For clustered trials authors should state whether the unit analysed differs from the unit of assignment, and if applicable, the analytical methods used to account for differences between the unit of assignment, intervention and analysis (CONSORT 12a).*
* *State clearly if any variable is transformed or scaled, providing a justification for this decision.*
* *State whether the methods of analysis were chosen a priori or decided after data were collected.*
* *Consider including your analysis syntax in an appendix, to increase transparency and minimise post-hoc decisions.*
* *Specify the software and version used to run the model.*

**Primary outcome analysis**

* *If more than one primary outcome is to be used, specify how the analysis will address multiple inference.*
* *For clustered data, confirm whether higher level identifiers (e.g., school, site, or area) within the model are fixed or random effects and justify your choice. For multi-site trials, this choice should be guided by the type of inference to be. ‘Conditional inference’ where we do not attempt to generalise beyond the sites within the trial is more appropriate for efficacy trials and requires the use of a fixed effects model. ‘Unconditional inference’, where we wish to generalise to the population of sites from which trial sites were sampled, is more appropriate for effectiveness trials and requires the use of a random effects model and site-by-treatment interactions. (see section on Multi-site trials in the YEF Statistical Analysis Guidance).*
* *Include the full equation for the model.*

**Secondary outcome analysis**

* *Follow the same model specification used for the primary outcome, unless there is a clear rationale against this (in which case, please explain and justify this choice).*
* *Provide the same level of detail as for the primary analysis.*

**Subgroup analyses**

* *Describe any subgroup analyses that are planned and indicate whether they were specified a priori in the protocol or have been added since (and how they are supported by the theory of change).*
* *Describe how the subgroups are constructed.*
* *When analysing subgroup effects include race and ethnicity where meaningful to do so.*
* *Describe the model including whether an interaction term or other appropriate test for heterogeneity, is used across the whole sample. Evaluators may also want to analyse a separate sub-sample containing only members of the subgroup.*
* *Distinguish between those analyses that are confirmatory and exploratory (CONSORT 12b and 18).*

**Further analyses**

* *Describe any further planned analyses (e.g., robustness checks or sensitivity analysis including other covariates, analysis to test causal mechanisms in the logic model) (CONSORT 12b).*
* *The level of detail should match that of the primary analysis.*
* *Specify whether these analyses were planned a priori and distinguish between confirmatory and exploratory analysis.*

**Interim analyses and stopping rules**

* *When applicable provide a detailed explanation of any interim analyses (including outcomes and methods of analysis) and /or stopping guidelines (CONSORT 7b).*

**Longitudinal follow-up analyses**

* *Specify any follow-up points agreed at set-up, including details of the outcome measures included, time points and number of follow-ups planned.*
* *Specify the analytical models used for these analyses.*
* *Specify whether any compliance analysis will be included in longitudinal follow-ups. If so, specify variables and analyses included.*

**Imbalance at baseline**

* *Describe how you will summarise baseline characteristics for each randomised group, including an assessment of imbalance between these group (CONSORT 15). This needs to include:*
  + *A table of baseline descriptive characteristics (including all relevant characteristics measured at baseline, including pre-intervention data on trial outcomes, potential prognostic variables and data relevant to interventions targeted at specific participant groups) for all units as they were randomised, and for those analysed. The former informs whether randomisation was successful at obtaining a balanced sample, while the latter provides evidence of whether sample attrition might have introduced an imbalance. This table may include cluster as well as participant-level characteristics. Include a justification for the characteristics chosen.*
  + *For continuous variables, report means and standard deviations. For categorical variables, report counts (including the numerator and denominator) and percentages in each category. Any differences should be discussed in the report.*

***Missing data***

* *Describe how you will consider the extent of missingness and evidence of the potential mechanism, through cross-tabulations and a ‘drop-out’ model, for example a logistic regression predicting missingness, before performing imputation (see section on Missing data in the YEF Statistical Analysis Guidance).*
* *Describe variables and specification of the drop-out model.*
* *Clarify the type and extent of missing data that will prompt imputation and/ or sensitivity analyses (including at both cluster and individual levels). When imputation is used, describe the variables used for imputation, the number of imputations performed, and the results of any sensitivity analyses to test assumptions about missing data.*

**Compliance**

* *Describe the variable(s) that will be used to define compliance with the intervention(s), clarifying the level at which compliance is defined (e.g., participant/ family/ practitioner/ setting). This might include an assessment what providers actually did (e.g. recording or coding sessions), the amount of an intervention the participants received (e.g. recording sessions attended) and contamination across groups (CONSORT-SPI 5a).*
* *Describe the analysis method to be employed including the specification of the model.*
* *Describe how you will use either Instrumental Variable (IV) or complier added causal effect (CACE) analysis to explore treatment effects in the presence of non-compliance, depending on how the variable is defined. This, or a suitable alternative, should be included here, except where intervention uptake is expected to be close to 100%. A clear justification should be provided in either case (see Section on treatment effects in the presence of non-compliance in the YEF Statistical Analysis Guidance).*

**Intra-cluster correlations (ICCs)**

* *Where relevant, describe the model that will be used to estimate the ICCs at pre- and post-test, for each level at which they will be computed (state which level they are computed at). These should be computed for an empty model (i.e. one without covariates), and for the primary analysis model.*

**Presentation of outcomes**

* *Describe the methods and formula used for the calculation of effect sizes (ES), e.g., Hedges’ g, including exact specification of the numerator and denominator, or risk ratios and natural frequencies for binary outcomes. Include all relevant parameters.*
* *For multi-level models, specify exactly how the effect size is calculated, including the formula.*
* *Specify how confidence intervals or Bayesian compatibility intervals will be calculated to reflect statistical uncertainty (****CONSORT 17a, and 17b).***

1. Please find the full statement at: http://www.equator-network.org/reporting-guidelines/consort-spi/ [↑](#footnote-ref-1)
2. Please make sure the title matches that in the header and that it is identified as a randomised trial as per the CONSORT requirements (CONSORT 1a). [↑](#footnote-ref-2)
3. Please adjust as necessary for trials with multiple primary outcomes, 3-arm trials etc. when a Bonferroni correction is used to account for family-wise errors. [↑](#footnote-ref-3)
4. Please adjust as necessary e.g., for trials that are randomised at the setting, practitioner or participant level. [↑](#footnote-ref-4)