*This template should be used to complete Statistical Analysis Plans (SAPs) for all trials three months after 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 EEF Evaluation Team and by a member of the EEF SAP review panel and will be published online after approval. The SAP should be read in conjunction with the protocol and it should not duplicate extensive content included in the protocol. 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 approved by the EEF. SAP revisions may require protocol revisions, and vice versa, though all revisions should be kept to a minimum.*

*This template should be used in conjunction with the revised* [*EEF Statistical Analysis Guidance (2018)*](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Writing_a_Protocol_or_SAP/EEF_statistical_analysis_guidance_2018.pdf) *and revised* [*EEF Report Template (2019)*](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Writing_a_Research_Report/EEF_evaluation_report_template_2019.docx)*.*

|  |  |
| --- | --- |
| PROJECT TITLE[[1]](#footnote-2) | e.g., Using the Moodle platform to improve GCSE Maths attainment, a two-armed cluster randomised trial |
| DEVELOPER (INSTITUTION) | e.g., University of Greenwich |
| EVALUATOR (INSTITUTION) | e.g., Education Research Foundation |
| PRINCIPAL INVESTIGATOR(S) | e.g., Amitha Vikram |
| PROTOCOL AUTHOR(S) | e.g., Amitha Vikram, Dr Simon Economou |
| TRIAL DESIGN | e.g., Two-arm cluster randomised controlled trial with random allocation at school level |
| TRIAL TYPE | Efficacy/ Effectiveness |
| PUPIL AGE RANGE AND  KEY STAGE | e.g., 15-16, KS4 |
| NUMBER OF SCHOOLS | e.g., 170 |
| NUMBER OF PUPILS | e.g., 8,500 |
| PRIMARY OUTCOME MEASURE AND SOURCE | e.g., GCSE Maths score (NPD) |
| SECONDARY OUTCOME MEASURE AND SOURCE | e.g., Self-efficacy score (Bespoke survey) |

# SAP version history

|  |  |  |
| --- | --- | --- |
| VERSION | DATE | REASON FOR REVISION |
| 1.2 [*latest*] |  |  |
| 1.1 |  |  |
| 1.0 [*original*] |  | *N/A* |

* Any changes to the design would need to be discussed with the EEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the trial design.
* Please ensure that any changes to the design of the trial are also reflected in a protocol amendment.

# Table of contents

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

# Introduction

* Brief description of the intervention and trial, clarifying the purpose of the analyses to be performed. (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., School |
| Stratification variables  (if applicable) | | e.g., Geographic area |
| Primary outcome | variable | e.g., Maths attainment |
| measure (instrument, scale, source) | e.g., KS2 Maths score, 0-100, NPD |
| Secondary outcome(s) | variable(s) | e.g., Self-regulation |
| measure(s)  (instrument, scale, source) | e.g., ELS Self-Regulation Scale, 0-5, bespoke survey |
| Baseline for primary outcome | **variable** | e.g., Maths attainment |
| measure (instrument, scale, source) | e.g., Progress Test in Maths (PTM5), 0-26, GL Assessment |
| Baseline for secondary outcome | **variable** | e.g., Self-regulation |
| measure (instrument, scale, source) | e.g., ELS Self-Regulation Scale, 0-5, bespoke survey |

# Sample size calculations overview

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

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

* Justify the choice of assumptions for the sample size calculations.
* Specify whether the trial is powered to detect an effect on the FSM sub-group as the primary population of interest (which will be the case in some effectiveness trials) and clarify what is meant by this.
* 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).
* 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.

# Analysis[[4]](#footnote-5)

* 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) (typically, prior attainment and any stratifiers) and their source measures (instruments, scales, datasets), making sure the clustered (nested) nature of educational data is explicitly accounted for.
* State clearly if any variable is transformed or scaled, providing a justification for this decision.
* Consider including your analysis syntax in an appendix, to increase transparency and minimise post-hoc decisions.

### Primary outcome analysis

* If more than one primary outcome is to be used, specify how the analysis will address multiple inference (see Primary Outcome Analysis in the EEF Statistical Analysis Guidance).
* Confirm whether higher level identifiers (e.g., class or school) 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 made (see section on Multi-site trials in the EEF Statistical Analysis Guidance).
* Include the full equation for the model.
* Specify the software and version used to run 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).
* If a different model is chosen, fully explain and justify your choice.
* Provide the same level of detail as for the primary analysis.

### Subgroup analyses

* Describe any subgroup analyses specified in the protocol (typically, FSM subgroup as identified by the EverFSM indicator) and other subgroup analyses that are supported by the theory of change. This decision will likely have already been made at protocol stage.
* Describe the model including whether an interaction term is used and/or a separate sub-sample containing only members of the subgroup (see Subgroup analyses section of the EEF Statistical Analysis Guidance).

### Additional analyses

* Describe any further planned analyses (e.g., robustness checks including other covariates, analysis to test causal mechanisms in the logic model).
* The level of detail should match that of the primary analysis.

### Longitudinal follow-up analyses[[5]](#footnote-6)

* 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 primary and secondary analyses.
* Specify whether Complier Average Causal Effect (CACE) analysis will be included in longitudinal follow-ups. If so, specify variables and analyses included.

### Imbalance at baseline

* Describe how you will assess imbalance between intervention and control groups at baseline. This needs to include:
  + Cross-tabulation of background characteristics (including any relevant characteristics for interventions targeted at specific participant groups) for all units as they were randomised, and for the sub-sample of those analysed. The former informs whether randomisation was successful at obtaining a balanced sample, while the latter provides evidence of whether attrition might have introduced an imbalance. This cross-tabulation is likely to include both school[[6]](#footnote-7) and pupil-level characteristics. Include a justification for the characteristics chosen.
  + For continuous variables, report means and standard deviations. For categorical variables, report counts and percentages in each category. Any differences should be discussed in the report.
  + Reporting of differences in pupil-level pre-tests as effect sizes.

### 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 EEF 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 estimate the extent of intervention dosage and/ or compliance.
* Clarify the level at which compliance is defined (e.g., pupil/ teacher/ class/ school).
* Describe the analysis method to be employed including the specification of the model.
* Describe how you will use either Instrumental Variable (IV) or 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 EEF Statistical Analysis Guidance).

### Intra-cluster correlations (ICCs)

* 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.

### Effect size calculation

* Include the formula for the calculation of effect sizes (ES), e.g., Hedges’ *g,* including exact specification of the numerator and denominator.
* For multi-level models, specify exactly how the effect size is calculated, including the formula.
* Specify how confidence intervals or Bayesian credibility intervals will be calculated.
* Report all relevant parameters used in ES calculations.

1. Make sure that the project title here matches the title of the document and the protocol. Please ensure that there is an identification as a randomised trial in the title as per CONSORT requirements. [↑](#footnote-ref-2)
2. 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)
3. Please adjust as necessary e.g., for trials that are randomised at the class level [↑](#footnote-ref-4)
4. Please see the [Statistical Analysis Guidance](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Writing_a_Protocol_or_SAP/EEF_statistical_analysis_guidance_2018.pdf). [↑](#footnote-ref-5)
5. Please see the [longitudinal analysis guidance](https://educationendowmentfoundation.org.uk/public/files/Grantee_guide_and_EEF_policies/Evaluation/Writing_a_Protocol_or_SAP/longitudinal_guidance.pdf). [↑](#footnote-ref-6)
6. In addition to the proportion of FSM pupils within a school, this should include the average school performance in the relevant key stage, whether schools are urban or rural, type of schools and Ofsted ratings so that readers can judge how able they are to apply the results to their own context of the final sample for each group. They should present other variables as relevant to the project. (Please note specific cell suppression rules apply for data accessed through the Office for National Statistics. Check the latest thresholds with the ONS.) [↑](#footnote-ref-7)