*This template should be used for all trial protocols (with adaptations, as necessary) and will be published on the EEF’s website. The protocol does not need to follow the order precisely, but evaluators should consider including the following items, based on the* [*CONSORT-SPI extension*](http://www.equator-network.org/reporting-guidelines/consort-spi/)*. The protocol should be read in conjunction with the Statistical Analysis Plan (SAP), when this is available, and it is the responsibility of the evaluator to ensure the SAP and the protocol are fully aligned and kept up-to-date. Protocol revisions may require SAP revisions, and vice versa, though all revisions should be kept to a minimum. The version history below will help to keep track of any changes to the protocol.*

*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)*, the* [*EEF IPE Guidance (2019)*](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting_up_an_Evaluation/IPE_guidance.pdf) *and the 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) |

# Protocol version history

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

* Any changes to the design 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 that affect the analysis to be undertaken are also reflected in the SAP.

# Table of contents

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

# Study rationale and background

* Provide an explanation of the theoretical and scientific background, policy context and rationale for the evaluation (including any contradictory evidence). Please include references to the academic and policy literature as relevant (and a full reference list for any in-text citations).
* Provide a brief overview of the integrated evaluation design (including impact evaluation and implementation and process evaluation), explaining why this is the best possible evaluation design for assessing the impact of the intervention on expected outcomes.
* If a previous EEF evaluation was conducted of the same intervention (i.e., a pilot or efficacy trial), describe it briefly here and how it informed this project, including any changes to the intervention (e.g., content, delivery) and evaluation design (e.g., unit of randomisation, outcomes, control condition). Please fill in appendix table 1 as relevant.

# Intervention

* Include a detailed description of the intervention being evaluated, including training and the model of delivery in school. Whilst much of this information will come from the delivery team, the evaluator needs to include sufficient information in the evaluation protocol to justify their evaluation design and will therefore need to have this information before finalising the protocol.
* Wherever possible, include as many TIDieR items as possible, i.e. Name, Why (theory/rationale), Who (recipients), What (materials), What (procedures), Who (provider), How (format), Where (location), When and how much (dosage), Tailoring (adaptation). [[2]](#footnote-3)
* Include the logic model diagram agreed with the developer during the set-up stage and a description of the underlying mechanisms and assumptions at each step, in line with the requirements of the IPE Guidance.[[3]](#footnote-4)
* Describe the control condition and any incentives/ restrictions for those in the control group.
* Define the date(s)/ period when the intervention is being delivered.

# Impact evaluation

### Research questions

* Provide the specific primary and secondary research questions the impact evaluation is designed to answer. These questions could be formulated using the PICO Framework (Population, Intervention, Comparison, Outcome). For example: “What is the difference in [maths attainment] measured by [GCSE Maths] of pupils in schools [receiving the treatment] in comparison to those pupils in [control schools receiving business-as-usual]?”.
* Please number the research questions for ease of reference.

### Design

* Provide a summary in the following table, detailing and fully justifying your choices in the text below the table. For amended protocols, please ensure all details are in line with the latest version of the SAP.
* Describe the type (e.g., efficacy or effectiveness) and design of the trial, including the unit of randomisation (e.g., whether pupil, school or class) and number of trial arms.
* Briefly describe the primary and secondary outcomes, to be described in detail in the Outcome measures section.

**Table 1: Trial design**

|  |  |  |
| --- | --- | --- |
| 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 |

### Randomisation

* Present the methods used to generate random allocation, including details and motivation for any restriction such as pairing, stratification, or minimisation. If the randomisation will be done in batches, describe this process.
* Outline plans for recording the randomisation process and specify whether analysts will remain blinded to group allocation.

### Participants

* Describe the study participants and set out any inclusion and/or exclusion criteria.[[4]](#footnote-5) This should define which pupils, year groups, and schools take part in the intervention.
* Present the number of planned treatment units[[5]](#footnote-6) included in the study and how they will be recruited.

### Sample size calculations

* Provide a summary in the following table, detailing and fully justifying your choices in the text below. For amended protocols, please ensure all details are in line with the latest version of the SAP. [[6]](#footnote-7)

**Table 2: Sample size calculations**

|  | | **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[[7]](#footnote-8)** | | 0.05 | 0.05 |
| **Power** | | 0.8 | 0.8 |
| **One-sided or two-sided?** | |  |  |
| **Average cluster size** | |  |  |
| **Number of schools[[8]](#footnote-9)** | Intervention |  |  |
| Control |  |  |
| **Total** |  |  |
| **Number of pupils** | Intervention |  |  |
| Control |  |  |
| **Total** |  |  |

* Explain how sample size was determined. 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 restrictions (e.g., the capacity of the developer). [[9]](#footnote-10) Describe whether all pupils in the intervention and control groups will be tested or a sample will be tested only.
* 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.
* Include separate sample size estimations for detecting effects in the Free School Meal subgroup (defined as EVERFSM in the NPD) .
* 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.
* Specify software used for MDES calculations.

### Outcome measures[[10]](#footnote-11)

**Baseline measures**

**Primary outcome**

**Secondary outcomes**

* We suggest you organise this section using the sub-headings above. Provide the information suggested below under each of the sub-headings.
* Clearly define each outcome and explain how it is aligned with the logic model.
* Specify how it will be measured, including source instruments or datasets. Explain whether an instrument will be used in its entirety, partially, or whether it will be adapted. Clarify the number of items / sub-scales, type of variable, range and psychometric properties. [[11]](#footnote-12) Clear rationales should be provided for all choices.
* If the trial includes a measure (e.g., a questionnaire) that is not available publicly, authors should include a copy of the instrument in the protocol. If it is not available at the time of the protocol publication, it should be added once available. Specify if the test is commercial and you are unable to include the instrument.
* When using NPD data, clearly specify the variables to be used and how they will be linked to pupil data collected during the trial.
* Provide details of who collected and scored the outcomes data, including any methods used to ensure data collection and scoring were blinded (e.g., by blind test administration or tests delivered under exam conditions with spot checks by evaluators).
* For trials with more than one follow-up point (e.g., delayed post-test), specify which time point constitutes the primary outcome.
* If using multiple primary outcomes, specify the approach to addressing multiple testing/ family-wise error rates.
* Describe any plans to ensure tests are administered and marked blinded to treatment allocation, if applicable.

### Compliance

* Describe the measure(s) that will be used to define compliance with the intervention, clarifying the level at which compliance is defined (e.g., pupil/ teacher/ class/ school).
* Specify any thresholds or minimal values agreed at set-up for the participants to be considered compliant.
* The approach to compliance analysis can be specified in detail in the SAP.

### Analysis

* Provide a high-level overview of the analyses that are planned. These analyses will be pre-specified in detail in the SAP.[[12]](#footnote-13) Describe the statistical methods to be used in the primary and secondary outcome analyses, including calculation of Hedges’ *g* effect sizes.
* Describe the comparisons that will be made between different arms of the trial.[[13]](#footnote-14)
* Specify what confidence/ credibility intervals will be used to reflect statistical uncertainty.
* Describe any subgroup analyses. All EEF evaluations should include subgroup analysis for FSM pupils. Evaluators should use the variable EVERFSM6 from the NPD in their analysis (see Subgroup analyses in the EEF Analysis Guidance).
* Fully clarify and justify all assumptions used, with sources.

### Longitudinal follow-ups

* Specify any follow-up points agreed at set-up, including details of the outcome measures included, time points and number of follow-ups planned.[[14]](#footnote-15)
* Specify the analytical models used for primary and secondary analyses.

# Implementation and process evaluation[[15]](#footnote-16)

### Research questions

* Specify research questions to be addressed by the implementation and process evaluation.
* Please number the research questions for ease of reference.

### Research methods

* Describe the research and data collection methods to address the implementation and process evaluation (IPE) research questions. Explain the contribution of each method to answering the IPE questions, using table 3 below.
* Include information about compliance, fidelity, usual practice and any implementation dimensions relevant to the study.
* Explain how data will be collected, how many participants or data sources each method will draw on and how participants or data sources will be sampled.
* Provide a brief description of the process for developing the data collection instruments if relevant, including piloting or validation exercises.
* Provide details of who will collect the data. Describe the approach to minimising bias and ensuring rigour in both the design and analysis of IPE data.

### Analysis

* Describe the approach to IPE data analysis, providing rationales for all choices and explaining their relevance to the project.
* Explain how the analyses will be used to test the logic model, including causal mechanisms (drawing on both quantitative and qualitative data).
* If responses or transcripts will be coded, clarify the approach to coding (i.e. inductive / deductive / mixed).

**Table 3: IPE methods overview *(adapt as necessary)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Research methods | Data collection methods | Participants/ data sources  (type, number) | Data analysis methods | Research questions addressed | Implementation/ logic model relevance |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

# Cost evaluation

* Description of how cost data will be collected, and a break-down of the costing scope (e.g., whether teacher time, administration, and others, are costed).[[16]](#footnote-17)
* Include procedures for cost calculations over three years, to facilitate comparisons between trials.

# Ethics and registration

* Clearly describe the process for obtaining ethical approval, including timelines and responsible parties.
* Describe the procedures for obtaining agreement to participate in the trial.
* Ensure the trial is registered at [www.controlled-trials.com](http://www.controlled-trials.com) and include the [ISRCTN](http://www.isrctn.com/page/why-register) (International Standard Randomised Controlled Trial Number) in the protocol as soon as it becomes available. Ensure the trial registry is updated with outcomes at the end of the project.

# Data protection[[17]](#footnote-18)

* Include a data protection statement relevant to the project (i.e., not a link to the organisation’s generic data protection policy). This may use information from the Memorandum of Understanding, information sheets and privacy notice.
* Specify your legal basis for processing personal data, with reference to the [General Data Protection Regulation (GDPR) Article 6](https://gdpr-info.eu/art-6-gdpr/) and/ or [Data Protection Act 201](http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted)8.
* Specify your legal basis for processing any special data with reference to [GDPR Article 9](https://gdpr-info.eu/art-9-gdpr/) and/ or Data Protection Act 2018.
* Provide a clear rationale for the legal bases selected for personal and special data, with reference to your organisational policies and the design of the specific evaluation project. If relying on legitimate interests, clearly specify what specific interests your organisation has in conducting the evaluation. These may include commercial interests, individual interests or broader societal benefits – please specify. (See [ICO guidance](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/legitimate-interests/) for more information.)
* Describe your approach to demonstrating GDPR compliance, including, but not limited to, how you will protect individual data subjects’ rights, purposes for data processing, all parties with access to data (and reasons), retention periods.
* Specify data processing roles (controller, any processors) during the evaluation up to the point of data being deleted from all locations by the evaluator and/ or delivery team. (N.B. The EEF becomes data controller for the datasets archived after the trial, once internal quality checks have been successfully completed by the archive manager.)

# Personnel

* List all members of the delivery team and the evaluation team, each with their role and responsibilities within the project, and their institutional affiliation

# Risks

* List key evaluation risks, with their likelihood of occurring and likely magnitude of impact.
* Describe your approach to mitigating or addressing each risk.

# Timeline

* Timetable including specification of who is responsible for completing each task
* Include specific dates or date intervals (rather than, for example, school terms only).

**Table 4: Timeline**

| Dates | Activity | Staff responsible/ leading |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

# Appendix 1: Changes since the previous EEF evaluation[[18]](#footnote-19)

**Appendix table 1: Changes since the previous evaluation**[[19]](#footnote-20)

|  |  |  |  |
| --- | --- | --- | --- |
| Feature | | Pilot to efficacy stage | Efficacy to effectiveness stage |
| Intervention | Intervention content | Describe any changes to the content. | Describe any changes to the content. |
| Delivery model | Describe any changes in the delivery mechanism (e.g., from developer-led to train-the-trainers; in-person vs online; etc.). | Describe any changes in the delivery mechanism (e.g., from developer-led to train-the-trainers; in-person vs online; etc.). |
|  | Intervention duration | Describe any changes in the duration of delivery (e.g., shortened due to the inclusion of a pre-test) | Describe any changes in the duration of delivery (e.g., shortened due to the inclusion of a pre-test) |
| Evaluation | Eligibility criteria | Describe any changes in the eligibility criteria for participation in the evaluation (schools, year groups, pupils etc.). | Describe any changes in the eligibility criteria for participation in the evaluation (schools, year groups, pupils etc.). |
| Level of randomisation | Not applicable to pilots. | Describe any changes to the design from efficacy to effectiveness stage to the level of randomisation |
| Outcomes and baseline | Not applicable to pilots. | Describe any changes to the design from efficacy to effectiveness stage in:  Outcomes  Baselines |
| Control condition | Not applicable to pilots. | Describe any changes to the design from efficacy to effectiveness stage to the control condition |

1. Make sure that the project title here matches the title of the document. Please ensure that there is an identification as a randomised trial in the title as per CONSORT requirements. [↑](#footnote-ref-2)
2. Please see the [TIDieR framework](http://www.bmj.com/content/348/bmj.g1687) paper for more information. [↑](#footnote-ref-3)
3. Please see the [IPE guidance](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting_up_an_Evaluation/IPE_guidance.pdf). [↑](#footnote-ref-4)
4. Please specify whether a pre-test availability and/or score will be used as an eligibility criterion. [↑](#footnote-ref-5)
5. ‘Units’ broadly defined as those who make the decisions to take up a programme and/or whose outcomes are expected to change as a consequence. These could be local authorities, groups of schools, schools, classes, teachers, and/or pupils depending on the characteristics of the programme under study. [↑](#footnote-ref-6)
6. Evaluators may want to consult [Allen et al. (2018)](https://educationendowmentfoundation.org.uk/public/files/Support/EEF_Research_Papers/Research_Paper_1_-_Properties_of_commercial_tests.pdf) and [Demack (2019)](https://educationendowmentfoundation.org.uk/public/files/Publications/Does_the_classroom_level_matter.pdf) when completing this section. Guidance on sample size calculations is currently being commissioned. [↑](#footnote-ref-7)
7. 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-8)
8. Please adjust as necessary, e.g., for trials that are randomised at the class level. [↑](#footnote-ref-9)
9. EEF is in the process of commissioning work to guide the choice of assumptions for its trials. [↑](#footnote-ref-10)
10. 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-11)
11. If any transformation of the data is necessary (e.g., z-scores), discuss this in the SAP. [↑](#footnote-ref-12)
12. It is the responsibility of the evaluator to ensure the protocol and SAP are fully aligned. Protocol revisions may require SAP revisions, and vice versa. The SAP is due 3 months after randomisation. [↑](#footnote-ref-13)
13. For instance, for a three-arm trial, specify whether all comparisons will be made (A vs B, A vs C, B vs C). [↑](#footnote-ref-14)
14. 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-15)
15. Please follow the principles detailed in the [Implementation and Process Evaluation Guidance (2019)](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting_up_an_Evaluation/IPE_guidance.pdf). [↑](#footnote-ref-16)
16. Please see the [cost guidance](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting_up_an_Evaluation/EEF_guidance_to_evaluators_on_cost_evaluation_2016_revision_FINAL.pdf). [↑](#footnote-ref-17)
17. Please see the [Data Protection Statement](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Data_protection/Data_protection_statement_EEF_evaluations.pdf) for EEF Evaluations. [↑](#footnote-ref-18)
18. Please delete this section if it is not applicable. [↑](#footnote-ref-19)
19. Delete columns from the table if they are not applicable or adjust titles as relevant. [↑](#footnote-ref-20)