

**Project title**

**Second line if needed**

**Pilot trial report**

Authors

Publication date

##

## Pilot trial report template

**Please type directly into this template or copy and paste unformatted text into the relevant sections. Please do not reformat tables or headings.**

**The standard YEF formatting to use throughout the document is:**

**Main headings should be formatted like this**

Secondary headings

**Third headings**

Body text should be justified black Calibri font size 12 with 10pt spacing before and after and multiple 1.15 line spacing.

*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.*

About the Youth Endowment Fund

The Youth Endowment Fund (YEF) is a charity with a mission that matters. We exist to prevent children and young people becoming involved in violence. We do this by finding out what works and building a movement to put this knowledge into practice.

Children and young people at risk of becoming involved in violence deserve services that give them the best chance of a positive future. To make sure that happens, we’ll fund promising projects and then use the very best evaluation to find out what works. Just as we benefit from robust trials in medicine, young people deserve support grounded in the evidence. We’ll build that knowledge through our various grant rounds and funding activity.

And just as important is understanding children and young people’s lives. Through our Youth Advisory Board and national network of peer researchers, we’ll ensure they influence our work and we understand and are addressing their needs. But none of this will make a difference if all we do is produce reports that stay on a shelf.

Together we need to look at the evidence and agree what works, then build a movement to make sure that young people get the very best support possible. Our strategy sets out how we’ll do it. At its heart it says that we will fund good work, find what works and work for change. You can read it [here](http://www.youthendowmentfund.org.uk).

For more information about the YEF or this report please contact:

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# About the evaluator

*Please fill in details of the evaluation team, including a contact email address here.*

# Executive summary

The project

***Please provide the following details about the project as bullet points. YEF will use them to draft a section about the project. The length of the executive summary is limited to two pages:***

* *Aims of pilot trial (e.g. this project aimed to assess the feasibility of an efficacy study of mentoring to improve the behaviour of 12 to 14 year olds).*
* *Target children (e.g. children scoring low on the SDQ behaviour sub-scale).*
* *Age and school year of target children.*
* *Basic delivery info: how often, how many weeks, nature of intervention.*
* *Who delivered the intervention (e.g. social workers, teachers, volunteers).*
* *Number of children and settings.*
* *Brief description of pilot study design and research questions.*
* *Brief details of developers and any funders other than YEF.*
* *Brief description of any quantitative or qualitative methods or measures undertaken.*
* *Dates when the pilot started and finished.*

**Figure 1: Summary of pilot findings**

|  |  |
| --- | --- |
| **Research question** | **Finding** |
|  |  |
|  |  |
|  |  |
|  |  |

Additional findings

*Any interesting findings that go beyond the scope of the research questions, or any detail about the research questions that was not included in the summary.*

Summary of cost information

*See*[***YEF cost evaluation guidance***](https://educationendowmentfoundation.org.uk/public/files/Evaluation/Setting_up_an_Evaluation/EEF_guidance_to_evaluators_on_cost_evaluation_2016_revision_FINAL.pdf) *(note, this does not apply to evaluations funded as part of YEF’s launch grant round).*

# Introduction

Background

* *A full explanation and discussion of the prior evidence, theoretical and scientific background and rationale for the intervention and its future evaluation, including how the prior evidence informs the research questions and need for the randomised pilot trial. Please include references to the academic and policy literature as relevant (and a full reference list for any in-text citations) (CONSORT 2a).*
* *Details of any relevant policy or practice context (e.g. How widely is the intervention or similar interventions being used? Is it relevant to any proposed or existing government policies?).*

Intervention

* *Provide a description of the intervention (or interventions) being evaluated sufficiently to allow replication (if there is a large amount of material, this can be included in appendices as appropriate). Please include as much information from Step 1 of EIF’s ten steps to evaluation success as possible, i.e. Who (recipients, universal/targeted), What (materials, procedures, providers, location, frequency, format, training and quality assurance), and How much (dosage) sufficient to enable replication (CONSORT 5).[[1]](#footnote-1) Alternatively, evaluators could use the TIDieR framework.[[2]](#footnote-2)*
* *Where possible explain where further information about delivering the intervention can be accessed.*
* *Please also include information on the logic model for the intervention (see Step 2 of EIF’s ten steps to evaluation success), including the hypothesised causal pathway for each participant group and assumptions at each step.*

Research questions

* *Please clearly and precisely outline the research questions, or aims and objectives of each stage of the pilot trial (if there is more than one), and the rationale (CONSORT 2b). These will have been set out in the study plan and agreed through discussion with the YEF EO, developer and the evaluator. These are likely to be related to the feasibility of the proposed efficacy evaluation design, and further refinement of the intervention’s theory of change and logic model.*
* *Please include a link to the pilot trial protocol on the YEF website (CONSORT 24).*
* ***Please note, if your pilot does not involve a control group you should be using the YEF pilot study reporting template, not this YEF pilot trial reporting template.***

Success criteria and / or targets

* *Where appropriate evaluators should also set out here the success criteria or targets that are applicable to the next stage of evaluation, and the rationale for these, linked to the research questions and study outputs (e.g. the efficacy study will be feasible if at least X participants are recruited and the attrition rate from the primary outcomes is less than X%) (CONSORT 6b).*

Ethical review

* *Briefly summarise the ethical review that was undertaken, including reference number (CONSORT pilot extension 26).*
* *Describe how agreement to participate in the study was obtained. Provide relevant documentation in an appendix (e.g., Memorandum of Understanding, participant information sheets).*
* *Include the trial registration number (ISRCTN) for randomised controlled trials (CONSORT 23). (Please remember that the trial registry needs to be updated once the project outcomes are available.)*

Data protection

* *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 (if applicable), information sheets and privacy notice.*
* *Describe the privacy or fair processing notice made available to participants, specifying all the purposes of data processing, retention periods and parties with access to the data during and after the pilot. This includes providing information about the YEF data archive and sharing YEF’s privacy notice (its guidance for participants). Provide relevant documentation in an appendix (e.g., information sheets, privacy notice, withdrawal forms).*
* *Describe relevant procedures for ensuring data quality, anonymity or confidentiality as applicable.*
* *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 YEF becomes data controller for the datasets archived at the end of the evaluation, once internal quality checks have been successfully completed.)*
* *If not already included above, specify your legal basis for processing personal data and, if applicable, special data, with reference to the* ***General Data Protection Regulation (Article 6 and Article 9, respectively)*** *and/ or the* [***Data Protection Act 201***](http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted)***8****.*
* *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.)*

Project team / stakeholders

* *Provide details of the project team including those who developed and delivered the intervention and the roles of different members of the evaluation team. Include affiliation for all staff.*
* *Provide details of any involvement of the intervention developer in the design, conduct, analysis or reporting of the trial as well as other stakeholder involvement in the trial design, conduct or analyses (CONSORT 25).*
* *Sources of funding and declaration of any other potential interests.*

# Methods

Trial design

* *Describe the pilot trial design including the unit of randomisation (e.g., participant or cluster) and number of trial arms. State the allocation ratio and its rationale (CONSORT 3a).*
* *Include a description of any important changes to the original trial design and the reason for these (e.g., eligibility criteria, number of trial arms) (CONSORT 3b).*

Participant selection

* *Explain how participants and settings were identified, sampled and recruited to each stage the pilot, including any eligibility criteria (CONSORT 4a). Explain from whom consent was sought, if applicable (CONSORT 4c).*
* *Explain the rationale for the planned number of participants in each stage of the pilot study, with reference to the study plan (CONSORT pilot extension 7a).*
* *The settings and locations where data were collected (CONSORT 4b).*

Data collection

* *Provide complete details of the pre-specified methods and measures that will be used to answer the research questions or pilot trial objective, and a rationale for why these methods were appropriate (CONSORT pilot extension 6a). A table could be included that shows what data will be used to answer the questions (example provided below). If a logic model was developed, provide a description of how the logic model was created, when it was created, who had input into the model and how it was reviewed.*
* *Where appropriate provide a brief description of the process for developing the data collection instruments, including any piloting or validation exercises.*
* *Provide details of who collected the data and when. If the project delivery team was involved outline any provision to minimise bias (e.g., telling the participants that survey data will be anonymous and analysed by the evaluators, shadowing a sample of interviews).*
* *Any changes to the pilot trial methods or measurements after the pilot trial commenced, with reasons (CONSORT 6b).*

**Table 1. Methods overview *(example – please adapt as necessary)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Research methods** | **Data collection methods** | **Participants / data sources** | **Data analysis method** | **Research questions addressed** | **Logic model relevance** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Randomisation

* *Present the methods that were used to generate random allocation, including details and motivation for any restriction such as pairing, stratification, blocking and block size, or minimisation. If the randomisation was done in batches, describe this process (CONSORT 8a, 8b).*
* *Explain who generated the random allocation, who enrolled participants and who assigned participants to the interventions (CONSORT 10).*
* *Outline how the randomisation process was implemented and recorded and describe any steps taken to conceal the allocation sequence until the intervention is assigned, or to blind participants, providers, data collectors and analysts to group allocation (CONSORT 9 and 11a).*
* *Describe any changes made to the approach, if applicable, with reference to the pilot research questions or objectives.*

Analysis

* *Describe your approach to analysing any qualitative and quantitative data collected as part of the pilot, including the rationale for the approach and how the analysis relates to the pilot objectives and success criteria (CONSORT 12).*
* *Describe, if applicable, how you triangulated data across sources methods, data sources and investigators to support interpretation, including how you planned to explain any inconsistencies between data sources. Please refer to the YEF guidance on pilot studies when developing your approach to analysis.*
* *When applicable provide an explanation of any interim analyses (including outcomes and methods of analysis) and /or stopping guidelines, and the rationale for their inclusion (CONSORT 7b).*

Timeline

* *Include a timeline of activities related to the evaluation and intervention delivery including recruitment period, data collection and delivery schedule, including who completes each activity (CONSORT 14a).*
* *Why the trial ended or was stopped, if applicable (CONSORT 14b).*

**Figure 2. Timeline**

|  |  |
| --- | --- |
| **Date** | **Activity** |
|  |  |
|  |  |
|  |  |
|  |  |

# Findings

Participants

* *Provide details of participant flow through each stage of the evaluation (e.g., using Figure 1 below). Including, where possible, the number of participants or clusters identified, approached, screened, and eligible prior to random assignment, as well as the number randomly assigned, receiving the treatment, completing and that were assessed for each objective (CONSORT 13a). 2-arm and 3-arm diagrams have been provided. Please delete the diagram that is not applicable.*
* *For each group, losses and exclusions after randomisation, together with the reasons (CONSORT 13b)*
* *Include a description of the participants involved in the pilot, including all baseline characteristics that are relevant to the research questions. This could take the form of a table(s) if appropriate (CONSORT 15).*
* *Provide a description of the settings (e.g. areas, schools, youth offending teams) involved in the study including compared to the population from which they were drawn, and state how this might influence the interpretation of results.**Report and explain any attrition, including reasons.*
* *For each research question or objective, provide the number of participants (denominator) included in each analyses. If relevant these numbers should be by randomised group (CONSORT 16).*

**Figure 2: Participant flow diagram (3 arms)**

Agreed to participate (n=)

Excluded (n=)

Not meeting inclusion criteria (n=)

Other - specify (n=)

Approached (n=)

Approached (n=)

proached (n=)

Did not agree to participate

(n=)

Post-test data collected

Not analysed

Recruitment

Allocation

Randomised

(setting n=; child n=)

T1

(setting n=; child n=)

Control

(setting n=; child n=)

T2

(setting n=; child n=)

Analysis

Not analysed

Not analysed

Not analysed

Analysed

Analysed

nalysed

d

Analysed

Post-test data collected

Lost to follow up

Post-test data collected

Lost to follow up

Post-test data collected

Lost to follow up

Follow-up

**Figure 3: Participant flow diagram (2 arms)**

Agreed to participate (n=)

Excluded (n =)

Not meeting inclusion criteria (n=)

Other - specify (n=)

Approached (n=)

proached (n=)

Did not agree to participate

(n=)

Post-test data collected

Not analysed

Recruitment

Allocation

Randomised

(setting n=; child n=)

T1

(setting n=; child n=)

Waitlist control

(setting n=; child n=)

Analysis

Not analysed

Not analysed

Analysed

Analysed

Post-test data collected

Lost to follow up

Post-test data collected

Lost to follow up

Follow-up

Evaluation feasibility

*This section should provide a summary of the findings related to the feasibility and practicality of the main stage efficacy evaluation. Please refer to the research questions and success criteria or targets, where applicable. Any inconsistencies between data sources will need to be explored and explained.*

*This section might include data and analysis relating to, for example:*

* *The acceptability and feasibility of different evaluation designs.*
* *The feasibility of recruitment procedures and strategies for improving retention to the evaluation.*
* *The feasibility of randomisation procedures.*
* *The reliability, validity and practicality of different outcome measures, procedures for minimising bias, or the availability of administrative data.*
* *Estimating the likely sample size required for the main stage study based on parameters explored during the pilot (e.g. likely attrition rate and study design).*

Evidence of promise

* *This section should summarise the results of any analyses relating to the intervention’s evidence of promise with reference to the logic model and research questions, including any revisions to the logic model based on the results of the pilot.*
* *It should report the results of any analysis of quantitative or qualitative data related to the hypothesised causal mechanisms or proximal outcomes (e.g. changes to practice, perceptions or attitudes related to how participants engaged with the intervention). Analysis of quantitative data should be descriptive and exploratory. For each quantitative analyses expressions of uncertainty (e.g. 95% confidence interval) should be included for any estimates (CONSORT pilot extension 17a). Any inconsistencies between data sources will need to be explored and explained. Please refer to the YEF guidance on pilot studies when developing your approach to analysis.*
* *This section should also report any important unintended consequences, harms or negative effects in each group (CONSORT 19 and CONSORT pilot extension 19a).*

Readiness for trial

* *This section should draw judgement about whether the intervention is ready to be evaluated at a larger scale (i.e. the extent to which the intervention is sufficiently well-defined and specified and scalable beyond pilot stage within the context of an efficacy trial or quasi-experimental study).*
* *Failure to meet success criteria does not necessarily mean that the main evaluation should be abandoned, but will suggest that the proposed design and methods require revision.*
* *Describe the results of any other analyses or lessons learned from piloting aspects of the evaluation design that could be used to inform the future trial, not already covered above (CONSORT pilot extension18).*

Cost information

* *See* ***YEF cost evaluation guidance*** *(note, this does not apply to evaluations funded as part of YEF’s launch grant round).*

# Conclusion

**Figure 3: Summary of feasibility study findings**

|  |  |
| --- | --- |
| **Research question** | **Finding** |
|  |  |
|  |  |
|  |  |

Evaluator judgement of evaluation feasibility

* *Are there any ways that the main stage evaluation design or intervention can be improved? Implications for progression from pilot to future efficacy study, including any proposed amendments with reference to the success criteria (CONSORT pilot extension 22a). Failure to meet success criteria does not necessarily mean that the main evaluation should be abandoned, but will suggest that the proposed design and methods require revision.*

Interpretation

* *A full discussion and interpretation of the results of the pilot trial research questions or objectives, including the feasibility of the main stage evaluation, any evidence of promise and readiness for trial, balancing potential benefits and harms and considering other evidence (CONSORT pilot extension 22). Discuss the results in the context of the existing evidence and policy context described in the introduction.*
* *Comment on the extent to which the pilot supports the logic model and explain how/ why the logic model was revised, if applicable.*
* *Discuss the generalisability (applicability) of the pilot trial methods and findings to the future efficacy study and other potential studies (CONSORT pilot extension 21).*
* *Outline any limitations of the pilot trial, including any potential sources of bias, or remaining uncertainty about feasibility or other findings (CONSORT pilot extension 20).*

Future research and publications

* *Suggestions for future study methodology, including design and outcome measures.*
* *Future research questions that need answering should be specified.*
* *Any further publications coming out of the evaluation should be signposted.*

# References

Footnotes and references

*Please provide references using the Harvard system (http://libweb.anglia.ac.uk/referencing/harvard.htm) and supply full references in a bibliography.*

*Please use footnotes sparingly. If you need to use footnotes, please use the Microsoft Word footnote function.*

# Appendices:

*Please submit any appendices as a separate document. We will be publishing these as a separately to reduce the length of reports.*

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1. <https://www.eif.org.uk/resource/10-steps-for-evaluation-success> [↑](#footnote-ref-1)
2. Please see the [TIDieR framework](http://www.bmj.com/content/348/bmj.g1687) paper for more information. [↑](#footnote-ref-2)