YOUTH ENDOWMENT FUND

Pilot study guidance

This document provides guidance on the Youth Endowment Fund's expectations for pilot evaluations.

Pilots

The YEF commissions pilots where an intervention is relatively well-specified and has been shown to be feasible in the UK (e.g. having already been delivered at a small scale), but where it is not yet clear whether a full efficacy study is feasible. In these cases, it may be beneficial to pilot the research instruments, potential impact evaluation designs and methods (e.g. randomisation procedures) and to identify and resolve as many potential problems as possible ahead of an efficacy trial.

In some cases, there may also be some aspects of the intervention that require further refinement. These intervention refinements should not be more substantial than can be easily addressed alongside piloting the evaluation procedures. Otherwise, a feasibility study would be more appropriate. Table 1 provides further examples of when a pilot study is appropriate.

Aims and objectives

The main aim of a YEF pilot is to ensure that the intervention is ready for an efficacy study. This mean that all of the steps 1 to 5 in the EIF 10 steps to evaluation success must be completed. The specific research questions or objectives of the pilot will need to be agreed through discussion between the YEF Evaluation Manager (EM), developer and evaluator and will fall into the following categories. All pilots will involve a judgement about the intervention's readiness for trial in a YEF impact evaluation.

1. Evaluation feasibility

Step 5 in EIF's 10 steps to evaluation success involves piloting aspects of a larger impact evaluation, including piloting outcome measures and recruitment. YEF pilots are likely to explore these aspects and also other crucial components of the full-scale study including:

Evaluation design:
Piloting may help to determine the most feasible design for the efficacy study, (e.g. randomised controlled trial (RCT) or quasi-experimental designs (QED)) by exploring the acceptability and feasibility of these designs. The pilot may explore the risk of bias and practicalities associated with different designs (e.g. potential spill-over effects, such as compensation rivalry, resentful demoralisation, or treatment diffusion, in within or between-cluster designs).

Evaluation procedures, such as:

- Recruitment to the evaluation, including the communications strategies proposed, feasibility of applying the eligibility criteria and consent procedures.
- Strategies for improving retention to the evaluation such as incentives, text messages and information letters and their cost.
- Randomisation procedures either by asking about acceptability or by piloting the procedures themselves in a small-scale version of the main-stage trial (the latter of which is often referred to as a 'pilot trial' and is YEF preferred approach ahead of an efficacy RCT as it is the best way to identify and address any issues, see also Box 2)[1].

Data management and quality, such as:

- Reliability, validity and practicality of specific measurement instruments with the target participant group, usually by delivering them to a small sample of targeted participants and checking for issues such as ceiling or floor effects, the burden on participants, attrition and missing data.

1 Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot and feasibility studies. 2016;2(1):64.

- Availability and variability of administrative data including piloting the procedures for data linking, exploring the proportion of positive matches and patterns of missing data;

- Procedures for minimising bias such as blinding to treatment allocation those conducting the randomisation, test administration and analysis, to minimise the risk of experimental effects or allocation subversion.

Sample size requirements:
An objective may be to estimate the sample size required for an efficacy study based on parameters determined during the pilot e.g. likely attrition rate, study design and estimated effect size (the latter of which will require a small-scale version of the main study, including a comparison group).

2. Evidence of promise

YEF pilots may also be used to assess evidence of promise by collecting data and evidence on aspects of the intervention logic model, for example related to the hypothesised causal mechanisms or proximal outcomes (e.g. changes to practice, perceptions or attitudes related to how participants engage with the intervention). [2] These may involve descriptive analysis of pre-post differences or against a comparison group (see next section on methods). It might also involve checking that there is no evidence of unintended or negative consequences.

Where service usage is an outcome of interest (see EIF Step 4) this may be tracked in a YEF pilot study, where the hypothesised changes in service usage are proximal to the intervention delivery.

3. Readiness for trial

An objective of all YEF pilot studies is to check that the intervention is 'ready for trial' in a YEF efficacy study. This means that the intervention is sufficiently well-defined and specified to be delivered in a YEF efficacy study. It also means that aspects of evaluation feasibility have been checked such that they do not interfere with the main causal pathways for the intervention.

All pilot studies should be carried out with due regard to racial and cultural sensitivity and for each project it will be important to explicitly assess the evaluation components and evidence of promise for different groups of children and young people who receive the project where possible.

2 This paper outlines the theory of change approach to planning an evaluation of interventions. It provides a case example of an urban education reform initiative to demonstrate how, for example, evaluators can select appropriate indicators of change for different elements of the theory: Connell, J. & Klem, A. (2000). You can get there from here: Using a theory of change approach to plan urban education reform. Journal of Educational and Psychological Consultation, 11, 93-120.

Box 2 provide some further detail about the differences and similarities between YEF pilot studies and EIF Step 5 in the EIF's 10 steps to evaluation success.

Box 2: Similarities and differences between YEF pilots and EIF's Step 5

The EIF Step 5 (piloting for outcomes) emphasises the importance of piloting outcome measures and recruitment strategies. It is also interested in assessing evidence of promise. However, the YEF pilot studies are also different from EIF Step 5 in two main ways:

1. **Piloting randomisation:** EIF Step 5 studies usually involve a single treated group and no comparison. YEF pilots are more likely to involve a comprehensive test of the feasibility of the efficacy design, including the construction of a comparison group (e.g. piloting randomisation procedures, piloting recruitment to randomisation, and assessing the risk of resentful demoralisation or compensation rivalry in the comparison group). This is because feasibility and acceptability of randomisation procedures is a common challenge for YEF efficacy studies and explicitly piloting the procedures is the best way of identifying and addressing any issues.

2. **Assessing evidence of promise:** Unlike EIF Step 5, YEF pilots avoid frequentist analysis of pre-post differences in outcomes due to difficulties in interpreting these (e.g. no difference in self-esteem could be a positive outcome if reductions in self-esteem in early adolescence is the counterfactual). Instead, YEF pilots are more likely to assess evidence of promise in two ways:

   (a) Descriptive analysis of proximal outcomes closely related to the intervention delivery (e.g. practice outcomes, proximal behavioural outcomes or causal mechanisms), either pre-post, or descriptively examining differences in differences if there is a comparison group.

   (b) Estimating the likely effect size on the primary outcome will only happen where a comparison group is included in the pilot. These effect sizes will be interpreted with caution due to the small sample size but might be used to check for negative effects and inform the sample size of the efficacy study.

The YEF is also flexible about the number of participants required for a YEF pilot and would expect this to be determined by the research questions. YEF does not require a statistically significant positive outcome to determine progression to an efficacy study, but would be looking for some early evidence of promise supporting the theory of change, e.g. changes related to the hypothesised causal mechanisms.

Methods

Methods used to address each pilot study objective can be qualitative or quantitative (e.g. the feasibility of an outcome measure could be assessed quantitatively by looking at acceptability through interviews or quantitatively by exploring missing data and the data distribution or variation). Most YEF pilots will involve a mixed-methods approach where both types of data are being used and reported. Any inconsistencies between different data sources will need to be explored and explained. As with all YEF evaluations, all participants in a YEF pilot study are expected to participate in both the intervention and the evaluation.

The number of participants in the pilot study should be based on the research questions or study objectives and some rational provided. The sample size for the pilot study should not be determined by the need to power the study to detect 'statistically significant' differences[3]. This is because formal hypothesis testing is not recommended in pilot studies because they will usually be underpowered to do this.

Most YEF pilot studies will involve some form of control group. This is because the acceptability and feasibility of an RCT vs a quasi-experimental design is often best tested by delivering a small-scale version of the main study. These types of studies are routinely performed in clinical research and are valuable in informing feasibility and design of large-scale and expensive RCTs.[4][5] An alternative would be to ask participants about the acceptability of the proposed approach and not actually pilot the randomisation procedures, but this approach has its limitations. For example, it is not possible to check whether there is likely to be differential attrition in the control group, or subversion of the random allocation by providers.

Small scale pilot RCTs are often called 'pilot trials'. All YEF pilot trials should be registered at www.controlled-trials.com and the ISRCTN (International Standard Randomised Controlled Trial Number) included in the study plan when it is available. The trial registry should be updated with the outcomes at the end of the project.

3 Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot of feasibility study? A review of current practice and editorial policy. BMC Medical Research Methodology. 2010;10(1):67.
4 Arnold, D. M., Burns, K. E. A., Adhikari, N. K. J., Kho, M. E., Meade, M. O., Cook, D. J., & McMaster, C. C. I. G. (2009). The design and interpretation of pilot trials in clinical research in critical care. Critical Care Medicine Baltimore, 37, 1, S69-S74.
5 Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L.P., Robson, R., Thabane, M., Giangregorio, L., & Goldsmith, C.H. (2010). A tutorial on pilot studies: the what, why and how. BMC Medical Research Methodology. 10, 1.

Success criteria and/or targets

As in YEF feasibility studies, where possible evaluators and developers are encouraged to agree together and set out in the evaluation plan any success criteria or targets that may be applicable. For example, 'the evaluation is feasible if at least 80% of participants are retained in the primary outcome measure'. It is important that these targets are realistic and meaningful and where appropriate they should be linked to the research questions or study objectives. Examples of success criteria or targets for YEF pilots include:

- Recruitment and randomisation criteria (e.g. 'the main-stage study will proceed if at least 10 participants are recruited and randomised over a two-month period').
- Spill-over criteria (e.g. 'the main-stage study will proceed if no more than 5% of control participants received the intervention').
- Outcome criteria (e.g. 'the main-stage study will proceed if there is no evidence of substantially important negative effects on participant well-being').

Analysis, reporting and next steps

Analysis will be descriptive and exploratory. YEF pilot studies should be reported in accordance in accordance with the CONSORT extension for randomised pilot and feasibility studies.[6] Any effect size estimates should be interpreted cautiously (thus 'evidence of promise' rather than efficacy or effectiveness) to avoid over-interpretation and undue enthusiasm or pessimism. As in CONSORT, formal hypothesis testing is not recommended in YEF pilots as they will usually be underpowered for this.[7]

It will be vital for the report to directly answer the research questions and objectives identified for the pilot study. evaluators should aim to draw judgements about the feasibility of carrying out an efficacy study where applicable and report on any success criteria or targets. If feasible, they should say whether any changes should be made to the main study design. Failure to meet success criteria, does not necessarily mean that the main evaluation should be abandoned, but will suggest that the proposed design or methods require revision.

Usually, the initial output of the pilot will be a presentation from the evaluators, to the developers and the YEF. The presentation will be used to inform a discussion about next steps (e.g. progression to a YEF efficacy study, further revisions to the evaluation design or intervention, or no further action). This will usually be followed by a written report of the results, to be published on the YEF's website.

6 Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot and feasibility studies. 2016;2(1):64.
7 Specifically CONSORT recommends any estimates of effect size to be reported with 95% confidence intervals but without p values.

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