# Project Title

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| --- | --- |
| **Intervention Developer** |  |
| **Delivery Organisations** |  |
| **Evaluator** |  |
| **Principal Investigator** |  |
| **Protocol Author(s)** |  |
| **Type of Trial** |  |
| **Age or Status of Participants** |  |
| **Number of Participating Sites** |  |
| **Number of Children and Families** |  |
| **Primary Outcome(s)** |  |
| **Secondary Outcome(s)** |  |
| **Contextual Factors** |  |

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| --- |
| Delete this box before publishingPlease ensure you use accessible language, and check the document for accessibility according to [WWCSC guidance](https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-Accessibility-Guidance-V1.1.pdf).Also, please delete any text highlighted in yellow prior to publication. |

# Summary

* Provide a short summary of the information contained within the protocol, including an introduction to the intervention, the aims and methods of the evaluation, and any key timelines.

# Table of Contents

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

# Background and Problem Statement

* An explanation of the theoretical and scientific background, policy context and rationale for the evaluation. This should include reference to key literature relevant to the evaluation.

# Intervention and Theory of Change

* Detailed description of the intervention being evaluated, including social worker / other staff training and the model of delivery.
* Wherever possible, please include as many TIDieR[[1]](#footnote-1) 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).
* Logic model / Theory of Change for the intervention here, with explanation

# Impact Evaluation

### Research Questions

* Specific questions the impact evaluation is designed to answer.

### Design

* Provide a summary in the following table, detailing and fully justifying your choices below.
* Describe the type of trial, including the unit of randomisation (e.g., whether child, local authority, LA cluster) and number of trial arms.
* Briefly describe the primary and secondary variables and measures. Variable should be a concise definition of the variable in question - for example “Whether or not a child has entered care 18 months after referral”; measure should provide details of the how the variable is defined, including how it will be coded e.g “A binary variable coded 1 if the child had entered care at any point between the referral date, and a date exactly 18 months later, otherwise 0. This will be derived from administrative data held by the local authority. You should also ensure that you appropriately define any nuances or exceptions to the coding (e.g. if you only code it as a 1 in the example above if the stay in care was over one week in length, it should be stated - either here or in the Outcome Measures section.
* Diagram showing participants’ journey through the trial, with data collection points. Consistent with the [CONSORT flow diagram](https://www.equator-network.org/reporting-guidelines/consort/).

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| --- | --- |
| Trial type and number of arms |  |
| Unit of randomisation |  |
| Stratification variables (if applicable) |  |
| Primary outcome | Variable |  |
| Measure (instrument, scale) |  |
| Secondary outcome(s) | Variable(s) |  |
| Measure(s)(instrument, scale) |  |

### Randomisation

* Methods used to generate random allocation, including details and motivation for any pairing, stratification, or minimisation.
* Outline plans for recording the randomisation process and whether analysts will remain blinded to group allocation.

### Participants

* What local authorities / organisations are eligible, and how will they be recruited.
* Which children are eligible and how they will be identified and recruited.

### Sample Size / Minimum Detectable Effect Size Calculations

* Provide a summary in the following table, detailing and justifying your choices and any assumptions in the text below.

|  |  |
| --- | --- |
| **MDES (Proportion of a Standard Deviation)** |  |
| **Proportion of Variance in Outcome Explained by Covariates[[2]](#footnote-2) (R2)** | Child |  |
| Family |  |
| Social Worker |  |
| **Intracluster Correlations Coefficient (ICCs)** | Family |  |
| Social Worker |  |
| Team |  |
| **Alpha** | 0.05 |
| **Power** | 0.8 |
| **One-Sided or Two-Sided?[[3]](#footnote-3)** | Two-sided |
| **Level of Intervention Clustering** |  |
| **Average Cluster Size (if Cluster-Randomised)** |  |
| **Sample Size**  | 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 local authority or other delivery partner).
* Please specify software used for MDES calculations, and packages used, where appropriate. If possible, please provide code used as an Annex.
* If a change to the analysis model changes the power of the design, this should be discussed here (for example, if a pre-test is no longer used).
* If you need to conduct adjustments for multiple comparisons (as outlined in [WWCSC’s statistical analysis guidance](https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf)) please ensure your calculations take these into account.

### Outcome Measures

* Clearly define the primary and secondary outcomes and how they will be measured, including source instruments or datasets. This should include how you intend the final variable to be coded.
* There should ideally be only one primary outcome. However, more than one can be used if there is a sound rationale in the theory of change of the intervention to support this decision.
* 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. Please see [WWCSC Statistical Analysis](https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf) Guidance for more details.
* Details of any plans to ensure tests are administered and marked blinded to treatment allocation, if applicable.
* Consider and identify any harms that are likely or possible consequence of the intervention, and consider whether and how they can be measured. As two interventions which each avoid harming people may be interpreted as equivalent, and their choice a matter for expert or professional judgement, harms analysis will be considered separately for multiple comparisons purposes.

### Analysis Plan

**Please see the** [**WWCSC Statistical Analysis Guidance**](https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf)**.**

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#### Primary Analysis:

* Analysis plans should be specified in as much detail as possible in advance of the trial beginning. Attempts should be made to pre-empt likely changes that may need to be made, and contingency plans detailed.
* Specify the chosen analysis model in full, including level(s) of analysis, covariate(s) and their source measures (instruments, scales, datasets), making sure the clustered nature of the data is explicitly accounted for (where applicable).
* Error structure and clustering should be taken into account at the level of randomisation.
* Describe how the outcome measures will be used in the analysis with a clear rationale for this choice.
* State clearly if any variable is transformed or scaled, providing a justification for this decision.
* Describe the comparisons that will be made between arms of the trial to estimate effect.
* Describe the statistical methods to be used in the primary and secondary outcome analyses, including calculation of Glass’ Delta effect size.
* Specify what confidence / credibility intervals will be used to reflect statistical uncertainty.
* Describe whether these analyses will be subject to multiple comparison adjustments in keeping with [WWCSCs Statistical Analysis Guidance](https://whatworks-csc.org.uk/wp-content/uploads/WWCSC-RCT-Statistical-Analysis-Guidance-V1.1-1.pdf).

#### Secondary Analysis

* Describe details of any subgroup or additional analyses here.
* Secondary outcome measures should in general use the same functional form for analysis as primary outcomes, but models should be specified here.
* For subgroup analyses, be clear whether analysis will be partitioned (considering only that sub-group), or conducted using interactions.
* Fully clarify and justify all assumptions used, with sources, where possible.
* For secondary analyses, follow the same model specification used for the primary outcome, unless there is a clear rationale against this, and provide the same level of detail as for the primary analysis. If a different model is chosen, fully explain and justify your choice.

#### Analysis of Harms

* As well as considering the potential benefits of the programme, analysis should also consider the potential harms, identified above and following the WWCSC guidance on harms analysis.

### Exploratory Analysis

Additional analyses can be conducted after the trial is completed that are not specified in the trial protocol. However, it is useful to specify areas of potential future interest here.

### Contextual Factors Analysis

Social Care does not exist in a vacuum, and contextual factors matter for the success of an intervention. Before the beginning of a trial, contextual factors which developers believe are important to success should be established by evaluators. These factors should be measured at the outset of the trial wherever possible, and additional analysis conducted to test the relationship between effect size and these factors.

For single-authority trials, contextual factors at team level should be collected and used for this analysis, while local authority level factors should be included in the description of the trial to provide context for translation. For multi-authority trials, where randomisation occurs below the level of the local authority, contextual factors at both team and authority level should be used in this analysis.

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# Implementation and Process Evaluation

### Aims

Present the aims of your IPE and how this enhances and complements the impact evaluation.

### Research Questions

Specify research questions to be addressed by the evaluation and process evaluation. Examples of possible research questions include. *Please note these are example questions. It is essential that you consider the most appropriate questions to address the aims of your specific project, it is very possible you may want to use only a subset of these or different questions entirely. For external evaluators the RQs should be agreed in partnership with WWCSC*:

* **Fidelity and adaptation** (the extent to which delivery adheres to the intended model)
* **Programme differentiation** (what does the service structure and practice look like prior to the introduction of the model, or in control conditions?)
* **Reach and acceptabilit**y (who the intervention reached and what the experience was of those delivering and receiving the intervention)
* **Mechanism** (whether we see changes that we expect to see, what are the perceived mechanisms of change by which outcomes are achieved. Are there any perceived unintended or negative consequences?)

### Design

Include a table which provides an overview of the quantitative and or qualitative indicators you intend to measure to answer each research question. Specify at which level you intend to measure them (e.g. individual, organisational) and how and when you intend to collect this data (e.g. staff interview, admin data). Where appropriate, include thresholds (such as expected thresholds for adherence). An example can be seen [here on page 29](https://whatworks-csc.org.uk/wp-content/uploads/WWCSC_Family-Safeguarding_TP_Final_V1.pdf).

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| --- |
| **IPE Design Table** |
| **Indicators** | **Method and Time Point** |
| 1. **Research Question 1**
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|  |  |
| 1. **Research Question 2**
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|  |  |
| 1. **Research Question 3**
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### Methods

#### Sample and Recruitment

* Describe the sample and approach to sampling, including the number of participants, how they will be selected and recruited, including details of any gatekeepers, any inclusion or exclusion criteria and any information sheets or consent procedures.
* Consider accessibility such as literacy and language, any adaptations that may be needed for certain participant groups, such as children. Consider any risks to obtaining any of the intended data or accessing the intended participant group.

#### Data Collection

* Describe the methods of quantitative and qualitative data collection you will use in the implementation and process evaluation. Provide details of what will be collected (e.g. survey, observation, interview, admin data) including a description of any tools (e.g. survey instruments, discussion guides, admin data proforma or templates), and where possible specific variables (e.g. admin data variables). Specify the number of participants for each type of data collection specified, and when each will take place.
* Ensure data collection methods are described in sufficient detail, e.g.
	+ Observation: what will be observed, will they be recorded, who will be carrying out the observation?
	+ Interviews: how will the interview schedule be developed, who is conducting the interviews, will interviews be by telephone or in person, how are they being recorded?
	+ Focus groups: specify the number and size of the focus groups, are there any group dynamics that need to be considered (e.g., sensitive topics or professional hierarchies)?
	+ Survey: how and when will the survey be shared with participants, what will the survey be measuring, how long is the survey expected to be?
	+ Admin data: will data be collected at the individual or aggregate level, what data items will be collected?
* It can help to set out your data collection schedule in a table, such as below.

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| --- | --- | --- |
| **Method** | **Sample size** | **Time point** |
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### Analysis

* Provide details of any (quantitative or qualitative) analysis that will be undertaken, including transcription and any software being used.
* Consider approaches to ensure rigor / quality assure (e.g., having multiple researchers involved with analysis)?

# Cost Evaluation

* Description of how cost data will be collected, and a break-down of the costing scope (e.g., whether or not social worker time, administration etc., are costed). Costs for social worker time should be reported separately from the main cost per child evaluation to ensure cost estimates are easy to use for local authorities and decision-makers.
* Include details of the cost of the intervention as it was delivered, but also include details where there is an intention to increase or decrease its cost in the future.
* Although the cost of interventions may sometimes be subsidised or directly funded by the WWCSC, cost evaluations should assume that no funding is being provided and calculate the total cost to local authorities if they were to implement the intervention independently.
* The cost per child calculations and reporting should be taken from the perspective of the local authority.
* Cost evaluations should also consider a range of perspectives. The intervention might create costs or savings to parents, schools or local authorities, for example, and where these are significant they should be reported separately from the costs to the local authority.

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# Risks

Document key risks that have been identified, and what actions that have been taken to mitigate against them. It can help to rate the likelihood and impact of each risk under low, medium or high.

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| --- | --- |
| **Risk** | **Mitigation** |
|  |  |
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# Ethics & Participation

* Clearly describe the process for obtaining ethical approval, including timelines and responsible parties.
* Where a generic ethical clearance has been issued, refer to the original judgement on this process.
* Describe the procedures for obtaining agreement to participate in the trial.
* Ensure ethical issues (e.g., protecting participants and researchers from harm, confidentiality, consent, right to withdraw, data security) are considered here or elsewhere within the protocol.

# Registration

* Ensure the trial is registered with the OSF and that the trial registry is updated with outcomes at the end of the project.

# Data Protection

* Include a data protection statement relevant to the project.
* Provide details of the categories of individuals (e.g. social workers, children in care etc..), the categories of personal data (i.e. contact details, children’s social care case data, demographic characteristics including gender) and the categories of special category (e.g. health, ethnicity) that are being processed in this project.
* Describe, at a high level, relevant procedures for ensuring data quality (if not already covered in the data analysis section above), anonymity or confidentiality, as applicable.
* Outline any key data protection related activities you’ve under-taken. This should include:
	+ Providing details of the data protection legislation being abided by (e.g. the Data Protection Act (2018)).
	+ Detailing whether or not you’ve conducted a Data Protection Impact Assessment (DPIA).
	+ Linking to (or providing as an Annex) relevant privacy notices.
	+ Outlining any data sharing that may take place, and any relevant agreements you have in place with other parties (Data Sharing Agreements or Data Processing Agreements).
	+ Explain the role of key parties - e.g. who are the data controllers and processors.
	+ Providing contact details of your DPO (if applicable).
* Reference relevant organisation policies (e.g. Data Protection Policy and Information Security Policy) or accreditations (e.g. ISO 27001, Cyber-Essentials).
* Describe your legal basis for processing personal data and / or for processing special categories of personal data, with reference to the [General Data Protection Regulation, Chapter 2, Article 6](https://gdpr-info.eu/art-6-gdpr/). Provided it’s documented elsewhere (e.g. DPIA or privacy notice, you do not have to provide your full rationale here).

# Personnel

* Delivery team: Roles and responsibilities within the project; institutional affiliation for each member
* Evaluation team: Roles and responsibilities within the project; institutional affiliation for each member

# Timeline

* Timetable including specification of who is responsible for completing each task
* Include specific dates or date intervals.

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| Dates | Activity | Staff Responsible/ Leading |
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1. <http://www.bmj.com/content/348/bmj.g1687> [↑](#footnote-ref-1)
2. This includes, and will most likely be most influenced by, a baseline measure of the outcome. [↑](#footnote-ref-2)
3. By default we would recommend two-sided tests. [↑](#footnote-ref-3)