

STATISTICAL ANALYSIS PLAN

A pragmatic cluster randomised controlled trial of the 'Fostering Connections' programme: Examining the impact of trauma-informed training and support for social workers on youth in care in family settings

Centre for Evidence and Implementation and Bryson Purdon Social Research

Principal investigator: Dr Ellie Ott

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Statistical analysis plan

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Project title	A pragmatic cluster randomised controlled trial of the 'Fostering Connections' programme: Examining the impact of trauma-informed training and support for social workers on young people in care in family settings
Developer (Institution)	National Children's Bureau
Evaluators (Institutions)	Centre for Evidence and Implementation and Bryson Purdon Social Research
Principal investigator(s)	Dr Ellie Ott
SAP author	Dr Susan Purdon, BPSR
Trial design	Two-armed cluster randomised controlled trial with random allocation at the level of the young person's social worker
Trial type	Efficacy
Evaluation setting	Family and children's services settings

Target group	Young people in care in foster care or supported lodgings, aged 10-17 years old
Number of participants	558 young people at baseline; 391 young people at follow-up
Primary outcome and data source	Young person outcome: Externalising behaviour measured through the Strength and Difficulties Questionnaire (carer report version, externalising score)
Secondary outcomes and data sources	<p>Young person outcomes:</p> <ol style="list-style-type: none"> 1. Internalising score of the Strength and Difficulties Questionnaire (carer report version, internalising score) 2. Prosocial subscale of the Strength and Difficulties Questionnaire (carer report version) 3. Involvement with criminal justice system measured through conviction or subject to youth caution (SSDA903) 4. Transition into residential care (SSDA903) 5. Placement stability measured through unplanned moves (SSDA903) 6. Missing from care (SSDA903) <p>Foster carer outcomes:</p> <ol style="list-style-type: none"> 7. Compassion satisfaction reported by foster carers, measured through the Professional Quality of Life (ProQOL) scale (self-report) 8. Burnout reported by foster carers, measured through the ProQOL scale (self-report) 9. Secondary traumatic stress reported by foster carers, measured through the ProQOL scale (self-report)

	<p>10. Trauma-informed knowledge reported by foster carers, measured through a bespoke questionnaire (self-report)</p> <p>Supervising social worker and young person’s social worker outcomes:</p> <p>11. Attitudes to trauma-informed practice reported by social workers, measured through the Attitudes Related to Trauma-Informed Care (ARTIC) scale</p>
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SAP version history

Version	Date	Changes made and reason for revision
1.2 [latest]		
1.1		
1.0 [original]		<i>[leave blank for the original version]</i>

Any changes to the design or methods need to be discussed with the YEF Evaluation Manager and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design. Please ensure that these changes are also reflected in the SAP (CONSORT 3b, 6b).

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Introduction

The National Children's Bureau (NCB) and Leap Confronting Conflict (Leap CC) have partnered to deliver the 'Fostering Connections' training programme for young person social workers (YPSWs) and supervising social workers (SSWs), aimed at enabling young people (YP) aged 10-17 years old in foster care or supported lodgings to have reduced emotional and behavioural difficulties, including through the strengthening of meaningful relationships with trusted adults. To do so, the training seeks to improve professional relationships and communication between young people's social workers (YPSWs) and supervising social workers (SSWs), improve support for foster carers (FCs) (including kinship/connected carers and host families of young people aged 16 and 17 in supported lodgings), and increase understanding of trauma and implementation of trauma informed practice from the adults supporting YP in care (FCs, SSWs and YPSWs).

The trial is being run in eight LAs across England.

YPSWs and SSWs assigned to the intervention arm of the trial will be offered the training. They will be provided with an e-learning module (around 45 min), 7 days of face to face training and 3 days of reflective practice over five months, followed by monthly cross-LA virtual follow-up workshops and an online peer support network. Trained staff work with the young person and/or their FC across the 10 to 12-month period from start of the training to follow-up (including after the intervention ends).

The trial aims to address a broad range of research questions:

The **primary** question to be addressed by the trial is:

Research Question 1 (RQ1): What is the impact of providing the training and support to both YPSWs and SSWs on the externalising behaviour of YP in care in family settings? This will be measured using the Strengths and Difficulties Questionnaire (SDQ), completed by FCs/supported lodgings providers at baseline and follow-up.

Secondary research questions focus on wider impacts on YP, as well as on impacts on SSWs, YPSWs and FCs. These ask questions about the impact of providing training and support to YPSWs and SSWs on:

Young people

RQ2: What is the impact of providing the training and support to both YPSWs and SSWs on the stability of foster care/supported lodging placements for YP, measured using

SSDA903 data¹ on reasons for moves (those categorised as ‘unplanned’) and transitions into residential care?

RQ3: What is the impact of providing the training and support to both YPSWs and SSWs on YP’s involvement with the criminal justice system, measured using youth cautions and convictions data in the SSDA903?

RQ4: What is the impact of providing the training and support to both YPSWs and SSWs on YP’s episodes missing from care² as reported in the SSDA903?

RQ5: What is the impact of providing the training and support to both YPSWs and SSWs on the internalising and prosocial subscales of the SDQ, completed by FCs/supported lodgings providers at baseline and follow-up.

YPSWs and SSWs

RQ6: What is the impact of providing the training and support to both YPSWs and SSWs on their attitudes towards TIP, measured using the ARTIC scale?

Foster carers

RQ7: What is the impact of providing the training and support to both YPSWs and SSWs on the compassion satisfaction, burnout, and secondary traumatic stress of FCs/caregivers in a family setting, measured using the ProQOL?

RQ8: What is the impact of providing the training and support to both YPSWs and SSWs on the FCs’ attitudes towards TIP, measured using a bespoke questionnaire that builds upon other TIP surveys.

Although the intervention is being delivered to YPSWs and SSWs, the trial primarily focuses on the measurement of the impact of the intervention on eligible YP. For a YP to be in scope for the trial, the young person needs to meet the basic age criteria (10-17), but also needs to have both a YPSW and SSW that is in-scope for the trial. If some YPSWs or SSWs are excluded from the trial (which can, for example, happen if Independent Fostering Agencies (IFAs) are excluded in some LAs) then the YP they are assigned to is not included in the trial.

Within each LA, the YPSWs and SSWs eligible for the trial are:

¹ That is, administrative data that is collected via the ‘Children looked after return’.

² Missing from care: a looked-after child who is not at their placement or the place they are expected to be (for example school) and their whereabouts is not known.

1. YPSWs whose caseload includes at least one young person aged 10 to 17 at the start of the trial;
2. SSWs working with a FC or supported lodgings provider with an eligible YP in their care at the start of the trial.

Design overview

The trial is being run as a two-arm cluster randomised controlled trial with random allocation at the level of the YPSW. Each SSWs is assigned to the same group as the YPSW with which they work most frequently. The unit of analysis for the primary outcome is the YP. As is explained in more detail in the randomisation section, **the randomisation leads to a trial with four arms as follows, but only the first two of the arms are to be used in the main trial analysis**³: (i) YP where both the YPSW and SSW are assigned to the training; (ii) YP where neither the YPSW nor the SSW are assigned to the training; and (iii) YP where the YPSW is assigned to the training but the SSW is not; and (iv) YP where the SSW is assigned to the training but the YPSW is not. This document focuses on the main trial analysis of the first two arms. Analysis that incorporates all four arms is described in the final section of this document 'Analysis of all four arms of the trial'.

Data collection

Data for the trial is being collected at two points in time, at baseline (prior to randomisation of the YPSWs) and at a follow-up point 10 to 12 months later, via online surveys directed at the in-scope YPSWs and SSWs, and FCs. The SDQ data for YP is being collected via the online surveys sent to the FCs. Social Worker involvement in the trial is not dependent on FCs agreeing to complete the surveys, so there is inevitably a fairly high percentage of missing data for YPs and FCs at both baseline and follow-up. Likewise, social workers are randomised to intervention or control irrespective of whether they complete a baseline or follow-up questionnaire.

FCs will be asked to complete a follow-up questionnaire to cover their own outcomes even if their eligible YP is no longer in their care. In cases where a YP moves to another FC, the new FC will be asked to complete the SDQ at follow-up. If a YP moves out of foster care entirely they will be excluded from the trial analysis, the exception being the secondary outcomes that capture moves. Social workers will be asked to complete follow-up questionnaires even if they have changed jobs, but we expect the response rate for movers to be low.

³ As is described later in the randomisation section, this is because the four arms are not all equivalent, with the first and second arms being balanced, and the third and fourth, but without balance across between the first/second and third/fourth arms.

Four secondary outcomes for YP are making use of standard administrative data collected for the SSDA903. We expect to have close to complete data on these outcomes for all YP who stay in foster care.

Table 1: Trial design

Trial design, including number of arms		Two-armed cluster randomised controlled trial
Unit of randomisation		Young person’s social worker (YPSW)
Stratification variables (if applicable)		Local Authority (LA)
Primary outcome	variable	Young person’s externalising behaviour
	measure (instrument, scale, source)	Externalising score, Strengths and Difficulties Questionnaire (Goodman, Meltzer & Bailey, 1998), carer-reported version, fielded in online survey 10-12 months after baseline
Secondary outcome(s)	variable(s)	Young person: SDQ Internalising and Prosocial sub-scales; Involvement with criminal justice system; transition into residential care, placement stability; missing from care episodes SSW / YPSW: Attitudes to trauma-informed practice FCs: compassion satisfaction, burnout; secondary traumatic stress; attitudes to trauma-informed practice
	measure(s) (instrument, scale, source)	Young person: SDQ, carer-report version; Child conviction or subject to youth caution (SSDA903 2024-25); transition into residential care (SSDA903 2024-25); unplanned moves (SSDA903 2024-25); missing from care episodes (SSDA9035 2024-25). SSW / YPSW: ARTIC scale at 12 month after baseline FCs: Professional Quality of Life Scale (self-report), bespoke questionnaire (self-report) at 10-12 months after baseline
Baseline for primary outcome	variable	Young person’s externalising behaviour
	measure (instrument, scale, source)	Externalising score, Strengths and Difficulties Questionnaire, carer-report (Goodman et al, 1998), fielded in online survey as close as possible to randomisation of YPSW

Baseline for secondary outcome	variable	<p>Young person: Emotional and behavioural difficulties; Involvement with criminal justice system; Transition into residential care, placement stability; missing from care episodes</p> <p>SSW / YPSW: Attitudes to trauma-informed practice</p> <p>FCs: compassion satisfaction; burnout; secondary traumatic stress; attitudes to trauma-informed practice</p>
	measure (instrument, scale, source)	<p>Young person: SDQ, carer-report version; Child conviction or subject to youth caution (SSDA903 2023-2024); transition into residential care (SSDA903 2023-2024); unplanned moves (SSDA903 2023-2024); missing from care episodes (SSDA903 2023-2024)</p> <p>SSW / YPSW: ARTIC Scale prior to randomisation</p> <p>FCs: Professional Quality of Life Scale (self-report); bespoke questionnaire (self-report) as close as possible to randomisation of YPSW</p>

Randomisation

There are constraints on the number of training places per LA⁴, so YPSWs per LA have not typically been allocated to intervention and control group in the ratio 50:50. Instead, the percentage allocated to the intervention was set so that all available places were filled, with up to a maximum of 70% being allocated to the intervention. In practice, for most LAs, the percentage allocated to the intervention was around 46%. Randomisation was run separately per LA by the trial statistician, giving implicit stratification by LA. Since the trial statistician is undertaking the randomisation and will conduct the statistical analysis, the analysis will not be blind to allocation.

A significant complication in this trial is that the primary analysis aims to test whether delivering the intervention to both SSWs and YPSWs improves outcomes for YP, rather than simply testing whether delivering the intervention to one set of professionals or the other has an impact. Yet, SSWs do not cluster within YPSWs (or vice versa), so straightforward randomisation of YPSW/SSW pairs is not feasible. Inevitably some young people in each LA will have a SSW who has been assigned to the intervention group and a YPSW who has been assigned to the control group, and vice versa. That is, when the randomisation is complete, there will be YP in each of four arms, with the first two (in bold) being the primary analysis arms:

⁴ Depending on the number of in-scope social workers in an LA, either one or two training groups were allocated to the LA, with the maximum number of places per group being 35.

Arm 1: T_{SSW}T_{YPSW} (i.e. both SSW and YPSW assigned to the intervention);

Arm 2: C_{SSW}C_{YPSW} (i.e. both SSW and YPSW assigned to the control group);

Arm 3: T_{SSW}C_{YPSW} (i.e. SSW assigned to the intervention and YPSW assigned to the control group);

Arm 4: C_{SSW}T_{YPSW} (i.e. SSW assigned to the control group and YPSW assigned to the intervention group).

As noted, the primary trial analysis will focus on YP within ‘Analysis Arms’ 1 and 2 (that is, pure intervention and pure control). Young people in Arms 3 and 4 will be excluded from the primary analysis. Arms 3 and 4 will however be included in an exploratory analysis, where the impact of just one of the two YPSWs/SSWs being assigned to the intervention is estimated. This is described in the final section ‘Analysis of all four arms of the trial’.

The randomisation method aims to maximise the sample size for the primary analysis. Each SSW was assigned to a ‘unique YPSW’ prior to the start of the trial, with this being done by assigning each SSW to the YPSW with whom they share the most eligible YP. To illustrate, if a SSW has 10 eligible YP, and for five of the 10 they work alongside YPSW-1, for three they work with YPSW-2, and for two they work with YPSW-3, then this SSW is assigned to YPSW-1.⁵ If YPSW-1 is then randomly allocated to the intervention group, this SSW will also be assigned to the intervention group (and vice versa). Note that two or more SSWs might be assigned to a single YPSW under this model. The aim in doing this assigning is to generate a set of YPSW/SSW ‘clusters’ that between them cover as many eligible YP as possible. The randomisation steps are described in detail in the Appendix.

The steps in the randomisation are summarised below:

Step 1	Assign each SSW to a unique YPSW (the one they work with for most YP)
Step 2	Randomly allocate YPSW to either intervention and control
Step 3	Assign each SSW to ‘intervention’ or ‘control’ with the allocation being the same as the allocation to group of their ‘unique YPSW’
Step 4	Having determined the group status for every YPSW and SSW, establish which of four arms each YP now belongs to:

⁵ With assignment to an SSW being done randomly if there are two or more SSWs with which they share the same number of families.

	<p>Arm 1 : Both of the YP's SSW and YPSW assigned to intervention;</p> <p>Arm 2 : Both of the YP's SSW and YPSW assigned to control;</p> <p>Arm 3: The YP's SSW assigned to intervention but their YPSW assigned to control</p> <p>Arm 4: The YP's SSW assigned to control but their YPSW assigned to intervention.</p> <p>Only those in Arms 1 and 2 are used in the primary analysis.</p>
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This approach to randomisation does not give a four-arm RCT with balance across all four arms. Analysis Arms 1 and 2 will be balanced (which is vital for the primary analysis), and Arms 3 and 4 will be balanced, but the YP in Arms 3 and 4 will have different experiences to those in Arms 1 and 2 in the sense that the Arms 3 and 4 YP will be more likely to have a YPSW and SSW who work together infrequently. This does not affect the primary analysis, which compares just Arms 1 and 2, but in the exploratory analysis that compares all four arms the lack of balance will be acknowledged.

Once randomisation has been completed, each young person will have been assigned to one of the four randomisation arms. Some contamination during the trial is inevitable (with some 'control' YP being assigned to a trained social worker during the trial and vice versa). This will be monitored and sensitivity analysis will be conducted to establish the degree to which this dilutes the overall effect sizes (see analysis section).

Sample size calculations overview

Our primary analysis (which uses externalising behaviour as measured through the SDQ as an outcome) focuses on the YP where both the YPSW and SSW have either been assigned to the intervention group or to the control group (Analysis Arms 1 and 2 as described in the randomisation section above). Arms 1 and 2 between them cover 66% of all the eligible YP identified as in-scope for the trial.

Table 2 sets out the MDES and sample sizes that were originally anticipated and as they were presented in version 1 of the trial protocol. The final column sets out our revised estimates after recruitment of LAs, baseline data collection, and randomisation. The original intention was to recruit 10 LAs to the trial rather than the eight achieved, and the initial predictions of response rate at baseline proved too optimistic. However, the number of social workers was much larger than anticipated, which reduces the average cluster size. Nevertheless, the MDES

has increased from the initial protocol estimate of 0.21 standard deviations to 0.24 standard deviations.

The assumptions behind the calculations are:

- Across the eight LAs, the total number of eligible YP is 1,477. Of these, 979 have been assigned to one of the two primary analysis arms: 458 to the group where both the YPSW and the SSW are assigned to the intervention group and 521 to the group where both the YPSW and the SSW are assigned to the control group.
- Of the YP in the primary analysis, baseline data has been collected for 57% of them, giving a trial 'baseline population' of 558. We do not expect there to be any major imbalances at baseline associated with FC non-response, because the decision taken by a FC on whether or not to take part should be independent of the randomisation. In most cases the baseline data was collected prior to randomisation, but where it was collected post-randomisation, the FC would have been very unlikely to be aware of the allocation of their SSW or their foster child's YPSW.
- Of the 558 YP with baseline data, we assume 70% will be eligible (that is, the YP is still in foster care) and will complete at follow-up. This will give an analysis dataset of around 391: 183 YP in the intervention arm and 208 YP in the control arm.
- We assume that the correlation between the externalising SDQ score between baseline and follow-up will be around 0.6. The Creative Life Story Work (CLSW) trial, which compared baseline and follow-up SDQ scores on the SSSA903 for a similar population found a correlation of 0.53 (Taylor et al., 2022). With more standardisation on data collection in the Fostering Connections Trial we expect the correlation to be slightly higher at 0.6, but if the 0.53 is replicated our MDES increases from 0.24sd to 0.25sd.
- The Intraclass Correlation Coefficient (ICC) associated with the clustering of the trial within YPSWs and SSWs is not known, and we do have data from which we can estimate it, but we have assumed it may be as high as 0.2. That is, we assume that between-SW variance in the SDQ externalising score accounts for quite a high percentage of total variance. This would be the case if social workers have a marked influence on SDQ scores. Given the hypothesis that the Fostering Connections training will affect SDQ scores, this seems the most reasonable assumption we can make. The average cluster size is expected to be around 3.7⁶ for all those in the trial, but in the analysis dataset is expected to be considerably lower because of non-response. It could potentially be very close to 1, but is set at 1.5 in the calculations. Consequently the MDES is not very sensitive to the ICC assumption.

⁶ Calculated as the ratio of YP to SSWs, because there are fewer SSWs than YPSWs in the trial

The MDES was calculated within Excel using the approximate formula:

$$MDES = (1.96 + 0.84) \sqrt{\left(\frac{1}{n_1} + \frac{1}{n_2}\right) * (1 + (m - 1)\rho) * (1 - R^2)}$$

where

n_1 is the achieved sample size in the intervention arm (Group 1);

n_2 is the achieved sample size in the control arm (Group 2);

m is the average cluster size;

ρ is the ICC; and

R is the correlation between the baseline and follow-up score.

The value 1.96 is the z-value for a type 1 error rate (alpha) of 0.05, and 0.84 is the z-value for 80% power.

Table 2 sets out the assumptions for the primary outcome (externalising SDQ score). The assumptions do not all hold for the secondary outcomes, the major differences being:

- For SSDA903 outcomes which are collected via administrative systems, the sample sizes will be somewhat larger because losses to the sample will be lower. The correlation between baseline and follow-up is not known but is likely to be low for the non-SDQ scores at least, and the ICC is not known, but overall we expect an MDES of around 0.20sd for these outcomes;
- There will be fewer FCs than YP in the analysis as FCs may care for more than one eligible YP, our best current assumption being that it will be around 139 in Group 1 and 163 in Group 2. We estimate an MDES of 0.27sd for their outcomes.
- There are 422 YPSWs and 264 SSWs in the trial (686 overall), divided into two groups, intervention and control, with around 316 in the intervention arm and 370 in the control arm per arm (139 and 163 respectively after non-response). For their outcomes we estimate an MDES of around 0.23sd.

Table 2: Sample size calculations

	Protocol version 1	Post randomisation
Minimum Detectable Effect Size (MDES)	0.21 sd	0.24 sd

		Protocol version 1	Post randomisation
Pre-test/ post-test correlations	level 1 (participant)	0.6	0.6
	level 2 (cluster)	0	0
Intracluster correlations (ICCs)	level 1 (participant)	0	0
	level 2 (cluster)	0.2	0.2
Alpha ⁷		0.05	0.05
Power		0.8	0.8
One-sided or two-sided?		Two	Two
Average cluster size		7.7	1.5
Number of clusters ⁸	intervention	70 YPSWs	198 YPSWs/124 SSWs at randomisation stage
	control	70 YPSWs	224 YPSWs/140 SSWs at randomisation stage
	total	140 YPSWs	422 YPSWs/264 SSWs
Number of participants	intervention	540	183 (after non-response)
	control	540	208 (after non-response)
	total	1,080	391

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.

⁸ Please adjust as necessary e.g., for trials that are randomised at the setting, practitioner or participant level.

Analysis

Primary outcome analysis

The analysis of the efficacy trial data will be on an intention-to-treat basis. Estimates of impact per outcome will be based on a multilevel linear regression model with two levels, YPSW and YP, with the baseline version of each outcome being entered as a covariate. LA will be entered as a fixed effect. The analysis will be conducted in SPSS v28.0.1.1 via the MIXED procedure.

If, after non-response, we have data that is essentially unclustered then a single-level model will be fitted.

Primary outcome analysis

The primary outcome measure for YP in the trial is the SDQ externalising score.

The SDQ questionnaire includes five subscales, each with five items, that measure: 1. Emotional symptoms; 2. Conduct problems; 3. Hyperactivity/inattention; 4. Peer problems; 5. Prosocial behaviour. FCs score from 0 to 2 on each item using a scale 'not true', 'somewhat true' or 'certainly true', thus producing a score for each subscale from 0 to 10, where a lower total score is a better outcome for subscales 1-4, and the reverse for subscale 5 (prosocial behaviour). The 'externalising' score (from 0 to 20), is generated by summing the scores of the conduct and hyperactivity subscales.

The calculation of the externalising score will follow the standard SDQ scoring rules. The score will only be calculated where both subscales have a valid score (that is, at least three of the five items have been answered), others being set to missing. Each subscale will be calculated as (total subscale score)*5/(number answered).

The main regression model specification is as follows:

$$Y_{ijk} = \beta_0 + \beta_1 \text{Group}_{jk} + \beta_2 X_{ijk} + \beta_3 LA_k + u_{ijk} + \varepsilon_{ijk} \quad (\text{Eq 1})$$

where

Y_{ijk} = externalising score at follow-up for young person i belonging to assigned at baseline to YPSW j within LA k;

$\beta_0, \beta_1, \beta_2, \beta_3$ = fixed effect parameters;

Group_{jk} = indicator variable for group allocation of the YP's YPSW and SSW (0=control; 1=intervention) within LA k;

X_{ijk} = baseline externalising score for young person i assigned at baseline to YPSW j within LA k;

LA_k = a vector for the local authority dummy variables, of which there will be seven. β_3 is a coefficient vector for the LA dummy covariates;

u_{ij} =random effect for i th member of YPSW j ;

ε_{ijk} = residual error term for i th member of cluster j .

If, at the analysis stage, the average cluster size proves to be very close to one (that is 1.1 or below) we will use a single-level model rather than two-level. In this case the model will be:

$$Y_{ik} = \beta_0 + \beta_1 Group_{ik} + \beta_2 X_{ik} + \beta_3 LA_k + \varepsilon_{ik} \quad (\text{Eq 2})$$

where

Y_{ik} =externalising score at follow-up for young person i within LA k ;

$\beta_0, \beta_1, \beta_2, \beta_3$ = fixed effect parameters;

$Group_{ik}$ = indicator variable for group allocation of the YP's YPSW and SSW (0=control; 1=intervention) within LA k ;

X_{ik} = baseline externalising score for young person i within LA k ;

LA_k = a vector for the local authority dummy variables, of which there will be seven. β_3 is a coefficient vector for the LA dummy covariates;

ε_{ik} = residual error term.

Secondary outcome analysis

There are a range of secondary outcome measures reflecting the fact that the Theory of Change suggests that impacts should be observed for all the groups potentially affected by the SW training, namely YP, FCs, and the social workers themselves.

1. Young people

There are six secondary outcomes for YP:

- The SDQ internalising score (continuous variable);
- The SDQ prosocial score (continuous variable);

and four outcomes taken from SSSA903 data:

- One or more unplanned moves (binary);

- Transition into residential care (binary);
- Conviction or subject to youth caution (binary);
- Any missing from care episodes (binary).

2. Foster carers

There are four secondary outcomes for foster carers (detailed in the trial protocol):

- The three Professional Quality of Life (ProQOL) subscales (continuous variables):
 - o compassion satisfaction;
 - o burnout;
 - o secondary traumatic stress.
- Knowledge and understanding of TIP score (continuous).

3. Social workers

For social workers in the trial, there is just one secondary outcome:

- ARTIC score (continuous)

The analysis of the secondary outcomes will be conducted following similar overall model specifications as the primary outcome analysis, but with some modifications to reflect the nature of the data. These are:

- The models for the binary outcomes will be logistic regressions rather than linear;
- For the SSDA903 outcomes, for YP just entering foster care there will be no applicable baseline data. To account for this, a baseline outcome will be included in the model coded as categorical: present, absent; not applicable.
- The regression model for social worker outcomes will be specified using the primary outcome model, but there will be no clustering effects for YPSWs given that these are the units of randomisation. Here the model will be:

$$Y_{jk} = \beta_0 + \beta_1 Group_{jk} + \beta_2 X_{jk} + \beta_3 LA_k + \varepsilon_{jk} \quad (\text{Eq 3})$$

where

Y_{jk} = ARTIC score at follow-up for SW j within LA k;

$\beta_0, \beta_1, \beta_2, \beta_3$ = fixed effect parameters;

$Group_{jk}$ = indicator variable for group allocation (0=control; 1=intervention) within LA k;

X_{jk} = baseline ARTIC score for SWj within LA k;

LA_k = a vector for the local authority dummy variables, of which there will be seven. β_3 is a coefficient vector for the LA dummy covariates;

ε_{jk} = residual error term.

Given the large number of secondary outcomes, the secondary outcome tests for YP will be corrected for multiple comparisons using Hochberg's step-up procedure⁹. Likewise, but independently, the tests for the four secondary outcomes for FCs will be corrected.

Subgroup analyses

The trial is relatively small, with an expected sample size of under 210 per arm with complete baseline and follow-up data on the primary outcome. There are no prior expectations of large differential impacts across sub-groups of YP, and the sample size is too small for modest differences across groups to be identified. For these reasons, very little sub-group analysis is planned. The exception is that the primary YP outcome will be presented split by ethnic group (generated by running separate regression models per sub-group) to facilitate future meta-analysis, but excluding any ethnic groups with less than 30 YP per arm.

For the secondary social worker outcome, ARTIC, a joint YPSW/SSW analysis will be undertaken but, subject to some evidence of impact, separate models will be run and presented for YPSWs and SSWs.

Further analyses of the primary trial data

Sensitivity of the effect sizes to changes in YP and FC social workers during the trial

This is a pragmatic trial and it is not possible for the evaluation team to influence the allocation of YPSWs to YPs or the allocation of SSWs to FC, or, of course, the matching of YPs to FCs. An issue that will inevitably arise during the trial relates to the fact that the intervention is being delivered to social workers rather than to the YP themselves. Because YP may change their YPSW, and their FCs may change their SSW, between baseline and follow-up, a control group YP could, during the trial, be re-assigned to a YPSW or SSW who has been trained, and an intervention group YP could be re-assigned to a YPSW or SSW who has not been offered the training¹⁰. These post-randomisation switches are likely to dampen the ITT effect sizes. To test the sensitivity of the ITT estimates to these issues, we will re-run the main

⁹ This is the approach recommended by the What Works for Children's Social Care.

¹⁰ Similarly a YP could move to a new FC with a SSW from the opposite arm of the trial.

two-group analyses per outcome after excluding these switched cases¹¹. Given that the switching is likely to be largely independent of the random allocation – it is more likely to be done by the LA teams for very practical reasons – this should still give close to unbiased estimates, albeit for what may be a non-random subset of YP. However, prior to running this analysis, we will test the assumption that the switching is independent of the random allocation, using a t-test for proportions.

Imbalance at baseline and follow-up

The trial report will summarise baseline characteristics for the two primary arms of the trial for all YP for whom we have baseline data, and separately, for those with both valid baseline and follow-up data. The differences at baseline will provide evidence on whether missing data at baseline (because of baseline non-response by FCs) introduced an imbalance across the arms; the differences at follow-up will provide evidence on whether attrition post-baseline has introduced an imbalance. Note, we do not expect there to be any major imbalances at baseline associated with FC non-response, because the decision taken by a FC on whether or not to take part should be independent of the randomisation. In most cases the baseline data was collected prior to randomisation, but where it was collected post-randomisation, the FC would have been very unlikely to be aware of the allocation of their SSW or their foster child's YPSW.

The characteristics shown will be: YP randomised per LA, gender, age, ethnic group, SDQ externalising mean at baseline, and SDQ internalising and prosocial score means at baseline.

Missing data

We will describe and summarise the extent of missing data per outcome, and the reasons for data being missing where known will be reported on. We will document how much missing data is unit non-response and how much is item non-response, and whether there is evidence for trial imbalance because of missing data either at baseline or follow-up.

The primary ITT regression analysis will be based on complete cases, that is those for which all of the variables needed for the model are complete. The implicit assumption here is that missing data at follow-up is 'missing completely at random' (MCAR). However, because the rate of missing data in this trial is inevitably high (because of non-response to the surveys by FCs either at baseline or follow-up), we will assess the sensitivity of the results to alternative assumptions about the mechanisms leading to missing data.

¹¹ We ruled out analysis that tries to control for these switches because we will not have rich enough data to know when during the trial period the switch occurred, and because of the additional complexity introduced because both or just one of the professionals could be switched

Firstly, we will use the baseline outcome variables for YP and FCs¹², together with other YP and FC characteristics to model (via a logistic regression) the probability per YP of a case being in the intervention arm rather than the control arm. This will identify any observable predictors of imbalance, and the regression model (Eq 1) will be re-run to include, as covariates, any significant predictors that are identified from this logistic regression. This will help establish whether the effect sizes are influenced by the level and nature of missing data, under an assumption of missing at random (MAR).

Secondly, we will make use of the fact that the SSDA903 data will provide total SDQ scores at baseline and follow-up for many of the young people in the trial, the main exceptions being those young people who have been looked-after continuously for less than 12 months and those aged 17¹³. We will test whether there is evidence of non-response bias in the trial by comparing the mean SSDA903 scores for respondents and non-respondents at each time point, separately within each arm of the trial. If there are observed differences in the means this will allow for an estimate of the magnitude and direction of any bias.

Finally, if there is evidence that outcomes data is missing not at random (MNAR) we will include some estimates of effect sizes based on a range of extreme assumptions about the missing outcomes. This will generate upper and lower bounds for the effect sizes. The assumptions adopted for this sensitivity analysis will include imputing the worst possible outcomes scores for those missing from the intervention arm and the best possible outcomes scores for those missing from the control arm.

The approach will be repeated across all of the secondary outcomes with the probable exception of the SSDA903 outcomes, where we do not anticipate much missing data.

Compliance

Defining 'compliance' for YP in the trial is not straightforward because of the fact that the intervention is being delivered to social workers rather than to the YP themselves, so YP 'compliance' is dependent on the decisions of their YPSWs and SSWs. Because YP may change their YPSW, and their FCs may change their SSW, between baseline and follow-up, compliance

¹² FC baseline data will be used in the model because it is FCs who complete the data about YP.

¹³ The SDQ scores from the SSDA903 will not be affected by attrition so the sample sizes will be larger and non-response bias less likely. However, it is being used as an outcome measure in its own right for a range of reasons. The SDQ recorded in the SSDA903 excludes YP who are over 16 and only includes YP who have been looked-after continuously for at least 12 months. Also, the timing of the data collection can vary during the year, so the data is not at a fixed outcome point. Experience on other studies (in particular the evaluation of the Mockingbird programme) has been that SDQ data is often missing from SSDA903 submissions which would reduce its usefulness. However, early indications on the current trial are that it is close to complete.

is not a binary variable per YP per social worker. Furthermore, a control group YP could, during the trial, be re-assigned to a YPSW or SSW who is in the intervention arm (and vice versa), further complicating the definition of compliance.

Compliance with the training for social workers will be defined as a binary variable. The definition of compliance to be used is attendance of 4 out of 7 training sessions plus 2 out of 3 reflective practice sessions. In light of this, we will define compliance for YP in the intervention group as that one or both of their YPSW and SSW at baseline are compliant with the training.

The problem of YP being re-assigned to a social worker from the opposite arm of the trial is likely to be unrelated to the trial itself, so it seems reasonable to assume it will affect both of the primary analysis arms of the trial equally. In light of this, we will run a CACE analysis to isolate the impact of compliance with the training after excluding these switched-arm cases from the data.

We will re-run the ITT primary outcome regression model to generate the ITT effect size for this reduced dataset. Complier Average Causal Effect (CACE) will then be used to estimate the effect size for the 'social worker compliers' (as defined above). This will be estimated using two stage least squares (2SLS) regression. The first stage will model the compliance variable using the same explanatory variables used for the headline ITT analyses. This will be a multilevel logistic regression model used to generate predicted compliance for use in the second stage model. The second stage models will use predicted compliance in place of the group identifier variable in the ITT analyses specified above to generate the CACE estimate.

A separate CACE analysis will be conducted for the secondary social worker outcome, ARTIC.

Intra-cluster correlations (ICCs)

The trial is clustered within YPSWs. For the YP primary and secondary outcomes, ICCs will be presented, calculated at pre and post-test as the between-cluster variance divided by the total variance from the regression models. In addition, for the post-test, the ICC using the variance components from the adjusted regression model will be presented.

Presentation of outcomes

Effect sizes will be calculated using Hedges' g , as specified in the following equation:

$$ES = \frac{(\underline{Y}_T - \underline{Y}_C)_{adjusted}}{s}$$

where \underline{Y}_T is the regression adjusted mean for the treatment group, \underline{Y}_C is the regression adjusted mean for the control group (computed using Eq 1), and s^2 is the pooled unconditional variance of the two groups (derived from the raw data).

Effect sizes will be reported along with confidence intervals and p-values to reflect statistical uncertainty.

Analysis of all four arms of the trial

An exploratory analysis for the primary and secondary outcomes will include Analysis Arms 3 and 4 in the regression model, that is the groups of YP where one social worker (YPSW or SSW) was randomised to training and the other to control. For this analysis the trial will be assumed to follow a factorial design. The regressions for this analysis will generate three effect estimates: the effect of the intervention being delivered to SSWs; the effect of the intervention being delivered to YPSWs; and the additive effect of the intervention being delivered jointly to SSWs and YPSWs (that is, the interaction effect). Differences between the effect sizes will be tested for significance, but given the relatively small sample sizes in Arms 3 and 4 we do not anticipate they will reach significance, so the results will be presented purely descriptively. Given that Arms 3 and 4 are not balanced with Arms 1 and 2 (see randomisation section), this analysis will be presented with suitable caveats, and the fact that the effect sizes may be biased, will be explained.

The model for this analysis is:

$$Y_{ijk} = \beta_0 + \beta_1 Z_{1ik} + \beta_2 Z_{2ik} + \beta_3 Z_{1ik} Z_{2ik} + \beta_4 X_{ijk} + \beta_5 LA_k + u_{ijk} + \varepsilon_{ijk} \quad (\text{Eq 4})$$

where

Y_{ijk} = outcome score at follow-up for young person i assigned at baseline to YPSW j within LA k;

$\beta_0, \beta_1, \beta_2, \beta_3, \beta_4, \beta_5$ = fixed effect parameters;

Z_{1ik} = indicator variable for allocation of the YP's YPSW (0=control; 1=intervention) within LA k;

Z_{2ik} = indicator variable for allocation of the YP's SSW (0=control; 1=intervention) within LA k;

X_{ijk} = baseline externalising score for young person i assigned at baseline to YPSW j within LA k;

LA_k = a vector for the local authority dummy variables, of which there will be seven. β_3 is a coefficient vector for the LA dummy covariates;

u_{ij} = random effect for ith member of YPSW j;

ε_{ijk} = residual error term for ith member of cluster j.

Appendix: Illustration of the random allocation steps

In this appendix the steps in the randomisation process for each LA are illustrated. For this illustration there are 46 YP, 14 YPSWs and 10 SSWs.

Table 1 shows the distribution of the 46 YP across the two teams of social workers. The rows represent the YPSWs and the columns the SSWs. The final columns and rows show the totals. The table is sorted on the total number of YP for each YPSW (high to low).

The cells in green (one per SSW) show the YPSW that each SSW is assigned to, this being the YPSW with whom they share the most eligible YP. The green cell is the cell with the maximum value in the column or, where there are ties for maximum, one is selected at random. This is the 'unique' YPSW for each SSW.

Table 1: The distribution of 46 YP across 14 YPSWs and 10 SSWs

	SSW001	SSW002	SSW003	SSW004	SSW005	SSW006	SSW007	SSW008	SSW009	SSW010	Total (sorted on total # YP)
YPSW14	1	1	1			2	1		1		7
YPSW13	3					1	1		1		6
YPSW02			1	1	1				2		5
YPSW12			2					1		2	5
YPSW01	1	1					1	1			4
YPSW04								1		3	4
YPSW06					1			1	1		3
YPSW11				3							3
YPSW09					1		1				2
YPSW10	1				1						2
YPSW05			1				1				2
YPSW03			1								1
YPSW07	1										1
YPSW08				1							1
Total	7	2	6	5	4	3	5	4	5	5	46

Table 2 repeats Table 1 but with a final column added showing the random allocation to intervention or control for the YPSWs.

Table 2: Random allocation of YPSWs to intervention or control

	SSW0 01	SSW0 02	SSW0 03	SSW0 04	SSW0 05	SSW0 06	SSW0 07	SSW0 08	SSW0 09	SSW0 10	Total (sorted on total # YP)	Random allocation of YPSW (1=interventi on; 0=control)
YPSW 14	1	1	1			2	1		1		7	1
YPSW 13	3					1	1		1		6	0
YPSW 02			1	1	1				2		5	1
YPSW 12			2					1		2	5	0
YPSW 01	1	1					1	1			4	1
YPSW 04								1		3	4	0
YPSW 06					1			1	1		3	1
YPSW 11				3							3	0
YPSW 09					1		1				2	0
YPSW 10	1				1						2	1
YPSW 05			1				1				2	0
YPSW 03			1								1	1
YPSW 07	1										1	0
YPSW 08				1							1	1
Total	7	2	6	5	4	3	5	4	5	5	46	

The final row of Table 3 now adds the assignment of each SSW to intervention or control, based on the random allocation of their unique YPSW.

Table 3: Assignment of SSW to match that of the allocation of their ‘unique YPSW’ (the green cells)

	SS W0 01	SS W0 02	SS W0 03	SS W0 04	SS W0 05	SS W0 06	SS W0 07	SS W0 08	SS W0 09	SS W0 10	Total (sorted on total # YP)	Random allocation of YPSW (1=intervention; 0=control)
YPSW14	1	1	1			2	1		1		7	1
YPSW13	3					1	1		1		6	0
YPSW02			1	1	1				2		5	1
YPSW12			2					1		2	5	0
YPSW01	1	1					1	1			4	1
YPSW04								1		3	4	0
YPSW06					1			1	1		3	1
YPSW11				3							3	0
YPSW09					1		1				2	0
YPSW10	1				1						2	1
YPSW05			1				1				2	0
YPSW03			1								1	1
YPSW07	1										1	0
YPSW08				1							1	1
Total	7	2	6	5	4	3	5	4	5	5	46	
Assignment of SSW to match that of the allocation of the YPSEW in the green cell	0	1	0	0	1	1	0	0	1	0		

Table 4 shows the arm that the young people in each cell are assigned to, based on the allocations of their YPSWs and SSWs. The colour coding is as follows:

Arm 1: Both YPSW and SSW assigned to the intervention

Arm 2: Both YPSW and SSW assigned to the control group

Arm 3: SSW assigned to the intervention and YPSW to the control group

Arm 4: SSW assigned to the control group and YPSW to the intervention

Table 4: Assignment of YP to each arm of the trial

	SS W0 01	SS W0 02	SS W0 03	SS W0 04	SS W0 05	SS W0 06	SS W0 07	SS W0 08	SS W0 09	SS W0 10	Total (so rte d on total # YP)	Rando m allocati on of YPSW (1=inter vention; 0=contr ol)
YPSW14	1	1	1			2	1		1		7	1
YPSW13	3					1	1		1		6	0
YPSW02			1	1	1				2		5	1
YPSW12			2					1		2	5	0
YPSW01	1	1					1	1			4	1
YPSW04								1		3	4	0
YPSW06					1			1	1		3	1
YPSW11				3							3	0
YPSW09						1	1				2	0
YPSW10	1				1						2	1
YPSW05			1				1				2	0
YPSW03			1								1	1
YPSW07	1										1	0
YPSW08				1							1	1
Total	7	2	6	5	4	3	5	4	5	5	46	
Assignment of SSW to match that of the allocation of the YPSEW in the green cell	0	1	0	0	1	1	0	0	1	0		

In this illustrative example:

- 7 of 14 YPSWs are allocated to the intervention
- 4 of 10 SSWs are allocated to the intervention
- 11 YP are allocated to Arm 1; 20 to Arm 2; 3 to Arm 3; and 12 to Arm 4.

Table 5 shows the allocation just for the YP in the primary analysis (Arms 1 and 2)

Table 5: Assignment of YP in the primary analysis

	SS W0 01	SS W0 02	SS W0 03	SS W0 04	SS W0 05	SS W0 06	SS W0 07	SS W0 08	SS W0 09	SS W0 10	Total (sorted on total # YP)	Random allocation of YPSW (1=inter vention; 0=contr ol)
YPSW14		1				2			1		7	1
YPSW13	3						1				6	0
YPSW02					1				2		5	1
YPSW12			2					1		2	5	0
YPSW01		1									4	1
YPSW04								1		3	4	0
YPSW06					1				1		3	1
YPSW11				3							3	0
YPSW09							1				2	0
YPSW10					1						2	1
YPSW05			1				1				2	0
YPSW03											1	1
YPSW07	1										1	0
YPSW08											1	1
Total	7	2	6	5	4	3	5	4	5	5	46	
Assignment of SSW to match that of the allocation of the YPSEW in the green cell	0	1	0	0	1	1	0	0	1	0		



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