

The Reflective Fostering Programme – improving the wellbeing of children in care through a group intervention for foster carers: a randomised controlled trial



Study Protocol

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1. General information

This document was constructed using the Norwich Clinical Trials Unit (NCTU) Protocol template Version 4 and the Health Research Authority (HRA) protocol template for Clinical Trials of an Investigational Medicinal Product (CTIMPs). It provides details regarding the setting up of, conduct, analysis and dissemination of the National Institute for Health Research (NIHR) Public Health Research programme (PHR) funded study (ref: NIHR127422), The Reflective Fostering Programme – improving the wellbeing of children in care through a group intervention for foster carers: a randomised controlled trial.

University College London (UCL) is the grant-holding body, and the University of Hertfordshire (UH) will sponsor this study. The Anna Freud National Centre for Children and Families (AFNCCF), Kent County Council (KCC), Kings College London (KCL) and NCTU will be the other collaborators in the study. As such, a collaboration agreement will be signed by the parties, specifying responsibilities and financial arrangements.

Chief Investigator	Nick Midgley
Academic Lead	David Wellsted
Trial Manager	Karen Irvine
Sponsors	University of Hertfordshire
Committees	Trial Team, Trial Management Group, Trial Steering Committee

2. Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator (CI) agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Good Clinical Practice (GCP) guidelines, the Sponsor's (and any other relevant) Standard Operating Procedures (SOPs), and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

Name: Nick Midgley

Role: *Chief investigator*

Signature:16th March 2021....

Date:16th March 2021....

Name: Lee Shepstone

Role: *Statistician*

Signature:

Date: 18th March 2021

Name: John Senior

Role: *Sponsor*

22/03/2021

Signature:

Date:

3. Abbreviations and key terminology

Organisations and personnel involved in the delivery of the study:

CI	Chief Investigator
TM	Trial Manager
UH	University of Hertfordshire
UCL	University College London
UEA	University of East Anglia
AFNCCF	Anna Freud National Centre for Children and Families
KCC	Kent County Council
KCL	Kings College, London
NCTU	Norwich Clinical Trials Unit

UCL are the grant holders, and UH will sponsor the programme of work. The CI will be responsible for delivery of the project.

Further abbreviations and definitions:

APR	Annual progress report
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CTU	Clinical Trials Unit
CTSN	Clinical Trials Support Network
CRN	Clinical Research Network
DHSC	Department of Health and Social Care
GCP	Good Clinical Practice
HRA	Health Research Authority
HRQoL	Health-Related Quality of Life
ISRCTN	International Standard Randomised Controlled Trial Number

LA	Local Authority
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NETSCC	NIHR Evaluation Trials and Studies Co-ordinating Centre
PHR	Public Health Research
PID	Participant identifier
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
QA	Quality Assurance
QC	Quality Control
QALY	Quality Adjusted Life Year
QMMP	Quality Management and Monitoring Plan
RCT	Randomised Controlled Trial
RDS	Research Design Service
REC	Research Ethics Committee
R&D	Research & Development Department
SOP	Standard Operating Procedure
TM	Trial Manager
TMG	Trial Management Group
TMF	Trial Master File
ToR	Terms of Reference
TSC	Trial Steering Committee
UK	United Kingdom

4. Trial summary

Trial title	The Reflective Fostering Programme – improving the wellbeing of children in care through a group intervention for foster carers: a randomised controlled trial
Short title	The Reflective Fostering Study
Clinical Trial Registration No.	
Ethics Reference number	cLMS/SF/UH04242
UH Protocol number	cLMS/SF/UH04242
Funder	National Institute for Health Research - Public Health Research
Trial Design	A definitive, pragmatic, randomised control trial, with a process evaluation and nested economic evaluation and an internal pilot.
Trial Participants	Local authority foster carers or kinship carers (also known as 'connected carers') who are currently looking after a fostered child, aged 4-13.
Planned Sample Size	720 participants: 360 in each arm across 12-14 sites
Intervention	Delivery of a 10-session Reflective Fostering Programme to foster carers in groups of 6-10 participants.
Comparison	Usual support, defined as the support, advice and guidance that all foster carers receive from their allocated social worker, plus any additional support services that they may receive as part of their role as a foster carer
Follow up duration	Four months and 12 months post-baseline
Planned Trial Period	40 months
Study objectives	Establish whether adding the Reflective Fostering Programme to usual support is more effective than usual support alone, in: promoting the emotional and behavioural well-being of children in care; reducing levels of foster carer stress and burnout; increasing foster carer parental reflective capacity; increasing foster carer quality of life and meeting their personalised goals improving the carer-child relationship; and in reducing placement instability.
Outcomes	Primary outcome measure:

	<ul style="list-style-type: none"> The behavioural and emotional well-being of the child 12 months post-baseline, as provided by their score on the carer-report Strengths and Difficulties Questionnaire (SDQ). <p>Secondary outcome measures:</p> <ul style="list-style-type: none"> Foster carer's level of stress Foster carer's quality of life Foster carer's compassion fatigue and burnout The carer-child relationship Child's capacity for emotional regulation Foster carer's reflective capacity Achievement of personalised goals set by the foster carer Placement stability <p>Health Economics measures:</p> <ul style="list-style-type: none"> Child's use of health and social care services Child's health related quality of life (HRQoL) for calculation of quality adjusted life years (QALYs)
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5. Roles and responsibilities of individuals and committees

These membership lists are correct at the time of writing; please see Terms of Reference (ToR) documentation in the Trial Master File (TMF) at the Clinical Trial Support Network (CTSN) at UH for current lists.

5.1. Protocol contributors

All contributed to specific areas of the study design and protocol development relative to their expertise. All Co-applicants approved the final submission of the funding proposal and the protocol and are the grant holders.

Name	Affiliation	Role
Nick Midgley	UCL	Chief Investigator; designed the study and led on the writing of the funding application.
Sarah Byford	KCL	Co-Applicant, Health Economic Evaluation Lead, designed the economic evaluation component of the study

Karen Irvine	UH	Co-Applicant, Trial Manager; wrote the initial draft of the protocol.
Jamie Murdoch	UEA	Co-Applicant, Process Evaluation Lead; designed the process evaluation element of the study
Martin Pond	UEA	Senior Data manager
Sheila Redfern	AFNCCF	Co-Applicant; Reflective Fostering Programme Lead
Zena Louise Richards	UCL	Co-Applicant; PPI – Foster carer, contributed to the study design
Lee Shepstone	UEA	Co-Applicant; Trial Statistician – provided statistical input including sample size calculations
Erika Sims	UEA	Senior Operations Manager – provided operational advice for set-up and delivery of the study
Caroline Smith	KCC	Co-Applicant; Local collaborator Social Care
Ann Marie Swart	UEA	Co-Applicant; Director of NCTU
David Wellsted	UH	Co-Applicant; provided expertise in the design and delivery of the trial
Solange Wyatt	UH	Co-Applicant; provided clinical trials expertise including governance, data management and contracting
Poushali Ganguli	KCL	Health Economist, contributed to the economic evaluation component of the study

5.2. Other key study personnel

- Research Assistants to be involved with participant recruitment and data collection
- Process Evaluation Research Assistant
- Project Manager at AFNCCF
- Data Management programmers

6. Background and rationale

The needs of children in care are a government priority (1) as they are “one of the most vulnerable and disadvantaged groups in our society” (2). Poor outcomes for children in care not only carry huge

personal cost for individuals, but also increase health inequalities across society, and impact on the public purse (3). The current project, building on a successful feasibility and preliminary evaluation study (4,5), therefore aims to test the effectiveness of a group-based intervention for foster carers, which is designed to improve the emotional well-being of children in care by supporting and strengthening the carer-child relationship.

In 2019, the number of children in care in England increased by 4% to 78,150. Of these children, 56,268 were in foster placements (72%); 13% (10,159) were in a foster placement with a relative or friend (6). Over 60% have experienced abuse or neglect prior to placement and frequently demonstrate troubled behaviour (7). Foster carers often struggle to respond to the complex needs of these children, leading to high levels of stress, which can affect the quality of caregiving, and may lead some to leave fostering because of burnout (8). In turn compromised care heightens the risk of negative outcomes for children in care, leading to increased placement instability (9) and poor health, educational and social outcomes (10). Given the importance of good quality foster care for this vulnerable group of children, there have been efforts to better support foster carers and enhance the quality of care provided (11)(12). Yet the provision of support services in UK fostering teams is variable, with no consistent models of support provided, and a lack of evidence for what is most effective (13). In 2013 NICE (The National Institute for Health and Care Excellence) guidelines on the emotional well-being of children in care concluded that “there is a lack of robust, adequately controlled, studies completed to a high standard”, especially when it comes to evidence of what will help foster carers best respond to the needs of primary school-aged children (14).

Despite evidence that high-quality foster care can support children to thrive (15), a survey of UK foster carers found that better support from their fostering service was the one thing respondents would most like to change to improve their lives and those of the children they foster (16). Formal support for foster carers in England and Wales comes primarily from their own social worker, which is highly variable across different regions of the UK (14)(17). Most parenting classes available to foster carers focus on practical behaviour management skills and do not normally include a focus on the complex emotional needs that may underlie their children’s behaviour (18). However a 2016 survey of UK foster carers concluded that local authorities (LA) fail to equip carers with the knowledge and skills needed to support children in care, especially those with emotional and behavioural difficulties (19). A survey of over 4,000 foster carers published in 2019 found that only four in 10 felt properly supported by existing support services (16). The survey also found that the provision and take up of training for foster carers is varied across the UK, with carers highlighting a need for greater training with regard to therapeutic parenting, mental health and attachment.

Research is therefore needed to establish whether the provision of a specialist training programme for foster carers alongside usual support would be more effective than the usual support provided by fostering teams in supporting the well-being of children in care. It is imperative that LAs have access to the high-quality evidence needed to inform budget allocation, including details regarding cost-effectiveness of support services. Hannon et al. (2010) demonstrated the financial benefits over a 15-year period of ensuring children receive good quality support to achieve positive outcomes, with costs to LAs amounting to £23,430 per annum for a child with a 'good' journey, compared to £56,226 per annum for those with a 'poor' journey (20).

A review of interventions to promote the well-being of children in care (21) identified only four interventions for those in middle childhood that have been tested using randomised designs, none of which have a primary focus on supporting the carer-child relationship. Meanwhile a systematic review of behavioural and cognitive behavioural interventions to assist foster carers in the management of behavioural problems in children in care showed very little evidence of effect on child outcomes (22). Some specially-designed programmes (23,24) have demonstrated an effect on problem behaviours, but these have been criticized for their lack of focus on improving the carer-child relationship (11). None of these studies has established long-term impact or cost effectiveness of interventions for children in care in the 4-13 age group.

An evidence review of the fostering system for the Department for Education (DfE) (13) concluded that "sensitive, emotional reflective caregiving is likely to be the key experience for children and young people which will enable them to develop the qualities they need to break links between their early experiences and poor outcomes" (p.180). 'Reflective caregiving' (also referred to as 'reflective capacity' or 'parental reflective functioning') refers to a caregiver's capacity to think about their own and their child's mental states and how these may underlie behaviour (25). It is associated with many important facets of parenting such as sensitive caregiving, strengthened parent-child relationships, and secure attachment (26,27). Parents with higher reflective capacity are more able to experience difficult and emotionally activating relational exchanges without becoming overwhelmed or shutting down (28). Research has also demonstrated that higher levels of reflective functioning can help parents tolerate distress in their children, which is thought to be helpful in managing parenting stress as well (29). A recent systematic review has explored the association between parental reflective capacity and children's mental health outcomes in some detail (30). This review highlighted evidence that higher maternal reflective capacity is associated with improved child attachment security (31)(32). It further indicated an association between low maternal reflective capacity and overcontrolling parenting (33), as

well as higher incidence of children's anxiety disorders (34), poor emotional regulation capacity (35) and greater externalising behaviours (36).

Given the increasingly strong body of evidence highlighting the impact of parental reflective capacity on children's wellbeing, it is unsurprising that there has been an interest in developing interventions focusing on promoting this capacity. A seminal demonstration of the effectiveness of this approach is outlined in evaluations of the Minding the Baby programme, a home-visiting based intervention with a key focus on supporting the development of maternal reflective capacity (37). A follow-up study of this intervention highlighted higher levels of attachment security (38) and lower rates of externalising behaviours (39)(40) in children of mothers who received the programme in comparison to mothers who did not. Studies of a similar intervention for substance-using mothers found that changes in maternal reflective capacity were directly associated with improvements in caregiving behaviours (41).

In the light of such findings, there has been growing interest in the development of interventions that focus on supporting the carer-child relationship by means of promoting reflective capacity in foster carers, as the backbone of a child's well-being (11,18,42). Recent studies, focusing specifically on reflective capacity among foster carers, have indicated that this group may be especially vulnerable to losing their reflective capacity, especially when faced by high-stress situations and the care of children who may place very high demands on them (43,44). Lower levels of foster carer reflective capacity was associated with increased levels of behavioural problems in the child (5). Helping carers manage their levels of stress through increased reflective capacity is essential, as such stress interferes with the skills they need to help children better manage their emotions (18).

Taken together, these findings support the view that the foster carer, as the most consistent relationship in the lives of children in care, should be offered help to build the skills of reflective parenting. A large body of evidence has demonstrated that achieving this leads to increased security, stability and promotes the child's ability to regulate and manage their own emotions (30). Placement stability is seen as vital to the child in care's general wellbeing and functioning.

The Reflective Fostering Programme builds on this evidence, and focuses on the practical application of reflective caregiving, for foster carers of children in care aged between four and 13. Unlike other programmes for foster carers, it focuses on improving the carer-child relationship, by helping carers to attend to their own state of mind and experiences. When carers are helped to do this, they can better manage their own feelings, and respond more effectively to the needs of the child in their care. An initial feasibility and evaluation study of the Reflective Fostering Programme (4), and an associated feasibility trial led by the same research team (45), demonstrated:

- it is possible to recruit and follow-up foster carers and children in care in a study;
- a low level of drop out from the intervention;
- and preliminary evidence that reflective fostering is effective in enhancing child well-being, reducing carer stress levels and increasing carers' reflective capacity.

The model of co-delivery of the Reflective Fostering Programme by experienced foster carers alongside LA social workers builds on the success of this approach in 'Skills to Foster' training (46). The co-delivery approach can build competence and capability within the system and expands the holding of 'expertise' within the system's network. In focus groups the participants in the feasibility study spoke of the Reflective Fostering Programme transforming how they approached their role, and they were passionate that it should be available to all foster carers in the UK. However, caution should be applied to these findings until fully tested in a randomised trial.

7. Aims and objectives

Building on the findings of the Reflective Fostering Programme feasibility study, the primary aim of this study is to establish whether adding the Reflective Fostering Programme to usual support is more effective than usual support alone, in: promoting the emotional and behavioural well-being of children in care; reducing levels of foster carer stress and burnout; increasing foster carer parental reflective capacity; increasing foster carer quality of life and meeting their personalised goals; improving the carer-child relationship; and in reducing placement instability.

Alongside, and contributing to this primary aim, the study will:

- (a) Conduct an internal pilot to assess recruitment and randomisation procedures, examine retention and data completion rate for the primary outcome at four months, and to explore any issues of contamination across the trial arms;
- (b) Conduct a mixed-methods process evaluation to describe how the Reflective Fostering Programme and usual support are delivered, assess intervention fidelity, understand how contextual factors shape intervention delivery, examine contamination across arms, and provide explanations for the observed effects of main trial findings;
- (c) Examine the cost-effectiveness of adding the Reflective Fostering Programme to usual support compared to usual support on its own.

8. Methods

8.1. Trial design

This is a pragmatic, randomised controlled trial (RCT), with a process evaluation and nested economic evaluation, to evaluate the effectiveness, and cost effectiveness, of the Reflective Fostering Programme alongside support, compared to usual support alone.

- An Internal pilot built into the first phase of the study, to assess recruitment levels and randomisation processes, retention and response rate for outcome measures at four months, feasibility of online programme delivery and to examine cross-arm contamination
- Assessments in the main trial carried out at baseline (T1), end of programme delivery (4 months from baseline, T2) and 12-month from baseline (T3)
- Primary analysis of effectiveness at the 12-month from baseline follow-up, allowing an exploration of longer-term impact, including placement stability, foster carer burnout and cost-effectiveness.
- Embedded process evaluation using mixed methods including site profiles, observations of facilitator training and Reflective Fostering Programme delivery, focus groups with Facilitators, interviews with carers, and observations of foster carer-child interactions.

The primary outcome will be the emotional and behavioural well-being of the child identified by the foster carer, as assessed by their carer at 12 months. Secondary outcomes will be levels of foster carer stress; foster carer quality of life; the quality of the carer-child relationship; placement instability; and levels of foster carer burnout. See section 14.1 for details about the instruments used for measuring these outcomes.

8.2. Setting

The study will be carried out in LA fostering teams across England and Wales. Thirteen LA fostering teams have so far been identified as collaborators for the study: Kent, Hertfordshire, Bristol, , Devon, Lancashire, North Tyneside, Wandsworth and in London, a consortium made up of the boroughs of Barnet, Camden, Islington, Hackney, Enfield and Haringey. However additional LAs may be recruited should recruitment be lower than anticipated.

All participants will be recruited from these sites for the internal pilot (see below) and second wave (see timeline); the research team will recruit additional LAs (depending on size) to join the third wave of recruitment if recruitment during the first two waves is slower than anticipated (e.g. due to COVID-19 restrictions). This will ensure sufficient numbers of foster carers are recruited to the study. The study team will work with partners including Research in Practice, the Social Care Learning Network and the Clinical Research Network (CRN) to identify suitable sites. Selection of sites will take into account the geographic and cultural diversity of carers and children in care in the UK, including both more rural and metropolitan settings, in order to ensure that both the intervention and the research study meet the needs of a culturally diverse population living in different parts of the country, and that any obstacles or barriers are identified as part of the process evaluation.

Foster carer recruitment targets for each site will be proportionate to overall size, with the aim to recruit more than 50% of all eligible carers over a 20-month recruitment period in order to meet recruitment targets. This is in line with previous clinical trials involving training programmes for foster carers, where 58-62% of eligible carers are reported to have participated (47).

8.3. Sample size

Previous experience with this population (48) suggests an effect size ranging from $d=0.3$ to $d=0.4$ (i.e. a mean difference in outcome between groups of 0.3 to 0.4 standard deviations) to be clinically relevant. In the first feasibility and evaluation study (5) the baseline standard deviation for the primary outcome measure (SDQ) was 6.8, and showed a change equivalent to an effect size of $d=0.3$. The current trial compares usual support plus the Reflective Fostering Programme to usual support alone, with the primary outcome assessed at 12 months. We have, therefore, based our sample size on a difference of 0.3 standard deviations in the SDQ, i.e. around 2.0 units.

On the basis of a review of previous clinical trials involving parenting programmes for foster carers, a reasonable estimate for dropout rates for the study is in the range is of 10-15% at the end of intervention (4 months), and 20-25% at 12 months.

The nature of the intervention will imply a form of 'clustering' i.e. outcomes amongst those in the same intervention groups will be correlated; the strength of this correlation is quantified through an intra-class correlation co-efficient (ICC). Whilst the intervention for the control group has a less clear 'clustered' structure, the assumption of zero clustering is likely to be incorrect, due to the delivery by allocated social workers. Therefore, a decision was made to consider both arms to have the same degree of 'clustering' to avoid potentially under-estimating the sample.

Table 2 provides the estimated statistical Power from four different sample sizes across eight different scenarios (varying by assumed ICC and drop-out rate). These estimates assume an average of seven foster carers in each group, an effect size of 0.3 and a fixed statistical significance of 5% (two-sided). A target sample size of 720 has been fixed for this trial. This was based upon the likelihood of a statistical power between 80% and 90% in most reasonable scenarios.

Table 2 Statistical power estimates for differing drop-out rates and ICCs

	Drop-out	15%		20%		25%		30%	
	Assumed ICC	0.05	0.10	0.05	0.10	0.05	0.10	0.05	0.10
	770	93%	88%	91%	86%	90%	85%	88%	82%
Total	720	91%	86%	90%	85%	88%	83%	83%	77%
Randomised									
	620	88%	83%	86%	81%	84%	79%	87%	76%
	500	82%	77%	79%	75%	78%	73%	82%	71%

8.4. Trial set-up

Trial set-up will involve obtaining ethical approval from the UH, registration on the CRN portfolio, clinical trials registration on ISRCTN (International Standard Randomised Controlled Trials Number) registry and database set-up. Sponsorship will formally be applied for to UH. Study personnel will be recruited: Trial Manager (TM), Research Assistants and a Research Fellow who will oversee governance of the study on behalf of the sponsor. GCP training will be undertaken by those the CI deem requires it for their role in the study. The Trial Steering Committee (TSC), Trial Management Group (TMG) and Stakeholder Forum will be established, and meeting dates will be agreed. A study website will be developed and launched.

8.5. Trial Sites

8.5.1. Site eligibility criteria

Eligibility criteria for sites:

- The LA provides support to foster carers looking after children in their care
- There are suitable staff available to be trained as Facilitators to run the programme
- Social care teams are sufficiently resourced to release staff from their usual duties to facilitate the running of a group

- There are systems in place that allow the site to share information about the study with eligible foster carers and to promote the study to them
- They have access to a venue where the Programme can be delivered to foster carers (or can source a suitable venue)
- There is someone at the site who can act as a Site Co-ordinator
- There is a minimum of 28 potentially eligible foster carers

If resources allow, sites will be asked to identify Study Champions within the team of social workers.

8.5.2. Facilitators at each site

Eligibility Criteria for social work team Facilitators

- LA social worker or other staff member with at least one year of experience working in children's social care
- Understanding or strong interest in group dynamics and group process, and the confidence to manage these in a group setting.
- Comfortable in using technology, specifically tablet or iPad and online resources
- Commitment to the full programme of 10 sessions with arrangements made for substitute facilitator where necessary in advance.
- Able to work collaboratively, practically and supportively with a co-facilitator, and to make this practically possible.
- Commitment to attend training, preparing for each session and attending regular online weekly consultations to support delivery of the Programme.
- Ability to deal appropriately and professionally with possible difficulties in a group context.
- Knowledgeable in the local process for escalating issues (e.g. safeguarding)
- Comfortable in having facilitation of each session video-recorded and uploaded for review
- Openness to reflection on practice with a supportive consultant – this involves taking a 'non-expert' stance

Eligibility Criteria for foster carer Facilitators

- Enthusiastic and committed foster carer who is not new to fostering
- Willingness to co-work with social care staff and interest in group process
- Some experience of using technology (e.g. tablet or iPad and online resources) and willingness to learn

- Commitment to attend training, preparing for each session with co-facilitator and attending regular online weekly consultations to support delivery of the Reflective Fostering Programme
- Comfortable in having facilitation of each session video-recorded and uploaded for review
- Willingness to take leadership role with other foster carers present.
- A non-defensive and reflective approach to working with other professionals and foster carers

8.5.3. Site Lead

The Site Lead(s) for each site must be willing to sign an investigator statement to comply with the trial protocol (confirming their specific roles and responsibilities relating to the trial, and that their site is willing and able to comply with the requirements of the trial). This includes confirmation of appropriate qualifications, agreement to undergo GCP training and comply with the principles of GCP, to permit monitoring and audit as necessary at the site, and to maintain documented evidence of all staff at the site who have been delegated significant trial related duties.

8.5.4. Resourcing at site

The Site Lead(s) should be able to demonstrate a potential for recruiting the required number of suitable participants within the agreed recruitment period. They should also have an adequate number of qualified staff and facilities available for the duration of the trial to enable them to conduct the trial properly and safely.

8.5.5. Site Co-ordinator

There should be someone at the site who can act as the Site Co-ordinator for the study at the LA. This should be someone that is responsible for the local organisation of the study and may already have a role in co-ordinating foster carer training or support services. This person will be the main liaison with the study team and the main contact point for foster carers.

8.5.6. Study Champions

If resources allow, sites should identify one or more Study Champions within the children's Social Care team, e.g. a supervising social worker who is part of the foster carer support team. This person will promote the study within the LA by discussing it with their colleagues and addressing questions and concerns social work teams might have about the study.

Sites will be expected to complete a delegation of responsibilities log and provide staff contact details.

8.5.7. Site approval and activation

On receipt of the signed investigator statement, approved delegation of responsibilities log and staff contact details, written confirmation will be sent to the Site Lead(s). The TM or delegate will notify the Site Lead(s) in writing of the plans for site initiation. Sites will not be permitted to recruit any participants until a letter of activation has been issued. The TM or delegate will be responsible for issuing this after an approval to recruit process has been completed.

The site must conduct the trial in compliance with the protocol as agreed by the Sponsor and which was given favourable opinion by the Research Ethics Committee (REC). The Site Lead(s) or delegate must document and explain any deviation from the approved protocol and communicate this to the TM.

A list of active sites may be obtained from the TM.

8.6. Participants

LA foster carers or kinship carers (also known as 'connected carers') who are currently looking after a fostered child, aged four to 13. In relation to participants, the term 'foster carer' will be used in this protocol to include kinship carers and connected carers.

8.6.1. Study entry criteria

Participants will be considered eligible for enrolment in this trial if they fulfil all the inclusion criteria and none of the exclusion criteria as defined below. Exceptions will not be made to these criteria. Where foster carers have more than one child in their care between the ages of four and 13, then they will be asked to choose one of them as the 'nominated child' for the purposes of data collection. They will be advised that this should be the child about whom they have the greatest concerns.

8.6.1.1. Participant inclusion criteria

- The carer is currently fostering a child aged between four and 13 years;
- The child has been in this placement for at least four weeks; and
- the care plan is for the child to remain in this placement for more than four months.

The inclusion criteria are in place to ensure that the intervention targets carers of children in medium- to long-term placements, rather than respite care or emergency placements.

8.6.1.2. Participant exclusion criteria

- Foster carer has insufficient English language ability to engage with the Programme and complete research assessments
- Foster carers where they, or their partner, have received the Reflective Fostering Programme

Foster carers whose partner has previously been part of the control arm (i.e. usual care) of the study may participate, as long as their partner has completed the Reflective Fostering Study, and they are able to complete all measures in relation to a different child in their care.

Recruitment of foster carers in England and Wales specifies that they must have sufficient English language ability to engage with the child's school and other services. For this reason, participating LAs have confirmed that they would expect no foster carers to be excluded on this basis. However, the process evaluation (see below) will include the number of potential participants excluded due to not meeting the language criteria, to check if this assumption is correct. The recruitment screening logs will also include this. Those with poor literacy will be supported through having a research assistant read questionnaires to them.

To ensure health inequalities are addressed, foster carers of any child with a disability (e.g. autism, developmental delay), and those currently caring for more than one child will be eligible to take part. If carers or the child in their care are currently receiving any other form of counselling or mental health support, this will *not* be a reason to exclude them from participating in the study. Attendance at the Reflective Fostering Programme is not designed to replace such usual support.

9. Procedure

Recruitment of foster carers will take place within each of the study sites (i.e. LA fostering teams).

9.1. Participant identification and screening of referrals

All foster carers in each LA will be sent information about the study by the Site Coordinator at each site (e.g. Social Care Administrator) and will be encouraged to consult with their allocated social worker about whether the study would be suitable for them. If they are interested, foster carers will be asked to contact the Site Coordinator by phone or email to register their interest in finding out more about the study. Other appropriate channels (e.g. local foster carer support groups) will also be targeted with information about the study. Supervising and/or child social workers in the LA will also be invited to speak to foster carers who they think could benefit from attending the Programme and who might be interested in joining the study.

When foster carers make contact, the Site Coordinator will screen for eligibility, and for those who do not meet the inclusion criteria, record the reasons why. Those who do meet the inclusion/exclusion criteria will be sent a Participant Information Sheet (PIS) and invited to an information (coffee morning) meeting with a member of the research team. They will also be sent a “non-participation questionnaire” which we would ask foster carers who do not wish to take part to complete and return. This will capture a limited amount of demographic data to allow us to check that the trial is including a representative group of foster carers. We will also ask them to advise why they chose not to respond.

Only one foster carer from each household can join the study as a participant. For those who are randomised to the intervention arm, there will be the option for a second carer from the same household to attend together, if they wish to do so. The attendance of both will be recorded, but only the primary carer will be asked to complete study outcome measures. We will report on how many couples choose to attend.

Recruitment of foster carers will take place across five cycles of recruitment and delivery (including the pilot phase – see below), timed in such a way that the start of each new wave of Reflective Fostering Programme groups will begin close to the start of a school term (i.e. January, April and September). At the start of each cycle, eligible foster carers who have expressed an interest in taking part in the study will be invited to a coffee morning information session. Should foster carers be unable to attend the scheduled coffee morning or are unable to commit to the trial at this stage but have indicated that they would still like to participate, the Site Coordinator will keep a record of their details in order to invite them for future cycles.

The plan is to hold the coffee morning at a venue central to the LA. However, if it is not possible to hold face to face meetings, these will become “virtual” meetings and conducted over the internet using a platform designed to facilitate such meetings.

The Site Coordinator will collect information on recruitment in the Recruitment Log. This will include information about: (1) the number of foster carers who showed an interest in the Programme; (2) how many carers were excluded and why; (3) the number of carers who decided to attend. This information will anonymously record numbers of foster carers falling into various categories of inclusion/exclusion.

9.2. Consent

All participants will be over 18 and all potential participants will be considered to have the capacity to consent on their own behalf for participation in this study. This is assured given these are two compulsory requirements to qualifying to be suitable as a foster carer in England and Wales.

At the coffee morning, the study will be fully explained to foster carers who will be able to ask questions. During this meeting, those foster carers who wish to participate will then be asked to provide informed consent. Those who choose not to take part at this stage will be asked to complete the “non-participation questionnaire” and to indicate if they wish to be considered at a later stage.

Consent may be provided either on paper versions of the consent form or online via the study database. For online consent, participants will be provided with a username and password (unique to them) so they can sign in to the database and indicate their consent to each of the options on the form.

The foster carers will be allowed as much time as they wish to decide whether to take part. If they are undecided at this stage, they will be able to go away and think about it. The Site Coordinator will contact them again to arrange for consent to be provided to a member of the research team at a later date or for their name to remain on the list for future cycles. A member of the research team might include clinical studies officers/clinical research practitioners, research nurses, research assistants and the Site Coordinator. The Site Lead(s) will ensure that any person delegated responsibility to participate in the informed consent process is duly authorised, trained and competent to participate according to the ethically approved protocol, principles of GCP and Declaration of Helsinki.

Informed consent will be obtained prior to the participant undergoing procedures that are specifically for the purposes of the trial. It will be made clear to foster carers that they have the right to refuse participation and are able to withdraw at any time from the trial without giving reasons and without prejudicing his/her further opportunities for development.

Although foster carers in England and Wales are required to have sufficient English language ability to engage with the child’s school and other services, some may not be able to easily read detailed information (such as the PIS) or complete legal documents (e.g. consent form). In this case, arrangement will be made to have the documents read to them.

If consent is provided on paper, the original signed form will be retained at the study site, in a locked and secure cabinet. Copies will be provided to the foster carer and UH, as the Sponsor. If consent is provided online, a PDF file will be stored in the Investigator Site File and access will be restricted to the team at the site. The consent will be stored on the database until the end of the study and then destroyed.

9.3. Group allocation

Foster carers will be randomised individually to the Reflective Fostering Programme arm or the control arm. Randomisation will be managed online (using a tool built by NCTU Data Management) and

overseen by the TM. Randomisation will be 1:1, stratified by age of child (4-9 vs 10-13), number of previous placements (1 or less, vs 2 or more) and recruiting region. The randomisation sequence will be blocked in random block lengths of two or four. Participants will be informed of group allocation by the local Site Coordinator, who will also contact the relevant social worker/s, so that they are aware that the foster carer is taking part in the study. If they are in the intervention group, the Reflective Fostering Programme Facilitators at each site will be informed.

9.3.1. Blinding

Due to the nature of the intervention, it is not possible for Facilitators and foster carers to be blind to allocation; however, the research assistants at site and the trial statistician will be blinded. Access to the database will be defined for each role in the study to maintain blinding. The TM will be unblinded to enable any queries from participants relating to the research to be addressed.

9.4. Baseline measures

Participants will be asked to complete the foster carer demographic form and study outcome measures before they are informed of which group they have been allocated to. They will receive notification by text or email asking them to complete outcome measures online (see section 14.1 for a full description of the measures). Those participants unable to complete the study measures online will be able to complete them with a member of the research team by telephone.

Strengths and Difficulties Questionnaire (SDQ; (49)): a routinely used clinical tool completed by caregivers and designed to assess emotional and behavioural difficulties in children aged 3-17.

Parenting Stress Index – Short Form (PSI 4-SF; (50)) -to assess caregiver functioning, the functioning of the child, and the level of stress in the caregiver-child relationship.

Parental Reflective Functioning Questionnaire (PRFQ; (51))- to measure the carers' capacity for reflective functioning in their caregiving role.

Professional Quality of Life Questionnaire (52) – to measure compassion fatigue and burnout.

Emotion Regulation Checklist (ERC; (53)) - to assess the carer's view of a child's emotional self-regulation and dysregulation.

Carer Defined Problem Scale (54) to record the achievement of carer's personalized goals in relation to the child.

Child Health Utility instrument (CHU9D) (55) A paediatric generic preference-based measure of health-related quality of life, completed by the carer for use in cost-utility analysis.

Child and Adolescent Service Use Schedule, adapted (CA-SUS) (56)(57) Developed to record service-use data in children in care.

Placement Stability Log. Data will be collected with regard to changes of social worker, change of school or placement change and reasons for any change.

Most of these measures takes around 5 minutes to complete; the CA-SUS, the SDQ and the PIS-4 may each take up to ten minutes. Testing of the measures indicated that completion of all measures will take around an hour.

9.5. Intervention

9.5.1. The Reflective Fostering Programme

The Reflective Fostering Programme is a group-based, psychoeducational intervention for foster carers. Reflective Fostering focuses on the practical application of a set of tools that represent the principles of reflective caregiving in a shortened, highly applicable form, for foster carers of children aged four to 13.

The focus of the intervention is on improving the capability of the foster carer in relation to a nominated child currently in their care. Unlike parenting programmes that focus more on behaviour management, it focuses on improving the carer-child relationship, by helping carers to attend to their own state of mind and experiences, so they can better manage their own feelings, and respond better to the needs of the child in their care. Reflective Fostering aims to provide carers with practical ways to help build and maintain supportive relationships with the children in their care, drawing on the model of 'reflective parenting' (58). The Programme uses both psychoeducation and practical activities that link directly to the foster carers' own experiences. The aim is to enhance the capacity of foster carers to be mindful of the impact that caring for the child has on their own thoughts and feelings, and the influences on their current state of mind on their reaction to their foster child, which in turn helps them to become more open and curious about the thoughts, feelings and experiences of the child (see Logic Model in Appendix 1).

The Reflective Fostering Programme (4) involves 10, 2-3 hour sessions offered to a group of 6-10 foster carers over a 12-14 week period. After the Programme ends, participants will be able to access materials about Reflective Fostering online and will be encouraged to form an online support group. If and when COVID-19 related social distancing regulations are sufficiently relaxed,, the groups will be held at a LA site easily accessible to the participants. However, if restrictions are in place that mean it is not possible

to hold face to face meetings, the sessions will take place online. The groups will be delivered by two trained Facilitators, one member of the children's social care team (e.g. a social worker) and one foster carer, who will be provided with weekly consultation from specialists at the AFNCCF.

There is a specific focus for each session:

1. Introduction to the Reflective Fostering Programme
2. Reflecting on yourself as a foster carer: The Carer Map
3. Seeing and Thinking about your foster child in different ways
4. Understanding and helping your foster child who has had experienced developmental or other trauma
5. Trust, relationships and helping your foster child get on better with other people
6. Responding to problematic behaviour in a reflective way
7. Understanding misunderstandings: putting your Carer map and APP together
8. Getting the help and support you need as a foster carer - family, friends, and the team around you
9. Moving on - getting ready for the end of the Reflective Fostering Programme
10. Review and ending session: how to keep the model in mind and stay feeling supported

Reflective Fostering groups are co-facilitated –by a social care staff member and an experienced foster carer based in the LA. Before starting, Facilitators attend three-days training , delivered by staff from AFNCCF, where they are trained in the Reflective Fostering approach by the team that developed the Programme. Should online delivery of training be appropriate due to conditions at the time, the three days of training may be delivered over a longer time period to limit online fatigue. Facilitators are also trained in how to co-facilitate and develop a co-working mentalizing relationship. They will have password-controlled access to a training manual and set of training slides, videos and structured activities, accessible via an online 'workbook'. Facilitators are provided with a weekly, one-hour consultation with a member of the Programme development team to support programme fidelity.

Intervention fidelity. In order to assess fidelity to the intervention, all Reflective Fostering sessions will be *video/audio* recorded, and for each session four purposively-selected five-minute extracts will be

rated using the Reflective Fostering Facilitator Adherence Rating (FAR, for details see section 14.1.4). Facilitators will be asked to provide consent for the sessions to be videoed.

9.5.2. Control condition

Usual Support is defined as the support, advice and guidance that all foster carers receive from their allocated social worker, plus any additional support services that they may receive as part of their role as a foster carer. Currently there is considerable variability in the kind of additional support services that may be available. Some LAs offer structured training and support networks, with possibility of referral to specialist services, but none currently offer a programme like the Reflective Fostering Programme, based on the principles of 'reflective parenting'. The process evaluation will document what "usual support" includes, and variation in usual support will be mapped onto variation in the primary outcome of the trial.

9.6. Follow up measures

Participants will be asked to complete the same study outcome measures as at baseline at two timepoints: four months (+/- four weeks) and 12 months (+/- four weeks) after baseline. They will be requested by the research team by text, email or phone call to complete the assessments. Those participants unable to complete the study measures online will complete these with a member of the research team by telephone. If they cannot be completed either online or by telephone, participants will be provided with paper copies to complete and return.

If the child is no longer with the same carer at either the four-month or 12-month follow up, relevant follow up assessments will still be completed with the original foster carer. Where possible, the child's current carer will be contacted by the LA to seek their consent to be contacted by the research team. If they agree to be contacted, a member of the research team will seek consent for the new carer to complete the child-focused measures in relation to the original 'nominated' child. The feasibility of doing this has already been established in the Herts and Minds study (45). The Site Lead, or their delegate, will be responsible for identifying the current carer and approaching them to provide consent to complete study outcome measures.

9.7. Provisions for post-trial care

Foster carers will continue to receive usual care from their LA once the trial ends, including any specialist training or support as per usual care in that LA. Participants randomised to the control arm may have the opportunity to attend the Reflective Fostering Programme after the study is finished, if there is evidence of effectiveness and the LA choose to continue offering the Programme. Neither the NIHR nor

the study Sponsor will be responsible for funding any intervention post-trial.

10. Participant timeline

A CONSORT diagram can be seen below (Figure 1). The Gantt chart is available to view on the TMF held at the CTSN at UH. The Case Report Form (CRF) has been designed to reflect and support the flow of the study, and to record details of actions taken and dates.

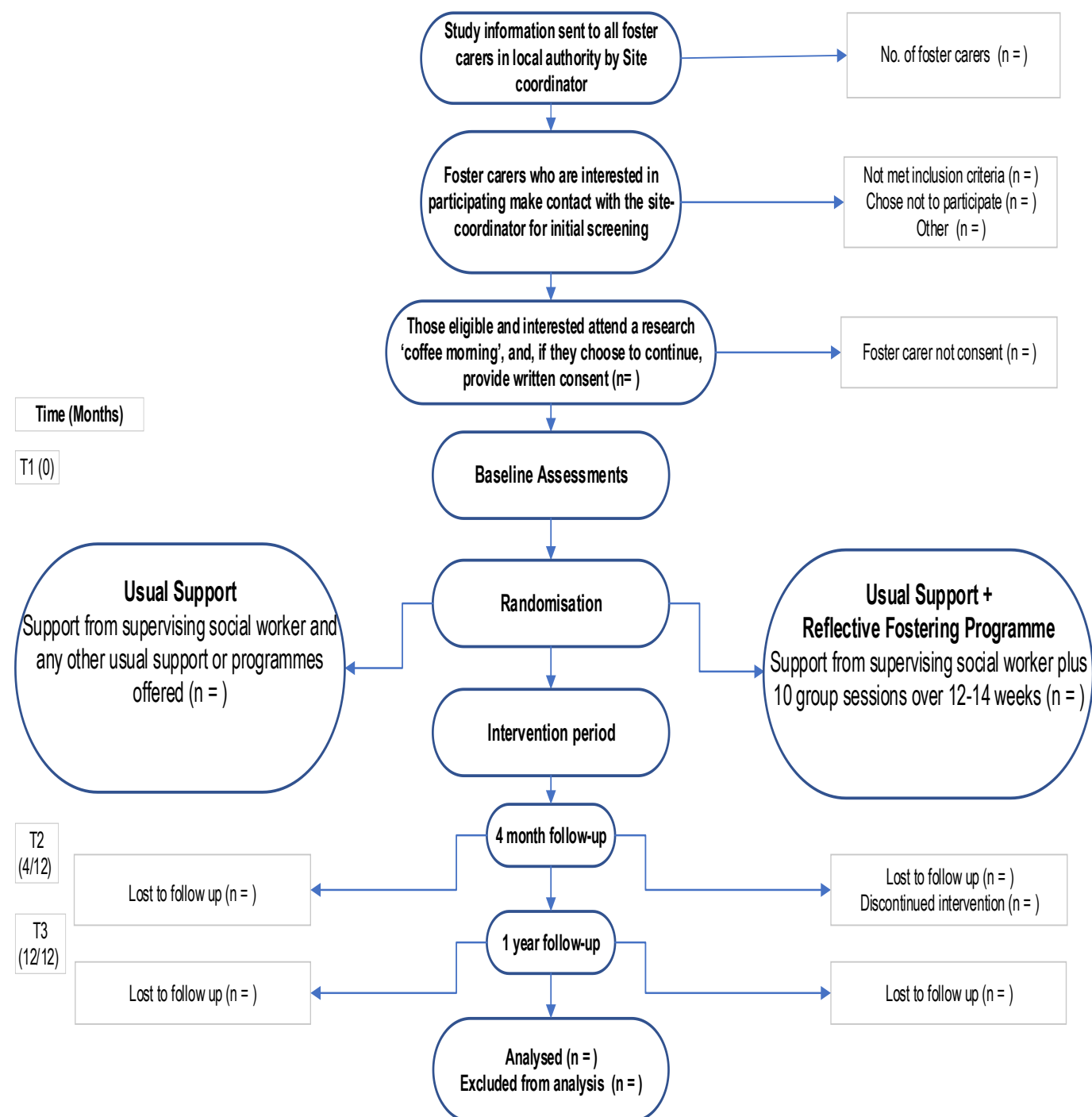


Figure 1. Study Flowchart

Table 1. Study schedule

	STUDY PERIOD						
	Screening	Randomisation	Post-randomisation				Post FU
	Pre-T0	Pre-T0	T0 Baseline	T0-T1	T1 +4 months	T2 +12 months	
ENROLMENT:							
Eligibility screen	X						
Coffee Morning	X						
Informed consent	X						
Randomisation		X					
<i>Fostering Team profile questionnaire</i>	X						X
Delivery of RFP				X			
Attendance Log				X			
Facilitator Adherence Rating				X			
Incidents of concern Log				X			
ASSESSMENTS:							
<i>Demographic information</i>			X				
<i>Strengths and difficulties questionnaire</i>			X		X	X	
<i>Parenting Stress Index – short form</i>			X		X	X	
<i>Professional QoL questionnaire</i>			X		X	X	
<i>Emotion Regulation Checklist</i>			X		X	X	
<i>Carer Defined Problem Scale</i>			X		X	X	
<i>Child Health Utility-9D</i>			X		X	X	
<i>Child and Adolescent Service Use Schedule</i>			X		X	X	
<i>Placement Stability</i>			X		X	X	
<i>Foster carer-child observations</i>			X		X	X	
<i>Pilot Study Focus Groups</i>					X		
<i>Focus Groups</i>							X
<i>Interviews</i>						X	

11. Internal pilot phase

An internal pilot phase will run for the first six months and has been designed to allow an assessment of stop/go criteria for progression to a full trial. During the internal pilot study, the aim will be to recruit sufficient participants, across four sites, with each site running one Reflective Fostering Programme group (6-10 participants per group) and one control group of foster carers (matched number of participants).

To explore any challenges identified in the recruitment and randomisation procedures we will review data from the non-participation questionnaire. Data from those eligible carers who chose not to participate will be analysed to identify any systematic obstacles to participation and reasons for not agreeing to take part. We will also hold telephone or online interviews with carers (10 per arm) at four months from baseline in order to identify carer's perspectives of how the Reflective Fostering intervention is received, and in the control arm to assess any contamination.

A one-day 'feedback and problem-solving' workshop will be held towards the end of the pilot study to identify challenges of recruitment, randomisation, retention, contamination and delivery of the Reflective Fostering intervention, before proceeding to the main trial. Participants will include the research team, Reflective Fostering Programme Facilitators, service managers and administrators responsible for screening potential participants. During the workshop, we will hold 2-3 group discussions to elicit feedback from different professionals working across the pilot sites in order to identify problems and solutions, which we can use to improve delivery of the main trial.

At the end of this phase a decision will be made by the Funder, in consultation with the TSC on whether to proceed with the trial. Recruitment will continue while data on patients in the internal pilot are analysed and reviewed by the TSC and a funder decision is obtained. As an internal pilot, all data collected on study participants will be included in the full trial analyses.

The objectives of the internal pilot phase are to confirm feasibility of:

1. Foster carer recruitment
2. Foster carer retention

3. Intervention and outcome assessment delivery, including the feasibility of online delivery, if COVID-19 related restrictions mean that face to face delivery is not possible

The stop/go criteria are:

1. Participant recruitment at expected rate (more than 50% of eligible participants), or evidence that identified barriers to recruitment can be overcome
2. Evidence of retention in the study at four months (less than 15% drop out from the study), or evidence that identified barriers to participant retention can be overcome.
3. No clear evidence of contamination across arms that cannot be remedied.
4. Evidence that the interventions and training can be delivered (whether remotely or face to face) and assessments can be completed within the proposed timeframes for the definitive trial, or evidence that identified barriers can be overcome.

12. Withdrawal criteria

In providing informed consent into the trial, participants are consenting to taking part in the Reflective Fostering Programme training (where appropriate), contact, randomisation, assessments, follow-ups and further data collection.

The participants will be explicitly made aware of their rights to withdraw from the trial and how to do this. This will be made clear to the participant within the information sheet and at the point of consent. Participants may withdraw from the study (before, during or after delivery of the Reflective Fostering Programme, and not agree to data collection) or withdraw from the intervention (during the Reflective Fostering Programme but agree to continue data collection). Although not obliged to give a reason for discontinuing in the study a reasonable effort will be made to establish this reason, whilst remaining fully respectful of the participant's rights.

Participants who discontinue with the Reflective Fostering Programme should remain in the trial for the purpose of data collected, follow up and data analysis unless explicitly stated by the participant. All data collected up to the point of withdrawal of consent will be retained in the trial dataset. Participants who agree to complete follow up data should continue to be followed up as closely as possible to the follow-up schedule defined in the protocol, providing they are willing and are still able to consent to this. If, however, the participant exercises the view that they no longer wish to be followed up, this view must be respected, and the participant withdrawn entirely from the trial. The reason for withdrawal, where given, will be documented in the trial database.

A study withdrawal form will be completed detailing how the participant communicated their wishes to withdraw, type of withdrawal, date, reasons (if obtained), and any discussion regarding withdrawal. All necessary records and databases will be updated to reflect the withdrawal status of the participant. Data already collected will be kept and included in analyses according to the intention to treat principle for all participants who stop follow up early and this will be made clear within the information sheet and if/when participants discontinue the Programme / withdraw. Once the intervention has started, those in the intervention arm who choose to withdraw from the study but wish to continue attending the Reflective Fostering Programme may do so, as long as they still give consent for sessions to be video recorded.

TMG and TSC will be made aware of withdrawals from the study and any reasons obtained. These should be considered as part of the meeting agenda and any themes identified and acted upon. An end of study form will be completed for all participants who complete the last follow up assessment. The date of their last assessment will be the date they completed the study.

13. End of trial

The end of trial will be when all participants have completed all scheduled assessments and all questionnaires/data items have been completed and interviews taken place.

A declaration of end of study form will be completed and sent to the REC within 90 days of the end of the study.

14. Data collection, management and analysis

Data will be collected at three time-points:

- Timepoint 1, baseline (prior to randomisation)
- Timepoint 2, four months post-baseline
- Timepoint 3, 12 months post-baseline

All assessments will be conducted remotely, using an on-line system of data collection. All measures can be accessed on the foster carers' own devices (phone or tablet). Foster carers will be automatically reminded by text, email or phone call to complete the assessments by the research team, and will be followed up in the same way, if necessary, to encourage completion. Those participants unable to complete the study measures online will complete these with a member of the research team by telephone.

It is anticipated that a significant proportion (around 70%) of identified children will be with the same foster carer at both the four- and 12-month follow up points (59). As described above (see section 9.6),

we have confidence that follow-up data can be collected in the majority of cases even if the nominated child has moved to a new placement. Previous experience has established that it is possible to successfully seek consent from new foster carers, and to collect follow-up data (45).

All instruments consist of online-administered self-report questionnaires with established validity and reliability.

14.1. Outcome measures

14.1.1. Primary outcome measure

Strengths and Difficulties Questionnaire (SDQ; (49)): a routinely used clinical tool completed by caregivers and designed to assess emotional and behavioural difficulties in children aged between three and 17. It was used in the preliminary evaluation and feasibility study (5), and is recognised as the UK government's preferred measure of well-being for children in care. The SDQ consists of 25 closed-ended questions and an impact supplement, which assesses the extent to which mental health problems have had an impact on aspects of the child's life. Each item is rated using response categories of "Not-true", "Somewhat true", and "Certainly true". The 25 items are scored across five (five-item) subscales:

- **Conduct problems** subscale inquiries about tantrums, obedience, fighting, lying and stealing
- **Emotional problems** subscale contains items that ask about fears, worries, misery, nerves and somatic symptoms
- **Hyperactivity** subscale covers restlessness, fidgeting, concentration, distractibility and impulsivity
- **Peer problems** subscale includes questions about popularity, victimization, isolation, friendship and ability to relate to children as compared to adults
- **Prosocial** subscale covers consideration of others, ability to share, kindness to younger children, helpfulness when other children are distressed, and willingness to volunteer to comfort

For all the subscales apart from the prosocial subscale, higher scores are designed to indicate that there are greater levels of difficulty. A total difficulties scale is generated by summing all of the scales except for the prosocial scale. It takes about 5-10 minutes to complete.

14.1.2. Secondary outcome measures

Parenting Stress Index – Short Form (PSI 4-SF; (50)): is designed to assess caregiver functioning, the functioning of the child, and the level of stress in the caregiver-child relationship. The measure consists of 36 items, each scored on a five-point scale (SA = "Strongly Agree"; A = "Agree"; NS = "Not Sure"; D =

“Disagree”; SD = “Strongly Disagree”). The 36 items are divided into three (12-item) subscales which combine to form a total stress score:

- **Parental distress**, which is designed to assess the level of distress a caregiver is experiencing in their caregiving role
- **Parent-child dysfunctional interaction**, which measures the extent to which the parent perceives interactions with their child to be not satisfying/reinforcing
- **Difficult child**, which examines how easy or difficult the parent perceives his/her child

Higher scores on these scales, and on the total stress score, are meant to reflect greater difficulties, with a scores of 90 and above (on both the total score and sub-scales) in the 'clinical' range.

Parental Reflective Functioning Questionnaire (PRFQ;(51)): is used to measure a carers' capacity for reflective functioning in their caregiving role. The PRFQ is an 18-item questionnaire including three main subscales:

- **Pre-mentalizing**, which assesses non-mentalizing of the child, or inability of the parent to acknowledge their child's mental states
- **Certainty about mental states**, which measures how certain caregivers are about the mental states of their child and their ability/inability to recognise the opacity of mental states
- **Interest and Curiosity**, which is designed to measure parental interest and curiosity in their child's mental states

High scores in Pre-mentalizing and Certainty about mental states reflect reduced capacity for reflective functioning, and high scores in Interest and Curiosity represent increased reflective functioning.

Professional Quality of Life Questionnaire (ProQol) (52). A 30 item self-report measure of the positive and negative effects of working with people who have experienced extremely stressful events. Items are scored using a Likert-type scale where 1= Never and 5 = very often. The ProQol contains three subscales measuring Compassion Fatigue, Burnout and Compassion Satisfaction.

Emotion Regulation Checklist (ERC;(53)): is used to assess the carer's view of a child's emotional self-regulation and dysregulation (e.g., emotional lability, intensity, flexibility, and situational appropriateness). The ERC consists of 24 items scored using a Likert-type scale (1 = “Never”; 2 = “Sometimes”; 3 = “Often”; 4 = “Always”), designed to be completed by an adult who knows the child well, such as a parent or carer. The measure has two subscales:

- **Lability/Negativity** (15 items), which is designed to assess emotional intensity, expression of negative emotions, arousal and reactivity, and lability of mood
- **Emotion regulation** (8 items), which measures adaptive regulation, such as socially appropriate displays of emotion, empathy and emotional understanding

Higher scores on the *Lability/Negativity* scale reflect greater dysregulation, while higher scores on the *Emotion regulation* scale indicate a higher capacity for emotion regulation.

Carer Defined Problems Scale (CDPS; (54)): is a measure adapted from the Goal Based Outcome Measure (GBO; (60,61)). The measure asks carers to rate and record up to three problems at the beginning of the intervention ('Please List below, in order of priority, three problems you have with your child that you would most like help with. Then rate the severity of the problem at present by indicating a number from 0 to 10'). In this version, adapted for online use, changes on the scale is rated by participants on a scale from 0 (no longer a problem) to 10 (couldn't be worse). The outcome is the amount of movement along the scale from the start to the end of the intervention. Evidence from Briskman and colleagues (2012) has indicated that this measure is highly sensitive to change for foster carers reporting on identified problems with the 'target' children they are considering in relation to a parenting-based intervention (23).

Placement Stability Log: Data will be collected with regard to changes of social worker, change of school or placement change and reasons for any change. In addition, data will be collected on what type of care the child moves to (e.g. adoption, return to birth parents, move to different foster carer) and information on any change in contact arrangements.

14.1.3. Health Economics Measures

Child Health Utility instrument (CHU9D) (55). A paediatric generic preference-based measure of HRQoL, to be completed by the carer. The CHU-9D covers nine dimensions (worried, sad, annoyed, tired, pain, sleep, daily routine, work, able to join in activities), each rated on five levels, and can be used to generate QALYs for use in cost-utility analysis.

Child and Adolescent Service Use Schedule (CA-SUS). Service-use data will be collected using an adapted version of the CA-SUS, a measure originally designed for young people in mental health populations, but which has been adapted and successfully implemented in a range of health and social care-based studies(56)(57). The version we will use was designed and tested for use with children in care in an earlier feasibility study (48), and an online, self-report version is now being developed. The CA-SUS will be completed remotely by carers at baseline, covering the previous three months, and at both follow-ups (four- and 12-months post-baseline), covering the period since last assessment. The adjusted CA-

SUS will be reviewed at the end of the Pilot Phase and has been designed to ensure coverage of remote on-line and telephone delivery of services, given the changes to service delivery as a result of Covid-19.

14.1.4. Other measures

Foster carer demographic form: a questionnaire collecting basic demographic information about foster carers, including sex, ethnicity, level of education and data about their foster caring history such as number of years fostering.

Reflective Fostering Programme Facilitator Adherence Rating (FAR): a 14-item observation-based assessment, covering the key components of the Reflective Fostering Programme, used to assess facilitators' adherence to the Programme.

14.1.5. Safety measures

The intervention being evaluated is a training intervention for foster carers. Foster carers in the intervention arm will decide for themselves which, if any, skills learned through the Reflective Fostering Programme they use; and those in both arms will continue to have usual support from their local fostering support teams. The intervention is not a medicinal product, or novel physiological or surgical procedure and the trial primary and secondary outcomes include safety outcomes (for example, placement stability). Therefore, no additional endpoints will be collected for safety (e.g. adverse events or serious adverse events) over and above the primary and secondary efficacy endpoints, other than an incident report from those attending the Reflective Fostering Programme (see section 18.6).

14.2. Data collection methods

Each participant will be given a unique trial Participant Identification Number (PID). Data will be collected at the time-points indicated in the Trial Schedule.

Clinical Trial Team members will receive trial protocol training. All data will be handled in accordance with the Data Protection Act 2018.

14.3. Data management

Data will be entered under each participant's PID onto the central database stored on servers based at NCTU, and collected at the time-points indicated in the Trial Schedule. Randomisation of participants will also be implemented within this database.

Data collection will be by direct online entry of data onto the central database, stored on servers based at NCTU by members of the Trial Team working within each research site. REDCap provides an option for offline data collection where there is poor internet connection, allowing for data upload to the central database when a good connection is available. Data may be entered onto paper Case Record Forms (CRFs) prior to entry onto the database. Should participants require it, support would be available to help participants complete the questionnaires over the telephone by a member of the research team. Staff will receive training on data collection and use of the online system.

Data collection, data entry and queries raised by a member of the trial team will be conducted in line with the NCTU and trial specific Data Management processes. Identification logs, screening logs and enrolment logs will be kept at the trial site in a locked cabinet within a secured room. Electronic copies of these logs will be kept on the Investigator Site Files which will be password protected. Clinical trial team members will receive trial protocol training. All data will be handled in accordance with the Data Protection Act 2018.

Access to the database will be via unique, individually assigned (i.e. not generic) usernames and passwords and only accessible to members of the study team, and external regulators if requested. Functional access within the database will be controlled and limited by role and, where appropriate, by site. This access to the study database is controlled and administered by NCTU Data Management. The servers are protected by University of East Anglia (UEA) firewalls and anti-virus products and are patched and maintained (including back-ups) according to best practice. The physical location of the servers is environmentally controlled and protected by CCTV and security door access.

Participant identifiable data will be stored in the database to enable participants to be contacted by site staff for the purpose of sending questionnaires. There will be a clear logical separation of participant identifiable data from the trial data (i.e. by user/role permissions and by data collection instrument).

The database software provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure/ missing data.

After completion of the study, the database will be retained on the servers of NCTU for on-going analysis of secondary outcomes.

After completion of the study, the study database and associated design documentation will be routinely archived for a period of 10 years unless otherwise advised by the TMG.

14.4. Statistics and data analysis

A statistical analysis plan (SAP) will be written prior to the commencement of any final data analyses. This plan will be approved by the TSC. Statistical reporting will follow the CONSORT standards. Statistical significance will be set at the two-sided 5% level and all estimates will be presented with 95% confidence intervals. There are no plans to adjust for any multiple hypothesis testing.

14.4.1. Primary outcome analysis

A general linear model, using general estimating equations (GEE), will be used for the analysis of the primary outcome, carer-reported SDQ at 12 months. The GEE approach to estimation will incorporate the clustering in outcome values by intervention groups within the intervention arm. As there is no overt clustering in the control arm (i.e. an example of 'partial clustering'), each participant within the control can be considered a 'cluster of one' for analysis purposes. The linear model will include recruiting 'site' (as a random effect), the SDQ score at baseline, age and previous number of placements (design factors) and intervention group. The primary outcome, SDQ, is assumed to follow a normal distribution. The residuals from this model will be checked against this assumption. The primary analysis will use the Intention-to-treat principle, i.e. analysing participants according to the group to which they were randomly allocated, irrespective of intervention received.

14.4.2. Secondary outcome analysis

Secondary outcomes, including the SDQ at four months, will be analysed in a similar fashion, i.e. through a linear model using GEE with an appropriate link and error term depending upon the nature of the outcome. No subgroup analyses are currently planned but should this become apparent during the course of the trial (for example due to new information) these will be specified in the SAP and most likely analysed using an interaction effect in the linear model. If the study includes a mix of face to face and online delivery of the RFP, a formal subgroup analysis comparing the two will be applied. This will involve the addition of a group-by-delivery type intervention term. However, the study has not been primarily designed to address any differences in outcome associated with delivery format

Reflective capacity, as measured by the PRFQ, is a target of the intervention and, therefore, needs to be considered as one of the secondary outcomes. However, reflective capacity is also one of the mechanisms of change of the intervention and may be important in mediating the effect of the intervention on both the child and the foster carer. Reflective capacity will therefore be considered as both a secondary outcome and a mediating factor.

14.4.3. Additional analyses

Three potential moderators of outcome have been identified and a formal subgroup analysis will be undertaken corresponding to each. The three are: (1) the foster carers reflective caring at baseline; (2) the child's age (from 4 to 9, versus 10 to 13); (3) the number of previous placements (none or one, versus 2 or more). In each case the analytical model for efficacy described above will have been extended to include an interaction term, i.e. the interaction between subgrouping variable and treatment arm. No formal sample size calculation has been carried out and the study has not been designed to provide a set level of statistical power for these subgroup analyses. Additional subgroup analyses may be suggested during the course of the trial in the light of emerging information from other studies. These will be kept to a minimum and explicitly stated in the SAP.

The change in foster carer's parental reflective functioning is proposed as a mediator of outcome, i.e. an intermediary variable on the causal pathway between intervention and primary outcome. To test this, a formal mediation analysis will be carried out using the approach suggested by Baron and Kenny (62). This involves firstly modelling the relationship between intervention and parental reflective functioning and between parental reflective functioning and outcome (i.e. along the mediated route), plus modelling the relationship between intervention and outcome (i.e. the direct route) whilst adjusting for parental reflective functioning. This analysis will only be carried out, conditional on a significant effect of intervention being found in the primary analysis.

14.4.4. Missing data

Missing data will be considered with potential mechanisms. If missing data is less than half but more than a trivial amount (say, 2%) then multiple imputation will be used with an imputation model containing at least those variables in the analytic model. Further details will be included in the SAP.

14.4.5. Data analysis for programme fidelity

All sessions of the Reflective Fostering Programme will be video-recorded and programme fidelity will be assessed using the Reflective Fostering Programme FAR. Four five-minute sections from each session will be purposively sampled and rated by one of the team of consultants involved in providing consultations to Facilitators. To establish inter-rater reliability, Consultants will be provided with training in the FAR prior to beginning rating and their inter-rater reliability will be assessed. Treatment fidelity will be considered satisfactory if sessions are rated with a mean score of 3 or above ('adequate') across the 14 items.

15. Economic evaluation

The aim of the economic evaluation is to establish whether the additional provision of the Reflective Fostering Programme would be a cost-effective and worthwhile use of LA fostering team's resources, compared to usual support alone. The economic evaluation will take a broad perspective covering: a) the NHS/personal social services perspective preferred by NICE, including any education-based health or social care services, given the age of the population, as well as health and social services provided by the private or non-statutory sectors and b) education facilities, to capture any use of specialist schools. We will include all health and social care services, not just those directly related to the intervention, and we will additionally include use of health and social services by the foster carer, as well as the young people.

The Reflective Fostering intervention will be directly costed using a micro-costing (bottom-up) approach (63). Data on the Reflective Fostering Programme groups, including attendance, will be collected from Facilitators. The salary costs of the group Facilitators including employer on-costs (national insurance and superannuation) and appropriate overheads (capital, management, administration etc.) will be weighted to include relevant non-face-to-face time spent on other activities (e.g. session preparation, writing up notes, meetings, training etc.) and used to calculate a cost per group. Cost per group will then be allocated across all foster carers invited to attend on the basis that the workshops are closed groups and will go ahead irrespective of attendance (64). All other services will be costed using nationally applicable unit costs (e.g. Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care compendium, NHS Reference Costs for hospital contacts, British National Formulary for medications).

The primary economic evaluation will be a cost-effectiveness analysis carried out at 12-months post-randomisation (T3) with outcomes expressed in terms of the primary measure of outcome (SDQ), in line with the primary clinical research question. This will allow an assessment of cost-effectiveness in the longer-term. A secondary economic evaluation will explore cost-utility using QALYs generated from the CHU-9D measure of health-related quality of life (55), proxy reported by foster carers. Guidance for proxy report and for application in children under the age of seven, available from the developers, will be adhered to. QALYs from the CHU-9D will be calculated using the recommended area under the curve approach (65). The CHU-9D was selected because it covers a wide range of dimensions (nine dimensions: being worried, sad, annoyed, tired, in pain, sleep, daily routine, school work and usual activities), which is broader than measures such as the EQ-5D-Y, the youth version of the EQ-5D, or the PedsQL, a broader measure of quality of life but still with a narrow range of dimensions.

15.1. Data analysis for health economic analysis

Costs and outcomes will be compared in terms of mean differences and 95% confidence intervals from non-parametric bootstrap regressions (1,000 replications) to account for non-normal distribution common to economic data. Missing data will be imputed using multiple imputation using chained equations (66) and all analyses will be adjusted for covariates in line with the data analyses for the main trial (described above). Cost-effectiveness will be assessed using the net benefit approach following standard approaches (67). A joint distribution of incremental mean costs and effects for the two groups will be generated using non-parametric bootstrapping to explore the probability that each of the treatments is the optimal choice, subject to a range of possible maximum values (ceiling ratio) that a decision-maker might be willing to pay for improvements in outcome (SDQ and QALYs). Cost-effectiveness will be explored using incremental cost effectiveness ratios (68), with uncertainty represented by cost-effectiveness planes and cost-effectiveness acceptability curves (69).

With regard to reference costs compared to other clinically trialled programmes designed to assist foster-carers, we will explore the availability of cost-effectiveness evidence for other interventions that may be available for foster carers, to support such comparisons. Review of available evidence will be carried out close to the end of the study to ensure that we identify any new studies completed and published during the course of the study.

16. Process evaluation

During the main RCT a parallel mixed methods process evaluation will:

- characterise “usual support”,
- investigate how different service models and the wider context of LAs shapes intervention delivery,
- evaluate implementation and theoretical fidelity to the Reflective Fostering intervention,
- evaluate how intervention implementation is affected by face-to-face, online or blended delivery,
- identify how carers experienced the intervention,
- assess non-receipt of the intervention in the control arm,
- provide explanations for the observed effects in the main trial, and
- identify strategies for wider implementation of the Reflective Fostering intervention.

Using a *fostering team profile questionnaire*, all LAs will be characterised at the beginning and end of the trial period to identify service characteristics (i.e. numbers of children placed in foster care, numbers of registered foster carers, and associated interpreting services, and existing foster caring policies, training

and support programmes in place), and changes in the service which might affect implementation of the Reflective Fostering intervention throughout the duration of the study.

Findings from the site profile questionnaire will be used to purposively select four case study sites to obtain maximum variation in LA characteristics. In these sites, the training of Facilitators will be observed to understand how the principles and content of the Reflective Fostering intervention is transferred to Reflective Fostering Programme Facilitators. If the intervention is delivered using a mixture of face-to-face and online delivery then a key consideration will be how implementation is affected by these different modes of delivery. A sub-sample of session recordings (approx. five hours) will be purposively selected, based on FAR ratings, to assess theoretical fidelity. Extracts from sessions will initially be selected to include sections where the theoretical mechanisms underpinning the Reflective Fostering intervention (i.e. mentalization, reflective capacity, and enhanced monitoring one's 'emotional temperature') are intended to be delivered (see Theory of Change model in Appendix 1). Extracts will be transcribed verbatim and using a Linguistic Ethnographic approach⁽⁷⁰⁾⁽⁷¹⁾, verbal and non-verbal communication will be analysed for evidence of how the theoretical mechanisms are enacted by Facilitators and received by carers within sessions.

Face to face, online or telephone interviews and Focus groups will coincide with the 12-month (T3) follow-up assessment.

Consent to be contacted about the interviews will have been sought at the information (coffee morning) event, where the process evaluation element will be fully explained to potential participants. Details of those who have provided optional consent to be contacted to take part in the interviews/focus groups will be included in the study database and be available to the process evaluation team. Those participants who have given consent and are purposively selected (see below) will be provided with information about the interviews/focus groups and asked to provide consent to take part. Face-to-face, online or telephone interviews with purposively selected carers in the intervention arm (five per site across the four case study sites) will take place. Carers will be purposively sampled to obtain maximum variation across years of experience as a carer, whether caring for children aged 4-9 years or 10-13 years, whether a kinship or foster carer, and whether one or both carers receive the intervention. This will be to understand their experience of receiving the intervention, how it affected their care of children, the extent to which this was sustained after the training programme was completed, and the source of any other support obtained during the study. Face-to-face, online or telephone interviews with 20 purposively selected carers in the control arm (5 per site) will be conducted to assess non-receipt of the intervention and experience of usual support, sampled to match characteristics of those interviewed in the intervention arm.

Face to face or online focus groups with those delivering the Reflective Fostering Programme and managers will take place to understand experiences of programme delivery, including co-delivery by carers and social workers; and how the wider context of LAs influenced intervention delivery. Semi-structured interviews, focus groups and observations of intervention delivery will be (audio/video) recorded and transcribed verbatim. Audio data will be uploaded onto OneDrive and filed using participant IDs before removing from the recorder.

Data will be transcribed by a professional transcription company who will be required to sign a confidentiality agreement and all identifiable information will be removed from the transcripts.

All interviews and focus groups will be analysed using NVivo software. In the intervention arm, we will then develop a coding scheme to thematically analyse how the process and content of the Reflective Fostering intervention functioned from the carer's perspective. A constant comparison approach will be adopted, working iteratively between data obtained from different interviewees within and between schools.

16.1. Process evaluation data synthesis

The analysis of process evaluation data will be iterative, moving between data collection and data analysis to test emerging theories. It may for example emerge that some carers have expectations about Reflective Fostering, which shape their experience and use of the intervention, and this may require deeper exploration. The analysis of the video/audio recorded sessions will therefore require knowledge from carer interviews to compare how reported experience relates to actual implementation of the intervention. Care will be taken to identify and follow up deviant cases which do not fit into emerging theories. This approach will involve working laterally across data types, focusing on identifying 'telling cases', triangulating and looking for connections between data. Emerging theories and the relationship of the data to the conceptual literature underpinning the intervention will be discussed and refined at team meetings throughout the research.

By examining the delivery of the Reflective Fostering intervention within the wider context of the LAs, we will be able to make the transition from the identification of routines and patterns of use of the intervention in specific sites, to theoretical explanations of how different structural relations organise different moments of delivery, which then impact on the specific outcomes we observed in the main trial findings. In doing so, we will be able to identify factors plausibly and/or consistently related to successful or unsuccessful delivery of the intervention, enabling the generation of strategies for wide-scale implementation of the Reflective Fostering intervention.

16.2. Ancillary process evaluation study of mechanisms of change

In order to examine the mechanisms of change, additional consent will be sought from a sub-group of parent-child dyads to carry out home-based observations of the parent-child relationships at each of the three time-points for the study. This analysis will examine three dimensions of reflective parenting including interest in the subjectivity of the child, affective communication, and capacity to play (72).

Within selected LAs additional consent will be sought for a researcher to visit the home of a sub-sample of foster carer-child dyads to observe their interactions. If COVID-19 restrictions mean that visits cannot take place, then observations will be done online. Up to 20 carer-child dyads will be observed 4-months post-baseline and observation data collected concerning the carer-child relationship. Carer and child will be asked to carry out a structured interaction task (involving a problem-solving task, or joint play activity), and video-taped to allow the researcher to directly rate the quality of the carer-child interaction and reflective parenting in action. The full content of this element of the study will be designed in conjunction with our Patient and Public Involvement (PPI) partners, including both foster carers and children in care, or care-experienced young people. There will be separate PIS and consent forms for the foster carer's and child's involvement in this aspect of the study. Once this phase has been fully designed, a linked protocol and related study documents (PIS, consent forms) will be developed and we will seek additional approval from the Ethics Committee for this sub-study.

17. Ethical considerations

This study will be conducted in accordance with the Data Protection Act (2018) and the guidelines of the Declaration of Helsinki (1964- Updated Tokyo, 2004)(73). In advance of the study start date, we will submit an application for review by the REC at UH. Research and Development (R&D) department approval will be sought from each LA site before recruiting foster carers from the LA. The trial will be undertaken according to the principles of ICH GCP, and all relevant ethics and governance processes, including the HRA approvals.

All participant data collected will be done so in accordance with the participant Consent Form and Information Sheet. Confidentiality and anonymity will be ensured and participants will be made aware of their right to withdraw from the study at any point. Each participant will be allocated a study identification code on entry to the study which will be used to identify data relating to that participant. Consent forms and other documents containing person identifiable information will be stored separately from participant data. Recordings and transcripts will be stored securely on LA and/or University computer systems. Password-protected encrypted memory sticks or an approved online secure file transfer system will be used to transfer recordings and transcripts between LA and University computer systems. The reporting of results (including quotations) will be fully anonymised so there is no

identifying information including, but not limited to, name, area, authority and age and excerpts will only be used with the explicit consent of participants.

It is the CI's responsibility to produce an annual progress report (APR) to be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended.

The CI will notify the REC of the end of the trial and if the trial is ended prematurely, the CI will notify the REC, including the reasons for the premature termination.

Within one year after the end of the trial, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

For those in the Reflective Fostering Programme arm of the study, attendance at the programme may involve discussing some sensitive issues, but this will be done in a supportive context, and two trained Facilitators will be available to support any participants who become distressed. All foster carers in both arms of the study will have their own supervising social worker and will have access to further support if required at any point during the study. To clarify, 'further support' refers to whatever additional services are already in place in each LA. Neither the research team nor the social care team will be expected to provide additional services beyond what is already offered as part of usual care, plus the Reflective Fostering Programme.

Many foster carers are time poor particularly if they are caring for several children or for children with additional needs and taking part in this study could provide an added burden. We have explored participant burden in our PPI work and with our foster carer co-applicant, but this will be important to monitor in process evaluation, and in reviewing any differences between eligible foster carers who do/don't participate in the study.

17.1. Safeguarding issues

If any risk disclosures occur during the Reflective Fostering Programme sessions, Facilitators will discuss this with their practice supervisor or team manager, or escalate to the safeguarding lead at the relevant LA. If any risk disclosures occur during focus groups or interviews in the Pilot phase and/or process evaluation the research team member will discuss these with the CI. If risk may be significant and/or imminent, the Site Lead(s) or local safeguarding officer would be contacted for further discussion and appropriate action. The Site Lead(s) will follow local procedures for dealing with safeguarding issues. The LA holds ultimate safeguarding responsibility.

18. Oversight and monitoring

18.1. Trial Steering Committee

The TSC will meet twice a year and will provide overall supervision for the study on behalf of the Project Sponsor and the Project Funder. It will ensure that the study is conducted to the rigorous standards set out in the Department of Health and Social Care's (DHSC) Research Governance Framework for Health and Social Care and the Guidelines for GCP. The TSC will operate according to NIHR Evaluation Trials and Studies Co-ordinating Centre (NETSCC) Project Oversight Groups Guidance. Details of membership of the TSC and its ToR will be held on the TMF.

18.2. Trial Management Group

This will comprise all co-applicants, members of the NCTU and Site Leads at each site. The TMG will be responsible for monitoring the progress of the study, addressing key issues that may arise and reporting to the Funder. Meetings will take place every three months, or more frequently if required. Those that coincide with the TSC meetings will meet a month before the TSC does.

18.3. Trial Team

A core team consisting of the CI and the TM will form the Trial Team to monitor day-to-day progress. Wider study team members, including Site Leads (via video or phone-conference) and Data Management will attend meetings where relevant to the phase of the study. This team will ensure all practical aspects of the trial are progressing well and identify potential issues as early as possible. They will meet regularly. Email discussion will also take place when appropriate.

18.4. Stakeholder Forum

A Stakeholder forum with representation from foster carers and professionals involved with children's social care services will be convened. They will meet three times during the study, providing a way for the study team to communicate with the wider community, to follow policy development, to receive input into the design and delivery of the trials, and to support the dissemination programme. This Forum will have input from PPI.

The TMG, and the TSC will receive reports from the Stakeholder Forum.

18.5. Clinical Trials Unit

The NCTU will lead on statistical input, including analysis of the internal pilot and full trial. They will oversee the design, development and delivery of data management, data collection and data monitoring processes, provide operational oversight and quality assurance of the trial and lead the process evaluation team. This will include input to development and delivery of the trial, drafting of the protocol, regulatory submissions, trial delivery and risk appropriate quality management and monitoring processes in collaboration with the CTSN at UH.

18.6. Safety monitoring

This is a low risk intervention. No specific risks or untoward incidents were reported during feasibility work. The Reflective Fostering Programme enables foster carers to reflect on their relationship with the child in their care and helps provide a framework for building and sustaining supportive relationships. If carers in the intervention arm become distressed during the Reflective Fostering Programme sessions, one of the Facilitators can attend to them if it is not appropriate to remain in the room, the carer will be supported until resolution, stabilisation, or until it has been shown that the distress will not have any adverse impact and/or the study intervention is not the cause. At the end of the session, an incident report form will be completed and passed to the TM who will keep a log of such events. This intervention log will be shared with the TSC as part of safety monitoring.

Study measures indicative of placement stability (placement changes and reasons for the placement change) and wellbeing of participants (foster carer burnout and stress - obtained from the ProQol and the PSI-SF, respectively) will be monitored for data completeness and reported to the TSC cumulatively, every six months after they have been collected. The data will be presented to the TSC by the trial statistician in a way that hides which is the intervention and which the control arm. If marked differences are noted between the groups which raise concerns, the TSC can ask for arms to be unblinded and reviewed by an independent group.

In the light of such information, the TSC could recommend halting the study, but also has the ability to recommend changes to the study protocol, e.g. if placement changes are substantially higher than expected in the intervention arm compared to the control group, unless the reasons given for the placement change are not considered to be problematic (e.g. the child has been moved to ensure permanency of placement, such as being placed for adoption).

18.7. Safe-guarding

The nature of the intervention is likely to increase identification and reporting of potential safeguarding issues or risks in the intervention arm. Safeguarding procedures are outlined in the Ethics section above.

19. Quality Assurance and Control

19.1. Risk Assessment

The Quality Assurance (QA) and Quality Control (QC) considerations for the Reflective Fostering trial are based on the formal Risk Assessment performed, that acknowledges the risks associated with the conduct of the trial and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on: the rights and safety of participants; project concept including trial design, reliability of results and institutional risk; project management and other considerations.

QA is defined as all the planned and systematic actions established to ensure the trial is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements. QC is defined as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the trial related activities are fulfilled.

19.2. Central monitoring

NCTU staff will review data for errors and missing key data points. The trial database will also be programmed to generate reports on errors and error rates. The TM will monitor the Investigator Site files and outputs from data review. Essential trial issues, events and outputs, including defined key data points, will be detailed in the trial Data Management Plan.

19.2.1. On-site monitoring

The frequency, type and intensity of routine and triggered on-site monitoring will be detailed in the Quality Management and Monitoring Plan (QMMP). The QMMP will also detail the procedures for review and sign-off of monitoring reports.

19.2.2. Direct access to participant records

Participating investigators must agree to allow trial related monitoring, including audits and REC review, by providing access to source data and other trial related documentation as required. Participant consent for this must be obtained as part of the informed consent process for the trial.

19.3. Trial oversight

Trial oversight is intended to preserve the integrity of the trial by independently verifying a variety of processes and prompting corrective action where necessary. The processes reviewed relate to participant enrolment, consent, eligibility, and allocation to trial groups; adherence to trial interventions and policies to protect participants, including reporting of harms; completeness, accuracy and timeliness of data collection; and will verify adherence to applicable policies detailed in the Compliance section of the protocol (section 21).

This oversight is considered and described both overall and for each recruiting centre by exploring the trial dataset or performing site visits as described in the Reflective Fostering Programme Quality Management and Monitoring Plan.

20. Public involvement

Foster carers have been involved with each stage of development, starting with the feasibility study. This included a series of consultations with foster carers, to ensure that the Reflective Fostering Programme was best designed to meet their needs. Foster carers were consulted about research design, including feedback on the participant information sheets and consent forms, selection and timing of research measures etc.

A foster carer from the feasibility study is a co-applicant, ensuring we keep the carers' needs and perspectives central to the design. The co-applicant has provided a view on: study aims; intervention design and content; the plain English summary; and proposed measures. This has led to some alterations, such as the decision to drop one measure of parental self-efficacy, and to put greater emphasis on mapping, describing and evaluating 'usual support'. The proposal was also presented to the Research Champions at AFNCCF (a group of parents and young people with experience of accessing help for mental health and emotional well-being), who gave feedback on the plain English summary of the study.

Continued PPI will be central throughout the study, with PPI representatives as part of the TSC. We have also established links with the Care Leavers apprentices and the Young People's Council in KCC, who have commented on the aims of the study and will continue to be involved, including with dissemination

activities. We were also advised to take note of the glossary on 'Language that Cares', produced for the Adolescent and Children's Trust (Tact) with the involvement of children in care aged from 11 up to older care leavers. On this basis, we have used the term 'Children in Care' throughout this document, rather than 'Looked After Children'.

The research team has a history of working closely with the public and patients, e.g. in one previous study carers and young people co-created two short animation films to help disseminate the findings of the study to a wider public (74), leading to extensive media focus, and two of the young people receiving community contribution awards. The current study also plans to co-produce a short film for foster carers, available on YouTube or to be used as part of training, as one element of the dissemination of findings.

Foster carers, care leavers and social workers will also be part of the wider stakeholder meetings held at three points during the study: start-up, mid-point and towards the end of the study. These meetings will also include service managers, charities such as Barnardo's and the Fostering Network, as well as key players such as the What Works Centre for Children's Social Care. The meetings will help to ensure that the study is both informed by a broader set of perspectives, but also that issues of scalability and translation can be considered with as broad an input as possible.

21. Protocol compliance

Although steps will be taken to avoid it, accidental protocol deviations may happen at any time. The Site Lead or delegate must document and explain any deviation from the protocol communicate this to the TM for review by the CI and Sponsor.

21.1. Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to effect to a significant degree –

- (a) the safety or physical or mental integrity of the participants of the trial; or
- (b) the scientific value of the trial

Participating sites should inform the TM as soon as they are aware of a possible serious breach, so that the study team and Sponsor can fulfil its requirement to report the breach if necessary within the timelines specified in the UK Clinical Trials Regulations (currently 7 days).

22. Amendments

The TM (or delegate) will be responsible for making amendments including updating the protocol and applying for ethical approval. This protocol will record the version history so that the most recent version can be identified.

Substantial amendments that require review by the ethics committee will not be implemented until the committee grants a favourable opinion for the trial (amendments may also need to be reviewed and accepted by the governance team at the LA before they can be implemented in practice at sites). All correspondence with the ethics committee will be retained in the TMF/Investigator Site File.

23. Data Protection and patient confidentiality

All investigators and trial site staff will comply with the requirements of the General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018 as well as the UH University Policies and Regulation document “Data Management Policy”.

Confidentiality and anonymity will be ensured throughout the study. Participants may discuss sensitive matters during recorded sessions, interviews or focus groups. This will be managed through close attention to confidentiality, and participants will be made aware of their right to withdraw from the study at any point. The reporting of results (including quotations) will be fully anonymised and excerpts will only be used with the explicit consent of participants.

The study staff will ensure that the participants’ anonymity is maintained. The participants will be identified only by a participant ID number on all study documents and any electronic database. Additionally, participant identifiers required for automated communication (including email address and mobile telephone number) will also be stored in the database, but logically separated from study data by interface and permission constraints. All documents will be stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so.

Following the Caldicott Principles; only data to be used in analysis relevant to the study and to facilitate running the study will be collected, limited to the surveys and demographic material to be used for data analysis, and contact details for electronic communication. All participants will be identified by a unique ID code that will only be linkable to their name via a password encrypted excel file. Only a limited number of researchers will have access to the link between participant names and ID numbers.

An electronic CRF will be produced. Each participant will have a corresponding CRFs unique to them. CRFs will not bear the participant's name. The participant's initials, date of birth and study PID will be used for identification on the database. Access to the database will be managed by NCTU and will be restricted and controlled to authorised personnel and will be password protected. The audit trail will be monitored regularly for any unauthorised access. It is the responsibility of the CI/Site Lead(s) to ensure that relevant personnel are delegated to carry out data collection and data entry. The delegation log will identify all those personnel with responsibilities for data collection and handling, including those who have access to the trial database.

23.1. Archiving

Once the study has officially completed and the End of Trial documentation has been submitted to the Sponsor and REC all essential documents retained within the TMF will be archived either on the UH Electronic Document Management system (EDRMS) or in the University's main storage facility. The Site Lead at each of the sites will arrange secure storage of Reflective Fostering study materials and records after the close of the trial for at least five years. Recordings and anonymised transcripts from the process evaluation will be archived at UEA in the University's main storage facility for five years prior to secure destruction in accordance with University procedures and policies.

Electronic archiving of study documents and the study database will be as described in the Data Management working instruction on electronic archiving (NCTU DM WI 4). It is initiated by the CI or appropriate delegated member of the TMG, no earlier than one year after publication of the study. The electronic archive will be stored in NCTU's archive storage space on UEA's secure research storage infrastructure. This is based on IBM enterprise-grade Storage Area Network (SAN) hardware housed in secure, environmentally controlled and monitored data centres. Data will be regularly backed up to tape with copies in both data centres at UEA. The electronic archive will include an anonymised backup of the database, in multiple formats to allow for format redundancy, together with all design and specification documentation necessary to recreate the database from first principals. The electronic archive will be held for a period of at least five years.

24. Dissemination Policy

A Dissemination Policy will be written and submitted for approval to the TSC.

The TSC have responsibility for ensuring effective dissemination of the study results. On completion of the trial, the data will be analysed and tabulated and a Final Trial Report prepared for presentation to the Funder (NIHR).

Dissemination activity will take a range of formats: (1) Publication in the NIHR PHR journal, social work journals and/or other suitable peer-review journals (2) Results shared with participants via a study Newsletter, disseminated at regional events, and included in newsletters of relevant organisations (3) The study team will host reports and blogs on the Anna Freud Centre's Learning Network on latest evidence and research, and findings will also be shared via university repositories and social media (4) Foster carers and care-leavers will work with a creative arts team to disseminate findings to the wider public, possibly through a short film and (5) Each social care team involved will gain skills which can be used beyond the trial to support fostering skills.

If the trial establishes that the Reflective Fostering Programme is effective in improving health-related quality of life of children in care and is cost-effective, there is potential for the programme to be rolled out nationally. Beyond that, there would be the potential to develop adaptations of the programme, e.g. for carers of adolescents in foster care, for adoptive parents, or for those working in residential care.

24.1. The role of the NIHR

The DHSC and NIHR require that NIHR-funded researchers publish their main study findings in a peer-reviewed, open access journal.

- When submitting an article for publication, the NIHR's contribution must be acknowledged in full.
- Research articles, papers and reports should not use the NIHR logotype, but must use a statement acknowledging funding/support together with the NIHR disclaimer.

Therefore, the following text should be included in articles and reports:

This study/project is funded by the NIHR under its Public Health Research programme (project reference: NIHR127422). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

- The NIHR programme manager should be informed of all accepted journal articles resulting from the study.
- A copy of the final manuscript of any research papers supported in whole or in part by the NIHR should be deposited with Europe PMC upon acceptance for publication, to be made freely available as soon as possible and in any event within six months of the journal publisher's official date of final publication to meet the NIHR open access commitment.

- The NIHR and the DHSC reserve the right to use data or other material from projects that it funds for policy development and publicity activities. The NIHR and the DHSC may publicise the outcome of NIHR-funded research studies through its website, in publications and in press releases where appropriate.

24.2. Expected output and impact

The most immediate anticipated impact is that foster carers who have attended the Reflective Fostering Programme will help the children in their care form more secure relationships, leading to positive outcomes for the children in both the short- and long-term. They will demonstrate greater emotional well-being, potentially greater placement stability, along with a range of positive outcomes associated with better relationships and placement stability. For foster carers themselves, we anticipate reduced levels of stress, and greater professional quality of life, including reductions in a sense of professional burnout. This could lead to better retention of foster carers in the system, at a time where there is a national shortage of carers. If the outcomes of the study demonstrate the effectiveness and cost-effectiveness of the Reflective Fostering Programme, then we anticipate that the approach would become embedded within Social Care by design. While background Intellectual Property is solely owned by the AFNCCF, which would provide the initial expertise (training and maintenance of quality standards by means of assessing programme fidelity), the Programme is designed to be cascaded out among Social Care organisations so that it will eventually become self-sustaining, enabling staff within Social Care to acquire the skills to train other staff and foster carers.

The programme developers and the research team already have strong partnerships with key organisations in the field, including the Departments of Education and Health and Social Care; but by continuing to build relationships with key organisations from the outset (e.g. through the stakeholder meetings), we anticipate that this will improve the potential for the Reflective Fostering Programme to be promoted and used widely.

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26. Appendices

26.1. Appendix 1 – Theory of Change model

Problem	Target	Intervention	Mechanisms of change	Anticipated Outcomes
<p><u>Looked After Children (LAC)</u></p> <ul style="list-style-type: none"> • Early childhood adversities (loss, trauma) and/or genetic and environmental difficulties. • Behavioural and emotional difficulties (high prevalence of mental health disorder). • Relational and attachment difficulties and history of placement instability. <p><u>Foster Carer (FC)</u></p> <ul style="list-style-type: none"> • LAC's challenging behaviours and history of relational trauma can place FCs under stress and reduce capacity to be reflective. • Challenges in establishing a positive relationship with the child. • Lack of evidence-based training to cope with the various demands of the role. 	<ul style="list-style-type: none"> • FCs (include connected carers / kinship carers) of children aged 4-13, who are experiencing relational and behavioural difficulties or challenges. • There is no immediate plan for the child to be removed from the placement. • Not targeted at children on very short-term or emergency placements; • Not an alternative to mental health treatment but could be offered alongside it. 	<ul style="list-style-type: none"> • A group-based programme aiming to support FCs to help them better meet the emotional needs of the children in their care. • Consists of 10 sessions, each of 3 hours' duration, over a period of 3-4 months. • Delivered by 2 trained facilitators to a group of 6-10 FCs. • an <i>experiential aspect</i>, whereby facilitators actively model and promote reflective capacity, and group members are invited to offer different perspectives and use tools of the RFP, e.g. the Carer Map and Carer APP • a <i>psycho-education aspect</i>, where information is offered through discussions, games, role-plays, and work sheets, to support the reflective fostering model 	<ul style="list-style-type: none"> • FCs learning to maintain a sense of curiosity and an open mind about their own and the child's mental states (reflective capacity). • FCs learning to monitor the "emotional temperature" in care situations, and better manage arousal and stress levels. • FCs helped to make a better distinction between their own thoughts and feelings and those of their LAC, seeing the child as a separate person with a mind of their own. • Group work: The new perspectives, support and trust facilitated by the group supports reflective capacity and quality of caregiving 	<p><u>Impact on carer</u></p> <ul style="list-style-type: none"> • Enhanced reflective capacities to help them meet their LAC's needs. • Reduced levels of stress and increased ability to manage challenging situations. • Reductions in compassion fatigue and burnout <p><u>Impact on the child and relationship</u></p> <ul style="list-style-type: none"> • Improved relationship between FC and child. • Improved behavioural and emotional wellbeing outcomes for LAC. • Increased placement stability.

Some potential mediators and moderators

- Child's age at time of coming into care, severity of difficulties and number of previous placement breakdowns
- Carer baseline reflective capacity
- Carer's own experience of previous placement breakdowns

26.2. Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2.0	7 th July 2020	Karen Irvine (Trial Manager)	<p><u>Changes made in response to TSC feedback</u></p> <p>Explains how the sample size was determined</p> <p>Provides that more than one foster carer per family could attend the intervention sessions</p> <p>Includes provision for the information (coffee morning) meetings to be held virtually</p> <p>Consent can be provided online</p> <p>Includes estimated time to complete study measures in total, clarifies the window for getting study outcome measures completed and that participants can complete them on paper if necessary</p> <p>Sets out more information about what will be asked in the Demographics form and the Placement Stability index</p> <p>Clarity on the process evaluation including how the data collected will be stored</p> <p>Changes to Safety Monitoring section</p> <p>Sets out how deviations from the protocol will be handled.</p> <p>Added the Carer Defined Problems Scale as the Goal-based outcome measures</p>

2	3.0	10th November, 2020	Karen Irvine (Trial Manager)	<p><u>Section 4 – Added Ethics number and ISRCTN number</u></p> <p><u>Section 8.1 added “feasibility of online programme delivery”</u></p> <p><u>Section 8.2 – changes to sites taking part. Added sentence to say we will recruit additional sites if COVID19 makes participant recruitment slower than anticipated.</u></p> <p><u>Section 9.1 – Streamlining the recruitment process</u></p> <p><u>Section 9.2 – Added details of how online consent forms will be stored.</u></p> <p><u>Section 9.3.1 – clarified that access to database will be defined to maintain blinding</u></p> <p><u>Section 9.5.1 - Changes made to reflect online delivery of the Programme and facilitator training due to COVID-19 restrictions meaning it is not possible to deliver the Programme face to face</u></p> <p><u>Section 11 – Added an objective relating to online delivery</u></p> <p><u>Section 14.1.3 – Clarified that the CASUS now makes reference to appointments being either face-to-face or online.</u></p> <p><u>Section 15 – The CASUS will not collect data on criminal activity</u></p> <p><u>Section 14.3 – Added sentence to say that REDCap has an option for offline data</u></p>
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				<p><u>collection. Confirmed storage of electronic screening and enrolment logs</u></p> <p><u>Section 14.4 – Added a statement that a subgroup analysis may be conducted for mode of delivery</u></p> <p><u>Section 14.4.5 – Removed double coding for FAR</u></p> <p><u>Section 16 - Clarifying the process of receiving consent for the Process Evaluation. Added evaluation of impact of mode of delivery</u></p> <p><u>Section 19.2 Added sentence to say TM will monitor ISF and outputs from data review.</u></p>
3	4.0	15th Feb 2021	Karen Irvine (Trial manager)	<p><u>To change eligibility criteria to exclude fc who have received the Reflective Fostering Programme before, and their partners. To exclude those whose partners are in the control arm until their partner has finished in the study.</u></p>
4	5.0	3 rd Mar 2021	Karen Irvine (Trial Manager)	<p><u>To change the retention period for study data from 10 to five years.</u></p>