



Research Article

Conducting a large-scale randomised controlled trial in children's social care: reflections on challenges, successes and lessons learned from the Reflective Fostering Study

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Abstract

Background: Research in Children's Social Care in the United Kingdom operates in a framework that was initially designed to support medical research within healthcare settings. Although adaptations to this framework have been made for social care settings, our experience suggested that significant systemic and organisational challenges to conducting large-scale randomised controlled trials in fostering services in the United Kingdom still remain, which work against the likelihood of such studies being completed successfully. A further challenge we faced was that many fostering services were relatively inexperienced with research and lacked the infrastructure to support it.

Objective: To report on the opportunities, obstacles and challenges faced when conducting a trial evaluating foster care support in a children's social care setting and to describe how those working on this research project came together to adapt the existing systems and processes and overcome the challenges.

Design: The Reflective Fostering Study was a randomised controlled trial evaluating an intervention to help foster carers care for the children they look after.

Setting and participants: Local authority and independent fostering services in the United Kingdom. The main study recruited 524 foster carers and kinship carers. The main study was evaluating the Reflective Fostering Programme, a group intervention designed to improve reflective functioning in foster and kinship carers.

Results: The main challenges identified in this study were lack of infrastructure, both within fostering organisations and outside, a lack of capacity, and on occasion, unnecessary bureaucracy. Working with fostering sites, the Clinical Research Network and across collaborating partners, we were able to make changes to existing processes so that the governance and oversight of the study were proportionate and the workload for our sites was minimised. Identifying likely departments to obtain key approvals, working with local Clinical Research Networks and providing templates made the site set-up process faster and supported recruitment.

Limitations: The challenges reported were those encountered by a study that took place in fostering services in the United Kingdom. The challenges faced, and solutions identified, may not be mirrored in other sectors of children's social care, or other countries.

Conclusions: Carrying out high-quality clinical trials within fostering services in the United Kingdom can face significant barriers. There has been a move to address these issues, but our study suggests that more could be done so that research in these settings increases. Ongoing review of the regulatory framework, which is designed to ensure best practice for research in children's social care, could ensure that research governance is proportionate while upholding safeguarding. Without doing so, high-quality clinical trials within fostering services in the United

Kingdom may face significant barriers. In the meanwhile, certain pragmatic steps can be taken by teams doing studies similar to ours, which can help to overcome some of the challenges faced.

Future work: Based on our experience with this randomised controlled trial, we encourage other research teams to use some of the pragmatic suggestions set out in this paper and evaluate whether these impact on their ability to conduct high-quality clinical trials within fostering services in the United Kingdom. If further review or changes are made to the research governance framework, we encourage researchers to evaluate and report on the impact this has on the process of conducting studies in children's social care.

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Background

An evidence-based practice approach indicates that social work practitioners should use research to inform effective interventions and use evidence to support their practice.¹ While the UK government and research funders have increasingly highlighted the importance of research in this field, progress has not always been easy. Children's social work is beset with operational and systemic challenges, with local authorities (LAs) and social work professionals reporting heavy workloads, competing demands on their time, resource constraints, staffing shortages and workforce retention problems.² The main priority of children's services is direct service provision – including responding to pressing issues to protect the welfare of looked-after children and carers. This can leave little dedicated time or capacity to engage with activities outside of this remit, including research, despite an awareness within the sector of the importance of building an evidence base to inform practice development.³

Randomised controlled trials (RCTs) are widely considered to be the 'gold standard' for assessing effectiveness of interventions.^{4,5} Despite this, RCTs are rarely implemented in children's social care settings, especially in the field of foster care,^{4,6-8} although there has been an increase in recent years with the advent of research being funded by organisations such as Youth Endowment Fund, What Works for Children's Social Care and so on. The type of research commissioned in LAs to examine the impact are typically smaller-scale service evaluations, which are less methodologically rigorous by design, bringing into question the quality of the research being used to inform service change/improvement.⁹ This caution about employing more robust research practices can be due to the pressures on the system and may also be because the use of RCTs in social care has been seen as controversial.⁷ Some voice concerns regarding the feasibility and ethics of a randomised design, a methodology originally developed in the field of medicine, which can be perceived to impose an inappropriate set of methodological assumptions and involve the unjustified withholding of potentially

beneficial support.^{4,7} Whereas others have concerns about relinquishing control over who is selected to receive required support.³

Children's social care generally faces significant challenges to engaging with and facilitating large-scale research compared to the healthcare sector, which has a longer history of research-informed practice.⁹ A well-established research infrastructure is essential to the successful implementation of high-quality research.⁴ Such an infrastructure has long been available to healthcare research in the UK with the establishment of the National Institute of Health and Care Research (NIHR). In 2006, the NIHR was funded by the Department of Health, in line with the UK government's 'Best Research for Best Health Strategy',¹⁰ with the aim of building a research system to facilitate high-quality healthcare research. As the UK's largest funder of clinical research, the NIHR's main objective has been to promote, fund and support the delivery of high-quality research in NHS settings to improve health care and outcomes.¹¹ Infrastructure for research is devolved to the local nations, with each nation setting its own strategy. NIHR research is guided by the Health Research Authority (HRA) UK Policy Framework for Health and Social Care research,¹² which provides guidance in line with good clinical practice¹³ (GCP) and streamlined ethics and governance pathways for healthcare research.

Having begun as an organisation focused on healthcare research, in 2018, the NIHR expanded its remit in response to increased recognition of the need for high-quality research to support evidence-based practice in social care.¹⁴ As a result of this change, the research governance systems developed in the UK for healthcare research have been expanded to also cover *adult* social care. However, the infrastructure to support research in children's social care has emerged more slowly. As this paper will illustrate, at the time we started the study, this framework had not yet fully attended to fundamental differences in how the sectors are organised, funded and governed and how, subsequently, research is delivered.¹⁵ This paper argues that the lack of a comprehensive framework to

govern research in children's social care, comparable to the UK Policy Framework which covers adult social care services, has practical consequences for those aiming to do research in this field. Absence of centralised regulatory guidance makes ethical and effective research conduct in this setting challenging to navigate.

Context: background to the Reflective Fostering Study and the impact of coronavirus disease

Within the broader context set out above, this paper reflects on the experiences, challenges and learning gained from setting up and implementing a large-scale RCT in the field of children's social care – the Reflective Fostering Study.¹⁶ The study was designed to be delivered across multiple LAs and independent fostering agencies (IFAs) in the UK, with the aim of improving the evidence for interventions that support fostering relationships and the well-being of children in foster care. In the UK, fostering teams within LAs are responsible for providing foster care for looked-after children in their location. IFAs are private organisations that are contracted by LAs to provide foster care for their looked-after children. They may be used by LAs to meet specific needs (e.g. older children or children of a particular faith).

The Reflective Fostering Study is a large-scale clinical trial to evaluate an intervention to support foster carers (also known as foster parents) and kinship foster carers (also known as connected person foster carers). The trial was funded by the NIHR Public Health Research Programme (NIHR127422) and was conducted in partnership with 23 UK fostering services (20 LAs and 3 IFAs) between April 2020 and December 2024. The trial evaluated the clinical effectiveness and cost-effectiveness of the Reflective Fostering Programme (RFP), a 10-session group-based programme targeted at foster carers, kinship and connected foster carers looking after children aged 4–13 years. The programme was designed to support carers to develop skills and tools in 'mentalising', that is, to better understand the behaviour of the self (as a carer) and other (the children they care for) in the context of underlying mental states.^{17,18} The RCT was set up to provide robust evidence of the effectiveness of the intervention to inform decision-making around service delivery in the context of fostering services in the UK.

The RCT recruited 524 foster and kinship carers. Participants were allocated 1 : 1 to either a group who received the RFP alongside usual care or to a group who would continue with usual care only. A study co-ordinator (usually a social work practitioner) was appointed in each fostering organisation. Their role was to liaise with the

central research team, supervising social workers and foster and kinship carers to provide details about the study to potential participants and to obtain consent to share their details with the central study team, who would then work with carers directly to obtain consent and collect baseline data. The study co-ordinator also advised carers of their allocation and, for those in the intervention arm, gave details of how to join the programme.

The research team working on the study mostly had a mental health research background in/or associated with the NHS; and although there was a significant involvement of foster carers and social care professionals in the initial design of the study, the core research team were mostly quite new to conducting research in a children's social care setting and likely brought certain assumptions about how research is conducted based on their own previous experiences. Moreover, the study launched in April 2020, coinciding with the onset of the first UK-wide lockdown in response to the coronavirus disease discovered in 2019 (COVID-19) pandemic. While most non-COVID-focused research was paused or halted to reallocate resources and focus attention on research addressing the pandemic,¹⁹ the Reflective Fostering Study continued, adapting its model of intervention delivery to an online format.²⁰ The pandemic had a significant impact for professionals working in children's social care and those served by the system, exacerbating existing workforce challenges and introducing new operational and systemic pressures.^{21,22} It is important to acknowledge that as social care keyworkers, children and family social workers continued to undertake face-to-face visits, throughout the pandemic, including national lockdowns, to safeguard children within the community. Despite these unprecedented challenges, fostering services maintained their commitment to support the study in recognition of its potential impact for improving the quality of support provided to foster carers.

During this period, LAs and IFAs strived to balance the needs and well-being of their workforce, as well as the protection of vulnerable children and families, while having to drastically adapt practice and ways of working to respond to the disruption caused by the pandemic.²¹ Like many sectors, many social workers shifted to home working, which meant navigating new (often underdeveloped) systems while juggling personal caring responsibilities (e.g. homeschooling children).^{21,23} Foster carers were often overwhelmed, managing additional burdens, such as home schooling, without the usual respite from the challenging behaviour of children they care for. The uncertainties, isolation and high-stress context of the pandemic impacted the emotional and psychological well-being of carers and the children they were caring for, which,

in turn, impacted placement stability.²⁴ All of these factors contributed to a high-pressure system context at the very start of the study. Although not the focus of this paper, this context needs to be kept in mind when considering the experiences that are described in what follows.

Public involvement

The paper sets out details of how we consulted with foster and kinship carers to address the challenges we faced. A foster carer was one of the co-applicants for the study, and we had two experienced foster carers on our Trial Steering Committee. All these provided input to study design and processes. Once the study was running, a key initiative was the establishment of a Foster Carer Advisory Group. This group consisted of six carers who had taken part in the study (from both arms). As is set out in more detail below, this group helped to maximise engagement with foster carers and speak to them about their experience of being part of the study. They also provided input to the central research team about improvements to study documentation. Another important initiative in the study was the Increasing Collaboration and Learning with Underserved communities for Diversity and Equity (InCLUDE) project (described below), which was coproduced with two foster carers and which looked at under-represented groups in the study. This group worked closely with Experts by Experience to understand issues and provide advice to the central research team about how to increase participation of particular under-represented groups

Equality, diversity and inclusion

The main study was conducted with equality, diversity and inclusion at the forefront of what was being done. We quickly realised that certain groups were under-represented, so we developed the InCLUDE project to address this. Included in this team were two male foster carers of South Asian origin (male carers and South Asian carers were under-represented groups during the pilot phase of the study). Details of how this was done are set out below.

The aims of this paper

Conducted within the remit of a healthcare research governance framework and during a global pandemic, the Reflective Fostering Study provides an insight into some of the opportunities, obstacles and challenges faced when conducting large-scale evaluation research in one sector of children's social care, that is, fostering services. In response to the current gaps in the healthcare research governance framework, our intention in this paper is to share the experiences and lessons learnt, with the hope that this will benefit other researchers who may face similar challenges when designing and conducting trials in children's social care settings. We set out five key

challenges that we experienced when conducting this study and describe some of the approaches taken to address these. In the discussion, we draw together key learning points and provide some recommendations for future research. We hope that the lessons we have learnt will support LAs and fostering agencies to participate in future research, as well as prove helpful to other research stakeholders, such as the NIHR, who fund and support research in children's social care.

The challenges faced and how the study responded to them

Challenge 1: lack of national infrastructure to support trials in children's social care

In the UK, the ethics and governance assurance processes for research that takes place in healthcare and adult social care settings are managed by the Integrated Research Application System and HRA systems which provide a single review process (specifically, establishing a study agreement, providing all study documentation and the ethics approval process). There is no such unified system to support, nor a standardised route to guide governance approval in *children's* social care, which falls outside of the remit of the HRA.²⁵ Furthermore, unlike HRA approved site agreements which cannot be negotiated by participating sites (such as the Organisation Information Document and the model Non-Commercial Agreement), research studies undertaken outside of HRA require the sponsor/lead organisation to prepare a bespoke site agreement that can be negotiated on a site-by-site basis as part of their own governance process. This not only extends the time required set up each study site but also involves lengthy discussions as part of site initiation with each participating organisation.

In the RCT we describe here, the amount of work involved in study initiation and in supporting a site to recruit was extensive. Many fostering support services are relatively small scale, and we had to decide early on not to include smaller LAs or IFAs, because the work involved in set-up would have been disproportionate to the number of potential participants who could be recruited. However, this meant there were large numbers of carers not being given the opportunity to take part in the research, including foster carers who prefer to work with specialist IFAs (such as those IFAs set up to engage with faith groups), which are often small in scale but who provide important services to minoritised foster carers. Ofsted reported that a higher number of foster carers from ethnic backgrounds were found in IFAs compared to LAs.²⁶ By excluding these smaller LAs and IFAs, we were therefore at risk of making

the profile of carers in the study unrepresentative of the wider population (for more on this issue, see [Challenge 5: ensuring equity of access to participation in the research](#)).

The lack of a national infrastructure to support research in children's social care has implications at a local level. In an NHS organisation, there can be staff who can help with recruitment (e.g. research nurses), which in England, are funded by the NIHR via the Clinical Research Network (CRN), which is comprised of 15 Local regional networks (LCRNs). This provides research delivery support and expertise to facilitate efficient and effective research in NHS and clinical settings.²⁷ Until recently, there has been no equivalent support available within children's social care settings. The CRN can agree to provide service support costs to pay for the time LA/IFA staff spent on these tasks. However, capacity constraints and high staff turnover means that there is often restricted capacity within fostering services for staff to take on this extra work, even if paid overtime. Both LAs and IFAs provide foster carers with Out of Hours support, meaning fostering social workers regularly undertake additional hours during the evening and weekends to be on call to offer support and to take referrals for emergency placements. This impacts the social workers' capacity to consider paid overtime for research tasks.

At the time this study began, there was a lack of clear guidance to support children's social care services taking part in research. This was despite a push by NIHR for increased capacity in social care research and a willingness of LCRNs to provide support. As a result of a national initiative that was initiated during the life of this study, some LCRNs had funded research staff located in LAs to increase the capacity of the organisation to be involved in research. However, we found that they were frequently located in public health teams (i.e. not where the fostering services were based) and their role was not to support recruitment. In larger LAs, there can be confusion about the process for agreement for large-scale research and governance around this, and the lack of research infrastructure in LAs/IFAs meant that there was no clear pathway to set up CRN support.

Lack of UK-wide systems had an impact as the Reflective Fostering Study scaled-up from a pilot phase to the full trial. In healthcare research, additional sites can be recruited via the CRN who have processes for reaching out to NHS organisations about the study and inviting expressions of interest, facilitated by their established relationships with NHS trusts and organisations. But, at the time of the Reflective Fostering Study, the CRN did not yet have established relationships with children's

social care teams or fostering services to be able to do this, which made adding additional sites to the study an arduous process.

How was this addressed? In the Reflective Fostering Study, various approaches were developed, and we were fortunate to find support and enthusiasm within many LCRNs to try and develop new ways of working together. In the most significant initiative, the Trial Manager engaged with LCRNs to seek practical (hands-on) research support for LA sites, including help with the set-up processes. The LCRNs identified that they could provide support from their agile workforce teams who had been set up to work flexibly on non-NHS research. However, as this was a new way of working, the mechanisms for this had to be worked out site by site. Further, once agreement was reached, it was sometimes difficult for the fostering services to arrange for the CRN staff to have access to the foster carer's records due to issues with General Data Protection Regulations (GDPR) and the lack of internal processes to facilitate this.

As the CRN promotes studies looking for new sites using their networks, we approached our lead CRN (Eastern) to support with this. Despite not having a network of relationships with children's social care and/or fostering support teams, they were keen to help and willing to explore establishing links and developing processes for increasing awareness of the study. The central research team was invited to national meetings with the Research Delivery Managers for public health. Following these meetings, we were contacted by a number of LCRNs about the study and they reached out to LAs/IFAs in their region, making introductions to a number of organisations. This helped the study team to identify potential new sites (two came from LCRN links) and also helped the LCRNs to expand their networks.

Challenge 2: lack of research culture and systems/processes within local authority fostering services and independent fostering agencies

Initiating a RCT in any setting is challenging and requires significant investment of time and resource,²⁸ but there are specific challenges to setting up in contexts which do not have the systems and processes to facilitate large-scale research. Locally, NHS organisations are more likely to have research and development (R&D) teams who oversee and run research within the organisation, so it is clear who needs to be approached to agree to take part in the study for approvals and so forth. It is very unusual for organisations responsible for children's social care to have this resource.

How did we address this? When we looked to increase the number of organisations we were working with, in the absence of local R&D teams, we tried to identify senior personnel (e.g. Heads of service) in LAs/IFAs using internet sources. As service directors rarely had time to respond to cold calls, a better avenue was asking the principal investigators (PIs) in our existing study sites for introductions to their counterparts in other organisations. We also asked to attend regional meetings of service managers. This allowed us to speak to key people to explore whether they would like to take part, and as the study progressed, we were gradually able to identify a greater number of potential sites and to contact the necessary people more quickly. The team also developed different recruitment materials and adopted new information methods to promote the research, including videos and newsletter style briefings to engage potential sites.

As work started to bring on board new sites, it was not always apparent who was best positioned to authorise sign off. Even when the right person/team was identified, further delays to obtaining governance approval were common due to lack of capacity and over-riding priorities. We addressed this by carrying forward feedback and learning from our pilot sites about set-up. First, we knew to allow for a long time period (5–6 months) for study set up with each new LA or IFA and to plan early with the fostering teams. Second, we were able to let new sites know which person (role) or team had provided approvals/agreements in the other fostering organisations we had worked with, so they might have a place to start. Third, signposting the most critical actions for site activation and starting this process as early as possible helped to mitigate some delays. Where possible, we pushed for direct contact with local legal teams or the local learning and development department (as the team generally responsible for organisation and delivering this type of intervention as part of usual support). This allowed for better communication of what was needed and also reduced the burden on the site staff we were working with. Another helpful process was to provide templates to complete – for example, for confirming capacity and capability so that local teams could better navigate the governance process. This was done to both conserve time and provide clarity on what was needed for organisations faced by a whole host of new procedures and the acronyms that went with them.

The relative lack of a research culture and systems at an organisational level could also be seen at individual level. LA children's social work staff tend not to have had direct experience of being involved with larger-scale research before. Each site needed to have a PI, and this role is

not always understood by practitioners working in this area. Delegation of tasks within local services was also challenging. Although there was often great enthusiasm and willingness to get involved, staff delegated to work on research lacked an understanding of complex research designs (especially RCTs). As a research team, we tried to have realistic expectations of each person taking on roles locally and to provide suitable training, but in reality, it was often a challenge for staff in LAs and IFAs to manage those requirements alongside their other, multiple commitments. The nature of the work in fostering services means that the staff group are often responding to emergency and crisis situations, needing to be available to match children to foster carers, attend court and abide by statutory timescales for the completion of key tasks for children in care. Ensuring children and young people are safeguarded in often unpredictable situations can lead to delay in the completion of research tasks.

We addressed the relative lack of experience of working in research among children's social care services by providing comprehensive research training to site staff – in addition to the usual site initiation training. This was time-consuming and the training (based on the GCP training developed by NIHR) was sometimes experienced as overwhelming by some site staff. The amount of general research training required had not been foreseen by the core research team and this added to the complexities of setting up a study in a children's social care setting. Another helpful strategy was to set up weekly drop-in meetings that staff from all our sites could join so that they could share best practice. These sometimes had a particular focus (e.g. on strategies for maximising recruitment). Later, CRN staff provided helpful support to teams inexperienced in research.

Challenge 3: capacity within children's social care fostering services and challenges to recruitment

The fundamental role of LAs and IFAs is not primarily to conduct research, so given the pressures that fostering services were facing, there was a need to find ways for research teams to support the tasks necessary at a local level. Once foster carers agreed to take part in the study, the central research team was able to manage participant queries, following up for outcome measures to be completed and so on. However, GDPR understandably restricts the ability of external people to have access to the contact details of potential participants. While this is not unique to children's social care, in some NHS settings, CRN-funded staff may be able to help with the recruitment by contacting potentially eligible individuals. Or the research team in a study may be provided with access to potential participants by way of a research passport or

letter of access. However, there are no equivalent staff/processes in children's social care settings. This reduced the ability of the central research team to support the research activity in each site and left the local site teams with the main responsibility for contacting potential foster carer participants and sharing initial information about the study. This is a time-consuming activity and one that fostering support services were required to do on top of their day-to-day tasks. Furthermore, it was not always clear who was responsible for leading on this.

The central research team gradually developed some ways to try and address these challenges. To ensure that the right people were identified for each role, more detailed role descriptions with an emphasis on estimated time commitment were developed. Those already working on the study were asked to speak to those considering taking on equivalent roles about what was involved, as we found that peer-to-peer guidance was more helpful than having someone from the research team trying to explain this. For example, sites were advised that the site co-ordinator role, which played a key role in sharing information about the study with potential participants, would suit someone who could be given dedicated time to undertake the tasks required. Or that the role could be shared (although good communication became even more essential, if this was the case). Feedback from the pilot sites meant that new sites could be provided with a more informed estimate of how much work was involved. Being advised of the extent of the commitment sometimes led to sites deciding they did not have the capacity to work with us. However, this was usually at an early stage before a lot of time and effort was spent setting up and so on.

As is often the case in trials (and even more so for one taking place during a national lockdown and pandemic), recruitment to the trial proved to be more time-consuming than initially expected. Lack of time and capacity was a recurring theme for all fostering organisations, and children's social care staff were under immense pressure from their regular social work role and responsibilities and this was exacerbated by the demands of the COVID pandemic, which impacted the ability to prioritise recruitment activities. The sites which recruited most successfully were those where the person co-ordinating recruitment had the capacity to be proactive in recruitment and act as a bridge between the research, foster carers and LA or IFA teams/supervising social workers. Communication between these groups was hugely important. However, reliance on remote working contributed to communication challenges, and our primary method of communication with sites was through e-mail rather than 'in-person' communication. A number of strategies were tried and

found to be helpful. Involving LA or IFA staff who were not in the social work teams (such as admin/business support staff) in following up invitations to take part and copying in the carers' supervising social worker relieved some of the pressures on the site co-ordinator. But, often, these teams were also busy. Probably, the greatest impact was in those sites where the CRN were able to support as, clearly, the demand on LA/IFA staff was reduced.

As described above, we set up agreements that allowed CRN staff to work alongside the site staff. It took time for sites to complete appropriate checks and ensure that external bodies complied with necessary procedures before accessing their sensitive information, including compliance with GDPR, especially given the already stretched capacity of fostering organisations' legal teams. However, once set up, the CRN staff were a valuable resource to the study and for stretched social work teams. Research expertise and practical assistance with contacting and following up with carers, record-keeping and managing informed consent processes with participants made effective recruitment more manageable in critical periods. Besides reducing workload for recruitment, LCRN staff provided some insight into potential barriers and made suggestions for how to overcome these. Furthermore, once embedded, they provided useful intelligence to the central research team about individual sites and an awareness of local organisational context and pressures, which may have impacted the ability to manage/prioritise research delivery. This helped develop the approach to supporting sites and highlight the additional support they may need (e.g. additional training and pushing back timescales to alleviate some pressures).

A key strategy to maximising engagement among carers to encourage them to take part was the Foster Carer Advisory Group, which was formed to provide expert-by-experience advice to the research team. The Advisory Group members were advocates for the study and steered the design (and redesign) of recruitment material and strategy, provided testimonial videos and promoted the study (i.e. among their own networks, on social media, adoption and fostering podcasts). A key role of the group, especially among those who had been participants in the pilot phase, was to speak about their experiences of being part of the study at study information sessions and to promote the study among carer peers and networks. Carers were keen to understand what the programme/participation in the study could offer for their practice. It was clear that hearing about the study from peers with a shared experience and motivations, using their position of shared identity as a carer and lived experience of the study added an additional and somewhat more powerful layer to

that of the research team (who may have been perceived by carers as ‘researchers’ – with little common ground or level on which they could connect). The Advisory Group became skilled in speaking about the importance of research and taking part regardless of whether the carer would be randomly allocated to the programme or to usual care. They were able to alleviate common concerns relating to the randomisation and the time commitment of participating in the study, balanced with the significant gains for both children in care and their foster carers, using specific examples from their caring role.

Challenge 4: burden of bureaucracy required to conduct trials

Key governance approvals and documentation are necessary to ensure that a trial is conducted ethically, with integrity and in line with GCP.²⁹ However, some of these processes can be viewed by practitioners on the ground (as well as research teams themselves) as unnecessarily bureaucratic and a more pragmatic approach may be required. The guidelines for conducting research using GCP have been designed to support healthcare research, and templates/documents are generally modelled on clinical trials of investigational products, such as medicines and devices [Clinical Trials of an Investigational Medicinal Product (CTIMPs)],³⁰ and so these guidelines are not always helpful for children’s social care research.

Sometimes, the challenges are very mundane but can create a vast amount of additional work. To take one example – GCP training is required for those working in healthcare research. This is provided by the NIHR either online or in person. However, to register and be accepted automatically for online NIHR GCP training, any individual must have an institutional e-mail address from the type of organisation that conducts research (e.g. NIHR, NHS and a UK university). LA ‘.gov’ e-mail addresses are not recognised, and therefore people working in children’s social care organisations often have to wait for a request to be approved. Furthermore, GCP training is primarily designed for CTIMPs (i.e. medical interventions) and not with non-NHS research in mind. Content is heavily focused on research principles of medical and pharmaceutical trials. The majority of the content (bar informed consent) does not align with the requirements, principles or context of many studies set in children’s social care. At 4-hour duration, and with little relevance to their role in this study, insisting staff in fostering service sites completed this training in addition to the comprehensive study-specific research training felt unjustified and was like an additional pressure for social work teams. To reduce the burden and risk of training fatigue, study training was reviewed and streamlined. Given that the CRN guidance

itself said that GCP training should be ‘proportionate’ to the needs of those involved, we worked with the CRN to identify key GCP principles relevant to our study (particularly, informed consent principles), and combined this with our study-specific site initiation training, to produce a more streamlined, relevant training. This was greatly appreciated by all those in our social care teams involved in research tasks.

In the absence of specific guidance for children’s social care research, our study processes were designed based on those used in (health-related) trials. Feedback from staff in the pilot sites was that many of these processes were onerous. For example, staff were initially asked to record every contact with foster carers approached to take part in the research in their foster carer case notes (in line with guidelines on research practice in NHS settings). Feedback from the pilot teams was that they felt this was unnecessary within their own best practice for recording contact with carers. We reviewed what was being asked and identified key information that should be recorded as a minimum to comply with the principles of GCP (including that they provided consent, which arm of the study they were in and when they were no longer in the study). However, where we were unable to remove the requirement for certain approvals and documentation, involved staff were more accepting of what we were asking of them when clear communication about why they needed to be done was provided.

Some requirements of healthcare research were deemed less relevant to the Reflective Fostering Study. For example, site staff working on the study were initially asked to provide research Curriculum Vitae (CVs) to show that they were ‘qualified’ to work on the study. However, it soon became apparent that this did not always make sense as social work teams often do not have research experience. Also, this sometimes led to social workers thinking we were questioning their professionalism/skills, which could be destructive to relationships. We therefore negotiated with our lead CRN, and following discussions with them, changed our approach and asked for a simplified CV from the PI only. Issues like this, while small in themselves, can take a disproportionate amount of time to resolve and tend to impact upon the goodwill that busy social care teams have about engaging in research.

Challenge 5: ensuring equity of access to participation in the research

Inclusivity and ensuring a diverse and representative sample within trials are essential to ensure that the findings are reliable and meaningful to all within the target population. Guidance on how to increase representation

in healthcare research is widely available, but less work has been done on inclusivity within children's social care research, especially with regard to fostering services.³¹

We specifically monitored the demographics of study participants during the pilot phase, and it became apparent that the study did not have a representative number of certain demographic groups – South Asian, male or kinship carers – compared to national data about the make-up of foster carers in England.²⁶ We were keen to understand what barriers might be preventing these carers from joining the study and to identify strategies to address these; so, we developed the 'InCLUDE' project.³² A group of foster carers from under-represented groups was established, who could be consulted on what would prevent/facilitate the involvement of under-represented carers in research and how we might change the study to increase representation [the INCLUDE-ME (INCLUDE-My Experience) group]. A striking finding was that the barriers to taking part in research mirrored the barriers they met in their role as foster carers more widely, including their sense of belonging within fostering services themselves.

Information from this project was used to provide feedback to sites about strategies that might encourage these groups to join the study (and so lead to higher recruitment overall). To increase engagement with minoritised groups, sites were provided with resources and training on how to conduct inclusive recruitment. Some things were straightforward, such as inviting both members of a carer household, rather than just assuming it should be a female carer who is invited. We also suggested actively targeting South Asian carers. The study documentation was changed to include images of minoritised carers, and to highlight that we particularly welcomed such carers. Many LAs have specialised kinship carer teams, so we asked them to ensure these groups were invited.

Discussion

In writing this paper, we were mindful of the risk that it would sound as if we were simply making a list of insurmountable challenges when conducting trials in children's social care, and specifically, in fostering services. In fact, the study was able to successfully recruit 524 foster carers/kinship foster carers from across England and Wales, and (generally) deliver on what we set out to do originally, despite the additional challenges of the COVID pandemic and lockdown in the first years of the study. This was thanks to the enormous hard work and dedication of all the individuals and services who worked with us, dealing patiently with the many demands we

made on their time, patience and resources. The Reflective Fostering Study is the largest RCT conducted to date on a parenting programme for foster carers in the UK in children's social care. The fact that such a study could be conducted shows what is possible, and the willingness on the part of everyone involved to do the kind of research that can make a meaningful difference to the lives of children in care. When we come to write up the final report on the study, there is a risk that it might sound as if the whole study proceeded without problems.

However, the study encountered significant systemic and organisational challenges which work against the likelihood of studies such as this being completed successfully. It is not by chance that there have been relatively few large-scale trials within children's social care. Of course, some of the challenges encountered are common to nearly all research, such as slow recruitment rates, under-representation of minoritised groups and the need to balance best research practice with the reality of services on the ground. However, the team did encounter several challenges particular to conducting research with fostering services in a children's social care setting despite adopting recommended strategies set out by other researchers.³

As we have tried to set out, using specific examples, there is currently a lack of an infrastructure to support research of this kind, both within the fostering organisations and nationally. The burden of bureaucracy required for healthcare research is cumbersome and often unnecessary for this type of research, and the lack of alternative processes developed specifically for children's social care presents a challenge. The issue is not simply one about conducting research; we were trying to conduct research in a system that is under immense pressure, so they have little capacity to do anything more than their primary social work role to safeguard children.

Nevertheless, positive developments were made during the 4-year study. The central research team supported fostering teams to develop knowledge and skills in research and made progress in establishing processes for setting up studies in LAs/IFAs and processes to involve LCRNs in children's social care research. Many of the changes we made to the study were suggested and/or made possible because of the willingness and support of our partners in the research. This includes the fostering organisations, the CRN and foster carers. The good will came from establishing good relationships and from good communication between all the parties. One of the advantages of the long set-up process and frequent meetings was that it allowed us to get to know each other

and to establish good working relationships. The way we worked in the study constantly evolved as we took stock of barriers, identified pinch points and listened to feedback from our fostering partners. We consulted widely with our site partners, with foster carers in the study and in our oversight committees and with the CRN about strategies to increase recruitment and follow-up completion rates. We worked with the CRN to develop support from their agile teams for recruitment at our sites, which they were committed to helping us to do. Also, we worked together to consider how to reduce the workload of the site team while still complying with GDPR and data protection legislation. Some of the strategies we tried were helpful; very early on, we slimmed down the recording processes to the minimum required to run the study in line with GCP.

The most powerful way to promote the benefits of and participation in research in social care is the link to how it can achieve better outcomes for vulnerable children. Working with foster and kinship carers to promote this message enhanced the recruitment of other foster carers and social workers into the study. We set up a Foster Carer Advisory Group and, later, a similar group – InCLUDE-ME – advising specifically on increasing inclusivity and representation in the study. InCLUDE-ME's feedback resulted in making the early information about the study much more appealing and eye-catching to a wider range of potential participants. The Advisory Group offered to attend sessions presenting the study to eligible foster carers – and the feedback from those considering taking part was that it was more powerful to hear from their peers than from researchers. They made suggestions for how to maximise completion of study outcome measures – certificates, a prize draw and a video explaining why it was important to stay in the study until the end. A key factor underlying the successful developments made was good communication. We consulted widely, with fostering organisations, foster carers and other stakeholders. We tried to listen to what was reported back to us and to suggestions made and to act on what we heard. We kept stakeholders updated on study progress with regular newsletters and annual study events, focused on inclusion and involvement in research. These communications reinforced a reflective fostering community and helped to build on existing relationships, sustain momentum and zeal.

Some of the strategies we tried were not as helpful as we hoped. For example, we were able to get agreement for service support costs to be paid (in lieu of dedicated staff to support the sites), and one of the suggested ways to use this money was to backfill the time of the staff working on the study. However, the fostering organisations were under-resourced, so there was not any capacity for

staff to do this. Strategies that increased what site staff were expected to do (even if beneficial to them) were (understandably) not helpful. We tried to set up regular meetings for site staff. These were set up in response to feedback from the site co-ordinators that they felt isolated, as they were often the only person in their organisation working on the study. The intention was for to make them to feel part of the study team and to share good practice and to learn from others about how to overcome issues and what had worked for them. This was not as successful as we had hoped, because they often did not have the capacity to attend these.

Barriers were not just those that were inherent in fostering services and the regulatory framework in place at the time the project was being set up. There were limitations within the study that created barriers – mostly around the amount that LAs/IFAs were being asked to do. We initially asked the site team to record a high level of information in the carer case notes that they found burdensome. We reviewed what we were asking for and agreed to a more proportionate approach. We tried to create a 'community' of Site Co-ordinators by having regular meetings, which they did not have time to attend. We relied on sites to recruit foster carers, which took a lot of their time. The CRN worked with us to support the fostering staff with this. But changing to a model of direct recruitment removed a lot of the reliance on sites to recruit.

Recommendations for researchers

Based on our experience in working on this study, and working within the regulatory framework in place at the time of the study, the following are some recommendations we would make to other researchers aiming to do trials in children's social care, especially for studies in fostering services:

- Aim to develop a cohesive team culture between the central research team and the site staff. Good working relationships lead to good will and eagerness of the recruiting sites to support the research, so meet regularly – face to face if possible – and be prepared to support them to understand what is needed.
- Good communication is essential – for developing relationships, for helping the team to understand why certain things need to be done, to set expectations of what is needed and so on. Ensure you consult widely, listen carefully and respond to feedback.
- Setting up and initiating fostering organisations into the study can take a long time, so start as early as possible. Identify early which processes are critical and/or important to get done first, or which take the longest time and focus on these.

- Engage with the target population, foster carers and kinship carers in our case (coproduction) and sources of support (LCRNs) early in the study.
- Make use of networks either organisational or personal to expand the visibility of the research and to reach out to potential partners.
- Make it a priority to engage and inform the whole service (social workers and managers) about the research. This is to ensure that they are fully aware of the time commitment required and so able to make an informed decision on whether they have the capacity to run the study and to decide on who is best positioned to work on the study.
- Recruitment of under-represented groups is likely to require targeted recruitment strategies, as these groups have experienced barriers in their fostering role and they will have expectations that this will exist in a research setting too.
- It can be a challenge to balance the regulatory requirements of a RCT, while recognising what is practical/realistic. We found that adopting a proportionate approach, which reduces the burden on the site team but prioritises what is necessary and purposeful for the specific study, was most helpful.
- Celebrate the achievements of the study at each stage and promote the benefits and potential positive outcomes for children and young people at every opportunity.

Suggestions for changes to support infrastructure

Carrying out high-quality research within fostering services in the UK can face significant barriers. Since this project was being set up, there has been a welcome move to address these issues, but our study suggests more could be done so that research in these settings increases. A review of the regulatory framework which is designed to ensure best practice for research in children's social care could ensure that research governance is proportionate while upholding safeguarding. Based on the experience with this one specific clinical trial, recommendations for changes to national and local support for studies running in children's social care could include:

- It could be helpful if HRA systems were open to children's social care research to reduce the need for obtaining and negotiating agreements individually with each site.
- The development of template documents and agreements that are more clearly relevant to the specific context of children's social care research.
- Further develop GCP guidelines and training for conducting research in social care (or non-NHS

settings generally) that ensure the training is proportionate to what is required to the specific context of children's social care research.

- Consider having trained staff within the CRN (preferably embedded within LAs/IFAs) who can support research being conducted in children's social care services.
- Develop systems for gaining timely agreement with the LAs/IFAs (e.g. research passports) that are streamlined and can be put in place relatively quickly.

It is heartening to note that during the lifetime of the Reflective Fostering Study, we saw progress in relation to several of these recommendations and a willingness to exchange ideas with research teams and children's social care services to address some of the underlying challenges that exist. For example, the Research Governance Framework now covers children's social care³³ and so we anticipate the HRA will now provide the framework for regulatory oversight and governance for research being conducted in this arena.

Conclusion

The Reflective Fostering Study began in April 2020, at the beginning of the COVID lockdown in the UK, and ran in a sector beset with operational and systemic challenges to research within a regulatory framework originally designed primarily to support health-related research. In the study, we encountered a range of challenges that were specific to this context as well as a willingness among key stakeholders to learn from our experiences and explore meaningful developments. The main challenges we faced when the study first started were lack of infrastructure, both within fostering organisations and outside, to support the set-up of large-scale randomised controlled trials such as the one we were conducting, and in certain areas, levels of bureaucracy that fostering services, who often lacked much research expertise or capacity, struggled to negotiate. By working as a cohesive team with our sites and with the CRN, we were able to develop a range of strategies to overcome many of the issues faced. But, if there is a wish to see further research in this field, our own experience suggested that further review of the regulatory framework which is designed to ensure best practice for research in children's social care may be needed to ensure that research governance is proportionate while upholding safeguarding. During the course of this 5-year study, we were pleased to see that this was already happening, and important developments were taking place. Despite the challenges that we faced, the research team successfully recruited over 500 foster carers to participate in the

largest research study of its type in the UK, demonstrating what is possible. We hope that this experience has provided some learning to build on for future research studies (and in particular clinical trials) within children's social care.

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Data-sharing statement

All requests for data should be submitted to the corresponding author for consideration.

Ethics statement

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Information governance statement

The University of Hertfordshire and UCL are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, University of Hertfordshire and UCL are the Data Controllers, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.herts.ac.uk/about-us/legal/freedom-of-information-data-protection/data-protection and www.ucl.ac.uk/data-protection. The Data Processors were the University of East Anglia, Anna Freud and the study sites (local authorities and independent fostering agencies).

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List of abbreviations

CRN	Clinical Research Network
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	good clinical practice

GDPR	General Data Protection Regulation
HRA	Health Research Authority
IFA	independent fostering agency
InCLUDE	Increasing Collaboration and Learning with Underserved communities for Diversity and Equity
LA	local authority
LCRN	Local Regional Network
NIHR	National Institute of Health and Care Research
PI	principal investigator
RCT	randomised controlled trial
R&D	research and development
RFP	Reflective Fostering Programme

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