Introducing a randomized controlled trial into Family Proceedings: Describing the 'how?' and defending the 'why?'

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ABSTRACT

In 2011, a randomized controlled trial (RCT) of a mental health intervention for families with children under the age of 5 years coming into the Scottish care system was launched, called the Best Services Trial (BeST). When attempts were made to expand the study to English sites, the local leadership Judge objected, concerned that randomization in family proceedings was unfair, potentially discriminatory, and unlawful. Considerations about parental consent, fairness of randomization, and an understanding that the new intervention might be no better, or even harmful, compared to current best practices were crucial in addressing these concerns. In 2017, BeST was launched in England utilizing a randomized methodology. Significant input into the design of BeST came from the leadership Judge who had previously considered randomization unlawful. In July 2021, 383 families with 488 children had been recruited across both Scottish and English sites. Follow-up continues and 76 per cent of families continue to participate at 2.5 years after entering the study. Although there were undoubted challenges in designing and implementing BeST, with hindsight, the objections raised to the testing of interventions randomly were demonstrably resolvable and the process of randomization encountered no legal challenges. This is the first time an RCT has been accommodated within live proceedings in the family justice arena in England and Wales and one of a relatively few such RCTs conducted internationally.

KEYWORDS: Randomized controlled trials, Family justice, Child protection, Ethics

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I. INTRODUCTION

In 2011, a University of Glasgow research team led by Helen Minnis, in partnership with a major UK charity, NSPCC https://www.nspcc.org.uk/ and a large Health Board area, NHS Greater Glasgow, and Clyde secured funding from the Chief Scientist Office of the Scottish Government to explore a mental health intervention aimed at children under the age of 5 years in the care system. The study used a randomized design comparing the intervention with standard care. The intervention had its roots in New Orleans (called the New Orleans Intervention Model, NIM). With funding from the National Institute of Health Research (NIHR), the next step was to test the same intervention using a full-scale randomized controlled trial (RCT) in both Scotland and England and examine whether NIM was clinically effective and cost-effective in more than one jurisdiction. A pilot study was conducted in England with the aim of eventually delivering the intervention at random to children subject to care proceedings in England. To operate within proceedings, the agreement of the judiciary was needed. The Designated Family Judge, East London, and the President of the Family Division of the High Court in England (who has a remit for governing all Family Courts in England) were approached; the response was a firm 'No'. The concern was that randomization in family proceedings was unfair, potentially discriminatory, and not lawful. The involvement of English sites in the RCT seemed unachievable.

Despite the initial rejection of an RCT, the research team persisted and, after around 18 months of consideration of the legal issues surrounding the trial, the judiciary listened. Consequently, October 2017 saw the official launch of the BeST in one London Borough issuing out of (ie, commencing legal proceedings in) the East London Family Court, with significant input into the design from Her Honour Judge Carol Atkinson, designated Judge for the East London Family Court. BeST eventually expanded to include four London Boroughs, all issuing out of the East London Family Court. The participant recruitment phase ended in July 2021 after 383 families with 488 children had been recruited across both English and Scottish sites. Follow-up of families continues and 76 per cent have participated in follow-up data collection at 2.5 years after recruitment. This gives the trial well over 80 per cent power to detect a clinically meaningful difference between the groups and is one of the largest trials ever conducted of an infant mental health intervention in any context.

This is the first time that research using a randomized methodology has been accommodated within live proceedings in the family justice arena in England,¹ and one of the few times that randomized methodology has been used in any branch of the judicial system internationally.² This article concentrates on the process by which researchers collaborated with family justice professionals and the judiciary to design a lawful and ethical research trial within care proceedings. We highlight the challenges thrown up by the implementation of a research trial within court proceedings, particularly when using a randomized methodology, and explain how those challenges were overcome.

Crucially, this article reminds us of the need for robust evidence to assist social work professionals, lawyers, and Judges working in the family justice system in assessing and determining the best possible placement outcomes for children. We ask whether this groundbreaking study demonstrates an unexpected receptiveness from within the legal community to projects that aimed at gathering research-based evidence to benefit families. Given that the judiciary led the way in this project, should the wider legal community be more proactive in its

¹ M. Baginsky and others, 'New Orleans Intervention Model: Implementing the Model and its Randomised Controlled Trial in a London Borough' (2020) 33 (2) *Journal of Children's Services* 75–87.

² D.J. Greiner and A. Matthews, 'Randomized Control Trials in the United States Legal Profession' (2016) 12 Annual Review of Law and Social Science 295–312.

engagement with social science and health researchers in order that a broader evidence base might emerge to provide more authoritative guidance in the best interest decision-making?

II. THE INTERVENTION TO BE TESTED

The NIM was developed over 20 years ago by a team led by Professor Charley Zeanah based in Tulane University, New Orleans.³ NIM offers an intensive infant mental health intervention to families in which a child has been 'maltreated', that is abused or neglected. In New Orleans, every child who has experienced maltreatment and enters the equivalent of foster care is referred to the service. Structured attachment-based assessments are carried out with the child and each carer (including foster carers). Following the assessment period, a therapeutic programme is tailored for each family aiming to maximize the chances of the child returning home. Therapy is provided by a multidisciplinary team including psychiatry, psychology, and social work professionals with a view to assessing and improving attachments and identifying whether the parents are susceptible to change. The intervention focuses on the attachments between the children and all significant adults (parents, family members, foster carers) in their lives. Where possible, the foster placement is the equivalent of an early permanence placement in which the foster carers are registered as potential adopters so that, if the child requires adoption, there is no need for a further break in attachment.⁴ The intervention goes beyond the current English concurrent planning regime (in which parallel plans are made for returning the child home and adopting the child) in that it provides the birth family with an intensive service aimed at improving family relationships and infant mental health while the child is living in a highly supported and nurturing foster placement. Recommendations are made to the court at the end of the intervention during which time the birth family has been offered the chance to change.

Zeanah proposes that this mental health-based intervention has the potential to deliver better outcomes for children in terms of their longer-term mental health and the stability of their future placements, whether rehabilitated to family or not. An evaluation comparing the 4 years prior to the introduction of the NIM in the USA with the 4 years after it commenced suggested that, during the years that the programme was running, there was an increased rate of adoption, but there was, for those returned to birth families, a relative risk reduction of more than 50 per cent in repeated maltreatment for both the child and subsequent siblings. A follow-up of children several years after exposure to NIM in infancy has shown that on many mental health measures, graduates of NIM, whether adopted or rehabilitated to birth families, differed only slightly from the general population.⁵ This contrasts with the high rates of psychopathology in populations of children in care.⁶

Yet, this evidence, while compelling, does not prove the effectiveness of NIM. In the absence of a randomized design, it is possible that other factors explained the apparent success of the Louisiana implementation of the model.⁷ Other important changes happened in the USA around the time NIM was implemented there, specifically the Adoption and Safe Families Act (AFSA) of 1997, which aimed to prevent maltreated children being returned to unsafe homes and to 'expedite permanency' in safe, loving adoptive homes where necessary.

³ C.H. Zeanah and others. 'Evaluation of a Preventive Intervention for Maltreated Infants and Toddlers in Foster Care' (2001) 40 (2) Journal of the American Academy of Child & Adolescent Psychiatry 214–221.

⁴ H. Minnis and others, 'The "Spirit of New Orleans": Translating a Model of Intervention with Maltreated Children and their Families for the Glasgow Context' (2010) 15(4) *Clinical Child Psychology and Psychiatry* 497–509.

⁵ L.R. Robinson and others, 'The Good Enough Home? Home Environment and Outcomes of Young Maltreated Children' (2012) 41 *Child Youth Care Forum* 73–88.

⁶ UK Gov. Report of the Children and Young People's Health Outcomes Form 2014/2015. (London, 2015). https://www.gov.uk/government/groups/children-and-young-peoples-health-outcomes-form accessed 21 October 2023.

⁷ Minnis and others (n 4).

It is possible that AFSA caused the improvements in children's mental health in Louisiana and not New Orleans. The fact that this natural experiment could not prove the effectiveness of NIM was a key justification for applying for funding to conduct an RCT.

III. RANDOMIZATION – THE THEORY

An experiment involves testing intervention, exposure, or event by comparing observations before the intervention/event and after in order to identify the effect or impact of that intervention/event. However, observational data are prone to bias, that is the tendency of extraneous factors associated with the design, conduct, analysis, evaluation, or interpretation of the results of a study to influence the outcome. If two or more groups are being compared in an observational study, there are often systematic differences between the groups, such that the outcomes for each of the groups may be different because of these differences rather than the actual exposure or intervention. This is known as confounding and, even in the best prospective longitudinal studies, it is impossible to be certain whether a new intervention received by one group in the population was responsible for the benefits experienced by that group. In certain study designs, such as natural experiments or before-and-after studies, researchers make a concerted attempt to eliminate confounding. For example, in a beforeand-after study, where intervention is introduced into one geographical area, a comparison area might be chosen that is similar demographically. In a natural experiment, where an intervention was introduced without the prior planning of a priori research, administrative data might be used to examine health outcomes in those who experienced the intervention compared to people who did not, and those comparisons might be selected in order to be as similar as possible to those who experienced the intervention.⁸ However, in such studies, it is only possible to minimize or eliminate the known confounders, but it is impossible to eliminate confounders that the researchers did not know to control for.

The only way to eliminate both known and unknown confounders is to allocate a sufficient number of eligible individuals to one or the other intervention at random. Therefore, the probability of any individual receiving the intervention is decided solely by chance. In this scenario, all the extraneous factors potentially influencing the outcome are likely to be distributed equally between the groups. Therefore, if the groups are then offered different interventions, any difference in the observed outcome between the groups is likely to be attributable to the intervention alone.

Medical policymakers regard RCTs as being a critical component in generating an evidence base for a new treatment or intervention. Correctly conducted RCTs are regarded as the bedrock of evidence by the National Institute for Health and Care Excellence (NICE) which determines health service resource allocation in the UK.⁹

Randomization is only ethical if there is genuine uncertainty as to whether the intervention being tested is better than the existing service – known as equipoise. In healthcare research, RCTs of new interventions are considered ethical when it is impossible to know whether an intervention is better than current best practice until an RCT has been conducted. Many children with cancer now participate in RCTs: in an RCT, they will receive either the existing 'gold standard' treatment or something new that doctors and scientists think might be better. RCTs can be important in establishing the safety of the interventions being

⁸ S.T. Leatherdale, Natural Experiment Methodology for Research: A Review of How Different Methods can Support Real-world Research' (2019) 22 (1) International Journal of Social Research Methodology 19–35.

⁹ NICE. The Guidelines Manual. Process and Methods [PMG6]. (National Institute for Health and Care Excellence, 2012) https://www.nice.org.uk/process/pmg6/resources/the-guidelines-manual-appendices-bi-2549703709/chapter/appendix-c-methodology-checklist-randomised-controlled-trials accessed 21 October 2023.

tested: full-scale RCTs are expected to have a Data Monitoring and Ethics Committee (DMEC) and a Trial Steering Committee. The DMEC has the power to examine the trial data mid-trial if there are concerns about adverse events, or if one of the interventions is so clearly better than the other that it is not ethical to continue. A good example of this was a trial of fluid bolus treatment in Africa in which the DMEC realized the intervention group contained more child deaths than the control group and recommended the trial be stopped early.¹⁰ A video made about this trial gives an excellent overview of RCT methodology https://www.youtube.com/watch?v=bS68W8AQjds. It is, however, crucial that RCTs are the right size: trials that have a sample size larger than required place an unnecessary burden on participants, research teams, and funders, while trials that are too small risk either missing important effects or basing policy decisions on effects that in fact came about by chance. Guidance has been developed to help trialists get this right, and include considerations about what size of a difference between groups needs to be demonstrated if findings are to change practice.¹¹

There is an ethical imperative to satisfy oneself that 'services as usual' (SAU) are not made artificially worse than usual during an RCT (eg, if resources were taken away from usual services to support the new intervention). Even in medicine, however, there are instances when randomization would not be considered ethical and, in such situations, natural experiments might provide the best available evidence.¹²

IV. TESTING NIM IN ENGLAND

In addition to the findings in Louisiana not being considered proof, the extent to which they could be generalized to a UK context was not known. There are certain key differences between the US and UK contexts: in the UK, no mental health interventions routinely inform social workers or court decisions about adoption versus rehabilitation home. Many social workers in the USA offer therapy, yet the USA has nothing like the intensity of preventative social services that we have in the UK. Unlike in the UK, US foster families are routinely registered as potential adopters.

Interested in the promise of better mental health outcomes for children in care, Professor Minnis and her colleagues determined to test a modified version of NIM in the UK. Intensive qualitative work was first carried out with stakeholders in both England and Scotland to inform the study design.¹³ The study received ethical clearance from an NHS Ethical Committee (West of Scotland Ethics Committee 3), and the first Scotlish families were randomized in January 2012.

The legal framework for safeguarding of children in Scotland is very different to the framework in England. The NIM service in Scotland was created as an alternative service within the range of services available to families in Glasgow. Although, in Scotland, a Sheriff (Judge equivalent) is required to adjudicate whether or not a child has been maltreated to a degree warranting entry to care, from there the Scottish system differs markedly from that in England. In Scotland, the welfare decisions about the child's care placements are taken largely in the Children's Hearing System, by a panel consisting mainly of lay members,¹⁴

¹⁰ K. Maitland and others, 'Mortality After Fluid Bolus in African Children with Severe Infection' (2011) 364 (26) *New England Journal of Medicine* 2483–2495.

¹¹ J.A. Cook and others, 'DELTA2 Guidance on Choosing the Target Difference and Undertaking and Reporting the Sample Size Calculation for a Randomised Controlled Trial' (2018) *British Medical Journal* 363.

¹² F. de Vocht and others, 'Conceptualising Natural and Quasi Experiments in Public Health' (2021) 21 BMC Medical Research Methodology 1–8.

¹³ Minnis and others (n 4).

¹⁴ H. Walker, P. Wilson and H. Minnis, 'The Impact of a New Service for Maltreated Children on Children's Hearings in Scotland: A Qualitative Study' (2013) 37 (1) Adoption & Fostering 14–27.

while case management regarding a child going through care proceedings rests with the social worker. Therefore, in Scotland, the framework within which NIM was conducted was social services provision and not the court arena.

Conducting an RCT within a social care arena, and prior to court proceedings, has precedent: for example, an RCT of Family Group Conferencing, a technique for supporting extended families to make decisions about children's care placements pre-proceedings, has recently been published.¹⁵ However, early discussions revealed that the introduction of the intervention in England would need to be within legal proceedings since this was more faithful to the intervention as originally designed in the USA where the intervention was mandated by the court and had significant judicial oversight. A proposal was therefore made to accommodate BeST within English care proceedings. To understand the potential hurdles to the implementation of a research trial within care proceedings, it is necessary to understand the structure of those proceedings and the role of the Judge.

V. CARE PROCEEDINGS IN ENGLAND

The legislative framework for safeguarding of children in England is largely contained in the Children Act 1989. Legal proceedings sit within the context of a whole range of local authority duties to safeguard and make provision for children and families in need.

When an application is made by a Local Authority for a Care Order, the case progresses through four separate phases. A care order gives the Local Authority parental responsibility for the child, which it shares with the parent. When the Local Authority provides an application for a Care Order, it is in contemplation of a temporary or permanent separation between the child and parent. The four stages are set out in the Public Law Outline¹⁶ (Family Procedure Rules, 2010, PD 12A) (ie, 'a tool for the management of care proceedings cases').¹⁷

As can be seen in Figure 1, once the court has issued the proceedings, the case proceeds to the first stage (days 1-3) and is allocated to the appropriate level of judiciary. The parties start considering the evidence necessary to enable the Judge to determine the issues fairly, and further applications may be sent to the court inviting the Judge to consider directing the involvement of experts. Those applications – and any emergency applications such as interim removal into foster care – will be considered by the Judge in the second stage.

The second stage (days 12–18) is case management during which decisions are made by the Judge as to the evidence and assessments that will be necessary to enable the court to determine the issues in the case fairly. Consideration is given to evidence required for factfinding and what assessments will be needed of the parents or extended family to determine whether the child can be cared for safely at home or within the extended family.

At stage 3, the Issues Resolution Hearing (IRH) (week 18/20), the court will have before it all evidence in the case and must actively seek to resolve or narrow the issues. Any issues that cannot be resolved are then determined at the fourth stage which is the trial of issues (see Figure 1).

¹⁵ Foundations. Implications for Policy & Practice (Family Group Conferences, 2023) https://foundations.org.uk/wp-content/uploads/2023/06/Family-Group-Conferencing-Implications-for-Policy-and-practice.pdf accessed 21 October 2023.

¹⁶ UK Gov. Justice. *Practice Direction 12A—Care, Supervision and Other Part* 4 Proceedings: Guide to Case Management UK. (2021) https://www.justice.gov.uk/courts/procedure-rules/family/practice_directions/pd_part_12a#para accessed 21 October 2023.

¹⁷ P. Jessiman, P. Keogh and J. Brophy, An Early Process Evaluation of the Public Law Outline in Family Courts. (The Open University's repository of research publications and other research outputs, 2009) https://oro.open.ac.uk/45013/1/public-law-family-courts-process-evaluation.pdf> accessed 21 October 2023.

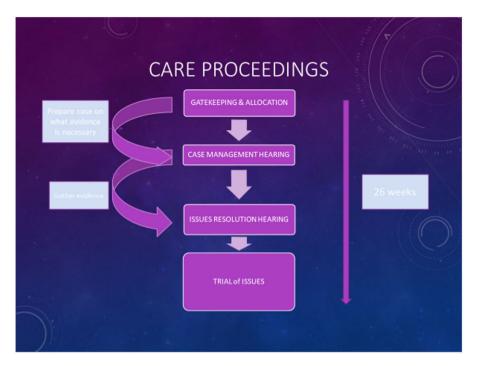


Figure 1. The four stages of care proceedings leading to a trial of Issues.

At the trial of issues, the Judge must decide whether the statutory threshold (section 31(2) Children Act 1989) for the intervention in the family is crossed, If so, the Judge goes on to consider whether it is necessary and proportionate to make orders that interfere with the parent's and/or the child's right to respect for family life (Article 8 European Convention on Human Rights and Fundamental Freedoms) and, here, the welfare of the child is paramount (section 1 Children Act, 1989). The Judge carries out a 'global holistic analysis', weighing each of the various realistic outcomes for the child against the others, before deciding which best meets the child's welfare needs (Re G (care Proceedings: Welfare Evaluation) [2013] EWCA Civ 965; [2014] 1FLR 670) in Re-B-S [2013] EWCA Civ 1146.

The legislation requires that from start to finish, proceedings are concluded within 26 weeks. That time limit can be extended, but its imposition through an amendment to the legislation (32(1)(a) Children Act 1989 as amended by Children and Families Act 2014) was intended to add necessary emphasis to the principle that decisions for children must be made in a timely fashion.

There are two further matters of significance, each bearing upon the introduction of this randomized RCT within proceedings. The first is that once proceedings are issued in respect of a child, the Judge in the case assumes a very significant role. All steps in the case, such as the gathering of evidence, the appointment of and approach taken by experts, the timetabling of evidence, listing, and determination of issues are a matter for the Judge to decide with the child's best interests always paramount. Even if the applicants wish to withdraw, they cannot do so without the permission of the Judge and, then, only after a welfare analysis and an examination of the welfare implications for the child (Re GC (withdrawal of care proceedings) [2020] EWCA Civ 848).

The second matter concerns the second phase of the intervention. In care proceedings, there is no power for the court to order the provision of treatment or to direct the local authority to provide it. Ordinarily, where the need for treatment or therapy for one of the parents is identified, evidence is presented (from a psychologist, psychiatrist, or social worker) on the likelihood of engagement by that parent in the therapy and the length of time such treatment will need before effecting the necessary changes. In short, a prediction of outcome with timescales. The Judge then must assess the likelihood that change will occur and if so whether it is compatible with the timetable for the child. In the trial, if the family is randomized to NIM, and the assessment provides evidence for parental capacity to change, a treatment plan is proposed, tailored to the individual needs of birth parents. This is delivered within the lifetime of the case. In both situations, the judge continues to have a key role, but the treatment is not something that the court can order.

VI. THE INTERVENTION'S FIT WITHIN CARE PROCEEDINGS

The BeST intervention (NIM) was aimed at children under the age of 5 years. It was a requirement that the child or children needed to be in a place of safety, so to qualify to take part in the trial, the child/ren needed to be placed in foster care or with a kinship carer under an Interim Care Order or with the agreement of the parents. A case only qualified to be included in the RCT if these conditions were met.

In any case, where those conditions were met, the parents and their lawyers were invited to consider whether they wished to take part in the trial. Full information was handed out and, where consent was forthcoming, the family would be randomly allocated to either an assessment by the team delivering NIM – the London Infant and Family Team (LIFT) – or SAU. SAU could be any parenting capacity assessment authorized by the court (described as 'standard assessment' in Figure 2). Randomization was achieved through a computerized system designed to make the order of allocation impossible to predict.

NIM, carried out by LIFT, begins with a 10-week assessment, during which a series of standardized measures are used to determine the parents' capacity to acknowledge the harm caused to their child, their ability to effect change, and their willingness to engage in a treatment programme. This assessment fitted acceptably within the court timetable (see Figures 2 and 3) and stood as an alternative to the standard parenting assessment gathered at the beginning of proceedings or in pre-proceedings work because it was capable of providing the court with evidence in preparation for the IRH. This lengthening of the timetable was approved by the President of the Family Division. Those allocated to SAU would be assessed in the proceedings in the usual way – through social work or other assessments as determined necessary by the Judge.

In situations where the initial assessment indicated insufficient parental capacity to change within the child's timescale, a recommendation was made that the child should be permanently placed away from home. If such a recommendation was presented to the court at IRH, then the case proceeded to a trial of the outstanding issues, as is usual in all cases.

Where the NIM assessment provided by LIFT offered evidence for parental capacity to change, a bespoke plan tailored to the individual needs of birth parents was created and treatment recommended. This treatment drew on attachment-focused interventions lasting an average of 6 months. This extended the case beyond the 26-week timetable (Figure 3). As with

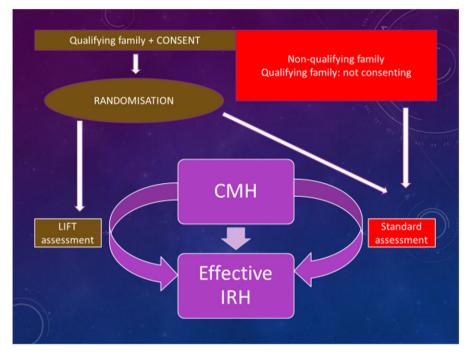


Figure 2. The figure showing how, after randomization, a NIM (LIFT) assessment, or a standard parenting capacity assessment (ie, SAU) originate at Case Management Hearing (CMH) and feed into the IRH

the Family Drug and Alcohol Court (an alternative problem-solving court model in limited areas for families in which drug and alcohol problems are central), LIFT cases required the approval of an extension beyond 26 weeks to enable purposeful therapeutic work to be carried out during care proceedings.

During the treatment phase, review meetings (approximately every 3 months) were held with the allocated social worker, social work team leader, the supervising social worker for the foster carer, and the guardian. At each review, the LIFT team presented recommendations based on evidence of birth parents' progress towards the treatment objectives, including recommendations about permanence. This information could be shared with the Judge and parents' lawyers, enabling them to assess the progress of the agreed treatment plan. Poor progress or lack of engagement threatened to bring the treatment to an earlier conclusion and prompt a return to court. At the conclusion of the treatment phase, a permanence recommendation was made in the form of a final report from LIFT.

VII. BARRIERS TO RANDOMIZATION: MORE IMAGINED THAN REAL?

As we have described, the use of a randomized methodology in the field of medicine or public health is not at all unusual.¹⁸ The faith invested in the RCT, however, does not always extend to those developing and testing social interventions. Academics have queried that opposition, which frequently, seems to be more imagined than real.

¹⁸ Greiner and Matthews (n 2).

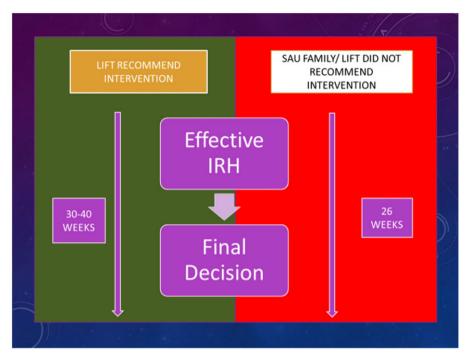


Figure 3. The figure showing how (red) a recommendation from LIFT or SAU can fit into the 26-week timeline if LIFT did not recommend intervention, or (green) how LIFT can be offered a longer timeline if BeST recommends intervention.

In their analysis of the three RCTs in social science settings, Oakley and others.¹⁹ observed that:

Objections to the use of RCTs to evaluate social interventions ignore the history of the successful conduct of many thousands of such studies. . .

The three trials described in that article used an RCT method to evaluate social interventions. The various hurdles encountered in setting those trials up were overcome, and the conclusion of the authors was that the examples demonstrated very clearly that 'random allocation as a research technique for social intervention evaluation is sound on grounds of science, ethical acceptance and feasibility.'

In the legal arena, the use of a randomized methodology to test interventions, approaches, or outcomes is virtually unheard of. This position has also been challenged.

In 2016, Greiner and Matthews challenged what they argued was a failure in the field of law to develop itself as a science and embrace the need for a proper scientific evidence base.

No field can claim to be evidence based without a central role for the RCT as a means of accumulating knowledge about what works and what does not. (Greiner and Matthews, p. 296)²⁰

¹⁹ A. Oakley A and others, 'Using Random Allocation to Evaluate Social Interventions: Three Recent UK Examples' (2003) 589(1) The Annals of the American Academy of Political and Social Science 170–189.

²⁰ Greiner and Matthews (n 2).

The barriers to randomization in the BeST were initially raised by the judiciary. They were:

- a) appropriateness of randomization without the consent of the parents;
- b) offering what seemed to be an obviously 'Rolls Royce' service in BeST to some families and not others; and
- c) concern that randomization would be potentially unfair and cut across the Judges' duty to determine all matters in the best interests of the child.

These 'barriers' have at their root issues which are commonly raised in opposition to the use of a randomized methodology in a social science setting. How they were overcome tells an important story about how perceived barriers can be overcome through education, persistence, discussion, and commitment.

VIII. BREAKING THROUGH THE BARRIERS 1. Redesigning trial processes to fit with judicial procedures

This instantaneous and instinctive 'legal' objection revealed practical problems which could have amounted to a real barrier to randomization. In the original design of the trial, there were procedures that did not sit comfortably with judicial processes in England, and that potentially diminished the role of the Judge.²¹

In the re-designed model, randomization to one or other of the processes only occurred after the parents (in consultation with their representatives) had agreed that they were content to be part of the trial and, if randomized to LIFT, to accept the initial assessment as the evidence in the case upon which the court could determine the outcome. Information was given to them as to how the LIFT, and SAU, worked. It was explained that they would not be able to choose which intervention (LIFT or SAU) they would receive if they agreed to enter the trial and that no one knows which is the better approach (ie, the purpose of the research). They were also clear that the Judge had complete oversight of the process and could end participation in the Trial at any time in the case, should it conflict with the welfare interests of the child.

2. Equipoise and the random allocation of scarce resources

When the proposal was first made to randomize families to LIFT, this was seen by the judiciary as a major and insurmountable barrier. How could one family in this London Borough be offered a multi-disciplinary team and possibly be delivered a bespoke programme of treatment in care proceedings whilst another family living in the same borough, possibly in greater need of the same sort of intervention, would at best have to wait for treatment or at worst never receive it? Would they not have a legitimate and legal cause for complaint?

In addition, in the initial stages of BeST, children's services in the participating English Borough were performing very poorly and publicly so. After a series of bad reports from statutory inspectors, they had suffered a fast turnover in staff, loss of experience, and an inability to recruit any replacements. Anecdotally, the view was that there was no adequate basic service provision in this Borough. It seemed obvious that providing a multi-disciplinary team and a mental health intervention randomly to one-half of the qualifying families would lead to a legitimate complaint that those left with barely adequate SAU and no mental health

²¹ V. Welch and others, 'Randomisation before Consent: Avoiding Delay to Time-critical Intervention and Ensuring Informed Consent' (2017) 20(4) International Journal of Social Research Methodology 357–371.

provision were not being treated equally or fairly. This raises questions about equipoise and the fair allocation of resources.

It is important to remember that BeST was primarily testing a mental health intervention against no mental health intervention. The standard of children's services in the English authority in question had no bearing upon that. However, those allocated to LIFT were in receipt of a mental health intervention denied to the other families. Was that fair?

In answer to those concerns, mental health intervention is not certain to improve outcomes for children or for parents. Other than the non-randomized comparisons made in the USA,²² there is no evidence of whether the intervention would achieve the desired results. That is the purpose of the research. That genuine uncertainty and the state of equipoise is an essential requirement in any RCT. An apparently Rolls-Royce service can still be a harmful service. Indeed, unless an innovative service has been rigorously tested, it is impossible to be certain that it has no unintended harmful effects. Two examples are the 'Scared Straight' interventions²³ and the Cambridge-Somerville Trial.²⁴ Scared Straight attempted to reduce criminal behaviour in young people by introducing them to adults who had been imprisoned for the crime, but the intervention had the opposite effect.²⁵ The Cambridge-Somerville Trial was a particularly well-conducted study: starting in 1939 with a group of more than 500 juvenile delinquents, participants were randomly allocated to either a range of services (including counselling, academic tutoring, medical, and psychiatric attention, referrals to YMCA, Boy Scouts, summer camps, and community programmes) or to simply 'checking in' at regular intervals. Ninety-four per cent of the participants were followed-up 30 years later and, despite all of the interventions appearing to be obviously benign, significantly more of those who had had the counselling and other services had committed criminal acts.²⁶ Exactly the opposite result to that most people would have predicted.

In BeST, the in-depth qualitative process evaluation conducted in Scotland prior to the expansion of the trial into England suggested that stakeholders perceived both advantages and disadvantages in NIM.²⁷

However, collateral to that primary question is whether the assessment evidence provided for the court by the multi-disciplinary LIFT was obviously better than the standard SAU assessments deemed necessary by the Judge to enable sound welfare decisions to be made. As a multi-disciplinary service, LIFT was seen, by some social care and judicial colleagues, as 'Rolls-Royce' provision when measured against any alternative standard social work assessment.

However, the point remains the same. There is currently no evidential basis for saying which of these forms of evidence-gathering produce the more accurate assessment or give the better outcomes either in terms of decision-making or actual long-term welfare. That may be something that we discover through the study. Discrimination only results in circumstances in which there is certainty as to which of the two randomized alternatives is better.

These arguments also raise the issue of fairness and the possibility that through randomization, there will be direct or indirect discrimination through the provision of 'something' to one family that is not available to the next. Social scientists might point to the 'morality' of delivering an intervention to one family but not to the next. As already observed, that was

²² Walker and others (n 12). F. Turner-Halliday and others, 'Clout or Doubt' Perspectives on an Infant Mental Health Service for Young Children Placed in Foster Care due to Abuse and Neglect' (2017) 72 Child Abuse & Neglect 184-195.

A. Petrosino, C.T. Petrosino and J. Buehler, "Scared Straight" and Other Juvenile Awareness Programs for Preventing Juvenile Delinquency' (2005) 1 (1) Campbell Systematic Reviews 1–62. ²⁴ S.N. Zane, B.C. Welsh and G.M. Zimmerman, 'Examining the Iatrogenic Effects of the Cambridge-Somerville Youth

Study: Existing Explanations and New Appraisals' (2016) 56 (1) British Journal of Criminology 141-160.

²⁵ Petrosino and others (n 23). ²⁶ Zana cr. 1 . . 1

Zane and others (n 24). 27

Turner-Halliday and others (n 22).

certainly something that caused concern in the social work teams first involved with BeST who were reluctant to consider randomization of this intervention pre-proceedings and within their working domain. Again, the assertion by sceptics that those randomized to SAU have missed out on the 'bonus' intervention is surely only legitimate if the intervention is known to bring favourable results. That is as yet unknown. That is the reason for the trial.

That uncertainty and the principle of equipoise surely answer this complaint. However, it is a fact of life that interventions and resources are delivered routinely without any evidential basis, or with a lesser body of supporting evidence, to suggest that they are better than no service at all. Prime examples of this are many domestic abuse intervention programmes. So, putting aside the fact that we do not know whether this intervention will produce results, is there anything inherently unfair in offering an intervention to one-half of the qualifying cohort but not the other?

We have stated that the availability of a treatment intervention was an apparent 'bonus' because it is something which is not available within proceedings and not capable of being made available on the direction of the Judge. There is no power to order any provider or local authority party to provide treatments or interventions to a parent or child - even those that are known to be successful. The random provision of this treatment bonus is arguably no different to the situation in which therapy is urgently needed for parents and one parent manages to secure it through their General Practitioner, whilst another has to wait. Furthermore, this is what results from the uneven distribution across the country of Family Drug and Alcohol Courts with their bespoke Family Drugs and Alcohol multi-disciplinary teams. Some local authorities buy in that resource; elsewhere this resource and the opportunity for drug treatment within proceedings is simply not available. This situation becomes ever more prevalent in the face of scarcity of resources and resource prioritization. Where there is a scarcity of resources, for example, whilst that resource may be allocated according to the greatest need or because a particular Local Authority area has additional resources, it can also be legitimately allocated randomly. In one of the three interventions examined by Oakley and others,²⁸ nursery places were allocated randomly and, after the Trial, the use of random allocation continued, the community considering it to be a 'fairer' way in which to determine who should receive a place. In some English schools, a proportion of places on intake are allocated randomly amongst those in the catchment area.

3. Not compromising the judicial role: was the RCT lawful?

The extent to which BeST compromised the role of the Judge as decision-maker in the case was the most troubling area for the judiciary. After lengthy discussions in which the legal context was described and explained, it was resolved by a careful reworking of the study design. This issue goes directly to whether the RCT could be said to be 'lawful'.

Dawson and others²⁹ most helpfully debated and defended the 'lawfulness' of an RCT of compulsory outpatient treatment under mental health legislation in England. The Mental Health Act 2007 introduced a new Community Treatment Order (CTO) regime for England and Wales. Responsible clinicians (RCs) administering the mental health legislation were given a number of choices when contemplating a sectioned patient's discharge from the hospital.

As a preliminary, the RC had to decide whether to use the Act's powers to supervise the patient's treatment on an outpatient basis, rather than discharge that person directly to voluntary community care. Having concluded that statutory supervision was required, the RC

²⁸ Oakley and others (n 19).

²⁹ J. Dawson, T. Burns and J. Rugkåsa, Lawfulness of a Randomised Trial of the New Community Treatment Order Regime for England and Wales' (2011) 19 (1) *Medical Law Review* 1–26.

then had to decide whether to use one of the two different supervisory regimes (leave or the CTO regime).

Consideration was given initially to the possibility of testing the relative merits of voluntary discharge as against statutory supervision. However, discharge from compulsory treatment was governed by defined statutory criteria and so the random allocation of half of the patients to discharge would have been an unlawful exercise of the statutory discharge power.

The research design was modified so that the randomization came after the RC had exercised the statutory powers and concluded that continued supervision was necessary. Those patients could then be allocated lawfully to treatment under either one of the two supervisory schemes. This modification opened the door to the use of an RCT. The design of the study was modified to reassert the role of the Judge.

In BeST, there have been subtle ways in which there has been a more generous ambit given to cases within the Trial in case management and in the application of the rules as to the authorization of expert evidence. However, this has not compromised the Judges' essential duty to the child. Where a family was randomized to LIFT, there was arguably a removal of the close judicial oversight in the choice of expert and, strictly speaking, no determination of whether a multi-disciplinary assessment was 'necessary' (the legal test for the court to allow assessments to progress). There was a judicial acceptance that LIFT was a multidisciplinary team capable of assessing a family and advising the court on the issues directly relevant to the making of the welfare decision. There is nothing unusual in that. In most cases, judges accept, unless it is suggested otherwise, that organizations or individuals putting themselves forward as capable of providing the necessary evidence are in fact able to do so. If they fail in that endeavour, then there is always the right to challenge the end report in the courtroom. That right was never removed from the parents randomized to LIFT. As for any other evidence, LIFT reports were occasionally challenged by parents, especially those who had received a recommendation that their child should not be returned home.

The Family Justice reforms, launched in 2014 aiming to 'put children clearly at the heart of the family justice system' (https://www.gov.uk/government/news/family-justice-reformsto-benefit-children), have required the judiciary to be robust in case management and not seek out the expertise of a multi-disciplinary team where a social work assessment would suffice or indeed any assessment unless 'necessary' for the fair determination of the issues in the case. There can be no doubt that in cases randomized to LIFT, there was frequently no further scrutiny of whether the LIFT, a multi-disciplinary assessment, was truly 'necessary' or whether a social work assessment would suffice. Furthermore, in cases in which, ordinarily, the Judge would be questioning the need for any further assessment evidence, we often saw the Judge step back at that moment to allow LIFT assessment to proceed. An example would be where a family came into proceedings with a child born very recently after the removal of a previous child. In these cases, there is often a successful argument that further comprehensive assessment of any sort is unnecessary as there is sufficient evidence before the court to determine the issues from the proceedings recently finalized. Such an argument might have been made by a Guardian (the child's legal advocate) on behalf of the child, preferring a swifter decision. Again, anecdotally, cases were not argued in this way. It is not clear why not, but it is reasonable to assume that no detriment to the child can have been identified and the family was able to take part in BeST. This was, nevertheless, a departure by the Judge from strict case management guidance.

Does that make BeST 'unlawful'? We argue that it does not. At the margins, there might have been cases in which the evidence could have been argued to be complete and the decision able to be made far more quickly than an allocation to LIFT would have allowed. Whether raised by a party or not, faced with those facts, technically, the Judge would have been duty bound to consider whether the interests of the child to have a swift determination were compromised by being part of BeST. As declining to take part in the Trial, in the interests of the child, was always open to the Judge, we would argue that a decision not to strictly stand by that case management guidance did not compromise the judicial role in this process.

IX. FROM THE SPECIFIC TO THE GENERAL: ESSENTIALS FOR AN RCT IN A LEGAL SETTING

Oakley and others³⁰ suggest that there are

certain strategies..... key to the successful implementation of studies using random allocation in social settings. These include designing research so that it:

- 1) addresses an important policy or practice question, which is considered a priority issue by trial participants;
- 2) has a clear scientific and policy rationale for using random allocation;
- 3) allows enough time for detailed discussions with the stakeholder groups that need to 'sign' up to random allocation and is sensitive to stakeholder perspectives;
- 4) includes the careful piloting of recruitment and informed consent procedures and ways of explaining RCT design; and
- 5) gives particular consideration to the position of control groups, including how best to encourage them to feel that it is worthwhile to make an active contribution to the research.

All of these points have equal applicability to the family justice setting, and potentially to other legal settings. They have informed our own list of essential considerations in BeST, but it is worth stressing that it is not possible to draw up a simple tick-box list of things which, if in place, will enable the use of an RCT in any legal setting. The adoption of each study will be heavily dependent upon the design, the participants, and the commitment that everyone is prepared to make to the venture, particularly the judiciary and the legal community.

1. A clear scientific rationale for the use of a randomized methodology

In keeping with Oakley and others,³¹ we consider it important that there are clearly identified reasons for choosing an RCT. As already set out, the RCT is ideally suited to the testing of interventions, or changes in practice where outcomes can be measured, and policy informed. Through the minimization of bias and confounding, the resulting evidence is optimal in each research setting. The 'sign up' to RCT methodology is as important as an acknowledgement of the importance of the research question. Furthermore, there needs to be clarity of thought on the issue of equipoise. We would suggest that the more demonstrable the uncertainty the greater should be the openness to randomization. This feeds into the next essential consideration.

³¹ Ibid.

³⁰ Oakley and others (n 19).

2. Stakeholder 'buy-in'

The study must invite active support and participation by essential stakeholders. In the family justice setting those essential stakeholders will be the judiciary and the legal community. There is no reason why this should not include lay parties – the litigants themselves. In BeST, birth parents have been involved in qualitative interviews,³² and the study is guided by an expert-by-experience stakeholder steering group as well as ongoing interviews with other key stakeholders such as social workers and foster carers.³³ There is a growing recognition of the value of involving experts-by-experience in every stage of the research process.³⁴

We would suggest that this is achieved, in part, if the research addresses an important policy question considered a priority by those stakeholders (as per Oakley and others)³⁵ and also by ensuring that the study is designed so as to be sensitive to the stakeholder perspective.

Greiner and others considered that the single biggest barrier to the introduction of RCTs into legal settings in the USA was the judiciary and the legal community. The authors use the term 'hostility' to describe that opposition. In seeking answers as to why the medical and legal professions differed in their approach to RCTs, they examine the differences between their respective diagnostic thought processes. The conclusion reached is that medical professionals employ an 'inquisitive diagnostic process' in seeking to understand and, where possible, resolve a patient's presenting problem, whereas for the lawyer 'the process of diagnosis is less inquisitive than instrumental' because the aim is not the search for answers but the search for arguments. Certainly, the adversarial nature of family proceedings and the impact that has upon the approach taken by the legal community has to be understood and factored in.

Our experience was that there was no open hostility to LIFT itself once lawyers representing parents and children understood why BeST was proceeding and how it would impact their client in the process. However, periodically, the LIFT team would find their access to a parent barred by over-protective lawyers who did not know about the Trial and were unsurprisingly suspicious of allowing a stranger to speak with their clients about assessments.

Given the need to secure consent from parents, collaboration with their lawyers was crucial to the accumulation of sufficient numbers to make the RCT viable. During BeST, there were vigorous and repeated efforts made to ensure that all lawyers were informed of the Trial, understood its importance, and crucially were persuaded that there was no prejudice to their client's position or their ability to represent that client. Those efforts were spearheaded by HH Judge Carol Atkinson in her role as the Designated Family Judge for the region. Leading several information exchange evenings and roadshows signified the support given to BeST by the local Judiciary as a whole. Crucially, this message was reinforced by the approval given by two successive Presidents of the Family Division of the High Court.

Interestingly, as BeST bedded down, there is no doubt that a number of lawyers were keen to encourage their clients' participation in the hope that they would receive what was perceived by them as the obviously 'better' service – LIFT. Importantly, there were no legal challenges made to the lawfulness of the process of randomization. Seeking the consent of the litigant after advice from their legal team undoubtedly limited the scope for opposition.

 $^{^{32}}$ Welch and others (n 20).

³³ G. Kainth and others, 'Process Evaluation Protocol for the BeST Services Trial' (2022) 4 (1) Developmental Child Welfare 56-72.

³⁴ NIHR, Involve Patient: Department of Health & Social Care (2023) <https://www.nihr.ac.uk/health-and-care-professio nals/engagement-and-participation-in-research/involve-patients.htm> accessed 21 October 2023.

³⁵ Oakley and others (n 19).

Furthermore, legal challenges to the evidence from LIFT were limited to situations in which there had been a negative assessment and a recommendation for separation.

Essentially, lawyers want to be reassured that the decision-making for their clients will not be 'random', that they are not compromising their role as advisors and representatives of the client. Of course, the central decision-making as to whether a child should return home to their family was not random. Had the decision as to outcome turned on the toss of a coin, it would have been unlawful. Those consenting to take part suffered limitations in their choice of assessment and faced lengthier proceedings. However, they were not limited in challenging the outcome of those assessments.

Any Trial, but more particularly an RCT in a legal setting, needs the full engagement of the Judiciary. Whilst support from the Senior Judiciary is essential, the Judges who will make a trial work are those who must see it operate on the ground. Our own experience demonstrates how crucial the involvement of the judiciary was in the success of the RCT. Indeed, it was not until the judiciary was on board that the randomized methodology was given the chance to breathe. Whilst there does seem to be a particular need to win over 'hearts and minds' in a randomized setting, it is also right that a legal setting – whichever branch of law – is highly specialized and having the judiciary involved and supporting BeST provided a sounding board to ensure that the design does not fall foul of the rules of court/processes/ basic fairness.

3. Planning, planning, and more planning: being prepared to remodel as problems arise

Planning in close collaboration with the judiciary in whose courtroom the trial will be played out is essential to the success of any RCT in a legal setting. As demonstrated by this example, the original research design, based on the researchers' experiences of a successful model in Scottish, did not fit into the English legal system, which is very different to the Scottish system. Even after the design modifications as the RCT progressed were implemented, there was a constant need to change parts of the design in order to make the operation smoother or to maximize interest and participation and therefore numbers.

For example, in the initial stages of the RCT, to keep the timelines as close to standard procedure as possible, the timetable envisaged the delivery of the information about the Trial at the Interim Care Order (ICO) hearing and a decision as to consent was expected there and then. It became obvious almost immediately that it was neither possible, practical, nor humane to ask parents whose children had just been removed to consider whether they wished to take part in the Trial at that moment. As a result, that part of the process was swiftly moved to the Case Management Hearing (CMH), and there was a clear direction given that in qualifying cases the CMH should not be listed at the same time as an ICO to avoid this happening. These changes were crucial to the numbers coming through into the Trial and would not have been possible without the active involvement of the Judiciary in the process and an equal willingness in the research team to listen to those who knew the process best.

X. DISCUSSION AND CONCLUSIONS

BeST is testing a mental health intervention using a randomized methodology within the vehicle of care proceedings. Without that vehicle, it is hard to imagine how the intervention, designed for children who had suffered or were at risk of suffering significant harm and needed to be in a place of safety before delivery of the intervention, could have been tested. Through careful collaboration, a randomized methodology was designed and so the manner of testing the intervention can be considered optimal.

The allocation of resources to one portion of the population at the toss of a coin understandably raises immediate concern. These concerns nearly ended randomization in the family courts in England. However, through the persistence of the research team, their careful explanation of the design principles, and a willingness in the judiciary to learn and reevaluate these barriers were overcome. As a direct result of this process, we have learned a great deal about how the search for research-based evidence can be accommodated in legal proceedings but why might this be important or significant?

During the 10 years following 2007, there was a rapid rise in the number of families subject to local authority scrutiny and in the number of applications made in respect of children.³⁶ In 2022, there were around 82,170 children 'looked after' by local authorities in England³⁷: some of these children are in voluntary placements, others are involved in legal proceedings more than once, while others encounter proceedings as part of a sibling group. In short, vast numbers of children and their families are impacted by our decision-making in the family courts, and children wait for lengthy periods before decisions are made for permanency. We know that timescales are of the essence. Adverse childhood experiences (ACEs) have a cumulative effect on mental and physical health across the lifespan³⁸ and, because the time of maximal brain development is the early weeks and months of life,³⁹ there is no time to waste if a child has already experienced ACEs in preventing further accumulation of these. Recent policy developments, such as the Family Justice Review in England and the Permanence and Care Team, launched by the English Government, have sought to remedy that. However, despite a rapidly growing body of knowledge about children's developmental needs in relation to attachment and parenting, there is a dearth of research into assessment and decision-making models or indeed on the impact of various outcomes.

Despite huge attention to improving the child protection system, coming into care is no guarantee of protection from further maltreatment. Data from the Department for Education show that of the 10,270 children who returned home from care in England in 2006–07, 30 per cent had re-entered care in the 5 years to March 2012.⁴⁰ Although there might be various reasons for children re-entering care, these findings suggest that there may be room for improvement in our decision-making about parental capacity. Robertson and Broadhurst⁴¹ highlight that there is a 'limited availability of authoritative reviews that provide guidelines for the family justice system' in stark contrast to the field of health, where 'evidence informed practice has a far longer history'. When we make decisions in care cases, we are frequently invited to assess the likely outcomes for the child: 'decisions in children's cases necessarily involve prediction and risk' Selwyn and Masson (2014).⁴² As Robertson and Broadhurst observe, it is at this juncture that 'social science evidence fills a gap about typical patterns and outcomes derived from population-based studies.'

³⁶ Rt. Hon. Sir Andrew McFarlane, President of the Family Division. Key Note address: "Crisis; What Crisis?": Judiciary of England and Wales. (Association of Lawyers for Children Conference, 2018) https://www.judiciary.uk/wp-content/uploads/2018/11/Speech-by-Rt.-Hon.-Sir-Andrew-McFarlane-Association-of-Lawyers-for-Children-Conference-2018.pdf> accessed 21 October 2023.

³⁷ UK Government Department for Education. Children looked after in England including Adoptions: OGL (2022) https://explore-education-statistics.service.gov.uk/find-statistics/children-looked-after-in-england-including-adoptions accessed 21 October 2023.

³⁸ V.J. Felitti and others, 'Relationship of Childhood Abuse and Household Dysfunction to many of the Leading Causes of Death in Adults: The Adverse Childhood Experiences (ACE) Study' (1998) 14 (4) *American Journal of Preventive Medicine* 245–258.

³⁹ M.H. Teicher and J.A. Samson, 'Annual Research Review: Enduring Neurobiological Effects of Childhood Abuse and Neglect' (2016) 57 (3) *Journal of Child Psychology and Psychiatry* 241–266.

⁴⁰ M. Wilkins and E. Farmer, Reunification: An Evidence Informed Framework for Return Home Practice (NSPCC-in Partnership with University of Bristol, 2015) [Reunification: An Evidence Informed Framework for Return Home Practice].

⁴¹ L. Robertson and K. Broadhurst, 'Introducing Social Science Evidence in Family Court Decision-making and Adjudication: Evidence from England and Wales' (2019) 33 (2) *International Journal of Law, Policy and the Family* 181–203.

⁴² J. Selwyn and J.M. Masson, 'Adoption, Special Guardianship and Residence Orders: A Comparison of Disruption Rates' (2014) 44 Family Law Journal 1709–1714.

By way of example, the impact of the reduction in the use of expertise beyond social work expertise as introduced by the Family Justice reforms and recently restated by the President of the Family Division (View from the President's chambers – November 2022) is still not known. Further, as the system struggles to cope, alternative problem-solving models such as FDAC have been explored and encouraged. These models, as distinct from proceedings, reintroduce the multi-disciplinary team of combined social care and health expertise. The dynamic nature of the multi-disciplinary team assessments and the regular opportunities (ie, fortnightly) for parents and professionals to be held to account and motivated regarding the progress being made against the intervention plan are key, but they are housed within the proceedings. This is contrary to standard processes and inevitably lengthens timelines. Indeed, the problem-solving model is an arguably illogical departure from the strong advice to restrict the involvement of multiple or higher-level expertise. As yet, whilst the impact of this problem-solving model has been considered in relation to outcomes for children and families,⁴³ the success of this courtroom process as against the standard model in terms of the effectiveness of decision-making has not been measured.

The decisions made by Judges in care proceedings are life changing. Interference with the right to respect for family life, whether by dictating the terms upon which a child can live with their family or by removing that child from its natural family could hardly be more serious. RCTs provide high-quality evidence about interventions offered to populations and, although their findings may well provide helpful evidence to guide judicial decisions, it is important to bear in mind that the judicial process relates to decisions in individual cases and that judicial insight on a case-by-case basis will always be required, even when supported by trial evidence. The judiciary and in particular the family judiciary has shown a growing interest in research and, with that, an acceptance that there is much that we do not know about our system and the outcomes for children. For example, the Family Justice Council, with its emphasis on interdisciplinary working, receives regular updates on research impacting family justice. This is replicated country wide through many local Family Justice Boards. In addition, the Judicial College disseminates important research to the Judiciary through its judicial courses.

Although the primary research question here was about a mental health intervention, there may be sufficient data to examine the collateral question of the effectiveness or otherwise of the multi-disciplinary team as measured against standard social work evidence. Further, it is not difficult to imagine social work-based interventions being tested in the same way, and it is difficult to understand why there could be objections to testing those interventions randomly. This applies to both family and criminal proceedings. For example, randomization could be used helpfully to evaluate the effectiveness or otherwise of different perpetrator programmes. An RCT could also provide gold standard evidence as to the relative merits of different court models, for example, randomizing qualifying families to a problem-solving model or a standard court model. The importance of determining the relative value of a problem-solving model as against standard adversarial proceedings would not be lost upon the family lawyer or Judge. Would random allocation in that setting be objectionable on the basis that it is not morally fair to give one-half of the families the chance to be in the problem-solving court or to deny all families a judicial determination as to which court would be best placed to serve the interests of the child subject to the proceedings. We would argue not. Again, we suggest that these imagined barriers are rooted in a belief that there is some

⁴³ J. Harwin and others, After FDAC: Outcomes 5 years later. (Lancester University, 2016). J. Harwin, M. Ryan and K. Broadhurst, 'How does FDAC Succeed with Parents with Substance Misuse Problems? Exploring Relational Practices within the English Family Drug and Alcohol Court' (2018) 27 (4) Child Abuse Review 266–279.

certainty as to which court model brings the best results in any given set of circumstances. There is no such certainty; none that has at its foundation any evidence.

XI. CONCLUSIONS

In this article, we did not aim to provide quantitative outcomes for BeST. Instead, our focus was to examine the legalities of randomization in a way that might be helpful to others, potentially in other jurisdictions, to conduct RCTs in the context of legal proceedings. Although there were undoubted challenges in designing and implementing BeST, with hind-sight, the objections raised to the testing of interventions randomly were demonstrably resolvable. Greiner theorizes that *'there is social value in appearing certain'* and that *'some judges may have internalized the belief that they must appear certain to be effective, and to appear certain they must be certain'*.⁴⁴ Indeed, he cites this as one of the reasons why RCTs cannot get off the ground in the legal setting because to do so would pierce the veil of certainty surrounding our decision-making. Our experiences in resolving the practical and legal barriers to randomization in BeST suggest four recommendations:

- legal systems become more open to research and, in particular, to the potential added value of randomized methodology;
- legal professionals are offered training in research methodologies, including randomization;
- the wider legal community become more proactive in its engagement with social science and health researchers in order that a broader evidence base can emerge to provide more authoritative guidance for best interest decision-making; and
- future RCTs proposed to test interventions offered within a judicial setting should be co-designed by researchers and members of the judiciary.

There may be some value in an acceptance that in family justice there is much that we do not know. This is a good starting point for the acceptance of research under any methodology but crucially it breathes life into the possibilities of rich research data through randomization.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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