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## **Trials and Tribulations - an RCT comparing manualized family therapy with Treatment as Usual and reflections on key issues that arose in the implementation.**

### **Abstract**

SHIFT has been one of the largest RCTs in the field of systemic family therapy in the UK. The study took place over 5 years, including three major centres with 15 Trusts and 25 family therapists who worked with a manualized treatment in CAMHS with adolescents who self harmed. While the results are not available at the time of this publication, this paper will briefly describe the pre-existing factors which were helpful in developing a successful bid, clinical and managerial elements of 'real world research' of complex psychological processes and the construction of the manualized systemic family therapy. It also offers examples of some of the unanticipated events in the life of such a large trial.

### **Practitioner Points**

- large trials develop from small studies and clinicians are urged to look for opportunities for research partnerships
- investment in time for consideration of difficult issues as they arise is essential for effective trial management
- the balance between research rigour and 'real life' practice is an inevitable area of tension and requires consideration of both immediate and outcome consequences

## **Introduction**

The Randomised Controlled Trial (RCT) is considered the best way to evaluate treatments in healthcare. Originally used in drug and medical trials, it is now well established in psychotherapy research. Furthermore, efficacy trials in very rigorously managed research environs have moved from the laboratory to ‘real world’ pragmatic trials in the mental health clinics. SHIFT (Self-harm: Intervention Family Therapy) is one of the largest pragmatic RCTs of its kind in the UK and as such, combines several Academic and NHS CAMHS (National Health Service Child and Adolescent Mental Health Services) organisations, researchers, clinicians and management structures along, with the provision of treatment, data collection and analysis. Essentially, a large RCT is an elaborate organization with a time-limited structure doing complex tasks.

While there are numerous papers reporting on the results of RCTs, there are not many which describe the actual process. An exception is a paper that discussed challenging issues arising from a RCT for adolescent anorexia nervosa (Lock et al. 2012). For example, they were surprised to find that recruitment was problematic as a result of the belief spread around clients’ social networks that one form of treatment was perceived to be better. Clients refused to participate in the trial on the basis that they would have a 50% chance of ending up in what they assumed was the inferior form of therapy. This phenomenon can happen in trials and perhaps could have been anticipated.

In the SHIFT trial, there were also quite a few of Donald Rumsfield’s (2002) ‘unknown unknowns—the ones we don’t know we don’t know’. The primary aim of this paper is to describe the RCT but also to include some of the unanticipated aspects of the experience for future researcher. The paper will include a discussion of the circumstances favourable to

obtaining the grant, an overview of the trial, the development of the manual and the issues that arose in the process.

This paper combines two perspectives: xxxxxxx\* and xxxxxxxx\*\*. XX and XXX were both involved in the MRC funded research project that led to the publication of the LFTRC (Leeds Family Therapy Research Centre) manual (Pote et al. 1999). In SHIFT, xxx had a major role in the management of the collaborations between sites, the relationship between the trial unit and the HTA funders, ethics committee and participating Trusts. XXXX was directly involved with Ivan Eisler in the adaptation of the manual, training of therapists and supervision.

### **The proposal: fertile ground**

The project was funded by the National Institute for Health Research, Health Technology Assessment programme (NIHR HTA). From the NIHR perspective even a psychotherapeutic intervention is a 'technology'. The NIHR, noting the lack of evidence, put out a call for bids to evaluate the effectiveness of family therapy interventions following self-harm in 11-17 year olds. We believe the initiative may have been based, in part, on positive findings from home-based family treatment (Harrington et al.1998).

Universities often have staff dedicated to matching research opportunities with local expertise. In Leeds, we were involved in both self-harm research and family therapy. We were also fortunate to have key participants in strategic roles in the University; the Dean of Medicine, the Director of the Institute of Health Sciences and the lead for family therapy training. XXX had also been involved with the local CAMHS as a child psychiatrist and in relation to other research projects. We also had

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\*Chief Investigator on SHIFT trial and a child psychiatrist and family therapist with extensive experience of secondary research into outcomes and effectiveness

\*\* Investigator on the trial, senior family therapist practitioner and trainer but whose experience with research is limited.

an excellent health economics team and an internationally recognised clinical trials unit.

There was the nucleus of a multidisciplinary team with potential to design a successful bid.

A multi-centre approach is usually required to recruit sufficient participants and offer a variety of 'real world' settings. Jonathan Green (Manchester) and Ivan Eisler and Mima Simic, provided access to more participants and considerable expertise on the design and delivering of the trial. Rob Senior later joined by Reenee Singh and Charlotte Burck (London) were also involved. These relationships were also forged from pragmatic considerations (geographical constellations to reduce travel costs and sufficient commitment and capacity for recruitment).

One of the aspects of the trial that is difficult to appreciate is the number of working groups required. The Trial Management Group, which had general oversight and met quarterly, comprised all the applicants, Clinical Trial Research Unit (CTRU) representatives (statisticians, trial managers, data entry staff), research assistants, FT supervisors, health economists, and lay representatives (approximately 20 members). The Trial Steering Committee, which had independent oversight of the trial, included a child psychiatrist, statistician, family therapist, and health economist alongside the Lead Investigator and CTRU staff.

The next phase involved considerable time liaising with clinical colleagues to obtain agreement to collaborate. Generally, these were either CAMHS psychiatric leads or senior family therapists. On the whole, local clinicians were enthusiastic, recognising the need to generate evidence for dealing with the worrying problem of adolescent self-harm. They, in turn, provided introductions to more senior managers within their organisations, who gave formal agreement. Trusts that had a positive commitment to research but were not inundated with other projects were responsive. One of the Trusts was actively involved in a trial that was considering treatment of adolescent depression and the eligibility overlap and competition for clinician's involvement proved problematic. Trusts where there had recently had one or more adolescent suicide or where they were facing a major reorganisation were reluctant.

Once the trial was running, local working parties of management from each Trust, along with the local SHIFT FTs and the supervisor, CTRU staff and researchers were formed. These groups often appointed a CAMHS 'champion' whose job it was to support recruitment and troubleshoot team issues. In total, there were about 40 CAMHS teams in 15 different organisations in our three hubs of West and East Yorkshire, Greater Manchester, and SE and NE London.

### **The research protocol**

The development of the protocol was a time consuming and iterative process incorporating numerous areas of expertise. For more detail of the protocol see Wright-Hughes et al. 2015. The reader also is referred to the very useful MRC document on the design of complex intervention research, which was refined after the start of this trial (Medical Research Council 2006). The overall time scales for the project are set out below.

February 2007	NIHR call for research bids
April 2007	Outline bid submitted

July 2007	Shortlisted to make full bid
September 2007	Full bid submitted
April 2008	Grant confirmed
January 2009	Formal commencement of research
April 2010	First participant recruited
October 2011	16-month funding extension granted
December 2013	Final participant recruited
April 2015	Final follow-up interview conducted
January 2016	Initial view of preliminary data
July 2016	Publication of results

## **Design**

The trial design was a pragmatic, multi-centre, individually randomised, controlled trial of manualised SHIFT family therapy compared with CAMHS TAU (CBT, Psycho-educational, generic counselling, psychodynamic therapy, etc.). The primary objective was to assess the effectiveness of each treatment arm as measured by rates of repetition of self-harm leading to hospital attendance 18 months after randomisation. Generally, adolescents do not tend to have a high rate of therapy completion (Trautman et al., Coatsworth et al. 2001, Nock & Ferriter 2005) so the choice of this as main outcome was based on the assumption that this data would be available from hospitals even if clients had withdrawn from treatment.

Secondary objectives included comparison of the cost per self-harm event, characteristics of further episodes, impact on suicidal ideation, quality of life, and mediator and moderator variables which might influence engagement and benefit from treatment.

## **Design issues, revisions and accommodations**

Young people who needed specialist services (eating disorder, early intervention in psychosis or in-patient psychiatric unit) or were subject to a current child protection investigation or living in short term foster care were not included in the trial. The exclusion of some children in care felt unfortunate, as self-harm is so prevalent in this group but it would have required modifications in the intervention and additional therapist availability for professional networks.

Another inclusion criteria was that of English proficiency. This inadvertent exclusion of non-

English speaking participants was heatedly grappled with and potentially polarizing. Family therapists were concerned not to marginalize clients and felt that such a large national trial had important political significance. They also pointed out that they had extensive experience in working with interpreters. Trial management shared these considerations but was concerned about costs and practicalities. Although some of the base line measurements had been translated into some of the required languages, many had not. Having interpreters attend home visits with researchers proved financially prohibitive. A compromise was reached. The inclusion criteria was revised to one adult care taker with English proficiency and the manual expanded to include working with interpreters. These issues give a flavor of the tensions in designing any large trial between sound research methodology, practitioner concerns, practicalities, and wider political implications.

In the design, we had planned to use the SOFTA therapeutic alliance measure (Friedlander et al. 2006) in both treatment groups but this proved much too demanding for the TAU staff and ultimately, we lowered our expectations for alliance data collection.

### **Recruitment - CAMHS support and participant experience**

NHS staff not only provided the TAU, but also were also essential in introducing the trial to eligible clients. In the early days, there was a campaign to enhance NHS staff commitment to the trial using informational team meetings, cake, newsletters, and good recruiter recognition. A DVD was made specifically to promote the trial and address clinicians' reservations. For example, it was important to explain to clinical staff that recruitment to the SHIFT trial might mean their clients return to them as TAU, rather than going to SHIFT FT. It was also important to repeat the fact that no one actually knows which treatment is best, so neither form of therapy is particularly disadvantageous.

CAMHS staff would conduct an initial self-harm assessment and then invite the family to attend a follow-up appointment. At this follow up appointment, the CAMHS clinician would introduce the trial. If agreed, a researcher would then visit the home to explain more about the research. Consenting families were randomized into one of the two treatment arms.

### **Researcher Interviews**

Structured baseline assessments were conducted by research staff on the first home visit and then at 12 and 18 month follow-up. Assessments included the Beck Scale for Suicide Ideation (Beck & Steer, 1991), Hopelessness Scale (Kazdin et al. 1986), McMaster Family Assessment (Epstein et al. 1983) Strengths and Difficulties Questionnaire (Goodman et al. 2000) and Children's Depression Scale (Poznanski & Mokros 1995). Sadly the SCORE 15 (Stratton et al. 2014) questionnaire was not available to us at the time of planning the study. The quantity and nature of the assessments was significant point of trial management discussion. Selection of these measures was based on factors the literature suggested might be important moderators and / or mediators of outcome. The desire to explore as much as possible had to be balanced against the burden on families of data collection and the risk of triggering drop-out from the research.

### **SHIFT Family Therapy in situ**

In most CAMHS teams, formal FT is not usually offered for treatment following self-harm. For many Trusts, the SHIFT project generated the first provision of formal systemic therapy. The SHIFT teams were 'parachuted in' for one day per week. However, some services already had systemic family therapy. These Trusts did not want to stop offering family therapy as a treatment option and to have required them to do so, for the sake of the research, would have jeopardised their commitment to the trial. Therefore, some families in the TAU arm of the trial had systemic family therapy. There were concerns about the methodological

management of the overlap in the two treatments and that the intentionally flexible design of the manual might mean that it was, in fact, much more similar to TAU family therapy. This was one of the areas in which different perspectives within the trial between the two authors was apparent. Ultimately, the TAU FT was included in the TAU arm. Without knowing the extent of TAU family therapy, it is difficult to know the impact on the results.

There was also the potential problem of ‘contamination’ (a term clearly linked to the physical science origins of RCTs) related to the possibility of leakage of the SHIFT FT manual into local CAMHS FT teams so that TAU FT might evolve to become even more similar to SHIFT FT. One of the contributing factors was that some SHIFT FTs were seconded from FT roles in their local CAMHS meaning they also worked part time as CAMHS family therapists in the same team as the SHIFT service. As described above, we did not wish to place too many constraints on local services, but in these cases it was agreed that SHIFT FTs did not see any TAU families during their routine CAMH sessions or discuss their SHIFT FT practice with local colleagues. They were, however, allowed to supervise non-TAU self-harm cases family therapy with the hope that this supervision did not generalise to TAU family therapy. These boundaries were difficult for the SHIFT therapist as they may have felt or been perceived by their colleagues to be withholding something useful. But for the most part, the SHIFT FTs and their employing Trusts understood the rationale for the restrictions.

### **Safe Treatment**

Most self-harm referrals to CAMHS do not repeat. The SHIFT sample of at least two incidents of self-harm was assumed to be at relatively ‘higher risk’ of persistent self-harm, seriousness of self-injury and suicidality. Being allocated to the SHIFT FT arm of the trial did not preclude other interventions if deemed appropriate. Clients in the SHIFT FT arm retained a ‘case manager’ in the local CAMHS who was a point of contact for the peripatetic SHIFT

FT team if they wished to discuss additional input. Initially, the manual was designed such that the FTs had an overview of treatment and responsibility for any additional referrals; thus avoiding potential overuse of individual work alongside FT or multiple referrals outside of FT. More cautious Trusts preferred that their own CAMHS staff member act as case holder to whom the SHIFT FT was accountable. The issue was one where there were initially different opinions between the two authors but a compromise was achieved by allowing adjustments to local concerns. The data about additional referrals in both arms of the trial will be available and so we will be able to determine if, for example, receiving SFT led to more or less prescribing or additional therapies than TAU.

### **The Manual (Boston et al. 2009)**

The purpose of manualisation is to standardize treatment so that it is consistently applied during the research evaluation and replicable afterwards. Standardization of treatment is challenging in the face of complex psychological issues and multiple participants and settings. In attempting to develop the manual, some guidelines were useful. Waltz (1993) suggests there are four elements in the construction of manuals; the 'unique and essential elements, essential but not unique elements, recommended elements and proscribed elements'. Carroll & Nuro (2002) add that an identifiable theory of change, the 'active ingredients', is also essential in a manual. In the simplest sense, the 'active ingredients' in this approach could be said to be the particular kinds of therapeutic conversations between participants that are supported by the therapist and team. The theory of change in the SHIFT manual was based on systems theory, family life cycle and social constructionism, which posits that problems need to be understood in their relational context, that changes in one part of a system influence other parts and that language, meaning, behaviour and emotions are all part of the change process (Carter & McGoldrick 1999, Hoffman 1981, McNamee & Gergen 1992, White 2007).

Other unique and essential elements of the SHIFT manual had to do with the focus on adolescent self-harm; there are no other manuals for systemic family therapy for self-harm. The family's self-harm discussions with the CAMHS clinician and researcher would be acknowledged at the beginning of the SHIFT FT and as well as attempting to understand the young person's current relationship to self-harm (Ungar, 2001, Bickerton et al. 2007, Lerner, 2009, Ougrin et al. 2009, Pocock 2010, Ougrin et al. 2012 ) With progress in the management of self-harm and reduction of risk, more emphasis in therapy would be placed on the factors which contributed to the original pattern of self-harm (feelings and reactions to parental conflict, parental mental health or peer group issues).

The developmental issues of adolescence were also essential aspects: considering increased autonomy, emotional regulation and the importance of sibling, peer groups and social networks (Baumrind 1987, O'Connor et al. 1996, Adams 2000, Werner-Wilson 2001, Jackson & Goossens 2006). The manual suggested that there might be times when it was best to see the adolescent alone or in a parallel session with a team member seeing the parents. This was particularly important where the young person was reluctant to speak in front of their parents. When returning to the family session, each therapist could represent aspects of the separate meetings; forging a conversational bridge by use of techniques aimed at reduction of blame, support for mutual understanding and re-contextualising as required.

Principle driven manuals, which are more 'loosely' specified, fit more complex interventions and use by experienced therapists who can make sophisticated clinical judgements (Schoenwald et al. 2000). For example, the manual suggests that self-harm is a central issue to be discussed and the therapist is also tasked with developing an alliance with both young person and parents. The therapist may have to suspend the focus on self-harm if the alliance is threatened or more actively engage in discussion of it when the degree of risk has

increased. Additionally, although the manual encourages use of the reflecting team, a family's reticence would indicate to the therapist to suspend this suggested technique.

Another essential aspect of the manual was that it was designed for use by clinicians who were qualified systemic psychotherapists. This degree of prerequisite training is very unusual in manualized psychotherapy research. The manual was theoretically inclusive so that most UK trained FTs would find it acceptable. This manual required there to be three qualified family therapists; one interviewing and two observing the family. Having worked with training teams for many years and seen the substantial benefits for families, we were advocates of both teamwork and the technique of reflecting team conversations (Andersen, 1987, Jenkins 1996, Sparks et al. 2011, Parker & O'Reilly 2013). As the trial progressed, the importance of good teamwork and reflecting team practice became a significant theme. The presence of a highly qualified team may pose challenges for generalisability if the trial proves positive, but we were also concerned to counter arguments that if the trial proved negative it might be because of insufficient therapeutic expertise. As is so often the case in quantitative research, attending to one issue raises another!

One of the standardized specifics included in the manual was that of a 'formulation letter' to be sent to the family from the therapist after the second session. The decision to include this was based on our interest in narrative letters (Penn & Frankfurt 1994, Rombach, 2003, Marner 2000, Shatavia et al. 2008, Moules 2009). It has also been supported by a presentation in Leeds about the benefits of sending automated follow up letters to clients from staff at the A and E service after an attempted suicide. Recipients had been positive and the presenter was convincing about the subsequent reduction of further attempts. The SHIFT letter, written with warmth and optimism, was meant to capture the young person and family member's explanation of the self-harm, possible contributing factors, the adolescent's

relationship to the self-harm, participant's hopes for therapy and an account of the participant's personal strengths. It was intended to enhance the therapeutic alliance.

A few years ago, a paper was published which found no such positive effect of letters (Milner et al. 2015). Over time, it became more apparent that the client's reactions to the letters varied. Some clients found them useful while many others really did not appear interested. The therapist took a good amount of time to produce these letters and while they reported that it got easier with practice and the activity enhanced their own thinking, in retrospect, this element of the manual may not have been justified.

To ensure that 'dose' of treatment was broadly equal in each arm and to produce an intervention that was affordable, the protocol specified parameters for treatment. Family therapy was to be completed within six months and approximately eight sessions, with greater frequency in the beginning. The sessions were generally an hour – to hour and a half. Clinical need determined any extension of these parameters.

Essential but not unique elements were initially based on the LFTRC manual (Pote et al. 1995). The LFTRC manual was written for general systemic practice and included a range of systemic skills (a relational and systemic understanding of family dynamics, the capacity to develop an alliance, an awareness of context, a reflexive use of self, the capacity to develop hypothesis, ask systemic questions, amplify change, and make use of a therapeutic genogram). It also included the notion that therapy is a process with a beginning, middle and end. The SHIFT version updated the LFTRC manual to include solution focused, narrative and post-modern discursive elements. There was a reduction in 'model specific' language and techniques to avoid theoretical polarization among the therapists.

The listing of proscribed elements was avoided on the basis that sophisticated systemic therapists could incorporate many activities that might appear at face value not to be systemic but could be seen as such within a systemic framework of delivery.

There have also been suggestions from the SHIFT FTs that the manual could have benefitted from inclusion of more material on attachment theory, creative techniques for less articulate young people and more coverage of therapeutic work around the impact of social media.

While the initial version of the LFTRC manual had been used in another large trial, the revised version for SHIFT had not been piloted as this was not required by the funding body. In retrospect, this would have been useful.

### **Employing FTs and life in the Trust**

In the UK, direct research costs are met by the project grant but any additional costs of treatment are funded by the Trusts. Trusts had to employ and fund the SHIFT FTs.

Negotiating these funding arrangements with the different Trusts took a surprisingly long time. FT appointments and prolonged periods of mandatory training prior to commencing work created delays. Training sessions had to be repeated with additional costs.

We wondered if it would have been better for the trial to employ the therapists directly. There were also some grey areas between line management and clinical supervision that might have been clearer if we had been the employers. On the other hand, this might have had the undesirable effect of making the therapists feel even more peripatetic.

Trusts had very different reactions to the SHIFT FTs. Some saw the SHIFT FTs as a very useful clinical resource, reducing the caseload for staff and bringing a high level of expertise. Other Trusts were very concerned about the financial obligations, fearing they would have to employ the FTs at the completion of the trial and some were pressured to 'earn their keep'

and kept on very short contracts. Some Trusts had concerns about the salary scale for the research FTs (NHS grade 8a) as this was a higher banding than they were paying.

There was variation in the SHIFT FT team structures. Most teams comprised three therapists from three geographically adjoining CAMH services. The team would rotate their clinic through the three services, the cases would be seen by the therapist employed by that locality and the others formed the observing team. One team, covering a very large territory, had a consistent team of two therapists working for four days together who were joined by a third for each half of the week. Most teams spent substantial time travelling between many different clinics and relating to a number of CAMHS teams. For example, the team might see one family in York in the morning and travel 32 miles to see another in Wakefield that afternoon or take a tube across north London between clinics.

The degree of restructuring in the NHS was not entirely unanticipated but its impact needs highlighting. When significant managers who had originally committed to the trial at various levels were no longer involved and many of the staff delivering TAU were working in fragmented teams or leaving the Trust, the SHIFT therapists had to spend more time building and rebuilding professional relationships and recruiting cases. The decision to use very well trained family therapists was important, as they worked with stressful cases in more autonomous environments but also managed the changing environments. Another point of interface and unanticipated additional work was that of recording and transporting of therapy sessions. At times this aspect of the trial was a 'perfect storm' of organisational fragmentation with problems of recording equipment, technical support, policy interpretation and managerial ownership. This issue consumed inordinate amount of time for most of the life of the trial.

## **Training and Supervision**

The first SHIFT training for all family therapists occurred over two days and included a review of the manual, discussion of the FT's relationship to risk, reflections on their own adolescence and discussion of alliance building. Each FT was to work with a pilot case prior to taking on trial cases. Subsequent training included annual meetings of all FTs and supervisors. Generally, each training meeting included a mixture of case presentations, discussion of 'trial issues' and particular themes generated by participants; the pros and cons of the formulation letter, whether the therapist should ask the young person to show the self-harm injury, the self-care of the therapist and issues with their local service.

Group training was beneficial as SHIFT therapists generally expressed a sense of belonging to something important and creative. Overtime, there was a feeling of the therapists gaining a depth of understanding about the issue that can only come from immersion in the work. In the final therapists meeting, there was a discussion of the experience of using the manual and most felt that their initial reservations had been replaced by a sense that the manual became a benign 'internal supervisor' that supported their work.

Each team met for supervision with trial supervisors for two hours per month. Supervision included case discussion, questions about adherence, team dynamics and relationship to the trial or employing Trusts. At times, some therapists were preoccupied with the difference in trial supervision and the peer team supervision.

## **Conclusion**

This SHIFT study has been successfully completed and has managed a number of significant challenges, some anticipated and others 'emergent'. It is also important to note that this paper has been written after the conclusion of the trial data collection but prior to publication of the results. However, the impact of this large trial can already be noted in the heightened recognition of systemic therapy training in CAMHS.

Not all practitioners will have the opportunity to participate in large scale research like the SHIFT project, but such large scale research often starts with smaller scale projects involving systematic measurement and evaluation of local practice. All major evidence based interventions have to start somewhere and it is usually with innovative clinical practice. This is something which all practitioners can engage. Clinicians interested in being involved in research need to be aware that there may be rich potential for collaborations within their local universities. Similarly, applied health research staff in universities could perhaps do more to reach out and engage with local clinicians around the development of novel research projects. We owe a great deal to the work of the trial management group, the NHS managers who were committed and responsive and most importantly, the SHIFT FTS, who were essentially the ‘intervention’ and the young people and families who were willing to participate.

#### Addendum

We want to mention the untimely death of two colleagues. Mike Gibson, who was a full time SHIFT FT died of an unforeseen medical condition in July 2013. It was a great tragedy to his family and friends and a major loss for his team. Mike Kerfoot, a researcher in the area of self-harm and original applicant sadly died and was greatly missed.

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