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Partnership approaches to the evaluation of complex policy initiatives: Qualitative research as key to building effective relationships

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Abstract

We argue that major health and social care policy initiatives are not too complex for randomised controlled trial (RCT) methodology and illustrate this using the example of the Best Services Trial (BeST?): a RCT of an infant mental health intervention for maltreated children. We suggest thatqualitative research, as a core part of the trial process from conception and development through to implementation and evaluation, is crucial in building, understanding and strengthening the partnership required to drive such a complex trial. Data pertinent to trial implementation demonstrate the iterative nature of the process whereby stakeholders are consulted and their views influence the conduct of the trial. Here we reflect on the bi-directional relationship between qualitative data collection and partnership working in a trial. For very complex trials to be possible, significant resource needs to be available for the qualitative component.

Key Practitioner Message:

- Qualitative research is key to understanding, building and strengthening partnership approaches to researching complex interventions;
- Qualitative research is vital to supporting randomised controlled trials involving multiple sectors;
- Qualitative research provides essential explanatory power to outcome data in research.

Randomised controlled trials (RCT) are the accepted 'Gold Standard' for healthcare research and while originally developed for single interventions, such as drug trials, they are now increasingly being used to test the effectiveness of a range of complex interventions. Complex interventions are defined as any intervention that involves multiple interacting components (Craig et al., 2008). While there is still some controversy about the use of RCTs in the evaluation of complex policy initiatives (e.g., Greiner & Matthews, 2016), their use is now widespread and they are recognised as the most effective way of evaluating interventions (Oakley et al., 2006). Their use is likely to increase as health and social care continue to merge and governments and funders demand evidence-based interventions, but implementing RCTs in complex circumstances is challenging.

In this article we use the example of a trial that is tasked with building a particularly complex partnership across landscapes with inherently different philosophies and approaches; a partnership that arguably goes even beyond the already documented challenges associated with the combining of health and social models (Greiner & Matthews, 2016). We build on previous research in this area, in particular the work of Oakley et al. (2006) and de Salis, Tomlin, Toerien, and Donovan (2009), to show how a qualitative component of a complex trial, combined with careful planning, can generate and strengthen partnerships and elucidate and respond to challenges throughout the entire process of a complex trial, from design to implementation. Here we reflect on this process.

The merits of using qualitative process evaluation in the evaluation of complex interventions is an increasingly recognised, but not a new, concept (e.g., Bonell, Fletcher, Morton, Lorenc, & Moore, 2012; Moore et al., 2014), however, little attention has been paid to its relationship with, and effects on, partner hip working in complex research contexts. Instead, the focus to date has been on its role in providing explanatory power to reported outcomes by identifying the mechanisms by which the intervention brings about change and how interventions interact with the context in which they are embedded (Komro, 2017; Oakley et al., 2006). This article, for the first time in the complex field of assessing child maltreatment and infant mental health, explores how qualitative work goes beyond these more traditional roles by strengthening the various relationships that underpin the partnership that supports the RCT.

The use of RCTs in very complex settings is not common practice (Haynes, Service, Goldacre, & Torgerson, 2012) and the uptake of 'evidence-based practice' varies across professions, with medicine adopting evidence-based decision-making into its culture in a way that public policy for example, has not (Macintyre, Chalmers, Horton, & Smith, 2001). However, there are some impressive examples of RCTs in highly complex contexts, including the Peru – PREVEN programme that informed international policy on the treatment of sexually transmitted diseases (Garcia et al., 2012). Other examples are an evaluation of an exercise referral scheme in Wales (Murphy et al., 2012) and a major programme to improve paediatric inpatient outcomes in Kenya (Ayieko et al., 2011; English, Nzinga, et al., 2011; English et al., 2009; Nzinga et al., 2009). Qualitative research has played a number of roles within RCTs including investigating acceptability of a complex intervention, defining the RCT components, developing hypotheses, identifying how an intervention works, exploring relationships and power imbalances and evaluating the process of a trial and an intervention (Campbell et al., 2000; Lewin, Glenton, & Oxman, 2009). Here we illustrate a further role for qualitative research in building and strengthening partnership, by describing its role in the implementation and optimisation of a RCT of a complex intervention involving a multi-professional team drawn from the charity sector, the National Health Service (NHS), social work services and the

legal system (Minnis, 2016; Pritchett et al., 2013; Walker, Wilson, & Minnis, 2013). In turn, such effective partnership has proven facilitative in generating qualitative data that provide vital insight into the complexities of the trial and current patterns of thinking in the trial context.

The Best Services Trial (BeST?)

There is a developing international consensus that achieving permanent nurturing family placements for maltreated infants is likely to improve infant mental health (Gauthier, Fortin, & Jeliu, 2004; Lindhiem & Dozier, 2007), and international and local policies have developed supporting this (Deacon, 2011; Scottish Government, 2011). Historically, in the UK, assessment of the placement needs of maltreated children entering care has been patchy (Walker, 2005). The decision to offer expert assessment to every child coming into an episode of foster care, and to offer an infant mental health service to a randomly chosen 50%, was a radical policy initiative on behalf of Glasgow City Council (GCC). BeST 120 ? is a key component of that policy; both were launched on 5th December 2011. The relationship between the academic, clinical and policy initiatives, developing in partnership, is outlined in Figure 1. The figure gives an overview of the development of the trial from conception to implementation and embeds the academic developments in the context of local policy/clinical and national/international policy developments.

BeST? (Minnis, 2016) aims to evaluate an infant mental health service for maltreated children developed by Zeanah and colleagues (Zeanah et al., 2001) (with ethical approval from West of Scotland Ethics Committee 5). It is a typical example of an exploratory complex intervention trial: multiple partners working across multiple settings, multi-disciplinary teams, multiple outcomes, multiple interventions within both arms of the trial and a need for flexibility and adaptability in the delivery of the programmes (Craig et al., 2008). All consenting families of maltreated children aged 0–60 months coming into foster care are randomised into either the Glasgow Infant and Family Team (GIFT) – the Glasgow version of service developed by Zeanah – or the Family Assessment and Contact Service (FACS) – an enhanced and standardised ‘services as usual’ (Figure 2). More than 60% of eligible families have agreed to participate. Figure 2 shows how BeST? is embedded within a major council/health policy initiative to provide expert assessment for every maltreated children under age 5 coming into an episode of care.

The programme is overseen in partnership by the National Society for the Prevention of Cruelty to Children (NSPCC) who fund and deliver the GIFT service, GCC who fund and deliver FACS, NHS Greater Glasgow & Clyde and the University of Glasgow. The GIFT service includes NSPCC, GCC and NHS staff. The development of this formal partnership largely grew out of the work of a steering group formed in 2008 (Figure 1) and was informed by qualitative work carried out in Glasgow and New Orleans (Zeanah et al., 2001.).

<Figs 1 and 2 near here>

	Academic	Local policy/clinical	National/International policy
1994			1994 Adoption and Safe Families Act (US) requiring decision about adoption/return to family after 15 months in care
2001	Zeanah publishes paper on Tulane Infant Team		
2004	Visit to New Orleans		
2007			Scottish Adoption Bill – aim to improve pathways to permanency
2008	Zeanah met Glasgow policy-makers		
2008		Local policy-makers determine to introduce NIM. Set up steering group including academics.	
	Qualitative mapping and modelling begins		
2008-2011	Visits by policy-makers, clinicians, social workers and academics to New Orleans. Informal discussions and qualitative interviews with stakeholders in Glasgow and New Orleans.		
2009	Local seminar with 43 delegates including policy makers, practitioners and academics.		
2009-2010		Local policy-makers liaise with central government resulting in funding for Glasgow to improve permanency, allowing setting up of FACS team. Another RCT is managed by health/social work partnership in Glasgow.	
2011	Successful funding applications to Chief Scientist Office of the Scottish Government with additional support from NSPCC, Scottish Mental Health Research Network, Glasgow Clinical Research Facility, NHS Greater Glasgow and Clyde (NHS GGC) and GCC social work.		
2012			Children and Families bill for England and Wales announced, creating a time limit of six months by which permanent care arrangements must be completed.

Figure 1. BeST? Timeline

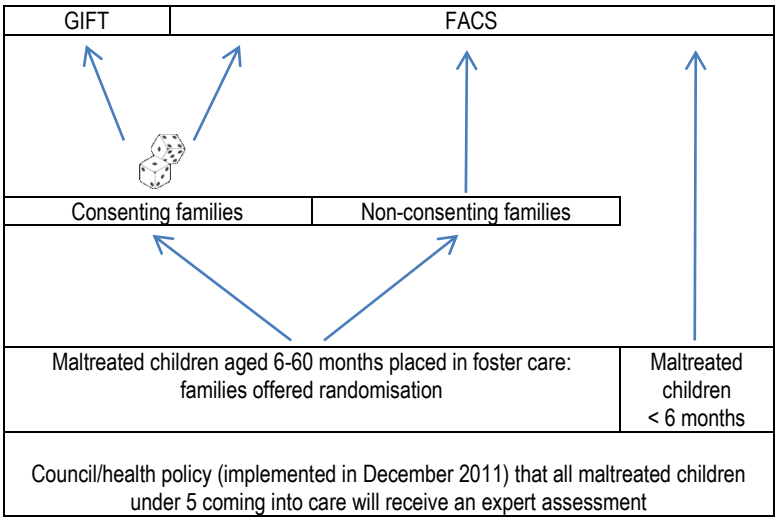

Figure 2. Outline of BeST? trial feasibility phase.

The launch of the trial followed several years of 'mapping and modelling' work (Figure 1). This developmental work, previously reported (Minnis, Bryce, Phin, & Wilson, 2010, Walker et al., 2013), was supplemented by many discussion meetings with clinicians, social workers and policy-makers both locally and nationally that were facilitated by multiagency members of the steering group. Mapping and modelling was supported through 'soft' funding, including two Winston Churchill Travelling Fellowships and small grants from the NHS, GCC and NSPCC.

Now the exploratory trial is fully operational, the qualitative component is delivered by a full time research associate. It follows a realist evaluation approach (Pawson & Tilley, 2004), which assumes that GIFT operates within an open social system, with a key task being to identify and unpack reactions among key stakeholders to a new intervention in this system, many of which we know will be unpredictable (Moore et al., 2014). This qualitative work, to date, has illuminated an interesting juxtaposition of opinion about GIFT, demonstrating the potential for perception to drive what happens in practice (Turner-Halliday et al., 2017). According to Pawson and Tilley (2004), the relationship between perception and practice is circular, but the relationship between qualitative research and partnership has not been specifically examined in terms of how the process of conducting qualitative research, as well as the findings, can strengthen relations. Using data collected as part of our ongoing qualitative process evaluation, we now reflect on the ways in which a partnership approach in the trial acts as both a facilitator and product of such important enquiry.

Methods

A number of individual research interviews and focus group discussions (Table 1) have been conducted to gather on the service changes from a purposive sample of all the relevant partners and stakeholders (including birth parents, foster carers, social workers, NHS staff and legal professionals and leaders within the Children's Hearing System). Focus groups were conducted with professional teams in the trial (GIFT, FACS, social work area teams and Children' Panel members), while individual interviews were used with service managers, foster carers and birth parents. Throughout the trial, we have learned that, while professionals are accustomed to sharing their perspectives in group settings, both foster carers and birth parents in this particularly sensitive context generally prefer to have the opportunity to give individual accounts of their experiences. Furthermore, we have learned that gathering professional views of the trial is facilitated by group dynamics where team members can reflect on shared experiences but provide different perspectives of those experiences through discussion and debate.

The focus groups and interviews followed a semi-structured approach to gathering data (Willig, 2013) and used topic guides that have evolved iteratively from the thematic analysis during the process of stakeholder engagement. For example, analysis of the data generated from early consultations with health and social work professionals led to the development of topic guides that specifically explored issues of consent with birth families (Welch et al., 2017). A semi-structured approach allows flexibility in question use, gaining a balance between exploring pre-defined areas of interest whist allowing participants to share experiences and views that are participant-led (Willig, 2013). The qualitative process evaluation continues to explore core areas of interest for the trial, while being led by particularly topical and pertinent areas of debate within the data, some of which have crucial wider implications than the trial alone (e.g., Turner-Halliday et al., 2017).

Table 1. Overview of qualitative data collection

Services	Foster carers	Social workers	Ad hoc exploration
FACS 1 team focus group; start of trial 1 interview with manager; start of trial	1 focus group; foster carers with children in FACS; start of trial 1 focus group; foster carers with children in GIFT; start of trial 7 telephone interviews; foster carers with children in GIFT; 1 year post-intervention) (those starting GIFT Jan-June 2012) 8 telephone interviews; foster carers with children in FACS; 1 year post-intervention (those starting FACS Jan-June 2012)	3 Area Team focus groups (covering the 3 sectors of the city); start of trial 3 Area Team focus groups (same sectors) 18 months after start of trial	CONSENT 8 face-to-face interviews – birth parents 1 face-to-face interview – original recruitment coordinator 1 face-to-face interview – current recruitment coordinator Probe on consent in 15 foster carer telephone interviews (see column 2)
GIFT 1 team focus group; start of trial 1 interview with manager; start of trial 1 GIFT social worker focus group; 1 year after start of trial 1 team focus group; delivery & progress; 1 year after start of trial 1 joint interview with managers; delivery & implementation; 1 year after start of trial			DUAL REGISTRATION OF FOSTER CARERS/ADOPTIVE PARENTS 1 joint interview – GIFT manager & NSPCC manager 2 focus groups – permanency steering group and post-New Orleans trip Question on topic within 7 foster carer interviews Strands of data within GIFT team focus group Strands of data within GIFT managers joint interview

All interviews and focus groups were audio-recorded and transcribed verbatim, followed by a period of thematic analysis (Braun & Clarke, 2006, 2013) where each transcript was examined in detail noting reflections and preliminary themes. Transcripts were read a number of times to identify repeating patterns and/or differences between transcripts and all new themes identified at this stage were noted. Themes were then clustered under supra-ordinate themes in a thematic table and each transcript reviewed again until the sub-theme data was organised into these overarching categories.

Results

The iterative nature of the qualitative research was crucial in optimising the implementation of the trial. Ongoing data analysis led, where possible, to the refinement of particular elements of the intervention or additional efforts to clarify why the chosen approach was necessary. For the purpose of this article, we report on themes that illustrate the relationship between qualitative research and a partnership approach to the implementation of the trial.

Four main themes have emerged:

- Understanding/scepticism about the overall need for a trial
- Understanding/scepticism about the rationale for some of the trial design decisions

- Understanding of the complexities of a trial – allaying fears that the process 'should be smoother'
- Understanding of the exploratory nature of the trial and the need for a qualitative component

Some examples of data that emerged within these themes follows.

Initially, even the suggestion of a RCT in this policy context aroused some disquiet that had the potential to destabilise the trial:

> *I've just spoken to a social worker five minutes ago and she goes 'do I have to go into this thing? Can I advise the family not to sign up to the research?* (Social work focus group).

Active listening in these early stages has allowed early synthesis of information gathered and feedback of relevant findings to research informants: all processes central to a qualitative 'knowledge transformation' process (Sandelowski, 2004). This has been essential in holding the trial together. The use of qualitative methods has enabled the researchers to better inform stakeholders about the rationale for particular aspects of the model and increase the overall acceptability of the methods among stakeholders:

> *We hold onto the context that it is a trial trying two different methods. . .I understand it is different services, and they are necessarily very different and they shouldn't be the same otherwise why would you be researching, but, you know, it's different. . .different focus, approach, perspective really. So it's confusing for the teams* (FACS focus group).

In response to this, and similar data, the researchers set up a series of information meetings for professionals, allowing us to ensure that all those involved were informed about the nature and underpinning academic principals of the trial and to promote a sense of ownership and involvement.

Over time there appeared to be an increase in understanding of the exploratory nature of the trial and the need for qualitative work to capture the process, regardless of the outcome:

> *If it turns out that we can do it, if we can replicate their findings [New Orleans services] in Glasgow, then that's great, but, you know, the other possibility is that we can't and it is really important to be able to say 'well why not?'* (GIFT staff member interview).

People came to understand the power of an RCT and, while many may have been suspicious of the process at the start, involvement in the qualitative process meant that participants became increasingly aware of the research, its aims and its objectives. The qualitative exploration extended beyond the professionals involved in the trial and created opportunities to enhance understanding about the overall purpose of the trial among all those consenting to participate:

> *Basically [the trial] needs to happen in order to make a comparison. . .so, at the end of the day I am all for it because if this is an improvement . . . and if it works then surely it has got to be a good thing. . .whether it is GIFT or the Family Contact Centre* (Foster carer interview).

In addition, the qualitative consultation has provided opportunities for all those involved in the trial to highlight concerns about the conduct of the trial or how taking part would impact on professional integrity and autonomy. For example, we have used interviews with parents to assess the

effectiveness and suitability of our ethics procedures, in particular our consenting process (Welch et al., 2017).

Discussing the many challenges inherent in delivering a complex trial also appeared to strengthen the partnership between those delivering it and those charged with implementing and evaluating it:

- *FACS staff member (interview): . . . no one ever said the social work clients come in nice little boxes, neatly packaged. . . .*
- *Interviewer: And neither do trials that are looking at such complex interventions. . . so it is notoriously challenging in this particular context.*
- *FACS staff member: Yeah it is? Is that what I'm experiencing? [Laughs]*
- *Interviewer: And I guess that doesn't make it any less stressful though?*
- *FACS staff member: But I suppose what should actually help to make it feel a bit more manageable is to hold on to the fact that it is a trial.*

Discussion

We have found qualitative consultation invaluable in guiding the launch of a RCT within the context of a radical health/social care policy initiative. In order to win the support of the wide network of partners and stakeholders involved, it has been important for them to have a sufficient understanding of the aims of the programme and some of the techniques being used to achieve those aims. Using qualitative techniques, we have been able to gather experiences of the actual policy initiative and how it is progressing, identify and address information needs bringing the most important people in the implementation of the trial on board, and implement the trial in a more pragmatic and effective way (Hotopf, 2002). We would argue that this is not simply 'public relations' and that it is essential to have skilled qualitative researchers doing this work so that the qualitative technique can 'activate the knowledge transformation cycle' to its fullest capacity (Sandelowski, 2004, p. 1366) as well as develop a thorough understanding of context. This, we argue, has helped to stabilise the trial implementation process and meet and overcome many of the challenges identified (Mackenzie, O'Donnell, Halliday, Sridharan, & Platt, 2010). The act of gathering the views of partners and stakeholders through the qualitative research process helps to affirm the importance of their contribution, while the information gathered provides invaluable feedback both about what is working well and where there is room for improvement.

It has been essential to build a partnership of participants, academics, clinicians and policy-makers. Our use of the term 'partnership' refers not only to the formal partnership that oversees the trial, but also to the clinicians and social workers within the intervention teams who drive the process forward alongside the researchers and policy-makers. If this programme had been led by academics alone, it is unlikely that the intervention would have developed in such a way as to fit the policy context and might, instead, have seemed like an 'off the shelf' product parachuted in from outside. If policy-makers or practitioners alone had led this programme, we may have experienced the kinds of problems that many evaluations of major policy initiatives face including poor standardisation of both intervention delivery and measurement (Mackenzie et al., 2010) or poor recruitment because of a lack of buy-in from potential participants and their gatekeepers. In partnership, we have been

able to iron out problems and/or understand these as the interventions develop in context. There is a need for continued careful characterisation of the context, including vigilance for contamination (English, Schellenberg, & Todd, 2011), monitoring of the turbulence created by the radical policy initiative and of both the intervention-in-context (GIFT) and control-intervention-in-context (FACS) now the trial has started.

If complex intervention studies of major policy initiatives are to be successful, researchers and funding bodies must recognise the value in in-depth qualitative analyses throughout the process.

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