



An application of Extended Normalisation Process Theory in a randomised controlled trial of a complex social intervention: Process evaluation of the Strengthening Families Programme (10–14) in Wales, UK

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ABSTRACT

Purpose: Process evaluations generate important data on the extent to which interventions are delivered as intended. However, the tendency to focus only on assessment of pre-specified structural aspects of fidelity has been criticised for paying insufficient attention to implementation processes and how intervention-context interactions influence programme delivery. This paper reports findings from a process evaluation nested within a randomised controlled trial of the Strengthening Families Programme 10–14 (SFP 10–14) in Wales, UK. It uses Extended Normalisation Process Theory to theorise how interaction between SFP 10–14 and local delivery systems - particularly practitioner commitment/capability and organisational capacity - influenced delivery of intended programme activities: fidelity (adherence to SFP 10–14 content and implementation requirements); dose delivered; dose received (participant engagement); participant recruitment and reach (intervention attendance).

Methods: A mixed methods design was utilised. Fidelity assessment sheets (completed by practitioners), structured observation by researchers, and routine data were used to assess: adherence to programme content; staffing numbers and consistency; recruitment/retention; and group size and composition. Interviews with practitioners explored implementation processes and context.

Results: Adherence to programme content was high - with some variation, linked to practitioner commitment to, and understanding of, the intervention's content and mechanisms. Variation in adherence rates was associated with the extent to which multi-agency delivery team planning meetings were held. Recruitment challenges meant that targets for group size/composition were not always met, but did not affect adherence levels or family engagement. Targets for staffing numbers and consistency were achieved, though capacity within multi-agency networks reduced over time.

Conclusions: Extended Normalisation Process Theory provided a useful framework for assessing implementation and explaining variation by examining intervention-context interactions. Findings highlight the need for process evaluations to consider both the structural and process components of implementation to explain whether programme activities are delivered as intended and why.

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1. Introduction

Adolescent substance misuse is a significant problem in developed countries (Currie et al., 2012; U.S. Department of Health and Human Services, 2007) and early initiation of substance use is associated with higher levels of substance-related harm during adulthood (Dawson, Goldstein, Chou, Ruan & Grant, 2008; Grant & Dawson, 1998). Because the consequences of early initiation are difficult to modify, an important response has been the development of family-based prevention interventions (Cuijpers, 2003; Kumpfer, Alvarado & Whiteside, 2003). One such intervention, the Strengthening Families Programme (SFP), aims to delay substance use initiation and prevent later misuse through strengthening family-based protective factors. In the United States of America trials of SFP 10–14 - a universal version of SFP for families with children aged 10–14, have found evidence of long-term effectiveness (Spath, Redmond & Shin, 2001; Spath et al., 2013; Spath, Redmond, Trudeau & Shin, 2002), though the methodological rigour of these studies has been criticised (Gorman, 2015). The evidence base for family-based prevention interventions such as SFP 10–14 is dominated by studies from the USA and there is a need for more research on whether effective interventions can be successfully ‘transported’ to other national contexts (Petrie, Bunn & Byrne, 2007), where they are more likely to be implemented under ‘real-world’ conditions, and without extensive input from programme developers (Axford & Morpeth, 2013).

Family-based programmes are complex interventions, with multiple components designed to work synergistically. Process evaluations, which analyse implementation, aid interpretation of complex outcome effects and understanding of intervention theory (Durlak, 1998; Durlak & DuPre, 2008). An important purpose of process evaluations is to assess the extent to which interventions are implemented with fidelity (Carroll et al., 2007; Moore, et al., 2014). This includes adherence (whether planned activities are delivered), dose (how much of an intervention is delivered/received), delivery quality, and reach and recruitment (Baranowski & Stables, 2000; Dusenbury, Brannigan, Falco & Hansen, 2003). Alongside these quantitative measures, qualitative research can provide important data on the processes which influence implementation, and their variation across contexts (Moore et al., 2014).

New interventions must operate within existing delivery systems and they depend upon cooperation from individuals and organisations, especially when delivered on a multi-agency basis (May, 2013) - a common social service delivery mechanism in the UK and elsewhere. Delivery settings are typically complex systems - characterised by the interaction of multiple individuals, social networks and organisations. Within these systems practitioners make meaning of interventions in ways which shape how they are delivered (Bisset, Daniel & Potvin, 2009; May, 2013) - though the study of these phenomena is limited (Bisset, Potvin & Daniel, 2013; Hill, Maucione & Hood, 2007). Practitioner engagement with an intervention may be emergent (and therefore hard to predict), and self-adaptive rather than centrally controlled (Stermann, 2006; Tan, Wen & Awad, 2005). Although studies in many countries have encountered variation in implementation across delivery contexts (Cantu, Hill & Becker, 2010; Durlak & DuPre, 2008; Lendrum & Humphrey, 2012), the role of intervention-context interaction in shaping this has often been overlooked (Bisset et al., 2009; Bonell, Fletcher, Morton, Lorenc & Moore, 2012; Glasgow, Lichtenstein & Marcus, 2006; Hawe, Shiell, Riley & Gold, 2004), and the narrow focus of process evaluations on quantitative assessment of pre-specified structural aspects of interventions (e.g. coverage of intervention activities) has been criticised for paying insufficient attention to the processes through which they occur (Bisset et al., 2009; Hawe et al. 2004). A previous trial of SFP 10–14 (conducted in the United States) - in which the programme was delivered by community-university partnerships, found no significant association between implementation team functioning and levels of

adherence, but suggested that potential relationships may have been masked by the consistently high rates of adherence across programmes (Spath, Guyll, Lillehoj, Redmond & Greenberg, 2007). However, evaluation of the programme in the USA as part of ‘real world’ dissemination found greater variation in adherence and other aspects of implementation (staffing levels, group size, children's age range), though no clear association between facilitator characteristics and fidelity (Cantu et al., 2010; Hill et al., 2007). Questions therefore remain about the key influences on the quality of implementation of SFP 10–14, the role of individual facilitators and their teams, and the influence of wider contextual factors.

Increasing attention is therefore being paid to intervention-context interactions, and their influence on implementation processes and hypothesized outcomes (Moore et al., 2014). It is important to understand how practitioners engage with interventions because this can provide insights into why fidelity and intervention effectiveness vary over space and time, and the extent to which an intervention may be adopted. One important contribution to the study of these processes is Extended Normalisation Process Theory (ENPT) (May, 2013) which seeks “to provide a more comprehensive explanation of the constituents of implementation processes” by integrating existing theories that are more concerned with specific processes, such as intervention delivery, integration and normalisation. ENPT conceptualises implementation as comprising practitioners - who have agency that is manifested when they interact with each other and with intervention components; and implementation contexts comprising “the socio-structural and social-cognitive resources that people draw on to realise that agency”. It therefore offers a useful framework for explaining implementation processes and the role played by intervention-context interactions.

ENPT has four main constructs. First, *potential* concerns practitioners’ commitment to deliver an intervention and behave in ways which are congruent with its aims, underpinning the action necessary to embed it within agents’ working practice (May, 2013). Whether practitioners value the changes an intervention brings about (change valence) and perceive that the changes are feasible within their local context (change efficacy), determine levels of commitment (Weiner, 2009). Second, *capability* concerns the possibilities presented by the intervention. *Capability* comprises: workability - how practitioners adjust what they do when organising an intervention - for example, (re) allocation of roles and responsibilities; and integration - how practitioners perceive implementation of an intervention to be linked to the wider social system. Third, *capacity* is the structure into which an intervention is introduced. Implementation depends on agents’ co-operation to accommodate the intervention by modifying norms and roles in social systems and redistributing resources, e.g. providing funding (May, 2013).

Potential, *capability* and *capacity* form the context for the fourth construct - *contribution*. This comprises the ways in which practitioners make sense of a complex intervention and their role in delivering it, the enactment of the intervention itself, and reflexive monitoring of its effects. The enactment of the intervention is expected to have specific qualities for each process evaluation component (e.g. adherence to programme manuals). Differences and similarities between expectations and practice can thus be explained in terms of *potential*, *capability* and *capacity*.

A small number of empirical studies have employed ENPT as a theoretical framework to understand the implementation of interventions within healthcare systems (Drew, et al., 2015; Thomas, Bendsten & Krevers, 2015). Our paper - which applies ENPT to a social intervention outside the healthcare system, reports findings from a process evaluation within a randomised controlled trial of the Strengthening Families Programme (SFP) 10–14 UK. We build on previous studies which have employed ENPT mainly to analyse implementation processes, by extending its application to explain how such processes shape the extent to which programme inputs and

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