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Implementation Issues in Functional Family Therapy: A Narrative Analysis of the
Evidence

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Abstract

This analysis of Functional Family Therapy (FFT) studies examines whether their variable outcomes are attributable to implementation issues. Studies were identified firstly, by way of a recent overview, supplemented by an update of a highly sensitive search including 15 databases, 10 websites, all existing relevant reviews, gray literature as well as contacting experts in the field. Updated searches were conducted in August 2018 and were analyzed according to the Oxford Implementation Index and an assessment of supervision quality. In total, the search yielded 150 records; 48 full texts were retrieved of which 32 were excluded leaving 16 studies containing 5320 unique participants included for analysis. There was no evidence of reported harm. Improved training and supervision were associated with better core outcomes. Although there was no apparent dose relationship, it appears that implementation issues are important and also that class and ethnicity were identified for areas of further study.

KEY WORDS

Functional Family Therapy, FFT, delinquency, implementation, juvenile justice, analysis

Implementation issues in Functional Family Therapy: A Narrative Analysis of the Evidence

Currently, Functional Family Therapy (FFT) is indicated as an effective treatment option for behavioral disorders in youth age 10 to 18. While there is a great deal of uptake and support for this intervention, results from systematic reviews, meta analyses and a recent overview suggest considerable heterogeneity in outcomes. The extant literature has indicated that implementation concerns may be the cause for much of the variability across trials and between outcomes, thus prompting this implementation analysis which is based in part on the Oxford Implementation Index.

Behavioral Problems in 10 – 18 year old youth

Behavioral problems refer to a wide array of psychiatric and psycho-social diagnoses, including Oppositional Defiant Disorder (ODD), Attention Deficit Hyperactivity Disorder (ADHD) and substance abuse disorders. Such problems in youth have an estimated prevalence as high as 20% and are often predictors of later symptoms including depression, alcohol and substance use, lower employment rates, delinquency, removal from the home, conduct disorder and criminal actions (Barlow, 2012). This group of disorders affects not only the youth and family but extends to have a negative impact on communities and society at large. Juvenile delinquency is often a result of these behavioral problems and issues that begin in the home or at school often transition into more serious criminal offenses (Rutter et al., 2015). With juvenile delinquency and behavioral disorders continuing to be a significant problem in the United States and worldwide, there must be continued efforts to address the specific needs of disparate client populations. There are a number of approaches to treating troubled youth and their families; the evidence surrounding and supporting these interventions must continue to be built in a high

quality and scientifically sound method. A number of interventions have been designed, developed and researched in the ongoing effort to prevent, reduce and treat these damaging and harmful behaviors. While the research base for these interventions is varied, family-based or systemic approaches may be the most effective (Muncie, 2015; Rutter et al., 2015).

Current treatment approaches

The past twenty years have seen a shift towards adopting research-supported practice and interventions, particularly in the area of family and youth treatment (Littell & Shlonsky, 2009). These often manualized and structured approaches are continuing to gain favor, and there exist a number of interventions that have been presented and accepted as having a strong evidence base which is used to support their continued adoption and uptake. Functional Family Therapy (FFT) is among these EBPs, and its uptake continues to increase. FFT is delivered in over 270 different locations predominately in the United States and United Kingdom; also it is endorsed as being effective by a number of key agencies including Blueprints for Violence Prevention (NCJRS.Gov), Action for Children in the UK (Actionforchildren.org.uk), and the Center for Disease Control and Prevention (CDC, 2018). It is important to examine family approaches and FFT in light of its inherent costliness, the number of individuals and families it serves (estimated to be over 50,000) and possible opportunity costs; it is vital that stakeholders have the best information and evidence around these interventions so their decision making is based on high quality research and reporting. After nearly four decades of use, the implementation of FFT has not been adequately examined or addressed in the research literature. Currently the published implementation studies focus primarily on the engagement process, or, 'delivery' of the intervention (Celinska, Furrer, & Cheng, 2013); Hartnett, Carr, Hamilton, & O'Reilly, 2017; McPherson & Macnamara, 2017;). This leaves out a great deal of valuable information regarding

the dose, uptake and context, three implementation elements which may factor considerably in the outcomes of FFT.

What is FFT?

FFT is firmly rooted in systems theory, and while it does share characteristics with other family approaches, it differs in its strict manualisation and phasic approach to treatment. Additionally, FFT is presented as a time-limited treatment, and should not take longer than 3 to 6 months. For further detail relating to the phases and processes of the intervention see Alexander, Waldron, Robbins, & Neeb (2013). FFT reflects a core set of theoretical principles, in which behavior is seen as a representation of the family relational system; i.e., as indicative of the communication, patterns and purposes of the family. The overarching goals of FFT may be described as follows: To change the maladaptive behaviors of youth and families, especially those identified as resistant to change; to reduce the personal, societal, and economic consequences of disruptive behavior disorders; to achieve core outcomes with less cost than many other interventions available. These core outcomes are 1) reduction in recidivism; 2) reduction in substance use and abuse and 3) reduction in out-of home placements. FFT's manualized approach includes reframing, interrupting of negativity or blame, redirection of focus, interpretations of patterns of maladaptive behavior with links to emotions, a deepening understanding of actions, and communication training with focus on positive communication. It incorporates theories of information processing, social cognition, and the psychology of emotion (Alexander et al., 2013). The model includes a Clinical Services System (CSS), an online portal that maintains all session notes, relational assessments, and therapist and client self-reported adherence and fidelity to the model guidelines. This system is monitored by both on and off-site supervisors who are well versed in the model.

Systemic theory posits that a child exists in a series of interconnected systems, Bronfenbrenner's theory of ecological development places a child within five levels of relatedness ranging from a micro system such as the immediate family to the macrosystem which

refers to the culture or community in which the child lives (Bronfenbrenner, 1979). Using this foundational theory, and when considering that a child's development and growth often begin and are anchored in the familial relationship, it follows that when treating behavioral difficulties, the family may be at the center of the treatment approach. Systems theory and family approaches to intervention are closely linked and one can be seen as informing the other; the beginnings of familial approaches are found in systems theory (Rutter et al., 2015). The current research base suggests that family interventions may be beneficial to youth aged 10 to 18 presenting with behavioral disorders as well as for those in danger of removal from the home for protective or legal reasons. Family interventions may also reduce the length of time spent by youth in institutions or in care (Woolfenden, Williams, & Peat, 2002).

A systemic approach to treatment will, normally, engage not only with the child, or even with the child and his or her family, but also with the larger systems such as the school, peers, church, probation and parole, child services and other community elements as needed. Systemic interventions are based in large part on understanding the connectedness of all these systems and influencing one while ignoring any of the others will undercut and lessen the value of any intervention or positive change (Rutter et al., 2015).

FFT is a short-term (90-day/8-30 hour), intensive and comprehensive program designed for the treatment of behavioural misconduct in youth aged 10 - 18. It is a treatment modality that can be delivered in clinical settings, school settings, or in the home. It is intended to address those youth and families with a wide array of presenting problems including but not limited to; criminal behaviour, truancy, running away, sexual misconduct, substance abuse, risk of out of home placement and as a re-entry program for youth returning to the community following release from institutional settings. Recent high-quality evidence has challenged the overall

effectiveness of the intervention (Weisman & Montgomery, 2018; Hartnett et al., 2017; Humayun et al., 2017; Darnell & Shuler, 2015). However, some studies suggest that there may be implementation explanations for the heterogeneity of outcome results across studies which is in line with broader psychology trial literature (Cunningham et al., 2018; Gottfredson & Gottfredson, 2002; Hawe, Shiell, & Riley, 2004).

FFT: Current Evidence and implementation

FFT's evidentiary status is inconsistent with systematic review results varying considerably and while it has not been shown to cause harm, there are questions regarding not only its efficacy and effectiveness, but also of implementation and fidelity (Baldwin et al., 2012; Bender et al., 2011; Hartnett et al., 2017; Weisman & Montgomery, 2018). Implementation may be measured in a number of ways, and includes the information related to an intervention's design, delivery, uptake and context. These four domains represent a broad spectrum of implementation elements, and aid in the more complete and thorough understanding of specific interventions; the domains can be adapted and different components or aspects of each may be identified by reviewers as being more germane to their particular topic or issue (Montgomery et al., 2013; Fixsen et al., 2005). It is important to note that harms may need to be considered more widely in order to determine what interventions to implement. While harm refers most commonly to injury, such as poisoning or psychological problems for an individual, it may also include opportunity costs of not spending on interventions with proven effects and thus spending valuable and limited resources in areas where we are uncertain of the outcomes (Bonell et al., 2012).

Conceptual Basis for Implementation Evaluation

The examination and analysis of implementation is a useful method of understanding the how and why of intervention effects, and for whom it may be effective. As evidence accumulates, there is naturally a progression from *if* a given intervention works to questions around its effectiveness for various populations and implementations- that is, for whom might it work and under what circumstances. It is understood that the transfer of an intervention from controlled clinical trials to broader contexts is dependent, at least partially, upon implementation concerns and processes (Durlak, 1998). The importance of implementation is apparent in three ways: first, it allows for understanding the effects of an intervention in practice; second, it assists in the better understanding of evidence supporting an intervention (mediation and moderation effects); and third, it is needed to facilitate the optimal uptake of evidence-based practices (Durlak & DuPre, 2008; Proctor et al., 2011). Intervention implementation presents a vital piece of how and why differences exist between primary trials. Implementation science, as a field, is broadly concerned with the scientific methodology that will contribute to, and promote, the uptake of quality research and evidence into common practice (Ghate, 2018; Mihalic, 2004). This work contains within it a number of aims, including the translation and uptake of research into practice, obtaining a greater and more complex understanding of what influences the outcomes of an intervention, and what are commonly referred to as evaluation frameworks (Elliot & Mihalic, 2004).

For any intervention to be successful, it must be both feasible and acceptable across different settings (Bonell et al., 2006). Frequently, changes may be made to better suit the characteristics of the participants or the setting. Different risk factors, prevalence and manifestations of a social problem exist in different cultural and social settings, and thus

responses may differ. These are frequently cited as the rationale for adaptation of an intervention (Moore et al., 2013).

Fidelity, broadly, is focused around noting adherence to the proscribed model guidelines and to the intervention manual, and while there are a number of ways to define implementation *fidelity*, the focus has traditionally centered on the need to remain adherent to the core components or active ingredients of an intervention (Mihalic, 2004; Arthur & Blitz, 2000). Strict manualisation has been seen as integral to the effective adoption of complex interventions. The rationale behind this is to keep the techniques, activities, and practices at the core of an intervention intact across different settings. However, it may be determined that adaptation to local circumstances is required which creates a tension between itself and manualisation. To address this issue a new approach and understanding of implementation is emerging where the emphasis shifts from standardization to a consideration of the underlying theories and mechanisms of change (Hawe et al., 2004). A 'theory of change', refers to the underlying principles, logic and rationale that link what an intervention does, and why or how these goals are accomplished. The outcomes that are intended by an intervention must have a clear and delineated course along which users progress through a causal pathway (Bonell et al., 2012). This current and more complex understanding of implementation attempts to understand and focus on the theory of change, suggesting that this will allow for adaptation and the maintenance of effect. What this essentially means is that the function, rather than the activities, may be what is most important in the successful adoption and adaptation of a complex intervention (Bonell et al., 2012). This functional approach does not need to undermine the intervention, rather it allows for both flexibility and theoretical adherence to the principles underpinning and supporting an intervention, which will in turn produce similar outcomes to other settings.

The role of the developer in interventions has come to the fore in recent research. It seems that larger, more positive effects are found in developer-led trials than in independent studies (Shadish, 2002; Eisner, 2009). There may be alternative explanations for these differences. The ‘high fidelity’ view posits that the implementation is of better quality *because* the developers are responsible for it. Thus, there is not an issue with the results, but only with their generalizability in a different setting delivered by different people. The ‘cynical’ view suggests that conflict of interest or biases (which may not be simply financial but also ideological in nature) may explain the differences in results (Eisner, 2009).

Objectives

The purpose of this narrative analysis is to examine the implementation of FFT as it modifies the intervention effects by way of the Oxford Implementation Index (Montgomery, Underhill, Gardner, Operario, & Mayo-Wilson, 2013). That is to say a consideration of the dose, delivery, uptake and context across trials. Further, to better understand how these elements, as well those of supervision quality and amount, may impact the differential effects found. This analysis stems from the published overview of FFT, and the protocol attached to the overview also supports this work (Weisman & Montgomery, 2018).

The core research question therefore is: To what extent are the differential effects found for FFT influenced by implementation factors?

Method

Some researchers have suggested that a high quality implementation of a poor intervention may be more effective than a low-quality implementation of the best practice intervention (Gottfredson & Gottfredson, 2002). Understanding and analysis of these aspects of

FFT research will create a broader and more nuanced understanding of the mechanisms and delivery of FFT across diverse populations. The intervention was designed and trialed primarily in Salt Lake City Utah, with a largely white middle class population. However, given that FFT is now being used with populations and locations that are very different, this is not likely to be the best reference point for its generalizability. It is important to understand and identify the elements of the intervention which are working and result in positive outcomes, and possible areas that require modification or adaptation. Recent overview and meta-analytic evidence illustrates the variability in core outcomes, thus confounding any certainties regarding the implementation and usage of FFT with such a heterogenous population and across varied settings (Weisman & Montgomery, 2018; Hartnett et al., 2017).

Search Strategy for Identification of Studies. All published reviews of FFT which were identified in Weisman and Montgomery (2018) were examined for lists and tables of included studies. Additionally, search terms were modified and used across relevant databases in order to update this overview and capture any relevant studies that were not reported or included elsewhere. Electronic searches were made of relevant databases, government policy reports and professional websites. Experts known to have conducted trials of FFT were contacted in order to augment our search of the grey literature and author called upon personal and professional resources to locate any studies that were complete but perhaps not yet published. There were no publication or geographic limitations although searches were conducted only in English. This search was designed to be highly sensitive and to capture all relevant studies and publications relating to this project. The updated search strategy was conducted in August 2018. The search terms (modified as necessary for specific databases) for MEDLINE, PsycINFO, Web of Science

and Cochrane Central Register of Controlled Trials were deliberately sensitive and as follows, adapted for each database as needed:

1. Functional Family Therapy. 2. (trial\$ or outcome\$ or effect\$ or study or analysis or implementation). 3. 1 and 2.

Criteria for considering studies in this analysis.

Study Design. Trials that were focused on randomized controlled trials (RCTs) and quasi-experimental designs (QEDs) which met the Cochrane Effective Practice and Organization of Care Review Group criteria (Higgins & Green, 2002) were included however they were not the sole source of information relating to implementation, adaptation or fidelity details. The inclusion criteria designed for use in the recent overview of FFT was also utilized for this analysis, with necessary additions to capture implementation and process studies (see Weisman & Montgomery, 2018). Still, of the identified trials, many were necessarily excluded because of failure to comply with criteria relating to outcomes (e.g. reporting only length of silences, defensiveness or self-reported family function); not containing a specifically licensed FFT program; or inappropriate referral information of participants. Expansions, interpretations, independent adaptation, or otherwise non-specified FFT models were not included. Functional Family Therapy – Child Welfare (FFT-CW) Functional Family Probation and Parole (FFP) and Functional Family Therapy Gang (FFT-G), which are newly expanded versions with different elements and core components of FFT were not considered for inclusion in this analysis.

Process evaluations and observational studies with no comparator group were examined for implementation and fidelity information. These studies also must have observable outcomes and concrete ratable information relating to the results of the intervention. Complete screening and extraction forms can be supplied upon request.

Types of participants. Youth aged 10 – 18 presenting with behavioral problems including Oppositional Defiant Disorder (ODD), Conduct Disorder (CD), Attention Deficit Hyperactivity Disorder (ADHD), truancy, sexual misconduct, substance abuse and other acting out or delinquent actions. Youth at risk of removal from the home or returning after either placement or incarceration are also included.

Types of outcome measures reported. Implementation data were included and considered with regard to core outcomes of FFT which are as follows: reduction in recidivism rates, fewer and shorter duration in removals from the home, and reduction of substance use or abuse (Alexander et al., 2013). Acceptable objective outcome measures include police and court records, out of home placement or the termination of parental rights, drug screening tests and school reports of truancy, suspensions or expulsions. FFT LLC, the dissemination organization for FFT, propose in their training, media and outreach materials that follow up periods should last anywhere from immediately after the conclusion of treatment to five years post-intervention, and the three primary outcomes of FFT have been used as measurement of the intervention since its original development (Alexander et al., 2013). While the primary outcome measures for FFT are clearly outlined, for purposes of this implementation analysis objective data relating to dose, delivery, adherence, supervision, training of therapists and context were also included and analyzed. The role of the researcher performing the study was also noted, coded appropriately and examined for possible conflict of interest, determining whether they are a developer, designer or stakeholder in FFT, or otherwise have a vested interest in the outcome of the study.

Data extraction and analysis. A data collection form, based on that used in the overview was used and all data coded and put into an extraction sheet. The four domains of dose, delivery, uptake and context which are set forth in Montgomery et al. (2013), were adapted in line with

this framework to be specifically appropriate to this intervention. Supervision amount, quality, and the training of therapists was recorded and narratively synthesized. Numbers of unique individual participants were used to avoid “vote counting” as participant numbers vary considerably across studies. When possible, therapist ratings relating to supervision were informed by CSS data, as well as in accordance with proposed guidelines for the measurement and valuation of therapist supervision relating to psychiatry and psychology (Weerasekera, 2013; Fairburn & Cooper, 2011). All data were double-coded and a third party resolved any disagreements. For additional information regarding data collection contact first author.

Results

Results of the search

The search strategy yielded 150 records of which 102 were excluded at abstract level; 48 full texts were retrieved. These texts reported primary studies and after examination of texts 32 were excluded for failure to meet inclusion criteria; most commonly the study did not contain a specific and licensed FFT program or it was conducted before the formalization of the model (10 studies with $n = 419$), or outcome measures were not sufficient for inclusion (11 studies with $n = 1063$). See Table of Included Studies (Table 1) and Table of Excluded Studies (Table 2) in line with Cochrane Handbook methodology below (Higgins & Green, 2011). Finally, 16 trials or studies of FFT were included for analysis in this paper falling into the categories of RCTs ($n = 1363$), non-random assignment with comparison groups ($n = 3795$) and those trials with no comparison groups ($n = 156$). See the PRISMA chart below (Figure 1).

Included studies

Dose. The number of sessions or hours of contact was reported in 8 studies ($n = 1235$), and ranged from 9-24 sessions, or approximately 30 hours of treatment. FFT guidance requires

12-15 sessions to be completed in approximately 3-6 months. There was no evidence of overall effect found for dose on any significant outcomes (see Table 1). For example, in a single study (n = 135) families received 24 sessions (Friedman, 1989) and reported no significant differences on objective outcomes, but participants did report they felt satisfied with treatment. Darnell and Schuler (2015), a study containing 524 participants, report an average of 9 sessions, which is significantly below the recommended dosage, and results seem broadly in line with studies run by independent evaluators. However, one QED study (n = 187) examined the length of time to arrest as it related to the number of sessions completed. The authors suggest that “those teens who completed only six or less [sic] sessions were significantly more likely to be arrested sooner after intake compared to those attending seven or more sessions” (Sholevar, Baron, Aussetts, & Spiga, 2010).

Delivery and Uptake. These domains are essentially reported as number of sessions completed by both therapist and clients. In order to make any determinations specific to delivery and uptake separate from each other, information would need to be provided relating to how many sessions therapists attempted, or how many times therapists arrived for sessions, versus how many times clients did not attend. There are insufficient data reported that is specific to delivery or uptake in any of the included studies to enable this comparison, and there is no indication of variability between number of sessions provided and number of sessions attended.

Context. Across all studies, the racial composition was predominately white, middle class and from low risk environments or neighborhoods. When information was included relating to location, the intervention was most often delivered in the home. 5 RCTs contained 1363 unique participants, of which over two thirds were Caucasian and over half came from two-parent households (Alexander & Parsons, 1973; Friedman, 1989; Humayun et al., 2017; Sexton &

Turner, 2010; Waldron, Slesnick, Brody, Turner, & Peterson, 2001). Those studies with comparators (n = 3795) also contained a largely white participant group. Although one independently led study in this group (n = 187) held 76% African American participants from impoverished, violent and high risk urban areas. This study shows a longer time until subsequent arrest after completion of the program (Sholevar et al., 2010). Darnell and Schuler (2015) contained participants from a largely African American and Hispanic high-risk population. This study (n = 524) reports fewer out of home placements immediately after completion but “by 36 months post treatment all groups had similar out of home placement rates” (p. 78). Across the no-comparator studies, three of the four studies (n = 70) contained a predominately white and middle-class population located in Utah (Alexander, Barton, Schiavo, & Parsons, 1976; Barton, Alexander, Waldron, Turner, & Warburton, 1985; Mas et al., 1985).

Some research has indicated that the therapeutic relationship, specifically the ethnic matching between patient and provider, may be an important factor in positive outcomes (Cabral & Smith, 2011). Flicker et al (2008) was conducted in New Mexico and contained 86 participants, half of whom were Hispanic; in this case, outcomes showed a decrease in substance abuse when Hispanic clients were matched with Hispanic therapists.

A number of studies reported in their discussion that they suspect gender and age of the identified youth may have impacts on the objective outcomes of FFT. These studies also brought attention to possible gender alliances between therapists and identified clients and noted, “different therapist gender conditions create a context that elicits varying responses from both therapists and family members” (Mas et al., 1985, p. 414). Celinska et al (2013) also state that, in their study examining whether FFT participants improve across the seven domains covered in the Strength and Needs Assessment (SNA), the study “uncovered a significant reduction in

emotional and behavioral needs and in risk behavior among participants...Only male participants improved on the Child Strengths Scale"(Celinska et al., p. 32). This may suggest that FFT has a stronger effect in this area on male participants than their female counterparts.

Supervision amount, quality and adherence. Supervision *amounts, quality and adherence* vary greatly in their reporting and analyses across trials of whatever design although no trials were found whose primary aim was to assess the supervision element and the outcomes under study. From the data available, the supervision levels across any trial conducted by developers or stakeholders were rated highly on all measures (Alexander and Parsons, 1973 (n=86); Flicker et al, 2008 (n=86) ; Sexton and Turner, 2010 (n=917); Waldron et al., 2001 (n=114)). In regard to the RCTs, therapists received high amounts of consistent and intensive training, and sessions were supervised rigorously with expert FFT clinicians, with providers receiving between 1.5 to 6 hours of face to face supervision per week. In some studies, sessions were videotaped and rated for adherence to model guidelines and activities (Waldron et al., 2001; Flicker et al., 2008) and CSS was utilized to measure model adherence as well. Additionally, 3 of these 4 studies (n = 286) reported significantly positive effects on objective outcomes. Notably, the most recent of these studies, while being rated as containing high levels of both supervision and therapist training, reported that there were no significant differences between FFT and services as usual in adjudicated recidivism rates, but those therapists who were rated as highly adherent achieved better outcomes, and “results indicate that when practiced with model specific adherence FFT resulted in a significant 34.9% and 30% (respectfully [sic]) reduction in felony and violent crimes and a non-significant, 21.1% reduction in misdemeanor crimes” (Sexton & Turner, 2010, p. 346).

In contrast, the two independently conducted RCTs (n = 246) were rated as having low or unknown rates of supervision and clinical training; model specific training is also not rated highly and was not intensive. The supervision quality, time, and intensity were reported as far less comprehensive or there was no information reported relating to these elements (Friedman, 1989; Humayun et al., 2017). These two independently conducted RCTs found in one case that “no significant difference was found between the two groups in the degrees of improvement reported” (Friedman, 1989, p. 346). The other study “failed to show greater reductions in offending and antisocial behavior in the group allocated to FFT (Humayan et al., 2017, p. 1031). Information was not included in part because Friedman (1989) was conducted prior to CONSORT reporting guidelines. Neither of these independent studies reports significantly positive findings, and there is a lack of data relating to supervision amount and quality, although supervision may be part of the explanation.

Poorer reported supervision and oversight appeared to be a feature of the seven studies with quasi-experimental designs, (n= 3795), five were conducted by independent researchers (n = 3686) and were rated as having either unknown or low levels of supervision amount and quality. There was little information relating to intensity of therapist training with the model or therapist characteristics; supervision quality is not reported comprehensively (Baglivio et al., 2010; Barnoski, 2004; Celinska et al., 2013; Sholevar et al., 2010; Darnell & Schuler, 2015). These studies reported non-significant outcomes on primary outcome measures. Baglivio (2010) reported that they “found few significant differences in the effectiveness of the two modalities” (p. 1050); Barnoski (2004) states “18-month felony recidivism rate for the control group is 27 percent compared with 24 percent for the FFT group” (p. 4).

The two included QEDs (n = 109) conducted by developers of the model were rated as having high levels of supervision, clinical training and oversight, and both reported significantly positive outcome measures (Barton et al., 1985; Robbins et al., 1996). Barton et al. (1985) reported a reduction in recidivism of 33%, which is significantly lower than the rate for the region (63%) and was rated highly on supervision, training and oversight.

The 4 studies with no comparator and classified as observational or process focused contained a total of 156 unique participants. These studies were conducted by developers of FFT and were rated as having high levels of both supervision and therapist training with the model. All four studies reported positive outcomes on not just recidivism rates but also a lessening in defensiveness and increases in alliance (Barton et al., 1985; Alexander et al., 1976).

Therapist training. For the purposes of this analysis, training refers to the education, training, and years of experience of the clinicians in a broad sense, not to FFT-specific training. Providers of the model ranged in experience and training level from undergraduate students with no clinical experience (Barton et al., 1985) to doctoral level clinicians with over 10 years' experience treating individuals and families (Humayan, 2017). However, these matters were inconsistently reported across trials of all designs.

One study (n = 35), reports on an effort to determine whether significant levels of FFT-specific training and oversight would result in positive outcomes when therapy was being conducted by graduate students; therapists received intensive and comprehensive training with the model but had little or no experience as clinicians. Also, every session was supervised in this case. This study did not report significant effects on core outcome measures but did report positive outcomes on reduction of negativity and positive alliance with therapists (Robbins et al.,

1996). This finding is also demonstrated in Barton et al (1985) (n = 27) with the use of undergraduate students undergoing intensive FFT specific training and supervision.

Discussion

Summary of Main Results

This paper analyzed data relating to FFT in order to better understand how the intervention is influenced by implementation and fidelity issues based on an established assessment tool. Across study designs, RCTs, QEDs and observational, studies that are rated highly with regard to not only therapist supervision but specifically the amount and quality of that supervision, resulted in better core outcome results. Importantly, no studies, even those with low or moderate levels of supervisory amount and quality reported any harms which may be a feature of poor reporting practice. However they did *not* show significant effects on core outcome measures. Notably, none of the studies conducted by independent investigators rated highly on quantity or quality of supervisory and oversight measures, which may be attributed to a number of factors.

Potential Bias/Role of the Designers

Of the included studies, approximately half (9 studies containing 1382 participants) were undertaken by trialists who were either original designers and/or developers of the model. All but one of these studies reported positive outcomes (n=1355). Half (7 studies containing 3932 participants) by independent researchers and all but one of these reported null findings (n=3860). Research has shown that there is a possibility of trials and studies conducted by individuals who have an allegiance to the program models they are investigating producing significantly more positive results than those conducted by investigators without such allegiance (Shadish, 2002; Eisner, 2009). Allegiance may be present when even *one* member of a team may benefit, either

financially or otherwise, from a trial's reporting of positive findings (Eisner, 2009). Reported effect sizes of prevention and intervention trials have been shown to be noticeably larger when program developers are involved in contrast to those conducted by independent researchers (Eisner, 2009). The studies included in this implementation analysis demonstrate that those undertaken by the designers of the model do indeed report more significant effects. However, when the issue of implementation and fidelity are also examined, it may not be simply allegiance, but may be also attributable to the fact that the oversight and involvement of intervention designers, the supervision and training of providers, or simply trial size, has a positive influence on the outcomes.

Allegiance effects are not limited to direct fiscal gain of the developer but extends to any member of the research team who may have an interest in the outcomes and may benefit from the findings. The rise of 'best practice' lists may also contribute to biases, in part because these lists aid state and federal agencies in determining what programs will receive funding. This creates a "strong incentive to achieve inclusion on those lists, and there is little doubt that some researchers actively lobby for inclusion of their products in those lists" (Eisner, 2009, p. 171). Additionally, there may be ideological interests which may arise when researchers hold a strong position relating to core issues, and thus may become an advocate for their position that does not allow for them to investigate as objective scientists (Gorman, 2006).

It is important to note that positive effects of an intervention during a study conducted by 'developers-as evaluators' may be attributed to either a) the possibility that the quality of implementation is of a higher standard when it is delivered by a developer of the intervention or b) can be attributed to systemic bias relating to an ongoing conflict of interest by a champion of the program, and possibly related to financial factors (Eisner, 2009). Disentangling which of

these two possibilities is in play becomes paramount when we are attempting to understand what intervention model is most effective and for whom, and perhaps most critically, when we are examining possible harms relating to the uptake of a specified evidence-based model.

Strengths and Limitations of this Analysis

This study analyzed, in a rigorous manner, implementation factors relating to the delivery of FFT. The Oxford Implementation Index provided a useful structure to approach and perform this analysis, and by doing so has begun to clarify some concerning questions regarding the model and its delivery with varied and heterogenous populations.

Analysis of what works for whom is limited because the included studies contain participants who were predominately Caucasian and from middle class families in developed areas of the United States. Of 5314 participants only 111 come from outside the United States (Humayun, 2017), suggesting it may be that FFT implementation has not yet adequately addressed racial and socio-economic issues. The independent researchers flag this issue and pose the question of whether FFT outcomes are influenced by these factors (Celinska et al., 2013; Baglivio, et al., 2010; Barnoski, 2004). However, there is not enough information relating to participant characteristics and outcomes to ascertain the relationship of these issues to the delivery and outcomes of FFT. Also of note is the possibility that gender matching between therapist and youth has a positive influence on the outcomes of FFT, and while research has suggested this as well, there was not adequate data to determine whether this is the case (Wintersteen, Mensinger, & Diamond, 2005).

There have been recent adaptations of the FFT model specific to child welfare (FFT-CW) and youth involved with gangs (FFT-G). There has not yet been enough research reported on these models to include in this analysis, or for a consideration of whether these adaptations were

made with a more functionalist approach to implementation. Until there are more data relating to these adaptations it is not possible to arrive at evidence-informed decisions regarding their use and uptake.

Much of the implementation data were poorly reported, particularly in earlier studies which were conducted before the advent of CONSORT and other reporting guidelines. Future studies should consider using in particular the Tidier Guideline (Hoffman, 2014) and CONSORT- SPI (Montgomery et al., 2018).

Conclusions

This analysis sheds light on whether the effects found for FFT were influenced by differential implementation. Most striking of these is the possible connection between supervision quality and quantity with positive outcomes. Unsurprisingly studies led by the developers of the model rank higher in this area and may indicate that it is the supervision, oversight, and model specific training of therapists that allows them to achieve more success with the model. It may be, however, that it is not merely due to supervision and oversight, but to allegiance effects. The understanding of fidelity is important, as it has been flagged as integral to success of the model; it may not be fidelity in the strictest and most narrow understanding of the word, but a fidelity to the *function* rather than the *form*. It is with continued high quality and in-depth research into the mechanisms of change and implementation of the model, and how FFT is understood, adapted and delivered by therapists to best serve their clients, that we can better understand how to achieve positive effects across an increasingly heterogenous and disparate population of youth and families in need of treatment.

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* Indicates inclusion in analysis

