REVIEW ARTICLE



The effect of family-based therapy on child physical abuse and neglect: a narrative systematic review

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Accepted: 3 July 2023 / Published online: 27 July 2023 © The Author(s) 2023

Abstract

Family-based therapy is a common front-line strategy to prevent child maltreatment in high-risk families. This review aimed to systematically assess the evidence of the effect of family-based therapy programs on child maltreatment outcomes. CINAHL, Scopus and PsycINFO were systematically searched to March 25, 2023. Outcome data were extracted for child protection reports and out-of-home care (OOHC) placements from administrative data, and parent- or child-reported maltreatment risk. 12 RCTs and two observational studies of 8,410 screened were included. All 14 studies had high risk of bias. Sample sizes ranged from 43 in an RCT to 3875 families in an observational study. In seven studies with child protection report risk estimates, five studies (3 RCTs, 2 observational) showed results in favor of the intervention (risk differences (RD) of 2.0-41.1 percentage points) and two RCTs in favor of the comparison (RD, 2.0-8.6 percentage points). In the four studies with OOHC risk estimates, three studies (2 RCTs, 1 observational) showed results in favor of the intervention (RD, 0.9–17.4 percentage points) and one observational study showed results in favor of the comparison (RD, 1.5 percentage points). Most studies had≤100 participants, did not estimate main causal effects, and had high risk of bias. Thus, although family-based therapy programs may reduce child maltreatment, the high risk of bias, typically small sample sizes (>62% of studies had sample sizes < 100), and inconsistent results across studies means it is currently unclear whether family-based therapy interventions achieve better child maltreatment outcomes, compared with usual care services.

Keyword Systematic review · child maltreatment · child protection · child notifications · out-of-home care

The numbers of children in out-of-home care (OOHC) due to maltreatment has risen in high-income countries (Australian Institute of Health & Welfare, 2021; Children's Bureau, 2017; Department for Education, 2021) in recent decades. By age five,





1–6% of children have experienced ≥ 1 OOHC placement in Australia (Falster et al., 2021, Pilkington et al., 2019), Canada (O'Donnell et al., 2016) and the United States (US) (Putnam-Hornstein et al., 2013) with 2–3% of children by age 18 years in the US (Wildeman & Emanuel, 2014) and New Zealand (Rouland & Vaithianathan, 2018). Supporting families to keep children safe at home is important for children, families, communities, and connection to culture (Davis, 2019). There is substantial policy interest in interventions to support high-risk families to keep their children safe at home, driven by the imperative to protect vulnerable children and to reduce the numbers of children in OOHC, which is extremely costly for governments (Australia Productivity Commission, 2018; Broadhurst & Mason, 2013).

First adapted for child maltreatment in the 1980s (Alternative for Families: A Cognitive Behavioral Therapy, n.d.; Brunk et al., 1987) family-based therapy interventions are one of a suite of frontline services provided to families at high risk of physical abuse and neglect. Family-based therapy is broad in definition, with the main distinction from individual-based therapy being that it treats the family unit as a system, which may include parents, extended family and children (Carr, 2000; Pardeck, 1989; Skuse et al., 2017). In child protection, family-based therapy involves psychologists or social workers who engage with family members to modify home environments, behaviors and interaction patterns of parents and children, with the goal of reducing physical abuse and/or neglect so children can safely remain or reunify with their family (Carr, 2009, 2019; Pardeck, 1989).

Most family-based therapy programs for child maltreatment were developed in the US and are now implemented internationally (Carr, 2019). Investment in such programs is not insubstantial. For example, estimated program costs per family range from 16,000–22,000USD for Multisystemic Therapy for Child Abuse and Neglect (MST-CAN) (Swenson et al., 2010) in the US (Dopp et al., 2018) and Functional Family Therapy – Child Welfare (FFT-CW®) (Alexander et al., 2011) in Australia (Shakeshaft et al., 2021). The extent to which these programs are effective at reducing maltreatment and child protection contacts is of significant policy interest because of the imperative to improve child outcomes, as well as the substantial costs associated with program investment and OOHC (Australia Productivity Commission, 2018; Broadhurst & Mason, 2013).

Given there is no published evidence synthesis on the effectiveness of a suite of family-based therapies for child maltreatment outcomes, this review was motivated to inform government decision making about the potential outcomes that may result from investment in these interventions. In this study, we conducted a narrative systematic review of the evidence on the effect of family-based therapy programs on reducing physical abuse and neglect among high-risk or maltreated children. We focused on the policy-relevant outcomes of child protection reports and OOHC placements, and parent- and child-reported maltreatment risk.

Methods

This review was undertaken according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (Moher et al., 2009) and registered with the International Prospective Register of Systematic reviews (PROSPERO).



Study inclusion criteria

Study designs

We included randomized controlled trials (RCTs) and non-randomized observational published and unpublished studies in English if they: included a parallel cohort as a comparison group (i.e., groups observed at the same points in time); aimed to estimate the effect of family-based therapy interventions on physical abuse or neglect; and met the following criteria laid out under sub-headers below (more details in Appendix 1).

Population

Families with an assessment of high risk, or substantiated physical abuse or neglect, for ≥ 1 children aged 0–17 years. Studies of families with substantiated sexual abuse only were excluded.

Intervention

Family-based therapy interventions that aimed to reduce physical abuse and/or neglect among high-risk families, which may have been delivered as a component of licenced programs, including: family preservation, parenting and community-based programs; home support and case management services (more details in Appendix 2). Family-based therapy is a broad definition, which we operationalized as follows: a psychological or sociological family therapy component (e.g., systemic family therapy) was described in the treatment protocol; therapy was delivered by qualified health professionals including psychologists, social workers and/or counsellors; and multiple family members (e.g., parents and children), participated in family therapy sessions.

Comparators

Usual care services for families at high risk of maltreatment including, but not limited to: parenting programs, psychoeducation, case management, home support and visitation, behavioural and emotional regulation workshops, or waitlist.

Outcomes

Policy-relevant outcomes of maltreatment included: (i) child protection reports of alleged maltreatment to child protection agencies; and (ii) OOHC placements, including placement of a child in care outside the family home by a child protection agency. Parent- and/or child-reported measures of maltreatment risk or experience were also included.



Search strategy

CINAHL, Scopus and PsycINFO were systematically searched for studies prior to the most recent search date (March 25, 2023). The three electronic database searches included unpublished research consisting of thesis dissertations, government, committee and research reports, conference abstracts, news articles, factsheets and statistical datasets. Manual searches of forward and backward citations of studies selected for review were also conducted. Appendix 3 summarizes the search strategy, which included search terms: family therapy, therapy, intervention, child-parent relations, high-risk families, risk factors, vulnerable populations, child abuse, child neglect, child abuse and physical abuse for CINAHL, and family therapy, child abuse and child neglect for Scopus and PsycINFO.

Study selection

Two authors screened the titles/abstracts and full texts of 8410 articles for eligibility after removing duplicates. After every 100 titles/abstracts screened, the small number of discrepancies (3% abstracts, 2% full texts) were resolved with two additional co-authors.

Data extraction

Information was systematically extracted on: author, year, country, study design, sample size, family therapy program, program duration, comparator, study period, loss-to-follow up, participant demographics, substantiated abuse/neglect history, participating family members, intervention setting, and therapist qualifications.

For child protection reports and OOHC placement outcomes, we extracted the absolute risk, mean days and placement changes in the intervention and comparison group and measures of effect for between-group comparisons of post-treatment outcomes, where reported. For parent and child-reported measures of maltreatment risk, we extracted the mean scores in each group, mean differences and standardized measures of effect (i.e., Cohen's *d*) for between-group comparisons of post-treatment outcomes (see Appendix 4), which summarize the magnitude of the absolute difference relative to the standard deviation of the outcome (Maxwell, 2004). We did not extract the within-group comparisons of pre- and post-treatment outcomes reported in some studies because between-group comparisons are necessary to estimate causal effects (Bland & Altman, 2015).

Risk of bias assessments

We used the Cochrane Risk-of-Bias tool for randomized trials (RoB) 2 (Sterne et al., 2019) to assess risk of bias in RCTs as low, moderate or high on five domains, and overall. The Risk Of Bias In Non-randomized Studies – of Interventions



(ROBINS-I) assessment tool (Sterne et al., 2016) was used to assess risk of bias in observational studies as low, moderate, serious or critical on seven domains, and overall. Three authors assessed the risk of bias with input from co-authors.

Synthesis of results

We conducted a narrative synthesis of results. We concluded it was not meaningful, and in most cases not possible, to quantitatively synthesize the results in a meta-analysis for several reasons. Family-based therapy was often delivered as part of complex, sustained programs and the interventions varied across studies. No RCTs reported a main causal effect of the intervention by calculating the absolute or relative risk difference in post-treatment outcomes between the intervention and comparison groups. Some studies did not report numerators and/ or denominators for post-treatment outcomes and/or confidence intervals. We calculated crude risk differences as the closest estimate of an Intention-to-Treat (ITT) effect using post-treatment absolute risks; however, we were unable and/ or did not calculate standard errors/confidence intervals for the causal contrast because of small study samples or adjust for differences in pre-treatment prognostic factors. Cluster RCTs were analysed at the identical 'level' as the clustered allocation, meaning each participant was treated as if they were their own cluster. Although the two non-randomized observational studies reported odds ratios and standard errors for child protection reports and OOHC outcomes, one study did not include all participants or adjust for confounding.

We calculated the fragility index (Walsh et al., 2014) for the child protection report and OOHC outcomes in studies reporting statistically significant results (i.e., p < 0.05) (Kane, 2018). The fragility index is a summary of the impact of small sample sizes on effects. It estimates the number of additional families in the smaller group that would be required to have the event to obtain a non-significant result (i.e., p > 0.05).

Because most studies did not estimate a main causal effect of the intervention or report standard errors, we could not assess publication bias using funnel plots.

Results

Study selection

Database searches identified 7550 studies and manual reference and citation searches identified 1648 articles (Fig. 1). Fourteen studies published in English met inclusion criteria; 12 RCTs (including one cluster RCT) and two non-randomized observational studies. Study participants had a substantiated maltreatment history in 10/14 studies (physical abuse in 3, neglect in 1, both in 6) and therapists had relevant tertiary qualifications in 11/14 studies; however, these inclusion criteria were not reported in all studies (Appendix 5).



Study characteristics

RCTs

Findings from eleven RCTs in the US and one in Australia were published between 1996 and 2021, including 9/12 since 2010 (Table 1). Average study sample size was 99 families, ranging from 44–195. Intervention and comparison groups included 18 vs. 12 families in the smallest RCT and 122 vs. 73 families in the largest RCT. Study follow-up ranged from 0 days to 24 months after completing treatment. Interventions were delivered in the home (4/12) and/or clinic or community settings (10/12) for 12–34 weeks. Comparison group families received usual care services or an alternative program (Table 1, Appendix 2).

Non-randomized observational studies

Two non-randomized observational studies were conducted in the US in 2013 and 2017. One study included 43 families (25 intervention, 18 usual care) to examine the effectiveness of the Multisystemic Therapy – Building Stronger Families (MST-BSF) program versus Comprehensive Community Treatment. The other study included 3875 families (1625 intervention, 2250 usual care) to examine the Functional Family Therapy – Child Welfare (FFT-CW®) program versus usual care. Both interventions were delivered in the home for 6–9 months, with study follow-up between 7–18 months post-treatment.

Risk of bias

Risk of bias for RCTs

All RCTs had a high overall risk of bias using the ROB-2 (Sterne et al., 2019) (Fig. 2). There were some concerns about the randomization process in all RCTs, mostly because allocation sequence concealment or pre-treatment characteristics were not reported, or pre-treatment prognostic factors differed between groups. All but one RCT (Runyon et al., 2010) had a high risk of bias on domain two, largely because blinding participants to the intervention was not possible and main causal effects were not reported for all outcomes. Risk of bias due to missing child protection service outcome data was low (Kolko, 1996; Schaeffer et al., 2021; Swenson et al., 2010) and high (Chaffin et al., 2004, 2011; Kolko et al., 2018) in three RCTs apiece. Risk of bias due to missing self-reported outcome data was low in five RCTs (Foley et al., 2016; Kolko, 1996; Schaeffer et al., 2021; Swenson et al., 2010; Villodas et al., 2021) and high in five RCTs (Donohue et al., 2014; Kolko et al., 2018; Meezan & O'Keefe, 1998; Runyon et al., 2010; Thomas & Zimmer-Gembeck, 2011). There were no sensitivity analyses on the impact of selection bias due to missing outcome data. Risk of bias for measurement of child protection report/OOHC outcomes was low in the six RCTs reporting these outcomes (Chaffin et al.,



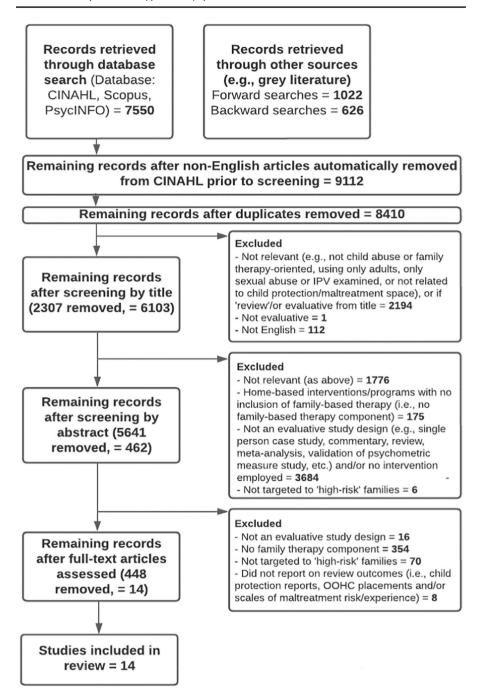


Fig. 1 PRISMA flowchart for included studies in the narrative systematic review



 Table 1
 Characteristics of studies included in review

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Author/ year	Country	Design	Intervention (Family-based therapy program ^a)	Intervention duration	Comparator ^b	Sample size at Duratior enrolment (No. of baseline families)	Duration of study period since baseline	Loss to follow up / missing outcome data, by outcome N (%)
Randomized Controlled Trials (RCTs	ntrolled Tria	ls (RCTs)						
Schaeffer et al. USA (2021)	USA	RCT	Multisy stemic Therapy – Building Stronger Fami- lies (MST-BSF)	6-9 months	Usual care	Total = 98 MST-BSF = 51 Usual care = 48	18 months	CP reports: 0 (0%) for both; OOHC: 0 (0%) for both Self-report measures: 0 (0%) for both
Villodas et al. (2021)	USA	RCT	Parent Child Interaction Therapy (PCIT)	Average of 10-83 sessions Usual care	Usual care	Total=55 PCIT=26 Usual care=29	18 months	CP reports: Not measured OOHC: Not measured Self-report measures: PCIT = 14 (54%); Usual care = 20 (69%)
Kolko et al. (2018)	USA	RCT	Alternatives for Families: Cog- nitive Behav- ioral Therapy (AF-CBT)	Average of 80 h over 24 weeks (Range, 1–66)	Usual care	Total = 195 AF-CBT = 122 Usual care = 73	18 months	CP reports: AF-CBT = 28 (23%); Usual care = 12 (16%) OOHC: Not measured Self-report measures: AF-CBT = 55 (55%, 18 mth); Usual care = 38 (48%, 18 mth)
Foley et al. (2016)	USA	RCT	Group format Parent Child Interaction Therapy (PCIT)	12 weeks	Usual care	Total = 44 PCIT = 20 Usual care = 24	12 weeks	CP reports: Not measured OOHC: Not measured Self-report measures: PCIT = 1 (5%); Usual care = 2 (4%)



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Author/ year	Country	Design	Intervention (Family-based therapy program ^a)	Intervention duration	Comparator ^b	Sample size at enrolment (No. of families)	Duration of study period since baseline	Loss to follow up / missing out- come data, by outcome N (%)
Donohue et al. (2014)	USA	RCT	Family Behavior Therapy (FBT)	6 months	Usual care	Total = 72 FBT = 35 Usual care = 37	10 months	CP reports: Not measured OOHC: Not measured Self-report measures: FBT = 11 (31%, 6 mth); 9 (26%, 10 mth); Usual care = 6 (16%, 6 mth); 5 (14%, 10 mth)
Chaffin et al. (2011)	USA	RCT	Self-motivation and Parent Child Interac- tion Therapy (PCIT) (com- bined)	Not specified	Usual care	Total = 153 PCIT = 70 Usual care = 83	Median, 904 days (129 weeks); Range, 229 to 1,282 days (33– 183 weeks)	CP reports: Not reported OOHC: Not reported Self-report measures: Not measured
Thomas & Zimmer- Gem- beck (2011)	Australia	RCT	Parent Child Interaction Therapy (PCIT)	12 weeks	Waitlist	Total = 150 PCIT = 99 Waitlist = 51	Mean = ~28.3 weeks	CP reports: Not reported OOHC: Not measured Self-report measures: PCIT = 57 (58%); Usual care = 15 (29%)
Runyon et al. (2010)	USA	RCT	Combined Parent-Child Cognitive Behavioral Therapy (CPC-CBT)	16–20 weeks	Parent-Only Cog- nitive Behavioral Therapy (CBT)	Total = 75 CPC-CBT = 40 Parent-Only CBT = 35	16–20 weeks of treatment (plus 3-months follow-up)	CP reports: Not measured OOHC: Not measured Self-report measures: CPC-CBT = 20 (50)%; Usual care = 21 (60%)



Table 1 (continued)	inued)							
Author/ year	Country	Design	Intervention (Family-based therapy program ^a)	Intervention duration	Comparator ^b	Sample size at enrolment (No. of families)	Duration of study period since baseline	Loss to follow up / missing outcome data, by outcome N (%)
Swenson et al. (2010)	USA	RCT	Multisy stemic Therapy for Child Abuse and Neglect (MST-CAN)	Average, 7.6 months; Range, 2–12 months	Enhanced Outpatient Therapy (EOT)	Total = 87 MST-CAN = 44 EOT = 43	16 months	CP reports: 0 (0%) for both; OOHC: 0 (0%) for both Self-report measures: MST-CAN=0 (0%); EOT=1 (2%)
Chaffin et al. (2004)	USA	RCT	Parent Child Interaction Therapy (PCIT)/ Enhanced PCIT	12–14 sessions, approx. 6 months	Usual care	Total = 110 PCIT = Not reported EPCIT = Not reported Usual care = Not reported	Median = 850 days	CP reports: Not reported OOHC: Not measured Self-report measures: Not measured
Meczan & O'Keefe (1998)	USA	RCT	Multifamily Group Therapy (MFGT)	34 weeks	Usual care	Total = 81 MFGT = 42 Usual care = 39	8 months	CP reports: Not measured OOHC: Not measured Self-report measures: MFGT = 12 (29%); Usual care = 16 (41%)
Kolko (1996)	USA	RCT	Family Therapy (FT)	12×1-h weekly sessions for 16 weeks	1) CBT only; 2) Usual care	Total = 55 FT = 18 CBT = 25 Usual care = 12	16 months (16 weeks treatment plus 12 months post treatment)	CP reports: FT = 1 (6%); $CBT = 5$ (20%); Usual care = 2 (17%) OOHC: Not measured Self-report measures: FT = 1 (6%); $CBT = 5$ (20%); Usual care = 2 (17%)



Table 1 (continued)

l at l	uthor/ year Country Design	Design	Intervention (Family-based therapy program ^a)	Intervention duration	Comparator ^b	Sample size at Duration enrolment (No. of baseline families)	Sample size at Duration of study period since Loss to follow up / missing ourenrolment (No. of baseline come data, by outcome N (%) families)	Loss to follow up / missing ourcome data, by outcome N (%)
5 D	Von-randomized observation (2017)	Non-randomized observational studies 'urner et al. USA Cohort (2017)	Functional Fam- 6–9 months ily Therapy – Child Welfare (FFT-CW®)	6–9 months	Usual care	Total = 3875 FFT-CW®= 1625 Usual care = 2250	16 months	CP reports: Not reported OOHC: Not reported Self-report measures: Not measured
Schaeffer et al. USA (2013)	SA	Cohort	Multisy stemic Therapy – Building Stronger Fami- lies (MST-BSF)	6–9 months	Usual care	Total = 43 MST-BSF = 25 CCT = 18	24 months	CP reports: 0 (0%) for both; OOHC: 0 (0%) for both Self-report measures: MST-BSF=2 (8%) Usual care = Not reported

Enhanced Outpatient Therapy; EPCIT, Enhanced Parent Child Interaction Therapy; FBT, Family Behavioral Therapy; FT, Family Therapy; FT-CW®, Functional Family Therapy – Child Welfare; MFGT, Multispatienily Group Therapy; MST-BSF, Multisystemic Therapy – Building Stronger Families; MST-CAN, Multisystemic Therapy for AF-CBT, Alternative for Families: Cognitive Behavioral Therapy; CP, child protection; CPC-CBT, Combined Parent-Child Cognitive Behavioral Therapy; BOT, Child Abuse and Neglect; OOHC, out-of-home care; PCIT, Parent Child Interaction Therapy; RCT, randomized controlled trial

^a Brief intervention descriptions provided in Appendix 2

^b Brief comparator descriptions provided in Appendix 2

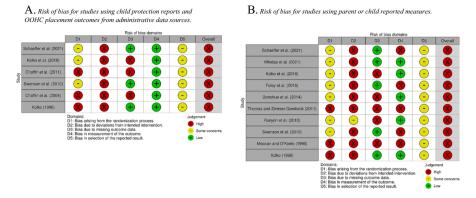


Fig. 2 Summary of risk of bias assessment for included randomized controlled trials

2004, 2011; Kolko, 1996; Kolko et al., 2018; Schaeffer et al., 2021; Swenson et al., 2010). In the ten RCTs reporting self-reported outcome measures (Donohue et al., 2014; Foley et al., 2016; Kolko, 1996; Kolko et al., 2018; Meezan & O'Keefe, 1998; Runyon et al., 2010; Schaeffer et al., 2021; Swenson et al., 2010; Thomas & Zimmer-Gembeck, 2011; Villodas et al., 2021), five had high risk of bias because blinding outcome assessors to treatment allocation was not possible and/or not clearly reported (Foley et al., 2016; Meezan & O'Keefe, 1998; Schaeffer et al., 2021; Swenson et al., 2010; Thomas & Zimmer-Gembeck, 2011). None of the RCTs reported pre-specified protocols resulting in some concerns about the potential for selected reporting.

Risk of bias for observational studies

The overall risk of bias was high in both observational studies (Fig. 3) (Schaeffer et al., 2013; Turner et al., 2017). Lack of reporting on loss to follow-up, missing outcome data and pre-specified protocols were issues. There was also concern about bias due to confounding in the analysis of child protection report outcomes in one study (Turner et al., 2017).

Child protection report outcomes

Six RCTs (Chaffin et al., 2004, 2011; Kolko, 1996; Kolko et al., 2018; Schaeffer et al., 2021; Swenson et al., 2010) and two observational studies (Schaeffer et al., 2013; Turner et al., 2017) examined child protection report outcomes using child protection service data.



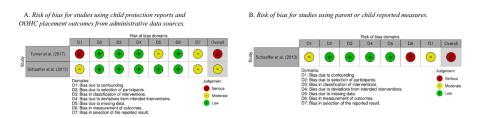


Fig. 3 Summary of risk of bias assessment for included non-randomized observational studies

RCTs

The post-treatment risk of \geq 1 child protection reports were extracted for the intervention and comparison groups in 5/6 RCTs (Chaffin et al., 2004; Kolko, 1996; Kolko et al., 2018; Schaeffer et al., 2021; Swenson et al., 2010), which we used to calculate risk differences as a policy-relevant measure of the ITT effect (Table 2). In three RCTs (Chaffin et al., 2004; Kolko, 1996; Swenson et al., 2010), risk differences were in favor of the intervention group, ranging from -7.4 to -30.0 percentage points in the 8–24 months after completing the intervention (Table 2). In two RCTs (Kolko et al., 2018; Schaeffer et al., 2021), there was a risk difference of 2.0 and 8.6 percentage points in favor of the comparison group. Fragility indexes for the four RCTs ranged from 0 to 3. This means that if up to 3 families had experienced the opposite outcome to the one recorded, the finding of a statistically significant effect (at p < 0.05) would have become non-significant.

In the remaining RCT (Chaffin et al., 2011), it was not possible to calculate the risk difference for child protection reports or fragility indexes. The authors in this study reported the numerator (for reports) and denominator for the entire study sample (58/153, 38%), but did not report numerators and denominators for the intervention (i.e., PCIT) or usual care groups, which are necessary to estimate the main causal effect of PCIT versus usual care.

Observational studies

The child protection report risk was lower in the intervention group than the comparison group, with risk differences of -2 and -41.1 percentage points and fragility indexes of 2 and 6 in the two observational studies (Table 2) (Schaeffer et al., 2013; Turner et al., 2017). One study reported an adjusted odds ratio of 5.01 (95% CI, 1.03–24.32) based on a sample of 43 families: 5/25 families (20%) in the intervention group, and 11/18 families (61.1%) in the comparison group had ≥ 1 reports (Schaeffer et al., 2013).

Out-of-home care placement outcomes

Three RCTs (Chaffin et al., 2011; Schaeffer et al., 2021; Swenson et al., 2010) and two observational studies (Schaeffer et al., 2013; Turner et al., 2017) reported OOHC placement outcomes.



Table 2 The absolute risk of ≥ 1 child protection reports and the main effect estimates for the intervention vs. comparator

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Study author/year	Intervention group	dnı	Comparison group	dn	Main Effect Estimate	Fragility Index ^{\$}	Fragility Index ^{\$} Comments on methods and results
	(%) N/u		(%) N/u				relevant to estimating the main causal effect of the intervention
	Baseline	E/U	Baseline	F/U			
RCTs (crude risk differences calculated from reported data)	ences calculated f	rom reported data)					
Schaeffer et al. (2021) 37/51 (72·5%) 12/51 (23·5%)	37/51 (72-5%)	12/51 (23·5%)	35/46 (76.6%) 7/47 (14.9%)		Crude risk differ-	0	 Pre-treatment factors prognostic of
					8.6% ence		the outcome were reportedly similar
							between groups, but some qualitative
							differences were evident in reported
							descriptive statistics
							 Intervention and comparison group
							numerators were calculated based on
							denominators reported in Fig. 1. Base-
							line numerator for comparison group
							was calculated from denominator and
							CP information reported in Table 2
							 The closest estimate of a main causal
							effect is the crude risk difference of
							8.6% at the end of follow-up
							 No effect estimates were adjusted for
							differences in pre-treatment factors
							prognostic of the outcome
							 There may have been an effect in
							favor of usual care, compared with the
							intervention

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Study author/year	Intervention group	dn	Comparison group	dno	Main Effect Estimate	Fragility Index ^{\$}	
	(%) N/u		n/N (%)				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
Kolko et al. (2018)	16/94 (17.0%)	5/94 (5·3%)	8/61 (13·1%)	2/61 (3.3%)	Crude risk difference = 2%	0	Cluster randomized trial; service providers were randomized to the intervention
							• Pre-treatment factors prognostic of the outcome were reportedly similar between groups, but some qualitative differences were evident in reported descriptive statistics
							Within-group comparisons of pre- and post-treatment outcomes were reported. Between-group comparisons of post-treatment outcomes were not reported, which are necessary for estimating causal effects of interventions
							• The closest estimate of a main causal effect is the crude risk difference of 2% at the end of follow-up
							No effect estimates were adjusted for differences in pre-treatment factors prognostic of the outcome
							• There may have been a small, if any, effect in favor of usual care, compared with the intervention

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Study author/year	Intervention group	dno	Comparison group	dno	Main Effect Estimate	Fragility Index ^{\$}	Fragility Index ^{\$} Comments on methods and results
	(%) N/u		(%) N/u				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
Swenson et al. (2010) 10/44 (22.8%)	10/44 (22.8%)	2/44 (4·5%)	10/42 (23.8%)	10/42 (23.8%) 5/42 (11.9%)	Crude risk difference = -7.4%	0	Pre-treatment factors prognostic of the outcome were reportedly similar between groups, but some qualitative differences were evident in reported descriptive statistics
							• Crude risk of CP reports at the end of follow-up were reported, but no causal effect was estimated
							• The closest estimate of a main causal effect is the crude risk difference of -7.4% at end of follow-up
							No effect estimates were adjusted for differences in pre-treatment factors prognostic of the outcome
							• The intervention may have had a beneficial effect on CP reports, compared
							with enhanced outpatient therapy, although there may be residual
							contolinging



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Study author/year	Intervention group	dno	Comparison group	dno	Main Effect Estimate	Fragility Index ^{\$}	Fragility Index ^{\$} Comments on methods and results
	(%) N/u		n/N (%)				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
Chaffin et al. (2004)	Unclear	PCIT: 8/N (19%)	Unclear	17/N (49%)	Crude risk difference PCIT vs. UC=-30-0%	PCIT vs. UC=3	Pre-treatment factors prognostic of the outcome were reportedly similar between groups; however, descriptive statistics of pre-treatment characteristics were not reported Crude risk of CP report at the end of follow-up and survival curves for each
							group were reported The main causal effect of the interventions (i.e., PCIT and EPCIT) compared with usual care were not reported; instead, a model with attrition pattern and intervention group included as an interaction term was reported
		EPCIT: 12/N (36%)			EPCIT vs. UC=-13.0% EPCIT vs. UC=0	EPCIT vs. UC=0	 Use of post-baseline information on attrition introduces bias when attempting to estimate an ITT effect The closest estimate of main causal effect are crude risk differences (-30.0%, -13.0%) at end of follow-up
							• The interventions (PCIT and EPCIT) may have had a beneficial effect on CP reports, compared with usual care, although there may be residual confounding

• No effect estimates were adjusted for differences in pre-treatment factors

have had beneficial effects on CP reports relative to usual care, although there may be residual confounding

prognostic of the outcome
• The interventions (FT and CBT) may

lable 2 (continued)							
Study author/year	Intervention group	dnı	Comparison group	roup	Main Effect Estimate	Fragility Index ^{\$}	Fragility Index ^{\$} Comments on methods and results
	(%) N/u		(%) N/u				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
Kolko (1996)#	FT: 5/N (28%)	FT: 5/N (28%) FT: 2/N (12%) 5/N (42%)	5/N (42%)	3/N (30%)	Crude risk difference FT vs. UC = -18%	FT vs. $CBT = 0$	FT vs. CBT=0 • Pre-treatment factors prognostic of the outcome were reportedly similar
	CBT: 5/N (20%)	(20%) CBT: 2/N (10%)			CBT vs. $UC = -20\%$	CBT vs. $UC=0$	between groups, except for racial background; however, descriptive sta-
							tistics of pre-treatment characteristics
							• Crude risk of CP reports at the end of
							follow-up were reported, but no causal
							effect was estimated
							• The closest estimate of a main causal
							effect is the crude risk difference of
							-18% at the end of follow-up



Table 2 (continued)

Table 2 (continued)							
Study author/year	Intervention group	group	Comparison group	roup	Main Effect Estimate	Fragility Index ^{\$}	I -
	(%) N/u		(%) N/u				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
RCTs (crude risk differ	rences unable to	RCTs (crude risk differences unable to be calculated from reported data)	orted data)				
Chaffin et al. (2011)* Unclear	Unclear	PCIT + SM: n/N	Unclear	UC-SM: n/N	UC-SM: n/N No main effect for PCIT		 Pre-treatment factors prognostic of
		(29%)		(41%)	vs. UC reported		the outcome were reportedly similar
		PCIT-SM: n/N		UC+SM: n/N			between groups; however, descriptive
		(47%)		(34%)			statistics of pre-treatment characteris-
							tics were not reported
							 Survival curves for each group were
							reported
							• The main causal effect of the interven-
							tion (i.e., PCIT) compared with usual
							care was not reported; instead, a
							model with attrition pattern and inter-
							vention group included as an interac-
							tion term was reported. The use of
							post-baseline information on attrition
							may introduce bias when attempting
							to estimate an ITT effect
							 Although the numerator (for CP
							reports) and denominator were
							reported for the entire study sample
							(58/153; 38%), they were not reported
							separately for each group. Therefore,
							it was not possible to estimate a crude
							risk difference for the main effect of
							PCIT vs usual care
							 Fragility index unable to be calculated

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Idole 2 (Continued)							
Study author/year	Intervention group	dno	Comparison group	dno.	Main Effect Estimate	Fragility Index ^{\$}	-
	(%) N/u		(%) N/u				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
Non-randomized observational studies	ervational studies					,	
Turner et al. (2017)	n/N (52·4%)	n/N (8%)	n/N (61-0%)	n/N (10%)	Crude risk differ- ence=-2%	9	 Families in the intervention and usual care groups differed on some pre- treatment factors that may confound the exposure-outcome relationship in this observational study
							• Although the authors stratified CP report outcomes in the intervention and usual care groups by two pre-treatment differences (i.e., domestic violence allegation histories and mental health histories), these comparisons do not equate to main causal effects of the intervention. Furthermore, no other confounders were considered
					Crude odds ratio = 0.788 (SE, 0.091)	∞	• The closest estimates to a causal effect are the crude risk difference of -2% and crude odds ratio of 0.788 at the end of the study period among the subset of families with ≥ 1 preservice allegations (Ns in each group not reported)
							• Although the intervention may have had a small beneficial effect on CP reports among some families within 18–24 months of starting the intervention, confounding has not been addressed in this observational study. Furthermore, CP report outcomes were not reported for the entire study sample.



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lable 2 (collulacu)							
Study author/year	Intervention group	dno	Comparison group	dn	Main Effect Estimate	Fragility Index ^{\$}	Fragility Index ^{\$} Comments on methods and results
	(%) N/u		(%) N/u				relevant to estimating the main causal effect of the intervention
	Baseline	F/U	Baseline	F/U			
Schaeffer et al. (2013) 24/25 (96%)	24/25 (96%)	5/25 (20%)	15/18 (83:3%)	11/18 (61-1%)	15/18 (83.3%) 11/18 (61.1%) Crude risk differ- ence = 41.1% Adjusted odds ratio = 5.01 (95% CI, 1.03-24.32)	2	• Pre-treatment factors prognostic of the outcome were reportedly similar between groups, and imbalances in some baseline characteristics were adjusted for in models to estimate the causal effect of the intervention • The best estimates of a main causal effect are the crude risk difference of -41.1% and adjusted odds ratio of 5.01 (95% CI, 1.03-24.32) at the end of follow-up. The wide confidence intervals for the OR reflect the small sample • The intervention may have had a beneficial effect on CP reports, although
							there may be residual confounding

F/U, follow-up; CBT, Cognitive Behavioral Therapy; CI, confidence interval; CP, child protection; EPCIT, Enhanced Parent Child Interaction Therapy; FT, Family Therapy; OR, odds ratio; PCIT, Parent Child Interaction Therapy; RCT, randomized controlled trial; SE, standard error; SM, Self Motivation; UC, Usual care

* Chaffin et al. (2011) recruited 153 families in total, including 70 families randomized to PCIT and 83 families to usual. However, the numbers randomized to PCIT±Self # Authors reported drop-out from program for N=1, N=5 and N=2 for FT, CBT and Usual care, respectively. Child protection outcome data obtained for 47 families, Motivation (SM) or Usual Care ± SM were not reported

^ Numbers not provided, only percentages (10% vs. 8%). Unclear if this is FFT-CW/UC sample size or indicative of individuals (n = 6249) who had recurring pre-service allegations (but unclear how many are in FFT-CW and usual care)

\$ A fragility index of 0 indicates p values were > 0.05 for these comparisons

(i.e., the total number of families that completed each program)



RCTs

The absolute risk of ≥ 1 OOHC placement in the intervention and comparison groups were extracted for 2/3 RCTs (Table 3) (Schaeffer et al., 2021; Swenson et al., 2010). The risk difference was -0.9 and -17.4 percentage points in favor of the intervention group (Table 3). In the other RCT (Chaffin et al., 2011), it was not possible to calculate the risk difference for OOHC placement because the authors only reported the numerator (for OOHC) and denominator for the entire study sample (58/153, 38%) rather than the intervention and comparison groups. Three RCTs (Donohue et al., 2014; Schaeffer et al., 2021; Swenson et al., 2010) reported mean days in OOHC in each group, with between group differences ranging from 8.6 to -36.4 days in the 10-18 months post-baseline follow-up (Appendix 6). One RCT (Swenson et al., 2010) reported placement changes in OOHC in each group, with a between group difference of -0.51 changes in the 16-months of post-baseline follow-up (Appendix 7).

Observational studies

In a study of 43 families (Schaeffer et al., 2013), there was a risk difference of -15.8 percentage points in favor of the intervention group and fragility index of 2 (Table 3). The authors reported an adjusted odds ratio of 3.12 (SE=1.13) for the between group comparison of OOHC placement risk, as well as a difference of -44.4 mean days in OOHC (Appendix 6) and -0.5 placement changes (Appendix 7) in the 24-months post-baseline (Schaeffer et al., 2013). In a study of 3875 families (Turner et al., 2017), OOHC placement risk was higher in the intervention group compared to usual care, with a risk difference of 1.5 percentage points and fragility index of 9.

Parent- and child-reported measures of physical abuse and neglect risk/experience

Although eleven included studies (10 RCTs: Donohue et al., 2014; Foley et al., 2016; Kolko, 1996; Kolko et al., 2018; Meezan & O'Keefe, 1998; Runyon et al., 2010; Schaeffer et al., 2021; Swenson et al., 2010; Thomas & Zimmer-Gembeck; Villodas et al., 2021, 1 observational: Schaeffer et al., 2013)) administered parent or child-reported measures of maltreatment risk (Tables 4 & 5, Appendix 8), standardized pooled measures of effect for between-group differences were only reported in 3 RCTs (Table 4) (Runyon et al., 2010; Thomas & Zimmer-Gembeck, 2011; Villodas et al., 2021). One RCT of 75 families reported moderate benefits of family-based therapy on the incidence of physical abuse (d=0.47), with the reverse association observed using the parent-reported measure (d=-0.57) (Runyon et al., 2010). A second RCT of 55 families reported a small beneficial effect of family-based therapy on the parent-reported measure (d=-0.13) (Villodas et al., 2021) whereas a third RCT of 150 families showed a marginally



beneficial effect of usual care on the risk of abuse and neglect (d=0.08) (Thomas & Zimmer-Gembeck, 2011).

In seven RCTs (Donohue et al., 2014; Foley et al., 2016; Kolko, 1996; Kolko et al., 2018; Meezan & O'Keefe, 1998; Schaeffer et al., 2021; Swenson et al., 2010) and one observational study (Schaeffer et al., 2013), the authors reported withingroup differences pre- and post- intervention for three measures and/or their relevant subscales (Table 5, Appendix 8).

Discussion

Summary of evidence

We systematically reviewed 12 RCTs and two non-randomized observational studies of family-based therapy programs for families with high risk or substantiated maltreatment, published between 1996 and 2021. The sample sizes of RCTs ranged from 44 to 195 families. The overall risk of bias was high in all studies, which was, in part, due to inherent challenges in recruitment and retention of families and outcome measurement in high-risk populations. However, there are opportunities to strengthen approaches to minimising bias and interpreting its impact when reporting study findings in child maltreatment intervention research. Evidence from three RCTs (Chaffin et al., 2004; Kolko, 1996; Swenson et al., 2010) and one observational study (Schaeffer et al., 2013) suggest family-based therapies may reduce the recurrence of physical abuse or neglect, compared with usual care up to 24-months post-treatment. In contrast, two RCTs (Kolko et al., 2018; Schaeffer et al., 2021) and one observational study (Turner et al., 2017) found a lower risk of child protection reports and OOHC placements in families receiving usual care, compared with family-based therapy. Fragility index calculations show that the statistical significance of the findings from all RCTs may have reversed if ≤ 3 children in the intervention or comparison group had experienced a different outcome to the one recorded. Although family-based therapy may have benefits for vulnerable families, studies published to date do not provide consistent, low biased evidence on whether family-based therapy reduces physical abuse or neglect among high-risk families, compared with usual care services. Our finding is similar to another recent systematic review that found mixed evidence of program efficacy across outcomes within and between RCTs published to date for Multisystemic Therapy programs (MST) that aim to improve child and adolescent behavioral, psychosocial and psychiatric outcomes (Littell et al., 2021).

Of the reviewed RCTs, the least biased evidence of the effect of a family-based therapy intervention on maltreatment outcomes comes from an RCT of 87 families randomized to Multisystemic Therapy for Child Abuse and Neglect (MST-CAN) or Enhanced Outpatient Therapy in the USA in 2010 (Swenson et al., 2010). In this study, results showed the MST-CAN program reduced the risk of child protection reports by 7.4% (based on 2/44 families in the intervention and 5/42 families in the comparison group) and OOHC placements by 17.4%



(based on 6/44 families in the intervention and 13/42 families in the comparison group) within approximately eight months of completing treatment. However, the results were fragile due to the small sample size. There was also a high overall risk of bias when considering the reported child protection and parent- and child-reported outcomes.

Of the observational studies, the Turner et al. (2017) study recruited 3875 families in the USA, which was the largest sample size of included studies in this review. Turner et al. (2017) reported the absolute risks of child protection reports and OOHC placements for children in the Functional Family Therapy - Child Welfare (FFT-CW®) and the usual care groups, within strata of several confounding factors, such as parental substance abuse and mental health. Beyond this descriptive analysis, the reported odds ratios (0.788 for child protection reports; 1.36 for OOHC) did not appear to be adjusted for multiple confounders, which is necessary to estimate unbiased program effects in observational studies. Our crude risk difference estimates suggest only small absolute differences in child protection report and OOHC outcomes between the FFT-CW and usual care groups (-2 and 1.5 percentage points, respectively). In contrast, the other observational study of 43 families in the US who received Multisystemic Therapy – Building Stronger Families (MST-BSF), or usual care, had a comparatively lower risk of bias, including > 90% ascertainment of study outcomes and adjustment for multiple confounders (Schaeffer et al., 2013). Although the Schaeffer et al. (2013) findings suggest MST-BSF may reduce the risk of child protection reports by 41.1% (based on 5/25 families in the intervention and 11/18 families in the comparison group) and OOHC placements by 15.8% (based on 3/25 families in the intervention and 5/18 families in the comparison group) in the 24-months since baseline, we found that the results were extremely fragile due to small numbers.

Strengths

This systematic review examined the effect of family-based therapies on the policy-relevant outcomes of child protection reports and OOHC placements. We reviewed 14 studies in accordance with PRISMA and Cochrane guidelines (Moher et al., 2009). We used the RoB 2 (Sterne et al., 2019) and ROBINS-I (Sterne et al., 2016) tools to assess the risk of bias, which were developed for studies examining the efficacy and effectiveness of clinical and pharmacological interventions, respectively. Although the same potential sources of bias are relevant when evaluating the effect of interventions for child maltreatment, it may be challenging to overcome some biases in studies of complex, sustained interventions for vulnerable families. For example, retention of vulnerable families in treatment and outcome measure collection are common challenges. It is also unrealistic to blind participants and therapists to treatment allocation, which is common in RCTs of pharmacological interventions.



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y author/	Intervention	Intervention Group Events n/N (%)	Comparison Gr	Comparison Group Events n/n (%)	Main Effect	Fragility index ^{\$}	Comments on methods and results relevant to estimating
year	Baseline	F/U	Baseline	F/U	Estimate		the main causal effect of the intervention
RCTs (crude ris	k differences	RCTs (crude risk differences calculated from reported data)	1 data)				
Schaeffer et al. (2021)	5/51 (9.8%)	5/51 (9.8%) 18/51 (35.3%)	2/46 (4.3%)	17/47 (36.2%)	Crude risk difference = -0.9%	0	• Pre-treatment factors prognostic of the outcome were reportedly similar between groups, but some qualitative differences were evident in reported descriptive statistics. • Intervention and comparison group numerators were calculated based on denominators reported in Fig. 1. Baseline numerator for comparison group was calculated from denominator and OOHC information reported in Table 2. • Crude risk of OOHC placement at the end of follow-up were reported, but no causal effect was estimated of a main causal effect is the crude risk difference of -0.9% at end of follow-up. • The intervention may have had a marginally beneficial effect on OOHC placements, compared with usual care, although there may be residual confounding
Swenson et al. (2010)	3/44 (6-8%)	6/44 (13-6%)	10/42 (23-8%) 13/42 (31%)	13/42 (31%)	Crude risk difference = -17:4%	2	• Pre-treatment factors prognostic of the outcome were reportedly similar between groups, but some qualitative differences were evident in reported descriptive statistics. • Crude risk of OOHC placement at the end of follow-up were reported, but no causal effect was estimated. • Closest estimate of a main causal effect is the crude risk difference of -17.4% at end of follow-up. • No effect estimates were adjusted for differences in pre-treatment factors prognostic of the outcome. • The intervention may have had a beneficial effect on OOHC placements, compared with enhanced outpatient therapy, although there may be residual confounding

• The absolute and relative differences in the risk of OOHC placements within 18–24 months between the intervention and usual care groups was negligible in this study

Table 3 (continued)	tinued)						
Study author/	Intervention	Study author/ Intervention Group Events n/N (%)	Comparison C	Comparison Group Events n/n (%)	Main Effect	Fragility index ^{\$}	Comments on methods and results relevant to estimating
year	Baseline	F/U	Baseline	F/U	Estimate		the main causal effect of the intervention
RCTs (crude risk differences unable to	isk differences		be calculated from reported data)	ıta)			
Chaffin et al. Unclear (2011)	Unclear	PCIT + SM: n/N (10%)	Unclear	UC-SM: n/N (18%)	No main effect reported	Unable to calculate from	 Pre-treatment factors prognostic of the outcome were reportedly similar between groups; however, descrip-
PCIT-S	ed observation	PCIT-SM: n/N (29		UC + SM: n/N (24%)		reported data	tive statistics of pre-treatment characteristics were not reported • The main causal effect of the intervention (i.e., PCIT) compared with usual care were not reported; instead, a model with attrition pattern and intervention group included as an interaction term was reported • The use of post-baseline information on attrition introduces bias when attempting to estimate an ITT effect • Although the numerator (for OOHC placement) and denominator were reported for the entire study sample (58/153; 38%), they were not reported separately for each group. Therefore, it is not possible to estimate a crude risk difference for the main effect of PCIT vs usual care
Turner et al. (2017)	n/N (17.4%) n/N (3.	n/N (3-6%)	n/N (10-6%)	n/N (2·1%)	Crude risk difference = 1.5% Adjusted odds ratio = 1.36 (SE, 0.21)	0	 Families in the intervention and usual care groups differed on some pre-treatment factors that may confound the exposure-outcome relationship in this observational study The crude risk difference in OOHC placements was 1.5% The closest estimate to a main causal effect is the adjusted odds ratio of 1.36 (SE, 0.21) at end of followup. The authors also reported an adjusted standardized magning of effect (dn=0.04)



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Study author/	Intervention	Study author/ Intervention Group Events n/N (%) Comparison Group Events n/n (%)	Comparison G	iroup Events n/n (%)	Main Effect	Fragility index ^{\$}	Fragility index ⁵ Comments on methods and results relevant to estimating
year	Baseline F/U	F/U	Baseline	F/U	Estimate		the main causal effect of the intervention
Schaeffer et al. (2013)	4/25 (16%) 3/25 (1	3/25 (12%)	3/18 (16-7%)	3/18 (16-7%) 5/18 (27-8%)	Crude risk difference = -15.8% Adjusted odds ratio = 3.12 (SE, 1.13)	2	 Pre-treatment factors prognostic of the outcome were reportedly similar between groups, and imbalances in some baseline characteristics (e.g., mother's race, number of prior CP reports and OOHC placements), were adjusted for in models to estimate the causal effect of the intervention
							• The best estimates of a main causal effect are crude risk difference (-15.8%) and adjusted odds ratio of 3.12 (SE, 1.13) at end of follow-up
							 The intervention may have a beneficial effect on OOHC placements, although there may be residual confounding

FU, follow-up; OOHC, out-of-home care; PCIT, Parent Child Interaction Therapy; RCT, randomized controlled trial; SE, standard error; SM, Self Motivation; UC, Usual care \$ A fragility index of 0 indicates p values were $>\!0.05$ for these comparisons



Limitations

Limitations of the review

Risk of bias of reviewed studies was undertaken as per Cochrane guidelines (Moher et al., 2009). Such assessments can be difficult when the necessary information is not reported. Although the overall risk of bias was high, we included all studies in this review to comprehensively summarize what is known to date about programs using family therapy in this evolving, interdisciplinary research field. It was not meaningful (and for most studies, not possible) to quantitatively synthesize the evidence because of the methodological and reporting limitations in the original studies. Many of these methodological limitations relate to the challenges of evaluating complex, sustained child maltreatment interventions with vulnerable families. Thus, we focused on realistic opportunities to improve the design and reporting of studies of health or child welfare sector interventions.

Limitations of the included studies

Pre-treatment factors prognostic of the outcome were not reported for each group in all studies, which is key to assessing bias related to randomization as outlined by Cochrane (Higgins et al., 2019). Some studies based decisions about treatment group comparability on statistically significant differences in pre-treatment risk factors (i.e., p-values < 0.05). Health and medical research reporting guidelines (Montgomery et al., 2018; Vandenbroucke et al., 2007) now strongly discourage the use of p-values for this purpose, instead recommending that sample size, size and variability of the difference, and the strength of association between pre-treatment prognostic factors and outcomes are considered.

Three studies did not report missing outcome data. Although outcome data were reported missing for up to 23% (administrative data outcomes) and 69% (parent- and child-reported measures) of participants in other studies, none reported pre-treatment characteristics between families with and without missing outcome data to assess the potential impact of selection bias.

While between-group comparisons of post-treatment outcomes are necessary to estimate causal effects, several studies only reported within-group pre- and post-treatment outcomes. Within-group comparisons do not compare the intervention group with a group that is similar on pre-treatment risk factors, and while potentially informative, they do not allow conclusions to be drawn about the real-world impacts of interventions (Bland & Altman, 2015).

In RCTs that examined child protection report and OOHC outcomes, the absolute risks were reported, but not an estimate of the main causal effect of the intervention, such as absolute and relative risk difference measures between the intervention and comparison groups. Where possible, we calculated crude risk differences as the best possible estimate of a causal effect; however, we were unable to adjust for differences in pre-treatment risk factors or generate confidence intervals because information to calculate standard errors was not



reported. Although one observational study adjusted for measured confounders (Schaeffer et al., 2013) the other observational study did not adjust for measured confounders, despite baseline differences between groups (Turner et al., 2017).

None of the RCTs referred to a publicly available, pre-specified analysis plan (i.e., published prior to the trial), which is now standard practice for clinical trials in health and medical research (Grant et al., 2018). This may in part be due to half of the RCTs being published on or before the publication of the CON-SORT-2010 guidelines (Schulz et al., 2010).

Implications for policy and practice

Current evidence of program efficacy or effectiveness

The current evidence examines the effects of family-based therapies on physical abuse or neglect in the 0 days to 24 months post-treatment (average follow-up 8-months post-treatment). Although family-based therapy programs may reduce child maltreatment in the short-term, the high risk of bias and inconsistent findings across studies means it is currently unclear whether family-based therapy programs achieve better child maltreatment outcomes, compared with usual care, in the settings and populations studied to date. Given most studies were conducted in the United States, the effect of family-based therapy programs in other settings and populations is under-studied, including among Indigenous populations who are often over-represented in child protection systems, such as Australia (Davis, 2019), Canada (O'Donnell et al., 2016) and New Zealand (Rouland et al., 2019).

Methodological challenges in evaluating program efficacy and effectiveness

There are many challenges to conducting high quality intervention studies in the child maltreatment field, including recruitment of participants representative of the target population, adequate sample sizes, and retaining families to study completion. Family-based therapy programs are often complex, sustained interventions and treatment protocols may be less defined than clinical and pharmaco-epidemiology intervention studies, which makes treatment adherence difficult to assess. Moreover, it is not always clear to what extent the intervention and comparison treatments differ. In the case that family-based therapy program and comparison treatments are not substantially different in their structure and design, then it is reasonable to expect small or no beneficial effects of the intervention, compared with the comparison condition.

Retention of disadvantaged families in sustained family-based therapy interventions or usual care services is often challenging in the child protection context, as evidenced by the missing outcome data in the included studies. It is likely that participants with complete outcome data in the intervention and usual care groups



Table 4 Post-treatment parent- and child- reported measures of child maltreatment risk (measure of effect for between-group comparison reported)

Study author/ year	Intervent	tion group	Comparis	Comparison group	Post-treatment difference		Comments on the analysis, design and interpretation
	"N/u	Mean (SD/MS)	*N/u	Mean (SD/MS)	in Means between groups, calculated for review	enect for between-group comparison	
Alabama Parenting Questionnaire-Preschool Revision (APQ-PR) (2007)#—Punitive Punishment sub-scale	ionnaire-F	Preschool Revision (AF	-Q-PR) (20C	77)#—Punitive Punish	ment sub-scale		
Villodas et al. (2021)	12/26	1·66 (SD, 0.12)	9/29	1.92 (SD, 0.11)	-0.26	d=13 [^]	• Pre-treatment factors prognostic of the outcome were reportedly similar between groups, but some qualitative differences evident in reported descriptive statistics
							 The intervention may have had a small beneficial effect on parent-reported measures, compared with usual care, although there may be residual confounding
Alabama Parenting Questionnaire (APQ) (1991) ^a —Corporal Punishment sub-scale	tionnaire (.	APQ) (1991) ^a —Corpo	ral Punishm	ent sub-scale			
Runyon et al. (2010) ^b Parent version	20/40	4·69 (MS, 3·23)	14/35	3·67 (MS, 3·23)	-1.02	d=-0.57 ^{\$}	• Post-treatment means and mean differences were adjusted for differences in pre-treatment factors prognostic of the outcome to estimate the causal effect of the intervention
							• The intervention may not have had a beneficial effect on parent-reported measures, compared with Parent-Only Cognitive Behavioral Therapy, although there may be residual confounding
Runyon et al. (2010) ^b Child version	20/40	4·19 (MS, 5·0)	14/35	5.25 (MS, 5.0)	1.06	d = 0.47	Post-treatment means and mean differences adjusted for differences in pre-treatment factors prognostic of the outcome to estimate the causal effect of the intervention
							• The intervention may have had a moderately beneficial effect on child-reported measures, compared with Parent-Only Cognitive Behavioral Therapy, although there may be residual confounding



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Study author/ year	Interven	Intervention group	Comparis	Comparison group	Post-treatment difference Measure of	Measure of	Comments on the analysis, design and interpretation
	*N/u	Mean (SD/MS)	»N/u	Mean (SD/MS)	in Means between groups, calculated for review	effect for between-group comparison	
Child Abuse Potential 1	Inventory-IV	hild Abuse Potential Inventory-IV (CAPI) (1986) ^c —Overall risk for physical abuse ^d	rall risk for	physical abuse ^d			
Thomas & Zimmer- Gembeck (2011) ^e	66/u	174-0 (SD, 119-3) n/51	n/51	170·8 (SD, 105·9) 3·2	3.2	d = 0.08	 Pre-treatment factors prognostic of the outcome were reportedly similar between groups; however, descriptive statistics of pre-treatment characteristics were not reported
							The intervention may not have had a beneficial effect on parent-reported measures, compared with the Waitlist Control, although there may be residual confounding

APQ, Alabama Parenting Questionnaire; APQ-PR, Alabama Parenting Questionnaire-Preschool Revision; CAPI, Child Abuse Potential Inventory; MS, mean squares; SD, standard deviation

- * Number with outcome measure/number assigned to intervention or comparison group
- # How often parents have ignored, spanked, slapped and screamed at their children
- ^ Villodas et al. (2021) report this Cohen's d value with a negative sign as relative to the control, the reported change on the APQ-PR Punitive Punishment sub-scale was lower in intervention than comparison group
- \$ Runyon et al. (2010) did not report the negative value for the Cohen's d estimate; however, the text and data suggest that it was a negative value
- a How often parents have spanked, slapped and screamed at their children
- b Runyon et al. (2010) report outcome data for 26 and 34 families in Table 3 in the intervention and comparison group, respectively. However, this number equates to the number of families who attended 3 or more treatment sessions and differs to the number of families reported in Fig. 1 who completed follow-up assessment (n = 20 intervention, n = 14 control)
- c Parent overall risk score for physical abuse
- d CAPI items aggregate to form an abuse scale. The high-risk category includes abuse scores of 166 to 215. The measure comprises 160 items in an "agree/disagree" format, 77 of which are summarized in the Abuse Risk Scale (which consists of six subscales: Distress, Rigidity, Unhappiness, Problems with Child and Self, Problems with Family, and Problems with others). The B-CAP consists of 33 items, 24 items of which are summarized in a child physical abuse scale
- e Thomas and Zimmer-Gembeck (2011) report in Table 1 CAPI data for 40 and 36 families in the intervention and comparison group, respectively. However, on p. 180, he authors note that 42 families in the intervention group completed all follow-up assessments (42%), whereas 36 families in the comparison group completed a single collow-up assessment after 12-weeks (71%)

were not representative of the whole target population for the included studies. Few studies included in this review reported the characteristics of participants with and without missing outcome data, which is best practice to facilitate assessment of the potential impact of selection bias on study findings.

Opportunities to leverage existing data to evaluate program effectiveness

To generate consistently high-quality evidence on the effect of family-based therapy interventions in local contexts and populations, adequate funding is needed to co-design evaluations with communities and service providers, to recruit and retain large appropriate sample sizes, and to develop protocols that minimize the risk of bias. As discussed, meeting the conditions to generate high-quality evidence from RCTs of family-based therapy can be challenging. One alternative to RCTs is to conduct cost-effective, large-scale, real-world interventions of program effectiveness by using quasi-experimental methods as part of emulating a trial using non-randomized observational study designs at scale (Hernán et al., 2008). This approach requires investing in routinely collected data on the type, timing and frequency of intervention delivery and linking this data to other whole-of-population health and human services administrative datasets for children and families. The resulting infrastructure can minimize bias from missing outcome data and enable longer-term evaluation of outcomes at low burden to children, families and service providers and at a relatively low cost, compared with conducting RCTs. Examples of using linked administrative data and observational study designs to estimate the effect of an intervention compared to usual care can be seen in the integration of nurse home-visiting program data with whole-of-population data from multiple agencies for children and families in South Australia (Moreno-Betancur et al., 2022), New Zealand (Vaithianathan et al., 2016) and Manitoba, Canada (Chartier et al., 2018).

Conclusions

Although family-based therapy programs may reduce child maltreatment, the high risk of bias and inconsistent findings across studies means it is unclear whether family-based therapy programs achieve better child maltreatment outcomes, compared with usual care. To understand whether investment in interventions achieve the intended outcomes for high-risk populations, adequate funding for high quality evidence is needed to guide policy decisions. In an era where data linkage capabilities have increased, there now exist opportunities to leverage routinely collected data on service delivery and outcomes to include larger sample sizes and emulate the target trial in observational study designs (Hernán & Robins, 2016), similar to comparative effectiveness studies of pharmacological interventions (Dagan et al., 2021; Dickerman et al., 2019) and secondary prevention programs in public health (Chartier et al., 2018; Moreno-Betancur et al., 2022).



Table 5 Post-treatment parent- and child- reported measures of child maltreatment risk (measure of effect for between-group comparison not reported)

Study author/ year	Intervention gro	group	Comparison group	group	Post-treatment difference in	Between-group	Comments on the analysis, design
	»N/u	Mean (SD/MS)	*N/u	Mean (SD/MS)	Means (calculated for review) comparison effect measu	comparison effect measure	and interpretation
Conflict Tactics Scale (CTS) (1990) – Violence subscale ^f	e (CTS) (1990) –	Violence subscale ^f					
Kolko (1996) Parent FT: 17/18 report ^g	FT: 17/18	6.9 (SD, 5.3)	UC:10/12	5.2 (SD,6.0)	For FT vs. Usual Care: Post-treatment = 1.7	No standardized measure of	• Pre-treatment factors prognostic of the outcome reportedly similar
		3.9 (SD, 3.8)		4.1 (SD, 4.0)	3-month post = -0.2	effect reported	between groups, except for racial
		2.3 (SD, 2.0)		5.0 (SD, 4.9)	1-year post = -2.7		statistics of pre-treatment charac-
	CBT: 20/25	3.6 (SD, 4.5)			For CBT vs. Usual Care:		teristics were not reported The interventions may not have
		4.1 (SD, 5.4)			3-month post = 0		had a beneficial effect on parent-
		4.5 (SD, 5.8)			$1-year\ post = -0.5$		reported measures, compared with usual care, although there may be
							residual confounding
Kolko (1996) ^a Child report ^g	FT: 17/18	5.3 (SD, 7.9)	UC: 10/12	2.8 (SD, 3.7)	For FT vs. Usual Care: Post-treatment = 2.5	No standardized measure of	 Pre-treatment factors prognostic of the outcome were reportedly simi-
		3.1 (SD, 4.6)		2.7 (SD, 3.9)	3-month post = 0.4	effect reported	lar between groups, except racial
		4.6 (SD, 7.6)		2.5 (SD, 5.2)	1-year post = 2.1		background; however, descriptive statistics of pre-treatment charac-
	CBT: 20/25	2.3 (SD, 4.4)			For CBT vs. Usual Care:		teristics were not reported
		5.0 (SD, 9.0)			3-month post = 2.3		have had a beneficial effect on
		2.6 (SD, 4.4)			1-year post = 0.1		child-reported measures, compared with usual care, although
							there may be residual confounding



Table 5 (continued)							
Study author/ year	Intervention gro	group	Comparison group	group	Post-treatment difference in		Comments on the analysis, design
	n/N*	Mean (SD/MS)	n/N*	Mean (SD/MS)	Means (calculated for review)	comparison effect measure	and interpretation
Weekly Report of Ab	ouse Indicators (W	Weekly Report of Abuse Indicators (WRAI) (1996) – Threat of Force subscale ^g	t of Force subs	cale ^g			
Kolko (1996) ^h Parent report	FT: 17/18	1.0 (SD, 0.9) 1.3 (SD, 0.9)	UC: 10/12	0.8 (SD, 0.8) 1.9 (SD, 1.1)	For FT vs. Usual Care: Post-treatment = 0.2	No standardized measure of	Pre-treatment factors prognostic of the outcome were reportedly
		0.9 (SD, 1.0)		1.4 (SD, 1.1)	3-month post = -0.6 1-year post = -0.5	effect reported	similar between groups, except for racial background; however, descriptive statistics of pre-
	CBT: 20/25	0.8 (SD, 1.1)			For CBT vs. Usual Care Post-treatment = 0		treatment characteristics were not reported The interventions may or may not
		1.6 (SD, 1.2) 0.9 (SD, 1.2)			3-month post = -0.3 1-year post = -0.5		have had a beneficial effect on parent-reported measures, compared with usual care, although there may be residual confounding
Kolko (1996) ^h Child report	FT: 17/18	0.31 (SD, 0.6)	UC: 10/12	0.56 (SD, 0.88)	For FT vs Usual Care: Post-treatment = -0.25	No standardized measure of	Pre-treatment factors prognostic of the outcome were reportedly
		0.27 (SD, 0.56) 0.33 (SD, 0.62)		0.43 (SD, 0.53) 0.57 (SD, 0.79)	3-month post = -0.16 1-year post = -0.24	effect reported	similar between groups, except for racial background; however,
	CBT: 20/25	0.18 (SD, 0.39) 0.50 (SD, 0.67) 0.65 (SD, 0.78)			For CBT vs Usual Care: Post-treatment = -0.38 3-month post = -0.06 1-year post = 0.08		descriptive statistics of pre- treatment characteristics were not reported The interventions may or may not have had a beneficial effect
							on child-reported measures, compared with usual care, although there may be residual confounding



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Study author/year	Intervention group	dnor	Comparison group	on group	Post-treatment difference in	Between-group	Comments on the analysis, des
					Means (calculated for review) comparison	comparison	and interpretation
	*Nu	Mean (SD/MS)	*N'u	Mean (SD/MS)		effect measure	

ideac (communed)							
Study author/ year	Intervention gro	group	Comparison group	group	Post-treatment difference in	Between-group	Comments on the analysis, design
	N/u	Mean (SD/MS)	n/N	Mean (SD/MS)	Means (calculated for review)	comparison effect measure	and interpretation
Child Abuse Potential	I Inventory-IV (C	Child Abuse Potential Inventory-IV (CAPI) (1986).—Overall risk for physical abuse ^d	ll risk for phys	sical abuse ^d			
Foley et al. (2016) 19/20	19/20	99.25 (SD, 69.75) 22/24	22/24	182.58 (SD, 114.92)	-83.33	No standardized measure of effect reported	Within-group comparisons of pre- and post-treatment outcomes reported (within-group Cohen's d), rather than between-group comparisons of post-treatment outcomes The intervention may have had a beneficial effect on parent-reported measures, although there may be residual confounding
Donohue et al. (2014) ⁱ	6-mth post: 24/35 10-mth post: 26/35	135.4 (86) 135.6 (89.7)	32/37	6-mth post: 144.2 (113.1) 10-mth post: 140.0 (112.0)	6-mth post:144.2 6-month post-treatment (113.1) = -8.8 10-mth post:140.0 10-month post-treatment (112.0) = -4.4	No standardized measure of effect reported	 Pre-treatment factors prognostic of the outcome were reportedly similar between groups, but some qualitative differences were evident in reported descrip- tive statistics Within-group comparisons of pre- and post-treatment outcomes were reported (within-group Hedge's g) The intervention may have had a beneficial effect on parent-reported measures, although there may be
							residual confounding



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Table 5 (continued)							
Study author/ year Intervention	Intervention group	dn	Comparison group	group	Post-treatment difference in	Between-group	Comments on the analysis, design
	n/N*	Mean (SD/MS)	n/N*	Mean (SD/MS)	Means (calculated for review) comparison effect measu	comparison effect measure	and interpretation
Meezan and O'Keefe (1998)	30/42	144.6 (81.0)	23/39	224.9 (82.0)	-80.3	No standardized measure of effect reported	Pre-treatment factors prognostic of outcome were reportedly similar between groups, but descriptive statistics of pre-treatment characteristics were not reported The intervention may have had a beneficial effect on parentreported measures, although there may be residual confounding
Kolko (1996) ^h	FT: 17/18	144.3 (SD, 100.7) 154.5 (SD, 122.3) 129.6 (SD, 113.7) 139.4 (SD, 96.3) 151.0 (SD, 93.6) 124.4 (SD, 19.8)	UC: 10/12	243.1 (SD, 130.2) 274.8 (SD, 133.7) 318.3 (SD, 105.8)	144.3 (SD, 100.7) UC: 10/12 243.1 (SD, 130.2) For FT vs. Usual Care: Post-treatment = -98.8 154.5 (SD, 122.3) 274.8 (SD, 133.7) 3-month post = -120.3 129.6 (SD, 113.7) 318.3 (SD, 105.8) 1-year post = -120.3 139.4 (SD, 96.3) For CBT vs. Usual Care: Post-treatment = -103.7 151.0 (SD, 93.6) 3-month post = -123.8 124.4 (SD, 19.8) 1-year post = -123.8	No standardized measure of effect reported	Pre-treatment factors prognostic of the outcome were reportedly similar between groups, except for racial background; however, descriptive statistics of pre-treatment characteristics were not reported The interventions may have had a beneficial effect on parent-reported measures, although there may be residual confounding

APQ, Alabama Parenting Questionnaire; APQ-PR, Alabama Parenting Questionnaire-Preschool Revision; CAPI, Child Abuse Potential Inventory; CBT, cognitive behavioural therapy; CTSPC, Parent-Child Conflict Tactics Scale; FT, family therapy; MS, mean squares; RCT, randomized controlled trial; SD, standard deviation; UC, Usual care; WRAI, Weekly Report of Abuse Indicators

\$ Runyon et al. (2010) did not report the negative value for the Cohen's d estimate; however, the text and data suggest that it was a negative value



^{*} Number with outcome measure/number assigned to intervention and comparison group

[#] How often parents have ignored, spanked, slapped and screamed at their children

[^] Villodas et al. (2021) report this Cohen's d value with a negative sign because relative to the control, the reported change on APQ-PR Punitive Punishment sub-scale was lower in intervention than comparison group

Table 5 (continued)

a How often parents have spanked, slapped and screamed at their children

b Runyon et al. (2010) report outcome data for 26 and 34 families in Table 3 in the intervention and comparison group, respectively. However, this number equates to the number of families who attended 3 or more treatment sessions and differs to the number of families reported in Fig. 1 who completed follow-up assessment (n = 20 intervention, n = 14 control)

c Parent overall risk score for physical abuse

d CAPI items aggregate to form an abuse scale. The high-risk category includes abuse scores of 166 to 215. The measure comprises 160 items in an "agree/disagree" format, 77 of which are summarized in the Abuse Risk Scale (which consists of six subscales: Distress, Rigidity, Unhappiness, Problems with Child and Self, Problems with Family, and Problems with others). The B-CAP consists of 33 items, 24 items of which are summarized in a child physical abuse scale e Thomas and Zimmer-Gembeck (2011) report in Table 1 CAPI data for 40 and 36 families in the intervention and comparison group, respectively. However, on p. 180, the authors note that 42 families in the intervention group completed all follow-up assessments (42%), whereas 36 families in the comparison group completed a single follow-up assessment after 12-weeks (71%)

f Parent-to-child score of violent behaviours (e.g., non-violent discipline and physical assault), neglect and sexual abuse within the past year

g Number of thoughts, threats or acts of physical force/discipline

h Kolko et al. (1996) report drop-out from the program for N=1, N=5 and N=2 for FT, CBT and Usual care, respectively. Post-assessment data obtained for total of 47 families, which equates to the total number and percentage of families who completed both the pre-treatment and post-treatment assessments = 47 (85%). However, unclear exactly how many families completed the CTSPC (1990), WRAI (1996) & CAPI (1986)

Donohue et al. (2014) report the number with follow-up at 6- and 10-months post-baseline (Fig. 1), but unclear if CAPI data was available for all children recruited (Table 2)



Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s42448-023-00170-z.

Author contribution Mr. Economidis conceptualized and designed the review, conducted the systematic review search, article screening, data extraction and risk-of-bias assessments, drafted the initial manuscript, and revised the manuscript. Dr. Falster contributed to the design of the review, supervised screening, data extraction and risk-of-bias assessments, supervised drafting of the initial manuscript, and critically reviewed and revised the manuscript for important intellectual content. Ms. Powell contributed to article screening, data extraction, risk-of-bias assessments, and revision of the manuscript. Dr. Pilkington contributed to the design of the review, screening, data extraction, risk-of-bias assessments, and interpretation of the results, and critically reviewed and revised the manuscript for important intellectual content. Dr. Eades critically reviewed and revised the manuscript for important intellectual content.

A/Prof. Dobbins contributed statistical expertise to the interpretation and reporting of results, and critically reviewed and revised the manuscript for important intellectual content. Prof. Shakeshaft conceptualized and designed the review, interpretation of the results and critically revised the manuscript for important intellectual content. Prof. Lynch contributed to the design of the review, interpretation of the results, and critically reviewed and revised the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Funding Open Access funding enabled and organized by CAUL and its Member Institutions Mr Economidis was supported by an Australian Government Research Training Program (RTP) Scholarship via the University of New South Wales (UNSW), Sydney, Australia, and a Higher Degree Research scholarship from the National Drug and Alcohol Research Centre (NDARC), UNSW. Rhiannon Pilkington is supported by an NHMRC Clinical Trials and Cohort Studies grant APP1187489. John Lynch was awarded a National Health and Medical Research Council (NHMRC) Centre of Research Excellence (1099422). The other authors received no additional funding.

Data availability The datasets used and/or analysed during the current study are available from the corresponding author on request.

Declarations

Patient consent for publication Not applicable.

Ethics approval This study does not involve human participants.

Competing interests Anthony Shakeshaft was the lead investigator on a competitive tender (FACS.17.266) awarded by the NSW Government Department of Family and Community Services (now Department of Communities and Justice) to evaluate the Functional Family Therapy – Child Welfare [FFT-CW®] and Multisystemic Therapy for Child Abuse and Neglect [MST-CAN®] programs in New South Wales, Australia (2018–2020). George Economidis was employed part-time at the National Drug and Alcohol Research Centre as a Project Coordinator for the FFT-CW® and MST-CAN program evaluation from May 2018 to August 2020. The other authors have no relevant conflicts of interest to disclose.

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Publisher's note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.



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