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A pragmatic randomised controlled trial of the fostering changes programme



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ABSTRACT

Background: Many looked after young people in Wales are cared for by foster or kinship carers, usually as a consequence of maltreatment or developmentally traumatising experiences within a family context. Confidence in Care is a pragmatic unblinded individually randomised controlled parallel group trial evaluating a training programme to improve foster carer self-efficacy, when compared to usual care.

Objective: To determine whether group-based training improves foster carer self-efficacy. Participants and setting: Participants are foster carers, currently looking after children aged 2+ years for at least 12 weeks. Carers from households where one or more carer had previously attended the training were not eligible. Sixteen local authorities and three independent fostering providers in Wales took part.

Methods: The primary outcome measure was the Carer Efficacy Questionnaire assessed at 12 months. Secondary outcomes included the Strengths and Difficulties Questionnaire, Quality of Attachment Questionnaire, Carer Defined Problems Scale, Carer Coping Strategies, placement moves.

Results: 312 consented foster carers were allocated to FC (n = 204) or usual care (n = 108) group. 65.3 % of FC group participants attended sufficient training sessions (8/12, including sessions three and four). There were no differences in carer-reported self-efficacy at 12 months (adjusted difference in means (95 % CI): -0.19 (-1.38 to 1.00)). Small differences in carer-reported child behaviour difficulties and carer coping strategies over time favoured the intervention but these effects diminished from three to 12 months. No other intervention effects were observed.

Conclusions: Although well-received by participants, training was associated with small and mostly short-term benefit for trial secondary outcomes.

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1. Introduction

There were 6845 looked after children and young people in Wales in 2019 (StatsWales, 2020), including many cared for by foster or kinship carers. The maltreatment and developmentally traumatising experiences within a family context experienced by many such young people can result in wide-ranging difficulties related to emotional wellbeing, mental health (Tarren-Sweeny, 2017) and education (Jackson, 2010; Stein, 2012). The consequent strain on carers can increase the likelihood of placement disruption (Farmer, Lipscombe, & Moyers, 2005) and lower self-efficacy, further exacerbating poor child outcomes (Rubin, O'Reilly, Luan, & Localio, 2007).

In Wales, new carers undertake pre-approval and induction training as a minimum (National Minimum Standards for Fostering Services, 2003). Statutory training is normally provided by Local Authority (LA) or Independent Fostering Providers (IFPs). Skill-based training can focus on children's developmental needs and techniques to manage difficult emotions and behaviours (Turner, Macdonald, & Dennis, 2007). Themes for group-based training programmes may include attachment, managing challenging behaviour, carer confidence and communication skills (Macdonald & Turner, 2005; Minnis, Pelosi, Knapp, & Dunn, 2001). While several programmes have been evaluated, many studies have methodological shortcomings such as small samples (Bywater et al., 2011; Gavita, David, Bujoreanu, Tiba, & Ionutiu, 2012), short follow-up (Mersky, Topitzes, Janczewski, & McNeil, 2015; Price, Roesch, Walsh, & Landsverk, 2015), and while randomised control trials (RCTs) are widely considered to be the gold standard for assessing effectiveness (Dixon et al., 2014; Macdonald, 2008; Mezey et al., 2015) few have been used to assess effectiveness (Gavita et al., 2012). Where trials have been undertaken, evidence reveals limited effectiveness (Kinsey & Schlösser, 2013).

The Fostering Changes (FC) programme aims to build positive relationships between carers and children, encourage positive child behaviour and set appropriate limits for behaviour, through a practical skills-based approach (Briskman et al., 2012). Briskman and colleagues' efficacy trial of FC involved 63 foster carers (Briskman et al., 2012). They found a difference in Carer Efficacy Questionnaire (CEQ) scores between the study groups, favouring the intervention arm although this did not reach statistical significance. Some statistically significant differences were found favouring the intervention arm of the trial including for carer-defined problems (effect-size 0.95 sd, p=0.003), for emotional and behavioural difficulties (effect-size 0.3 sd, p=0.03) and quality of attachment (effect-size 0.4 sd, p=0.04).Limitations of the Briskman trial include the small sample size, and that a relatively short follow-up was conducted with outcomes assessed immediately following programme delivery. Of the six evaluation measures used, three were designed in house and were not standardised, including the CEQ, however the measures they used were tailored to the intervention and therefore likely had good content validity. The study was not published in a peer review journal. It remains unknown whether benefits endure over time and are evident in a larger real-world setting. We aimed to esFIGlish whether FC can deliver important differences in how foster carers build positive relationships with their foster children, encourage positive child behaviour and set appropriate limits, when compared to usual care.

2. Methods

2.1. Trial design

This was a pragmatic (Thorpe et al., 2009) unblinded individually randomised controlled trial. Intervention training was organised by the Confidence in Care consortium of third sector providers responsible for delivering FC across Wales. We planned to recruit participants to trial groups alongside non-trial groups, both of which were run by consortium facilitators. The consortium liaised with the research team to ensure intervention delivery but, like the funders, played no further part in trial design, implementation or reporting. The published trial protocol provides more detail while key design features are described below (Moody et al., 2018).

2.2. Participants, setting and recruitment

Participants were LA foster carers, those recruited through independent or not-for-profit agencies, or kinship carers in Wales. Participants could either self-select by responding to a postal invite, or were nominated by provider agencies. Provider agencies selected participants to nominate based on various criteria, some of which were locally determined. These included perceived needs of a foster carer, or apparent availability based on absence of competing commitments. We sought to recruit sufficient carers to fill the group to the desired capacity (n = 18). However, when this was not possible, participation in the programme was supplemented by allowing some non-trial participants to also attend the group. Which foster carers were invited to attend as non-trial participants was arranged by the local provider agency.

2.3. Randomisation, masking and procedures

Carers were allocated to trial group with an assignment ratio 2:1 (FC: Usual care) and minimised by type of carer (family carer / unrelated carer) and whether the household included a looked after child aged 12 years and older (<12/12+ years) for each site. After a participant was consented to the study, baseline data collection was completed. Then, participant details were passed to the core trial team via telephone following notification of recruitment and participants were then allocated to trial arm. Participants were telephoned by the trial manager and informed of their allocation within 6 weeks of the start of the FC programme. Apart from the Trial Manager and Administrator, all trial team and field recruitment staff were blinded to allocation.

Table 1
Primary and secondary outcome measures details.

	Timepoint			
Assessment	Baseline	Follow-up		
		3 month follow- up	12 month follow- up	
Carer efficacy in supporting child education and carer quality of life (both 3-item sub-scales from Carer Efficacy Questionnaire (CEQ)) (Briskman et al., 2012)	X	X	X	
Carer defined problems (Carer Defined Problems Scale (CDPS))* (Scott, Spender, Doolan, Jacobs, & Aspland, 2001).	X	X	X	
Carers' coping strategies (Carers' Coping Strategies scale, CCS) (Briskman et al., 2012)	X	X	X	
Quality of carer-child relationship (Quality of Attachment Relationship Questionnaire, QUARQ)* (Briskman et al., 2012)	X	X	X	
Child behaviour and emotional problems (Strengths and difficulties Questionnaires (SDQ))* (Goodman, 1999)	X	X	X	
Carer-reported child engagement with education			X	
Rates of unplanned placement changes	X	X	X	
Use of services and support	X	X	X	

^{*} Outcomes assess with the index child in mind (i.e. the looked after child with most challenging behaviour at baseline and who is expected to still be placed with carer for at least 3 months), unless at 3 or 12 months the child was no longer placed with the participant, in which case the foster carer answers hypothetically or with another child in mind.

2.4. Outcomes and assessment schedule

The primary outcome was carers' self-reported ability to cope with and make positive changes to the lives of their foster children, measured by the 9-item CEQ (Briskman et al., 2012). The link between the measure of carer efficacy and coping underpins the logic model of the intervention and is described in the Briskman report (Briskman et al., 2012). This measure also assesses the confidence of carers to facilitate education by, for example, feeling able to contact their foster child's school if they have concerns. Three final questions relate to stress and quality of life.

All secondary outcomes are described in Table 1. Most of the measures included were the same as those in the Briskman trial (Briskman et al., 2012) with two exceptions. A specific measure of engagement with education at the 12 month follow-up was included in the current study that Briskman et al. did not use. This was included as supporting children's education was identified by the FC developers as an important aspect of the programme. The Alabama Parenting Questionnaire used in the Briskman trial was not used. This decision was taken to reduce the assessment burden for participants as it had a significant crossover with the Carer Coping Strategies measure which had been highlighted by Briskman et al.

Programme attendance data for trial and non-trial groups were recorded by facilitators and reported descriptively.

2.5. Intervention

Each FC programme comprises 12 weekly group-based sessions lasting three hours for up to 12 carers and a support group meeting designed to reinforce and maintain learning in each of the first three terms following course completion (Briskman et al., 2012; Moody et al., 2018). Adherence was defined following guidance from the intervention developers as attending eight or more sessions out of a possible 12 (including sessions three and four which focus on praise and positive attention and are central to course ethos). Where facilitators merged sessions 11 and 12, adherence was attending seven sessions out of 11 (including sessions three and four). Local social workers joined some groups as participants, an addition to the original FC model. This addition was not driven by the research design, but was rather an innovation in practice encompassed into it. The comparator was usually-provided support and advice with carers offered the opportunity to attend FC 12 months after recruitment. Usually provided support and advice services include, but are not restricted to, support from the local fostering team, access to The Fostering Network helpline, universal health and education services, and locally organised foster carer support groups.

2.6. Statistical analysis

Sample size estimation used previously reported CEQ data (Briskman et al., 2012) and assumed a mean (standard deviation) score of 27.1 (3.9) in the usual care group (Haight et al., 2005), and a 2:1 allocation ratio to maximise the number of carers attending each training programme. 213 carers (142:71) would provide 80 % power at the 5% level to detect a difference of 1.6 points on the CEQ, inflated to 237 (158:79 respectively) to allow for 10 % loss to follow-up.

Data were analysed using the intention-to-treat (ITT) principle. This is a principle recommended by the European Medicines Agency (EMA) ICH Statistical Principles for Clinical Trials (European Medicines Agency, 1998). This principle has some potential limitations which may become apparent when a proportion of the individuals randomised do not adhere to the intervention or a loss-to-follow-up is observed. The risk of bias however is increased whenever intervention groups are not analysed according to the group to which they were originally assigned which can have significant implications for the results and conclusions of a study. Sensitivity

analysis using a complier average causal effect (CACE) model was therefore utilised to investigate the effect of programme adherence (White, 2005; White, Kalaitzaki, & Thompson, 2011). This model preserves randomisation and attempts to obtain an unbiased treatment effect that incorporates treatment compliance. The primary comparative analyses applied an analysis of covariance model to the 9-item CEQ score (adjusting for baseline CEQ score) at 12 months. Additional covariates included were those used in minimisation (type of carer, age of looked after children in household). Mixed-effects three-level regression models were used to adjust for site (LA/IFP) as a stratification variable and to allow for clustering by programme in the intervention group. Results are presented as the (adjusted) difference in mean CEQ score between the intervention and usual care group, with 95 % confidence interval (CI). Exploratory sub-group analyses were run for age, gender, placement history of the index foster child, foster carer experience and qualifications, and size of household. A secondary analysis of CEQ examined the score over time (at three and 12 months) and included an interaction term for time and trial group to investigate any divergent/convergent pattern in outcomes (Molenberghs, 2007). Secondary outcomes were similarly analysed at three and 12 months follow-up using linear, logistic or ordinal regression models. The use of the CEQ was validated and reliability assessed using Cronbach's alpha. Analyses were performed using SPSS version 25 and Stata version 16.

2.7. Ethics approval and consent to participate

This trial was approved by Cardiff University's School of Social Sciences Ethics Committee (ref. no. SREC1515). Informed consent was obtained from each participant before data collection and randomisation.

This publication follows CONSORT (Consolidated Standards of Reporting Trials) guidelines (Schulz, Altman, Moher, & for the CONSORT Group, 2010).

3. Results

Twenty-seven programmes across 19 sites (17 LAs/2 IFPs) were open to recruitment at five different time points between January 2016 and April 2017. 1824 foster carers were identified as eligible, of whom 1638 (90 %) were approached for the trial (Fig. 1). 527 (32 %) carers expressed an interest, were contacted and assessed for eligibility. 26 carers could not be further contacted. 29 were ineligible. 472 carers (90 %) were successfully contacted and eligible, of whom 137 declined to take part and 16 could not participate due to the course being full or no longer run. 319 (68 %) consented to trial participation. Following consent, seven carers were withdrawn due to either having previously attended training (n = 1) or the course being full or no longer being run (n = 6). Therefore, 312 foster carers from 19 sites were assigned to FC (n = 204, 65.4 %) or usual care (n = 108, 34.6 %). The number of carers per programme ranged from 2 to 20 (mean = 12). Baseline characteristics for carers were well balanced between trial groups (Table 2) and also for their looked after children and household level characteristics (supplementary tables 1–3). Baseline outcome data were comparable between groups (supplementary tables 4–6). Due to an error, the fifth CEQ item ("The things I do make a difference to my foster child's behaviour") was missing for 75 (24 %) carers at baseline (FC: 25 % vs UC: 22 %). No differences in carer characteristics were found between those for whom the item was and was not available (supplementary table 7). Validation of the CEQ showed a similar pattern of completeness and floor/ceiling effects for each item as observed in Briskman's trial (Briskman et al., 2012) (supplementary tables 8–9). Internal consistency of the CEQ was 0.59 (supplementary table 10).

3.1. Attendance data

Fifteen percent (30/199) of carers randomised to FC did not attend any sessions and 64.8 % (129/199) attended ten or more sessions (25.1 % attended all sessions). 130 foster carers adhered to the intervention (130/199, 65.3 %).

3.2. Primary outcome

The CEQ score at 12 months follow-up did not differ between groups (Table 3). Four sensitivity analyses were carried out. The first included the 8-item CEQ score, the second included all participants irrespective of intervention compliance (attended all sessions offered), the third explored the effect of missing data. Finally, a post-hoc analysis explored the effect of partial clustering. All four sensitivity analyses supported the findings of the primary analysis (Table 3). Using CACE analysis to account for attendance made no difference to the ITT results (difference -19.40, 95 % CI: -178.44-139.64; p=0.81). There was no evidence of an intervention effect in the pre-specified subgroup analyses (supplementary tables 11a to g).

3.3. Secondary outcomes

Secondary analysis of overall CEQ scores over time showed no differential trend by group (Table 4). Small differences in carer-reported child difficulties (SDQ total score) (Goodman, 1999) and carer's reported use of coping strategies (CCS) in favour of FC were observed over time (interaction follow-up time x trial arm = 1.90 (0.07–3.72) and -1.81 (-3.60 to -0.02) respectively) (Table 4). The effect sizes in these two outcomes were larger at three months (unadjusted effect size of -0.34 and 0.30 respectively) but these tended to converge by 12 months (unadjusted effect size of -0.04 and 0.15 respectively) (Table 4). The categorical version of SDQ did not show a similar pattern over time (table S12). Rates of carer-reported positive engagement with child's education were higher at three months (FC: 54.3 %, UC: 41.7 %), as were rates of carer-reported quality of life (FC: 51.6 %, UC: 40.5 %) but converged at 12 months.

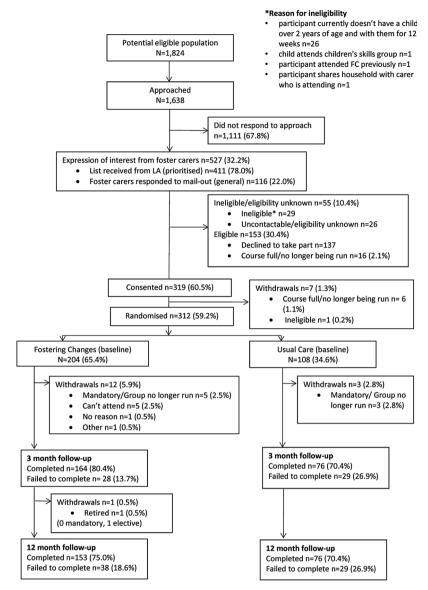


Fig. 1. CONSORT flow diagram.

There were no other differences found.

At three and 12 months follow-up a comparable proportion of children were still placed with the carer (three months - FC: 89 % (125/141) and UC: 93 % (57/63); 12 months - FC: 69 % (97/141) UC: 75 % (47/63)). Of those not still placed with the carer at 12 months, FC: 34 % (15/44) and UC: 25 % (4/16) were planned moves, FC: 21 % (9/44) and UC: 38 % (6/16) were unplanned moves, it was unknown whether the reminder were planned or unplanned (FC: 46 % (20/44), UC: 38 % (6/16). Information on whether moved were planned or unplanned was not collected at 3 months.

A higher proportion of carers in the usual care group had accessed other training courses compared to carers in the FC group by three months follow-up (FC: 69/162 = 42.6 % vs 45/76 = 59.2 %) and by 12 months follow-up this had increased to 116/148 (78.4 %) and 63/74 (85.1 %) respectively. At 12 months follow-up, the proportion of other services accessed by carers in the preceding 12 months were higher in the usual care group than the FC group, (73/150 (48.7 %)) and 43/74 (58.1 %) respectively).

4. Discussion

We randomised 312 foster carers to either receive group-based training or usually-available support. Most carers attended a sufficient number of sessions. At 12 months we found no difference between trial groups for the primary outcome of carer efficacy. There were small statistically significant differences between trial groups on carer-reported child behavioural problems and carer-reported use of coping strategies. These differences reduced over time. There was no overall intervention effect for carer-reported

 Table 2

 Sociodemographic characteristics of foster carers at baseline.

Variable	Fostering Changes (n = 204)	Usual care (n = 108)
Age (years) Mean (SD)	52.5 (8.23)	50.4 (8.51)
Gender N(%)		
Male	31/203 (15.3)	16 (14.8)
Female	172/203 (84.7)	92 (85.2)
Marital status		
Single	22/203 (10.8)	12/108 (11.1)
Married/cohabiting	155/203 (76.4)	85/108 (78.7)
Divorced	22/203 (10.8)	7/108 (6.5)
Widowed	4/203 (2.0)	4/108 (3.7)
Ethnicity		
White (Welsh/English /Scottish/Northern Irish/ British)	194/201 (96.5)	100/106 (94.3)
Other background	7/201 (3.5)	6/106 (5.7)
Highest qualification		
Above 16 years education level*	143 (70.8)	77 (72.6)
Below 16 years education level	59 (29.2)	29 (27.4)
Duration of being a foster carer (years)	N = 200	N = 106
Mean (SD)	7.9 (6.83)	6.8 (5.45)
Median (25th to 75th centile)	6.0 (3.00–10.54)	5.7 (3.00–9.25)
Offer respite care	3.0 (0.00 10.0.)	0.7 (0.00 7.20)
Yes	92/200 (48.4)	53/102 (52.0)
No	98/200 (51.6)	49/102 (48.0)
Approximate number of foster children ever cared for	N = 196	N = 104
Median (25th to 75th centile)	8.0 (3.00–16.50)	7.5 (3.00–19.00)
0 to 5	75/196 (38.3)	46/104 (44.2)
6 to 10	48/196 (24.5)	18/104 (17.3)
11 to 20		
21 to 30	40/196 (20.4)	18/104 (17.3)
	14/196 (7.1)	12/104 (11.5)
31 or above	19/196 (9.7)	10/104 (9.6)
Type of foster carer	151 (100 (75.0)	70 (106 (70 6)
Local Authority	151/199 (75.9)	78/106 (73.6)
Independent not-for-profit agency	37/199 (18.6)	19/106 (17.9
Kinship or family	11/199 (5.5)	9/106 (8.5)
Number of currently placed looked after/foster children [®]	- 0.400.000	
1	78/198 (38.2)	48/108 (44.4)
2	90/198 (44.1)	36/108 (33.3)
3+	30/198 (17.6)	24/108 (22.3)
Recent training (past 3 months)		
No	82/203 (40.4)	41/107 (38.3)
Yes	121/203 (59.6)	66/107 (61.7)
Number of training courses attended in the past 3 months		
1	61/121 (30.0)	36/66 (33.6)
2	34/121 (16.7)	11/66 (10.3)
3 to 12	26/121 (12.8)	19/66 (17.8)
Type of training course [§]		
Foster carer role	44 (21.7)	20 (18.7)
Child and adolescent development	13 (6.4)	8 (7.5)
Behavior	17 (8.4)	8 (7.5)
Managing conflict	11 (5.4)	7 (6.5)
Mental health	10 (4.9)	5 (4.7)
General safety and health	19 (9.4)	10 (9.3)
Relationship	15 (2.4)	11 (10.3)
Safeguarding	29 (14.3)	12 (11.2)
Sexual abuse and exploitation	12 (5.9)	7 (6.5)
Substance misuse	10 (4.9)	8 (7.5)
Attachment	27 (13.3)	15 (14.0)

^{*} A higher or first degree, certificate or diploma in higher education, A, AS or S levels any other qualification.

engagement with child's education and carer quality of life. Untested group differences for both outcomes were apparent at three months but reduced by 12 months. We found no group differences for carer-defined problems or carer-reported attachment. We found that by 12 months a higher proportion of participants in the usual care arm had accessed both other training courses and other services compared to carers in the FC group.

Comparing these results with other studies of in-service foster care training, a recent systematic review by Uretsky and Hoffman (2017) was optimistic about effectiveness in terms of child externalising behaviours. Their meta-analysis of seven studies indicated a

[†] O levels or GCSE grades A–C/ None of these qualifications.

^{*} Full-time and under 18 years of age.

 $[\]S$ Multiple training course per foster carer.

Table 3
Primary outcome results: Carer Efficacy Questionnaire at baseline and 12 months.

	I	Baseline	12	2 months	Adjusted* effect estimate	
	FC N = 146	Usual care N = 74	FC N = 146	Usual care N = 74	Difference [†] (95% CI)	p-value
Main analysis (ITT)	26.6 (4.4)	26.4 (4.3)	27.7 (4.3)	27.8 (4.4)	-0.19 (-1.38 to 1.00)	0.75
Main analysis (ITT) (Partial clustering in FC group)	-	-	-	-	-0.19 (-1.35, 0.96)	0.74
8 items only N=219	23.7 (3.9)	23.4 (4.0)	24.5 (3.8)	24.5 (3.9)	-0.11 (-1.14, 0.91)	0.83
Per protocol N = 113	25.5 (4.4)	26.5 (4.3)	27.3 (3.9)	27.9 (4.5)	-0.35 (-1.93, 1.22)	0.66
Imputation [‡] N = 312	-	-	-	_	-0.19 (-1.37, 0.99)	0.75

Data are mean (SD).

CEQ score ranges from 0 to 36, with a higher score indicating stronger beliefs about their own ability to make positive changes to children's behaviour and outcomes.

FC group = Fostering Changes.

small to moderate positive short-term effect. However, no studies in the meta-analysis have follow-up of more than six months. The review authors concluded that the programmes were effective in different countries and for ethnically diverse samples, and had similar results for children of different ages and sexes. Our results do not really contrast with the studies in this review, as we found more positive results for carer-reported child difficulties in the intervention group at shorter-term follow-up. Child behaviour seems to be the most commonly measured outcome in studies of foster carer training. Fewer studies seem to have measured carer efficacy. Of those studies which have, findings are more positive than in our study. Staines, Golding, and Selwyn (2019) found increased carer efficacy after attendance at a nurturing attachment group work programme for foster and adoptive parents in England. However, adoptive parents identified more children having greater emotional and peer difficulties after group attendance. The evaluation of the six-session trauma-informed Fostering Connections programme in Ireland (Lotty, Dunn-Galvin, & Bantry-White, 2020) found a gain in carer efficacy in the intervention group that was sustained over 15 months with a large effect size over time. In the current study carer efficacy is a mediator, where improved carer efficacy leads to better child outcomes. If child outcomes don't improve over time (despite training) then that may in turn reduce carer confidence. It is possible that the differences in our results with regards to carer efficacy may be partly due to facilitation. We were unable to directly observe session delivery and so have less evidence about training quality. We had a larger diverse group of experienced trainers, who were not the developers of FC. This may explain a lack of effect, however it is a strength of the study when considering whether this intervention can be rolled out effectively in usual practice. The current study was unusual compared to others examining this type of intervention, it was an RCT with a relatively large number of participants, thus making the results an important contribution to the field.

While the eligibility criteria and outcomes assessed in both Briskman's trial and our trial were comparable, three notable differences were duration of follow-up, presence of social workers in sessions and training delivery model. Similar to Briskman's trial, we found some differences at three months but which appear clinically modest. Process evaluation interviews with participant foster carers, facilitators and LA social workers examined contextual factors, causal mechanisms and fidelity of programme intervention and are reported separately. Qualitative data collection was completed with various stakeholders. This included foster carers views of attending the programme alongside social workers. Although some carers saw the presence of social workers as a barrier to enrolment into FC (and by extension recruitment into the trial), others found the presence of the social worker to be quite positive. Results from the qualitative work examining the challenges of recruiting to the trial will be published separately. Recruitment is often challenging in the roll-out of evidence-based interventions (Chamberlain et al., 2012). What this trial adds is evidence about the subsequent trajectory for intervention effects which then diminish over time despite some additional supportive input. This additional support consisted of three termly support groups designed to reinforce and maintain programme learning. The fact that gains at three months were not sustained may suggest that ongoing support needs to be increased in regularity of needs to take a different form. We may speculate that that foster carers who took part in the FC group felt saturated by the commitment of a lengthy programme and did not feel able to seek further training, which may have attenuated some of the effects of the intervention.

Scaling up intervention delivery in real-world settings following initial developer-led efficacy studies is challenging (Eyberg, Edwards, Boggs, & Foote, 2006) and has commonly been associated with reduced effectiveness (Glasgow, Lichtenstein, & Marcus, 2003). While we were unable to directly observe session delivery, we were able to undertake qualitative interviews with participants to capture their experiences and perceptions. This will be published separately in a publication covering the process evaluation of the trial. We found comparable session attendance rates for trial and non-trial samples. Training delivery in the trial was undertaken over five consecutive terms in the first stages of broader programme implementation. Experiential learning for facilitators may lead to optimisation subsequent to the trial period. However, facilitators were recruited as experienced trainers to deliver a structured programme based on well-established theory. Facilitators were trained to deliver the programme and could also choose to be accredited in the delivery by the programme developers (Adoption and Fostering National Team at the Maudsley Hospital, South London, in conjunction with King's College London), but were under no obligation to do this. Greater embedding of the programme may enhance outcomes, but it seems unlikely that this would change the pattern of longer-term outcomes. The 12 weekly sessions,

^{*} Adjusted for stratification (site and programme), and minimisation variables (age of looked after children in household and type of carer at recruitment) and baseline CEQ score; †Adjusted difference in means for FC minus usual care. ‡‡ Imputed one baseline CEQ score and 92 12 months CEQ score. Multiple imputation performed 100 times.

Table 4
Secondary analysis of the primary outcome and secondary outcomes.

Outcome	Group*	Baseline N = 312 (FC = 204, UC = 108)	3 months N = 240 (FC = 164, UC = 76)	12 months N = 229 (FC = 153, UC = 76)	Interaction (group x time) (95 % CI)	p-value	Treatment effect (FC vs UC) (95 % CI)	p-value	Time effect (12 vs 3 month) (95 % CI)	p-value
Carer Efficacy Question	naire (CI	(Q) [‡]								
Overall score Mean	FC	25.8 (4.24	27.6 (4.00)	27.7 (4.29)	-0.92 (-2.26,	0.18				
(SD)	UC	26.4 (4.27)	26.9 (4.63)	27.8 (4.43)	0.43) [§]					
Subscales										
Education N (%) carer	FC	107/190	82/151	69/142	0.37 (0.12,	0.09				
fully engaged with		(56.3)	(54.3)	(48.6)	1.16)** ^{††}					
education (score	UC	56/103	30/72	35/71						
11-12)		(54.4)	(41.7)	(49.3)						
Quality of Life N (%)	FC	94/203	81/157	70/142	0.67 (0.23,	0.46				
higher quality of		(46.3)	(51.6)	(49.3)	1.94)** ^{††}					
life (score 11-12)	UC	51/108	30/74	33/74						
		(47.2)	(40.5)	(44.6)						
Strength and Difficultie	s Questic	onnaire (SDQ)								
Total difficulties	FC	18.8 (6.78)	16.5 (7.38)	15.5 (7.32)	1.90 (0.07,	0.04	-1.94 (-3.52,	0.02	-2.27	0.002
score ^{‡‡} Mean (SD)	UC	18.8 (6.67)	18.8 (6.82)	15.8 (6.95)	3.72) [§]		-0.37) [§]		(-3.74, -0.81) [§]	
SDQ subscales Mean (SD)										
Emotional problems	FC	3.8 (2.61)	3.0 (2.47)	2.6 (2.24)	0.52 (-0.13,	0.12				
score	UC	3.9 (2.56)	3.8 (2.35)	2.8 (2.11)	1.17) [§]	0.12				
Conduct problems	FC	4.3 (2.60)	3.7 (2.62)	3.5 (2.67)	0.63 (-0.08,	0.08				
score	UC	4.1 (2.43)	3.9 (2.39)	3.1 (2.47)	1.34)					
Hyperactivity score	FC	6.7 (2.75)	6.2 (2.75)	5.8 (2.75)	0.23 (-0.43,	0.49				
, p	UC	6.6 (2.61)	6.8 (2.63)	6.0 (2.89)	0.90)	*****				
Peer problems score	FC	3.9 (2.42)	3.6 (2.46)	3.5 (2.50)	0.46 (-0.18,	0.16				
r cer problemo seore	UC	4.2 (2.32)	4.3 (2.53)	3.9 (2.50)	1.11)	0.10				
Prosocial score	FC	3.9 (2.42)	6.3 (2.52)	6.4 (2.32)	-0.40 (-1.06,	0.24				
1 1030ciai score	UC	4.2 (2.32)	6.0 (2.40)	6.3 (2.08)	0.26)	0.2 .				
Impact score	FC	3.5 (2.50)	3.1 (2.54)	3.0 (2.59)	-0.14 (-0.90,	0.71				
impact score	UC	3.2 (2.46)	3.0 (2.40)	2.9 (2.46)	0.61)	0.7 1				
Quality of attachment r				2.5 (2.10)	0.01)					
Total score Mean (SD)	FC	48.9 (10.35)	47.7 (12.02)	48.9 (11.46)	-164.3	0.21				
Total score mean (62)	UC	50.1 (8.50)	46.2 (11.66)	47.5 (9.59)	(-421.9 to 93.2) ***	0.21				
Carer coping strategies	(CCS)†††				/					
Total score Mean (SD)	FC	59.6 (8.05)	58.5 (6.89)	58.4 (7.00)	-1.81 (-3.60	0.048	2.68 (0.89,	0.003	0.96 (-0.50,	0.20
Core meun (ob)	UC	58.0 (7.95)	56.4 (6.78)	57.3 (7.51)	to -0.02)	0.0 10	4.47)	0.000	2.43)	0.20
Carer defined problems			50 (0./0)	5,.0 (7.01)			,		,	
N (%) main concern	FC	113/197	_	22/84			0.72 (0.29,	0.47		
score 70 or above	- 0	(57.4)		(26.2)			1.78) §§§	5.17		
22010 / 0 01 00000	UC	61/105	_	16/48			0)			
	55	(58.1)		(33.3)						

Data are n (%), mean (SD), median (25th to 75th centile) or n/N(%).

* FC = Fostering Changes, UC = usual care. †Adjusted for stratification (site and programme), programme, foster carer and minimisation variables (age of looked after children in household and type of carer at recruitment) and baseline score. ‡ Overall CEQ score ranges from 0 to 36 with a higher score indicates carer with higher efficacy. §Adjusted difference in means: FC minus UC. **Adjusted odds ratio: FC compared to UC. ††Model could not be adjusted for site. ** SDQ score ranges from 0 to 40, with a lower score indicating a child with less difficulties. §§Quality of attachment relationship score ranges from 0 to 64, with a higher score indicating better quality of relationship. ***Squared transformation of raw score. †††Carer coping strategies score range from 0 to 80, with a higher score indicating better coping strategies. ‡‡‡CDPS score range from 0 to 100, with a lower score indicating less concerns with child. §§§Analysis performed on 12 month follow-up.

may be a barrier for some carers. Children in Briskman's trial were younger than children in our trial (mean ages of 7.9 years and 11.3 years respectively). This raises the question as to whether age contributed some differences in effect between the two trials (Briskman et al., 2012). However, Schoemaker's review found intervention effectiveness for sensitive parenting, dysfunctional discipline and parenting stress greater in older children (Schoemaker et al., 2019). This leaves age as an uncertain explanation for differences between the two trials.

FC was trialled by Briskman and colleagues in London. Wales is a different context, with mix of urban, semi-urban and rural areas. However the intervention was adapted slightly for the Welsh (less urban) context by including a wider age group, inviting a social worker to attend and the introduction of the termly follow-up groups. Although recent years have seen some divergence in social care legislation between England and Wales, the foster care systems in the two countries are still very similar and it is unlikely that this would have explained any differences in results found in the two studies. The intervention was also delivered in Wales by a larger group of trainers than in the Briskman trial, and the intervention was not being delivered by the team who developed it, a reason why

the current study is described as pragmatic.

It may be that FC does not include enough of the elements found to be effective in other interventions. A systematic review of psychosocial interventions in foster and kinship care (Kemmis-Riggs, Dickes, & McAloon, 2018) found the effective approaches had clear aims, targeted specific issues and developmental stages, included role play and coaching and were specifically developed to respond to the effects of child maltreatment and prevent disruption of placements. The adaptations made to FC reduced specificity of focus on developmental stages with the shift to an all-age model.

We identified practical challenges in our trial reflecting those previously identified in this context (Dickes, Kemmis-Riggs, & McAloon, 2018). These included difficulties in identifying and approaching potential participants, and being unable to directly observe intervention delivery. We found, as part of the feedback during the process evaluation, that some social workers expressed unease regarding randomisation. This was in part influenced by their subsequent role in the group or involvement with recruitment. Some had been involved in engaging foster carers in the training before the trial phase and so resisted the introduction of a different approach. The process of randomisation caused some disappointment for social workers involved in the delivery of the training when foster carers who they deemed to be 'in need' were perceived to have "missed out". Some of the social workers interviewed had really not been happy to - as they saw it - relinquish their usual control over who attended and who did not. It should be noted that the eligibility criteria were set by the programme rather than being a trial requirement and that access to the programme was limited i.e. not all eligible carers would have been able to access the programme, and that FC is not emergency support. Participant willingness to be randomly allocated could also have been a challenge, however we did not find this to be a barrier. Social worker and participant views on randomisation in the trial are explored in greater detail in the aforementioned qualitative publication on recruitment. Another practical challenge included ensuring that the blinding of the field recruitment staff was retained. This was important to eliminate the possibility of predicting the next allocation and attempting to randomise carers deemed to be most 'in need' to FC. This was addressed by ensuring that all trial team and field recruitment staff, except the Trial Manager and Administrator, were blinded to allocation. Recruiting sufficient carers in time to form adequately sized training groups was another challenge. This was addressed by the 2:1 allocation ratio and using a longer lead-time within which we recruited at any one site.

Trials in children's social care are scarce compared to public or clinical health and a limiting factor is the infrastructure to support high quality trials. We were able to employ experienced field-based health research staff to support recruitment. Considerable effort went into clarifying the rationale for the trial design for professional stakeholders, and offering the training to the control group post-trial to allay concerns about the intervention being withheld.

5. Limitations of the current study

Outcomes were assessed with the index child in mind (i.e. the looked after child with most challenging behaviour at baseline and who is expected to still be placed with carer for at least three months), unless at three or 12 months the child was no longer placed with the participant, in which case the foster carer answered hypothetically or with another child in mind. In total, 60 children were no longer placed with the carer by 12 months, and an additional one left the carer at three months but returned at 12 months. Asking participants to make a hypothetical estimate lacks the validity of real-life judgements and is therefore a limitation of the study. The alternative to this could have been to not collect these data if a child moved. The decision to collect the data was made to examine whether the training would have had a generalisable impact on the carer and as the training is not a crisis intervention package, we would hope that it has some enduring and generalisable value. We concede however that the training is also meant to be responsive the needs of the carer and child at the time. We observed a lower level of internal consistency for the primary outcome measure than found in Briskman's trial (Briskman et al., 2012) which may be another limitation. We selected the measure based on its use, and psychometric performance in the Briskman trial. We report the Cronbach alpha with an aim to re-examine scale properties. Cronbach's alpha is an assessment of item equivalence rather than validity or dimensionality, and its construction by the FC team to assess the programme likely increased the likelihood of its high content and face validity in the Briskman trial. Further validation of the measure would be useful in future research.

6. Conclusions

In conclusion, small predominantly short-term programme benefits were observed and reduced in the long-term. The programme was well-received but aside from attendance metrics we have little other direct evidence about quality of provision and fidelity. Differences in observed benefit compared to a previous trial may reflect the larger and diverse trial population, variation in delivery quality, and the longer-term perspective for outcome assessment. Future research directions include examining the embedding of interventions such as FC within existing delivery systems, and the implementation of this. The extent to which these interventions should be targeted at specific groups of participants should also be examined further.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request but which would require additional processing to ensure confidentiality.

Authors' contributions

Study conception: Professor Sally Holland, MR, RCJ, EC, JSc; study design and conduct: MR, RCJ, JSc, EC, GM, AR, SC, JSe, LBH, ML; drafting manuscript: RCJ, EC, ML, GM, MR; statistical lead: RCJ; statistical analysis: RCJ, ML. RCJ, SC, EC, ML, GM, AR, MR, JSe, JSc critically reviewed and approved the final version of the submitted manuscript. MR is chief investigator of the Confidence in Care Trial

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Declaration of Competing Interest

MR was a member of the Confidence in Care consortium board as the academic evaluation partner. He had no role in deciding programme implementation strategy but was involved in discussions regarding coordination of programme rollout and trial implementation. The authors declare that they have no other competing interests.

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Appendix A. Supplementary data

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