Research Article

Self-Reported Data are Not Sufficient to Distinguish Benefits of One Psychological Intervention Compared to Another, both Aimed at Improving the Parent-Toddler Relationship

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Abstract

This paper reports on a Randomized Clinical Trial (RCT) where mothers at risk of maltreating their infants were randomly assigned to either a widely used parenting training known as Systematic Training for Effective Parenting (STEP), a 12-week once weekly session (n=35), or the Group Attachment-Based Intervention (GABI), a multi-family 26-week treatment (n=43). ANCOVA results compared STEP versus GABI groups' end-of-treatment scores, with intake scores controlled for, on standardized measures of children's exposure to Adverse Childhood Experiences, social isolation, and difficulties with impulse control, were considered. Mothers in both groups reported no significant increase in children's exposure to ACEs, and significant decreases in self-reported social isolation and impulse control difficulties. Discussion focuses on self-reported benefits of both treatment arms, and the need for future intervention studies to include observational measures of maternal sensitivity and of the overall quality of the mother-toddler relationship.

Three Practitioner Points

i.   Self-report indices from mothers re their social isolation, self-esteem, and poor impulse control (positive symptoms, SCL-90, all showed improvements from intake to end-of-treatment in both arms of the RCT, both sharing parenting groups as a central if Not the only part of treatment.

ii. For both arms of the RCT mothers reported no significant increase in their children's exposure to Adverse Childhood Experiences.

iii. Future intervention studies aimed at preventing child maltreatment must include observational measures of maternal sensitivity, and the overall quality of the mother-child relationship.

Introduction

This brief report concerns an investigation of the efficacy of a preventive intervention, specifically the Group Attachment Based Intervention (GABI©) designed for parents struggling to retain custody of their offspring, with the aim of preventing child maltreatment via enhancing parent-child relationships. GABI is rooted in attachment theory [1]. Attachment theory (Bowlby, 1969) [1] defines the infant's relationship to a primary caregiver as an essential part of a child's life that forms the basis for subsequent development. Parent- child experiences contribute to the infant's internal working mental model of how the world of the self, others and relationships seem to work. Once developed, these models are resistant to change but are nonetheless permeable to both favorable and unfavorable influences. Elaborations of attachment theory and related empirical work on intergenerational patterns of attachment [2-4] informed the development and implementation of GABI. The development of GABI was also greatly influenced by the findings from the seminal Adverse Childhood Experiences (ACEs) study [5]. Over decades it has been robustly demonstrated that relationship patterns tend to persist across the lifespan, and across generations, such that if a parent experienced abuse and neglect during childhood, without therapeutic intervention and current social support [6,7], there is a strong likelihood that abuse and neglect will be visited on the next generation. Indeed, the powerful influence of social isolation as an influence on the child maltreatment has been cross-culturally confirmed in Spanish and Columbian countries [8]. And we know that emotion-regulation difficulties or poor impulse control plays a putative role as both cause [9] and consequence [10,11] of child maltreatment.

In the study reported here, the comparison treatment, STEP is a parent training intervention that integrates teaching about parenting from the perspectives of social learning theory and cognitive-behavior therapy [12]. STEP is deemed suitable for parents of children aged 0-18 years, while GABI is tailored for work with parents and their very young children aged 0-3 years. STEP is delivered in didactic parent-group meetings, with a facilitator who guides parents to attend to the child behavior they want to encourage (reinforce) and ignore the unfavored child behavior, while also learning cognitive reappraisal strategies for anger management, and how to defuse emotion laden situations that could result in non-optimal parent-child interactions and domestic violence. Step is delivered over 12 weeks, one-hour once weekly. GABI is a two-hour (3X weekly) structured intervention which includes parent-child, child only and parent group components, delivered over 26 weeks in this RCT report. We have previously reported on the mother-child relationship outcomes from the RCT [13] that relied on discrete rating scales from the Coding Interactive Behavior scales [14], applied to five-minute unstructured parent-child interactions at baseline, and end-of-treatment, while controlling for the influence of maternal ACE exposure – shown to have a minimal effect. In other words, it seems GABI is particularly well suited to helping mothers carrying a high ACE burden. This paper extends the previous report on the GABI RCT insofar as this paper uniquely includes data concerning mother's mental health in terms of two consistently reported parent factors linked to child maltreatment: (1) poor impulse control and (2) social isolation [15]. Additionally, (3) maternal reports of their toddlers' exposure to adverse experiences is reported on. We predicted that GABI, with the more explicit goal of enhancing parent-child relationships

via much practice at interacting together with therapeutic support, would result in significant improvements across all four domains, not expected for children and parents randomly assigned to STEP, hypotheses included in the ClinicalTrials.gov registration of the RCT.

Method

The RCT was conducted at the Rose F. Kennedy Children's Evaluation and Rehabilitation Center (RFK CERC), Montefiore Medical Center in the Bronx, New York from 2012-2017. Families who declined study participation were still eligible for clinical services at the center. This study was approved by the Montefiore-Einstein Committee on clinical investigations, and by the Human Research Protection Program at The New School. The study was thus undertaken in the Bronx, the nation's poorest urban county; its poverty rate among families and children is greater than two times state and national averages. Bronx residents are also young; the Bronx is the youngest county in New York, and 1 of only 5 in the US with more than 30% of children living in a single parent household. The main criteria for inclusion in the RCT was concern about parenting capacity (vs. evidence of symptomology in the child) due to the parent's own history of maltreatment, social isolation or having lost custody of a child in the past. The largest source of referrals came from pediatricians (GABI: 51%, STEP: 38%), with other referrals coming from Administration for Children's Services (GABI: 18%, STEP: 14%), adult mental health or psychiatric referral (GABI: 11%; STEP: 19%), referral by self or family member (GABI: 14%, STEP: 14%), and finally referral by a Family Court judge or lawyer (GABI: 11%, STEP: 14%). Criteria for inclusion were: a) Biological parents b) of birth-36 month old children with custody of their child. Exclusion criteria were: a) Parent inability to provide informed consent due to mental illness or cognitive impairment, b) Parent lack of fluency in English.

Interested parents (exclusively mothers) were screened and, if eligible, scheduled for a study visit to be consented, complete baseline questionnaires, and randomized. For randomization, research staff opened sealed envelopes which allocated participants in a 1:1 ratio to treatment (GABI© or Control) groups, stratified by child age (<vs.≥18 months). Parents and children were then scheduled for a visit to the New School Attachment laboratory for baseline behavioral observations of the mother-child interaction. All measures were obtained at baseline (T1), and again at end-of-treatment (T2) except for parent report of ACEs, only collected at baseline. Participants received a $50 per person incentive after each lab visit, so a family would typically earn $100 for each of the two lab visits., with a few earning $150 (if father also come for the visit). In practice, one quarter of mothers visiting the lab came with the child's father, but fathers were not included in the study as their attendance was sporadic and not tracked

Treatment arms

Intervention: GABI©, a 26-week manualized intervention [13,16], aims to strengthen the mother-child relationship in birth parents and their birth to 3-year-old children, as they attend GABI together. Each 2-hour session begins with a 45-minute dyadic parent-child psychotherapy session which is delivered in a group context. Next, parents and children separate into concurrently run 60-minute group sessions. Each session ends with a final group 15-minute parent-child reunion. GABI© was offered three (3) times weekly for two hours. Parents could attend for the morning or afternoon session (3 sessions/week). In addition, GABI© offers families 24/7 text access to on-call clinicians available to consolidate family engagement by helping to address sources of stress as they arise.

Control: Controls were assigned to attend Systematic Training for Effective Parenting (STEP) [12], a parenting class offered over one hour, once weekly (over 12 weeks). At the time the RCT was begun, based on a telephone survey of Bronx Prevention Agencies, STEP was the prevailing maltreatment education program in the study locale. After completing the STEP group and the end-of-treatment follow-up (six months on – not the focus of this report), families could choose to receive GABI. This report focuses on 78 mothers and their infants/toddlers, 43 randomly assigned to GABI and 35 randomly assigned to STEP.

Training protocols: All clinicians (LMSW or PhD psychologists) were trained in either GABI© or STEP, and delivered interventions based on training protocols throughout the trial period. Monthly fidelity scores exceeded 90% agreement, with

items in distinctive GABI and STEP checklists, across all months of the RCT in both arms.

Measures

Child outcomes

Clinical Child Adverse Childhood Experiences: Parents completed a 25- item questionnaire [17] asking parents to report on their child's lifetime exposure to abuse, neglect and household dysfunction (e.g. parental incarceration, substance abuse, domestic violence). Child-ACE items mirror those of the original adult ACE study, asking the parent to comment on the extent of their child's exposure to the specified forms of abuse, neglect or household dysfunction.

Parent outcomes

Adverse Childhood Experiences (ACEs): Maternal reports of their own exposure to ACEs was collected at baseline, relying on a 25-item (tapping 10 domains of ACEs) clinician-administered Clinical ACE Questionnaire based on the original ACE study [5], assessing the adult's recollection of exposure to traumatic events and circumstances over the first 18 years of life [17]. ACE scores range from 0-10, depending on levels of agreement to 3 forms of abuse (physical, psychological, sexual abuse) 2 categories of neglect (physical neglect and emotional neglect) and 5 forms of household dysfunction (parental mental illness, incarcerated parent, substance abuse, exposure to domestic violence and parental separation/divorce). Exposure to 4 or more of these ACEs has been shown to have associations to all range of adult psychological and physical health problems [5]. We have demonstrated the validity of our clinician-administered Clinical ACE Questionnaire in association to the parenting domain, e.g. in showing a significant association between parents with exposure to four or more ACEs and those same parents' unresolved loss or trauma or can't classify responses to the Adult Attachment Interview [18]. We have also shown a significant link between parents with exposure to four or more ACEs in the first 18 years of their life and clinical levels of parenting stress, in both low SES and high SES contexts [19].

Interpersonal Support Evaluation List (ISEL): 40-item multi-dimensional inventory measures perceived social support [20]. The ISEL yields a global scale score, and four factors related to support: tangible, belonging, appraisal, and self-esteem, and a summary total score relied on in this report [21].

Symptom Checklist (SCL90-Revised): 90-item checklist, measures current psychiatric symptoms yielding alphas ranging from 0.77 to 90, and test-retest reliabilities from 0.78 to 0.90 [22]. The Positive Symptom Index reflects anxiety, hallucinations, delusions, and all range of mental health problems reflecting an over-abundance of mental and emotional activity and, by implication, difficulties with impulse control. Thus, the Positive Symptom score (including hallucinations and delusions) from the SCL-90 was relied on in this report as a proxy for difficulties with impulse control.

Sample size, power calculations, attrition/retention
Sample size was determined from prior work on disorganized parent-child attachment (Cicchetti et al. 2006) and following conventional approaches to power computations and sample size considerations [23]. Assuming STEP controls remain at 88% with disorganized attachment as is common in child maltreatment contexts, and that GABI©'s rate declines to <60% by end-of-treatment (T1), 35 subjects per group are required to detect this effect with 80% power. Given an expected attrition rate of 30%, we aimed to recruit 50/group with a target N of 70, 35 in each group. There were a large number of cases (35) who dropped, after initial contact, or started but did not complete baseline measures (35). When these numbers are taken into consideration, retention from initial allocation to end-of-treatment was 37% for families assigned to GABI and 32% for families assigned to STEP. In other words, attrition rates were high (63% for GABI and 68% for STEP), more than twice the level expected. These failed intakes, and attrition after some contact or some information was collected, was due mainly to housing instability with families moving and becoming uncontactable.

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Page 2/5

Demographic characteristics of the sample

Table 1: Summarizes the socio-demographic characteristics of the mothers who were in the GABI or STEP arm who were followed from intake to end-of-treatment.

	GABI (n=43)	STEP (n=35)
Ethnicity		
White	1 (2%)	2 (5%)
Black	12 (28%)	13 (37%)
Hispanic	20 (47%)	14 (40%)
Bi-Racial	10 (23%)	6 (17%)
Schooling		
No High School	3 (7%)	4 (11%)
Some High School	21 (49%)	9 (26%)
High School Diploma	9 (21%)	9 (26%)
Some College	7 (16%)	10 (29%)
College Degree	2 (5%)	3 (9%)
Advanced Degree	1 (2%)	0 (0%)
Unemployed	27 (63%)	22 (63%)
Ever Lost a Child to Foster Care?	8 (19%)	6 (17%)
Previous Psychiatric Hospitalization	6 (14%)	9 (26%)
Currently taking psychotropic meds	7 (16%)	8 (23%)
Housing		
Private home	15 (35%)	17 (48%)
Gov't housing	6 (14%)	3 (9%)
Living with Family or Friend	10 (23%)	8 (23%)
Shelter	10 (23%)	7 (20%)
Foster Care	2 (5%)	0 (0%)
4 or more Adverse Childhood Experiences (ACEs) Reported re 1st 18yrs of life	31 (72%)	28 (80%)

Table 1 reveals an ethnically diverse sample, with GABI/STEP distributions as follows: 28%/37% Black, 47%/40% Hispanic and 10%/6% Bi-Racial. Table 1 also shows that 7%/9% of parents have some college, 21%/26% received a high school diploma, while 56%/37% did not complete high school. About half of the families lack stable housing and are living in the shelter system or have temporary housing arrangements with a family or friend. Two-thirds of the parents were unemployed, while nearly 20% had previously lost custody of a child who was placed in foster care. In terms of the demographic characteristics shown in Table 1, no significant differences were observed when comparing mothers from one arm with the other arm of the RCT [13]. This non-significance of comparison across treatment groups holds as well for the reported incidence of adverse childhood experiences (72% of mothers in GABI and 80% of mothers in STEP reported 4 or more ACEs). Notably, this high ACE (4 or more) threshold was observed in less than 10% of the original ACE sample recruited from a large middle-class sample of more than 17,000 individuals by Felitti et al. [5], revealing significant histories of ACEs among the vast majority of mothers in both arms of the RCT. Regarding age of child and gender, these demographic characteristics were similarly distributed across treatment groups. At baseline, age of child in months in GABI (mean=16.1, sd=9.0, n=43), and in STEP (mean=16.9, sd=12.1, n=35), t-value <1, NS. Regarding child gender, 27/43 or 63% were boys in GABI, and 18/35 or 51% were boys in STEP, Chi-Sq <1, NS.

Data analytic plan

Salim, et al. [24] reported on multiple simulations for dealing with substantial dropout rates in clinical trials, and conclude that "complete-case (CC) analysis produces unbiased estimates only when the dropout mechanism does not depend on pre-test values." (p. 335). Therefore, in the statistical analyses that follow we first explore if pre-test values differed between those families who completed intake but dropped out in contrast to those that remained until post-treatment. We then proceed to a per protocol Complete-Case (CC) series of analyses rather than attempt to impute missing values given that missing values would need to be imputed for more than >51% families – when it is suggested that as a 'rule of thumb' imputation should only be attempted when dropped cases are 40% or less of the available cases to consider [25].

Results

Results are presented below in two sections. The first section is relevant to Intent-To-Treat considerations insofar as baseline information are looked at as a function of whether or not the case proceeded to end-of-treatment, and with attention to randomization to GABI or STEP. The second section of results considers the end-of treatment scores obtained from mothers on repeat measurements of the baseline assessment, controlling for possible variations in baseline measures in a series of ANCOVA results reporting on each of the study's three questions about the possible benefits of GABI as compared to STEP: (1) children's exposure to ACEs; (2) mothers' reported social support; (3) mothers' positive symptoms (SCL-90). In order to consider whether dropout depended on pre-treatment values obtained, a series of independent samples t-test were computed with baseline mean scores grouped by drop out versus Completed Cases (CC) status and shown separately for those randomized to GABI and those randomized to STEP. These results are shown below in Table 2.

Table 2: Intake mean scores (and standard deviations) grouped by those randomized to GABI or STEP who did, and did not, complete end-of-treatment measures

	Dropped (n=48)	Completed Cases (N=43)	t-value
GABI			
Child ACEs	2.00 (1.34)	2.30 (1.89)	t<1, NS
Maternal ACEs	5.50 (2.46)	5.09 (2.51)	t<1, NS
Social Support	72.61 (21.61)	71.20 (24.49)	t<1, NS
Current Stress	8.74 (5.97)	10.58 (5.89)	2.41, p=0.16
SCL-90 Positive Symptom-index	2.30 (0.66)	2.30 (0.73)	t<1, NS
	Dropped (n=32)	Completed Cases (N=35)	t-value
STEP			
Child ACEs	2.28 (1.76)	2.51 (2.02)	t<1, NS
Maternal ACEs	5.32 (2.31)	5.74 (2.81)	t<1, NS
Social Support	80.13 (21.45)	65.71 (29.09)	t=2.17, p <.05
Current Stress	8.88 (5.07)	8.30 (5.78)	t<1, NS
SCL-90 Positive Symptom-index	2.27 (.58)	2.25 (.72)	t <1, NS

Note: T-value for Social Support re STEP group is the t-value assuming unequal variances as Levene's F=4.04, p<0.05.

Table 2 shows, with respect to those cases randomized to GABI, there were no significant differences at baseline, across the measures obtained, for those who

dropped versus those who completed treatment. Table 2 also shows, with respect to those cases randomized to STEP, across the four measures obtained, there was one significant difference observed insofar as those who dropped reported higher levels of social support than those mothers who completed STEP treatment. With this one exception, Table 2 confirms that a CC per protocol analysis would provide unbiased estimates of treatment efficacy, as drop out largely did not depend on pre-treatment measures [24].

Completed Cases (CC) results

Section two of results focuses on ANCOVA results –typically relied on in test-retest designs where analysis of variance between the two arms of the RCT at end-of-treatment are looked at, while treating intake values as covariates. ANCOVA controls for possible differences between treatment groups at baseline (T1) by creating an overall adjusted T1 mean, to be compared to an overall adjusted T2 mean. Table 3 below shows the adjusted T1 means and end-of-treatment means for each of the four self-reported measures. The ANCOVA statistics relevant to these means are shown below in Table 3 which provides answers to the questions of whether mothers in GABI fared better from treatment than those who received STEP, In terms of children's exposure to ACEs, maternal reports of social support and impulse control difficulties (SCL-90 positive symptoms)? Table 3 provides the F-value for the Group Effect that would suggest GABI fared better than STEP. All F-values were non-significant, less than one. But post-hoc t-tests described below all show that both groups, GABI and STEP, changed significantly in the expected direction.

Type of Treatment	T2 Maternal Report of Children's ACE Exposure			
	Observed Mean	Adjusted Mean	SD	n
GABI	2.51	2.58	2.18	43
STEP	2.6	2.51	2.32	35
Note. Overall Adjusted Mean for Children's ACE exposure at T1=2.40, F<1, NS				
T2 Maternal Reports of Social Support				
GABI	78.58	77.25	24.05	43
STEP	76.31	77.96	21	35
Note. Overall Adjusted Mean for Social Support at T1=68.72, F<1, NS				
T2 Positive Symptom Distress Index scores				
GABI	2	1.99	0.85	43
STEP	1.98	1.99	0.75	35

Table 3 shows that the level of Adverse Childhood Experiences reported by mothers regarding their toddlers' exposure is very similar at intake and end-of-treatment with a negligible increase for each group from the overall adjusted mean of 2.4 at intake to adjusted mean of 2.58 for those children in the GABI arm, and 2.51 for those children in the treatment-as-usual STEP arm, 2.51. The group effect is not significant, and the pair-wise repeated measures t-test for the full group (N=78) confirmed no significant change in children's exposure to ACEs, t<1, NS.

Table 3 also portrays the ANCOVA results comparing intake maternal reports of Social Support, with those same reports at end-of-treatment. Table 3 indicates that the overall adjusted mean at intake was 68.72, and that the adjusted means for both arms of the RCT was circa 9 points higher at end-of-treatment, 77.25 for GABI and 77.96 for STEP, hardly distinguishable from one another. In other words, both groups reported similarly higher social support at end-of-treatment compared to intake. The pair-wise repeated measures t-test for the full group (N=78) confirmed a significant overall increase in parents' reports of social support, t=3.47, p<0.001. Table 3 shows that this same global decline in positive symptoms and no significant difference between groups. Table 3 shows that the overall adjusted mean at intake was 2.27, and that the adjusted means for both arms of the RCT was circa 0.3 points lower at end-of-treatment, 1.99 being the adjusted mean for mothers in both GABI and STEP. The pair-wise repeated measures t-test for the full group (N=78) revealed a highly significant overall reduction in parents' reports of positive symptoms, t=4.86, p<0.0001.

Discussion

Counter to expectation, this study found that mothers in both treatment groups showed significant improvements in reports of social support, reductions in impulse control difficulties, and no change in maternal reports of their children's exposure to ACEs. These results stand in stark contrast to our previously published findings showing that mother-child interactions improved significantly, but only for families receiving GABI, not STEP. Discussion below addresses these findings, commenting on the unique benefits GABI has in terms of increasing the quality of the parent-child interaction, very likely on account of including children in the treatment, and the shared benefits observed across both arms of the RCT in terms of self-report. With regard to aim of preventing child maltreatment, and addressing the parental factors linked to child maltreatment, namely difficulties in impulse control and social isolation, both arms of the study showed themselves to be effective. The evidence base for STEP [26] has thus been extended by the current report just as it has been further confirmed for GABI [13]. Notably, with respect to the central aim of preventing child maltreatment, the measure of this was via parental report (not an independent observer). Admittedly, the ACE questions were administered via interview following a modified version of the original adult ACE questionnaire [17], and no significant increase in lifetime exposure to ACEs was evident for the children in the study, irrespective of the arm of the RCT. Consistent with this picture, no child was removed from a parent by Protective Services while the families were participating in this clinical trial.

With respect to social isolation, the results confirm that both arms of the RCT were deemed helpful by the parents involved. Both arms of treatment were group-oriented, with routine opportunities for the parents to discover commonalities with the other parents in the group, as was benign or positive non-judgmental guidance from the therapists. Thus, it is likely that the parents genuinely felt a reduction is social isolation over the time of treatment, as indicated by their responses to the Interpersonal Support Evaluation List [20,21]. These findings offer support for the ongoing relevance of this questionnaire, which was developed over thirty-five years ago, and the current findings speak for the measure's suitability for a diverse population of parents, burdened with poverty and trauma histories. Eliminating social isolation and promoting social support, the readiness to accept it and value it, is vital to child maltreatment prevention efforts [15].

With respect to difficulties with impulse control, we relied on the SCL-90 index of positive symptoms, we found that mothers in both arms of the RCT reported significantly lower scores at end-of-treatment as compared to baseline/intake. Here again, the expectations of the study were not confirmed, as GABI did not provide a unique benefit. Parents in both arms of the RCT reported significantly lower levels of positive symptoms at the end of treatment, as compared to their intake reports. This speaks for the therapeutic value of GABI or STEP --- with the agent of change likely to include support from peer parents, and from the therapeutic team delivering the intervention. This result, based on self-report, speaks to the parent's increased sense of emotion-regulation that improved across both arms of the RCT. And, clearly a multi-method approach to studying this phenomenon would be preferred, given the central role impoverished impulse control plays in triggering child maltreatment. Yet, the importance of these questionnaire-based results is underlined by recent reports of the deleterious effects of early exposure to ACEs and impoverished emotion-regulation strategies [27], and the links among child maltreatment, difficulties with emotion-regulation and later PTSD [28]. Improving parents' emotion-regulation skills is likely to have an immediate positive impact on their children's developmental trajectory.

Limitations of the current report include the high level of dropout. While this is not surprising given the many challenges the families face including unstable housing, domestic violence, partner incarceration and other corollaries of living in poverty, additional efforts to engage and keep families in treatment need to be made. These might include offering the intervention at times when families who are studying or working might be more inclined to attend, for example on weekends. Further extensions of GABI could include greater efforts to involve fathers in the intervention program. And further work based on STEP could include opportunities for parents and toddlers to interact together with therapeutic support. Additionally, it is a limitation of the current work that maternal reports of children's exposure to ACEs was the only measure obtained of child maltreatment risk. Clearly, a multi-method approach is to be preferred and one that follows children long into the future so that their risk of being harmed is tracked and minimized, while their school readiness is likely to be increased.

Conclusion

Finally, the current paper confirms that conscious deliberate responses to questions about social support and mental health show improvements in BOTH groups, unlike the previously published observations of the parent-child interaction that did reveal GABI uniquely benefitted these families [13]. In conclusion, reliance on self-report data alone is insufficient when intervening early in life when observations of maternal sensitivity are vital to the child's immediate and long-term health [1].

Acknowledgements

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Page 5/5