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Sequential, Multiple Assignment, Randomized Trial (SMART) Study Design Example

Parents and Adopted Adolescents Study (PAAS)

Methods

Study Design

The Parents and Adopted Adolescents Study (PAAS) was a sequential, multiple assignment, randomized trial (SMART) conducted to identify the most effective methods for promoting parent-child attachment and healthy behavioral development among newly adopted adolescents. In the first stage of the study, we compared the effectiveness of the usual post-adoption follow-up to adoption-specific family counseling. Adolescents who responded to stage 1 interventions continued to receive them in stage 2; those who did not respond to their assigned intervention in stage 1 continued the same intervention and also received either individual child education about adoption or individual child therapy sessions.

The complete study period was May 1, 2016, to May 1, 2018. Recruitment, enrollment, and randomization to stage 1 interventions took place immediately after adoptions were finalized. Recruitment and enrollment continued from May 1, 2016, to November 1, 2017. We conducted the study over 2 years so that we could recruit enough participants, as well as have enough time for the recruited adolescents and their families to participate in the interventions.

Study Participants

Participants were recruited from public child welfare agencies in the United States. Physically healthy adolescents aged

12 to 17 were eligible to participate in the study. Although the adoptive parent or parents worked with the adolescents as part of the intervention, parents were not considered to be enrolled in the study. All adolescents were eligible for adoption because their biological parents' parental rights had been terminated. Adolescents were excluded from the study if they had been diagnosed with autism spectrum disorder, fetal alcohol spectrum disorder, or another developmental disability that would potentially limit their participation in the educational part of the intervention. Any adolescents with a secure attachment to their adoptive parents, as a result of foster-to-adopt family placement, were also excluded. We expected that, as a result of preplacement trauma, adolescents recruited into the study would exhibit high levels of externalizing and internalizing behaviors.

The study protocol was reviewed and approved by the Virginia University's College of Arts and Sciences Institutional Review Board. Written informed consent from one or both adoptive parents was required for the adolescent to participate in the study. In addition, written assent was obtained from all adolescents in the study.

Study Procedure and Randomization

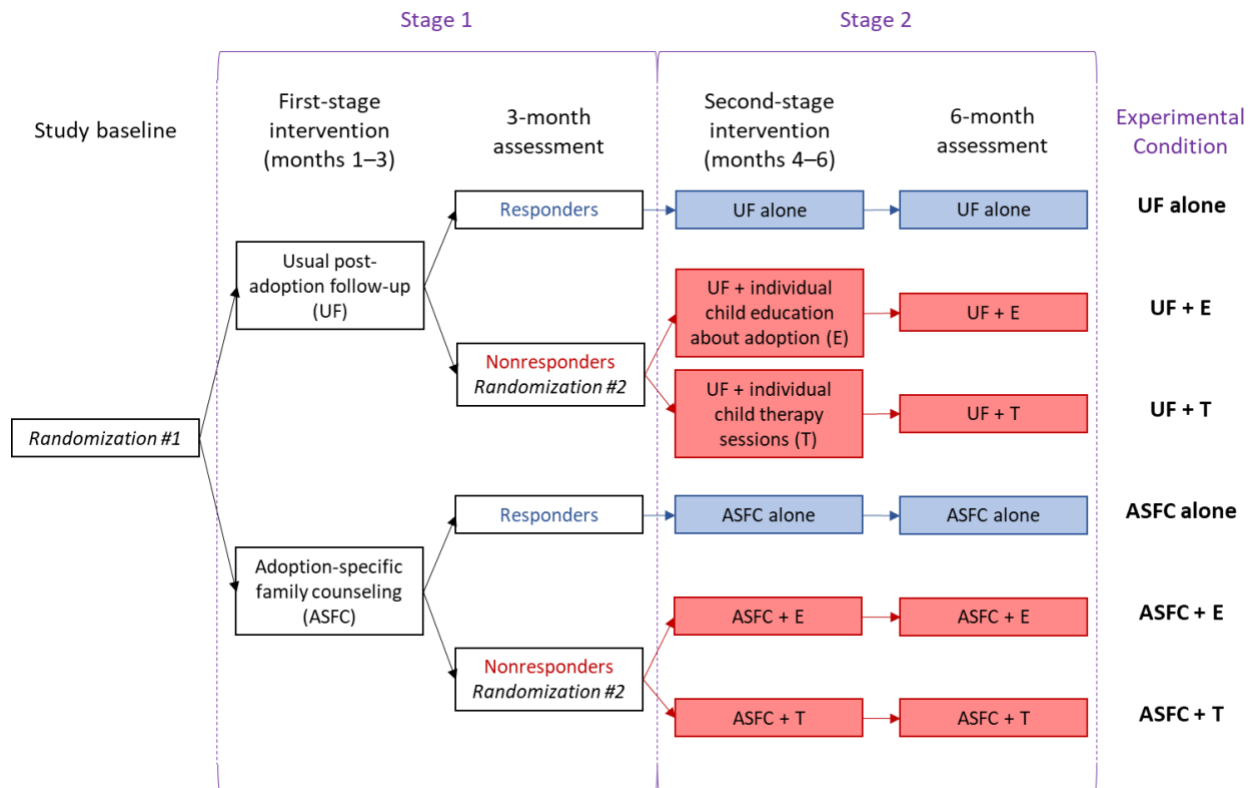
Participants who met the eligibility criteria were randomized into one of the following two intervention groups for stage 1 of the study immediately after their adoption was finalized: (1) usual post-adoption follow-up visits by the adoption specialist social worker (UF) or (2) adoption-specific family counseling delivered by a licensed clinical

social worker or psychotherapist (ASFC). At the beginning of the study (baseline, as shown in Figure 1), the adolescents completed the Friends and Family Interview (FFI) to determine their attachment category. At the same time, one parent per family completed the Child Behavior Checklist/6-18 (CBCL) to assess adolescent baseline externalizing and internalizing behaviors. (These assessments are described in the Outcome Measures section.) During stage 1, families were required to attend at least 8 of the 12 usual post-adoption follow-up visits or adoption-specific family counseling sessions to continue in the study. They were also required to complete the FFI and CBCL

assessments again after 3 months at the end of stage 1 to determine their responses to the stage 1 intervention. Adolescent participants were considered “responders” if they met all three of the following conditions:

- Their FFI attachment classification changed from insecure disordered (disorganized) to insecure ordered or secure or from insecure ordered to secure
- Their CBCL Internalizing Behavior subscale scores were reduced by 20%
- Their CBCL Externalizing Behavior subscale scores were reduced by 20%

Figure 1. SMART design schematic illustrating adolescent participant assignments to stage 1 and 2 interventions and assessments for the six experimental conditions.



In stage 2, families were retained in the originally assigned intervention if the adopted adolescent had responded to it. If not, they were randomized a second time, and one of the following two additional services was assigned along with the

original intervention (UF or ASFC): (1) individual child education about adoption (E) or (2) individual child therapy sessions (T). Table 1 presents the intervention components for both stages.

Table 1. Intervention components for stage 1 and stage 2.

Stage 1 Interventions		Stage 2 Interventions for Nonresponders to Stage 1 Interventions*	
Usual post-adoption follow-up (UF)	The adoption caseworker provided weekly post-adoption visits to record information about the adolescent’s nutrition and growth, activities, and adjustment to school and the new family. The caseworker provided educational materials to the parents and general advice about adolescent development and parenting techniques for adolescents.	Usual post-adoption follow-up (UF) AND Individual child education about adoption (E)	The caseworker provided weekly post-adoption visits, as in stage 1. In addition, the adolescent accessed educational resources. Education consisted of access to online training about adoption and books about the experiences of other adopted adolescents.
		Usual post-adoption follow-up (UF) AND Individual child therapy sessions (T)	The caseworker provided weekly post-adoption visits, as in stage 1. In addition, the adolescent participated in weekly individual child therapy sessions. A licensed clinical social worker provided individual therapy to each adolescent, with emphasis on the adoption experience and how the adolescent could handle difficult feelings, school challenges, and integration into his or her new family.
Adoption-specific family counseling (ASFC)	A licensed clinical social worker provided weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. Counseling aimed to educate parents about the best parenting practices for healing traumatized adolescents and the best ways to handle their behavioral issues.	Adoption-specific family counseling (ASFC) AND Individual child education about adoption (E)	The social worker provided weekly family counseling sessions, as in stage 1. In addition, the adolescent accessed educational resources. Education consisted of access to online training about adoption and books about the experiences of other adopted adolescents.
		Adoption-specific family counseling (ASFC) AND Individual child therapy sessions (T)	The social worker provided weekly family counseling sessions, as in stage 1. In addition, the adolescent participated in weekly individual child therapy sessions. A licensed clinical social worker provided individual therapy to each adolescent, with emphasis on the adoption experience and how the adolescent could handle difficult feelings, school challenges, and integration into his or her new family.

* Responders continued to receive either the usual post-adoption follow-up (UF) only or adoption-specific family counseling (ASFC) only for an additional 12 weeks.

After 3 months of stage 2 interventions (6 months into the study), participants were assessed a final time. As in stage 1, families were required in stage 2 to attend at least 8 of the 12 usual post-adoption follow-up visits or adoption-specific family counseling sessions to complete the study. They were also required to complete the FFI and CBCL assessments again at the end of stage 2. In addition, adolescents who were randomized to the supplemental individual child education about adoption intervention had to access educational materials at least once a week for at least 8 of the 12 weeks, and adolescents who were randomized to the supplemental individual child therapy sessions intervention had to attend at least 8 of the 12 sessions.

Outcome Measures

This study was designed to investigate the following:

- (1) Primary Questions:
 - a. Which stage 1 intervention, usual post-adoption follow-up (UF) or adoption-specific family counseling (ASFC), results in more secure attachment at the end of the study?
 - b. In participants who did not respond to the intervention in stage 1, which stage 2 intervention, individual child education about adoption (E) or individual child therapy sessions (T), results in more secure attachment?
- (2) Secondary Questions:
 - a. Which stage 1 intervention results in lower Internalizing Behavior and Externalizing Behavior scores at the end of the study?
 - b. In participants who did not respond to the intervention in stage 1, which stage 2 intervention results in lower Internalizing Behavior and Externalizing Behavior scores?

To answer the primary questions, the FFI was used to assess adolescent attachment to adoptive parents over time. This semi-structured interview was adapted from the Adult Attachment Interview and

has eight dimensions (Coherence, Reflective Function, Evidence of Secure Base, Evidence of Self-Esteem, Peer Relations, Sibling Relations, Anxieties and Defenses, and Differentiation of Parental Representations). The interview protocol also includes criteria for coding non-verbal expressions of fear/distress and frustration/anger. The transcript dimensions and video codes are scored using four ratings (1 = no evidence, 2 = mild evidence, 3 = moderate evidence, and 4 = marked evidence). Scoring of the FFI yields one of four global attachment classifications: secure (linked to the most positive results), insecure/ambivalent and insecure/avoidant (linked to moderately positive results), and disorganized (linked to the least healthy results). The secure and the two insecure classifications are considered “ordered,” in contrast to the disorganized type of attachment. For our analyses, we determined the percentages of participants with secure or insecure ordered classifications. The protocol coding guidelines note that different types of emotion regulation are associated with each possible attachment style. For example, secure adolescents cope somewhat easily with challenging situations, will turn to others for support, and will offer support to others, while avoidant adolescents inhibit their expressions of distress and either idealize or denigrate others. Adolescents with an ambivalent attachment style have high ratings of either anger or passivity. Those with a disorganized attachment style have high scores on fearfulness and nonverbal distress. Each FFI lasted an average of 35 minutes. We videotaped and transcribed every interview, then coded both verbal and nonverbal observations. Two trained evaluators conducted and coded each of the first 10 interviews and achieved inter-rater reliability (Cohen’s kappa = 0.92). Subsequent interviews were conducted and coded by only one of the two evaluators.

To answer the secondary questions, we used the school-age version of the

CBCL, a component of the Achenbach System of Empirically Based Assessment, scored by parents, to assess adolescents' behavior over time. The school-age CBCL is designed for children and adolescents ages 6-18 and consists of 120 questions, 113 of which are scored on a three-point Likert scale (0 = not true (as far as you know), 1 = somewhat or sometimes true, 2 = very true or often true). The scored questions are organized into eight syndrome scales; three of these, Anxious/Depressed, Withdrawn/Depressed, and Somatic Complaints, consist of a total of 32 questions and are summed to produce an Internalizing Behavior subscale score ranging from 0 to 64, while two others, Rule-Breaking Behavior and Aggressive Behavior, consist of a total of 35 questions and are summed to produce an Externalizing Behavior subscale score ranging from 0 to 70. We used the Internalizing Behavior and Externalizing Behavior subscales for our analyses, and we determined the average score on each for the interventions of interest. Higher scores on both subscales indicate more numerous and frequent behavioral problems.

Additional secondary analyses compared FFI classifications and CBCL scores for adolescents in families assigned to the usual post-adoption follow-up or adoption-specific family counseling at the end of stage 1 (3 months).

Data Analysis Plan

To determine which stage 1 intervention resulted in a more secure or ordered attachment style or improved behavior as the study progressed, we compared the FFI classifications and CBCL scores for the combination of participants in conditions UF Alone, UF + E, and UF + T, shown in Figure 1 (i.e., all participants who received the usual post-adoption follow-up throughout the study) with scores for the combination of participants in conditions ASFC Alone, ASFC + E, and ASFC + T

(i.e., all participants who received adoption-specific family counseling throughout the study) after 3 and 6 months of intervention. To determine which stage 2 intervention resulted in a more secure or ordered attachment or improved behavior for adolescents who did not respond to the intervention in stage 1, we compared the FFI classifications and CBCL scores for the combination of participants in conditions UF + E and ASFC + E (i.e., all participants who received individual child education about adoption) with scores for the combination of participants in conditions UF + T and ASFC + T (i.e., all participants who received individual child therapy sessions) at 6 months.

FFI Assessment

Parent-child attachment was represented by the percentage of adolescents classified as secure or insecure ordered on the FFI. We calculated odds ratios with 95% confidence intervals to determine whether there was a significant difference between the percentages of participants classified as insecure ordered or secure post-intervention. Data were compared at 3 months and 6 months for adolescents in families assigned to the usual post-adoption follow-up or adoption-specific family counseling for the duration of the study (i.e., combined conditions UF Alone, UF + E, and UF + T vs. combined conditions ASFC Alone, ASFC + E, and ASFC + T) and at 6 months for adolescents assigned to individual child education about adoption or individual child therapy sessions (i.e., combined conditions UF + E and ASFC + E vs. combined conditions UF + T and ASFC + T). Odds ratios were calculated as the odds of being categorized as insecure ordered or secure after the adoption-specific family counseling intervention versus the usual post-adoption follow-up intervention or after the addition of individual child therapy sessions versus individual child education about adoption for nonresponders. The threshold for statistical significance was set to $p = 0.05$. Analyses

were performed with SAS software, version 9.4 (SAS Institute).

CBCL Assessment

We designed the study to have 80% power at $\alpha = 0.05$ to detect a small effect size (Cohen's $d \leq 0.20$) for the effect of the interventions (usual post-adoption follow-up, adoption-specific family counseling, individual child education, and individual child therapy) on differences in Internalizing Behavior and Externalizing Behavior as assessed via the CBCL. Effect sizes ranging from 0.21 to 0.79 were considered moderate; any effect ≥ 0.80 was considered large.

We used regression modeling techniques with effect-coded group membership as a predictor to compare CBCL scores at 3 months and at 6 months for adolescents in families who were assigned to either usual post-adoption follow-up or adoption-specific family counseling for the duration of the study (i.e., combined conditions UF Alone, UF + E, and UF + T vs. combined conditions ASFC Alone, ASFC + E, and USFC + T). Each result was predicted by a combination of variables.

We also compared CBCL scores of nonresponders who also received either individual child education or individual child therapy as an additional intervention (i.e., combined conditions UF + E and ASFC + E vs. combined conditions UF + T and ASFC

+T). Three-month outcome measure data from stage 1 were used as baseline data in stage 2. For these analyses, we used effect coding to show group membership and generalized linear models to compare CBCL scores at 6 months.

Results

Study Participants

A total of 278 adolescents and their families were recruited for the study. Their progression through the study is displayed in Figure 2. Two adolescents had been placed with caregivers who served first as their foster parents, who later adopted them. Because both these adolescents had secure attachment to their new adoptive parents, they were excluded from the study. A total of 276 adolescents were randomized into one of two interventions in stage 1. Over the course of the study, 76 adolescents dropped out; therefore, data for 200 participants were included in the final analysis of outcomes. Analyzed participants completed the required number of usual follow-up visits, counseling sessions, or therapy sessions and accessed educational resources the required number of times. In addition, they completed the 3-month and 6-month FFI and CBCL assessments. There were no systematic or significant differences between the assigned and analyzed groups. Baseline data for the analyzed participants are reported in Table 2.

Figure 2. CONSORT diagram of participant flow for all adolescent study participants.

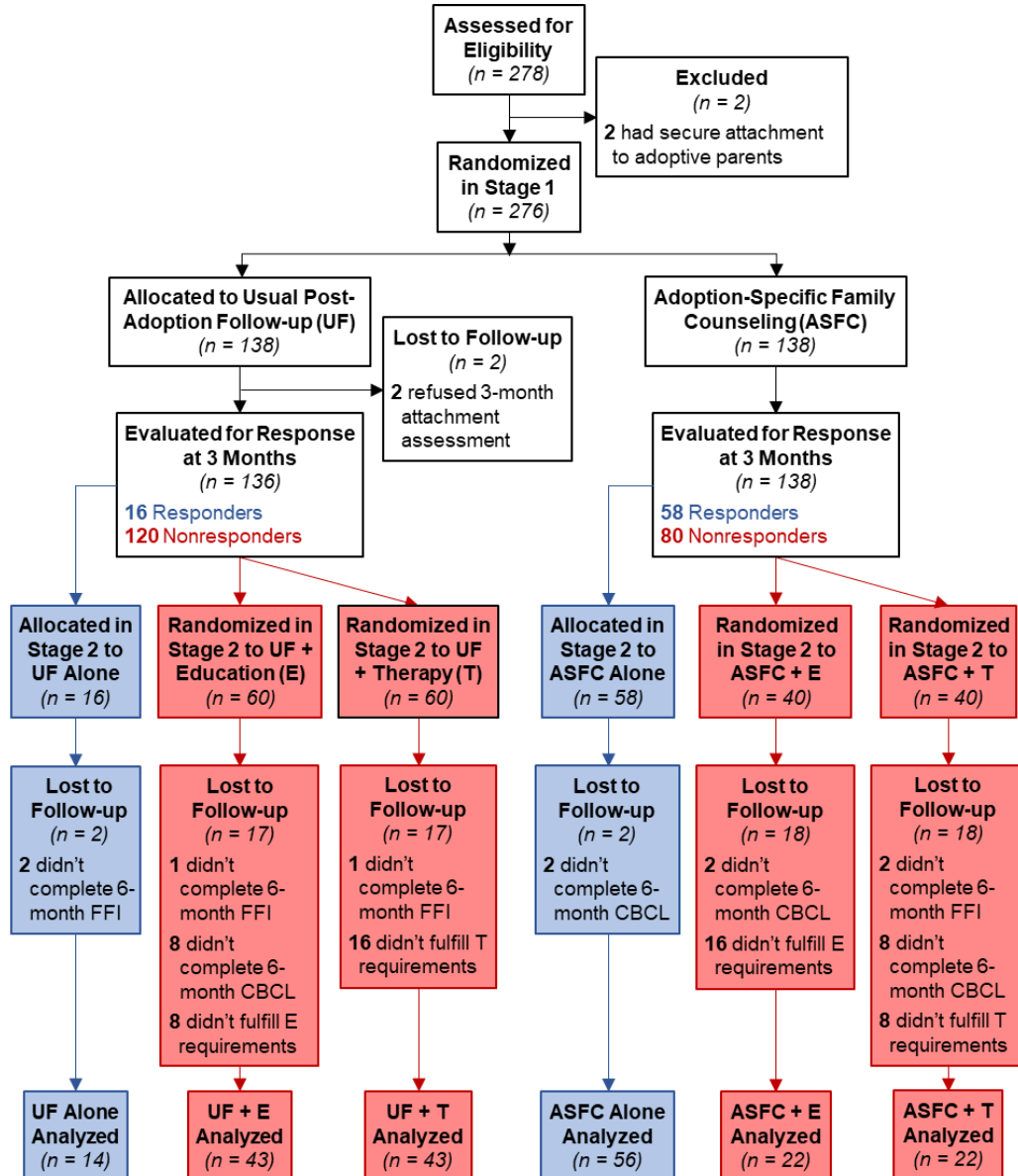


Table 2. Participant characteristics for the enrolled population or all participants starting stage 1 (N = 276) and baseline data for the primary and secondary outcome measures for the analyzed population or all participants completing stage 2 (N = 200).

Participant Characteristics for Enrolled Population	Usual Post-Adoption Follow-up Group <i>(n = 138)</i>	Adoption-Specific Family Counseling Group <i>(n = 138)</i>	Total <i>(N = 276)</i>
Age (<i>mean, SD</i>)	13.9 (1.90)	14.2 (2.5)	14.1 (2.2)
Female (<i>number, percentage</i>)	76 (55%)	68 (49%)	144 (52%)
Race and ethnicity (<i>number, percentage</i>)			
American Indian or Alaska Native	1 (1%)	0 (0%)	1 (0.5%)
Asian	88 (64%)	91 (66%)	179 (65%)
Black or African American	43 (31%)	40 (29%)	83 (30%)
Native Hawaiian or Other Pacific Islander	0 (0%)	0 (0%)	0 (0%)
White	6 (4%)	7 (5%)	13 (4.5%)
Hispanic or Latino	0 (0%)	0 (0%)	0 (0%)
Baseline Assessments for Analyzed Population	Usual Post-Adoption Follow-up Group <i>(n = 100)</i>	Adoption-Specific Family Counseling Group <i>(n = 100)</i>	Total <i>(N = 200)</i>
FFI attachment classification <i>(percentage of participants with secure or insecure ordered attachment)</i>	35%	38%	36.5%
CBCL score (<i>mean, SD</i>)			
Externalizing Behavior	12.68 (5.30)	11.22 (4.58)	11.95 (5.01)
Internalizing Behavior	13.61 (5.38)	13.32 (5.14)	13.47 (5.26)

Outcomes

Table 3 presents primary and secondary comparisons of intervention groups at the end of stage 1 (3 months) and

stage 2 (6 months) for the FFI attachment classification. Table 4 presents secondary comparisons of the same groups and time points for the CBCL score (Externalizing Behavior and Internalizing Behavior).

Table 3. Primary and secondary endpoints: comparison of FFI attachment classification at the end of stage 1 (3 months) and at the end of stage 2 (6 months), N = 200.

Time Point	Percentage of Participants with Secure or Insecure Ordered Attachment		
Comparison of Interventions Assigned in Stage 1 (n = 200)			
	UF <i>(UF Alone, UF + E, and UF + T)</i> <i>n = 100</i>	ASFC <i>(ASFC Alone, ASFC + E, and ASFC + T)</i> <i>n = 100</i>	OR (95% CI), p-value
3 months†	44%	73%	3.44 (1.90 to 6.22), p < 0.001
6 months‡	61%	90%	5.75 (2.67 to 12.39), p < 0.001
Comparison of Stage 2 Interventions for Nonresponders (n = 130)			
	Addition of E <i>(UF + E and ASFC + E)</i> <i>n = 65</i>	Addition of T <i>(UF + T and ASFC + T)</i> <i>n = 65</i>	OR (95% CI), p-value
3 months§	37%	35%	
6 months‡	49%	75%	3.16 (1.50 to 6.65), p = 0.003

Key: UF = usual post-adoption follow-up, ASFC = adoption-specific family counseling, E = individual child education about adoption, T = individual child therapy sessions

† Secondary analysis

‡ Primary analysis

§ Baseline for stage 2

Comparisons of the adolescent outcomes after 3 months, at the end of stage 1, and after 6 months, at the end of stage 2, found significant differences for participants assigned to either the usual post-adoption follow-up or adoption-specific family counseling for the course of the study. The odds of establishing secure or insecure ordered attachment in the adoption-specific family counseling group were significantly higher (p < 0.001) than in the usual post-adoption follow-up group at

both assessment points. At 3 months, effect size differences for CBCL scores between the usual post-adoption follow-up and adoption-specific family counseling groups were moderate. The 6-month effect size differences for CBCL scores between the combined usual post-adoption follow-up and adoption-specific family counseling groups (i.e., conditions UF Alone, UF + E and UF + T vs. conditions ASFC Alone, ASFC + E, and ASFC + T) were moderate to large.

Table 4. Secondary endpoints: comparison of CBCL scores by intervention at the end of stage 1 (3 months) and at the end of stage 2 (6 months), N = 200.

Time Point	Externalizing Behavior (mean, SD)			Internalizing Behavior (mean, SD)		
Comparison of Interventions Assigned in Stage 1 (N = 200)						
	UF (UF Alone, UF + E, and UF + T) n = 100	ASFC (ASFC Alone, ASFC + E, and ASFC + T) n = 100	Effect size d	UF (UF Alone, UF + E, and UF + T) n = 100	ASFC (ASFC Alone, ASFC + E, and ASFC + T) n = 100	Effect size d
3 months	11.57 (6.29)	7.56 (4.45)	0.71	12.30 (4.95)	8.72 (4.44)	0.69
6 months	10.98 (6.37)	6.13 (3.92)	0.95	10.75 (4.43)	7.78 (3.77)	0.65
Comparison of Stage 2 Interventions for Nonresponders (n = 130)						
	Addition of E (UF + E and ASFC + E) n = 65	Addition of T (UF + T and ASFC + T) n = 65	Effect size d	Addition of E (UF + E and ASFC + E) n = 65	Addition of T (UF + T and ASFC + T) n = 65	Effect size d
3 months [†]	9.63 (5.61)	11.40 (5.93)		11.39 (5.21)	10.86 (4.61)	
6 months	10.31 (5.70)	9.40 (6.46)	0.15	10.39 (5.13)	8.89 (4.52)	0.31

Key: UF = usual post-adoption follow-up, ASFC = adoption-specific family counseling, E = individual child education about adoption, T = individual child therapy sessions

[†] Baseline for stage 2

Differences between stage 1 nonresponders receiving either individual child education or individual child therapy in addition to usual post-adoption follow-up or adoption-specific family counseling were generally less pronounced, although the difference in attachment was notable. Adolescents who received individual child therapy had significantly higher odds of having an attachment that was secure or insecure ordered than those who received individual child education ($p = 0.003$). For all

nonresponders, there were only small to moderate effect size differences for CBCL scores following the addition of therapy or education to the stage 1 intervention. Responders to the intervention assigned in stage 1 continued to improve while continuing to receive the intervention in stage 2. All retained a status of secure or insecure ordered on the FFI. In addition, all achieved lower average scores on the CBCL at 6 months than were documented at 3 months (see Table 5).

Table 5. Comparison of CBCL scores by intervention for stage 1 responders at the end of stage 1 (3 months) and at the end of stage 2 (6 months).

Time Point	Externalizing Behavior (mean, SD)		Internalizing Behavior (mean, SD)	
<i>End of Stage 1 and End of Stage 2 Results for Responders (n = 70)</i>				
	UF Alone <i>n = 14</i>	ASFC Alone <i>n = 56</i>	UF Alone <i>n = 14</i>	ASFC Alone <i>n = 56</i>
3 months [†]	11.01 (5.99)	6.99 (4.80)	12.49 (5.31)	8.59 (4.63)
6 months	10.63 (4.29)	5.01 (3.49)	11.56 (3.65)	7.82 (2.39)

Key: UF = usual post-adoption follow-up, ASFC = adoption-specific family counseling

[†] Baseline for stage 2

Adverse Events

For all participants, PAAS staff recorded any adverse events that occurred, for example, truancy and in-school suspensions from school administrators. The researchers also obtained police reports for arrests of study participants.

There were 13 adverse events for the study, in 4.7% of the 276 participants. Each participant who experienced an adverse event experienced only one. None of the adverse events were serious because none were life-threatening or required hospitalization or residential mental health treatment (see Table 6).

Table 6. Nonserious adverse events by stage and allocation during the 6-month intervention period, N = 276.

Nonserious Adverse Events	Stage 1 (Months 1–3)		Stage 2 (Months 4–6)					
	UF (<i>n = 138</i>)	ASFC (<i>n = 138</i>)	UF Alone (<i>n = 16</i>)	UF + E (<i>n = 60</i>)	UF + T (<i>n = 60</i>)	ASFC Alone (<i>n = 58</i>)	ASFC + E (<i>n = 40</i>)	ASFC + T (<i>n = 40</i>)
Total	3	4	0	1	1	1	1	2
In-school suspension	0	0	0	1	0	1	1	0
Running away	0	1	0	0	0	0	0	1
Misdemeanor arrest*	2	2	0	0	0	0	0	0
Felony arrest [†]	0	1	0	0	0	0	0	0
Truancy	1	0	0	0	1	0	0	1

Key: UF = usual post-adoption follow-up, ASFC = adoption-specific family counseling, E = individual child education about adoption, T = individual child therapy sessions

* For example, stealing or possession of small amounts of drugs

[†] For example, fighting or distribution of drugs