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

Disclaimer: The following information is fictional and is only intended for the purpose of illustrating key concepts for results data entry in the Protocol Registration and Results System (PRS).

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00055659

Recruitment Status: Completed
First Posted: May 1, 2016
Results First Posted: January 2, 2019
Last Update Posted: January 2, 2019

Sponsor:

PRS Results Training

Information provided by (Responsible Party):

PRS Results Training

Study Description

Brief Summary:

The Parents and Adopted Adolescents Study (PAAS) is a sequential, multiple assignment, randomized trial (SMART) to identify the most effective methods for promoting parent-child attachment and healthy behavioral development among newly adopted adolescents. In stage 1, participants (adolescents) will be randomized to receive either usual post-adoption follow-up (UF) or adoption-specific family counseling (ASFC). After 3 months of intervention in stage 1, participants will be assessed for response to the intervention. Responders to either intervention will continue with the same intervention in stage 2. Nonresponders will continue to receive the same stage 1 intervention (UF or ASFC) and will also be randomized to receive either individual child education about adoption (E) (UF + E or ASFC + E) or individual child therapy sessions (T) (UF + T or ASFC + T).

Condition or disease	Intervention/treatment	Phase
Parent-Child Relations	Behavioral: Usual Post-Adoption Follow-up Behavioral: Adoption-Specific Family Counseling Behavioral: Individual Child Education about Adoption Behavioral: Individual Child Therapy Sessions	Not Applicable

Detailed Description:

The Parents and Adopted Adolescents Study (PAAS) is a sequential, multiple assignment, randomized trial (SMART) to identify the most effective methods for promoting parent-child attachment and healthy behavioral development among newly adopted adolescents. In stage 1, participants will be randomized to receive either usual post-adoption follow-up (UF) or adoption-specific family counseling (ASFC). At the beginning of the study, the adolescents will complete the Friends and Family Interview (FFI) to determine their attachment category. At the same time, one parent per family will complete the Child Behavior Checklist/6-18 (CBCL) to assess adolescent baseline externalizing and internalizing behaviors. After 3 months of intervention in stage 1, participants will be assessed for response to the intervention.

Adolescents will be considered “responders” in stage 1 if:

- Their Friends and Family Interview (FFI) attachment classification changes from insecure disordered (disorganized) to insecure ordered or secure or from insecure ordered to secure
- Their Internalizing Behavior subscale scores on the Child Behavior Checklist/6-18 (CBCL) are reduced by 20%
- Their Externalizing Behavior subscale scores on the CBCL are reduced by 20%

Responders to either intervention will continue with the same intervention in stage 2. Nonresponders will continue to receive the same stage 1 intervention and will also be randomized to receive either individual child education about adoption (E) (UF + E or ASFC + E) or individual child therapy sessions (T) (UF + T or ASFC + T).

Study Design

Study Type: Interventional

Actual Enrollment: 278 participants

Allocation: Randomized

Intervention Model: Factorial Assignment

Intervention Model Description: Sequential, Multiple Assignment, Randomized Trial (SMART)

Masking: None (Open Label)

Primary Purpose: Other

Official Title: Parents and Adopted Adolescents Study (PAAS)

Actual Study Start Date: May 1, 2016

Actual Primary Completion Date: May 1, 2018

Actual Study Completion Date: May 1, 2018

Arms and Interventions

Arm	Intervention/treatment
Active Comparator: Usual Post-Adoption Follow-up (UF) Alone This arm included participants who responded to UF in stage 1. In stage 1, an adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent and provide the parents with instructions and advice. In stage 2, responders to UF received 12 additional weekly adoption caseworker visits, as in stage 1.	Behavioral: Usual Post-Adoption Follow-up 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.
Active Comparator: UF Plus Individual Child Education about Adoption (E)	Behavioral: Usual Post-Adoption Follow-up 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

Arm	Intervention/treatment
This arm included participants who did not respond to UF in stage 1. In stage 1, an adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent and provide the parents with instructions and advice. In stage 2, nonresponders to UF received 12 additional weekly adoption caseworker visits, as in stage 1, plus 12 weeks of access to individual child education about adoption (UF + E).	caseworker provided educational materials to the parents and general advice about adolescent development and parenting techniques for adolescents. Behavioral: Individual Child Education about Adoption Individual child education about adoption consisted of access to online training about adoption and books about the experiences of other adopted adolescents.
Active Comparator: UF Plus Individual Child Therapy Sessions (T) This arm included participants who did not respond to UF in stage 1. In stage 1, an adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent and provide the parents with instructions and advice. In stage 2, nonresponders to UF received 12 additional weekly adoption caseworker visits, as in stage 1, plus 12 weekly individual child therapy sessions with a licensed social worker (UF + T).	Behavioral: Usual Post-Adoption Follow-up 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. Behavioral: Individual Child Therapy Sessions A licensed clinical social worker provided weekly individual therapy to each adolescent, with emphasis on the adoption experience and how the adolescent could handle difficult feelings, school challenges, and integration into the new family.

Arm	Intervention/treatment
Active Comparator: Adoption-Specific Family Counseling (ASFC) Alone This arm included participants who responded to ASFC in stage 1. In stage 1, a licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. In stage 2, responders to ASFC received 12 additional weekly family counseling sessions, as in stage 1.	Behavioral: Adoption-Specific Family Counseling 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.
Active Comparator: ASFC Plus Individual Child Education about Adoption (E) This arm included participants who did not respond to ASFC in stage 1. In stage 1, a licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents, and new siblings if applicable.	Behavioral: Adoption-Specific Family Counseling 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. Behavioral: Individual Child Education about Adoption

Arm	Intervention/treatment
In stage 2, nonresponders to ASFC received 12 additional weekly family counseling sessions, as in stage 1, plus 12 weeks of access to individual child education about adoption (ASFC + E).	Individual child education about adoption consisted of access to online training about adoption and books about the experiences of other adopted adolescents
Active Comparator: ASFC Plus Individual Child Therapy Sessions (T) This arm included participants who did not respond to ASFC in stage 1. In stage 1, a licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. In stage 2, nonresponders to ASFC received 12 additional weekly family counseling sessions, as in stage 1, plus 12 weekly individual child therapy sessions with a licensed social worker (ASFC + T).	Behavioral: Adoption-Specific Family Counseling 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. Behavioral: Individual Child Therapy Sessions A licensed clinical social worker provided weekly individual therapy to each adolescent, with emphasis on the adoption experience and how the adolescent could handle difficult feelings, school challenges, and integration into the new family.

Outcome Measures

Primary Outcome Measures:

1. Percentage of Participants with Secure or Insecure Ordered (Insecure/Ambivalent or Insecure/Avoidant) Attachment on the Friends and Family Interview (FFI): Usual Post-Adoption Follow-up (UF) vs. Adoption-Specific Family Counseling (ASFC) [Time Frame: Month 6 (end of stage 2)]

   Each participant's attachment to his or her adoptive parents was assessed with the FFI, a semi-structured interview adapted from the Adult Attachment Interview. 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.

2. Percentage of Participants with Secure or Insecure Ordered (Insecure/Ambivalent or Insecure/Avoidant) Attachment on the Friends and Family Interview (FFI): Individual Child Education vs. Individual Child Therapy [Time Frame: Month 3 (baseline for stage 2) and Month 6 (end of stage 2)]

   Attachment classification based on the FFI. 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.

Secondary Outcome Measures:

1. Percentage of Participants with Secure or Insecure Ordered (Insecure/Ambivalent or Insecure/Avoidant) Attachment on the Friends and Family Interview (FFI): Usual Post-Adoption Follow-up (UF) vs. Adoption-Specific Family Counseling (ASFC) [Time Frame: Month 3 (end of stage 1)]

   Attachment classification based on the FFI. 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.

2. Externalizing Behavior and Internalizing Behavior Subscale Scores on the Child Behavior Checklist/6-18 (CBCL): UF vs. ASFC [Time Frame: Month 3 (end of stage 1) and Month 6 (end of stage 2)]

   The CBCL was used to assess adolescent behavior. 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. Higher scores on both subscales indicate more numerous and frequent behavioral problems.

3. Externalizing Behavior and Internalizing Behavior Subscale Scores on the Child Behavior Checklist/6-18 (CBCL): Individual Child Education vs. Individual Child Therapy [Time Frame: Month 3 (baseline for stage 2) and Month 6 (end of stage 2)]

   Adolescent behavior based on the CBCL. 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. Higher scores on both subscales indicate more numerous and frequent behavioral problems.

Eligibility Criteria

Ages Eligible for Study: 12 Years to 17 Years (Child)
Sexes Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Physically healthy

- Newly adopted adolescents aged 12 to 17

Exclusion Criteria:

- Diagnosis of autism spectrum disorder, fetal alcohol spectrum disorder, or another developmental disability that would potentially limit the adolescent's participation in the educational part of the intervention
- Any adolescent with a secure attachment to his or her adoptive parents (as determined via the FFI), as a result of foster-to-adopt family placement

Contacts and Locations

Locations

United States, Virginia

Virginia University's College of Arts and Sciences

Alexandria, Virginia, United States, 22304

Study Documents (Full-Text)

Documents provided by PRS Results Training

Study Protocol and Statistical Analysis Plan [PDF] March 30, 2016

More Information

Responsible Party:	PRS Results Training
ClinicalTrials.gov Identifier:	NCT00055659
Other Study ID Numbers:	TTTSMARTR
First Posted:	May 1, 2016
Results First Posted:	January 2, 2019

Last Update Posted: January 2, 2019

Last Verified: December 2018

Human Subjects Protection Review Board Status: Approved

Studies a U.S. FDA-regulated Drug Product: No

Studies a U.S. FDA-regulated Device Product: No

Study Results

Participant Flow

Recruitment Details	Participants were recruited from public child welfare agencies in the United States. Recruitment and enrollment occurred between May 1, 2016 and November 1, 2017.
Pre-assignment Details	Enrollment/randomization to stage 1 interventions took place immediately after adoptions were finalized. Two adolescents had been placed with caregivers who served first as their foster parents, then later adopted them. Because both of these adolescents had secure attachment to their new adoptive parents, they were excluded from the study (were not randomized).

Arm/Group Title	Usual Post-Adoption Follow-up (UF) Alone	UF Plus Individual Child Education about Adoption (E)	UF Plus Individual Child Therapy Sessions (T)	Adoption-Specific Family Counseling (ASFC) Alone	ASFC Plus Individual Child Education about Adoption (E)	ASFC Plus Individual Child Therapy Sessions (T)
Arm/Group Description	This arm included participants who	This arm included participants who	This arm included participants who	This arm included participants who	This arm included participants who	This arm included participants who

	responded to UF in stage 1 and participants who were not assessed for response at the end of stage 1. In stage 1, an adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent and provide the parents with instructions and advice. In stage 2, responders to UF received 12 additional weekly adoption	did not respond to UF in stage 1. In stage 1, an adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent and provide the parents with instructions and advice. In stage 2, nonresponders to UF received 12 additional weekly adoption caseworker visits, as in stage 1, plus 12 weeks of access to individual child	did not respond to UF in stage 1. In stage 1, an adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent and provide the parents with instructions and advice. In stage 2, nonresponders to UF received 12 additional weekly adoption caseworker visits, as in stage 1, plus 12 weekly individual child therapy sessions	responded to ASFC in stage 1. In stage 1, a licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. In stage 2, responders to ASFC received 12 additional weekly family counseling sessions, as in stage 1.	did not respond to ASFC in stage 1. In stage 1, a licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. In stage 2, nonresponders to ASFC received 12 additional weekly family counseling sessions, as in stage 1, plus 12 weeks of access to individual child education about	did not respond to ASFC in stage 1. In stage 1, a licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. In stage 2, nonresponders to ASFC received 12 additional weekly family counseling sessions, as in stage 1, plus 12 weekly individual child therapy sessions with a

	caseworker visits, as in stage 1.	education about adoption (UF + E).	with a licensed social worker (UF + T).		adoption (ASFC + E).	licensed social worker (ASFC + T).
Period Title: **Stage 1 Intervention (Months 1-3)**						
Started	18 [1]	60	60	58	40	40
Completed	16 [2]	60 [2]	60 [2]	58 [3]	40 [3]	40 [3]
Not Completed	2	0	0	0	0	0
Reason Not Completed						
Refused 3-Month FFI Assessment	2	0	0	0	0	0

[1] Includes two participants who started the UF intervention but were not assessed for response

[2] Completed 3-month FFI and CBCL; attended ≥ 8 UF visits

[3] Completed 3-month FFI and CBCL; attended ≥ 8 ASFC sessions

Period Title: **Stage 2 Intervention (Months 4-6)**						
Started	16	60	60	58	40	40
Completed	14 [1]	43 [2]	43 [3]	56 [4]	22 [5]	22 [6]
Not Completed	2	17	17	2	18	18
Reason Not Completed						

Failed to Complete 6-Month FFI	2	1	1	0	0	2
Failed to Complete 6-Month CBCL	0	8	0	2	2	8
Failed to Access Educational Resources	0	8	0	0	16	0
Failed to Complete Therapy Sessions	0	0	16	0	0	8

[1] Completed 6-month FFI and CBCL; attended ≥ 8 UF visits

[2] Completed 6-month FFI and CBCL; attended ≥ 8 UF visits; accessed E materials ≥ 1x per wk ≥ 8 wks

[3] Completed 6-month FFI and CBCL; attended ≥ 8 UF visits and ≥ 8 T sessions

[4] Completed 6-month FFI and CBCL; attended ≥ 8 ASFC sessions

[5] Completed 6-month FFI and CBCL; attended ≥ 8 ASFC sessions; accessed E materials ≥ 1x per wk ≥ 8 wks

[6] Completed 6-month FFI and CBCL; attended ≥ 8 ASFC and ≥ 8 T sessions

Baseline Characteristics

Arm/Group Title	Stage 1: Usual Post-Adoption Follow-up (UF)	Stage 1: Adoption-Specific Family Counseling (ASFC)	Total
Arm/Group Description	The adoption caseworker provided 12 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.	A licensed clinical social worker provided 12 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.	Total of all reporting groups
Overall Number of Baseline Participants	138	138	276
Baseline Analysis Population Description	Includes all participants who started stage 1		

Age, Continuous Mean (Standard Deviation) Unit of measure: years							
	Number Analyzed	138 participants		138 participants		276 participants	
		13.9 (1.9)		14.2 (2.5)		14.1 (2.2)	
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants							
	Number Analyzed	138 participants		138 participants		276 participants	
	Female	76	55.1%	68	49.3%	144	52.2%
	Male	62	44.9%	70	50.7%	132	47.8%
Ethnicity (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants							
	Number Analyzed	138 participants		138 participants		276 participants	
	Hispanic or Latino	0	0.0%	0	0.0%	0	0.0%

	Not Hispanic or Latino	138	100.0%	138	100.0%	276	100.0%
	Unknown or Not Reported	0	0.0%	0	0.0%	0	0.0%
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: Participants							
	Number Analyzed	138 participants		138 participants		276 participants	
	American Indian or Alaska Native	1	0.7%	0	0.0%	1	0.4%
	Asian	88	63.8%	91	65.9%	179	64.9%
	Native Hawaiian or Other Pacific Islander	0	0.0%	0	0.0%	0	0.0%
	Black or African American	43	31.2%	40	29.0%	83	30.1%
	White	6	4.3%	7	5.1%	13	4.7%
	More than one race	0	0.0%	0	0.0%	0	0.0%
	Unknown or Not Reported	0	0.0%	0	0.0%	0	0.0%

Region of Enrollment Measure Type: Count of Participants Unit of measure: Participants				
United States	Number Analyzed	138 participants	138 participants	276 participants
		138 100.0%	138 100.0%	276 100.0%
Friends and Family Interview (FFI) Attachment Classification [1] [2] Measure Type: Number Unit of measure: Percentage of Participants				
	Number Analyzed	100 participants	100 participants	200 participants
		35	38	36.5
		[1] Measure Description: The FFI is a semi-structured interview used to classify adolescent attachment to adoptive parents as secure (best), insecure/ambivalent, insecure/avoidant, or disorganized (worst). The percentage of participants with either secure or insecure ordered (insecure/ambivalent or insecure/avoidant) attachment is reported. [2] Measure Analysis Population Description: This assessment is reported for participants who completed stage 2 (outcome measure analysis population).		

Child Behavior Checklist (CBCL) Score [1] [2] Mean (Standard Deviation) Unit of measure: units on a scale				
Externalizing Behavior	Number Analyzed	100 participants	100 participants	200 participants
		12.68 (5.30)	11.22 (4.58)	11.95 (5.01)
Internalizing Behavior	Number Analyzed	100 participants	100 participants	200 participants
		13.61 (5.38)	13.32 (5.14)	13.47 (5.26)

[1] Measure Description: The Child Behavior Checklist/6-18 (CBCL) was used to assess adolescent behavior. The school-age CBCL is designed for children and adolescents ages 6-18 and includes eight syndrome scales. Three syndrome scales, Anxious/Depressed, Withdrawn/Depressed, and Somatic Complaints, are summed to produce an Internalizing Behavior subscale score ranging from 0 to 64, while two others, Rule Breaking Behavior and Aggressive Behavior, are summed to produce an Externalizing Behavior subscale score ranging from 0 to 70. Higher scores on both subscales indicate more numerous and frequent behavioral problems.

[2] Measure Analysis Population Description: This assessment is reported for participants who completed stage 2 (outcome measure analysis population).

Outcome Measures

1. Primary Outcome

Title	Percentage of Participants with Secure or Insecure Ordered (Insecure/Ambivalent or Insecure/Avoidant) Attachment on the Friends and Family Interview (FFI): Usual Post-Adoption Follow-up (UF) vs. Adoption-Specific Family Counseling (ASFC)
Description	Each participant's attachment to his or her adoptive parents was assessed with the FFI, a semi-structured interview adapted from the Adult Attachment Interview. 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.
Time Frame	Month 6 (end of stage 2)

Outcome Measure Data

Analysis Population Description
Only those participants who completed stage 2 are included in the analysis. Participants who received UF throughout the study are compared to participants who received ASFC throughout the study; data are averaged over all stage 2 intervention options for responders to the intervention in stage 1 and nonresponders.

Arm/Group Title	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2	Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
Arm/Group Description:	The adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent's nutrition and growth, activities, and adjustment to school and the new family in stages 1 and 2. The caseworker provided educational materials to the parents and	A licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings, if applicable, in stages 1 and 2. Counseling aimed to educate parents about the best parenting

	general advice about adolescent development and parenting techniques for adolescents.	practices for healing traumatized adolescents and the best ways to handle their behavioral issues.
Overall Number of Participants Analyzed	100	100
Measure Type: Number Unit of Measure: Percentage of Participants	61	90

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2, Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	< 0.001
	Comments	The threshold for statistical significance for all analyses was set to p = 0.05.
	Method	Regression, Logistic
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	5.75
	Confidence Interval	(2-Sided) 95% 2.67 to 12.39
	Estimation Comments	Calculated as the odds of being categorized as insecure ordered or secure after the ASFC intervention vs. the UF intervention

2. Primary Outcome

Title	Percentage of Participants with Secure or Insecure Ordered (Insecure/Ambivalent or Insecure/Avoidant) Attachment on the Friends and Family Interview (FFI): Individual Child Education vs. Individual Child Therapy
Description	Attachment classification based on the FFI. 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.
Time Frame	Month 3 (baseline for stage 2) and Month 6 (end of stage 2)

Outcome Measure Data

Analysis Population Description
Only those participants who completed stage 2 are included in the analysis. Nonresponders who received individual child education in stage 2 are compared to nonresponders who received individual child therapy; data are averaged over both stage 1 interventions.

Arm/Group Title	Stage 2: Individual Child Education about Adoption	Stage 2: Individual Child Therapy Sessions
Arm/Group Description:	Individual child education about adoption consisted of 12 weeks of access to online training about adoption and books about the experiences of other adopted adolescents. This intervention was a stage 2 add-on intervention for stage 1 nonresponders.	A licensed clinical social worker provided weekly individual therapy to each adolescent for 12 weeks, with emphasis on the adoption experience and how the adolescent could handle difficult feelings, school challenges, and integration into the new family. This intervention was a stage 2 add-on intervention for stage 1 nonresponders.
Overall Number of Participants Analyzed	65	65

Measure Type: Number Unit of Measure: Percentage of Participants		
Month 3	37	35
Month 6	49	75

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Stage 2: Individual Child Education about Adoption, Stage 2: Individual Child Therapy Sessions
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	0.003
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	3.16
	Confidence Interval	(2-Sided) 95% 1.50 to 6.65
	Estimation Comments	Month 6 comparison; calculated as the odds of being categorized as insecure ordered or secure after the addition of therapy vs. education

3. Secondary Outcome

Title	Percentage of Participants with Secure or Insecure Ordered (Insecure/Ambivalent or Insecure/Avoidant) Attachment on the Friends and Family Interview (FFI): Usual Post-Adoption Follow-up (UF) vs. Adoption-Specific Family Counseling (ASFC)
Description	Attachment classification based on the FFI. 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.
Time Frame	Month 3 (end of stage 1)

Outcome Measure Data

Analysis Population Description
Only those participants who completed stage 2 are included in the analysis. Participants who received UF throughout the study are compared to participants who received ASFC throughout the study.

Arm/Group Title	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2	Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
Arm/Group Description:	The adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent's nutrition and growth, activities, and adjustment to school and the new family in stages 1 and 2. The caseworker provided educational materials to the parents and general advice about adolescent development and parenting techniques for adolescents.	A licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings, if applicable, in stages 1 and 2. Counseling aimed to educate parents about the best parenting practices for healing traumatized adolescents and the best ways to handle their behavioral issues.
Overall Number of Participants Analyzed	100	100

Measure Type: Number Unit of Measure: Percentage of Participants	44	73

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2, Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
	Comments	[Not specified]
	Type of Statistical Test	Superiority
	Comments	[Not specified]
Statistical Test of Hypothesis	P-Value	< 0.001
	Comments	[Not specified]
	Method	Regression, Logistic
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Odds Ratio (OR)
	Estimated Value	3.44
	Confidence Interval	(2-Sided) 95% 1.90 to 6.22
	Estimation Comments	Calculated as the odds of being categorized as insecure ordered or secure after the ASFC intervention vs. the UF intervention

4. Secondary Outcome

Title	Externalizing Behavior and Internalizing Behavior Subscale Scores on the Child Behavior Checklist/6-18 (CBCL): UF vs. ASFC
Description	The CBCL was used to assess adolescent behavior. 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. Higher scores on both subscales indicate more numerous and frequent behavioral problems.
Time Frame	Month 3 (end of stage 1) and Month 6 (end of stage 2)

Outcome Measure Data

Analysis Population Description
Only those participants who completed stage 2 are included in the analysis. Participants who received UF throughout the study are compared to participants who received ASFC throughout the study, at both time points; data are averaged over all stage 2 intervention options for responders and nonresponders.

Arm/Group Title	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2	Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
Arm/Group Description:	The adoption caseworker provided 12 weekly post-adoption visits to record information about the adolescent's nutrition and growth, activities, and adjustment to school and the new family in stages 1 and 2. The caseworker provided	A licensed clinical social worker provided 12 weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents, and new siblings, if applicable, in stages 1 and 2. Counseling

	educational material to the parents and general advice about adolescent development and parenting techniques for adolescents.	aimed to educate parents about the best parenting practices for healing traumatized adolescents and the best ways to handle their behavioral issues.
Overall Number of Participants Analyzed	100	100
Mean (Standard Deviation) Unit of Measure: units on a scale		
Month 3 Externalizing	11.57 (6.29)	7.56 (4.45)
Month 6 Externalizing	10.98 (6.37)	6.13 (3.92)
Month 3 Internalizing	12.30 (4.95)	8.72 (4.44)
Month 6 Internalizing	10.75 (4.43)	7.78 (3.77)

Statistical Analysis 1

Statistical Analysis Overview	Comparison Group Selection	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2, Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
	Comments	Month 3 comparison of UF vs. ASCF on Externalizing Behavior score.
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Cohen's d (effect size)]
	Estimated Value	0.71
	Estimation Comments	Effect sizes ranging from 0.21 to 0.79 were considered moderate; any ≥ 0.80 were considered large.

Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2, Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
	Comments	Month 6 comparison of Externalizing Behavior scores
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Cohen's d (effect size)]
	Estimated Value	0.95
	Estimation Comments	Effect sizes ranging from 0.21 to 0.79 were considered moderate; any ≥ 0.80 were considered large.

Statistical Analysis 3

Statistical Analysis Overview	Comparison Group Selection	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2, Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
	Comments	Month 3 comparison of UF vs. ASCF on Internalizing Behavior score
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Cohen's d (effect size)]
	Estimated Value	0.69
	Estimation Comments	Effect sizes ranging from 0.21 to 0.79 were considered moderate; any ≥ 0.80 were considered large.

Statistical Analysis 4

Statistical Analysis Overview	Comparison Group Selection	Received Usual Post-Adoption Follow-up (UF) in Stages 1 and 2, Received Adoption-Specific Family Counseling (ASFC) in Stages 1 and 2
	Comments	Month 6 comparison of Internalizing Behavior scores
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Cohen's d (effect size)]
	Estimated Value	0.65
	Estimation Comments	Effect sizes ranging from 0.21 to 0.79 were considered moderate; any ≥ 0.80 were considered large.

5. Secondary Outcome

Title	Externalizing Behavior and Internalizing Behavior Subscale Scores on the Child Behavior Checklist/6-18 (CBCL): Individual Child Education vs. Individual Child Therapy
Description	Adolescent behavior based on the CBCL. 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. Higher scores on both subscales indicate more numerous and frequent behavioral problems.
Time Frame	Month 3 (baseline for stage 2) and Month 6 (end of stage 2)

Outcome Measure Data

Analysis Population Description
Only those participants who completed stage 2 are included in the analysis. Nonresponders who received individual child education in stage 2 are compared to nonresponders who received individual child therapy; data are averaged over both stage 1 interventions.

Arm/Group Title	Stage 2: Individual Child Education about Adoption	Stage 2: Individual Child Therapy Sessions
Arm/Group Description:	Individual child education about adoption consisted of 12 weeks of access to online training about adoption and books about the experiences of other adopted adolescents. This intervention was a stage 2 add-on intervention for stage 1 nonresponders.	A licensed clinical social worker provided weekly individual therapy to each adolescent for 12 weeks, with emphasis on the adoption experience and how the adolescent could handle difficult feelings, school challenges, and integration into the new family. This intervention was a stage 2 add-on intervention for stage 1 nonresponders.
Overall Number of Participants Analyzed	65	65
Mean (Standard Deviation) Unit of Measure: units on a scale		
Month 3 Externalizing Behavior	9.63 (5.61)	11.40 (5.93)
Month 6 Externalizing Behavior	10.31 (5.70)	9.40 (6.46)
Month 3 Internalizing Behavior	11.39 (5.21)	10.86 (4.61)
Month 6 Internalizing Behavior	10.39 (5.13)	8.89 (4.52)

Statistical Analysis 1

	Comparison Group Selection	Stage 2: Individual Child Education about Adoption, Stage 2: Individual Child Therapy Sessions

Statistical Analysis Overview	Comments	Month 6 comparison of Externalizing Behavior scores
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Cohen's d (effect size)]
	Estimated Value	0.15
	Estimation Comments	Effect sizes ranging from 0.21 to 0.79 were considered moderate; any ≥ 0.80 were considered large.

Statistical Analysis 2

Statistical Analysis Overview	Comparison Group Selection	Stage 2: Individual Child Education about Adoption, Stage 2: Individual Child Therapy Sessions
	Comments	Month 6 comparison of Internalizing Behavior scores
	Type of Statistical Test	Other
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Other [Cohen's d (effect size)]
	Estimated Value	0.31
	Estimation Comments	Effect sizes ranging from 0.21 to 0.79 were considered moderate; any ≥ 0.80 were considered large.

Adverse Events

Time Frame	3 months during stage 1 and 3 months during stage 2
Adverse Event Reporting Description	Includes all participants who started stage 1 or stage 2. Events were collected separately for each stage.
Source Vocabulary Name for Table Default	[Not specified]
Collection Approach for Table Default	Non-systematic Assessment

Arm/Group Title	Stage 1: Usual Post-Adoption Follow-up (UF)	Stage 1: Adoption-Specific Family Counseling (ASFC)	Stage 2: UF Alone	Stage 2: UF Plus Individual Child Education about Adoption	Stage 2: UF Plus Individual Child Therapy Sessions	Stage 2: ASFC Alone	Stage 2: ASFC Plus Individual Child Education about Adoption	Stage 2: ASFC Plus Individual Child Therapy Sessions
Arm/Group Description	The adoption caseworker provided 12 weekly post-adoption	A licensed clinical social worker provided 12 weekly	The adoption caseworker provided 12 additional weekly post-	The adoption caseworker provided 12 additional weekly post-	The adoption caseworker provided 12 additional weekly post-	A licensed clinical social worker provided 12 additional	A licensed clinical social worker provided 12 additional	A licensed clinical social worker provided 12 additional

	visits to record information about the adolescent and provide the parents with instructions and advice.	trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable.	adoption visits to record information about the adolescent and provide the parents with instructions and advice.	adoption visits to record information about the adolescent and provide the parents with instructions and advice. Adolescents also had access to 12 weeks of individual child education about adoption.	adoption visits to record information about the adolescent and provide the parents with instructions and advice. Adolescents also had access to 12 weekly individual child therapy sessions with a licensed social worker.	weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable.	weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. Adolescents also had access to 12 weeks of individual child education about adoption.	weekly trauma-informed adoption counseling sessions for the adopted adolescent with his or her new parents and new siblings if applicable. Adolescents also had access to 12 weekly individual child therapy sessions with a licensed social worker.

All-Cause Mortality

	Stage 1: Usual Post-Adoption Follow-up (UF)	Stage 1: Adoption-Specific Family Counseling (ASFC)	Stage 2: UF Alone	Stage 2: UF Plus Individual Child Education about Adoption	Stage 2: UF Plus Individual Child Therapy Sessions	Stage 2: ASFC Alone	Stage 2: ASFC Plus Individual Child Education about Adoption	Stage 2: ASFC Plus Individual Child Therapy Sessions
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/138 (0%)	0/138 (0%)	0/16 (0%)	0/60 (0%)	0/60 (0%)	0/58 (0%)	0/40 (0%)	0/40 (0%)

Serious Adverse Events

	Stage 1: Usual Post-Adoption Follow-up (UF)	Stage 1: Adoption-Specific Family Counseling (ASFC)	Stage 2: UF Alone	Stage 2: UF Plus Individual Child Education about Adoption	Stage 2: UF Plus Individual Child Therapy Sessions	Stage 2: ASFC Alone	Stage 2: ASFC Plus Individual Child Education about Adoption	Stage 2: ASFC Plus Individual Child Therapy Sessions
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/138 (0%)	0/138 (0%)	0/16 (0%)	0/60 (0%)	0/60 (0%)	0/58 (0%)	0/40 (0%)	0/40 (0%)

Other (Not Including Serious) Adverse Events

Frequency Threshold for	0%

Reporting Other Adverse Events								
	Stage 1: Usual Post-Adoption Follow-up (UF)	**Stage 1: Adoption-Specific Family Counseling (ASFC)**	**Stage 2: UF Alone**	**Stage 2: UF Plus Individual Child Education about Adoption**	**Stage 2: UF Plus Individual Child Therapy Sessions**	**Stage 2: ASFC Alone**	**Stage 2: ASFC Plus Individual Child Education about Adoption**	**Stage 2: ASFC Plus Individual Child Therapy Sessions**
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	3/138 (2.17%)	4/138 (2.9%)	0/16 (0%)	1/60 (1.67%)	1/60 (1.67%)	1/58 (1.72%)	1/40 (2.5%)	2/40 (5%)
Social circumstances								
Felony arrest * [1]	0/138 (0%)	1/138 (0.72%)	0/16 (0%)	0/60 (0%)	0/60 (0%)	0/58 (0%)	0/40 (0%)	0/40 (0%)
In-school suspension *	0/138 (0%)	0/138 (0%)	0/16 (0%)	1/60 (1.67%)	0/60 (0%)	1/58 (1.72%)	1/40 (2.5%)	0/40 (0%)
Misdemeanor arrest * [2]	2/138 (1.45%)	2/138 (1.45%)	0/16 (0%)	0/60 (0%)	0/60 (0%)	0/58 (0%)	0/40 (0%)	0/40 (0%)
Running away *	0/138 (0%)	1/138 (0.72%)	0/16 (0%)	0/60 (0%)	0/60 (0%)	0/58 (0%)	0/40 (0%)	1/40 (2.5%)
Truancy *	1/138 (0.72%)	0/138 (0%)	0/16 (0%)	0/60 (0%)	1/60 (1.67%)	0/58 (0%)	0/40 (0%)	1/40 (2.5%)

* Indicates events were collected by non-systematic assessment

[1] For example, fighting or distribution of drugs

[2] For example, stealing or possession of small amounts of drugs

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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