Study Protocol: Building Resilience Program for Preschool Children with ACEs

NCT number: TBD

Date: August 1, 2024 (last reviewed by IRB; original approval March 18, 2022)

1. Protocol Summary

Protocol Title: The Building Resilience Program: Examining Self-Regulation, Behavior, and Resilience in Under-Resourced Preschoolers with Adverse Childhood Experiences

Protocol Version: 2.0 (updated January 2024)
Principal Investigator: Dr. Kelle DeBoth Foust, PhD, OTR/L
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Study Site: YWCA Early Learning Center, Cleveland, Ohio
IRB Approval: IRB-FY2022-23

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2. Study Objectives

2.1 Primary Objectives

Child Participants (Aim 1):

1. To examine the effects of the Building Resilience Program (BRP) on coping skills, engagement, self-regulation, emotional health, quality of life, and stress in preschool participants aged 24-66 months with history of ACEs
2. To evaluate the effectiveness of Goal Attainment Scaling (GAS) as a measurement tool for tracking individual progress and changes pre-post intervention

Caregiver Participants (Aim 2):

3. To examine the effects of the Building Resilience Program on caregiver resilience, emotional management, and coping strategies

4. To assess caregiver satisfaction with program methods and outcomes

2.2 Primary Hypotheses

Child Participants:

- All child participants will demonstrate improved coping skills, engagement, quality of life, self-regulation, and emotional health by the end of the intervention period as measured by standardized assessments and individualized Goal Attainment Scaling
- GAS will prove an effective tool for capturing individualized therapeutic change in trauma-exposed preschoolers

Caregiver Participants:

- Caregivers participating in the BRP will demonstrate improved resilience and coping strategies as measured by standardized self-report assessments
- Caregivers will report high satisfaction with program methods and perceived benefits for both themselves and their children

3. Background and Rationale

Children living in under-resourced, poverty-stricken neighborhoods face significantly elevated risks for adverse childhood experiences (ACEs) and trauma. The study location serves neighborhoods where 36.5-41.6% of residents live in poverty (compared to 11.9% nationally), with 52.8-54.9% of children living in poverty. The Early Learning Center annual data indicates 97% of children come from single-parent households, 88% live in poverty, 51% report 1-5 ACEs, and 14% report 6-10 ACEs.

Preschool-aged children (ages 3-5) are particularly vulnerable to ACEs impacts due to rapid brain development and critical socioemotional growth occurring during this period. Recent neurobiological research demonstrates that toxic stress during preschool years can significantly alter developing brain architecture, particularly in regions associated with executive function, emotion regulation, and stress response systems.

The American Academy of Pediatrics identifies the critical need for interventions that build resilience and address maladaptive responses due to toxic stress from ACEs. Occupational therapists are well-suited to integrate trauma-informed care into service delivery through their expertise in occupation-based interventions, particularly using play as the primary occupation for young children.

4. Study Design

4.1 Study Type

Randomized controlled trial with waitlist control design. *Original program was designed for two, 8-week sessions totaling 16 weeks. Unforeseen circumstances (a flood at the facility) shortened the available study period to 14 weeks, so the control condition was shortened and the content condensed and combined to maintain intervention integrity.

4.2 Study Design Overview

- Phase 1: Intervention Group 1 (IG1) receives BRP intervention for 7 weeks while Intervention Group 2 (IG2) receives standard care (waitlist control)
- Phase 2: IG2 receives BRP intervention for 7 weeks while IG1 continues standard care activities
- Total study duration: 14 weeks

4.3 Randomization

Participants will be randomly assigned to IG1 or IG2 within each of the four pre-existing classrooms using a random number generator, with 5-6 students from each classroom assigned to each condition to eliminate potential bias from natural classroom differences.

5. Study Population

5.1 Target Population

Preschool children enrolled at the YWCA Early Learning Center in Cleveland, Ohio, serving under-resourced families with high ACEs exposure

5.2 Sample Size

Target enrollment: n=40 participants (based on total ELC enrollment) Achieved enrollment: n=38 participants Final analytic sample: n=32 participants with complete assessments

5.3 Inclusion Criteria

- Children aged 24-66 months at time of enrollment
- Enrolled at YWCA Early Learning Center during study period
- Parent/caregiver consent for participation
- Ability to participate in group activities

5.4 Exclusion Criteria

- Limited English-speaking fluency requiring translator services
- Parent-reported cognitive delays or medical conditions preventing independent participation in program groups
- Inability to provide informed consent

5.5 Withdrawal Criteria

- Parent/caregiver request for withdrawal
- Child safety concerns identified during intervention
- Consistent non-attendance preventing meaningful intervention participation
- Development of medical condition preventing continued participation

6. Interventions

6.1 Building Resilience Program (BRP) Intervention

Duration: 7 weeks (modified from original 8-week protocol due to facility closure) **Frequency:** 3 sessions per week **Session Length:** 30-45 minutes **Setting:** Separate room from regular classroom **Group Size:** 5-6 participants per group

6.1.1 BRP Weekly Themes:

- Week 1: Introduction to Resilience
- Week 2: Identifying and Communicating Emotions
- Week 3: Emotional Regulation
- Week 4: Coping Strategies for Self-Regulation: Body and Hands
- Week 5: Coping Strategies for Self-Regulation: Ears, Eyes and Mouth
- Week 6: Coping Strategies for Self-Regulation: Breath Awareness
- Week 7: Applying Positive Coping Strategies

6.1.2 Staffing

Each BRP group will be led by:

- One licensed occupational therapist
- One occupational therapy doctoral capstone student
- 2-3 occupational therapy doctoral research students

6.2 Standard Care Control Condition

Purpose: Control for positive researcher interaction effects while providing beneficial activities **Duration:** Concurrent with BRP intervention periods **Content:** School readiness skills supplementing existing curriculum **Weekly Domains:**

- Perceptual motor skills
- Fine motor skills (tool use and coloring)
- Problem solving
- Teamwork and coordination
- Motor planning

Staffing: One licensed occupational therapist

6.3 Caregiver Intervention Component

Duration: 3 caregiver-only sessions and one joint child-caregiver sessions over 8-week period (reduced from weekly caregiver sessions to accommodate participation challenges) **Format:** In-person group sessions **Staffing:** Occupational therapists and occupational therapy students

6.3.1 Caregiver Session Schedule:

1. **Pre-intervention meeting:** BRP and study description, introduction to resilience, highlights from Inside Out movie, Zones of Regulation overview, Q&A
2. **Week 3 session:** Family resilience, high vs. low resilience, resiliency BINGO activity, Kawa River model, Q&A
3. **Week 6 session:** Adaptive vs. maladaptive behaviors, coping strategies, mindfulness, sensory processing and "sensory solutions," community resources
4. **Post-intervention meeting:** Child and self-advocacy, joint plant activity, program review

6.3.2 Participation Requirements:

- Caregivers attend sessions during their child's intervention period only
- Both post-intervention periods required for complete assessment battery
- Attendance at weeks 3 and 6 sessions only when child participating in BRP intervention

7. Outcome Measures

7.1 Primary Outcome Measures

7.1.1 Standardized Assessment Battery

NIH Toolbox Parent Report Emotion Measures:

- Negative Affect subdomain (anger, fear, sadness/depression)
- Psychological Well-being subdomain (positive affect, life satisfaction)

PROMIS Early Childhood Measures:

- Flexibility
- Persistence (Note: Curiosity and Frustration Tolerance removed due to ceiling effects)

Pediatric Quality of Life Inventory (PedsQL):

- Physical Functioning
- Emotional Functioning
- Social Functioning
- School Functioning

- Composite Score

Canadian Occupational Performance Measure (COPM):

- Parent proxy report of child's occupational performance
- Used primarily for Goal Attainment Scaling development

7.1.2 Goal Attainment Scaling (GAS)

Domains: Three individualized goals per participant

- Behavior
- Engagement/Participation
- Resilience

Scoring: -2 (much worse than expected) to +2 (much better than expected outcome) **Frequency:** Weekly observations during both intervention and control periods **Conversion:** Raw scores converted to T-scores (M=50, SD=10) for statistical analysis

7.2 Data Collection Schedule

Assessment Period	IG1	IG2	Measures
Baseline (Week 0)	X	X	All standardized measures, initial GAS
Week 6/7	X	X	All standardized measures
Week 14	X	X	All standardized measures
Weekly	X	X	GAS observations

8. Statistical Analysis Plan

8.1 Sample Size Justification

This pilot study was powered based on available population at the ELC (n=40 maximum enrollment). Post-hoc power analyses indicated observed power below 20% for standardized measures due to small sample sizes, despite meaningful effect sizes. Future studies require:

- PROMIS Flexibility (d=0.68): 21 participants per group for 80% power
- PROMIS Persistence (d=0.63): 25 participants per group for 80% power
- PedsQL Social Functioning (d=0.53): 35 participants per group for 80% power

8.2 Statistical Methods

8.2.1 Primary Analysis - Standardized Measures

Baseline Comparisons: Independent samples t-tests for continuous variables to assess randomization success

Primary Efficacy Analysis: Analysis of Covariance (ANCOVA)

- Independent Variable: Group assignment (IG1 intervention vs. IG2 waitlist control)
- Dependent Variables: Week 7 standardized assessment scores
- Covariates: Baseline scores, any maturation effects identified in IG2 waitlist period
- Effect sizes: Cohen's d with 95% confidence intervals

Secondary Analysis: Paired samples t-tests for within-group changes

- One-tailed tests for intervention effects (directional hypotheses)
- Two-tailed tests for control period effects

8.2.2 Primary Analysis - Goal Attainment Scaling

Data Conversion: Individual GAS scores converted to T-scores (M=50, SD=10)

Baseline Comparisons: Independent samples t-tests for GAS T-scores across three domains

Primary Efficacy Analysis: ANCOVA comparing IG1 (weeks 0-7) vs. IG2 (weeks 7-14)

- Covariates: Baseline domain differences, IG2 control period changes
- Combined score calculated by averaging three domain T-scores

Secondary Analysis:

- Within-group paired samples t-tests for intervention effects
- Maintenance analysis for IG1 (weeks 8-14)
- Clinical significance threshold: 10+ T-score point improvements

8.3 Missing Data Handling

Approach: Listwise deletion for each analysis **Rationale:** Participants included only with complete baseline and outcome data for each specific measure **Impact:** Sample sizes range from n=17-19 for primary ANCOVA analyses (8-10 participants per group)

8.4 Significance Level

Alpha set at 0.05 for all analyses

9. Data Management

9.1 Data Collection Procedures

- Standardized assessment forms completed by parents/caregivers
- GAS observations recorded by trained research team members
- Weekly scoring reviewed by occupational therapy leads for reliability
- Data entry into secure database by participant number

9.2 Data Storage

- Electronic data stored on password-protected, encrypted servers
- Physical forms stored in locked cabinets in secure research offices
- Data de-identified for analysis using participant ID numbers
- Data retention period: 7 years post-study completion

9.3 Data Quality Assurance

- Regular data monitoring for completeness and accuracy
- Inter-rater reliability checks for GAS observations
- Standardized training for all data collection staff

10. Ethical Considerations

10.1 IRB Approval

Study approved by overseeing institution under IRB-FY2022-23

10.2 Informed Consent Process

- Written informed consent obtained from all parents/caregivers
- Consent process includes study description, risks, benefits, voluntary participation
- Right to withdraw at any time without penalty
- Translation services available as needed

10.3 Risk-Benefit Assessment

Minimal Risks:

- Potential emotional responses during intervention activities
- Breach of confidentiality (mitigated through data security protocols)

Benefits:

- Access to evidence-based trauma-informed intervention
- Potential improvements in self-regulation, behavior, and resilience
- Contribution to research benefiting similar populations

10.4 Participant Safety

- Trained occupational therapy staff monitor for adverse reactions
- Protocols for managing emotional dysregulation during sessions
- Referral pathways for participants needing additional support
- Regular safety monitoring throughout study period

11. Quality Assurance and Monitoring

11.1 Protocol Adherence

- Standardized BRP manual followed for all intervention sessions
- Regular weekly team meetings to review protocol implementation
- Documentation of any protocol deviations

11.2 Staff Training

- All intervention staff trained in BRP protocol delivery
- Training in trauma-informed care approaches
- Regular supervision by licensed occupational therapists
- Inter-rater reliability training for GAS observations across all persons recording data

11.3 Data Monitoring

- Weekly review of attendance and assessment completion
- Monthly data quality checks (Foust and DeLisio)
- Progress reports to funding agencies as required (midterm and final to AOTF)

12. Adverse Event Reporting

12.1 Adverse Event Definitions

- Any negative emotional or behavioral reaction requiring intervention cessation
- Physical injury during intervention activities
- Disclosure of child abuse or neglect requiring mandatory reporting

12.2 Reporting Procedures

- Immediate documentation of adverse events as required by YWCA site
- Notification of PI within 24 hours
- IRB reporting within required timeframes
- Appropriate referrals for participant safety and support

13. Protocol Amendments

13.1 Amendment Process

- All protocol changes require PI approval
- Significant amendments require IRB approval prior to implementation
- Documentation of all amendments with rationale

13.2 Implemented Modifications

Duration Change: Original 8-week intervention modified to 7 weeks due to facility closure from flooding

- All content maintained with combined final caregiver-child session
- Timeline adjustments documented and approved

14. Study Timeline

Phase	Duration	Activities
Recruitment	2 months	Participant enrollment, consent, baseline assessments
Phase 1	7 weeks	IG1 intervention, IG2 waitlist control
Assessment	1 week	Mid-study assessments
Phase 2	7 weeks	IG2 intervention, IG1 standard care
Final Assessment	1 week	Final assessments, study conclusion
Analysis/Reporting	3 months	Data analysis, manuscript preparation

15. Publication and Dissemination Plan

15.1 Primary Publications

- Primary efficacy results and GAS methodology findings in peer-reviewed occupational therapy journal
- Implementation lessons learned in community-based intervention journal

- Caregiver results and supplemental qualitative analysis of interviews in occupational therapy journal

15.2 Conference Presentations

- American Occupational Therapy Association Annual Conference
- International Association of Trauma-Informed Care
- Society for Research in Child Development

15.3 Community Dissemination

- Report to YWCA Early Learning Center and families
- Community presentation to local healthcare providers
- BRP manual availability for clinical implementation