The Role of Emotion Regulation and Socialization in BPT Efficiency and Outcomes

NCT number NCT03597789
Document Date 06/24/2021

Complete Title:	The Role of Emotion Regulation and Socialization in BPT Efficiency and Outcomes
Short Title:	Tantrum Tamers 2.0: The Role of Emotion
Clinical Trials Identifier:	NCT03597789
Drug or Device Name(s):	N/A
FDA IND/IDE (if applicable):	N/A
Sponsor:	University of North Carolina at Chapel Hill
Protocol Date:	June 24, 2021

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Definition
BD	Behavior Disorder
BPT	Behavioral Parent Training
ER	Emotion Regulation
ES	Emotion Socialization

PROTOCOL SYNOPSIS

Study Title	Tantrum Tamers 2.0: The Role of Emotion
Funder	National Institute of Mental Health (R21MH113887)
Clinical Phase	N/A
Study Rationale	There is variability in standard of care Behavioral Parent Training (BPT) outcomes for early- onset (3 to 8 y.o.) Behavior Disorders (BDs), suggesting yet unidentified causal mechanisms. One candidate, emotion regulation (ER), has been implicated in the development of early-onset BDs. This study explores ER in the context of BPT.
Study Objective(s)	**Primary** Describe child behavior and emotion regulatory processes in BPT. **Secondary** Use preliminary results to inform future research on BPT adaptations.
Test Article(s) *(If Applicable)*	N/A
Study Design	Single-arm, open trial of Behavioral Parent Training (BPT) for early-onset behavior disorders (BDs)
Subject Population **key criteria for Inclusion and Exclusion:**	Inclusion Criteria 1. 3-8 year old child 2. Parent is legal guardian 3. Child has clinically significant problem behavior 4. English-speaking Exclusion Criteria 1. Parent current mood, psychotic, substance use disorder 2. Current involvement child protective services 3. Child developmental/physical disability precludes BPT
Number Of Subjects	45
Study Duration	Each family: Approximately 12 weeks All families: Approximately 2 years
Study Phases **Screening** **Study Treatment** **Follow-Up**	(1) Screening/Baseline: screening to determine eligibility and obtain consent and (2) Intervention: study intervention; 3) Post-assessment: repeat baseline measures.
Efficacy Evaluations	N/A
Pharmacokinetic Evaluations	N/A
Safety Evaluations	N/A

Statistical And Analytic Plan	Given pilot nature of study and small sample size, trends in the data will be examined, including means and standard deviations.
DATA AND SAFETY MONITORING PLAN	Dr. Jones responsible for data and safety monitoring. No data or safety issues emerged, but would have been/will be discussed with IRB and NIMH.

1 BACKGROUND AND RATIONALE

1.1 Introduction:

Eight-million (16%) U.S. children have a Behavior Disorder (BD), which is linked to a ten-fold increase in education, health care, and criminal justice costs. Early intervention is thus critical, yet outcomes for the standard of care, Behavioral Parent Training (BPT), vary suggesting the likelihood of a yet to be identified underlying mechanism. One likely candidate, emotion regulation (ER), has been implicated in a broad range of adult and child outcomes, including early-onset BDs. For example, parental difficulties with ER, as well as difficulties helping children to navigate and regulate emotion (i.e., emotion socialization), are linked to the etiology, maintenance, and severity of early-onset BDs. As such, this NIMH Exploratory and Developmental Research Grant (Parent R21) aims to further explore the ER in the context of BPT process and outcomes.

1.2 Name and Description of Investigational Product or Intervention:

Behavioral Parent Training (BPT) is the well-established, standard of care treatment for early-onset BDs. Both a parent and the target child attend sessions which focus on parents learning, practicing and effectively using new skills to manage child behavior. Phase I skills focus on teaching parents to provide positive attention to behaviors they want to increase and Phase II focuses on improving child compliance by using effective and consistent consequences for noncompliance. Treatment is an average of 8-12 weeks. This study is exploring the mechanisms underlying BPT.

1.3 Non-Clinical and Clinical Study Findings:

BPT is the recommend first line of treatment and standard of care for early-onset BDs. Therefore, the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered if families were seeking psychological services in the community. In turn, the benefit of improving child behavior outweigh risks.

1.4 Relevant Literature and Data:

This is a pilot study, so it will serve as preliminary data for future work.

2 STUDY OBJECTIVE

2.1 Primary Objective:

Describe patterns of child behavior and emotion regulatory processes in BPT.

2.2 Secondary Objective:

Use preliminary results to inform future research on BPT adaptations.

3 INVESTIGATIONAL PLAN (brief overview)

3.1 Study Design:

Single-arm, open trial of Behavioral Parent Training (BPT) for early-onset behavior disorders (BDs).
Study phases: Screening/Baseline, Treatment, Post-treatment.

3.2 Allocation to Treatment Groups and Blinding (if applicable):

N/A

3.3 Study Duration, Enrollment and Number of Subjects:

N = 45 children;
Each child participates in BPT treatment with a parent for an average of 10 weeks (M = 8 to 12);
Total study time with screening and post-treatment assessment approximately 12 weeks/family.

3.4 Study Population:

Inclusion Criteria: 3-8 year old child; Parent legal guardian; Child meets criteria for clinically significant problem behavior; English-speaking.

Exclusion Criteria: Parent has current mood, psychotic, substance use disorder; Current involvement child protective services; Child has developmental/physical disability that precludes BPT

4 STUDY PROCEDURES

4.1 Screening/Baseline Visit procedures:

Interested families contact study coordinator to determine elibility and, if eligible, are scheduled for a baseline assessment to assess primary other study variables.

4.2 Intervention/Treatment procedures (by visits):

Both a parent and the target child attend sessions which focus on parents learning, practicing and effectively using new skills to manage child behavior. Phase I skills focus on teaching parents to provide positive attention to behaviors they want to increase and Phase II focuses on improving child compliance by using effective and consistent consequences for noncompliance. Sessions recorded for therapist supervision and study purposes.

4.2 Follow- up procedures (by visits):

Screening/baseline measures repeated at treatment completion.

4.3 Unscheduled visits:

N/A

4.4 Concomitant Medication documentation:

N/A

4.5 Rescue medication administration (if applicable):

N/A

4.6 Subject Completion/ Withdrawal procedures: Completion determined by parent meeting established BPT skill mastery criteria. Parents unable to continue with treatment (e.g., moving), referred for other services/providers when possible.

4.7 Screen failure procedures:

Ineligible families referred to local providers who provide BPT (or other relevant psychological treatment for children).

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Efficacy Evaluation (if applicable):

N/A

5.2 Pharmacokinetic Evaluation (if applicable):

N/A

5.3 Safety Evaluations:

N/A

6 STATISTICAL CONSIDERATION

6.1 Primary Endpoint:

Eyberg Child Behavior Inventory (ECBI; Eyberg & Pincus, 1999)

6.2 Secondary Endpoint:

Difficulties with Emotion Regulation Scale (DERS; Gratz & Roemer, 2004)
Coping with Children's Negative Emotions Scale (CCNES; Fabes et al., 2002)

6.2 Statistical Methods:

Given the pilot nature of the study and small sample size, trends in the data are focus of analyses, including means and standard deviations for aforementioned measures.

6.3 Sample Size and Power:

This is a pilot study with insufficient sample size and power to achieve statistical significance. Trends examined to inform sample size to achieve adequate power in future work.

6.4 Interim Analysis:

N/A

7 STUDY INTERVENTION (drug, device or other intervention details)

Behavioral Parent Training is the recommend first line of treatment and standard of care for early-onset BDs. Both a parent and the target child attend sessions which focus on parents learning, practicing and effectively using new skills to manage child behavior. Phase I skills focus on teaching parents to provide positive attention to behaviors

they want to increase and Phase II focuses on improving child compliance by using effective and consistent consequences for noncompliance.

8 STUDY INTERVENTION ADMINISTRATION (if applicable)

Single-arm, open trial of well-established, evidence-based intervention (BPT), so no randomization or blinding.

9 SAFETY MANAGEMENT

Data safety monitored throughout course of study (see Data Collection and Management).
Given that BPT is a well-established intervention, Adverse Events extremely unlikely.
No Adverse Events occurred.

10 DATA COLLECTION AND MANAGMENT

- All families assigned study identification number (Family ID).
- Identifying information maintained for contacting families for study purposes only.
- Identifying information stored separately from study data, which is coded by Family ID.
- Study data stored on password protected server with 2-step verification and limited to study staff.
- All hard copies stored in locked, passcode protected laboratory space.

11 RECRUITMENT STRATEGY

Families recruited from local community and agencies serving young children.
Methods included flyers, advertisements, and word-of-mouth.
Interested families contact study coordinator to do initial elibigility screen.

12 CONSENT PROCESS

Parental consent for self and child at baseline assessment.
Consent included a description of study procedures, benefits, and risks.
Assessor also reviewed consent with parent and addressed any questions/provided additional information .

13 PLANS FOR PUBLICATION

Given preliminary nature of data, results will be published in a primary outcomes paper (e.g., brief report) as well as serve as pilot data for a subsequent grant.

14 REFERENCES

Eyberg, S.M., & Pincus, D. (1999). *Eyberg Child Behavior Inventory and Sutter-Eyberg Student Behavior Inventory-Revised: Professional Manual.* Odessa, FL: Psychological Assessment Resources.

Fabes, R. A., Poulin, R. E., Eisenberg, N., Madden-Derdich, D. A. (2002). The Coping with Children's Negative Emotions Scale (CCNES): Psychometric properties and relations with children's emotional competence. *Marriage & Family Review, 34*(3-4), 285-310.

Gratz, K. L. & Roemer, L. (2004). Multidimensional assessment of emotion regulation and dysregulation: Development, factor structure, and initial validation of the Difficulties in Emotion Regulation Scale. *Journal of Psychopathology and Behavioral Assessment, 26,* 41-54.

15 APPENDIX

N/A