

Regulating Together in Tuberous Sclerosis Complex (RT-TSC):

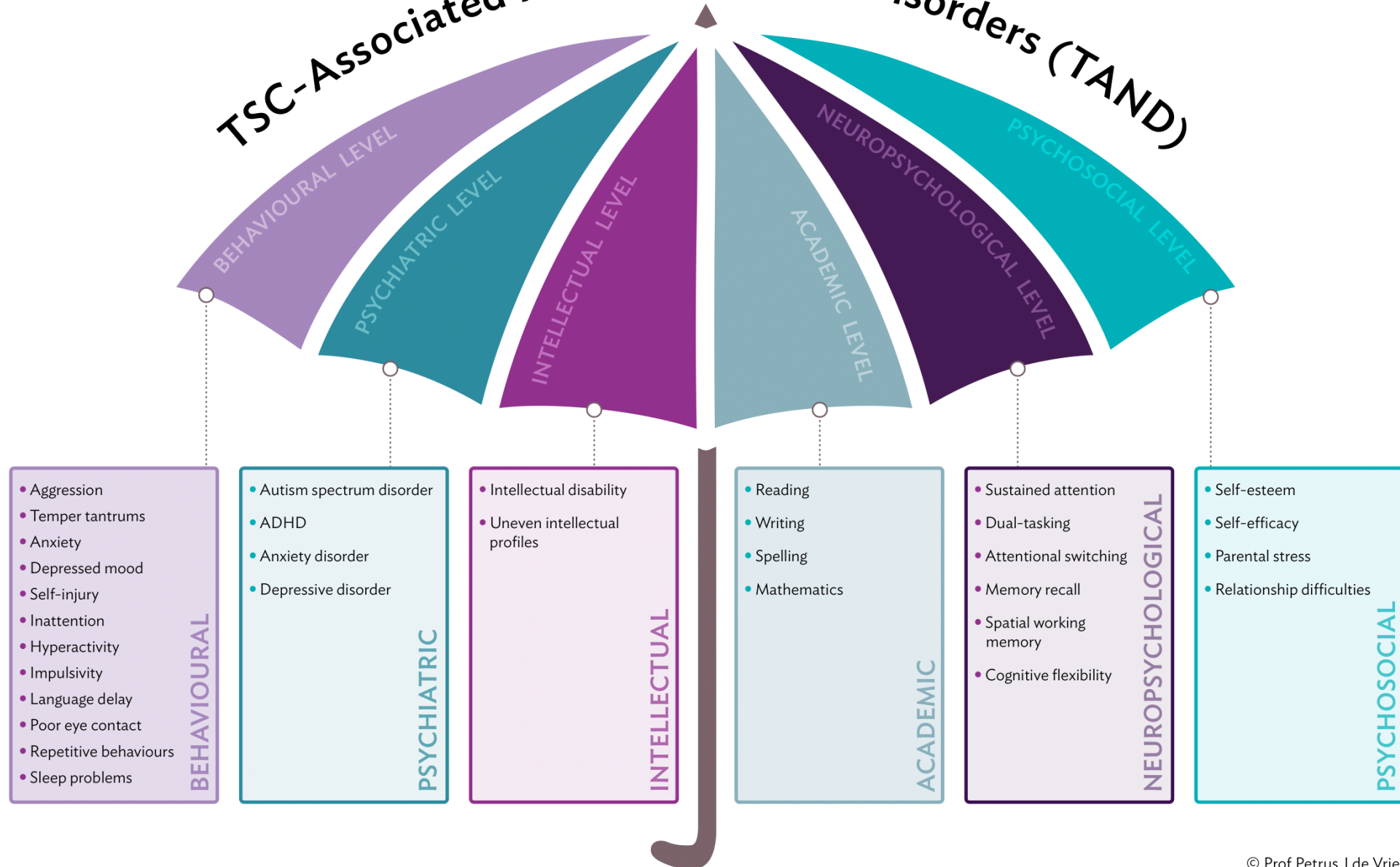
**A Pilot Feasibility Study in Children and
Adolescents with TSC-Associated
Neuropsychiatric Disorder (TAND)**

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TSC-Associated Neuropsychiatric Disorders (TAND)



90% of individuals with TSC experience 1 or more of these symptoms

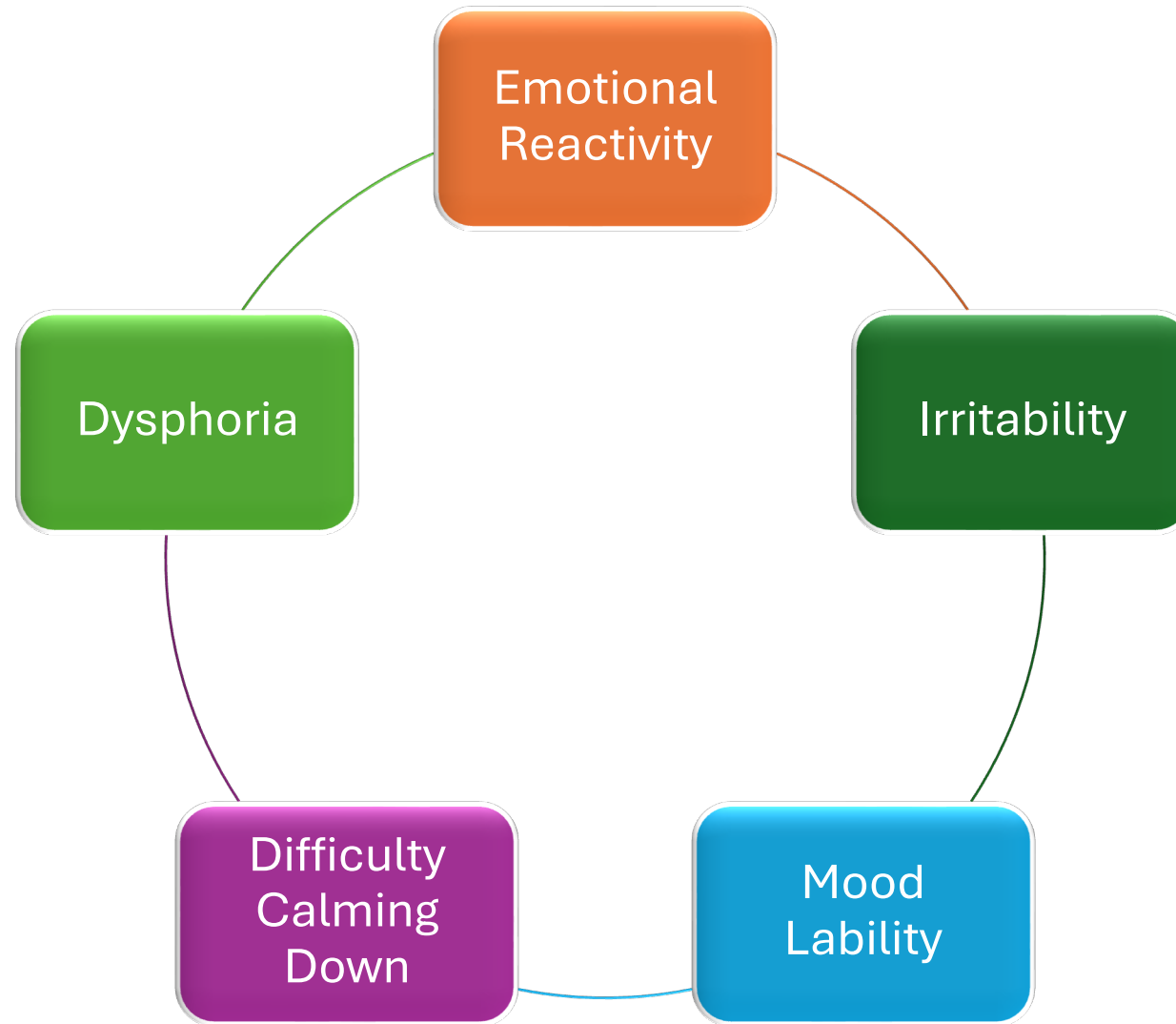
Emotion Regulation

- **Emotion Regulation** is...
 - the ability to modulate experiences and expression of emotions in a socially acceptable manner
 - a method of controlling the intensity of one's emotion, at either a conscious or unconscious level, before or after a triggering event
- **Adaptive Emotion Regulation** = coping strategies

Emotion Dysregulation

- General deficit in one's ability to modulate the intensity or duration of emotional responses in an adaptable and contextually appropriate manner.
- **Maladaptive Emotion Regulation**= dysregulation, tantrums, outbursts
- High rates in ASD and syndromic causes of intellectual disability
- Major source of stress for parents and caregivers.
- Believed to be an identifiable and targetable driver of many TAND symptoms and behaviors.

Emotional Dysregulation (ED)

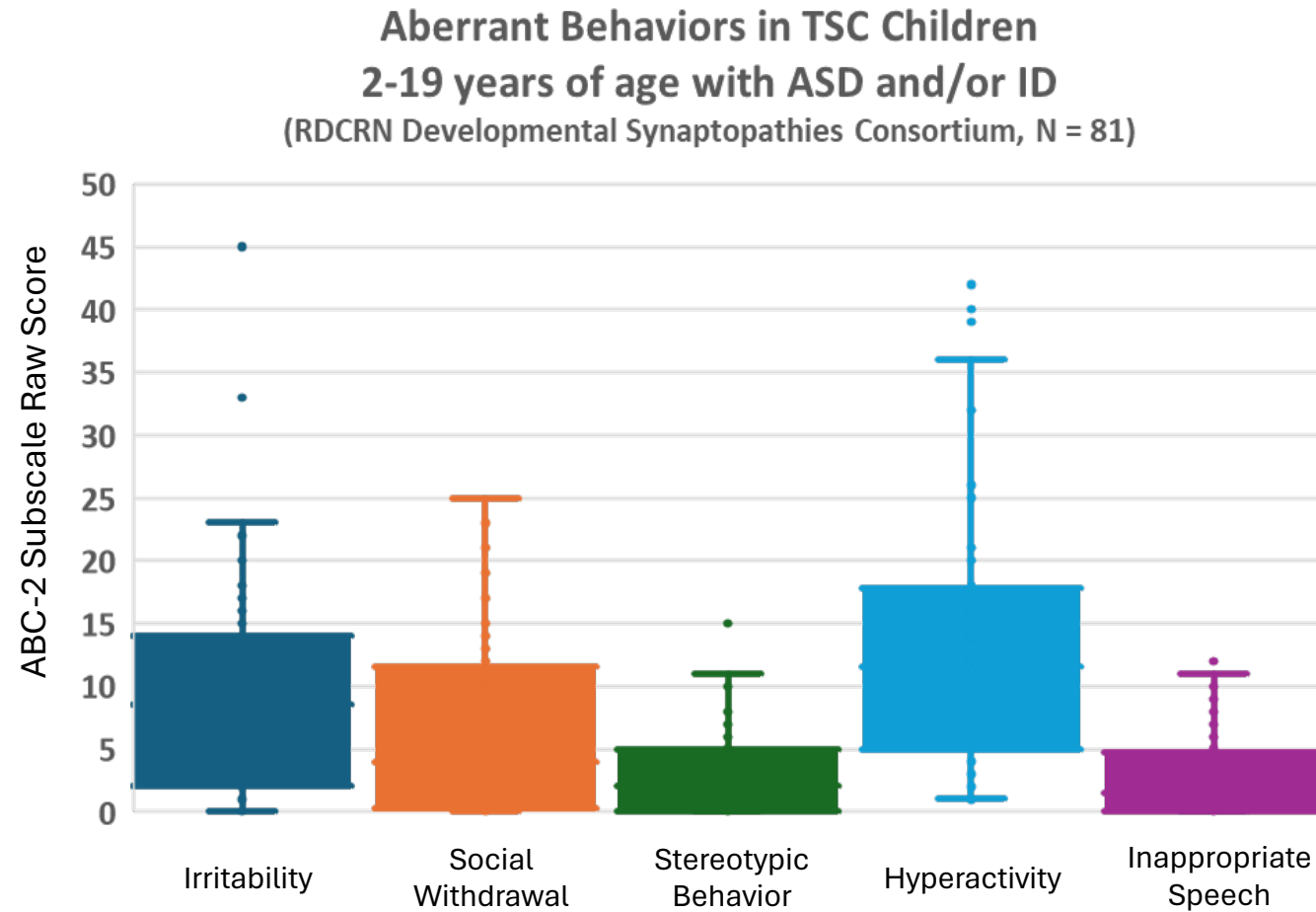


Behavioral Symptoms Indicative of ED in TSC

TAND-L Checklist, N = 488 children and 250 adults

TAND Cluster	Behavioral Symptom	Overall (%)	Child (%)	Adult (%)
Behavioral Dysregulation	Rigid/Inflexible	43.4	40.7	48
	Difficulty with Peers	32.5	33	31.6
	Impulsivity	44.3	47.6	38.8
	Repetitive Behaviors	41.2	41.1	41.2
	Repeats Words	35.6	35.6	35.6
	Temper Tantrums	42.5	48.6	32.4
	Aggressive Outbursts	42.1	40.9	44
	Self Injury	25.1	26.3	23.2
Vegetative Symptoms	Sleep Difficulties	46.7	41.4	55.6
	Eating Difficulties	36.8	38	34.8
	Restlessness	46.1	48.1	42.8
	Overactive/Hyperactivity	34.9	40.2	26
Depressed Mood and Shyness	Extreme Shyness	21.6	19.6	24.8
	Depressed Mood	30.2	17	52.4
Mood Swings and Anxiety	Mood Swings	52.4	47.8	60
	Anxiety	52.5	43.3	68

Emotion Dysregulation in TSC

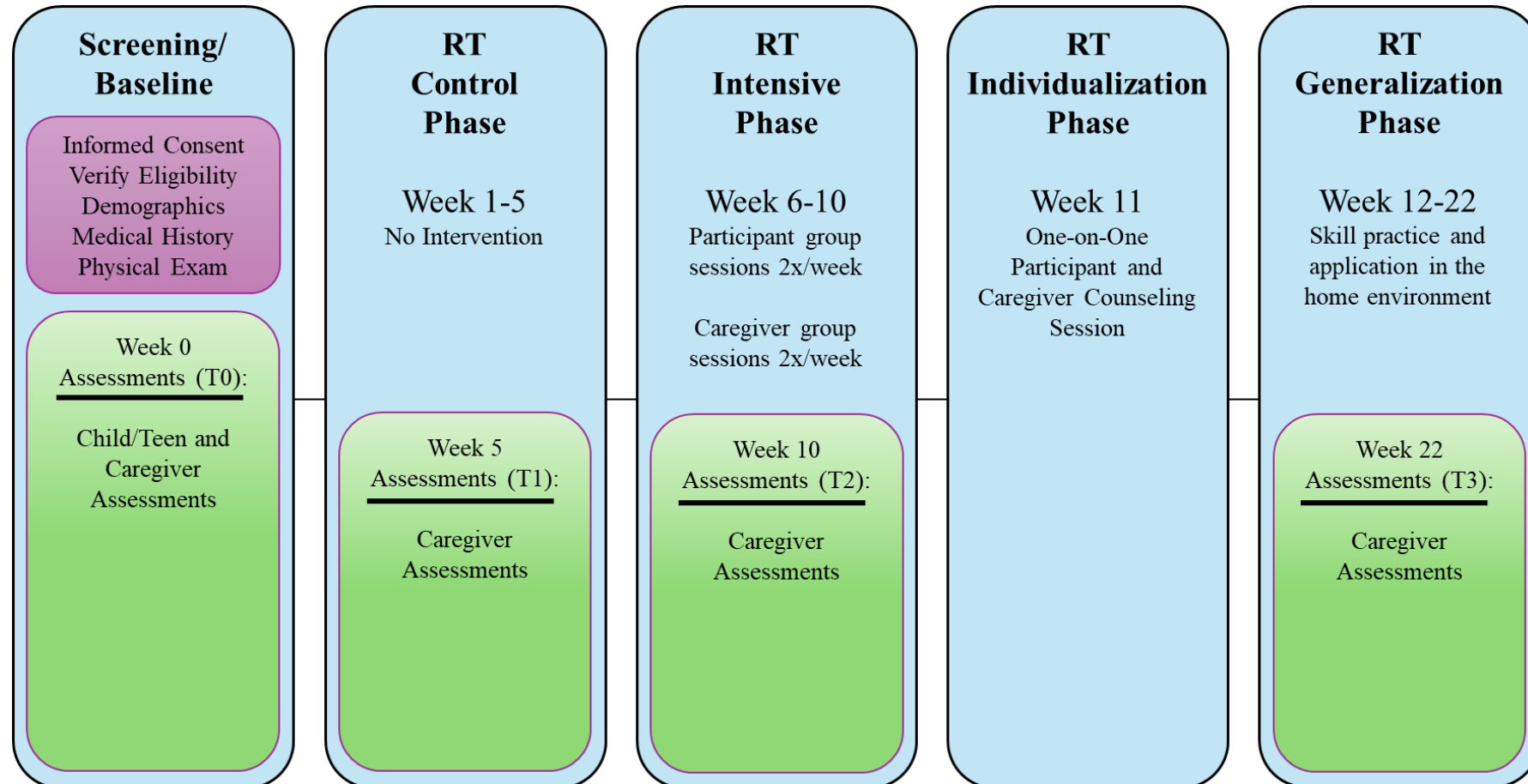


Regulating Together-TSC

RT-TSC GOALS

- Better understand emotion regulation difficulties in children and teens with TSC.
- Understand the efficacy of RT-TSC on emotion regulation.
- Understand who this intervention works best for (e.g., age, intellectual functioning, TAND symptomology, etc.).
- Feasibility of remote/virtual delivery of the intervention.
- Hope to utilize this pilot intervention study to refine the treatment curriculum and delivery to facilitate development into a larger study with plans for eventual clinical implementation.

RT-TSC



Program Structure

Group Treatment

Address social and educational environments

Increase access and treat more children

Virtual delivery

Intensive Model

~90 minutes

Twice weekly

Five weeks

Caregiver Group

Direct instruction

Support and normalize caregiver experiences

Increase durability post treatment

Emotion Regulation Intervention

- Cognitive-Behavior Therapy (CBT)
- Reinforcement
- Visuals
- Scaffolding
- Mindfulness and Acceptance-Based Interventions
 - Present-moment awareness
 - Coping with stressful thoughts, emotions, and physical sensations

Regulating Together-TSC

- Evidence-Based Components of RT:
 - Caregiver Engaged as Coach
 - Caregiver Training & Didactic
 - Prompting & Fading
 - Individualized Visual Supports
 - Reinforcement Strategies
 - Peer Interaction (virtual)
 - Weekend Activities
 - Social Reinforcement & Modeling
 - Practice & Feedback (virtual)



Inclusion and Exclusion Criteria

- Ages 8-18 (Child: 8-12, Teen: 13-18)
- TSC and TAND behaviors identified on TAND Checklist
- Access to a device (tablet, computer)
- Fluent in English
 - Flexible “fluent” speech, estimated at a 4-year-old level in functional expressive language or higher
- IQ>65
- Stable medication regimen (4-weeks prior)
- No initiation of new psychosocial treatment or medication 30 days prior to RT-TSC
- Potential participants with significant disruptive behaviors, co-occurring neuropsychiatric symptoms requiring other treatments, and sensory impairment limiting participation will be excluded.

Intake Process

- Telephone Screening
- Baseline Assessment (currently in person, plan to move to virtual)

Treatment Overview

Curriculum

	RT Child Sessions	RT Caregiver Sessions
1	Group Rules, Introductions, Emotion Identification	Introductions and Crisis Management
2	Relaxation Skills	Relaxation Skills and Functions of Behavior
3	Triggers and Body Signs	Triggers, Body Signs, and Prevention Strategies
4	Rating Emotions	Rating Emotions and Problem Sizes
5	Problem Size	Reinforcement Systems
6	Problem Solving	Problem Solving
7	Positive and Negative Thoughts	Positive and Negative Thoughts
8	Cognitive Flexibility	Cognitive Flexibility
9	Review	Community/ Personal Supports, Treatment Planning
10	Graduation	Review, Treatment Planning, and Graduation

General Group Session Structure

- Review
 - Relaxation Practice
 - Learning
 - Activities
 - Family Wrap-up
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- Practice of skills and completion of weekend activities is an important aspect of the intervention.

Questions?

- For additional information on RT-TSC please contact **Julia Flynn** at:

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Subject: RT-TSC