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James G. Waxmonsky, MD, reports he is a researcher for Supernus and performs regular consulting work with Adlon Pharmaceuticals and Intracellular Therapies, Inc. He will discuss off-label pharmaceutical use in the treatment of irritability and aggression.

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Learning Objectives

After this lecture, registrants will be able to:

1. Outline the key aspects of assessing irritability in youth.
2. Describe key components of efficacious psychosocial treatments for irritability in youth with ADHD.
3. Discuss the evidence base for the pharmacological treatment of irritability in youth with ADHD.

The Assessment and Management of Irritability in Children with Disruptive Behavioral Disorders

James Waxmonsky MD
Professor,
Penn State College of Medicine
Division Chief of Child Psychiatry,
Department of Psychiatry & Behavioral Health

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Disclosures in the 3 last years

Source	Consultant	Advisory Board	Stock Equity >$10,000	Speaker's Bureau	Research Contract
Adlon	X				
Intracellular Therapies	X				
Supernus					X

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ADHD and Irritability: Why do We Care?

- ADHD diagnosed in 10% of American school children (Visser et al, 2015)
- Up to half have prominent irritability (Bunford 2015, Shaw 2014)
- Those with prominent irritability are more likely to present for treatment (Anastopoulos 2011)
- Irritability is associated with a host of poor outcomes (Copeland 2014, Orri 2018, Vidal Ribas 2021)
- Limited study of the treatment of irritability in ADHD (Vidal Ribas 2016)
- Anxiety/ODD responded best to combined treatment in MTA (*d*=.58) as did children with manic like symptoms (Galanter 2003/2005; Jensen 2001)
- Impulsive aggression improved with treatment in the MTA (*d*=.84) (Jensen 2007)

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DSM Symptom Based Measures

- 3 irritability items for Oppositional Defiant Disorder
  - sum of “loses temper”, “touchy or easily annoyed”, “angry/resentful”
- In common ADHD scales: Vanderbilt, Disruptive Behavior Disorder RS
- Items 20, 24, 25 on Vanderbilt
- Use threshold of often/very often on 0-3 likert
  - Measures frequency better than severity
  - Parents still care about occasional severe temper outbursts
- Sum scores above 3 considered concerning
- Mood lability (Conners): easily frustrated, cries easily, mood changes quickly, temper outbursts
- Parent ratings are standard method of assessment
- Teachers informative: cross domain more severe
- Children viewed as poor self raters for external behaviors (temper outbursts) but not internal mood states (irritability)

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Affective Reactivity Index (Stringaris, 2012)

- In the last SEVEN (7) DAYS and compared to others of the same age, how well does each of the following
- Not True Somewhat True Certainly True
- 1. Am easily annoyed by others. ▫ 0 ▫ 1 ▫ 2
- 2. Often lose my temper. ▫ 0 ▫ 1 ▫ 2
- 3. Stay angry for a long time. ▫ 0 ▫ 1 ▫ 2
- 4. Am angry most of the time. ▫ 0 ▫ 1 ▫ 2
- 5. Get angry frequently. ▫ 0 ▫ 1 ▫ 2
- 6. Lose temper easily. ▫ 0 ▫ 1 ▫ 2
- 7. Overall irritability causes me problems. ▫ 0 ▫ 1 ▫ 2

- Scores of 7+ considered concerning
- Just starting to be used a measure of treatment with clinician version (Haller 2020)

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The Temper Outbursts are the Bomb

- Timing (links with psych meds)
- Triggers (Antecedents-anxiety/ADHD)
- Duration
- Frequency
- Intensity
- Remitting factors
  - Effect of parents
  - Effect of child

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Carlson Outburst Measure

Questions about your child's anger

1. HOW EASY IS IT FOR HIM/HER TO GET ANGRY? (Please circle the letter of the **ONE BEST** response)

a. S/he is rarely irritable or angry
b. S/he is mostly reasonable but has days at a time where s/he is very touchy and gets very angry very easily.
c. S/he rarely gets angry but when s/he does, the explosion is huge compared to the incident that provoked it.
d. S/he has always been cranky and easily angered.

2. WHAT CAUSES HIM/HER TO GET ANGRY? (Please circle **ALL THAT APPLY**)

a. S/he feels s/he is being criticized
b. S/he misunderstands what others are saying
c. Her/his demands must be met immediately
d. S/he can't handle change in routine
e. S/he is frustrated because s/he can't do something (task or activity)
f. S/he is hungry, tired, or pre-menstrual

3. WHICH OF THE FOLLOWING DOES YOUR CHILD USUALLY DO? (Please circle **ALL THAT APPLY**)

a. Expresses anger in an appropriate way (e.g., explains her/his perspective; goes to her/his room to cool down)
b. Argues, whines or sulks
c. Becomes verbally insulting, swears, shouts
d. Threatens
e. Slams doors, punches walls, makes a mess, destroys property
f. Self-mutilates, bangs head, or otherwise takes it out on self
g. Throws things
h. Hits, kicks, bites, spits
i. Needs physical restraint

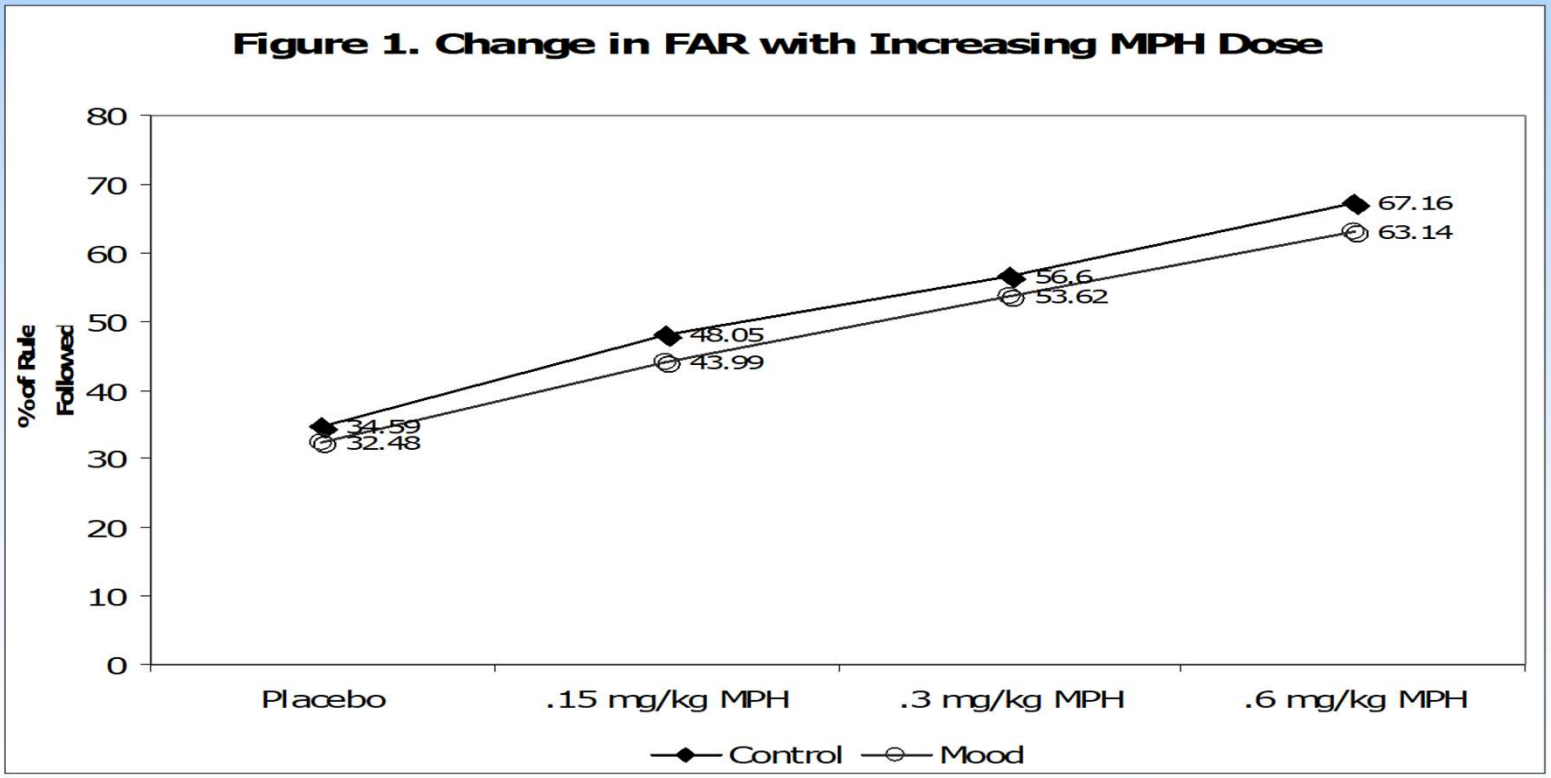
(please circle THE BEST RESPONSE to EACH QUESTION BELOW)

4. **HOW OFTEN DOES A SERIOUS TANTRUM OR OUTBURST OCCUR?**	a. Never____ b. Rarely____ c. several times a month____ d. Weekly_____ e. at least 3 times/week____ f. Daily____
5. **HOW LONG DOES A TANTRUM OR OUTBURST LAST?**	a. a few minutes ____ b. up to 15 minutes____ c. up to half an hour_____ d. Up to an hour_____ e. Up to half a day_____
6. **IS YOUR CHILD ANGRY OR IRRITABLE BETWEEN OUTBURSTS?**	a. Not at all_____ b. Sometimes _____ c. often_____ d. very often_____
7. **HOW DOES YOUR CHILD UNDERSTAND THE OUTBURST?**	Remorseful_____ Forgets or denies it_____ Blames others_____ Spiteful_____

WHAT HELPS YOUR CHILD CALM DOWN?_____

_____

Improvement in Following Activity Rules with MPH in ADHD Youth with and without SMD (Waxmonsky 2008 JCAP)



Waxmonsky, 2008 et al., JCAP

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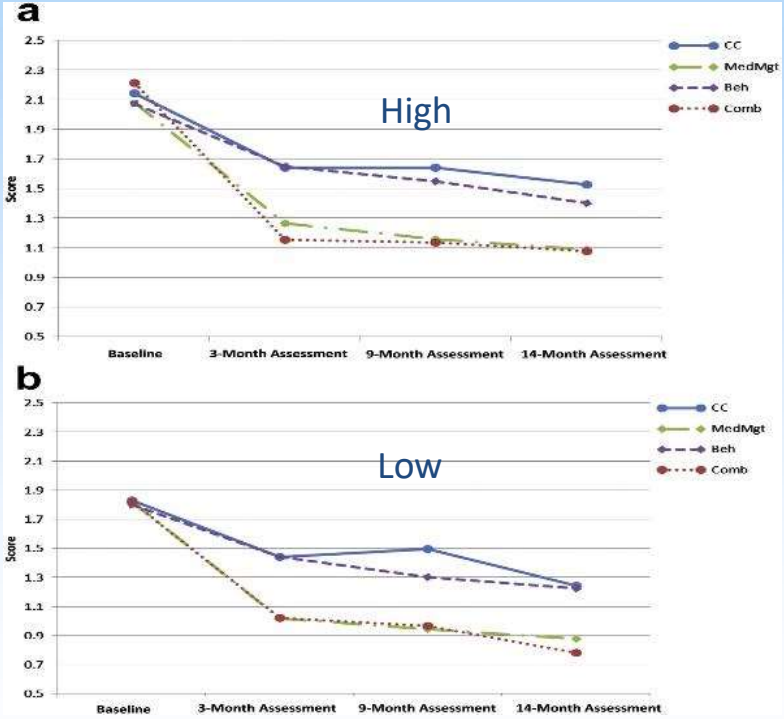
MTA Irritability Findings (De La Cruz et al, JAACAP 2015)

- Examined 14 month ratings (at end of RCT phase) in 579 ADHD youth
- Irritability did not moderate response to ADHD treatments
- MTA study med moderators: parent dep sx/education, severity of ADHD, child IQ, NOT ODD (Owens 2003, MTA 1999)
- Irritability decreased over time: Comb (*d*=.82) > Beh (*d*=.42), CC (*d*=.48) but not med (*d*=.63)
- Remission of irritability not seen
- For aggression: All 3 study arms > community control vs just comb>CC for irritability



Journal of the American Academy of Child & Adolescent Psychiatry 2015 54, 62-70.e3DOI: (10.1016/j.jaac.2014.10.006)

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Long-term MPH study

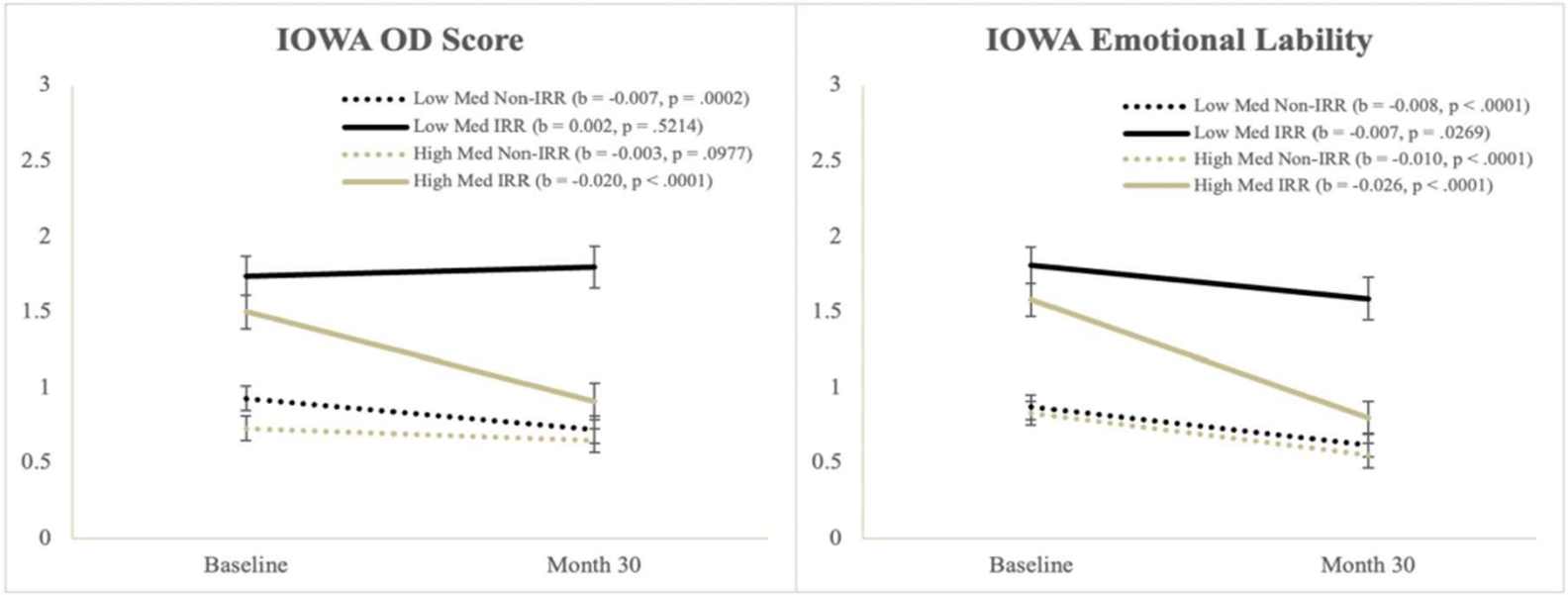

FIGURE 1 | Illustration of the Time*Med*IRR interaction from the IOWA scale.

The Impact of Persistent Irritability on the Medication Treatment of Paediatric Attention Deficit Hyperactivity Disorder

Raman Baweja[1], Daniel A. Waschbusch[1†], William E. Pelham III[2], William E. Pelham Jr.[3] and James G. Waxmonsky[1]*

frontiers in Psychiatry
BRIEF RESEARCH REPORT
published: 21 July 2021
doi: 10.3389/fpsyt.2021.699687

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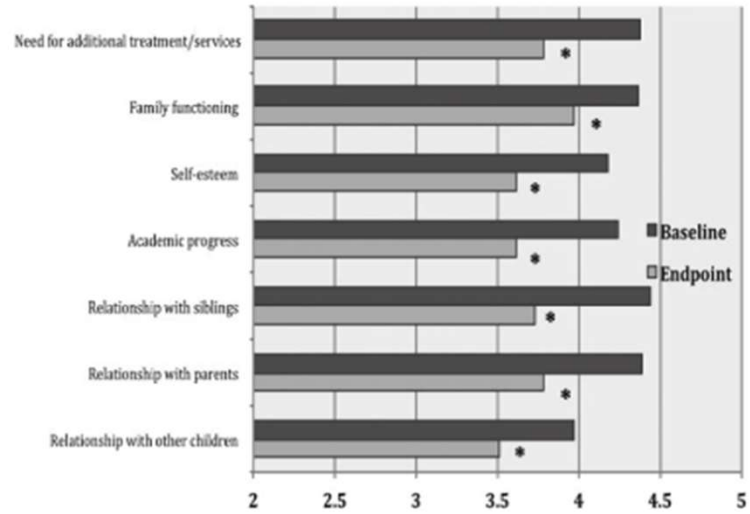
CNS Stimulants: ADHD & DMDD

- Prospective open-label trial
- Both MPH and AMPH preparations were well tolerated
- Clinically significant reduction in externalizing symptoms, DSM-5 ODD irritability subscale (effect size=0.29)
- Most participants still exhibited significant impairment



Parent Impairment Rating Scale: 1 = Definitely Not a Problem, 2 = Probably Not, 3 = Maybe, 4 = Probably Yes, 5 = Definitely Yes a Problem; *p value: <0.05.

FIG. 1. Parent rating on the Impairment Rating Scale.

(Baweja et al, JCAP, 2016)

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Who Gets Less Aggressive with ADHD Meds?

- Blader 2010 (Pediatrics): primary outcome was R-MOAS
  - 51% remit their aggression after med dose optimized
    - Mean MPH dose 54mg and AMPH of 24mg
    - IRR responders had lower mean doses/attended less PT sessions
    - ADHD effect size larger in responders
  - Irritability and depression seem to improve as aggression improves (excludes those with full MDD; 30% had DMDD)
  - Irritable youth may respond more robustly to stimulants than non irritable youth
  - Optimize that med and retry again

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Blader 2021 (JAACAP)

- 55% remitted with BMOD and CNS stim opt
  - Less likely: White, prior AP, prior BMOD, more school impairment
  - Some with prior AP did optimize
  - Sultan 2019: almost 50% of youth with ADHD get AP before stimulant
  - Mean MPH dose 41mg (had to be on 30mg pre-trial)
    - –not diff vs nonremitters
  - 63% OROS, 10% other ER MPH , 27% AMPH ER
  - What this means: psychosocial distress (?) , poor compliance (no) , poor skill utilization (not measured)

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Do We Know Who Gets Worse: No!

- Winters- (JCAP 2018)
  - 22 DMDD youth treated with CNS Stims
  - 71% better, 19% worsened, 10% no change
  - Baseline ADHD or irritability sx didn't predict change
  - Baseline severity does typically predict ADHD sx change (Faraone 2021)
- Froehlich (JCAP 2019)
  - inattentive type not selected for IRR
  - Low base internalizing sx predicted more of these sx
  - Higher base internalizing sx predicted less of these sx
- Pozzi (JAD2018) Stuckleman (JCP 2018)
  - MPH reduces IRR with signal of worse IRR with AMPH
  - Dose, ER vs IR age, rater not linked to IRR- some associations with duration of use (early in course)
- Baweja 2021: high base IRR predicts improved IRR with increased med use

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Assessing Impact of ADHD meds on IRR

1) Level of residual ADHD sx when outburst occur
2) When are ADHD meds clearly active and not active?
   How do you know?
3) Impact of ADHD meds on arguing/compliance/outbursts
4) Have more confidence when clear residual ADHD sx and pattern of better behavior when med is active (TOSCA)
   - Kutlu (2017 JCCP): CNS improved IRR independent of ADHD
   - Blader 2009: couldn't find that sx change mediated aggression change even though strongly correlated

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Anxiety Meds and IRR

- Much less data on this
- PK profile of anxiety meds makes this more challenging
- Easier to look for consistent triggers that are associated with anxiety (separations, precluding compulsions, fearful event approaching) and cognitions indicating fear/worry
- Very challenging in younger children

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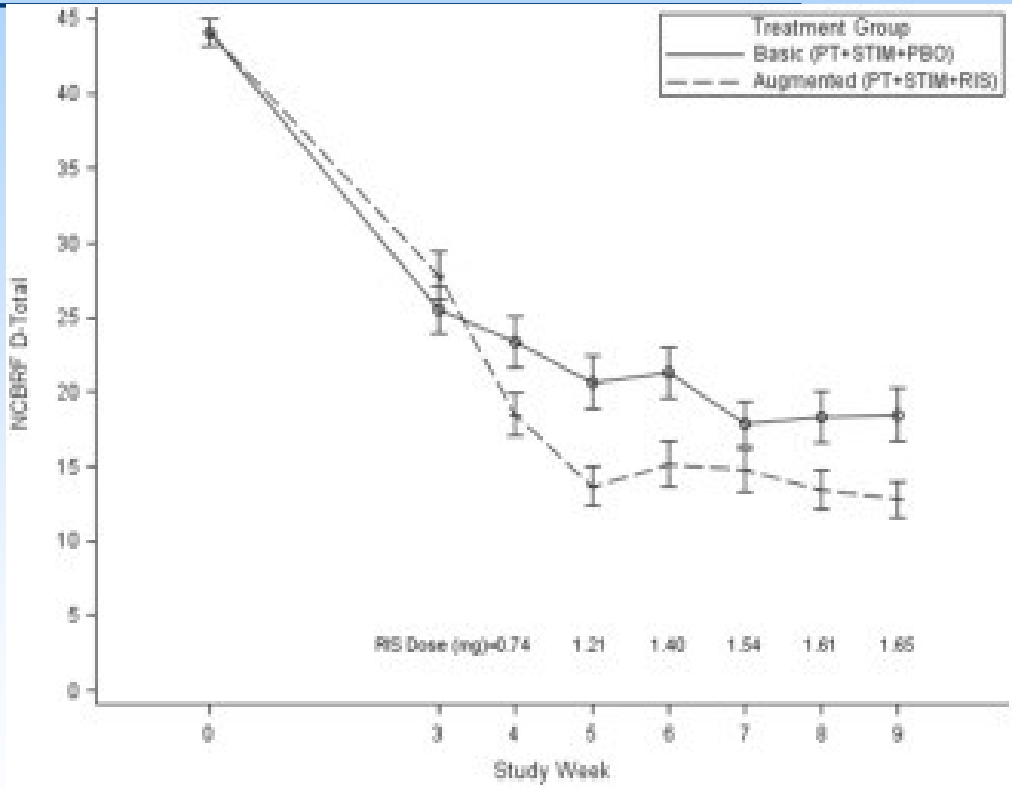
The Treatment of Severe Child Aggression (TOSCA) study (Aman et al, 2014)

- N168, ADHD and recurrent aggression, treated with BT & MPH
- If not optimized after 3 weeks (95%), randomized to risperidone vs placebo
- Adding risperidone led to larger effects for ODD (*d*=.27) and aggression (*d*=.32) rated by parents
- NCBRF: Risp: 42% decrease over lead in
  - Placebo: 28.5% decrease (ES=.46) with 70% improved by CGI
- Extended BMOD effects as it continued to into RCT phase (week 9)
- Mean dose 1.65mg
- Weight gain: -1.2kg vs + 1.8kg (3kg over 9 weeks)
- 65% on Risp with increased prolactin
- Farmer 2015: more IRR =faster response
- ADHD severity moderated response



Journal of the American Academy of Child & Adolescent Psychiatry 2017 56, 1026-1033DOI: (10.1016/j.jaac.2017.09.426)

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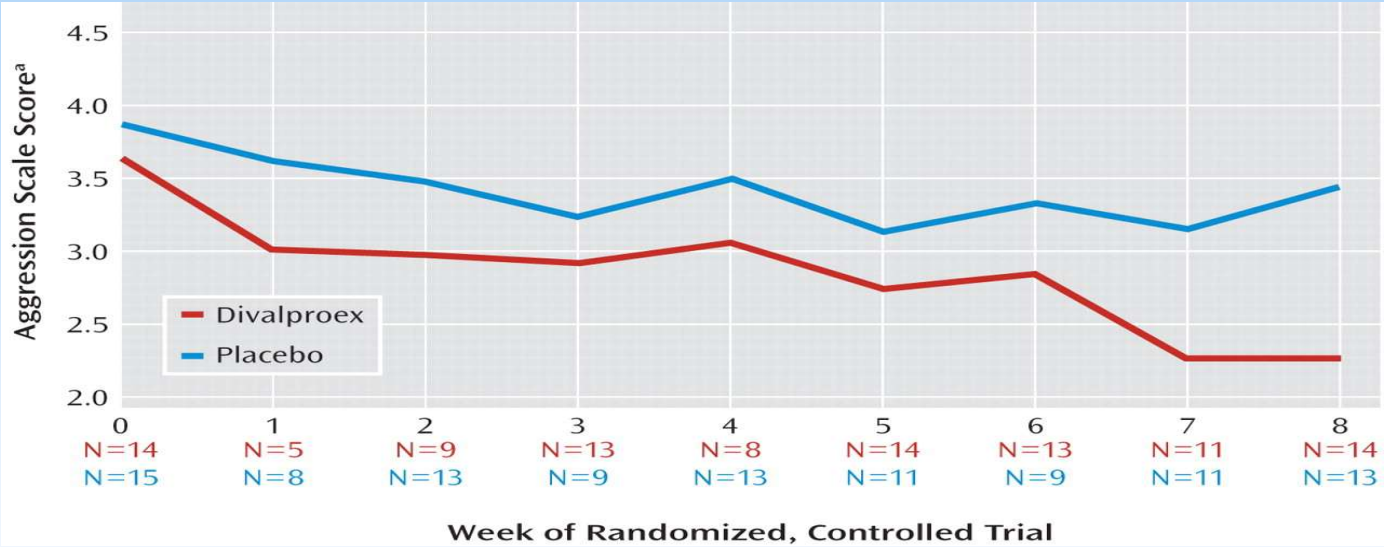
Divalproex For Aggression

Blader et al American Journal of Psychiatry 166(12), 2009



- In contrast, Depakote for broad phenotype of pedi BP without optimization of ADHD med was not strongly efficacious (24% response rate and inferior to risperidone) (Geller, 2012)
- Adjunctive mood stabilizers appear to work better once ADHD is under best control
- Jumping to mood stabilizers or antipsychotics before stabilizing ADHD may not work as well

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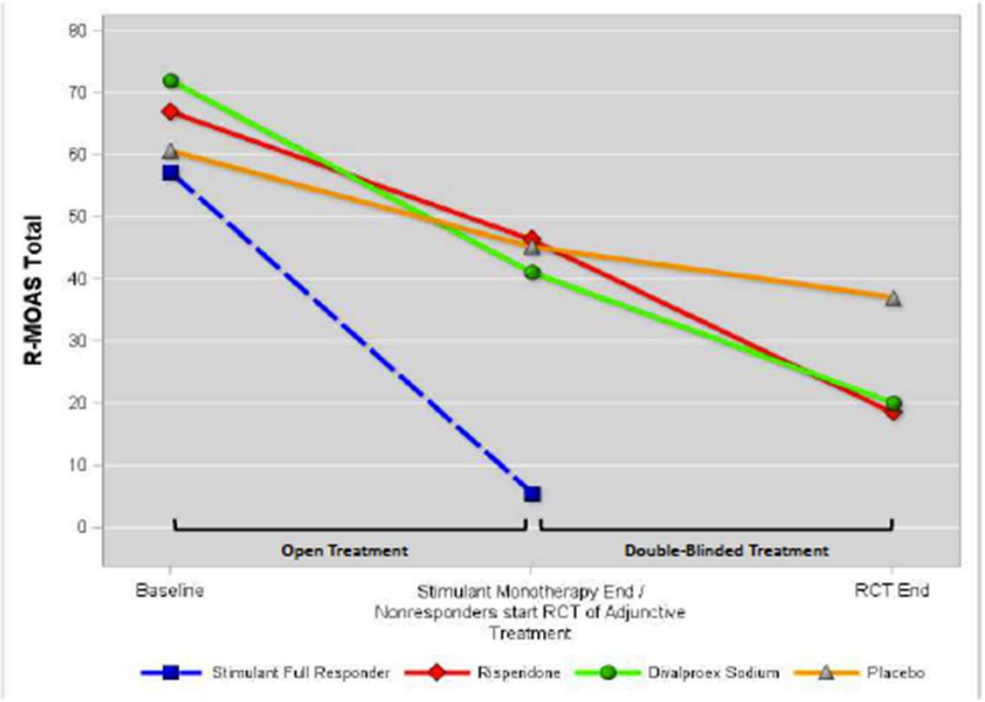
ADHD & Aggressive Behavior: Risperidone vs. Divalproex (Blader 2020)

- 174, 6-12 year old first optimize with CNS stimulants +behavioral treatment
- Response (RMOAS): risp 69% DVPX 40% Pla 37%
- Aggression Δ– RISP (ES -1.32); DVPX (ES, -0.91)
- Risp 1.1mg DVPX 713mg
- Wt gain- risp 2.3kg, DVPX .65kg Pla-0.0kg
-



Journal of the American Academy of Child & Adolescent Psychiatry 2021 60236-251DOI: (10.1016/j.jaac.2019.12.009) Fig 3

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Molindone & Impulsive Aggression in ADHD

(*Ceresoli-Borroni JAD 2020*)

- N152, ages 6–12 years,
- Optimized on monotherapy treatment for ADHD (AMPH, MPH nonstimulants) plus BT over 3 weeks
- Randomized to placebo, low-dose (12/18 mg/day), medium-dose (24/36 mg/day) or high-dose (36/54 mg/day) molindone
- Aggression improved significantly with low (Cohen's *d* .60) and medium doses (*d* .59), but not with high doses (*d* .04)

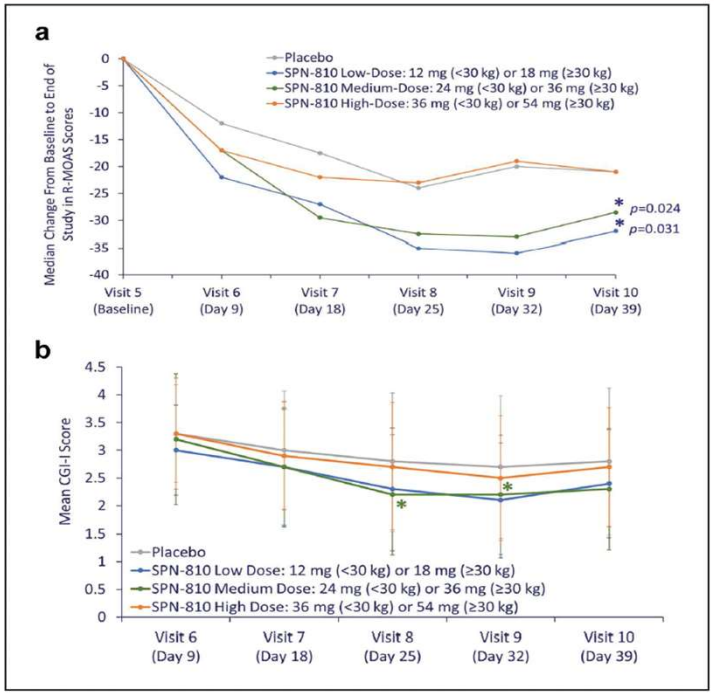

Figure 2. Change from baseline to end of study in R-MOAS and CGI-I scores.

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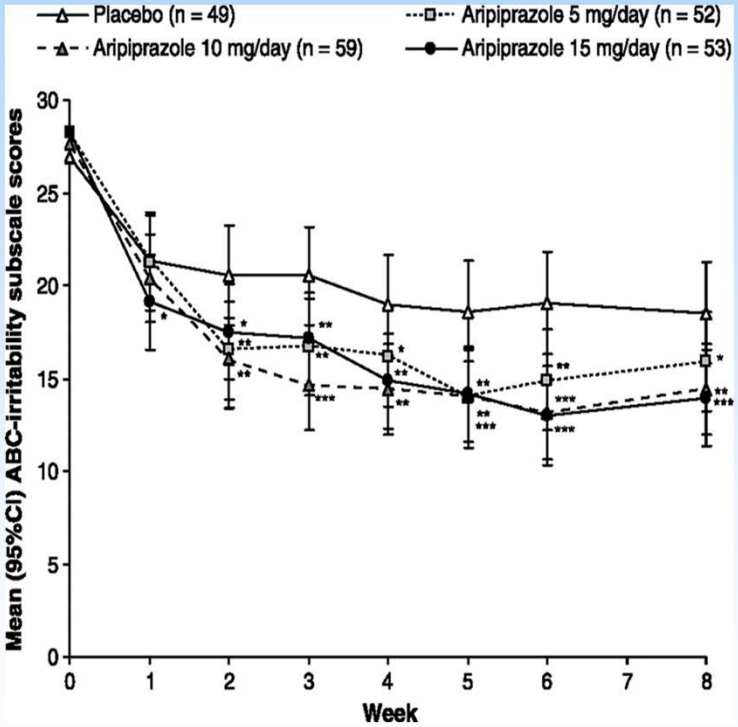
Aripiprazole in Children (pedi BP)

- 296 youth ages 10-17 manic or mixed episode, with or without psychosis. (Werner, 2008)
- Randomly assigned to receive aripiprazole 10 mg, 30 mg or placebo daily.
- Outperformed placebo but 10mg=30mg
- Effects seen in 1 week
- Also data for treating irritability in ASD (Owen, 2009)
  - Most common dose was 10mg
- Like risperidone, approved for use in children with BP and ASD (managing irritability/aggression)



Journal of the American Academy of Child & Adolescent Psychiatry 2009 48, 1110-1119DOI: (10.1097/CHI.0b013e3181b76658)

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Citalopram for DMDD (JAACAP 2019)

- Inpatient care where optimized stimulant and tapered other meds
- Stim effects: hyperarousal (ES 1.1); Outbursts (ES.5) Interval Mood (ES -0.1)
- Only 17% remitted : why? More severe? No BMOD?
- Citalopram: 5mg q5 days ; could go home when at 20mg
  - Avg dose 28mg
  - Reductions in irritability (ES=.85) and outbursts seen (ES=1.12), not hyperarousal
  - Response 35% vs 6% NNT=3l
  - CGAS NS, CDRS NS, PARS NS
  - Differences emerged week 5
  - No persistent SI or mania;
  - 83% rate of anger across participants and 74% rate of aggression with citalopram vs 85%/46% (NS) with placebo
- TADS: fluoxetine and to lesser degree CBT associated with reduced ODD sx (Jacobs 2010)

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Citalopram for DMDD

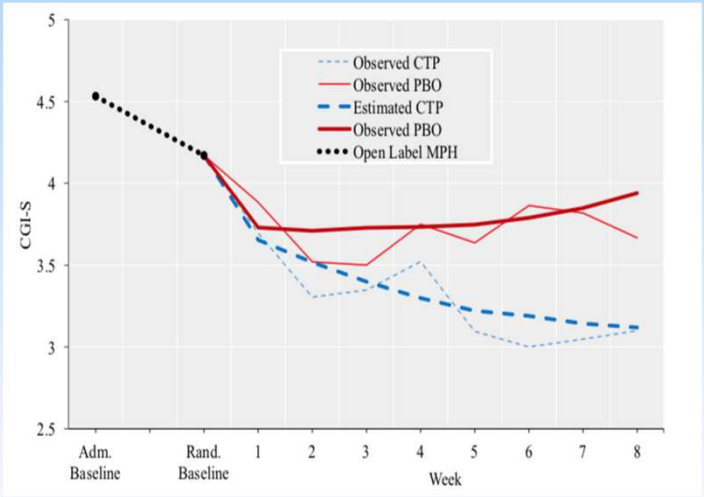

FIGURE 2 Change in Irritability Severity Before and After Randomization in the Sample Included in the Intent-to-Treat Analysis

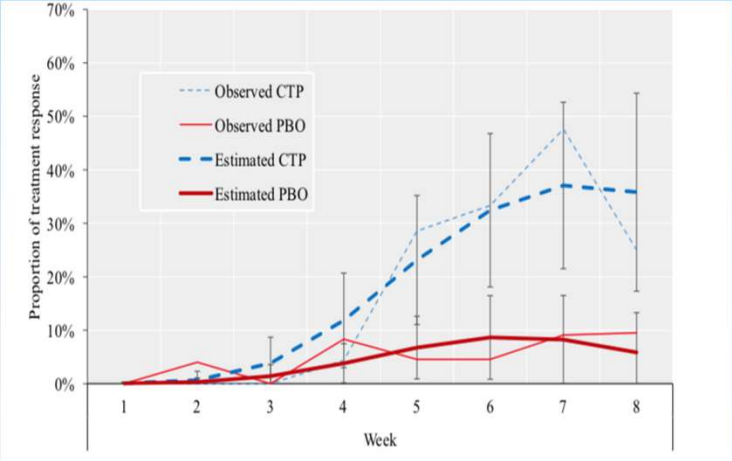

FIGURE 3 Proportion of Treatment Response by Week and Treatment Group

A Double-Blind Randomized Placebo-Controlled Trial of Citalopram Adjunctive to Stimulant Medication in Youth With Chronic Severe Irritability

Journal of the American Academy of Child & Adolescent Psychiatry
Volume ■ / Number ■ / ■ 2019

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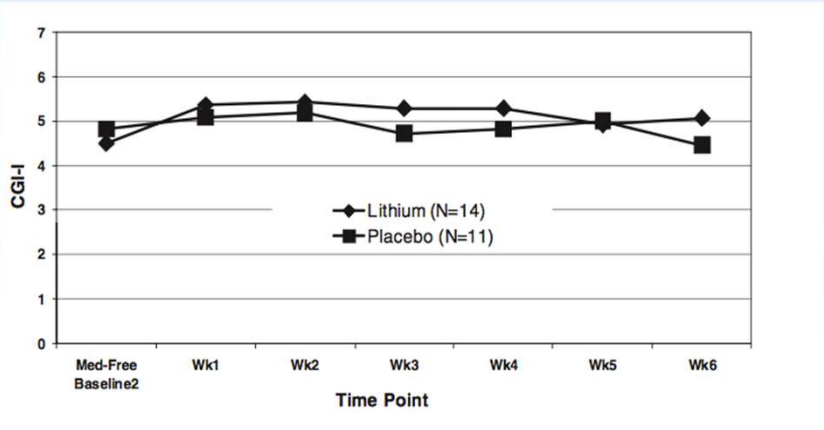
Lithium for SMD

(Dickstein et al, JCAP 2009)

- Set at the NIMH inpatient unit, 45 children were first taken off all medication and Standard behavioral procedures
- After 2 weeks, 45% improved too much to stay in study
- Randomly assigned to 6 weeks of Lithium (mean level of .82) or placebo
- No differences across almost all outcomes



Suggests removal from stressors and intensive behavioral treatment is effective for SMD

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Conclusions for Adjunctive Meds

- Most data in youth getting BT on optimized CNS stimulant
- Best data for low dose risperidone
- Next is Divalproex then Citalopram
- Need to also consider long term tolerability
- Effects are less than see during BT/stimulant phase

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Targetable Facets of Emotion Dysregulation

- Recognition: attending to and appraising stimuli
- Reactivity: immediate response to stimuli
- Regulation: capacity to reach a goal when experiencing emotional reactions

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Type of Psychosocial Interventions for Emotion Dysregulation (ED)

Parent-directed therapy

- Parent training (4)

Social Emotional Child-directed therapy (SET): focus in on identifying and regulating emotions with parents trained to be emotion coach (2)

Cognitive Behavioral Therapy: target cognitive distortions (5)

- DBT
- Emotion regulation intervention
- Social skills Training
- ERP for irritability

Multimodal (7)

-Summer treatment Program

-Integrative Group Based Therapy (AIM)

-Multi Family Psychoeducation Groups

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Recognition Training

- Stoddard 2016/2020: DMDD associated with labeling neutral faces as hostile
- computerized training did create shift towards more happy judgements
- Not associated with improved irritability

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Parent Training (PT)

- Ameliorate patterns of family interactions that produce antecedents and consequences of maintaining tantrums, aggression, and noncompliance.
- Adds benefit to medication treatment in ADHD and ASD
- Standardized PT improves ED

PT techniques

  - Parents are taught to identify the function of maladaptive behavior
  - To give praise for appropriate behavior
  - To communicate directions effectively
  - To ignore maladaptive attention-seeking behavior,
  - To use consistent consequences for disruptive behaviors

- Parent Child Interaction Therapy: adds the child to the session
  - Improved child behavior (not parent) in session predicted gains at home (Rothenberg 2019)

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Mods to PT for Irritability/ED

- Teach parents to attend to their emotions first
- Then move child to calm state
- Then engage in emotion coaching so as not to attend to child when in dysregulated state
- Key is to attend when engaging in positive vs negative behaviors
- Don’t need to apply immediate consequences at peak of frustration
- Taking space is not a punishment – done to allow child to self soothe

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To Modify or Not

- Unmodified PT/PCIT appears to work well
- Modify for age (DBT) or condition (PCIT for MDD)
- PCIT example:
  - Just increasing pos parenting behaviors doesn't reduce ED
  - Luby 2020: enhanced PCIT improved mood and behavior outcomes
  - Two studies found reduced behavior effects when emotion coaching modules were added (Tuscano 2016, Salmon 2014)

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Summer Treatment Program

- Treatment of Children with ADHD and DMDD in an Intensive Summer camp Setting (Waxmonsky 2008)
  - 9 weeks with intensity of behavior therapy Weekly PT
  - No specific adaptions for IRR (point system, home DRC)
  - Similar dose dependent effects were seen in DMDD and non DMDD group
  - Most common optimal treatment was combined treatment

- Preschool STP : 8 weeks comparison of PT only vs STP vs enhanced STP with SET (Graziano & Hart 2016)
  - Change in behavior comparable across groups (BASC/IRS)
  - STP/SET experienced greater growth across time in emotion knowledge, emotion regulation, and executive functioning
  - Enhanced STP showed most gains over 6 months

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Child-Directed CBT Approaches

- Targets deficits in emotion regulation and social problem solving skills that are associated with aggressive behavior
- Cognitive-behavioral techniques
  - Identifying the antecedents and consequences of aggressive behavior
  - Learning strategies for recognizing and regulating anger expression
  - Problem-solving and cognitive restructuring techniques
  - Modeling and rehearsing socially appropriate behaviors that can replace angry and aggressive reactions

(Sukhodolsky et al, 2016, Lochman 2017)

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Evidence for CBT

- Meta-analysis of CBT for anger/aggression in youth: mean effect size 0.67 (Sukhodolsky et al, Aggress Violent Behav 2004)
- Lochman JE, Powell NP, Boxmeyer CL, Jimenez-Camargo L. Cognitive-behavioral therapy for externalizing disorders in children and adolescents. Child and Adolescent Psychiatric Clinics. 2011 Apr 1;20(2):305-18.
- Evidence-Based Psychosocial Treatments for Children and Adolescents With Attention Deficit/Hyperactivity Disorder (Evans et al, JCCAP 2018)
  - Integrating parent CBT and PT (Chacko, Chronis Tuscano)
- Schatz NK, Aloe AM, Fabiano GA, et al. Psychosocial Interventions for Attention-Deficit/Hyperactivity Disorder: Systematic Review with Evidence and Gap Maps. Journal of Developmental & Behavioral Pediatrics. 2020 Jan 30.
- Thornback & Muller 2015: TF CBT improves ED and improved ED translates to improved PTSD

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Multifamily Psychoeducational Psychotherapy –For Pedi Mood disorders

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Table 3. Multifamily Psychoeducational Psychotherapy Session Content

Session No.	Parent Group	Child Group
1	Childhood mood disorders and their symptoms	Childhood mood disorders and their symptoms
2	Medications: names and classes of medications; monitoring effectiveness and adverse effects	Medications: symptoms and the medications that target them; "naming the enemy"
3	"Systems of care": mental health and educational services	"Tool kit" to manage symptoms and emotions
4	Negative family cycle; review first half of the program	Connection between thoughts, feelings, and actions; thinking-feeling-doing exercise
5	Develop problem-solving and coping skills	Develop problem-solving skills; stop-think-plan-do-check exercise
6	Improve verbal and nonverbal communication skills	Improve nonverbal communication skills
7	Symptom management	Improve verbal communication skills
8	Review second half of the program; graduate	Review and graduate

MFPG was associated with lower MSI scores at follow-up in intent-to-treat analyses compared with WLC (effect size=0.53).

Arch Gen Psychiatry. 2009;66(9):1013-1021

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Integrative Group Based Therapy for ADHD and DMDD

Session	Parent Group	Child Group
1	Social Learning Theory, Goals	Symptoms vs. Self, Goals
2	Identifying your Child's Strengths & Positive Attending	Emotion Recognition, Promoting the Positive
3	Antecedents & Warning Sign	What Anger Looks & Feels Like
4	Coping Skills, House Rules & Planned Ignoring	Identifying Triggers & Developing Coping Skills
5	How to Give Good Commands, Time Out	Using Coping Skills
6	Negative Family Cycles	Perspectives & Consequences
7	Verbal & Nonverbal Communication	Verbal & Nonverbal Communication
8	Problem Solving	Problem Solving
9	Identifying & Coping with Depression	Coping Skills for Depression
10	Applying Skills in the Real World (Issues with School and Siblings)	Review – Putting it all together
11	Review	Practicing Skills for the Real World

(Waxmonsky et al, JAACAP 2016,)

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Exposure Based CBT for Irritability (Kircanski 2019)

- Based on exposure work for anxiety
- Controlled, graduate exposure to non-reward
- 12 weekly sessions that mixes ERP and parent training
  - Examples: turning off screens
- Train children to accurately evaluate level of frustration, tolerate frustration and inhibit maladaptive responses to it
- Minimize negative parental affect and attention to outbursts
- Initial small pilot shows benefit (Kircanski 2018)

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DBT Adapted for Preadolescent Children (DBT-C)

(Perepletchikova et al, JACCAP, 2017)

- Incorporates all 4 modes of standard outpatient DBT for adults
  - Individual therapy,
  - Skills training,
  - Phone coaching calls
  - therapist team consultation
- Addition of a parent training component
- 32 90 minute sessions
- 7 to 12 years old with DMDD (N = 43)
- DBT-C attended 89% of sessions compared with 48.6% in TAU (ind therapy)
- Response: 90.4% in DBT-C vs 45.5% in TAU,
- 3 times as many participants in TAU receiving psychiatric medications.
- Remission rates: 52.4% for DBT-C and 27.3% for TAU.
- Improvements were maintained at 3-month follow-up.

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Conclusions for Therapy for Irritability

- At least for broader construct of emotion dysregulation, many existing interventions work
- Parent training/PCIT for younger children
- CBT for older children
- Specialized more child focused treatments being developed (DBT, ERP)
- Baseline severity not a moderator with some signal that youth with high levels of ED benefit more from PCIT (Evans 2020; Waxmonsky 2021)
- Need to identify which components are critical

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