START NOW: A program to inprove emotion regulation in female patients with disruptive behaviour disorder

START NOW

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The future of CNS treatments
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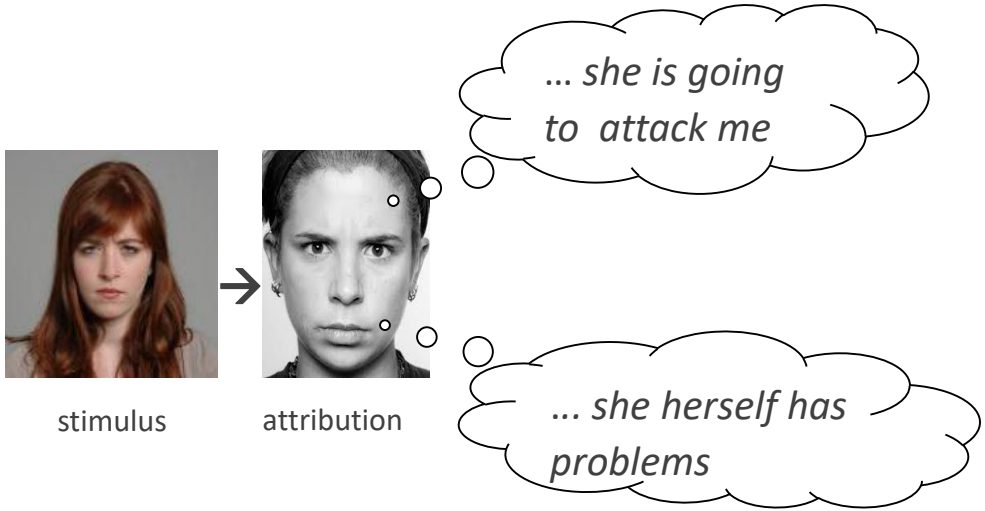
Are deficits in emotion regulation core symptoms in conduct disorder?

› Qualitative study (Kostiuk LM, Fouts GT, 2002): Girls with conduct disorder state that they do not have strategies to cope with intense emotions

› Reappraisal is affected in CD



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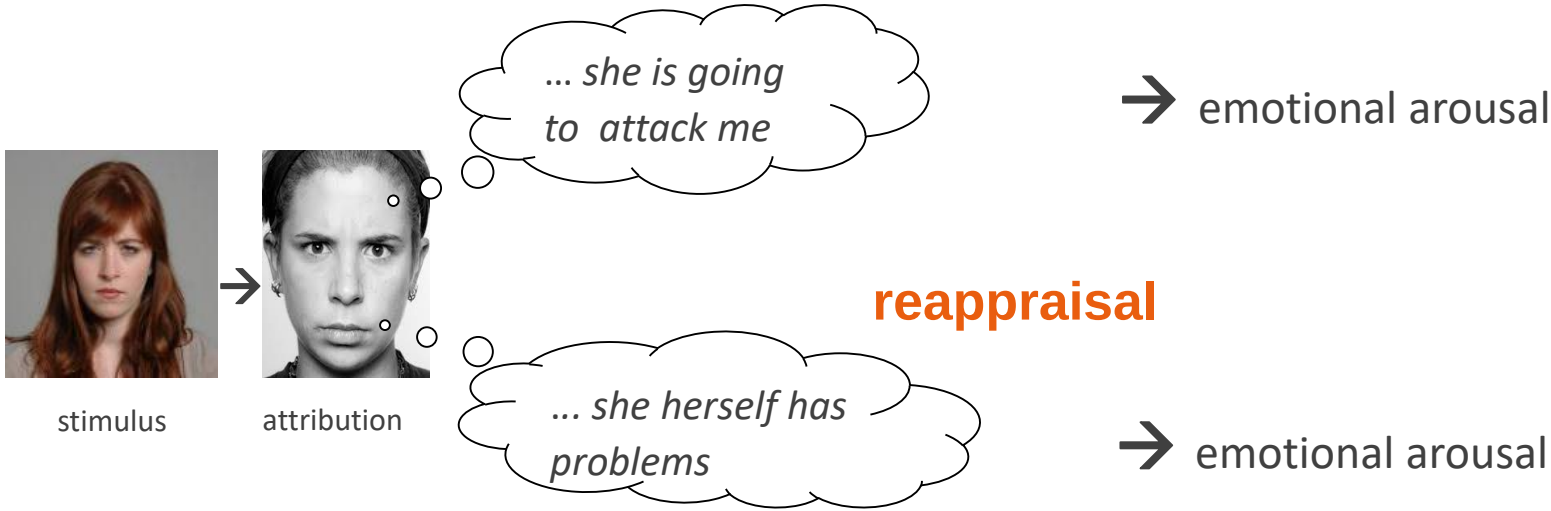
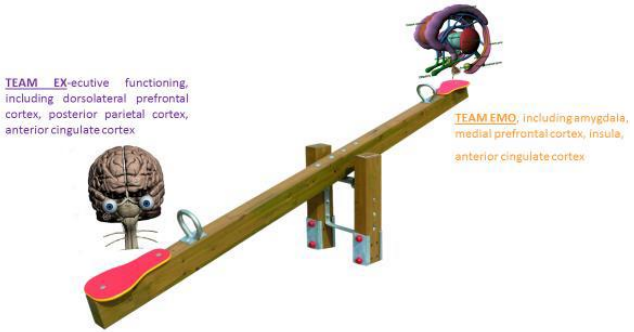


Neural basis of deficient emotion regulation

Nora Raschle

fMRI pardigm

- decrease negative (reappraisal)
- look at negative (non-regulation)
- look at neutral (non-emotional)



Raschle, N., …. C. Stadler (2019). Atypical Dorsolateral Prefrontal Activity in Female Adolescents With Conduct Disorder During Effortful Emotion Regulation in Biological Psychiatry CNNI

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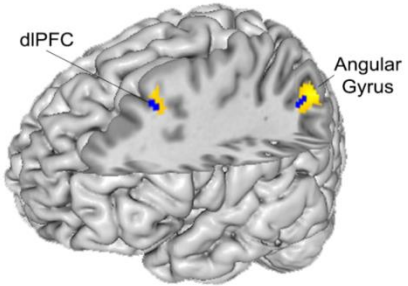
Neural basis of deficient emotion regulation

- Atypical left angular gyrus and dlPFC activation during emotion regulation in female adolescents with CD
- Reduced functional connectivity between the left dlPFC and cortical (vlPFC/OFC/ putamen) and subcortical (amygdala) regions

Raschle, N., …. C.Stadler (2019) in BPCNNI

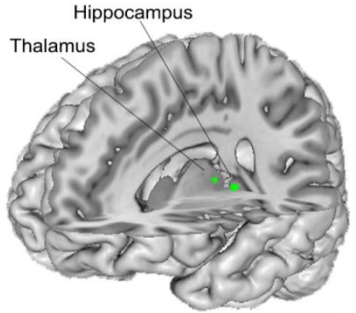
Activation by emotion regulation
(decrease negative > look negative)

Two-sample *t*-test: CD<TD
One-sample *t*-test: TD



Modulation by emotion regulation
(decrease negative < look negative)

Two-sample *t*-test: not significant
One-sample *t*-test: CD



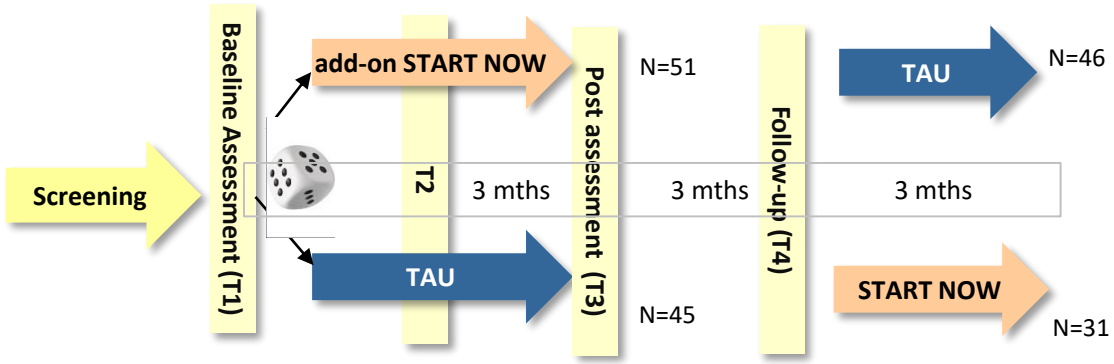
p<0.05, FWE-corr

Objectives and aims

- to develop a skillstraining aiming to enhance emotion regulation
- in adolescents with CD and ODD: Adolescence is one of the key periods for intervening, most notably in CD girls due to their late onset.
- provide the skillstraining in youth wellfare institutions: High prevalence rates of CD/ODD (Bronsard et al., 2016)
- testing the efficacy of START NOW within a RCT

Methods: Study Design

Prospective, confirmatory, cluster-quasi-randomised, parallel group, multi-centre and international phase III-trial (Switzerland, Netherland, Germany)



Eligible: N= 212
20 groups randomized
(N= 100)

7 groups quasi-randomized
(N=24)

Kersten, L., ... Stadler, C. (2016) START NOW - a comprehensive skills training programme for female adolescents with oppositional defiant and conduct disorders: study protocol for a cluster-randomised controlled trial. Trials. 2016 Dec 1;17(1):568

German Clinical Trials Register (DRKS) identifier: DRKS00007524

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Methods: Study Design

› **Control group:**

TAU including treatment as usual in youth welfare settings, excluding group-based therapy/skills training and START NOW-/ DBT-A- or similar interventions

› **Experimental group:**

Weekly group-based START NOW training (12 weeks) + 12 individual sessions, add-on therapy to TAU

START NOW
Cognitive-behavioural training

- Developped by Bob Trestman, adopted for adolescents
- Strongly influenced by DBT, ACT: Focus on emotions
- ABC: Emotions and behavior not directly determined by events
- Mindfulness exercises
- Manualized, highly structured

Shelton D, … Trestman R (2011) Impact of a Dialectic Behaviour Therapy – Corrections Modified (DBT-CM). Journal of Child and Adolescent Psychiatry Nursing.

Kersten L ..., Trestman R (2015) A Skills-Based Psychotherapy for Inmates of Correctional Systems. Psychiatr Serv.

Film-Clip 20 Emotions in 30 seconds

Practice of new strategies: In vivo coaching by staff workers

Slow down

Being within the moment, mindfulness

Take a distance

Observe your behaviour

Accept

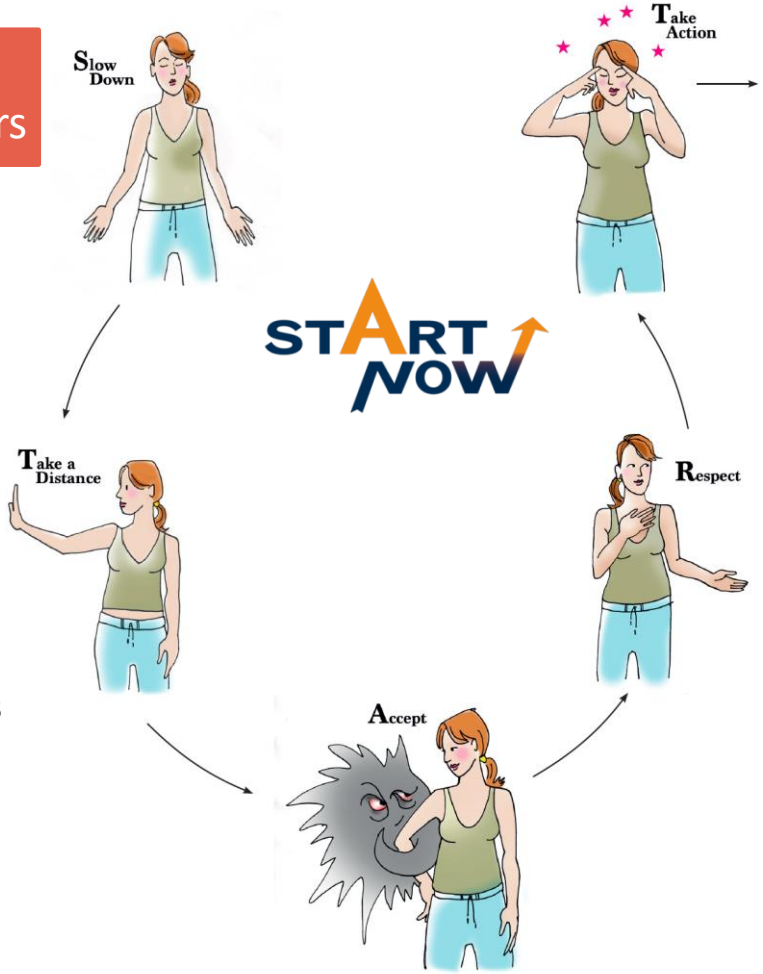
Accepting emotions non-judgmental

Respect

Appreciate & respect individual differences

Take action

your actions lead you closer to your goals/values



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Methods: Primary endpoint and hypotheses

Two primary endpoints

(1) H_{0I} Change in the number of CD/ODD symptoms between T1 and T3 is equal for both intervention (K-SADS interview)

(2) H_{0II} Change in the number of CD/ODD symptoms between T1 and T4 is equal for both intervention (K-SADS interview)

Statistics

With respect to the primary endpoint a linear mixed model was applied with the primary endpoint including baseline CD/ODD symptoms, treatment group (randomized to), site, age, IQ and time between baseline and T3 or T4 as fixed factors and the respective cluster (group condition) as random factors.

Methods: Secondary endpoints

- Subjective level: Self-/caretaker ratings (CBCL, DERS, ARI, ICU, etc.)
- Observational level: Modified-aggression scale (M-OAS)

- Neuropsychological level: Emotion regulation
- Neurobiological level: heart rate variability, neural functional correlates

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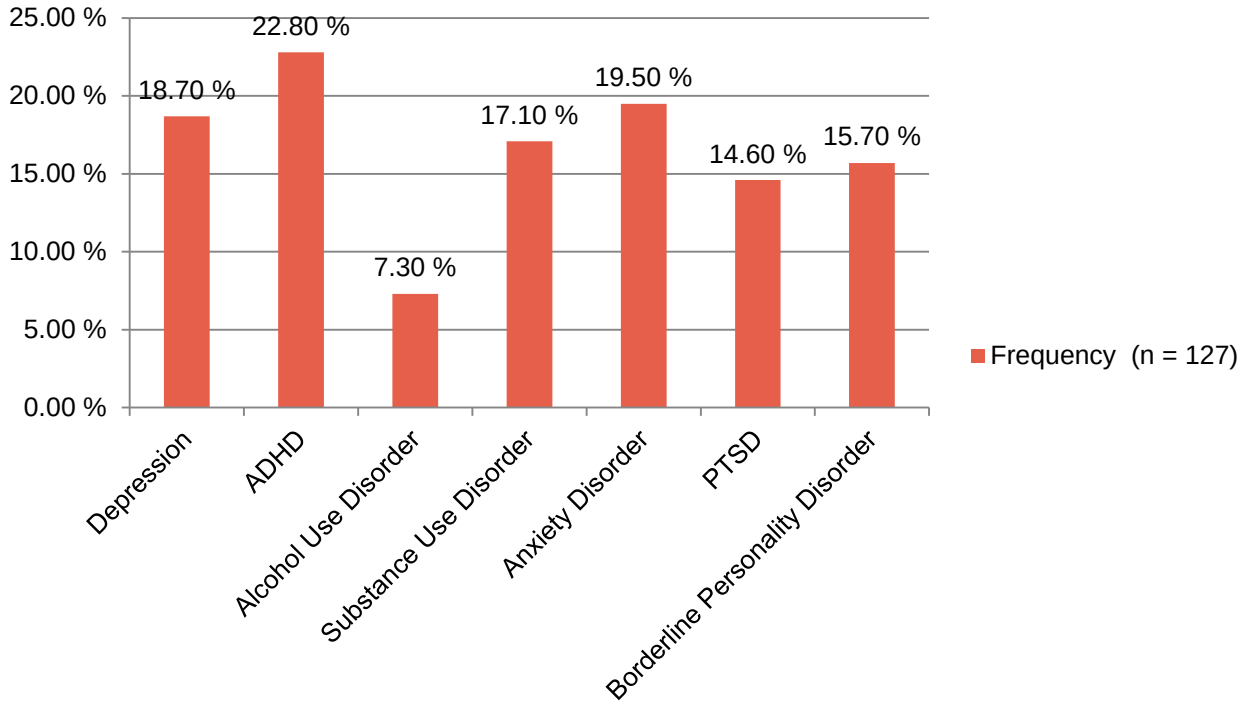
Sample and Descriptive statistics

Intervention	START NOW (N=72)		TAU (N=55)		P-value
CD diagnosis	54 (75%)		44 (86.1%)		n.s.
ODD diagnosis	62 (86.1%)		44 (86.3%)		n.s.
	mean	SD	mean	SD	
Age	15.9	1.4	15.1	1.5	n.s.
IQ total	93.7	10.9	92.5	11.7	n.s.
CD symptoms	4.8	2.7	4.7	2.3	n.s.
ODD symptoms	5.3	1.8	5.3	1.8	n.s.
Average length of stay (mths)	18.3	10.3	16.5	12.9	n.s.

Results

Relative Frequency of Comorbidities (current episode)



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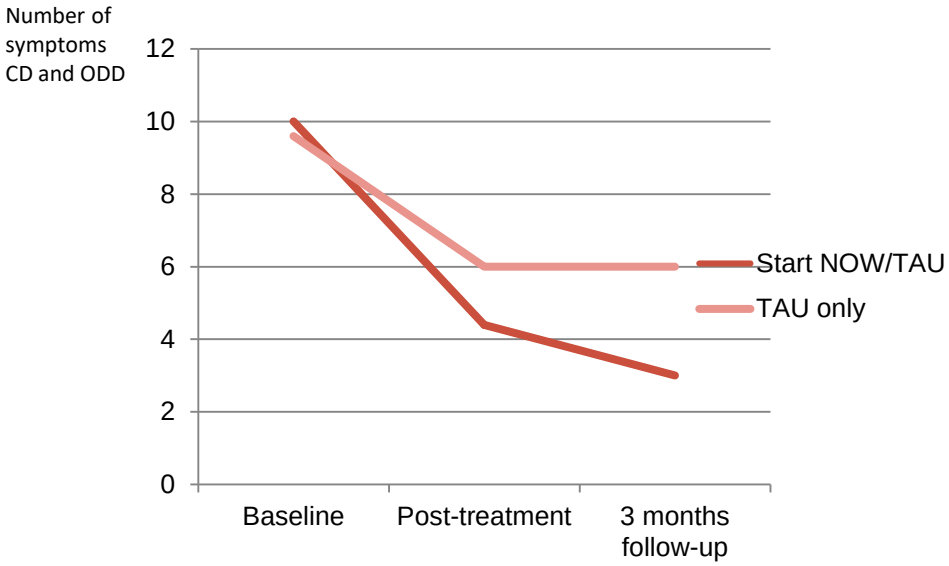
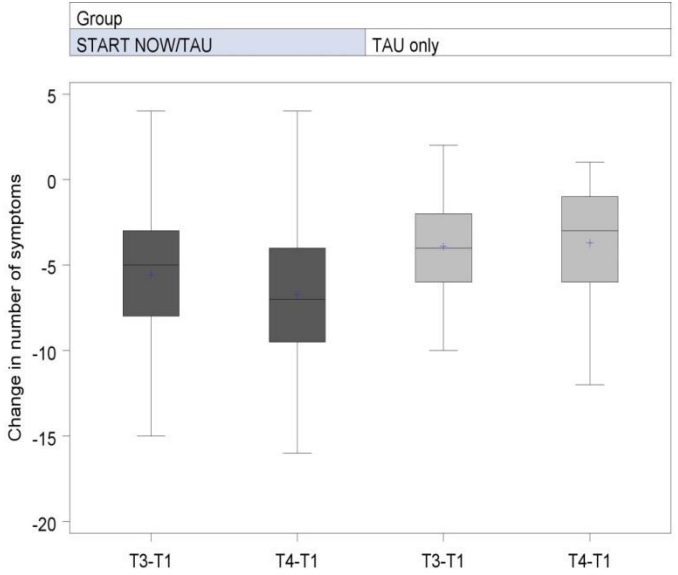
Primary outcome: ODD/CD symptoms

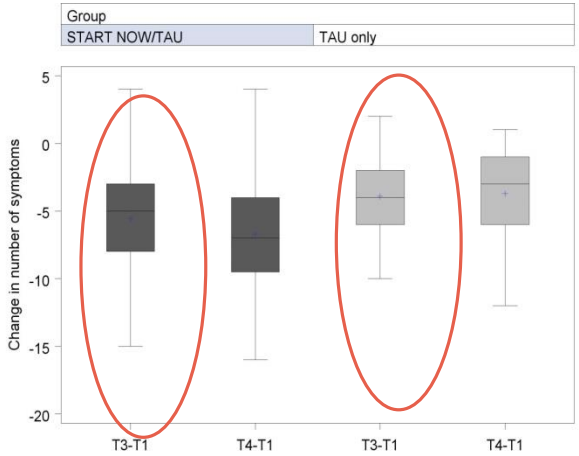
Raw scores and least mean scores for change





Results: Testing first hypothesis

Is there a significant change in CD/ODD symptoms between T1 and T3?



FAS (subjects as treated), imputed data

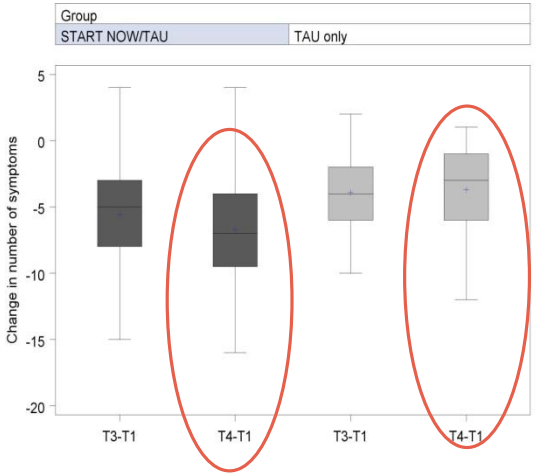
Intervention	Estimate	SE
START NOW/TAU (N=62)	-3.99	0.64
TAU only (N=65)	-3.34	0.61

Difference in least squares means between the two treatment groups:

	Estimate	SE	t Value	P-value	Hedge´s g
START NOW vs. TAU	-0.65	0.89	-0.72	0.47	-0.13

Results: Testing first hypothesis

Is there a significant change in CD/ODD symptoms between T1 and T4?



FAS, imputed data

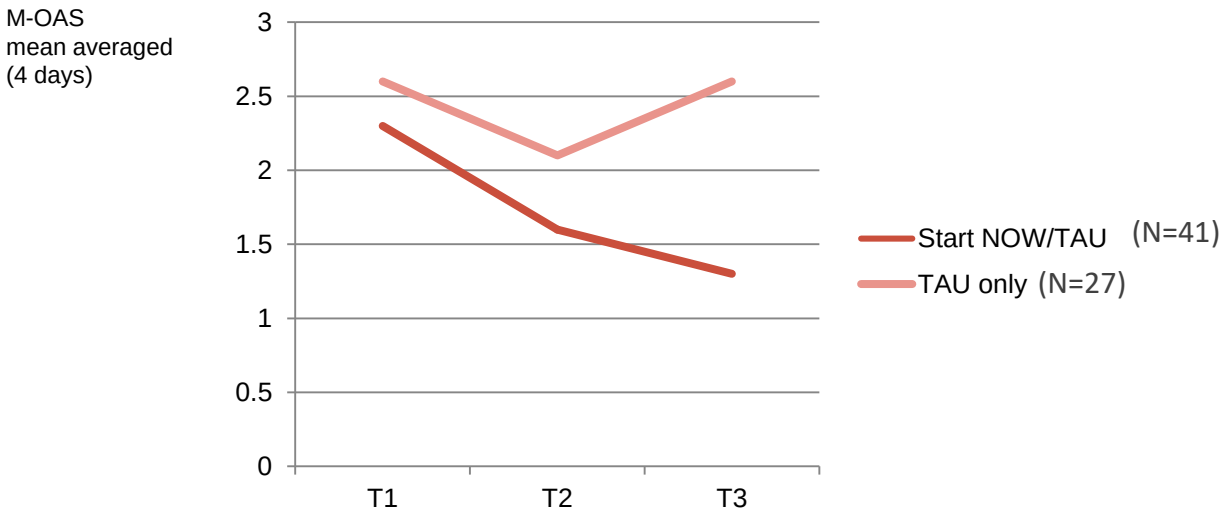
Intervention	Estimate	SE
START NOW/TAU (N=44)	-5.60	0.77
TAU only (N=30)	-3.67	0.69

Difference in least squares means between the two treatment groups:

	Estimate	SE	t Value	Pr > |t|	Hedge´s g
START NOW vs. TAU	-2.33	0.97	-2.40	0.0203	-0.56

Results: Observational data (M-OAS)

How often have you seen direct or indirect aggression today?



Change T3-T2: p= 0.01, Change T3-T1: p=0.01

Results: Subjective data

- CBCL (Child Behavior Checklist, 113 items): Self-rated internalizing and externalizing symptoms: no significant improvment
- ARI (Affective Irritability Questionnaire, 7 items): Significant reduction in affective irritability (Hedge´s g: -0.32)
- DERS (Difficulties in Emotion Regulation Scale, 36 items): Self-rated emotion regulation skills (DERS): no significant improvement for total score

Summary and Discussion

- Significant reduction CD/ODD symptoms (primary outcome variable) three months after end of intervention: median effect size
- Skillstraining promising intervention approach

Parent-training

Problem-solving training

Multi-systemic therapy

NICE Guidelines (2013)
AWMF Guidelines (2018)

- Participants were very highly satisfied with the program

Summary and Discussion

Are there effects on emotion regulation?

- Mixed results in self-rating questionnaires:
  no improvement in self-rated emotion regulation skills,
  but in affective irritability
- Future studies:
  Take into consideration reading skills or limited motivation to answer long questionnaires
- Are there significant effects on a neurobiological level indicating improved emotion regulation capacities?

Thank you for your attention!

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