

First results of the randomised controlled trial START NOW

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START NOW

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Evidence-based intervention in CD

Open issues

Parent-training



Problem-solving training



Multi-systemic therapy



- Treatment programs are not widely implemented and evaluated in middle childhood and adolescence, although adolescence is one of the key periods for intervening, most notably in CD girls due to their late onset.
- Core deficit of CD deficits in emotion processing and emotion regulation

Objectives and aims

Testing the efficacy of the skillstraining program START NOW

- › ... to enhance emotion regulation skills in adolescents with CD and ODD
- › ... in residential care settings: High prevalence rates of CD/ODD (Bronsard et al., 2016)
- › ... to reduce the risk of repeated placement and turnover in staff
- › ... to train social workers (motivational interviewing and trauma sensitive care, supervision)



START NOW

Cognitive-behavioural training

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



Film-Clip 20 Emotions in 30 seconds



Shelton D, ... Trestman R (2011) Impact of a Dialectic Behaviour Therapy – Corrections Modified (DBT-CM) Upon Behaviourally Challenged Incarcerated Male Adolescents. *Journal of Child and Adolescent Psychiatry Nursing*.

Kersten L ..., Trestman R (2015) A Skills-Based Psychotherapy for Inmates of Correctional Systems. *Psychiatr Serv*. 2016 Jan;67(1):37-42.

Practice of new strategies: In vivo coaching by staff workers

Slow down

Being within the moment, mindfulness

Take a distance

Observe your behaviour

Accept

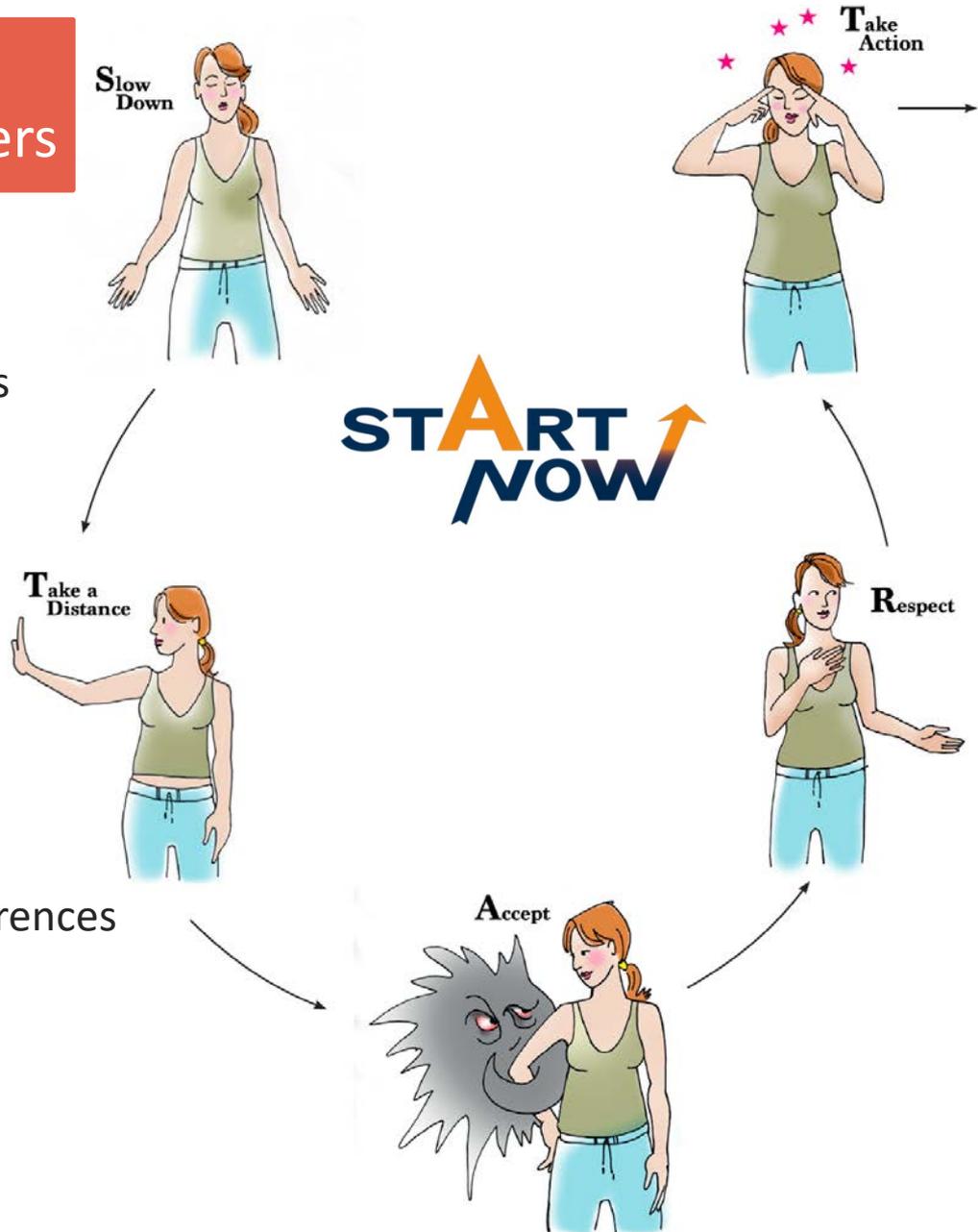
Accepting emotions non-judgmental

Respect

Appreciate & respect individual differences

Take action

your actions lead you closer to your goals/values



Methods: Study Design

How do we investigate the efficacy?



› **Control group:**

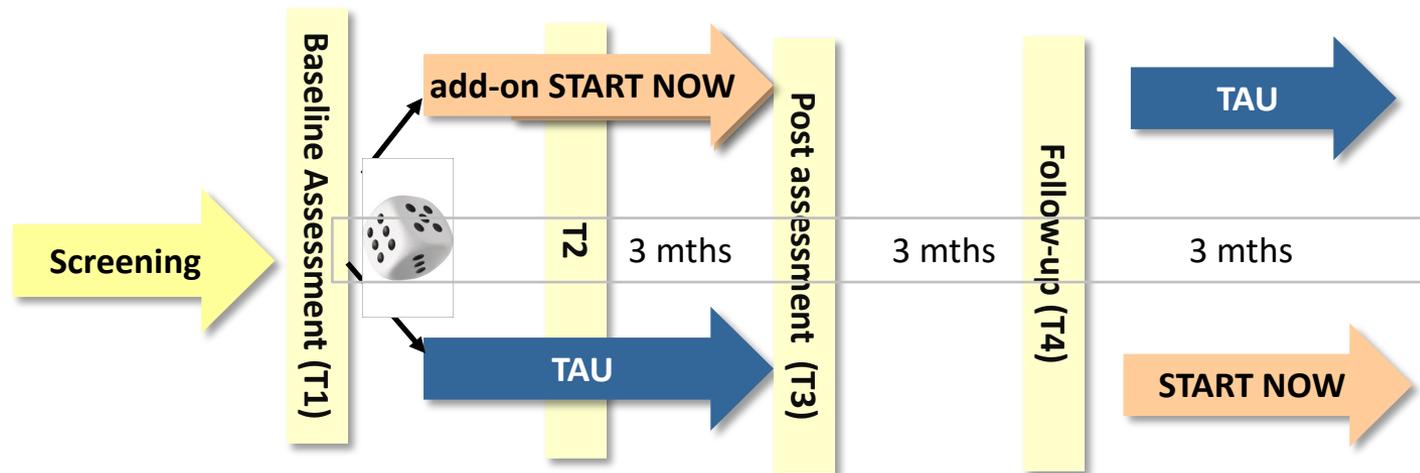
TAU including treatment as usual in youth welfare settings, excluding group-based therapy/skills training and START NOW-/DBT-A- or similar interventions

› **Experimental group:**

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

Methods: Study Design

How do we investigate the efficacy?



Prospective, confirmatory, cluster-quasi-randomised, parallel group, multi-centre and international phase III-trial

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

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 and hypotheses

- 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



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

Sample and Descriptive statistics

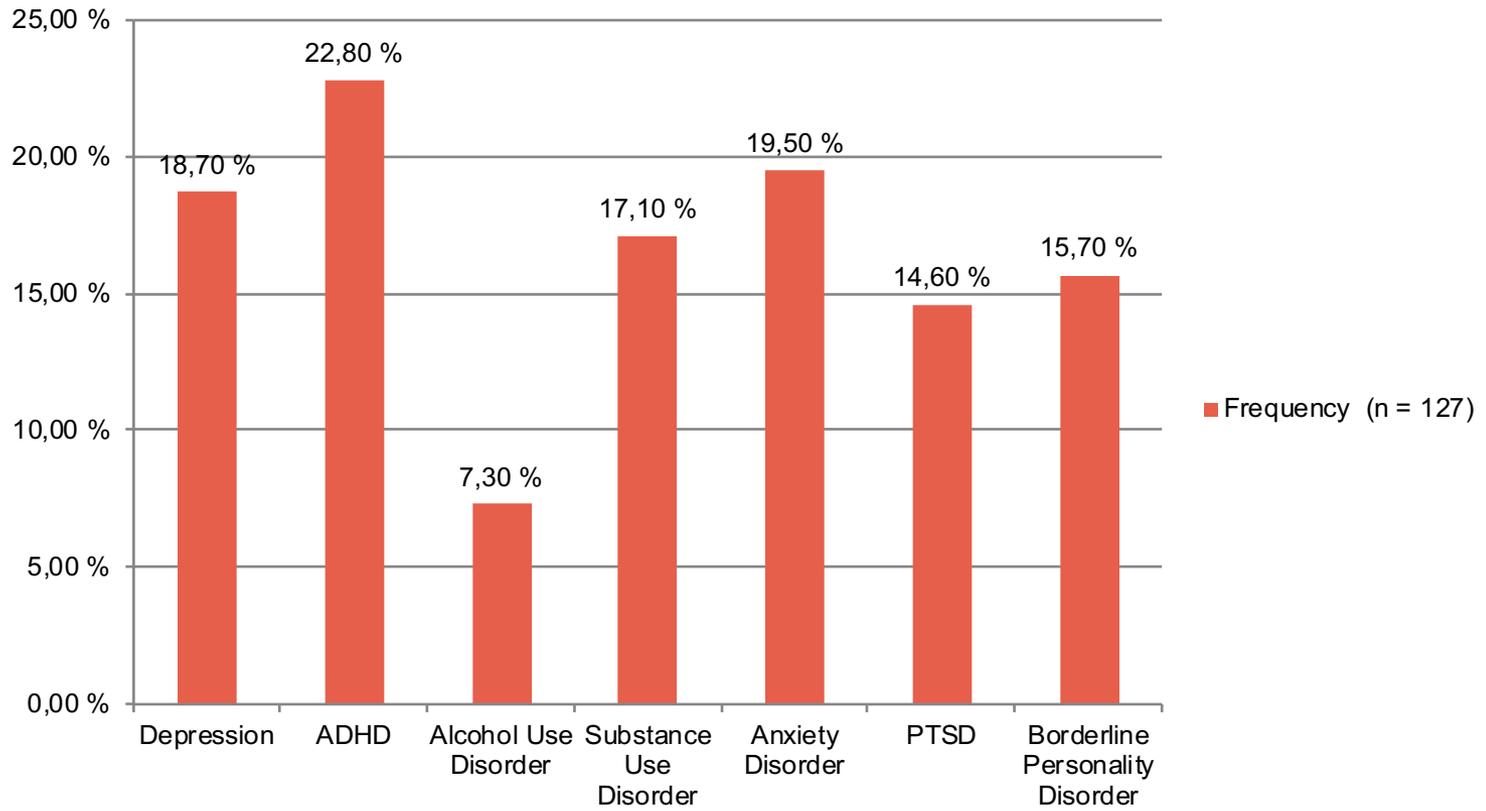
127 subjects were included

(86 with all information available, 41 subjects with imputed data)

Intervention	START NOW (N=72)		TAU (N=55)		P-value
	mean	SD	mean	SD	
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.

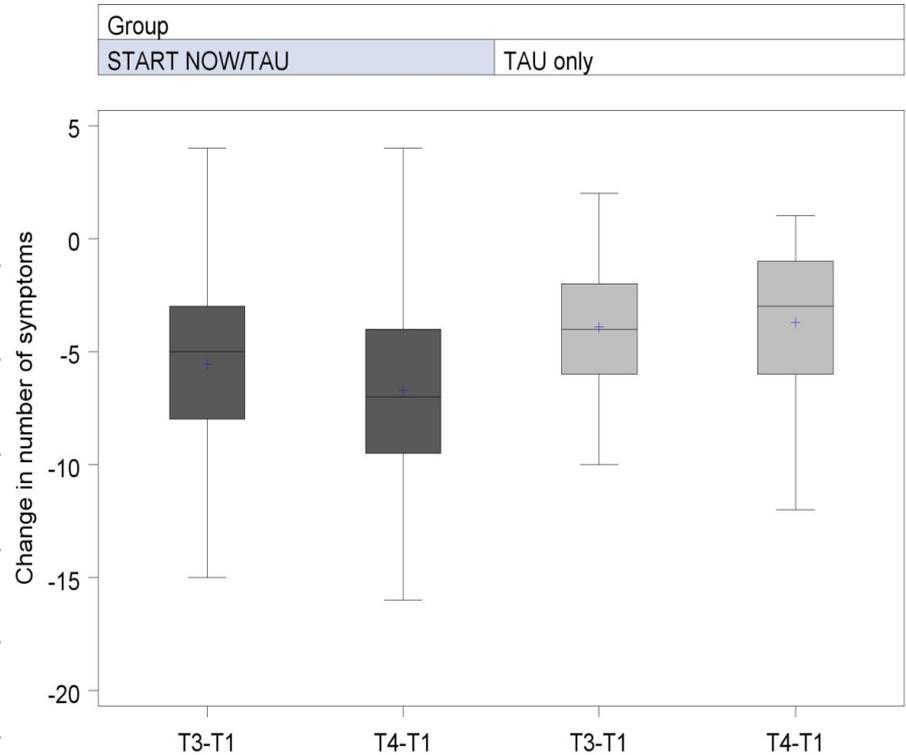
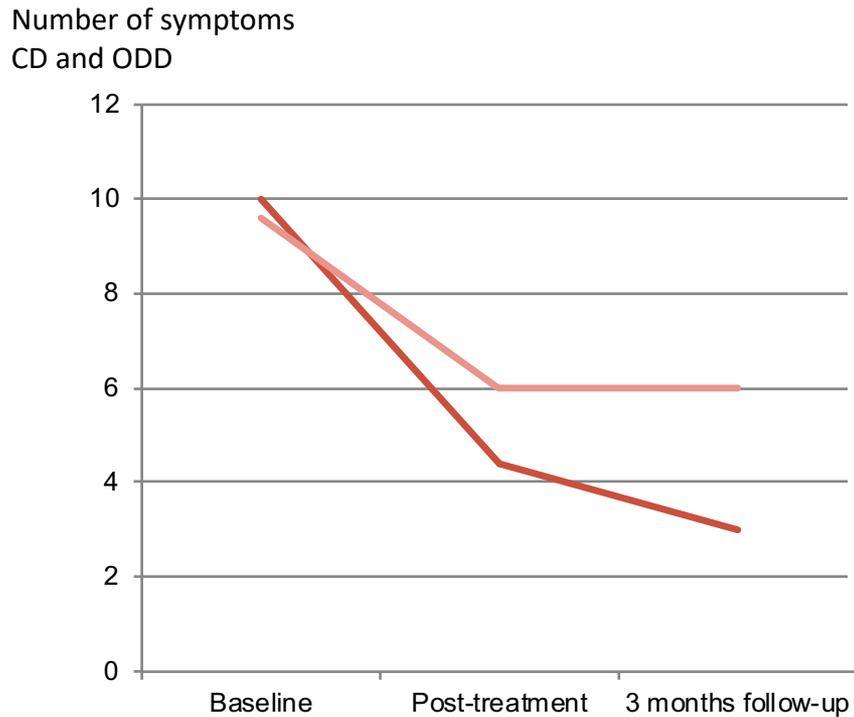
Results

Relative Frequency of Comorbidities (current episode)



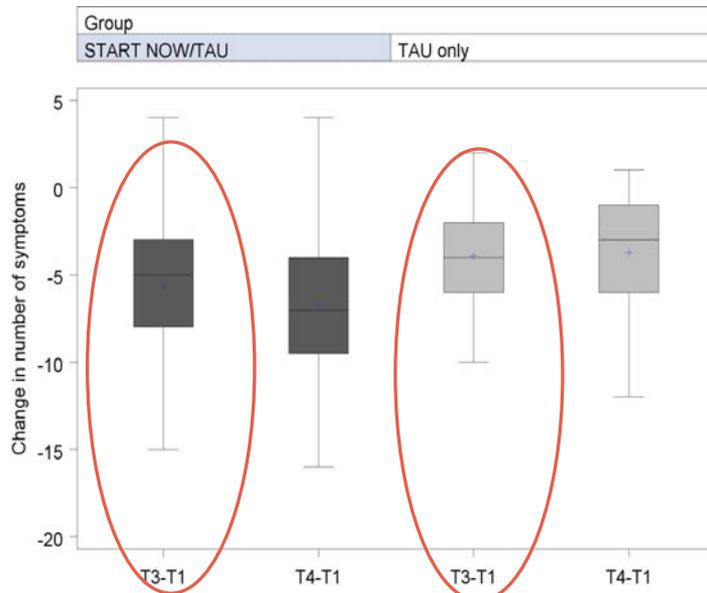
Primary outcome: ODD/CD symptoms

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, imputed data

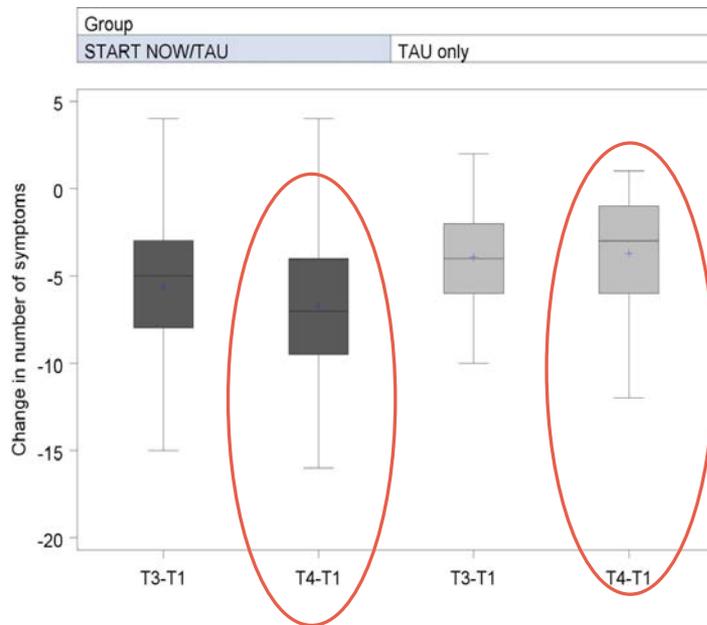
Intervention	Estimate	SE
START NOW/TAU	-3.71	0.61
TAU only	-3.64	0.68

Difference in least squares means between the two treatment groups:

	Estimate	SE	t Value	Pr > t
START NOW vs. TAU	-0.073	0.93	-0.08	0.94

Results: Testing second hypothesis

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



FAS, imputed data

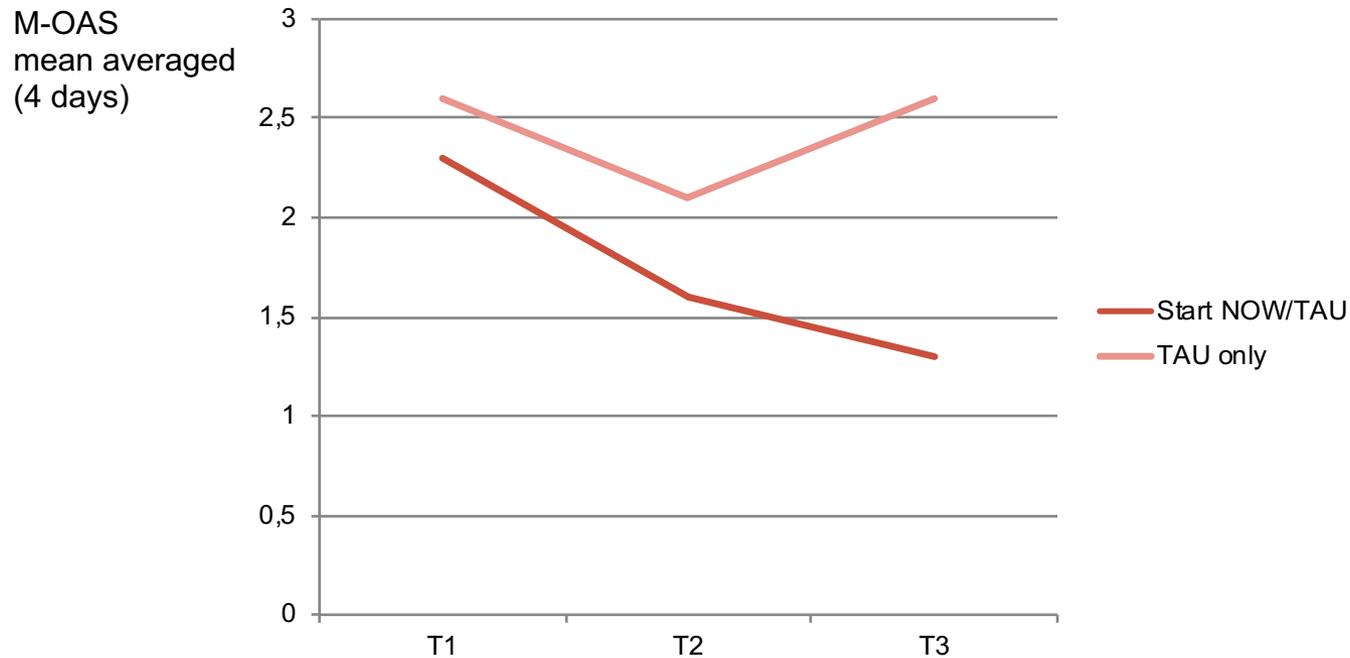
Intervention	Estimate	SE
START NOW/TAU	-6.00	0.77
TAU only	-3.67	0.70

Difference in least squares means between the two treatment groups:

	Estimate	SE	t Value	Pr > t
START NOW vs. TAU	-2.33	0.97	-2.40	0.0203

Results: Observational data

How often have you seen direct or indirect aggression today?



Change T3-T2: $p = 0.01$

N (START NOW): 41, N (TAU): 27

Summary and Discussion

What we have learnt....

- Results indicate START NOW is a promising approach: Significant reduction of primary outcome variable at follow-up assessment
- Self-rating assessment: Mostly no significant results
- However: Participants were very satisfied with the program
- Program is practical, age-appropriate, adolescents like film clips cartoons
- Adolescents do not feel stigmatized
- Empowerment of adolescents and social workers



Thank you for your attention!



Thank you to all PhD students
Linda Kersten
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