UNIKLINIK KÖLN

Ausbildungsinstitut für Kinder- und Jugendlichen-psychotherapie an der Uniklinik Köln (AKiP), www.akip.de

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# Forschungsgruppe ESCA-LIFE

**E**vidence-based **S**tepped **Ca**re of ADHD

ESCALIFE

**Mitglieder der Forschungsgruppe:**
Die Forschungsgruppe ESCA am Standort Köln ist Teil der nationalen Forschungsgruppe ESCAlife

Paula Altenberger, M.Sc. (Psych) (ESCA)
Manfred Döpfner, Univ.-Prof. Dr. Dipl.-Psych. (KLINIK, AKiP)
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Ilka Eichelberger, Dr. Dipl.-Päd. (ausgeschieden)
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**Finanzierung**
- Bundesministerium für Bildung und Forschung (BMBF)
- Ausbildungsinstitut für Kinder- Jugendlichenpsychotherapie an der Uniklinik Köln (AKiP)
- Klinik für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters an der Uniklinik Köln

**Allgemeine Projektbeschreibung**
Das nationale Projekt ESCA (Koordination Prof. Tobias Banaschewski, Mannheim) ist Teil des vom BMBF finanzierten Forschungsnetzes zu psychischen Erkrankungen, in dem insgesamt 30 wissenschaftliche Einrichtungen aus ganz Deutschland an Depression, Angststörungen, Schizophrenie, Suchterkrankungen, ADHS und Autismus forschen.

Das nationale Projekt ESCA ist unterteilt in vier Projekte zur Überprüfung der Wirksamkeit gestufter Behandlungsprogramme (stepped care) bei Vorschulkindern, Grundschulkindern, Jugendlichen und Erwachsenen mit ADHS und in zwei ergänzende Projekte zur Entwicklung von Messinstrumenten und zur Prädiktion von Therapieeffekten. Der Forschungsverbund ESCA besteht aus universitären kinderpsychiatrischen und psychiatrischen Einrichtungen (Bochum, Köln, Freiburg, Mannheim, Marburg, Rostock, Homburg, Tübingen, Würzburg). Der Standort Köln ist an allen drei Projekten zur Wirksamkeit gestufter Behandlungsprogramme im Kindes- und Jugendalter (ESCApreschool, ESCAschool, ESCAadol) und federführend an den Projekten für das Vorschulalter (gemeinsam mit Prof. Katja Becker, Universität Marburg) und für das Schulalter (gemeinsam mit Prof. Dr. Tobias Banaschewski, Zentralinstitut für Seelische Gesundheit, Mannheim) beteiligt. Außerdem ist der Standort Köln federführend (gemeinsam mit Prof. Michael Rösler, Homburg) an dem Projekt zur Entwicklung von Messinstrumenten zur Erfassung von ADHS (ESCAassess) beteiligt. Weitere Informationen können der website http://www.esca-life.org/ entnommen werden

**Teilprojekte (mit Beteiligung des Standortes Köln**

**Laufende Teilprojekte**

- **ESCApreschool: E**vidence-based, **S**tepped **C**are of **A**DHD in **preschool**-children aged 3;0 to 5;11 years
- **ESCAschool: E**vidence-based, **S**tepped **C**are of **A**DHD in **school-**aged children
- **ESCAadol: E**vidence-based, **S**tepped **C**are of **A**DHD: individualized short-term therapy for adolescents
- **ESCAtash: E**vidence-based, **S**tepped **C**are of **A**DHD: telephone assisted self help for preschool-children, school-age children and adolescents
- **ESCAassess: E**vidence-based, **S**tepped **C**are of **A**DHD: Psychometric analyses on rating scales and checklists for the **assess**ment of ADHD

**Publikationen aus der Forschungsgruppe**

Döpfner, M., Hautmann, C., Dose, C., Banaschewski, T., Becker, K., Brandeis, D., Holtmann, M., Jans, T., Jenkner, C., Millenet, S., Renner, T., Romanos, M., & von Wirth, E. (2017). ESCAschool study: trial protocol of an adaptive treatment approach for school age children with ADHD including two randomized trials. *BMC Psychiatry,* 17. Retrieved from doi:10.1186/s12888-017-1433-9.

Geissler, J., Jans, T., Banaschewski, T., Becker, K., Renner, T., Brandeis, D., Döpfner, M., Dose, C., Hautmann, C., Holtmann, M., Jenkner, C., Millenet, S., & Romanos, M. (2018). Individualized short-term therapy for adolescents impaired by attention-deficit/hyperactivity disorder despite previous routine care treatment (ESCAadol) – Study protocol of a randomized

controlled trial within the consortium ESCAlife. *Trials, 19*, 254. doi: https://doi.org/10.1186/s13063-018-2635-2

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**Teilprojekt ESCApreschool:**
**Evidence-based, Stepped Care of ADHD in preschool-children aged 3;0 to 5;11 years**

**Forschungs-Team:**
Paula Altenberger, Christina Dose, Christopher Hautmann, Claudia Kinnen, Lea Jendreizik, Julia Kellner, Daniela Perri, Julia Plück, Stephanie Schürmann, Ann-Katrin Thöne, Anne-Katrin Treier, Tanja Wolff Metternich-Kaizman und Manfred Döpfner (Leitung)

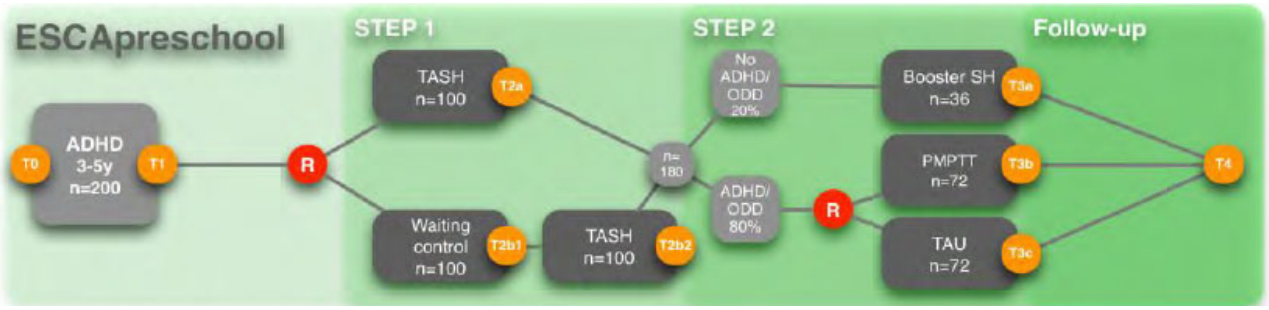
**Laufzeit:**
Voraussichtlich bis 2021

**Website**
http://www.esca-life.org/

**Zielsetzung:**
Objectives are:
*Primary:* To determine the effectiveness of an individualized stepwise intensifying treatment program based on evidence-based psychosocial interventions in ADHD patients aged 3 to 5;11 years by randomized controlled trials (between subjects comparisons) and by within-subjects comparisons (change in step1 compared to change in step2).

*Secondary:* (1) To evaluate the feasibility of the implementation of this stepped care approach in a routine clinical setting; (2) to evaluate predictors of response/non-response to the different treatment conditions.

**Interventionen:**




*Experimental intervention:* Stepped care design with two separate steps (see fig. 1): Step1 (3 months): Telephone-assisted self-help for parents and preschool teachers (RCT with waiting list control group). Step2 (6 months), depending on outcome in step1: Step1 responders without significant symptoms of ADHD/ODD receive booster sessions of

telephone assisted parental self-help. Step1 partial or non-responders with persisting ADHD and/or ODD will be randomized either

- to parent management and preschool teacher training or
- treatment as usual.

*Telephone assisted self-help intervention*: eight self-help booklets for parents of the Self-help Program ADHD-Team [6] adapted to preschool children and 8 x 20 minutes telephone coaching sessions for parents plus four newly developed self-help booklets for preschool teachers with accompanying 4 x 20 minutes telephone coaching sessions for teachers. Parent management and preschool teacher training: Individualized parent management training and preschool based interventions based on Therapieprogramm für Kinder mit hyperkinetischem und oppositionellem Problemverhalten (THOP) and Präventionsprogramm für Expansives Problemverhalten (PEP]); in total 20 sessions.
Follow-up per patient: 3 months after T3.

*Duration of intervention per patient*: step1: 3/6 months (intervention/waiting+intervention), step2: 6 months. *Study visits:* T0 screening, T1: baseline, T2: post treatment step1; T3: post treatment step2, T4: follow-up

**Methoden:**
*Key inclusion criteria:* age 3;0-5;11 y., at least 9 months before enrolment in primary school, ADHD (DSM-5), clinician-rated ADHD-Checklist (DCLADHS). *Key exclusion criteria:* IQ < 80; pervasive developmental disorder; parents with insufficient German language skills, current psychotropic medication. *Primary efficacy endpoint*: change in blinded clinician-rated ADHD+ODDChecklist (DCL-ADHS+SSV) based on parent interview. *Key secondary endpoint(s):* change in parent and teacher rated ADHD (FBB-ADHS-V) and ODD (FBB-SSV), comorbid symptoms (CBCL 1½-5, CTRF), impairment (WFIRS), and quality of life-score (KIDSCREEN).

*Sample size:*
To be assessed for eligibility (n = 300)
To be allocated to trial (randomised at step 1 and 2): n = 200 and 144)
To be analysed at step1 and 2 (n =200 and 144)

**Ergebnisse:**
Die Datenerhebung hat im Januar 2016 begonnen.

**Publikationen zu diesem Teilprojekt:**
Noch keine Publikationen

**Teilprojekt ESCAschool:**
**Evidence-based, Stepped Care of ADHD in school-aged children**

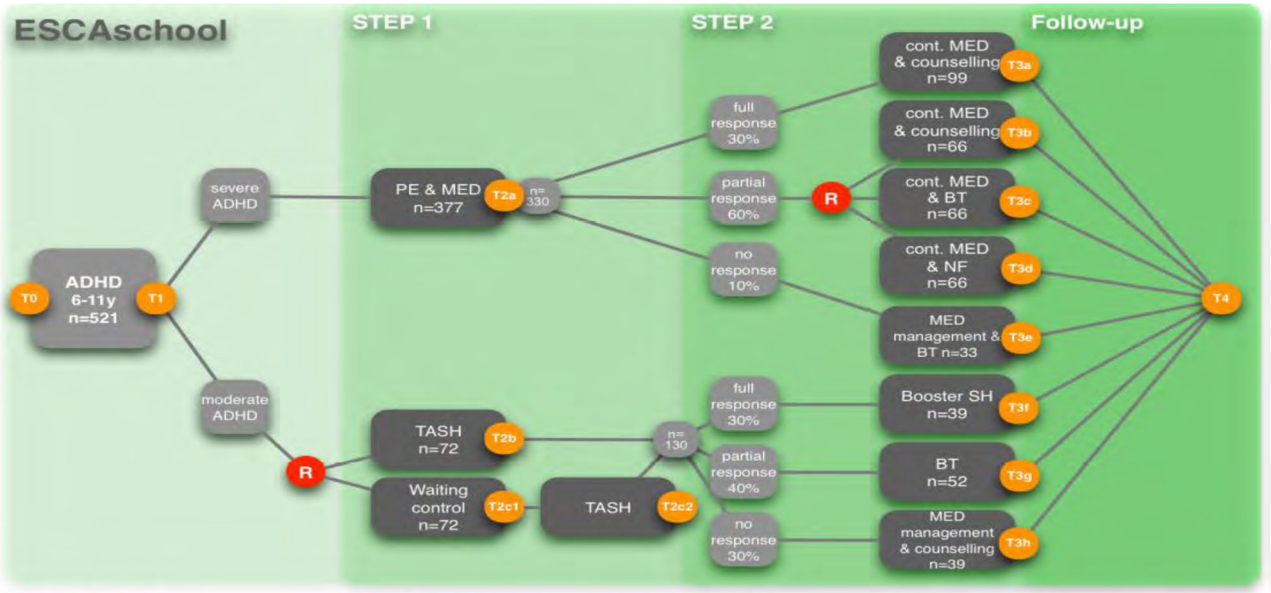
**Forschungs-Team:**
Paula Altenberger, Christina Dose, Christopher Hautmann, Claudia Kinnen, Lea Jendreizik, Julia Kellner, Daniela Perri, Julia Plück, Stephanie Schürmann, Ann-Katrin Thöne, Anne-Katrin Treier (koordinierend), Tanja Wolff Metternich-Kaizman und Manfred Döpfner (Leitung)

**Laufzeit:**
Voraussichtlich bis 2021

**Website**
http://www.esca-life.org/

**Zielsetzung:**
*Primary:* To determine the effectiveness of each step of an individualised stepwise intensifying treatment based on evidence-based behavioural and pharmacological interventions in ADHD patients aged 6 to 11 years by randomised controlled trials (between subjects comparisons) and by within-subjects comparisons (change in step1 compared to change in step2).
*Secondary:* (1) To evaluate the feasibility of the implementation of this stepped- care approach in routine clinical setting (2) to evaluate predictors of treatment response intensity in the different treatment conditions

**Interventionen:**




*Experimental intervention:* Stepped care design with two treatment pathways for (a) severe ADHD and (b) mild to moderate ADHD according to current guidelines (see fig.1). *In severe ADHD*: Step 1 (3 months) psychoeducation (PE) (4 individual sessions) and ADHD Medication (MED) treatment (according to guidelines and Summary of Product Characteristics SPC). Step2 (6 months): treatment will depend on outcome in step 1: (a) Step1 responders without significant ADHD-symptoms will receive continued MED plus counselling, (b) Step 1 partial responders with persisting moderate ADHD will receive in a RCT either (1) continued MED plus counselling, (2) continued MED plus behaviour therapy, or (3) continued MED plus neurofeedback; (c) Step1 nonresponders with persisting severe ADHD will be referred to standard care to receive alternative pharmacotherapy according to treatment guidelines plus behaviour therapy.
*In mild to moderate ADHD:* Step1 (3/6 months) consists of telephone- assisted self-help intervention for parents (RCT with waiting-list control group). Step2 (6 months): treatment depending on outcome in step 1: (a) Step1 responders without actual significant ADHD symptoms receive booster sessions of telephone-assisted parental self-help; (b) Step1 partial responders with persisting mild to moderate ADHD symptoms will receive behaviour therapy; (c) Step1 non-responders with persisting moderate to severe ADHD will receive (if indicated clinically) ADHD medication plus behaviour therapy. All medication will be prescribed as indicated clinically in routine ADHD management management by the patients´ attending physicians, independent of the study setting, by physicians who in general will follow national treatment guidelines.

*Description of the interventions:*

*Pharmacotherapy:* Regulatory-approved/licensed ADHD medication will be used according to the attending physician´s clinical judgement (non-interventional) based on respective guidelines and clinical discretion of the investigator.
*Telephone-assisted self-help intervention:* 8 self-help booklets for parents of the Self-help Program ADHS-Team (Döpfner et al., 2010) and 8x 20 minutes telephone coaching sessions for parents plus 2 newly developed self-help booklets for teachers with accompanying 2 x 20 minutes telephone coaching sessions for teachers.
*Behavior Therapy:* Individualized parent management training, school –based interventions and child-focused interventions based on the 'Therapieprogramm für Kinder mit hyperkinetischem und oppositionellem Problemverhalten' (THOP) (Döpfner et al., 2013); 20 sessions in total.
*Neurofeedback:* 25 sessions of feedback of slow cortical potentials.

*Follow-up per patient:* 3 months after T3. *Duration of intervention per patient:* step1: 3/6 months (intervention/waiting+intervention), step2: 6 months.
*Study visits:* T0 screening, T1: baseline, T2: post-treatment step 1; T3: post treatment step2, T4: follow-up

**Methoden:**
*Key inclusion criteria:* age 6;0-11;11 years, visiting school, ADHD (DSM-5 criteria, clinicians rated ADHD-Checklist (DCL-ADHS)). *Key exclusion criteria:* IQ < 80; pervasive developmental disorder, schizophrenia, bipolar disorder, severe depressive episode, epilepsia, heart disease, insufficient knowledge of German language *Primary efficacy endpoint:* Change in blinded clinician-rated ADHD-Checklist (DCLADHS) based on parent interview. *Key secondary endpoint(s):* Change in parent- and teacher-rated ADHD (FBB-ADHS) and ODD (FBB-SSV), comorbid symptoms (SDQ), impairment (WIFRS), quality of life (KIDSCREEN). *Assessment of safety:* Assessment of tolerability/safety, predefined safety parameters at T1, T2, T3 (PAERS, SAEs)

*Sample size*
To be assessed for eligibility (n=600)
To be allocated to trial (step 1: n=521 included, n=144 randomised; step 2: n=521 included, n=198 randomised)
To be analysed (n=521)

**Ergebnisse:**
Die Datenerhebung hat im Januar 2016 begonnen.

**Publikationen zu diesem Teilprojekt:**

Döpfner, M., Hautmann, C., Dose, C., Banaschewski, T., Becker, K., Brandeis, D., Holtmann, M., Jans, T., Jenkner, C., Millenet, S., Renner, T., Romanos, M., & von Wirth, E. (2017). ESCAschool study: trial protocol of an adaptive treatment approach for school age children with ADHD including two randomized trials. *BMC Psychiatry,* 17. Retrieved from doi:10.1186/s12888-017-1433-9.

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**Teilprojekt ESCAadol:**
**Evidence-based, Stepped Care of ADHD: individualized short-term therapy for adolescents**

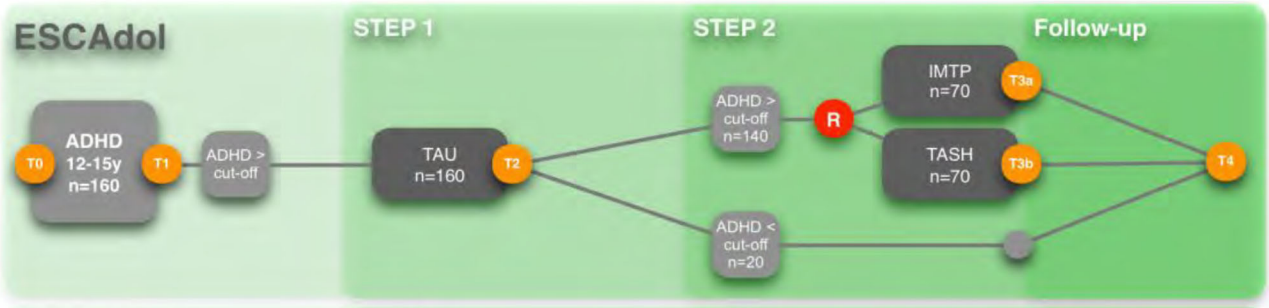
**Forschungs-Team:**
Paula Altenberger, Christina Dose, Christopher Hautmann, Claudia Kinnen, Lea Jendreizik, Julia Kellner, Daniela Perri, Julia Plück, Stephanie Schürmann, Ann-Katrin Thöne, Anne-Katrin Treier (koordinierend), Tanja Wolff Metternich-Kaizman und Manfred Döpfner (Leitung)

**Laufzeit:**
Voraussichtlich bis 2021

**Website**
http://www.esca-life.org/

**Zielsetzung:**
1) To determine the efficacy of an individualized manualized short-term psychosocial treatment based on evidence-based interventions in adolescent ADHD patients who are still significantly impaired despite established routine care. (2) To evaluate predictors of treatment response.
Primary hypothesis: There is more improvement in ADHD core symptoms in patients who received individualized manualized multimodal short-term treatment (experimental intervention) as compared to patients whose parents received telephone-assisted self-help (active control intervention).

**Interventionen**




*Experimental intervention:* individualized modular treatment program comprising 10 sessions:

- Sessions 1 and 2: psychoeducation and individual treatment plan.

- Sessions 3-8: three modular treatment components (2 sessions each) chosen from: a) medication adherence, b) organisational skills and planning, c) impulsivity management and emotion regulation, d) substance abuse, e) family interaction, f) parental mental health, g) parent training
- Session 9: individual repetitorium
- Session 10: conclusion and planning of further routine care interventions

*Control intervention:* telephone-assisted self-help for the parents

Follow-up per patient: 12 weeks after treatment phase
Duration of intervention per patient: total of 36 weeks (*week 1*: T1; *weeks 2-11*: treatment-asusual stabilization phase; *week 12/13*: T2; *weeks 14-23*: experimental or control intervention; *week 24*: T3; *week 35/36*: T4 follow-up)

**Methoden:**
Key inclusion criteria: age 12;0-15;11 years; ADHD (DSM-5), patient has been in ADHD routine care for 1y or more, clinician-rated ADHD-Checklist (DCL-ADHS > 28 points, i.e. mean > 1.5 per item); CGI-S > 4). Key exclusion criteria: IQ < 80; pervasive developmental disorder, schizophrenia, bipolar disorder, severe depressive episode

Primary efficacy endpoint: change in blinded clinician-rated ADHD-Checklist (DCL-ADHS) scores between T2 and T3. Key secondary endpoint(s): change in patient-, parent- and teacher-rated ADHD (SBB-ADHS, FBB-ADHS) and in symptoms of oppositional-defiant and conduct disorder (SBB-SSV, FBB-SSV), ADHD-related functional impairment (WFIRS-P), internalizing and externalizing symptoms (patient, parent, teacher SDQ), quality-of-life (patient and parent KIDSCREEN-10), parenting (PSBC, PPS), process quality (patient and parent FBB; feasibility, adherence and satisfaction ratings). Assessment of tolerability/safety: Assessment of predefined safety parameters at T1, T2, T3, T4 (PAERS, SAEs)

**Sample size**
To be assessed for eligibility (n = 250)
To be allocated to trial (TAU-stabilisation) (n = 160)
To be randomized and analysed (ITT) (n = 140)
Sample size estimation: Alpha 0.05; power 0.80; assumed effect size between groups d= 0.5: n=2x64 evaluable subjects needed.

**Ergebnisse:**
Die Datenerhebung hat im Januar 2016 begonnen.

**Publikationen zu diesem Teilprojekt:**

Geissler, J., Jans, T., Banaschewski, T., Becker, K., Renner, T., Brandeis, D., Döpfner, M., Dose, C., Hautmann, C., Holtmann, M., Jenkner, C., Millenet, S., & Romanos, M. (2018). Individualized short-term therapy for adolescents impaired by attention-deficit/hyperactivity disorder despite previous routine care treatment (ESCAadol) – Study protocol of a randomized controlled trial within the consortium ESCAlife. *Trials, 19*, 254. doi: https://doi.org/10.1186/s13063-018-2635-2

**Teilprojekt ESCAtash:**
**Evidence-based, Stepped Care of ADHD: telephone assisted self help for preschool-children, school-age children and adolescents**

**Forschungs-Team:**
Paula Altenberger, Christina Dose, Christopher Hautmann, Claudia Kinnen, Lea Jendreizik, Julia Kellner (koordinierend), Daniela Perri, Julia Plück, Stephanie Schürmann, Ann-Katrin Thöne, Anne-Katrin Treier, Tanja Wolff Metternich-Kaizman und Manfred Döpfner (Leitung)

**Laufzeit:**
Voraussichtlich bis 2021

**Website**
http://www.esca-life.org/

**Zielsetzung:**
In diesem Projekt werden die telefonassistierende Selbsthilfe-Interventionen der drei Projekte ESCApreschool, ESCAschool und ESCAadol gebündelt. Diese Interventionen werden für alle Standorte des ESCAlife Projektverbundes in Köln durchgeführt.

**Methoden:**
In einem ersten Schritt werden die schriftlichen Materialien für die Selbsthilfe-Interventionen entwickelt. Für ESCA-preschool werden 8 Elternhefte und 4 Erzieherhefte entwickelt. Für ESCAschool sind es 8 Elternhefte und 4 Lehrerhefte und für ESCAadol 8 Elternhefte. Diese Hefte werden auf der Basis der in anderen Projekten entwickelten und evaluierten Materialen weiterentwickelt.

**Ergebnisse:**
Die Datenerhebung hat im Januar 2016 begonnen.

**Publikationen zu diesem Teilprojekt:**
Döpfner, M., Hautmann, C., Dose, C., Banaschewski, T., Becker, K., Brandeis, D., Holtmann, M., Jans, T., Jenkner, C., Millenet, S., Renner, T., Romanos, M., & von Wirth, E. (2017). ESCAschool study: trial protocol of an adaptive treatment approach for school age children with ADHD including two randomized trials. *BMC Psychiatry,* 17. Retrieved from doi:10.1186/s12888-017-1433-9.

**Teilprojekt ESCAassess: Evidence-based, Stepped Care of ADHD: Psychometric analyses on rating scales and checklists for the assessment of ADHD**

**Forschungs-Team:**
Anja Görtz-Dorten (koordinierend), Linda Hofmann und Manfred Döpfner (Leitung)

**Laufzeit:**
Voraussichtlich bis 2019

**Zielsetzung:**
Research questions are:

1. What is the reliability, factorial structure and convergent and divergent validity of the updated self-report, parent report and teacher-report rating scales for the assessment of ADHD according to DSM-5?
2. What is the reliability, factorial structure and convergent or divergent validity of the updated expert-report and the self report ADHD rating scale (ADHD-DCQ and ADHD-SB) for the assessment of the ADHD psychopathology according to DSM-5 in adults?
3. Can adaptive scales based on Item-response theory be developed, which would allow a more economic assessment of ADHD and reduce the assessment burden of the patients?
4. What are norms and cut-offs for severity based on clinical samples and depending on age and gender of the patients?
5. What is the best model to define ADHD severity by integrating symptom severity, symptom pervasiveness and functional impairment?
6. What are the consequences of the changes in DSM-5 regarding the number of diagnostic criteria needed to establish the diagnosis and the change in the age of onset criterion?

**Aims are**

1. To revise current DSM-IV/ICD-10 based rating scales and checklists according to DSM-5 criteria and to add screening items for the assessment of comorbid conditions
2. To evaluate the revisions in smaller clinical samples regarding reliability.
3. To use these revised rating scales in the assessment of ADHD in the ESCAlife projects
4. To conduct comprehensive psychometric analyses in the ESCA-life samples for children, adolescents and adults. Especially to conduct analyses on item-severity, factorial structure (explorative and confirmative factor analyses), reliability (Cronbach's alpha), convergent and divergent reliability (i.e. correlation with other ratings of other informants, correlations with ratings of other mental health problems like oppositional

defiant disorder, conduct disorders, emotional problems assessed in the ESCAlife projects.

5. To develop norms based on clinical samples, including age and gender
6. To develop the basis for item response theory (IRT) item banks for computerized adaptive tests (CATs) that minimize respondent burden.
7. To test alternative models for the definition of ADHD severity by integrating a) symptom severity, b) impairment (CGI and the WFIRS), pervasiveness (teacher and parent ratings, adult patient report) and c) norms of patient samples of different ages.

**Ergebnisse:**
Die Verfahren sind in modifiziert worden und werden in den Projekten eingesetzt.

**Publikationen zu diesem Teilprojekt:**
Noch keine Publikationen