Trial Description

Title

Evidence-based, stepped care of ADHD in school-aged children between 6-11 years (ESCAschool)

Trial Acronym

ESCAschool

URL of the trial

http://esca-life.org/

Brief Summary in Lay Language

Currently, there is only little knowledge about the effects of adaptive treatment strategies for children with ADHD. With few exceptions, studies basically demonstrate effects of singular interventions (pharmacotherapy or behaviour therapy). Some studies give hints for additive effects of psychosocial interventions in partial responders to medication, showing additional improvement in ADHD symptoms through behaviour therapy. Particularly, low-threshold therapeutic services like telephone-assisted self-help (TASH) or neurofeedback are easily implemented. Therefore, in case of evidence for their effectiveness, they could lead to positive effects in a variety of clinical practice. This study will evaluate the individualised stepwise implementation of mentioned interventions.

Brief Summary in Scientific Language

German and European clinical guidelines (Deutsche Gesellschaft für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie [DGKJP] et al., 2007; National Institute for Health and Clinical Excellence, 2009; Taylor et al., 2004) recommend a stepped care approach with individualised adaptive treatment strategies which differentiate between patients with severe symptoms and patients with mild to moderate symptoms. A stepwise approach with individualised adaptive treatment strategies has not yet been empirically validated, which is why feasibility, efficacy and effectiveness have not been assessed to date.

ESCAschool aims at demonstrating the effectiveness of an individualised stepwise intensifying treatment approach based on evidence-based behavioural and pharmacological interventions in ADHD patients aged 6 to 11 years in between-subjects comparisons and within-subjects comparisons. Furthermore, the study will evaluate the feasibility of the implementation of this stepped-care approach in routine care. According to treatment guidelines, different treatment strategies for children with mild to moderate versus severe ADHD will be investigated. Results aim at improving individualised treatment strategies for children with ADHD as well as treatment algorithms for non-pharmacological and pharmacological components and to strengthen the empirical foundation of non-pharmacological therapeutic approaches. The evaluation of a stepwise approach in routine care is

of particular importance for clinical practice. Furthermore, results will help to optimise cost-efficiency in ADHD treatment.

Organizational Data

- DRKS-ID: **DRKS00008973**
- Date of Registration in DRKS: **2015/12/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **15-216 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **F90 - Hyperkinetic disorders**

Interventions/Observational Groups

- Arm 1: **Step 1, severe ADHD, non-randomized group allocation: Psycho-education and ADHD medication treatment for 3 months (assessment T1 to T2a)**
- Arm 2: **Step 1, mild to moderate ADHD, randomized group allocation: Telephone-assisted self-help for 3 months (assessment T1 to T2b)**
- Arm 3: **Step 1, mild to moderate ADHD, randomized group allocation: Waiting-list control group for three months (assessment T2 to T2c1) followed by telephone-assisted self-help (TASH) for 3 months (assessment T2c1 to T2c2)**
- Arm 4: **Step 2, severe ADHD and full response in step 1, non-randomized group allocation: Continuing medication combined with counselling for 6 months (assessment T2a to T3a)**
- Arm 5: **Step 2, severe ADHD and partial response in step 1, randomized group allocation: Continuing medication combined with counselling for 6 months (assessment T2a to T3b)**
- Arm 6: **Step 2, severe ADHD and partial response in step 1, randomized group allocation: Continuing medication combined with behavioural therapy for 6 months (assessment T2a to T3c)**
- Arm 7: **Step 2, severe ADHD and partial response in step 1, randomized group allocation: Continuing medication combined with neurofeedback for 6 months**

(assessment T2a to T3d)

- Arm 8: **Step 2 severe ADHD and no response in step 1, non-randomized group allocation: Medication management combined with behavioural therapy for 6 months (assessment T2a to T3e)**

- Arm 9: **Step 2, mild to moderate ADHD and full response in step 1, non-randomized group allocation: Booster sessions telephone-assisted self-help for 6 months (assessment T2b/T2c2 to T3f)**

- Arm 10: **Step 2, mild to moderate ADHD and partial response in step 1, non-randomized group allocation: Behavioural therapy for 6 months (assessment T2b/T2c2 to T3g)**
- Arm 11: **Step 2, mild to moderate ADHD and no response in step 1, non-randomized group allocation: Medication management combined with behavioural therapy for 6 months (assessment T2b/T2c2 to T3h)**
- Arm 12: **3 months after step 2, all interventions: Follow-up (assessment T3a-T3h to T4)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Primary outcome is the blinded clinician-rated total score of the ADHD-Checklist (DCL-ADHS) based on parent interview.

For children with mild to moderate ADHD analysis of the randomized between-group comparison in step 1 (arm 2 vs. arm 3 with the assessments T1 and T2b/T2c1).

For children with severe ADHD and partial response to treatment in step 1 analysis of the randomized between-group comparison of corresponding interventions in step 2 (arm 5 vs. arm 6 vs. arm 7 with the assessments T2a and T3b/T3c/T3d).

Secondary Outcome

Secondary outcomes are:
- Blinded clinician-rated symptoms of conduct disorder and impairment due to these symptoms (DCL-SSV, based on parent interview)
- Clinical global impression (CGI, clinician-rated) - Symptoms of ADHD (FBB-ADHS, parent- and teacher-rated)
- Symptoms of conduct disorder (FBB-SSV, parent- and teacher-rated)
- Behavioural and emotional problems of child (CBCL/6-18R, parent-rated)
- Functional impairment (WFIRS, parent-rated) - Quality of life of patients (KIDSCREEN, parent-rated)
- Perceived parenting sense of competency (VER, parent-rated)
- Parenting behaviour (FZEV, short version of negative scale of FPNE, parent-rated)
- Treatment satisfaction
- electrical brain activity (electroencephalogram)
- Safety parameters

The secondary outcome will will be analysed the same way as the primary outcome.

Furthermore, the following analyses will be conducted (primary outcome included). For children with severe ADHD and full or no response in step 1 treatment effects of the corresponding interventions from step 2 (arm 4, arm 8) will be contrasted each with treatment effects of step 1 (arm 1) intervention (arm 1 vs. arm 4 with the assessments T1, T2a and T3a; arm 1 vs. arm 8 with the assessments T1, T2a and T3e). For children with mild to moderate ADHD and full response, partial response or no response in step 1, treatment effects of corresponding interventions from step 2 (arm 9, arm 10, arm 11) will be contrasted each with treatment effects of step 1 intervention (arm 2, arm 3) (e.g., arm 2 vs. arm 9 with the assessments T1, T2b and T3f). For analyses all secondary outcome measures and blinded clinician-rated ADHD-Checklist (DCL-ADHS) based on parent interview will be considered.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Köln**
- University Medical Center **Würzburg**
- University Medical Center **LWL Universitätsklinikum der Ruhr Universität Bochum, Hamm**
- other **Zentralinstitut für seelische Gesundheit, Mannheim**
- University Medical Center **Marburg**
- University Medical Center **Tübingen**

Recruitment

- Planned/Actual: **Actual**

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- (Anticipated or Actual) Date of First Enrollment: **2016/03/09**
- Target Sample Size: **521**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **6 Years**
- Maximum Age: **11 Years**

Additional Inclusion Criteria

Attending of school (including special schools); Meeting criteria for ADHD according to DSM-5; Informed consent of guardians and child assent

Exclusion criteria

IQ below average (IQ<80), diagnosis of pervasive developmental disorder, schizophrenia, bipolar disorder, severe depressive episode, epilepsy, heart disease, current or planned intensive behavioural therapy for ADHD or oppositional behavior on a weekly basis, for children with severe ADHD known non-response to all standard ADHD medication (methylphenidate,dexamphenidate, atomoxetine) psychotropic medication (other than for ADHD) or neuroleptic medication (other than for the treatment of disturbance of impulse control), insufficent German language and reading skills of participating parent

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*