

# The Cost Effectiveness of Clinically Proven Treatment Strategies for ADHD in Adult Patients



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## Overview

### Objectives:

- Despite recent progress in understanding of the economics of ADHD in children and adolescents, little is known about the comparative cost effectiveness of treatment strategies for adult ADHD.
- Even for ADHD in children, there is a shortage of robust data supporting the cost effectiveness of psychotherapeutic interventions.

### Methods:

- A randomized, double-blind, placebo-controlled multicenter study has been initiated in Germany, enrolling 448 adult patients with ADHD.
- Patients are assigned to one out of four parallel treatment arms:
  - a structured disorder tailored psychotherapy (dialectical behavioral therapy, DBT) plus medication (methylphenidate),
  - DBT and placebo,
  - psychiatric counseling without specific behavioral interventions (clinical management) plus medication,
  - clinical management and placebo.
- DBT and clinical management are administered weekly for the first 12 weeks and on a four-weekly basis thereafter, until the end of the one-year-observation period. An additional follow-up investigation is scheduled at 18 months after treatment termination.

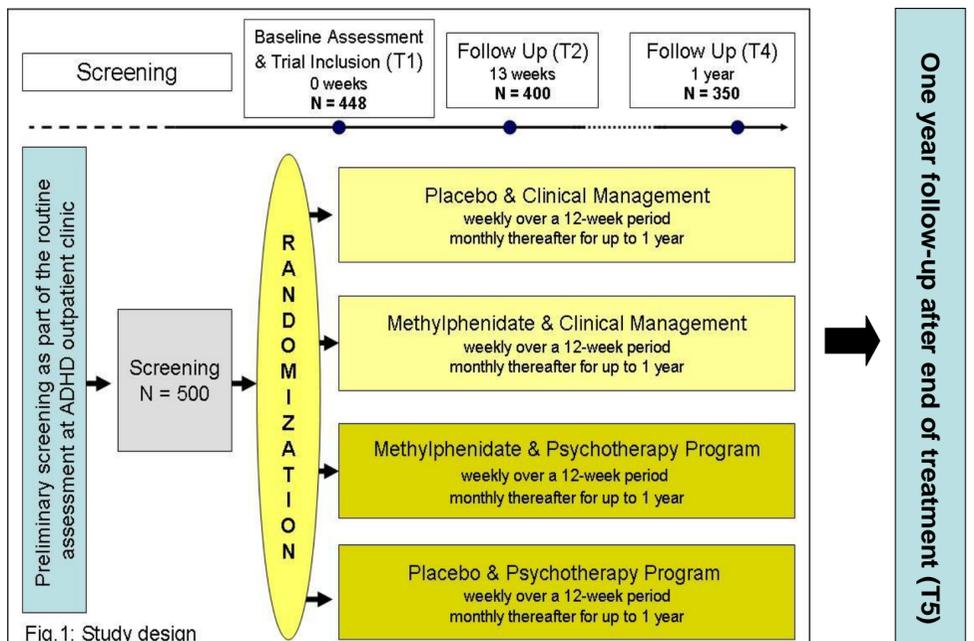
### Results:

- Endpoints include symptomatic improvement (primary endpoint: Conners' Adult Rating Scale, blind-observer rated), general psychopathology, clinical global impression, and a disorder-specific quality of life questionnaire.
- In order to facilitate cost utility analysis, health-related quality of life is also measured by means of the EQ-5D and SF-36.
- For primary analysis, the perspective of Statutory Health Insurance will be adopted; resource use and costing from a societal perspective will be done for secondary analyses.
- Probabilistic sensitivity analyses will be done using nonparametric bootstrapping on the basis of patient-level study data.

### Conclusions:

- The COMPAS Study will, for the first time, provide insights into the cost effectiveness of a disorder tailored psychotherapy for adult ADHD.
- Key hypotheses are
  - that combined treatment (study arm 1) is more effective than either option (DBT or medication) alone, both short and long term,
  - that a tailored psychotherapeutic intervention will meet broadly accepted benchmarks of cost effectiveness.

## Study Design



## Clinical Hypotheses

The main study question is to assess if treatment outcomes are stable over time. Key study hypotheses are:

- ADHD symptoms are less prominent in the treatment group who received a disorder tailored psychotherapy compared to patients who were treated with supportive counselling ("clinical management"). Decrease of ADHD symptoms will be assessed with the Conners' Adult ADHD rating scale by blind investigators (CAARS-O).
- ADHD symptoms are less prominent in the treatment group receiving a combination of methylphenidate and a disorder tailored psychotherapy compared to medical treatment and disorder tailored psychotherapy only (CAARS-O).
- Outcome at the time of follow-up is moderated by treatments administered during the follow-up period.

## Follow-Up Measures

### Primary efficacy endpoint:

- Conners' Adult Rating Scale (CAARS-O, blind-observer rated)

### Key secondary endpoints:

- CAARS-O (30% sum reduction)
- Conners' Adult ADHD Rating Scale (CAARS-S, patient rated)
- ADHD-Checklist (ADHD-DC)
- General Psychopathology (SCL-90-R)
- Beck Depression Inventory (BDI)
- Clinical Global Impression (CGI)
- Quality of Life Questionnaire (Q-LES-QSF)
- Follow-up-interview (treatments during the follow-up period)
- Evaluation of cost effectiveness (SF-36, EQ-5D)

## Elements of Economic Evaluation

- Socioeconomic Questionnaire to be completed by patients
- Costing based on resource utilization data
- Anticipated scope of economic evaluation:
  - cost effectiveness analysis (CEA)
  - cost utility analysis (CUA)
  - CEA/CUA by subgroup x domain
  - all of the above supported by probabilistic sensitivity analyses using patient-level data (incremental cost effectiveness ratios [ICERs]; CE scatter plots, ICER confidence intervals, and cost effectiveness acceptability curves [CEACs] by means of non-parametric bootstrapping)