Prevention of Comorbid Depression and Obesity in Attention-deficit/ Hyperactivity Disorder (PROUD)

This study is currently recruiting participants.

Verified December 2017 by Christine M. Freitag, Goethe University

Sponsor:
Goethe University

ClinicalTrials.gov Identifier:
NCT03371810

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The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Know the risks and potential benefits of clinical studies and talk to your health care provider before participating. Read our disclaimer for details.

Collaborators:
Heidelberg University
Radboud University
Hospital Vall d'Hebron
King's College London

Information provided by (Responsible Party):
Christine M. Freitag, Goethe University

Purpose
Depression and obesity are very common among adolescents and young adults with attention-deficit/ hyperactivity disorder (ADHD). However, intervention programmes to prevent these comorbid disorders rarely exist. In a pilot randomized-controlled study we test two newly developed intervention programmes that do not involve medication: bright light therapy and physical exercise. Both interventions will be supported by a mobile Health application to monitor and feedback intervention success and booster patients' motivation.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
<th>Phase</th>
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<tbody>
<tr>
<td>Attention-Deficit / Hyperactivity Disorder</td>
<td>Behavioral: Bright light therapy</td>
<td>Phase 2</td>
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<tr>
<td>Depression</td>
<td>Behavioral: Physical exercise</td>
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<tr>
<td>Obesity</td>
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Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Intervention Model Description:

Prospective, randomized, observer-blinded, controlled, multi-centre, pilot phase-IIa parallel-group design with three arms (two treatment groups and one control group); three trial phases: baseline assessment, 10 weeks of treatment versus treatment as usual; 12 weeks post-treatment observation period.
Masking: Single (Outcomes Assessor)

Masking Description:

Observer-blinded assessment of the primary outcome measure

Primary Purpose: Prevention

Official Title: Pilot Randomized-controlled Phase-IIa Trial on the Prevention of Comorbid Depression and Obesity in Attention-deficit/ Hyperactivity Disorder

Resource links provided by NLM:

MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Exercise and Physical Fitness

U.S. FDA Resources

Further study details as provided by Christine M. Freitag, Goethe University:

Primary Outcome Measures:

- Change from baseline in clinician-rated depressive symptoms (observer-blinded assessment)
  [ Time Frame: baseline, end of intervention (10 weeks after baseline) ]
  Inventory of Depressive Symptomatology (clinician-rated)

Secondary Outcome Measures:

- Change from baseline in clinician-rated depressive symptoms (observer-blinded assessment)
  [ Time Frame: baseline, follow up (22 weeks after baseline) ]
  Inventory of Depressive Symptomatology (clinician-rated)

- Change from baseline in clinician-rated ADHD symptoms [ Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline) ]
  ADHD Rating Scales for adults and children

- Change from baseline in self-reported severity of depressive symptoms [ Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline) ]
  Beck Depression Inventory II

- Change from baseline in self-reported health status [ Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline) ]
  Health Questionnaire EQ-5D-3L

- Change from baseline in self-reported health related quality of life [ Time Frame: baseline, end of intervention (10 weeks after baseline) ]
  Short Form Health Questionnaire General Health Questionnaire

- Change from baseline in self-reported general health status [ Time Frame: baseline, end of intervention (10 weeks after baseline) ]
  General Health Questionnaire General Health Questionnaire
• Change from baseline in self-reported emotional and behavioural problems in adolescents
  [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Youth self-report

• Change from baseline in self-reported emotional and behavioural problems in adults [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Adult self-report

• Change from baseline in circadian rhythm [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Munich Chronotype Questionnaire

• Change from baseline in cognitive emotion regulation [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Cognitive Emotion Regulation Questionnaire

• Change from baseline in neurocognitive functions: verbal memory [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Rey Auditory Verbal Learning Test

• Change from baseline in neurocognitive functions: Digit span [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Digit span

• Change from baseline in self-reported physical fitness [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  International Fitness Scale

• Change from baseline in general muscular fitness [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  handgrip strength test

• Change from baseline in muscular fitness [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  standing long jump test

• Change from baseline in aerobic fitness [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  Chester step test

• Change from baseline in body mass index [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  body mass index measured by clinician

• Change from baseline in waist circumference [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  waist circumference measured by clinician
• Change from baseline in waist-to-hip ratio [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  waist-to-hip ratio measured by clinician

• Change from baseline in body fat percentage [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  based on skinfold thickness measurements using a skinfold caliper

• Change from baseline in heart rate [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  heart rate measured by clinician

• Change from baseline in blood pressure [Time Frame: baseline, end of intervention (10 weeks after baseline), follow-up (22 weeks after baseline)]
  blood pressure measured by clinician

• Change from baseline in number of steps [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  number of steps measured with the mobile Health app

• Change from baseline in movement acceleration [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  movement acceleration measured with the mobile Health app

• Change from baseline in sleep time [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  sleep time measured with the mobile Health app

• Change from baseline in context parameters [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  context measured with the mobile Health

• Change from baseline in mood regulation [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  mood regulation measured with the mobile Health app

• Change from baseline in reward reactivity [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  reward reactivity measured with the mobile Health app

• Change from baseline in stress reactivity [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  stress reactivity measured with the mobile Health app

• Change from baseline in inattention [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  inattention measured with the mobile Health app

• Change from baseline in melatonin concentration [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  Saliva sample will be taken to measure melatonin concentration
• Change from baseline in cortisol concentration [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  Saliva sample will be taken to measure cortisol concentration

• Change from baseline in leptin concentration [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  Saliva sample will be taken to measure leptin concentration

• Change from baseline in ghrelin concentration [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  Saliva sample will be taken to measure ghrelin concentration

• Change from baseline in neural activity associated with reward processing [Time Frame: baseline, end of intervention (10 weeks after baseline)]
  Striatal functional magnetic resonance imaging signal related to reward processing

Estimated Enrollment: 219

Actual Study Start Date: March 13, 2017

Estimated Study Completion Date: March 2020

Estimated Primary Completion Date: March 2020 (Final data collection date for primary outcome measure)

<table>
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<th>Assigned Interventions</th>
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| **Arms**| **Experimental: Bright light therapy** Mobile therapeutic light (10,000 LUX), daily (except Sunday) for 30 min in the morning or evening for 10 weeks in total. Additional treatment as usual comprising pharmacotherapy, group based or individual cognitive behavioural therapy (not including elements of bright light therapy or exercise) is allowed. | Behavioral: Bright light therapy Mobile therapeutic light (10,000 LUX, white light without UV light), daily (except Sunday) for 30 min in the morning or evening for 10 weeks in total at home provided by a bright light therapy device (Philips EnergyLight HF 3419). Monitoring and feedback will be realized with the m-Health system comprising of a smartphone equipped with the m-Health App, and an activity sensor equipped with a light sensor to monitor the light exposure of the participant. Other Names:  
- Device: smartphone with m-Health app  
- Device: Philips EnergyLight HF 3419 |
| **Behavioral: Physical exercise** During 10 weeks participants perform three days of aerobic activities proposed and in two of these days also do muscle-strengthening exercise. Specifically, a training day consists of: (i) a 5-min warm-up period, (ii) a 10-35 min of muscle-strength training on two of the three days, (iii) a 20-40 min of aerobic training, (iii), and a 5-min of flexibility/stretching cool-down. During the course of the 10 weeks, the duration and intensity of the exercises will increase gradually. Instruction, monitoring, and feedback will be realised by the m-Health system including a smartphone equipped with the m-Health app and Secure Digital Memory cards to store the exercise videos as well as an activity sensor equipped with a mobile sensor for the | Experimental: Physical exercise Aerobic exercise of moderate-to-vigorous intensity three days a week plus muscle-strengthening exercises two days a week during 10 weeks in total. Additional treatment as usual comprising pharmacotherapy, group based or individual cognitive behavioural therapy (not including elements of bright light therapy or exercise) is allowed. |
acquisition of physical activity.
Other Name: Device: smartphone with m-Health app

No Intervention: Treatment as usual Stable treatment as usual comprising pharmacotherapy, group based or individual cognitive behavioural therapy (not including elements of bright light therapy or exercise).

**Detailed Description:**
The risk for comorbid major depressive disorder and obesity is increased in adolescents and adults with attention-deficit/ hyperactivity disorder (ADHD), and adolescent ADHD predicts adults major depressive disorder and obesity. Nonpharmacological interventions to prevent these comorbidities are urgently needed. Bright light therapy (BLT) improves day-night rhythm and is an established therapy for major depression in adolescents and adults. Exercise prevents and reduces obesity in adolescents and adults and also improves depressive symptoms. Interestingly, a reinforcement-based intervention using a mobile health app (m-Health) resulted in improved effects on weight loss in obesity. The aim of the current pilot randomized-controlled phase-IIa study is to establish feasibility and effect sizes of two kinds of interventions, BLT and exercise, in combination with m-Health based monitoring and reinforcement in adolescents and young adults aged 14 to 29 years old with ADHD, targeting the prevention of depressive symptoms and obesity. In addition, immediate and long-term treatment effects on ADHD specific psychopathology, health related quality of life, fitness and body related measures, neurocognitive functions and chronotype are explored. Furthermore, saliva samples are taken in a subgroup of adult patients to explore the effects of BLT and exercise on concentrations of hormones. This subgroup of adult patients will also participate in an additional neuroimaging study of the reward system in order to explore intervention effects on striatal reward reactivity.

**Eligibility**

**Information from the National Library of Medicine**

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies.](#)

**Ages Eligible for Study:** 14 Years to 29 Years (Child, Adult)
**Sexes Eligible for Study:** All
**Accepts Healthy Volunteers:** No

**Criteria**

**Inclusion Criteria:**
- Diagnosis of ADHD according to Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria
- Stable treatment as usual comprising pharmacotherapy, group based or individual cognitive behavioural therapy (not including elements of bright light therapy or exercise)

**Exclusion Criteria:**
- Intelligence Quotient (IQ) below 75
- Any severe (comorbid) psychiatric disorder with necessary additional psychopharmacotherapy or daycare/ inpatient therapy beyond treatment as usual
- Severe medical/ neurological condition not allowing bright light therapy or exercise
- History of epilepsy
- Use of antipsychotics, antiepileptic or photosensitising medication
- Substance abuse/ dependency

**Contacts and Locations**
Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): **NCT03371810**

Contacts

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Sponsors and Collaborators

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Heidelberg University
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King’s College London

Investigators

Principal Investigator: Christine M Freitag, Prof. Dr.
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More Information
Additional Information:
Homepage of the CoCA project (Comorbid Conditions of Attention-deficit / hyperactivity disorder). The PROUD study is work package 6 of the CoCA project.

Responsible Party: Christine M. Freitag, Prof. Dr., Goethe University
ClinicalTrials.gov Identifier: NCT03371810
Other Study ID Numbers: CoCA-PROUD
First Submitted: March 3, 2017
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Last Update Posted: December 13, 2017
Last Verified: December 2017

Individual Participant Data (IPD) Sharing Statement:
Plan to Share IPD: Undecided

Studies a U.S. FDA-regulated Drug Product: No
Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Christine M. Freitag, Goethe University:
attention-deficit / hyperactivity disorder  bright light therapy
depression  exercise
obesity  mobile healthy system
prevention

Additional relevant MeSH terms:
Disease  Body Weight
Obesity  Signs and Symptoms
Depression  Behavioral Symptoms
Depressive Disorder  Mood Disorders
Attention Deficit Disorder with Hyperactivity  Mental Disorders
Hyperkinesis  Attention Deficit and Disruptive Behavior Disorders
Pathologic Processes  Neurodevelopmental Disorders
Overnutrition  Dyskinesias
Nutrition Disorders  Neurologic Manifestations
Overweight  Nervous System Diseases