Bright light therapy versus physical exercise to prevent co-morbid depression and obesity in adolescents and young adults with attention-deficit / hyperactivity disorder: study protocol for a randomized controlled trial

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Abstract

Background

The risk for major depression and obesity is increased in adolescents and adults with attention-deficit / hyperactivity disorder (ADHD) and adolescent ADHD predicts adult depression and obesity. Non-pharmacological interventions to treat and prevent these co-morbidities are urgently needed. Bright light therapy (BLT) improves day-night rhythm and is an emerging therapy for major depression. Exercise intervention (EI) reduces obesity and improves depressive symptoms. To date, no randomized controlled trial (RCT) has been performed to establish feasibility and efficacy of these interventions targeting the prevention of co-morbid depression and obesity in ADHD. We hypothesize that the two manualized interventions in combination with mobile health-based monitoring and reinforcement will result in less depressive symptoms and obesity compared to treatment as usual in adolescents and young adults with ADHD.

Methods

This trial is a prospective, pilot phase-IIa, parallel-group RCT with three arms (two add-on treatment groups [BLT, EI] and one treatment as usual [TAU] control group). The primary outcome variable is change in the Inventory of Depressive Symptomatology total score (observer-blinded assessment) between baseline and ten weeks of intervention. This variable is analyzed with a mixed model for repeated measures approach investigating the treatment effect with respect to all three groups. A total of 330 participants with ADHD, aged 14 – < 30 years, will be screened at the four study centers. To establish effect sizes, the sample size was planned at the liberal significance level of $\alpha = 0.10$ (two-sided) and the power of $1\text{-}\beta = 80\%$ in order to find medium effects. Secondary outcomes measures including change in obesity, ADHD symptoms, general psychopathology, health-related quality of life, neurocognitive function, chronotype, and physical fitness are explored after the end of the intervention and at the 12-week follow-up.

Discussion

This is the first pilot RCT on the use of BLT and EI in combination with mobile health-based monitoring and reinforcement targeting the prevention of co-morbid depression and obesity in adolescents and young adults with ADHD. If at least medium effects can be established with regard to the prevention of depressive symptoms and obesity, a larger scale confirmatory phase-III trial may be warranted.

Trial registration

German Clinical Trials Register, DRKS00011666. Registered on 9 February 2017.
ClinicalTrials.gov, NCT03371810. Registered on 13 December 2017.