Pilot Randomized-controlled phase-IIa trial on the prevention of comorbid Depression and Obesity in Attention-deficit / Hyperactivity disorder

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Primary objective: To assess the prevention of depressive symptoms by 10-weeks BLT and 10-weeks AEI vs. TAU, and to establish feasibility and effect sizes of these two kinds of interventions in combination with a m-Health app based reinforcement in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cognitive and attention disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON45280

Source
ToetsingOnline

Brief title
PROUD

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD ; attention deficit hyperactivity disorder

Research involving
Human

Sponsors and support

Primary sponsor: Department of Child and Adolescent Psychiatry, Psychosomatics and

Psychotherapy University Hospital Frankfurt, Goethe Universität
Source(s) of monetary or material Support: EU Framework Programme for Research and Innovation;Horizon 2020 (Project Number: 667302)

Intervention

Keyword: ADHD, comorbidity, Intervention

Outcome measures

Primary outcome

To assess the prevention of depressive symptoms by 10-weeks BLT and 10-weeks AEI vs. TAU, and to establish feasibility and effect sizes of these two kinds of interventions in combination with a m-Health app based reinforcement.Descriptive analyses of treatment response group; exploratory analysis of intervention effects in subgroups and of potential prognostic factors.

Secondary outcome

To assess the prevention of obesity and the improvement of general health and ADHD symptoms by 10-weeks BLT and 10-weeks AEI interventions vs. TAU in combination with a m-Health app based reinforcement. Descriptive analyses of treatment response group; exploratory analysis of intervention effects in subgroups and of potential prognostic factors.

Study description

Background summary

The risk for comorbid obesity and major depressive disorder is increased in adolescents and adults with attention-deficit / hyperactivity disorder (ADHD) and adolescent ADHD predicts adult obesity and major depressive disorder. 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. In addition, it has been shown that reinforcement-based exercise interventions using a mobile health (m-Health) approach resulted in improved effects on weight-loss in obesity. To date, it is not known whether BLT and exercise interventions in combination with m-Health based reinforcement prevent and/or reduce depression and obesity in adolescents and young adults with ADHD.

Study objective

Primary objective: To assess the prevention of depressive symptoms by 10-weeks BLT and 10-weeks AEI vs. TAU, and to establish feasibility and effect sizes of these two kinds of interventions in combination with a m-Health app based reinforcement in adolescents and young adults aged 14 to 30 years old with ADHD.

Secondary objectives: To assess the prevention of obesity and the improvement of general health and ADHD symptoms by 10-weeks BLT and 10-weeks AEI interventions vs. TAU in combination with a m-Health app based reinforcement in adolescents and young adults aged 14 to 30 years old with ADHD. Descriptive analyses of treatment response group; exploratory analysis of intervention effects in subgroups and of potential prognostic factors.

Study design

The study is a three arm (two treatment groups and one control group) phase-IIa pilot randomized, observer-blinded, controlled, prospective, multi-centre study with five measurement points.

Intervention

In the planned pilot randomized-controlled Phase-IIa study, we will establish feasibility and effect sizes of two interventions, Bright Light Therapy (BLT) and Aerobic exercise intervention (AEI), in combination with m-Health based monitoring and reinforcement in adolescents and young adults with ADHD as add-on treatment to TAU compared to TAU alone.
BLT: Mobile therapeutic light (10.000 LUX, white light without UV light), daily (except Sunday) for 30 min for 10 weeks in total provided by a BLT device (Philips EnergyLight HF 3419). The exact time of day of implementation (either during the morning or the evening) is determined by the type of Chronoprofile (Morning- or Evening type) of each study participant determined by the MEQ.
AEI: The physical exercise intervention consists in training three days a week during 10 weeks. Participants will 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.

Study burden and risks

Generally, both, BLT and AEI, are considered as safe interventions with no specific, relevant risk conferred to the trial participants. The BLT device implemented in this study (Chronolux Medic-4) uses UV and IR filtered therapeutic light (10.000 LUX) and is thus safe for eyes and skin. If side effects occur (e.g. nausea, headache, eyestrain), they are usually mild and short lasting. In rare circumstances, BLT can trigger a manic episode in bipolar disorder, which therefore is an exclusion criterion. Regarding the AEI arm of the intervention, it should be said that the risks associated with exercise are directly related to the *dose* of exercise and top athletes are at a high risk of suffering different type of injuries. However, in this study, the exercise administered will be recreational and only small injuries (e.g. ankle sprain) might occur with a similar probability than when being at the school recess (in the case of adolescent participants) or in any daily activity. All participants will undergo a medical examination to exclude any severe medical or neurological condition not allowing BLT (i.e. an eye condition that makes your eyes vulnerable to light damage or other diseases with effects on the retina such as Diabetes mellitus) or AEI (i.e. heart disease, high blood pressure, injuries).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- All subjects must meet DSM-5 criteria for a lifetime history of childhood onset ADHD (DSM-5 314.00, 314.01) as well as current ADHD criteria
- Age: 14-30 years old.
- Stable TAU comprising pharmacotherapy, group based or individual cognitive behavioural therapy (not including elements of BLT or AEI).

Exclusion criteria

- Any severe medical or neurological condition interfering with interventions.
- Any severe medical or neurological condition not allowing BLT or AEI.
- Use of antipsychotic or anti-epileptic medication, photos-sensitising medication (e.g., Lithium, St. John's Wort)
- Substance use disorder (DSM-5) or dependency (DSM-5)
- History of epilepsy
- Acute suicidal ideation
- Pregnancy

Study design

Design

Study phase: 2

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-04-2018
Enrollment:	55
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL60194.091.17