PowerCoaching: A multiple domain CBT coaching program for adolescents with attention deficit hyperactivity disorder

Submission date	Recruitment status	Prospectively registered
18/04/2016	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
18/04/2016	Completed	☐ Results
Last Edited	Condition category	Individual participant data
18/04/2016	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Background and study aims

Attention deficit hyperactivity disorder (ADHD) is a common childhood disorder in which the sufferer struggles with attention, impulsivness and hyperactivity. Almost all treatments for ADHD have been adjusted for treating children or adults, and little research has been done to evaluate their effectiveness in adolescents. Adolescence is a time involving rapid physical, mental and social development takes place, which can lead to feelings of inner turmoil, emotional instability and negative mood. Adolescents with ADHD have a high risk of experiencing problems in development in these areas because of issues with being able to manage disruptive emotions and impulses. PowerCoaching is an ADHD treatment specifically designed for adolescents. The aim of this study is to evaluate the effectiveness of this treatment.

Who can participate?

Adolescents with ADHD between the ages of 12 and 18 years old.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive PowerCoaching immediately. This involves sessions at the participant's home every week for 18 weeks. The sessions last for about an hour and involve discussions about a range of topics and the teaching of stratagies to help cope with ADHD related problems. Those in the second group receive treatment as usual for the 18 weeks of the study. Participants in both groups complete a number of questionnaires at the start of the study and then again after 18 weeks. After participants in both groups are assessed, participants in this group are able to take part in the PowerCoaching, but no further measurements are taken.

What are the possible benefits and risks of participating?

The coaching program may benefit participants in helping them to cope with daily problems related to ADHD and improve their quality of life. There are no notable risks involved with taking part in the study.

Where is the study run from? Yulius Academie (Netherlands)

When is the study starting and how long is it expected to run for? February 2014 to December 2016

Who is funding the study? Yulius (Netherlands)

Who is the main contact? S. Kapiteijn, MSc. s.kapiteijn@yulius.nl

Study website

https://yuliusacademie.nl/powercoaching

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

An RCT pilot of treatment as usual compared to PowerCoaching: An multiple domain CBT coaching program for adolescents between 12 and 18 years old with Attention Deficit Hyperactivity Disorder

Study objectives

- 1. Adolescents' quality of life is enhanced after participating in PowerCoaching compared to a control condition
- 2. Adolescents in the intervention condition will show more self-efficiency and selfregulating behavior and less psychosocial problems than adolescents in the control condition

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medisch Ethische Toetsings Commissie TWOR, 06/03/2014, ref: MEC-2013_50, general reference number: NL47364.101.13

Study design

18-week immediate versus delayed intervention randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Attention deficit hyperacitivty disorder (ADHD) and problems in daily functioning

Interventions

Adolescents are randomized to one of two groups:

Immediate treatment group: Participants receive the PowerCoaching for a total of 18 weeks. Sessions are given once a week at the participant's home, lasting for 45 to 60 minutes, and involve the discussion of different themes (i.e. psycho-education, planning and organisation, school and study, self-image, emotion regulation, relations, risk and control and lifestyle). During the sessions, participants will learn new strategies to cope with ADHD related problems.

Delayed treatment group: For the 18 week duration of the study, participants continue as usual. Following collection of the final outcomes, the treatment is made available from week 19 to week 37.

Participants in both groups complete outcome measurements at baseline and 18 weeks.

Intervention Type

Primary outcome measure

Quality of life is measured using "Weiss Functional Impairment Rating Scale (WFRIS) excluding the subscale 'work' at baseline and 18 weeks.

Secondary outcome measures

- 1. Self-efficiency measured using a self-constructed questionnaire at baseline and 18 weeks
- 2. selfregulating behavior measured using the Behavior Rating Iventory Executive Functions's subscales emotion regulation, planning and organizing, and organization of materials at baseline and 18 weeks
- 3. Psychosocial problems measured using the Strengths and Difficulties Questionnaire at baseline and 18 weeks

Overall study start date

01/01/2014

Completion date

31/12/2016

Eligibility

Key inclusion criteria

- 1. Aged 12 to 18 years
- 2. An official Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV ADHD diagnosis (all subtypes). The diagnosis must have been previously set by a child and adoelscent psychiatrist, Healthcare psychologist, clinical psychologist or paediatrician specialized in social paediatrics. Adolescents with common diagnosed comorbid disorders (i.e., dyslexia, oppositional defiant disorder) can participate in the study as long as ADHD is the main disorder.
- 3. Stable ADHD treatment, both pharmacological and psychological
- 4. Minimum total intelligence quotiënt (TIQ) score must be greater than or equal to 85
- 5. Fluent in Dutch
- 6. Provision of written informed consent

Participant type(s)

Patient

Age group

Child

Lower age limit

12 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Key exclusion criteria

- 1. Addiction to drugs or alcohol
- 2. Severe psychotic disorder
- 3. Another acute Axis-I disorder

Date of first enrolment

12/02/2015

Date of final enrolment

01/03/2016

Locations

Countries of recruitment

Netherlands

Study participating centre

Yulius Academie

Dennenhout 1 Barendrecht

Netherlands

2994 GC

Sponsor information

Organisation

Maasstad Hospital Rotterdam (Maasstadziekenhuis Rotterdam)

Sponsor details

Maasstadweg 21 Rotterdam Netherlands 3007AC

Sponsor type

Hospital/treatment centre

Website

https://www.maasstadziekenhuis.nl

ROR

https://ror.org/01n0rnc91

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Yulius

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

01/05/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available