Thin Bizzy: A pilotstudy of a multimodal treatmentprogram for children with ADHD who are overweight

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In this research, a new, complementairy treatment for children with ADHD and overweight is studied, which combines regular ADHD treatment with a lifestyle intervention focussed on healthy diet, excersize and sleep routines. This intervention can...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Developmental disorders NEC
Study type	Interventional

Summary

ID

NL-OMON38770

Source
ToetsingOnline

Brief title
Thin Bizzy

Condition

- Developmental disorders NEC

Synonym
Attention Deficit Hyperactivity Disorder (ADHD) & overweight

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Yulius
Source(s) of monetary or material Support: ADHD netwerk en De Gezonde Regio

Intervention

Keyword: Attention Deficit Hyperactivity Disorder (ADHD), children, intervention, overweight

Outcome measures

Primary outcome

Primary study parameter in this study is BMI.

Secondary outcome

Secundairy parameters are ADHD symptoms, self-efficacy, quality of life.

Study description

Background summary

Children with the combination ADHD and overweight are largely neglected in the clinical practice. Most practicioners have the assumption that children with ADHD are physically more active compared to children without this developmental disorder, and as a result have a normal weight. However, recent studies indicate that a third of the children with ADHD are at enhanced risk for being overweight (Holtkamp et al., 2004; Curtin, Bandini, Perrin, Tybor, & Must, 2005; Fliers et al., submitted). The current treatments for children with ADHD and overweight are limited and not filling in with the needs of these children.

Study objective

In this research, a new, complementairy treatment for children with ADHD and overweight is studied, which combines regular ADHD treatment with a lifestyle intervention focussed on healthy diet, excersize and sleep routines. This intervention can have an enduring effect on weight loss. We expect decreasing ADHD symptoms and that quality of life and healthy lifestyle self-efficacy of the child are enhanced. Involvement and self-efficacy of the families are enhanced by individual home coaching. In addition, this enhances an enduring change in lifestyle. First results regarding the effectiveness of this intervention are studied in this pilot study.

Study design

The design of this pilot study consists of an open, pre-post treatment design with a follow-up, without control group. All children involved in the study

will receive the intervention.

Intervention

The intervention consists of a 12 week exercise and diet program. In addition, lifestyle intervention at home is provided. During the intervention, children exercise three times a week, under supervision of a coach. Furthermore, a diet is provided which is fitted for their personal weightloss goal.

Study burden and risks

Measures
No risks are expected for the children participating in the study. The children fill out questionnaires for approximately 80 minutes at three time points (T0, T1, and T2). To measure the physical condition of the children, weight, length and bloodpressure of the child is measured during T0, T1, T2 and two times during the intervention. Before the intervenion starts, the children perform a fitness test on a treadmill. In addition, children fill out a list of what they ate each day for two weeks (one week before T0, and one week before T1). This will take the child approximately 10 minutes a day which makes a total of 140 minutes.

Intervention
During the intervention, the child will exercise 135 minutes each week, which makes a total of 27 hours of exercise during the intervention. The lifestyle coaching will last 45 minutes, 9 times in total, which makes a total of 6 hours and 45 minutes. The intakeappointment with the dietist will take 45 minutes.

Expected gains are weightloss, enhanced self-efficacy and enhanced feelings of physical and mental wellbeing.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

1. All children included in the study will be from 10 to 16 years of age.
2. Overweight is defined as a BMI score above the Cole and collegues (2000) cut-off scores according to the child's age and sexe.
3. All children must have an official DSM-IV ADHD diagnose (all subtypes).
4. All children need to be stable on ADHD treatment, this can include pharmacological and/or psychological, for at least two months prior to start of the intervention. It is important that participants continue this treatment throughout the intervention period and between measurement moments.
5. Minimum total intelligence score must be 70. If the total intelligence score is not known, has been established by a non-COTAN approved test or has been performed more than two years previous to the start of the intervention, total intelligence score will be established using two subtests of the Wechsler Intelligence Scale for Children third version (WISC-III-NL; Wechsler, 2005).
6. Both children and at least one of the parents/legal guardians must have a reasonable understanding of the Dutch language.
7. Children can only be included after a written informed consent has been signed by both parents or legal guardians. It is important that parents understand the information and are able to fill out the consent form. Children older than twelve year olds have to give their own written informed consent in addition to their parents/legal guardians.

Exclusion criteria

1. Because severe physical or cognitive disabilities may cause problems for the standardized

measures, excersize and the dietplan, children with specific intolerances or allergies for nutricions are excluded. The diet is specifically focussed on decreasing the colarie intake and eating healthy, therefore children with protein allergies, gluten allergies or lactose intolerance are excluded. Examples of other physical or cognitive problems in children are instable Diabetes Mellitus Type I, instable epileptic, congenital heart conditions or severe sensoric disabilities.
2. Children with genetic heart conditions who are not able to sport maximal and children with acute epilepsy are excluded
3. Furthermore, children who are addicted to drugs, alcohol or have severe acute psychotic disorder will be excluded.
4. Children and adolescents with Axis 1 problems will be excluded.
5. Children and adolescents with eating disorders such as anorexia nervos, boulimia nervosa, and binge eating disorder will be excluded.
6. Children with a BMI score above a score of 40 are not included, they need more medical attention then can be provided through this intervention.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-10-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	03-07-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek

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	NL44114.101.13

Study results

Date completed:	25-11-2015
Actual enrolment:	22