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Thin Bizzy: a multimodal lifestyle intervention for children with attention deficit hyperactivity disorder and overweight

Submission date
02/09/2015

Recruitment status
No longer recruiting

Registration date
05/10/2015

Overall study status
Completed

Last Edited
05/10/2015

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Attention deficit hyperactivity disorder (ADHD) is a group of behavioural symptoms that include poor concentration, hyperactivity and impulsiveness. A multimodal lifestyle intervention (Thin Bizzy) may help overweight children with ADHD to lose weight. The main aim of this study is to examine the effectiveness of this treatment in addition to treatment as usual.

Who can participate?
Overweight children with ADHD will be randomly selected among registered mental health care institutions, private psychology practices and paediatric practices across The Netherlands.

What does the study involve?
Children are randomly allocated to either receive the lifestyle intervention immediately (from week 0 to week 12) or to receive the treatment later (week 13 to week 24), both in addition to treatment as usual (medication or psychological treatment). Children receiving the lifestyle intervention will play sports three times a week and receive lifestyle training once a week under supervision of a Thin Bizzy coach. Assessments are carried out at the start of the study, during the intervention, after the intervention and at 3 months follow-up.

What are the possible benefits and risks of participating?
This study provides overweight children with ADHD the opportunity to join this lifestyle intervention to reduce BMI and ADHD symptoms, and improve their quality of life. Risks of participation in this study are limited as children receive training under supervision. Possible side effects are mild side effects that can be expected from exercising in the gym.

Where is the study run from?
This study has been set up by Yulius Academie (Netherlands).

When is the study starting and how long is it expected to run for?
January 2013 to December 2015.

Who is funding the study?
Not provided at time of registration.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Dennenhout 1
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Thin Bizzy: a multimodal lifestyle intervention for children with attention deficit hyperactivity disorder and overweight - a randomized controlled pilot study

Study objectives
The effectiveness of a multimodal lifestyle intervention called 'Thin Bizzy' is assessed in this study. The main aim of the trial is to optimize daily functioning of children with attention deficit hyperactivity disorder (ADHD) and comorbid overweight by means of losing weight and enhancing their quality of life.

Does this multimodal lifestyle intervention reduce body mass index (BMI) and enhance quality of life in children with ADHD and comorbid overweight from 10 to 16 years of age? The expectation is that children will show a significant reduction in BMI after participating in this study compared to a control condition. Another expectation is that children will display less symptoms of ADHD and better self-efficiency and quality of life after participating in the intervention group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Ethische Toetsings Commissie TWOR, 03/07/2013, ref: MEC-2013_11, general reference number: NL44114.101.13

Study design
12-week immediate versus delayed intervention randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Attention deficit hyperactivity disorder (ADHD) and overweight/obesity

Interventions
The intervention in this study is a multimodal lifestyle intervention called Thin Bizzy consisting of lifestyle coaching and sports coaching. This treatment is offered as an additional intervention to treatment as usual.

Children are randomized to one of the following two groups:
1. An immediate treatment group (in which the treatment is available from week 0 to week 12).
2. A delayed treatment group (in which the treatment is available from week 13 to week 24)

In the first 12 weeks, children from the immediate treatment group will be asked to participate, continuing their treatment as usual. The results from this group will be compared to the other group following treatment as usual. After 12 weeks, the intervention will be available for the delayed treatment group. Several sports and lifestyle sessions are planned during the intervention under supervision of a Thin Bizzy coach. Several measures take place before, during and after the intervention. Children will be encouraged to continue this lifestyle after the intervention. They play sports three times a week and receive lifestyle training once a week (one hour both).

Intervention Type
Behavioural

Primary outcome measure

Body weight measured using Body Mass Index (BMI) at baseline, after 12 weeks (shortly after the intervention) and at 3 months follow-up (late after the intervention)

Secondary outcome measures
1. ADHD symptoms measured using the ADHD-vragenlijst (AVL)
2. Quality of life measured using the Impact of Weight on Quality of Life Questionnaire (IWQOL)
3. Self-efficiency measured using a self-constructed questionnaire

These outcome measures will be evaluated at baseline, during the intervention (week 5 and week 9), after 12 weeks (shortly after the intervention) and after 3 months follow-up by different questionnaires filled out by parents and the child. Socio-demographic information will be available through a parent-reported questionnaire at baseline.

Overall study start date
01/01/2013

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. All children included in the study will be from 10 to 16 years of age
2. All children must have 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 adolescent psychiatrist, healthcare psychologist, clinical psychologist or paediatrician specialised in social paediatrics. Children with common diagnosed comorbid disorders (i.e., dyslexia, oppositional defiant disorder) can participate in the study
3. All children must have a comorbidity with overweight
4. All participants need to be stable on ADHD treatment, both pharmacological and psychological
4. Minimum total intelligence quotient (TIQ) score must greater than or equal to 80
5. Children can only be included after a written informed consent has been signed by both parents or legal guardians, indicating that they understand the purpose of and procedures required for the study and are willing to participate in the study. Twelve year olds must give their own written informed assent in addition to their parents/legal guardians

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
22

Key exclusion criteria
1. Children with a severe physical (i.e., developmental coordination disorder), neurological (i.e., epilepsy), or cognitive (i.e., mental handicap) disability will be excluded
2. Furthermore, children who are addicted to drugs, alcohol and/or gaming, have conduct disorder (CD) or have severe acute psychiatric disorders, psychotic disorder, major depressive disorder and mania will be excluded
3. Parents/legal guardians without a reasonable understanding of the Dutch language will be excluded

Date of first enrolment
01/09/2013

Date of final enrolment
01/06/2014

Locations

Countries of recruitment
Netherlands

Study participating centre
Yulius Academie
Dennenhout 1
Barendrecht
Netherlands
2994 GC

Sponsor information

Organisation
Maasstad Hospital Rotterdam (Maasstadziekenhuis Rotterdam) (Netherlands)

Sponsor details
Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam (TWOR)
Maasstadweg 21
Postbus 9100
Rotterdam
Netherlands
3007 AC

Sponsor type
Hospital/treatment centre

Website
www.maasstadziekenhuis.nl

ROR
https://ror.org/01n0rnc91

Funder(s)

Funder type
Other

Funder Name
ADHD netwerk (Netherlands)

Funder Name
De Gezonde Regio (Netherlands)

Results and Publications

Publication and dissemination plan
We hope to finish our article in December 2015.

Intention to publish date
01/12/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available