Long term effectiveness and cost-effectiveness of an elimination diet trajectory compared to care as usual in the treatment of Attention Deficit/ Hyperactivity Disorder in children aged 5 to 12 year

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Determining the long-term (18 months) effectiveness and cost-effectiveness of an elimination diet (ED) as the first addition to care as usual (CAU) in comparison to providing CAU only in children with ADHD (5-12 years). Hypotheses: Long-term...

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

Summary

ID

NL-OMON41838

Source
ToetsingOnline

Brief title
TRACE: Treatment of ADHD with Care as usual versus an Elimination diet

Condition

- Cognitive and attention disorders and disturbances

Synonym
ADHD, attention-deficit/hyperactivity disorder

Research involving

Human

Sponsors and support

Primary sponsor: Psychiatrie
Source(s) of monetary or material Support: ZonMw,Innovatiefonds Zorgverzekeraars

Intervention

Keyword: (cost-)effectiveness, ADHD, Elimination Diet, randomized controlled trial

Outcome measures

Primary outcome

Primary outcome: % children showing excellent response (>30% symptom reduction)

based on blind assessment.

Secondary outcome

ADHD and comorbid behavior rated by parents and teachers, objective cognitive

measures and motor activity, school functioning, quality of life, health

status, adequacy of final diet assessed by a dietician and cost-effectiveness.

Study description

Background summary

There is growing societal discussion and concern about year by year increasing prescription rates of medication (mostly psychostimulants) to children with ADHD. Food seems to trigger ADHD symptoms in some children and an individually constructed elimination diet (ED) might be an effective treatment for ADHD.

Study objective

Determining the long-term (18 months) effectiveness and cost-effectiveness of an elimination diet (ED) as the first addition to care as usual (CAU) in comparison to providing CAU only in children with ADHD (5-12 years).
Hypotheses: Long-term treatment with ED in addition to CAU (ED-trajectory) is superior in effectiveness to CAU and more cost-effective because fewer children will require long-term treatment with medication. After 5 weeks ED is superior

to a control diet.

Study design

RCT with two parallel groups (and a limited comparison with a control diet) performed in 3 child and adolescent psychiatric centers in the Netherlands, with randomization within each participating center.

Intervention

The ED trajectory consists of a 5-week elimination phase, in which children consume a standardized diet, and a 12-18 months reintroduction phase to find those products triggering ADHD symptoms. Non-responders to ED and children who drop out during the reintroduction phase will switch to CAU.
Standard intervention to be compared to:
- CAU consisting of medication and / or psychosocial interventions.
- Control diet comparable to a normal dietary pattern prescribed in a very strict and structured way, requiring the family, as in ED, to adapt the rules and structure of the family during 5 weeks.

Study burden and risks

Burden for the ED participants are mainly related to the reintroduction phase of the diet, which can take up to 1,5 years, in which ADHD symptoms may re-occur after the reintroduction of a food. Burden for ED and CAU participants consist of a 15 ml venepuncture at the start of the study, after 5 weeks of treatment and at the end of the study. Burden for all participants and parents are the recurrent non-invasive assessments: For children (IQ, behaviour observation, cognitive test) the time duration per assessment varies between 1.5 and 2.5 hours (three assessments in total in 1.5 years). For parents (parent-child observation, questionnaires) the time duration of the begin/end point assessment (T0, T1, T4) is around 60 to 90 minutes and at other time points (T2, T3) around 15 minutes. We believe this is feasible.
Benefits for the participants are good monitoring of treatment effectiveness and the possibility to be treated with an elimination diet free of charge, which is currently not yet covered by health insurance. Parents receive ¤25 per assessment for compensation of travel expenses and time investment; children receive a small gift (worth ¤3,-).

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

• clinical ADHD diagnosis according to the DSM-5 (any subtype)
• ADHD treatment abstinence in past 2 months
• 5-12 years old
• ADHD Rating Scale (ARS) score higher than 1.5 SD above the mean
• confirmed research diagnosis by a structured psychiatric interview with the parents (K-SADS) [26].
• comorbidities are allowed, except for eating disorders

Exclusion criteria

• children with current treatment for ADHD, or in the past two months (either receiving medication or behavioral therapy or a diet),
• use of any other psychotropic medication, elimination diets, behavioral therapies
• children and/or parents with inadequate mastery of the Dutch language
• diabetes

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2015
Enrollment:	301
Type:	Actual

Ethics review

Approved WMO Date:	22-01-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-05-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-09-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-05-2016
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-10-2020
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	NL50015.091.14