

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### Source

NTR

### Brief title

TRACE

### Health condition

English:

ADHD, attention deficit and hyperactivity disorders, diet intervention, elimination diet,

Dutch:

ADHD, aandachtstekortstoornis met hyperactiviteit, dieetinterventie, eliminatie dieet

### Sponsors and support

Primary sponsor :	Karakter, kinder- en jeugdpsychiatrie
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Source(s) of monetary or material Support :	- Innovatiefonds verzekeraars - ZonMw Doelmatigheidssubsidie - Eat2beNice
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### Intervention

No registrations found.

### Outcome measures

## Primary outcome

ADHD symptoms & emotion regulation symptoms

## Secondary outcome

- cognitive performance
- motor activity
- school performance
- direct and indirect costs

## Study description

### Background summary

-

### Study objective

Treatment of ADHD with an elimination diet is more (cost-)effective than the care as usual after 1 year

### Study design

three timepoints:

1. baseline
2. after 5 weeks of treatment
3. after 1 year of treatment

## Intervention

1. care as usual

Diet interventions:

2. eliminating major allergens/triggers

3. balanced diet

## Contacts

### Public

Karakter Child and Adolescent Psychiatry, Nijmegen -  
Radboud UMC, Nijmegen - Donders Institute, Centre for Neuroscience, Nijmegen

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### Scientific

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## Eligibility criteria

### Inclusion criteria

- children, age 5-12 years
- diagnosis for ADHD, any sub-type, according to DSM V

- clinical diagnosis for ADHD confirmed by information from parents and school teacher

## Exclusion criteria

- use of psychotropic medication or a strict (elimination) diet
- children who have received treatment for ADHD in the past two months
- children who are diagnosed with diabetes melitus
- children who are diagnosed with an eating disorder
- children with an inadequate mastery of the Dutch language
- children who require therapy from the care as usual immediately (e.g. in case of parent-child relationship problems)
- children who refuse to have meat or animal food products in general in their diet (e.g., vegetarian, vegan)

## Study design

### Design

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

### Recruitment

NL	
Recruitment status :	Recruiting
Start date (anticipated) :	29-09-2015
Enrollment :	230
Type :	Anticipated

## IPD sharing statement

Plan to share IPD : Undecided

## Ethics review

Positive opinion

Date : 05-10-2015

Application type : First submission

## 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
NTR-new	NL5324
NTR-old	NTR5434
Other	local CMO Arnhem-Nijmegen : 2014-1349

## Study results