

Treatment of ADHD with care as usual versus an elimination diet

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25997

Source

Nationaal Trial Register

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

Source(s) of monetary or material Support: - Innovatiefonds verzekeraars

- ZonMw Doelmatigheidssubsidie

- Eat2beNice

Intervention

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

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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