

# Multidisciplinary approach of lifestyle intervention and physical examination of children with mental health disorders

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Determining the short-term and long-term (12 months) effectiveness and cost-effectiveness of a lifestyle intervention treatment as the first addition to care as usual (CAU) in comparison to providing CAU only, in children with psychiatric disorders (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON54366

### Source

ToetsingOnline

### Brief title

Lifestyle intervention for children with mental health disorders

### Condition

- Other condition
- Psychiatric disorders NEC

### Synonym

lifestyle, mental health, Quality of Life

### Health condition

Kwaliteit van Leven, Leefstijl

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum

**Source(s) of monetary or material Support:** ZonMw

## Intervention

**Keyword:** Children, Intervention, Lifestyle, Psychiatry

## Outcome measures

### Primary outcome

Quality of life.

### Secondary outcome

Emotional and behavior problems

Cognitive assessment (COTAPP and IQ)

Physical, somatic and biological measurements

Lifestyle parameter - sleep, diet, physical activity, screen time.

Measurement of costs.

Parenting styles and family functioning.

Prior beliefs/satisfaction/adherence.

## Study description

### Background summary

Unhealthy lifestyle is frequently seen among children in the Netherlands. Most common forms of unhealthy lifestyle in this population include the consumption of diet rich in saturated fats and sugar, inactivity, excessive gaming and distorted sleep patterns. Unfortunately, unhealthy lifestyle and poor physical health are even more frequently seen among children with mental health illness such as autism, ADHD, depression and anxiety disorder. However, research on lifestyle interventions among children with mental health illness is lacking. As a result, there are currently no guidelines, treatment programs or equipped treatment centers where children with mental health problems and poor lifestyle

quality can receive proper treatment. The aim of this study is to develop and implement a multi-modal lifestyle intervention program in routine clinical care for children with mental health disorders.

## **Study objective**

Determining the short-term and long-term (12 months) effectiveness and cost-effectiveness of a lifestyle intervention treatment as the first addition to care as usual (CAU) in comparison to providing CAU only, in children with psychiatric disorders (6-14 years).

Hypotheses: Offering a lifestyle intervention ensures that not only physical health, but also mental health improves.

## **Study design**

RCT with an intervention group and a control group performed in one psychiatric centre in the Netherlands.

## **Intervention**

In the lifestyle intervention condition, patients will start with an awareness consult and psycho-education on a healthy lifestyle. The 12-week intervention involves family-based education on healthy lifestyle in combination with the following elements depending on which lifestyle factors need to be improved or a combination of treatment: (1) optimization of sleep based behavioural therapy by a sleep expert, (2) physical activation/sport activity supervised by an psychomotor therapist, (3) dietary treatment provided by a dietician following national guidelines for a healthy diet according to age and sex, and/or (4) restoration of a balanced use of \*screen time\* according to age specific guidelines. To generalize healthy behaviour in the family a home coach will be involved to visit the families at their homes, schools and sport clubs of the child to give education on healthy lifestyle.

Standard intervention to be compared to:

- CAU consisting of an awareness consult and psycho-education focused on lifestyle followed by the regular care (medication and / or psychosocial intervention).

## **Study burden and risks**

Burden on the participants in the lifestyle intervention is mainly related to the different measurement moments (four times during a period of one year). Burden consists of a venipuncture (15 ml, twice). This can be experienced as annoying.

Burden for all participants are non-invasive measurements. For children (IQ, Cognitive assessment (COTAPP), physical fitness test, wearing an actigraph) the

time duration per assessment varies between 1,5 and 2 hours (four assessments in total in 1 year) . For parents (questionnaires) the time duration of the begin/end point assessment (T0, T1, T4) is around 30 and 60 minutes. We believe this is feasible.

Benefits for the participants are good monitoring of treatment effectiveness and the possibility to receive treatment on lifestyle, while this is not (yet) covered by the health insurance.

Parents receive 20 euros per assessment for compensation of travel expenses and time investment; children receive a small gift (worth 3 euros).

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Children (2-11 years)

### Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all

of the following criteria:

- between 6-13 years old;
- a diagnosis according to the DSM-5 (any presentation);
- somatic concern assessed by medical examination and/or lifestyle screening (overweight, obesity, underweight, unhealthy diet, sleeping problems, inactivity and screen time use);
- willingness to set lifestyle goals;

Comorbidities are allowed except for severe eating disorders (i.e. anorexia) and diabetes mellitus type I and II.

## Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- unable to respond to questions (parents or children);
- no access to a home internet connection;
- insufficient mastery of Dutch language in parents or children;
- unwillingness to have meat or animal food products in the diet (without these products it is impossible to achieve nutritional adequacy of the overall);
- physically incapable to do physical exercises;
- surgery in past 6 months or next 12 months impacting physical activity or dietary intake;
- any, medical condition severely restricting diet.

## 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):	11-04-2022

Enrollment:	80
Type:	Actual

## Ethics review

Approved WMO	
Date:	21-10-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	16-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	18-12-2024
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	NL77440.091.21