# Lifestyle intervention for children with mental health disorders

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON28236

**Source**
NTR

**Brief title**
Movementss

**Health condition**

Children with psychiatric disorders (e.g. ADHD, Autism, Anxiety disorders, Depression) and an unhealthy lifestyle.

### Sponsors and support

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

### Intervention

### Outcome measures

**Primary outcome**

Primary Objective:
The primary objective of this study is to test the effectiveness of a multi-modal lifestyle intervention program in routine clinical care compared to care as usual (CAU) for children (6-12 years) with mental health problems in increasing their Quality of Life (QoL) using the

KIDSCREEN-27 Questionnaire.

### Secondary outcome

Secondary Objectives:
Additional objectives are (1) to investigate the effectiveness of the program compared to CAU on mental health, (2) to investigate the effectiveness of the program compared to CAU on physical health and lifestyle parameters, (3) to identify potential moderators and mediators of the response to the lifestyle program and (4) to assess cost-effectiveness the lifestyle program for these specific children.

## Study description

### Background summary

Study design: This study entails a randomized controlled intervention study with two arms; a lifestyle intervention condition versus a care as usual (CAU) control condition. The effects on quality of life, health resource use and health parameters will be assessed after 3, 6 and 12 months. Moreover, a qualitative study design will be used to get more insight into the experiences of children, caregivers en team members and to evaluate the infrastructure and implementation processes.
Study population: Participants are individuals between 6 and 12 years, with problems on their lifestyle. Patients will be recruited from different departments of Karakter Nijmegen, a large mental health organization for children in the Netherlands.
Intervention (if applicable): 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.
Main study parameters/endpoints: In this study, the objective is to evaluate the effectiveness of the lifestyle intervention. To determine the effects of the lifestyle intervention on the health of the child, we will assess quality of life using the Kidscreen-27 (primary measure), as well as psychometric measures, physical and lifestyle measures, costs- effectiveness measures, and an assessment of treatment compliance and satisfaction.

### Study objective

In an unselected, heterogeneous group of children with mental health problems assigned for

evaluation to Karakter Child and adolescent psychiatry:
1. Treatment with the multi-modal lifestyle intervention is more effective than CAU in improving QoL on the short term (3 months) and longer term (6 and 12 months).
2. Treatment with the multi-modal lifestyle intervention is more effective than CAU in improving mental health on the short term (3 months) and longer term (6 and 12 months).
3. On the short term (3 months) and long term (6 and 12 months), physical health and lifestyle parameters of children treated with the multi-modal intervention program is superior to that of children receiving only CAU.
4. Potential moderators of respondership and adherence to the program include SES, ethnicity, one/two parent household and comorbidity.

**Study design**

Measurement points at: T0, T1 (after 12 weeks), T2 (after 6 months) and T3 (after 12 months)

**Intervention**

Lifestyle intervention group
The intervention combines an awareness consult, psycho-education on healthy lifestyle, and optimization of pharmacotherapy (i.e., CAU) together with a lifestyle program that consist of improvement of physical condition, dietary consults, sleep education and education on screen time use for both the child and his/her family depending on what is needed. We propose to target dietary habits, physical activity, screen use and sleep not at the same time, but rather (if needed) create a hierarchy and start with the different interventions in a specific order, that is made in alliance with the parents.
The lifestyle intervention will be based on cognitive behavioural therapy combined with psychomotor therapy, and has a systematic approach, parents (and preferably the entire family) will actively participate in the treatment. Moreover, a homecoach will guide the family at home on a weekly base, and will learn them to apply the learned techniques in the home situation.

# Contacts

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# Eligibility criteria

## Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- between 6-12 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.

## 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;
- 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.
- severe underweight

# Study design

## Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 16-01-2022 |
| Enrollment: | 80 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion

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|---|---|
| Date: | 01-11-2021 |
| 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 | NL9822 |
| Other | METC Oost Nederland : 2021-8224 |

## Study results