Lifestyle intervention for children with mental health disorders

Gepubliceerd: 01-11-2021 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28236

Bron
NTR

Verkorte titel
Movementss

Aandoening

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

Ondersteuning

Primaire sponsor: ZonMw
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Karakter Kinder- en Jeugdpsychiatrie en Radboud UMC
Emilie van Tetering

0650005544

Wetenschappelijk

Karakter Kinder- en Jeugdpsychiatrie en Radboud UMC
Emilie van Tetering

0650005544

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	16-01-2022
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	01-11-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9822
Ander register	METC Oost Nederland : 2021-8224

Resultaten