

De Coaching op Leefstijl (CooL) Interventie voor Obesitas

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Ethische beoordeling Positief advies

Status Anders

Type aandoening Overige aandoening

Onderzoekstype Interventie onderzoek

Samenvatting

ID

NL-OMON28211

Bron

NTR

Verkorte titel

CooL

Aandoening

- Overige aandoening

Aandoening

Overweight, Obesity, Lifestyle Coaching, Children, Adults, Overgewicht, Obesitas, Leefstijlcoaching, Kinderen, Volwassenen.

Betreft onderzoek met

Mensen

Ondersteuning

Primaire sponsor: CZ (health care insurer)

Overige ondersteuning: CZ (health care insurer)

Onderzoeksproduct en/of interventie

- Leefstijlinterventie

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

Children: objectively measured BMI and self-reported quality of life.

Adults: objectively measured BMI, self-reported quality of life, and biomedical data (Hb1AC, blood pressure, and fasting glucose).

Toelichting onderzoek

Achtergrond van het onderzoek

The Coaching on Lifestyle (CooL) intervention is a new Dutch CLI, in which the lifestyle coach coaches participants with (a high risk of) obesity. In group and individual sessions the lifestyle coach addresses themes such as sleep, stress, physical activity, and dietary behaviours. The goal of the intervention is to structurally embed lifestyle coaching in the health care process and to promote sustained lifestyle changes in the participants related to physical activity and diet.

Doel van het onderzoek

Hypotheses are that the long-term supervision of the CooL intervention will be related to beneficial changes in the participants; energy-balance related behaviours, body composition, and quality of life. Besides, the goal of the intervention is to structurally embed lifestyle coaching in the health care process.

Onderzoeksopzet

Baseline:

Children: objectively measured BMI and self-reported quality of life, the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, sleeping behaviour, personality, cognitive determinants, general parenting, and parenting styles.

Adults: objectively measured BMI, self-reported quality of life, and biomedical data (Hb1AC, blood pressure, and fasting glucose), the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, personality, and cognitive determinants.

32 to 44 weeks follow-up:

Children: objectively measured BMI and self-reported quality of life, the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, sleeping behaviour, personality, cognitive determinants, and process measures (number of participants and drop-out).

Adults: objectively measured BMI, self-reported quality of life, biomedical data (Hb1AC, blood pressure, and fasting glucose), the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, personality, cognitive determinants, and process measures (number of participants and drop-out).

18 months follow-up:

Children: objectively measured BMI and self-reported quality of life, the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, sleeping behaviour, personality, cognitive determinants, general parenting, and parenting styles.

Adults: self-reported quality of life, the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, personality, and cognitive determinants.

Onderzoeksproduct en/of interventie

The Coaching on Lifestyle (CooL) intervention is a new Dutch CLI, in which the lifestyle coach coaches participants with (a high risk of) obesity. In group and individual sessions the lifestyle coach addresses themes such as sleep, stress, physical activity, and dietary behaviours.

In the adult basic program, participants are coached for 6 to 8 months (see Table 2 for an overview of the sessions). The groups consist of 4 to 12 participants. Adults receive 8 group sessions (of 90 minutes) and 4 individual sessions (of 30 minutes). The child program consists of 8 group sessions with parents, 4 individual sessions at home with the family, and around 6 telephone sessions with the child. The focus is to provide the parents tips for positive parenting styles and for changing their child's lifestyle into a healthier one. The adolescent program is a combination of the children and adults program, with a greater emphasis on

social influences of, for example, peers.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd

Volwassenen (18-64 jaar)
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In this intervention, the lifestyle coach coaches individuals from 4 years and older with (a high risk of) obesity. These are persons with either obesity (BMI ≥ 30) or overweight (BMI \geq

25) with a (moderately) increased risk of cardiovascular diseases or diabetes mellitus type II, according to the National Integrated Health Care Standard Obesity. For children and adolescents (under 18 years) a BMI cut-off point per age has been set in this Care Standard Obesity. Also, the participants must have a health insurance policy at the Dutch health insurance companies CZ or VGZ or one of their subsidiaries.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A lack of motivation to participate into the intervention or having medical problem(s).

Onderzoeksopzet

Opzet

| | |
|------------------|-------------------------|
| Fase onderzoek: | N.V.T. |
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blinding: | Open / niet geblindeerd |
| Controle: | Geen controle groep |
| Doel: | Preventie |

Deelname

| | |
|-------------------------|-----------------------|
| Nederland | |
| Status: | Anders |
| (Verwachte) startdatum: | 01-05-2014 |
| Aantal proefpersonen: | 0 |
| Type: | Werkelijke startdatum |

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies
Datum: 31-03-2014
Soort: Eerste indiening
Toetsingscommissie: MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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 | NL6061 |
| NTR-old | NTR6208 |
| Ander register | Research Ethics Committee of the Faculty of Health, Medicine and Life Sciences of Maastricht University (FHML-REC/2019/073) |

Resultaten

Samenvatting resultaten

Not applicable