

Coaching On Lifestyle

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Ethical review	Positive opinion
Status	Other
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON28211

Source

Nationaal Trial Register

Brief title

CoolL

Condition

- Other condition

Health condition

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

Research involving

Human

Sponsors and support

Primary sponsor: CZ (health care insurer)

Source(s) of monetary or material Support: CZ (health care insurer)

Intervention

- Life style intervention

Explanation

Outcome measures

Primary outcome

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).

Secondary outcome

Children: the quality of motivation for physical activity and for diet, physical activity level, dietary behaviours, sleeping behaviour, personality, cognitive determinants, general parenting, parenting styles, and process measures (number of participants and drop-out).

Adults: 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).

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

"The inclusion criteria for CoolL: (1) being 18 or older; (2a) having a Body Mass Index (BMI) between 25 and 30 kg/m² in combination with a waist circumference over 88cm for women or over 102cm for men, or with comorbidity ((increased risk of) diabetes or cardiovascular disease, osteoarthritis or sleep apnea), or (2b) having a BMI > 30 kg/m² regardless of waist size or comorbidity; and (3) being sufficiently motivated to complete the two-year intervention as judged by the referrer (e.g. the general practitioner or practice nurse) and the CLI-coach."

Exclusion criteria

Not applicable

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	01-05-2014
Enrollment:	0
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	31-03-2014
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

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 NL6061

NTR-old NTR6208

Other Research Ethics Committee of the Faculty of Health, Medicine and Life Sciences of Maastricht University (FHML-REC/2019/073)

Study results

Summary results

Not applicable