# A pilot study of the effectiveness of a maintenance treatment by Short Message Service (SMS) in overweight and obese children, after a short-term multidisciplinary cognitive behavioural group therapy.

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To determine the effectiveness of a maintenance treatment by SMS (SMSMT) in overweight and obese children, after a short-term multidisciplinary cognitive behavioural group therapy (CBGT).

Ethical reviewApproved WMOStatusRecruitingHealth condition typeOther conditionStudy typeInterventional

## Summary

#### ID

NL-OMON31274

**Source** 

**ToetsingOnline** 

**Brief title** 

**DVC-pilot study** 

#### Condition

Other condition

#### **Synonym**

Overweight and obesity

#### **Health condition**

In deze studie gaat het om gevolgen van verkeerde eet- en beweeggewoonten. Kinderen met overgewicht en obesitas tengevolge van een somatische aandoening worden uitgesloten.

#### Research involving

Human

#### **Sponsors and support**

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam **Source(s) of monetary or material Support:** Ministerie van OC&W,Stichting

YouTurn, Vodafone

#### Intervention

**Keyword:** Behavior Therapy, Child, Obesity, Overweight

#### **Outcome measures**

#### **Primary outcome**

Dropout rate and BMI-SDS. Since overweight and obesity are measured in terms of BMI and BMI-values are corrected for age and gender in children, the outcome measure will be BMI-SDS.

#### **Secondary outcome**

Energy uptake, physical fitness, problem behaviour, family functioning, health-related quality of life.

## **Study description**

#### **Background summary**

Overweight and obesity in children are rapidly increasing in the Netherlands, and are associated with overweight and obesity in adulthood, other serious health problems, and psychosocial problems. According to the recent Health Council report on overweight and obesity, it is important to develop multidisciplinary cost-effective treatment programs that lead to long-term weight reduction in order to prevent secondary illnesses and psychosocial problems. These treatment programs should include behavioural strategies, such as goal setting, monitoring, environmental control and reinforcement of healthy

behaviours. Positive outcomes of the current study may lead to the nationwide implementation of the proposed CBGT/SMSMT treatment program.

#### Study objective

To determine the effectiveness of a maintenance treatment by SMS (SMSMT) in overweight and obese children, after a short-term multidisciplinary cognitive behavioural group therapy (CBGT).

#### Study design

RCT with 2 groups. After a cognitive-behavioral group treatment (CBGT). After the CBGT, patients will be randomized to Short Message Service Maintenance Treatment (n=50) and no maintenance treatment (n=50).

#### Intervention

SMSMT: Over a 42-week period, participants will input self-monitoring data on relevant parameters (exercise, eating pattern, and mood) in a standardized format directly into their mobile phone once a week and will receive a feedback message on their progress via a semi-automated software program.

#### Study burden and risks

The burden and risks due to filling in questionnaires is minimal, both for children and parents. Psychologists are present during filling in of questionnaires, in order to anwer any questions that may arise and to help parents and children. The maintenance treatment implies receiving and answering SMS-messages. This will hardly cause any burden or risk for children and parents. Indeed, this type of aftercare aims at supporting children and parents, parallel to the follow-up sessions during the 42 weeks of maintenance treatment.

## **Contacts**

#### **Public**

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#### Scientific

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## **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

#### Age

Children (2-11 years)

#### Inclusion criteria

Age 7 to 12 yrs, Body Mass Index - Standard Deviation Score (BMI-SDS) >= 1.1.

## **Exclusion criteria**

Problem behavior (Youth Outcome Questionnaire score >= 46), insufficient command of Dutch language, other disease causing overweight that can be treated with drugs, diagnosis of eating disorder (DSM-IV).

# Study design

### **Design**

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

**Primary purpose:** Treatment

#### Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 09-07-2007

Enrollment: 100

Type: Actual

## **Ethics review**

Approved WMO

Date: 03-07-2007

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

# **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 NL16866.078.07