

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

Submission date

13/04/2010

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

29/04/2010

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

29/07/2013

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

METC -2007-129

Study information

Scientific Title

Short Message Service Maintenance Treatment (SMSMT) and the influence on dropout, lifestyle behaviour, competence and quality of life: a randomized controlled trial

Acronym

NTT-CO (New Technology in the Treatment of Childhood Overweight and Obesity)

Study objectives

Short Message Service Maintenance Treatment (SMSMT) reduces the dropout rates in a paediatric lifestyle program for overweight and obese children

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ethics Committee of the Erasmus University of Rotterdam approved on the 3rd of July 2007 (ref: MEC-2007-129)

Study design

Randomised controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Childhood obesity

Interventions

Cognitive behavioural group therapy (CBGT):

The Big Friends Club intervention. The BFC program is a family-based multidisciplinary cognitive behavioural group therapy (CBGT) intervention for children aged 7 to 12 years that is limited to groups of 10 children. The treatment team includes a psychologist, dietician, paediatrician, and physiotherapist. The therapy is aimed at reducing Body Mass Index (kg/m^2) Standard Deviation Scores (BMI-SDS), preferably by maintaining weight during growth, adopting a healthy lifestyle and creating a positive self-image. The program provides for an intake session, 8 childrens sessions, and a minimum of 3 parents sessions during the first 3 months. At 6, 9, and 12 months after start of the program, childrens and parents sessions and individual appointments are organized.

After the primary cognitive behavioural treatment participants will be randomised into two groups, maintenance treatment (SMSMT) and no maintenance treatment (no SMSMT)

Short Message Service Maintenance Therapy (SMSMT):

Over a 42-week period, the children will input self-monitoring data on relevant parameters (weight change, exercise, and eating pattern) in a standardized format directly into their mobile phone once a week. Once per week, they receive a feedback message on their progress via a semi-automated software program. Staff-members read incoming SMSs, check the feedback suggested by the program for plausibility, and send it to the participant. Feedback messages are formulated according to two rules: 1) signalling social support and 2) reinforcing positive changes and suggesting behaviour modification strategies in case of negative developments. The children must receive and send the messages by themselves. The parents are allowed to support them if necessary.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Dropout rate

Secondary outcome measures

1. BMI-SDS, measured at baseline, 3, 6, 9 and 12 months
2. Problem behaviour, measured with Youth Outcome Questionnaire (YOQ) at baseline, 3 and 12 months
3. Family functioning, measured with the Dutch version of the Family Adaptability and Cohesion Evaluation Scale (FACES III) at baseline, 3 and 12 months
4. Health-related quality of life, measured with the Child Health Questionnaire-Parent Form (CHQ-PF-50) at baseline, 3, 6, 9 and 12 months
5. Perceived competence, measured with Dutch version of the Self-Perception Profile for Children (SPPC) at baseline, 3, 6 and 12 months
6. Eating behaviour, measured with the Dutch Eating Behaviour Questionnaire (DEBQ) at baseline, 3, 6, 9 and 12 months

Overall study start date

01/07/2007

Completion date

01/12/2010

Eligibility

Key inclusion criteria

1. Overweight and obese children (Body Mass Index-Standard Deviation Score [BMI-SDS] ≥ 1.1)
2. Aged 7 to 12 years
3. Youth Outcome Questionnaire [Y-OQ] < 46
4. Command of Dutch language
5. No drug-treatable disease as the cause of excess weight
6. No diagnosis of eating disorder as defined by Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV)

Participant type(s)

Patient

Age group

Child

Lower age limit

7 Years

Upper age limit

12 Years

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Behavioural problems defined as a score exceeding 70 on the Child Behaviour Checklist (CBCL)
2. Drug-treatable disease as the cause of excess weight
3. Mental retardation
4. Insufficiently fluent in the Dutch language
5. Parents or a child with insufficiently motivation to actively participate in the program

Date of first enrolment

01/07/2007

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Netherlands

Study participating centre
Erasmus MC - Erasmus University Medical Center
Rotterdam
Netherlands
3000 CA

Sponsor information

Organisation

Erasmus Medical Centre / Medical Research Advice Commission (MRACE) (Netherlands)

Sponsor details

c/o Rikard E. Juttman MD PhD
Department of Research Policy
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Sponsor type

Hospital/treatment centre

Website

<http://intranet.erasmusmc.nl/onderzoeksbeleid/subsidiesinvesteringen/internesubsidie/emczorgonderzoek/>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre / Medical Research Advice Commission (MRACE) (Netherlands) - Grant No. 2006-26

Funder Name

Innovation Fund Insurances (Innovatiefonds Verzekeringen) (Netherlands) - Grant No. 06-334.

Funder Name

Vodafone (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No