Het HELIOS onderzoek naar behandeling van kinderen en adolescenten met ernstige obesitas.

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Een klinisch behandelprogramma met een opnameduur van acht weken gevolgd door een intensief vervolgprogramma voor kinderen (8-19 jr.) met ernstige obesitas is kosten effectiever dan een klinische interventie met een opnameduur van zes maanden en...

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

Samenvatting

ID

NL-OMON20813

Bron
NTR

Verkorte titel
HELIOS

Aandoening

Obesity, adiposity
Obesiteit, zwaarlijvigheid

Ondersteuning

Primaire sponsor: Type organisation: Universiteiten
Name organisation: Vrije Universiteit
Address De Boelelaan 1085
Postal code and place: 1081 HV Amsterdam
Country: The Nederlands
Telephone nr: 020-5986995
Fax 020-5986940
Email: jaap.seidell@falw.vu.nl
Overige ondersteuning: - ZonMW

- Ministerie van VWS

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

SDS-BMI (costs of treatment per change in relative BMI).

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Severe obesity is increasingly common in The Netherlands and poses a dilemma in clinical medicine. Intensive treatment is required but evidence-based cost-effective options are not yet available. The best practice that has been proposed by the soon to be released Dutch "Guideline for Diagnosis and Treatment of Obesity in Children and Adults" is an intensive combined lifestyle therapy but it is acknowledged that programs that are effective on the long-term are not yet available. Previously, an extensive six-month inpatient treatment program has shown to be much more effective in one year than ambulatory usual care but there are some critical issues remaining. Long-term treatment outcomes are not available and long-term inpatient programs are undesirable for both the patients and their families. Moreover, this option is extremely expensive. The Ministry of Health, Welfare and Sports has now agreed to fund intensive treatment of severe obesity on an experimental research basis with the requirement that less intensive and more cost-effective treatments are being developed and evaluated. This is the basis of the current proposal. In addition, there is little insight in the psychological features that may be crucial in determining the long-term outcome. Finally, such intensive treatment programs need to be integrated in a chronic disease management program. It is currently poorly defined what the pretreatment requirements are before a patient is referred to an intensive inpatient program. Similarly, there is not a long-term care protocol following the intensive treatment program.

Objective of the study:

The objectives of this proposal are 1. to compare the effects and costs of two intensive one-year interventions in severely obese children and adolescents of which the first six months are different with respect to the length of hospitalization; there will also be a comparison with a one year usual care treatment (waiting list control)

2. to study psychosocial determinants in the children and their parents relevant to the outcome of the interventions (change in behaviour, change in BMI, improvement in quality of life (generic, weigh-specific and health-related quality of life));

3. to integrate intensive lifestyle treatment in a national standard for chronic disease management in collaboration with the relevant professional organizations (paediatricians, general practitioners, dieticians, physiotherapists, psychologists etc); health care insurance companies and patient organizations.

Study design:

A randomized clinical trial with three study arms. There will be a triage system at which patients are evaluated for inclusion in the trial. There will be two intervention-groups: one with a six months intensive multidisciplinary inpatient treatment program and one arm with an intensive multidisciplinary program with twee months continuous hospitalization (on weekdays) followed by biweekly hospital admissions of two days during the following four months. Both treatment programs are followed by six months follow-up of monthly clinical booster sessions of one day each. The second year, children and adolescents will receive usual care in their local environment. A third arm will be an evaluation of ambulatory usual care treatment after which they will be randomized into each of the two treatment groups (waiting list control).

Study population:

Study population: Children and adolescents (8-19 years) with a SDS-BMI ≥ 3.0 (99.9th age- and sex-specific percentile of BMI in the fourth Dutch nationwide growth study of 1997), or a SDS-BMI ≥ 2.3 (99th age- and sex-specific percentile of BMI in the fourth Dutch nationwide growth study of 1997) in combination with obesity-related comorbidity.

Intervention (if applicable):

The treatment program lasts one year for both groups. Patients will be randomized into three groups. Group A will be hospitalized for six months during weekdays. Group B will be hospitalized during weekdays for two months, followed by biweekly hospital admissions for two days during four months. Group C will receive usual care for a year after which they will be randomized into one of the two inpatient intervention groups. Both intervention programs are intensive lifestyle intervention programs with emphasis on nutrition, exercise, behaviour (especially self-regulation). During the second six months there will be six 'clinical booster sessions' each of two days duration aimed at reinforcement of the interventions. The second year, children and adolescents will receive usual care in their local environment. In both

intervention programs there is an active participation of the parents.

Primary study parameters/outcome of the study:

BMI (costs of treatment per change in BMI).
Secondary study parameters/outcome of the study (if applicable):

1. Psychological and psychosocial data on issues such as motivation, competence, self-esteem, anxiety, mental stress;

2. Cardiovascular risk factors (blood pressure, serum lipids, liver function tests, glucose and insulin);

3. Waist circumference;

4. Dietary behaviour by Food Frequency Questionnaire;

5. Questionnaires on eating behaviour, physical activity (sedentary behaviour);

6. Quality of life (generic, weigh-specific and health-related quality of life).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable): Because of the health risks and the importance of effective therapy with children and adolescents with severe obesity this study is conducted in children and adolescents in the age of 8-19 years.
De questionnaires and interviews, the physical examination, the venapunctions and other treatments during the hospital stay are part of the normal therapy. The extra burden for the patients consists only of extra psychological and psychosocial questionnaires. The study will not cause any additional risk for the participants.

Doel van het onderzoek

Een klinisch behandelprogramma met een opnameduur van acht weken gevolgd door een intensief vervolgprogramma voor kinderen (8-19 jr.) met ernstige obesitas is kosten effectiever dan een klinische interventie met een opnameduur van zes maanden en effectiever dan ambulante usual care in de eerstelijn.

Onderzoeksopzet

0, 6, 12 en 24 maanden.

Onderzoeksproduct en/of interventie

Control group (current protocol): there will be an exercise program for three days per week

(30-60 minutes each, mean duration of exercise sessions 43 minutes) and nutrition education/behavior modification sessions once per week (60 minutes each).
Behavior modification: topics include self-regulation, self-awareness, goal setting, stimulus control, coping skills training, cognitive behavior strategies and contingency management. Behavior modification classes for caregivers will include the same topics but also those that reflected the challenges parents verbalized to extend one or more of the above-mentioned parts of the program.
Further, private meetings with psychologists, dietitian or social worker as and when children and/or parents, or professionals, will indicate that it is necessary. Furthermore, patients will be encouraged and coached to stimulate playing outdoors or participating in outside activities daily, with other patients or on their own, and to decrease sedentary behavior. The nutritional education component of the program will use a non-dieting approach and will focus on improving the quality of the dietary intake, while also trying to establish a flexible control of eating behavior. Caloric requirements of each child are measured using the Schofield-formula presuming a P50 weight for length. Thus, caloric restriction is limited as long as the child's weight exceeds this parameter.
Intervention group (modified intervention; less intensive and less costly): The treatment here is identical to the control group except for the first six months. Instead of six months hospitalization this group will be hospitalized for two months, followed by biweekly hospital admission for two days during four months.

Treatment in both groups is based on intensive lifestyle intervention programs with emphasis on nutrition, exercise, behavior (especially self-regulation). During the second six months there will be six 'clinical booster sessions' each of two days duration aimed at reinforcement of the interventions. The second year, children and adolescents will receive usual care in their local environment.

In both intervention programs there is an intensive participation of the parents.

Contactpersonen

Publiek

VU University Medical Center,
Afdeling Voeding en Gezondheid/ Instituut Gezondheidswetenschappen, Faculteit Aard en Levenswetenschappen,
De Boelelaan 1085
J.C. Seidell
De Boelelaan 1085
Amsterdam 1081 HV
The Netherlands
+31 (0)20 5986985

Wetenschappelijk

VU University Medical Center,
Afdeling Voeding en Gezondheid/ Instituut Gezondheidswetenschappen, Faculteit Aard en Levenswetenschappen,
De Boelelaan 1085
J.C. Seidell
De Boelelaan 1085
Amsterdam 1081 HV
The Netherlands
+31 (0)20 5986985

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Children and adolescents (8-19 years) with a SDS-BMI ≥ 3.0 (99.9th age- and sex-specific percentile of BMI in the fourth Dutch nationwide growth study of 1997), or a SDS-BMI ≥ 2.3 (99th age- and sex-specific percentile of BMI in the fourth Dutch nationwide growth study of 1997) in combination with obesity-related comorbidity. All participants were referred by their local pediatrician after insufficient response to ambulatory treatment to reduce weight.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Syndromal/chromosomal determined obesity;
2. Obesity cause by endocrine disorders (e.g. hypothyroidism, Cushing syndrome, primary hyperinsulinemia, pseudohypoparathyroidism, acquired (structural) hypothalamic damage) or use of medication (e.g. antiepileptic drugs, antidepressants);
3. Psychiatric disorders (e.g. severe depression, schizophrenia) that may obstruct adequate treatment;
4. Presence of eating disorders (e.g. binge eating disorder, bulimia nervosa) to such a degree that specific therapeutic attention is needed before starting the intervention;
5. Children/adolescents or parents that can or will not give `informed consent`, parents that can or will not participate in the treatment;
6. Children/adolescents with an IQ below 75 or attending a school for intellectually challenged children.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-02-2009
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	NL1598
NTR-old	NTR1678
Ander register	ABR/ZonMW : 25157/80-82310-98-9107
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A