A new dietary intervention for children with hypothalamic obesity after treatment for a craniopharyngioma: a pilot-study

Published: 20-04-2016
Last updated: 19-04-2024

This pilot-study is designed to assess the feasibility and efficacy of a new dietary intervention (Happy Weight Dotsplan) and therefore to learn if it might be effective on a broad scale with the inclusion of a larger cohort nationwide. We will...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON46114

Source
ToetsingOnline

Brief title
A new dietary intervention for children with hypothalamic obesity

Condition

- Hypothalamus and pituitary gland disorders
- Appetite and general nutritional disorders

Synonym
Hypothalamic Obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: Craniopharyngioma, Happy Weight Dotsplan, Hypothalamic Obesity

Outcome measures

Primary outcome

BMI (before, during and after cessation of the intervention)

The criteria for success regarding feasibility of this pilot study are:

- At least 70% of all eligible subjects can be recruited

- Completion of intervention in at least 80% of subjects included

The criteria for success regarding efficiency of this pilot study is:

- 80% of subjects show weight reduction or stabilisation during the 1 year intervention period

Secondary outcome

Secondary outcomes:

- The Quality of Life (measured with PedsQL)

- The effect of the intervention on the metabolic profile (i.e. blood pressure, cholesterol profile, glycemic control)

- Physical activity (measured with GENEactiv wristband and HAES 1.6 questionnaire)

- The correlation between daily activity measured by the HAES questionnaire and

the GENEActiv wristband

Study description

Background summary

Hypothalamic obesity (HO) due to hypothalamic damage is a major concern in children and adults treated for craniopharyngioma. It greatly disrupts quality of life, increases the risk for cardiovascular complications and up to now therapeutic interventions have been disappointing. These children have a lack of hunger satisfaction and also a the lower metabolic state. The Happy Weight Diet has been designed for children with HO in patients with Prader Willi syndrome, which is comparable to children with HO due to a craniopharyngioma, and has demonstrated a significant weight reduction in this patientgroup.

Study objective

This pilot-study is designed to assess the feasibility and efficacy of a new dietary intervention (Happy Weight Dotsplan) and therefore to learn if it might be effective on a broad scale with the inclusion of a larger cohort nationwide. We will therefore investigate the effect of *The Happy Weight Diet* on BMI, metabolic profile and quality of life in a small group of children with hypothalamic obesity after treatment for a craniopharyngioma or suprasellar tumor.

Study design

In total, a small cohort of children will be included in this prospective intervention pilot-study. A dietary intervention (The Happy Weight Dotsplan) will be offered to these patients, including a coaching trajectory. Differences in BMI before, during and after cessation of intervention will be compared. Three monds after the end of the active intervention period, BMI will be defined again.

Intervention

Subjects will be assigned for intervention with *The Happy Weight Diet* with personal support by the dietician and the coach of *s Heeren Loo. The dietary advice will be calculated by the kilocalorie use of 65-70 % of normal, as calculated by the following method (7-8 kcal/cm body height).
In these children, *The Happy Weight Diet* will be followed according to the happy weight method (www.happyweight.nl) and a coaching program is also included.
Daily activity will be stimulated but no active intervention will be done.

Daily activity will be measured at start and after twelve months of the intervention by an accelerometer and a questionnaire.

Visits:
1.Pediatric endocrinologist:
All children will have their regular check-ups at the endocrinologist (every three months)
2.Dietician:
The patients will been seen by the dietician at intake, after 3 months and after 1 year. In between the visits, the dietician will have monthly contact with the patient for 30 minutes by telephone, email or skype.
3. Coach:
The coach will have an intake, an evaluation at 3 months, at 6 months and after one year.
4. Pediatric physiotherapist:
The physiotherapist will have an intake and an evaluation after one year.

Study burden and risks

All included patients will be intensively active with their diet and psychological coaching during one year. The burden or risk for the subjects is considered as acceptable as there is currently no treatment available for hypothalamic obesity after treatment for craniopharyngioma.
The possible benefit for the subjects may be great with possible weight reduction or stabilization, resulting in improvement of glycemic control, improvement of cardiovascular risk profile and improvement of quality of life.
There are no possible risks for the patients.

Group relatedness:
The incidence of severe obesity after treatment for craniopharyngioma ranges from 22 to 62%. Patients with craniopharyngioma have a 3-fold greater cardiovascular mortality rate associated with morbid obesity as compared to the normal population . Due to the fact that hypothalamic obesity is a such a clinical relevant problem for craniopharyngioma patients already during childhood and young adulthood, research into new treatment strategies must be done in all relevant patient groups, thereby involving minors. The Happy Weight Dotsplan is developed for children with Prader Wille syndrome, which have a comparable lack of hunger satisfaction and obesity. This Dotsplan might also be effective in children with hypothalamic obesity after treatment for a suprasellar tumor.

Contacts

Public

Universitair Medisch Centrum Utrecht

Lundlaan 6 Lundlaan 6
Utrecht 3584 EA
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6 Lundlaan 6
Utrecht 3584 EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Children or adolescents with hypothalamic obesity, BMI > 1,9 SD, currently visiting a pediatric endocrinologist after treatment for sellar or suprasellar lesions are eligible for this study.
- patients must be in complete remission or have residual disease > 1 year

Exclusion criteria

- Children < age of 5 years
- Current progression of disease.
- Diabetes Mellitus type 1

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2016
Enrollment:	8
Type:	Actual

Ethics review

Approved WMO Date:	20-04-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL54980.041.15

Study results

Date completed:	19-01-2018
Actual enrolment:	6