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A randomised controlled trial of a reduced carbohydrate diet versus a low fat diet for the treatment of childhood obesity: the Eat Smart Study

Submission date
25/03/2008

Recruitment status
No longer recruiting

Registration date
16/05/2008

Overall study status
Completed

Last Edited
30/03/2016

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.som.uq.edu.au/research/cnrc/eatsmart.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2008000262

Study information

Scientific Title
A controlled trial of a reduced carbohydrate diet versus a low fat diet on weight, body composition and metabolic profile in obese adolescents

Acronym
Eat Smart

Study objectives
There will be no differences between a reduced carbohydrate diet and a low carbohydrate diet in markers of body composition after 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Royal Children's hospital Human Ethics Committee, 08/01/2007, ref: 2006/096
2. University of Queensland Ethics Committee, 25/10/2006, ref: 2006000667
3. Mater Hospital Ethics Committee, 01/08/2007, ref: 1140C

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Childhood obesity

Interventions

1. Low fat diet (25% fat, 55% carbohydrate, 20% protein) for 24 weeks
2. Reduced carbohydrate diet (35% carbohydrate, 35% fat, 30% protein) for 24 weeks
3. Wait list control group. Those families allocated to the wait list control group will receive the full dietary program of their choice at the end of the control period (i.e. 12 weeks)

Both dietary programmes are structured with a lunch box and a standardised plate template system for dinner for portion size control. These are used across both intervention arms to ensure fidelity of intervention and increase compliance with dietary advice. Compliance is measured by diet diaries and activity diaries. Subjects are monitored weekly by phone and have 5 face-to-face sessions with study dietitian to assist with dietary adherence.

Duration of interventions: 24 weeks

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Change in body mass index standard deviation score (BMI Z score), assessed at baseline, 12 weeks (all three arms) and 24 weeks (only in active diet arms).

Secondary outcome measures
The following will be assessed at baseline, 12 weeks (all three arms) and 24 weeks (only in active diet arms):
1. Change in percentage body fat
2. Cardiometabolic markers of disease risk, including insulin level

Overall study start date
02/02/2008

Completion date
02/02/2011

Eligibility

Key inclusion criteria
1. Age 11- 17 years, both males and females
2. Body mass index >90th percentile for age
3. Parents/guardians are able to give informed written consent and child to give assent

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
135

Key exclusion criteria
The following will be assessed at baseline, 12 weeks (all three arms) and 24 weeks (only in active diet arms):
1. Obesity with known medical cause
2. Taking stimulants, psychotropic medication, steroids or insulin senstisers

Date of first enrolment
02/02/2008

Date of final enrolment
02/02/2011

Locations

Countries of recruitment
Australia

Study participating centre
Royal Children's Hospital
Herston
Australia
4029

Sponsor information

Organisation
National Heart Foundation (Australia)

Sponsor details
411 King Street
Melbourne 3003
Melbourne
Australia
3003
-
research@heartfoundation.com.au

Sponsor type
Charity

Website
http://www.heartfoundation.org.au

ROR
https://ror.org/039d9wr27

Funder(s)

Funder type
Charity

Funder Name
National Heart Foundation of Australia (ref: G 07B 3130)

Alternative Name(s)
Heart Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Australia

Funder Name
Royal Children's Hospital Foundation, Near Miss Fund (Australia)

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?
Protocol article	protocol	09/08/2010		Yes	No

Results article	results	29/03/2016	Yes	No