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	Recruitment status	Prospectively registered		
25/03/2008	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/05/2008	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
30/03/2016	Nutritional, Metabolic, Endocrine			

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

Contact name

Dr Helen Truby

Contact details

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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