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National Adolescent Treatment Trial for Obesity in Kuwait

Submission date	Recruitment status	[_] Prospectively registered
09/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/06/2014	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Randomised controlled trial of a behavioural treatment programme for obesity in Kuwaiti adolescents

Acronym

NATTO

Study objectives
To test whether parent-directed group-based behavioural treatment offers improved weight management over standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Medical Research, Ministry of Health of Kuwait, 12/02/2009, ref: MPH/112

Study design
Assessor blinded two arm randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obesity

Interventions
Random allocation to intervention or standard care control group:
1. Standard care control: referral to primary care, where treatment will be limited to a little health education
2. Intervention group: invited to 10 session of behavioural change counselling targeted at changes in physical activity, diet, and sedentary behaviour, over a 24 - 26 week period

Of the 10 sessions, five will be delivered by a dietician, five by a physician. Sessions 1 - 8 fortnightly for first 16 weeks, session 9 at week 20 and session 10 at week 26.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in BMI z score from baseline to 6 months after the start of treatment or standard care control.

Key secondary outcome(s))
1. Change in quality of life from baseline to +6 month follow up
2. Change in blood pressure and blood-based cardiometabolic risk factors (fasting lipids, triglycerides, insulin, glucose) from baseline to +6 months
3. Changes in estimated fat and fat free mass from baseline to +6 month follow up (using bioelectrical impedance)

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Boys and girls
2. Obese (body mass index [BMI] at or above 95th percentile on US CDC 200 BMI charts)
3. Aged 10 - 14 years inclusive
4. With no major chronic disease or disability
5. With no obvious underlying pathological cause of obesity
6. At least one parent willing to attend treatment sessions if randomly allocated to intervention
7. Attending a mainstream school in the public sector

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
14 years

Sex
All

Key exclusion criteria
1. Non-obese
2. With major disease
3. With underlying pathological cause of obesity
4. Less than 10 years or greater than 14 years at study inception
5. Not attending a mainstream school in the public sector
6. Unable or unwilling to attend treatment sessions if randomised to intervention group

Date of first enrolment
11/11/2009

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
United Kingdom

Scotland

Kuwait

Study participating centre
University of Glasgow Division of Developmental Medicine
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Sponsor information

Organisation
Civil Service Commission (Kuwait)

ROR
https://ror.org/02htmn026

Funder(s)

Funder type
Government

Funder Name
Civil Service Commission (Kuwait)

Results and Publications

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	19/06/2014		Yes	No