

National Adolescent Treatment Trial for Obesity in Kuwait

Submission date 09/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/12/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/06/2014	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Reilly

Contact details
University of Glasgow Division of Developmental Medicine
1st Floor Tower QMH
Yorkhill Hospitals
Glasgow
United Kingdom
G3 8SJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

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

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 measure

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

Secondary outcome measures

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)

Overall study start date

11/11/2009

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

Age group

Child

Lower age limit

10 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

100 - 140 at study entry

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**

Kuwait

Scotland

United Kingdom

Study participating centre

University of Glasgow Division of Developmental Medicine

Glasgow

United Kingdom

G3 8SJ

Sponsor information**Organisation**

Civil Service Commission (Kuwait)

Sponsor details

Scholarships Department

State of Kuwait

Kuwait City

Kuwait

KCL889

Sponsor type

Government

Website

<http://www.csc.net.kw/>

ROR

<https://ror.org/02htmn026>

Funder(s)

Funder type

Government

Funder Name

Civil Service Commission (Kuwait)

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?
Results article	results	19/06/2014		Yes	No