

Malaysian Childhood Obesity Treatment Trial (MASCOT)

Submission date 25/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 04/07/2019	Condition category Nutritional, Metabolic, Endocrine	<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
First Floor Tower QMH
Yorkhill Hospitals
Glasgow
United Kingdom
G3 8SJ
+44 (0)1412 010710
jjr2y@clinmed.gla.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

MASCOT1

Study information

Scientific Title

Exploratory randomised controlled trial of a behavioural treatment programme for obesity in Malaysian children

Acronym

MASCOT

Study objectives

To test the hypothesis that group based behavioural change counselling for childhood obesity produces greater improvements in weight status and psychosocial outcomes than (waiting list) control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the National University of Malaysia (University Kebangsaan Malaysia) (UKM), approved on 16/10/2008 (ref: FF-255-2008)

Study design

Randomised assessor-blinded controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

The participants will be randomly assigned to either the intervention group or the "waiting list" control group.

Exercise sessions with children. 8 x 60 minute sessions involving fun aerobic games led by a physiotherapist.

Behaviour change counselling delivered to parents in group sessions. 8 x 60 minute sessions, 7/8 treatment sessions led by a dietitian, the other one led by a health psychologist.

The 8 treatment sessions are delivered over 6 months (24-26 weeks).

Sessions 1-4 are delivered fortnightly for first 8 weeks.

Session 5 at 12 weeks

Session 6 at 16 weeks

Session 7 at 20 weeks

Session 8 at 24 weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in BMI standard deviation score from baseline to 6 and 12 months.

Secondary outcome measures

Changes from baseline to 6 and 12 months in the following:

1. Health related quality of life, assessed by the Pediatric Quality of Life Inventory™ (PedsQL)
2. Objectively measured habitual physical activity and sedentary behaviour (accelerometry)
3. Changes in estimated fat and fat free mass (impedance)

Overall study start date

01/12/2008

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Both males and females
2. Children and adolescents aged 6-13 years
3. No major chronic disease or disability
4. No obvious underlying pathological cause of obesity
5. Obese (Body mass index [BMI] above 95th percentile on US Centers for Disease Control and Prevention [CDC] percentile charts)
6. Parents (at least one) and children willing to attend treatment sessions if randomly allocated to treatment group
7. Attending a mainstream school in the public sector

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

13 Years

Sex

Both

Target number of participants

Approximately 110

Total final enrolment

107

Key exclusion criteria

1. Non-obese
2. Not attending a mainstream school
3. Serious chronic or acute illness
4. Not within age range
5. Not willing to attend treatment sessions

Date of first enrolment

01/12/2008

Date of final enrolment

31/12/2009

Locations**Countries of recruitment**

Malaysia

Scotland

United Kingdom

Study participating centre

University of Glasgow

Glasgow

United Kingdom

G3 8SJ

Sponsor information

Organisation

National University of Malaysia (University Kebangsaan Malaysia) (Malaysia)

Sponsor details

Faculty of Allied Health Sciences
Jln Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300
+60 3 4040 5512
webmaster@ukm.my

Sponsor type

University/education

Website

<http://www.ukm.my/portal/index.html>

ROR

<https://ror.org/00bw8d226>

Funder(s)**Funder type**

Government

Funder Name

Ministry of Higher Education (Malaysia)

Alternative Name(s)

Ministry of Higher Education, Egypt, Egyptian Ministry of Higher Education, MOHE

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Egypt

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	01/06/2011	04/07/2019	Yes	No
Results article	results	01/08/2011	04/07/2019	Yes	No