

# Malaysian Childhood Obesity Treatment Trial (MASCOT)

<b>Submission date</b> 25/11/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/02/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/07/2019	<b>Condition category</b> 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

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 years

**Upper age limit**

13 years

**Sex**

All

**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**

United Kingdom

Scotland

Malaysia

### **Study participating centre**

**University of Glasgow**

Glasgow

United Kingdom

G3 8SJ

## **Sponsor information**

### **Organisation**

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

### **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

### 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?
<a href="#">Results article</a>	results	01/06/2011	04/07/2019	Yes	No
<a href="#">Results article</a>	results	01/08/2011	04/07/2019	Yes	No