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Malaysian Childhood Obesity Treatment Trial (MASCOT)

Submission date	Recruitment status
25/11/2008	No longer recruiting
Registration date	**Overall study status**
18/02/2009	Completed
Last Edited	**Condition category**
04/07/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

ClinicalTrials.gov (NCT)
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?
Results article	results	01/06/2011	04/07/2019	Yes	No
Results article	results	01/08/2011	04/07/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes