

# The Malaysian Childhood Obesity Treatment Trial (MASCOT)

Sharifah WW<sup>1</sup>, Nur Hana H<sup>2</sup>, Ruzita AT<sup>2\*</sup>, Roslee R<sup>2</sup> & Reilly JJ<sup>1</sup>

<sup>1</sup> University of Glasgow School of Medicine, Yorkhill Hospitals, Glasgow G3 8SJ, Scotland

<sup>2</sup> Department of Nutrition & Dietetics, Faculty of Allied Health Sciences, Jalan Raja Muda Abdul Aziz, 50300 Kuala Lumpur, Malaysia

## ABSTRACT

**Introduction:** The present study describes a randomised controlled trial (RCT) based on a novel, generalisable intervention for childhood obesity, comparing the intervention with a no-treatment control group. **Method:** The Malaysian Childhood Obesity Treatment Trial (MASCOT) was a single-blind RCT of a dietetic treatment for childhood obesity in children of primary school age (7 to 11 years old) in Kuala Lumpur, Malaysia. The MASCOT comprising eight sessions, of an 8-hour family-centred group treatment programme is described, based on behavioural change techniques. The study sample was characterised by BMI z-score, health related quality of life reported by participants and their parents (PedsQL questionnaire), objectively measured habitual physical activity and sedentary behaviour (Actigraph accelerometry) **Results:** The MASCOT sample of 107 children was characterised by a low quality of life, mean total score on PedsQL 67.7 (4.5) as reported by the children, and 66.0 (16.4) as reported by their parents. The children spent, on average, 89% of their waking day on sedentary activity, and 1% of the day in moderate-vigorous intensity physical activity, equivalent to only around 8 minutes/day. **Conclusion:** Obese children in the MASCOT study had an impaired quality of life, high levels of sedentary behaviour and very low levels of physical activity.

**Keywords:** BMI, childhood obesity, obesity treatment, physical activity, quality of life, sedentary behaviour

## INTRODUCTION

Approximately 75% of all obese children live in low-middle income countries (Kipping, Jago & Lawlor, 2008). While obesity is a public health problem which requires preventive measures, treatment for those already obese is urgently required. A recent systematic review reported that most treatment randomised controlled trials

(RCTs) for childhood obesity were from the USA (56%), Europe (22%), South America or Middle East (9%) and Australia (7%) (Luttikhuis *et al.*, 2009), leaving doubts over generalisability of the published literature on obesity treatment to low-middle income countries.

There has been considerable progress in the development of treatment for childhood obesity giving rise to a number of promising

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\* Correspondence author: Ruzita Abd Talib; Email: [rzt@medic.ukm.my](mailto:rzt@medic.ukm.my)

strategies for the successful management of childhood obesity (Epstein *et al.*, 1994; Savoye *et al.*, 2007). Recent systematic reviews (Luttikhuis *et al.*, 2009) and clinical management guidelines (NICE, 2006; ADA, 2006) have described *what* behaviours to target for change (diet, physical activity and sedentary behaviour). However, practitioners and researchers need guidance on *how* to encourage behavioral change in the form of published treatment programmes (Hughes *et al.*, 2008). Evidence-based-literature descriptions of treatment programmes for childhood obesity are scarce, and only a few describe interventions which are simple and readily generalisable (Stewart *et al.*, 2005; Nowicka, Pietrobelli & Flodmark, 2007) and none of these have been written with low-middle income countries in mind. There is therefore a need for practical guidance as to how to implement current evidence-based recommendations for childhood obesity treatment in low- and middle-income countries.

There is a lack of evidence on important variables such as quality of life, objectively measured physical activity and sedentary behaviour in obese children. The present study therefore aims to describe a behavioral, family-centred, group based treatment programme for childhood obesity in Malaysia - the MASCOT (Malaysian Childhood Obesity Treatment ([www.control-led-trials.com/ISRCTN14241825](http://www.control-led-trials.com/ISRCTN14241825)), that is, evidence-based recommendations of recent systematic reviews and clinical guidelines that need to be put into practice. A second aim is to characterise the MASCOT sample for quality of life, objectively measured habitual physical activity and sedentary behaviour, and other characteristics.

## **RATIONALE FOR MASCOT TREATMENT PROGRAMME**

The development of the treatment programme was based on an adaptation of guidelines to the Malaysia setting. The MASCOT treatment focuses on change in the

three key behaviours recommended as the principal targets of obesity treatment in recent systematic reviews of childhood obesity treatment (Luttikhuis *et al.*, 2009) and evidence based clinical guidelines on childhood obesity treatment (NICE, 2006; ADA, 2006) such as reductions in sedentary behaviour, particularly screen-time, increases in physical activity and changes in diet. Parents are targeted as the main agents of lifestyle change, as recommended by recent systematic reviews and clinical guidelines and Golan, Kaufman & Shahar (2006).

It is felt that an eight-session intervention (with a total dose of patient contact of around eight hours) delivered by a dietitian/nutritionist to groups of parents would be more generalisable than the more intense and longer duration interventions which have been described in the US (Savoye *et al.*, 2007), many of which require much greater patient contact over a much longer period.

The MASCOT treatment is intended as a family-centred approach based on a heavily adapted version of treatments used in two recent RCTs for childhood obesity treatment (Savoye *et al.*, 2007; Hughes *et al.*, 2008). The intervention is underpinned by two well recognised theories of behavioral change: the transtheoretical model (Prochaska & DiClemente, 1986) and the social cognitive theory (Newman, Steed & Mulligan, 2004). Various behavioral change techniques were employed in the MASCOT trial intervention in order to (i) assist the parent and child in raising their awareness of their lifestyle; (ii) help them focus on the aspects of their lifestyle which require changes; (iii) motivate the child and family to make lifestyle changes; and (iv) help the child and family monitor those changes. The behavioural change techniques used include assessing readiness to change, self-monitoring, goal-setting, rewards and contracting, problem-solving, and preventing relapse (Stewart *et al.*, 2005).

The content and timing of treatment sessions are described in Table 1. There were

**Table 1.** Components and schedule of the MASCOT treatment programme

Session	Topics	Contents	Behavioral change technique	Week
1	Wake up call	Risky life The benefits and sacrifice of weight management Readiness to change	<ul style="list-style-type: none"> <li>• Readiness to change and decisional balance</li> </ul>	1-2
2	Eat well, be well	Energy balance Healthy eating plan-Traffic Light Diet Food reference guide	<ul style="list-style-type: none"> <li>• Goal setting, contracting and rewards</li> <li>• Self-monitoring</li> </ul>	3-4
3	Be active!	How to motivate child to initiate physical activity How to decrease sedentary behaviour	<ul style="list-style-type: none"> <li>• Goal setting, contracting and rewards</li> <li>• Self-monitoring</li> </ul>	5-6
4	Make a better life	Eating a daily breakfast Family meal Fast food Label reading	<ul style="list-style-type: none"> <li>• Problem-solving</li> <li>• Self-monitoring</li> </ul>	7-8
5	I feel good	Parenting skills How to be a good role model? Dealing with stress	<ul style="list-style-type: none"> <li>• Problem-solving</li> <li>• Self-monitoring</li> </ul>	11-12
6	Let's cook together	Making foods together How to modify food in a healthy way		15-16
7	Simply the best	Understand a relapse How to improve current diet and physical activity Tips maintaining a successful routine	<ul style="list-style-type: none"> <li>• Problem-solving</li> <li>• Preventing relapse</li> </ul>	19-20
8	Sharing is caring	The most admirable family of the programme Sharing tips with other parents Long-term goal setting	<ul style="list-style-type: none"> <li>• Goal setting, contracting and rewards</li> </ul>	23-24

†Behavioural change techniques were used in every session except for Session 6. However, only specific techniques were used in each session.

four groups, each consisting of thirteen children and their parents. Treatment sessions were directed at parents only and were facilitated largely by a dietician (eight hours) with some input from a psychologist.

Concurrently, while their parents were participating in the treatment sessions, children in the MASCOT intervention group participated in a physical activity class facilitated by an exercise physiologist. The MASCOT intervention also focused on physical activity and sedentary behaviour in the sessions directed at the parents (Table 1); goals were set in relation to physical activity and sedentary behaviour.

The intervention used a simplified 'Traffic Light Diet' in order to teach parents and subsequently their children the foods that should be avoided/reduced and which could be consumed freely (Stewart *et al.*, 2005). The MASCOT nutrition education content (Table 1) also included teaching the concepts of energy balance, and appropriate food label reading, and encouragement towards more modest portion sizes.

MASCOT Treatment Programme is described here to facilitate its application in obesity treatment trials in Malaysia.

## METHODOLOGY

### Study Participants

A list of 136 government-owned-primary schools in Kuala Lumpur was obtained from the Kuala Lumpur Federal Territory Education Department. From these 136 schools, 10 schools were selected randomly. Schoolchildren were then screened to determine if they had a BMI  $\geq$ 95th percentile for age and sex relative to the US Center for Disease Control 2000 reference, a definition used for classification of obese children (<http://www.cdc.gov/growthcharts>). Other inclusion criteria were children aged 7-11 years old and with at least one parent willing to take part in the study. Children were excluded if they had an obvious underlying medical cause of obesity, or had serious co-

morbidity. In total, 107 children met the inclusion criteria and agreed to participate in the study; 52 subjects were randomised to receive the treatment and 55 to the no-treatment control group.

The study was approved by the Medical Research & Ethics Committee, Faculty of Medicine, Universiti Kebangsaan Malaysia, Kuala Lumpur. The parents and children provided informed written consent to take part in the study.

### Sample size, power, and statistical analysis

The present study was powered using BMI data from the Scottish Childhood Obesity Treatment Trial (SCOTT) RCT (Hughes *et al.*, 2008). With a difference in the change in BMI z-score of -0.25 at six months between groups and the SD of the change in BMI z score of 0.21, giving a delta of 1.15, a sample size of around 30 children per arm at 6 months would give 90% power at the 0.05 significance level. It was intended that around 100 children would enter the trial to allow for sample attrition during the 6-month study.

Data were analysed using SPSS version 14.0. All the data are reported as mean and standard deviation as they were normally distributed.

### Anthropometric measurements

The child's height was measured using the Leicester height measure with socks and shoes removed. To ensure accuracy of measurements, height was measured 2-3 times for each subject and the mean was recorded. Height was measured to the nearest 1mm. The child's weight was measured using a TANITA with children lightly clothed and without shoes. Again, height was measured 2-3 times for each subject and the mean was recorded to ensure accuracy. Weight was measured to the nearest 0.1 kg.

Weight status was expressed as BMI z-scores calculated relative to US 2000 CDC

BMI for age reference data (<http://www.cdc.gov/growthcharts>).

### Habitual physical activity

In the MASCOT study, habitual physical activity and sedentary behaviour were measured objectively over five days at baseline using a MTI GT1M accelerometer (MTI, Pensacola, Florida). Participants were instructed to wear the accelerometer on a waist belt as described previously (Reilly *et al.*, 2008). The accelerometers were set to record activity in one-minute epochs; accelerometry counts per minute (cpm) were used as a measure of total volume of physical activity (Reilly *et al.*, 2008). Habitual physical activity data were also summarised as percentage of the time spent in sedentary light intensity physical activity and moderate to vigorous intensity physical activity (MVPA) – these constructs were determined from the accelerometer output by use of empirically determined cut-off points based on previous paediatric validation studies (Reilly *et al.*, 2008). The cut off points used in the present study were as follows: <1100 cpm (sedentary behaviour) (Reilly *et al.*, 2003); 1100-3200 cpm (light intensity activity) (Reilly *et al.*, 2008); >3200cpm (MVPA) (Reilly *et al.*, 2008).

### Health-related quality of life (QoL)

Health related QoL was measured using the Paediatric Quality of Life Inventory (UK) version 4.0 (PedsQL™ 4.0), translated into Malay. The PedsQL was chosen due to its ability to provide parent-proxy and child self-report measures and the evidence that it is both valid and reliable (Varni, Burnwinkle & Seid, 2006). In brief, the PedsQL is both a child self-report and a parent proxy-report scale consisting of 23 items in four domains: physical, emotional, social and school functioning. The physical domain consists of 8 items, emotional domain of 5 items, social domain of 5 items and the school-functioning domain of 5 items. This measure

was scored as described previously (Varni *et al.*, 2006) using a five-point scale (0 = never; 1 = almost never; 2 = sometimes; 3 = often; 4 = always). Items were reverse-scored and linearly transformed to a 0–100 scale (0=100, 1=75, 2=50, 3= 25, 4=0), so that higher scores indicate better QoL (Varni *et al.*, 2006). A total scale score, from all 23 items, was calculated to provide an overall measure of the QoL (Varni *et al.*, 2006), and two sub-domains were also calculated from composites of the 23 items, that is, a physical QoL and psychosocial sub-scale (2,5).

## RESULTS

### Characteristics of participants

The sample consisted of 107 children, 54 boys and 53 girls, with the mean age of the study sample being 9.8 (SD 1.5) years.

### Anthropometry of study participants

The anthropometric characteristics of the study participants are given in Table 2. The mean BMI z-score relative to US-CDC reference data was  $2.9 \pm 0.6 \text{ kg/m}^2$ . Mean height's score relative to US-CDC reference data was 0.5 (SD 0.9).

### Objectively measured habitual physical activity and sedentary behaviour of study participants

Data on objectively measured habitual physical activity and sedentary behaviour are shown in Table 2. For habitual physical activity and sedentary behaviour, 20 data points were missing due to accelerometer failure, or poor compliance with the accelerometry protocol, and therefore only 87 data points are presented from the 107 study participants. The proportion of monitored time spent in sedentary behaviour was high in both groups, at around 89% of the waking day time, or about 12 waking hours of the day. Participation in moderate to vigorous physical activity was extremely low in both groups at an average



methods to measure physical activity and sedentary behaviour of obese children. Very low levels of objectively measured physical activity and very high levels of objectively measured sedentary behaviour may be very common among obese children (Hughes *et al.*, 2006).

The present study also suggests that quality of life is low among obese children in Malaysia. For quality of life, the child self-reported total scale score for the sample of the present study of 67.7 (14.5), was below the score reported by Varni, Seid & Curtin (2001) for chronically ill children, mean 77.2 (15.5). Parents reported mean total score was also below the Varni *et al.* (2001) score for chronically sick children, mean 74.2 (18.4). The scores of both the children and the parents for QOL in the present study were therefore down in the range for children with serious chronic disease. The present study was also consistent with results reported by Hughes *et al.* (2007) that showed that both children and parents in a UK childhood obesity treatment trial reported quality of life down in the range of chronically sick children using the same PedsQL method. The results of this study suggest that impaired quality of life among obese children is not unique to the western world.

The main strength of this study is its novelty - no studies of this kind have been undertaken in Malaysia. The treatment programme which is described should be generalisable, and therefore might be suitable for inclusion in current treatment service delivery models within the Malaysian public healthcare system, and elsewhere. Systematic reviews have suggested that longer and more intensive treatment programmes might produce greater improvements in weight status, but such interventions are much less likely to be practical. The efficacy of the MASCOT treatment programme which is described here is not conclusive as the study is ongoing and further results will be published

separately. However, attendance/adherence to the treatment intervention was fairly similar to that described in studies of childhood obesity treatment in the West which suggests that the treatment is practical in Malaysia.

## CONCLUSION

In conclusion, obese children in Malaysia have an impaired quality of life, high level of sedentary behaviour and very low level of physical activity. Additionally, the description given of a novel treatment programme which is based on systematic reviews and clinical management guidelines for childhood obesity will strengthen childhood obesity management in Malaysia.

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