Randomized controlled trial of a good practice approach to treatment of childhood obesity in Malaysia: Malaysian Childhood Obesity Treatment Trial (MASCOT).

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Abstract

Context. Few randomized controlled trials (RCT) of interventions for the treatment of childhood obesity have taken place outside the western world.

Aim. To test whether a good practice intervention for the treatment of childhood obesity would have a greater impact on weight status and other outcomes than a control condition in Kuala Lumpur, Malaysia.

Methods. Assessor blinded RCT of a treatment intervention in 107 obese 7-11 year olds. The intervention was relatively low intensity (8 hours contact over 26 weeks, group based), aiming to change child sedentary behavior, physical activity, and diet using **behavior change counselling .** Outcomes were measured at baseline and 6 months after the start of the intervention. Primary outcome was BMI z-score, other outcomes were weight change, health-related quality of life (Peds QL), objectively measured physical activity and sedentary behavior (Actigraph accelerometry over 5 days).

Results. The intervention had no significant effect on BMI z score **relative to control. Weight gain was reduced significantly in the intervention group compared to the control group (+1.5kg vs. +3.5kg respectively, t test p<0.01**). Changes in health related quality of life and objectively measured physical activity and sedentary behavior favored the intervention group.

Conclusions. Treatment was associated with **reduced rate of weight gain, and improvements in physical activity and quality of life**. More substantial benefits may require **longer term and** more intensive interventions which aim for more substantive lifestyle changes.

Keywords. Obesity; overweight; children; treatment; BMI; randomized controlled trial.

INTRODUCTION

Prevalence of childhood obesity has increased rapidly in Malaysia in recent years (1,2) as in much of the rest of the world (3,4). While prevention strategies for obesity are paramount, systematic reviews have concluded that most preventive interventions have had limited impact (5,6). Childhood obesity has a large number of short and long-term co-morbidities (7), and there is an ever-greater need to offer weight management interventions (8). In addition, successful treatment of childhood obesity might be useful as secondary prevention, by reducing the impact of childhood obesity on obesity and its co-morbidities later in life (8).

Despite the importance of treatment interventions for childhood obesity, recent systematic reviews have found almost no evidence on treatment interventions outside the developed world (9-11). Specifically, the recent Cochrane review (9) found no **eligible** randomised controlled trials (RCT) of treatment interventions from the developing world, with the exception of **one single study from** China. As a result, the generalisability of the existing evidence base on treatment of childhood obesity to much of the world is questionable. The primary aim of the present study was therefore to test the hypothesis that a 'good practice' intervention for the treatment of childhood obesity in Kuala Lumpur, Malaysia, would have a greater effect on primary and secondary outcomes than allocation to a control group.

METHODS

Participants

The study was conducted at the National University of Malaysia, (UKM), Kuala Lumpur, during 2009. For entry into the study, children age 7–11 years had to: be obese (BMI above the 95th percentile relative to US reference data) **(12); have** at least one parent who perceived their child's weight status as a problem and were willing to attend the intervention described below. **The perception that child weight status was a problem was considered important to obtaining a sample which was receptive to treatment, and sufficiently motivated to attend treatment and measurement sessions.** Children were excluded if they had serious co-morbidity requiring treatment. Children were recruited from their primary schools after BMI screening conducted by one of the researchers (SWW). Ethical approval was obtained from the UKM (FF-255-2008), and written informed consent was obtained from both parents and children.

Randomisation and allocation concealment

Participating children attended a research clinic where all baseline measures (see below) were taken, then assigned a unique study code prior to random allocation into treatment or control group. To ensure concealment of allocation, codes were sent electronically to a statistician (JHM) who produced a computer generated randomisation list which allocated participants to intervention or control group so that groups were balanced in blocks of 20. The statistician informed the researchers responsible for delivering the intervention (HNH, LN) of the allocation, and families were invited to intervention or waiting list control groups as appropriate.

Intervention

In brief, the intervention was intended as a relatively low intensity (8 session, 8 hour contact time, delivered as group sessions) program, delivered over a 26-week period largely by a dietitian (HH) **who led every session**. Input from a clinical psychologist (LN) supported the work of the dietitian outside treatment sessions, and provided support to parents directly **during one session. This input helped ensure that the program remained parent-centred and the psychologist advised on decisional balance, self-monitoring, goal setting, contracting, use of rewards, and relapse prevention**. **The dietitian and psychologist had limited experience of childhood obesity management prior to the trial**. The program was adapted from the Scottish Childhood Obesity Treatment Trial (SCOTT) **(13).** The treatment program involved greater contact time than SCOTT and was delivered as a group intervention targeting the parents only, unlike SCOTT **(13, 14).** Modifications to the 'SCOTT' treatment program were made **in order to use the parents as the main agents of change, a successful approach in some studies (9,15),** and **because** group sessions **were less expensive** . The first four sessions were held every 2 weeks and the next four every month for 4 months There were four groups, each consisting of thirteen parents **(52 parents in total, 47 mothers, five fathers).** Parents were provided with treatment **materials that were adapted from those used in the SCOTT (13,14) and ;'Bright Bodies (16) childhood obesity treatment RCT.** The content of each session is outlined **in Table 1.**

The intervention is described here as a 'good practice' intervention because it was parent-centred (13,14,17), focused on changing the behaviors recommended in recent evidence based management guidelines (11, 18-21) for the treatment of childhood obesity (sedentary

behavior, particularly TV viewing; diet, using a modified version of the 'traffic light diet' system (13, 14; and physical activity (11, 18-21), and used a variety of behavior change techniques which are grounded in models of behavior change, particularly the trans-theoretical model and social cognitive theory (13,14, 17). These behavior change techniques were applied to all three of the targeted behaviors during parent-only intervention sessions, and consisted of: exploration of the pros and cons of change**s in diet, physical activity, and sedentary behavior**; exploration of motivation to change **diet, physical activity, and sedentary behavior**; self monitoring of sedentary behavior **(recording of screen time in diaries)**, diet, and physical activity **(recording of walking, sport, and physically active play in a diary)**; identifying the main barriers to behavior change and problem solving in relation to these barriers; goal setting **in relation to diet, physical activity, and sedentary behavior** and behavioral contracting; use of appropriate rewards for achieving **diet goals, physical activity goals, and sedentary behavior** goals; relapse prevention.

During the eight intervention sessions directed at parents, participating children attended a physical activity session led by an exercise instructor (RA)**.**

Control group

Children who were allocated randomly to the control group did not receive treatment until at least 6 months had elapsed, after the study had ended.

Outcome measures and blinding

Outcome measures were made at baseline and again at 6 months (25-27 weeks) after the start of the intervention by the same trained researcher (SWW) who was blinded to group allocation and was not involved in delivery of the treatment program. In the absence of Malaysian reference data for BMI for age, the primary study outcome measure was BMI z-score calculated relative to US CDC 2000 BMI for age reference data (12, see also **www.cdc.gov/growthcharts).** Weight was measured to 0.1kg in light indoor clothing with children not wearing shoes, and height was measured to 0.1cm with a portable stadiometer **(Leicester Height Measure, SECA, UK)** and children not wearing shoes.

A number of secondary outcomes were also measured. Habitual physical activity and sedentary behavior were measured objectively (22,23) over five days-during the waking hours- at baseline and follow up using a CSA/MTI GT1M accelerometer (The Actigraph, Fort Walton Beach, Florida, USA). Accelerometry data were included so long as at least 4 days of monitoring with at least 10 hours per day were obtained. In children this age 3-4 days of accelerometry provides high reliability for the assessment of all constructs of physical activity and sedentary behavior (24,25). Participants were instructed to wear the accelerometer around the waist on a waist belt as described previously (22). The accelerometers were set to record activity in 15 second epochs, collapsed to 1 minute when cut-points were applied to measure the intensity of physical activity and sedentary behavior. Accelerometry counts per minute (cpm) were used as a measure of total volume of physical activity. Accelerometry data were also summarised using cut-points as percentage of the time spent in sedentary behavior (<1100cpm; 23) light intensity physical activity (1100-3200 cpm), and moderate to vigorous intensity physical activity (MVPA; 26) –these are all empirically determined cut-off points based on previous pediatric validation studies (23,26).

Health- related Quality of Life (QoL) of participating children was assessed by using the validated Pediatric Quality of Life Inventory ('PedsQL') 4.0 Generic Core Scales (27). The Peds QL scales produce a Physical Health Summary Score (the total of the physical functioning subscale) and a Psychosocial Health Summary Scale (from the emotional, social and school functioning subscales) which add to give a Total Score. Both the participating parents and children were asked to complete the Peds QL, providing separate parent and child perspectives since these can be quite different and both are important (28).

Sample size, power, and statistical analysis

The present study was powered using BMI data from the Scottish Childhood Obesity Treatment Trial (SCOTT) RCT (13). 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 be entered into the trial to allow for sample attrition during the 6-month study.

Outcomes were analyzed in two ways. First, changes in outcome variables *within* each group (intervention and control) between baseline and 6 month follow up are presented, and the significance of within group (within participant) changes analysed by paired t-tests. Second, the issue of whether changes in outcome variables differed significantly between groups (intervention versus control) was examined using independent sample t-tests. The analysis **used** all children for whom data were available on the basis of the group they were allocated regardless of their adherence to the protocol (i.e. attendance). A pre-planned secondary analysis was also conducted using the 'per-protocol' approach (13) and involved participants

who attended at least 75% of scheduled sessions (≥ 6/8 sessions) defined as 'completers'; participants with <6 of the 8 sessions attended are referred to as 'non completers' .The planned per protocol analysis was performed for BMI z-score and weight for the completers in order to test whether adherence to the treatment programme (as indicated by attendance, a proxy measure of adherence) had any greater impact on these outcomes.

RESULTS

Flow of participants through the trial and participant characteristics

Figure 1 describes the flow of participants through the trial**.** Of the 107 participants entered at baseline, 80 (75%) attended for outcome measures at the six-month follow-up. There were no significant differences between intervention and control groups for child age, anthropometric measures and weight status, or for physical activity, sedentary behavior, or quality of life (**table 2)**. All study participants were obese defined using both US-CDC BMI for age criteria (above the 95th percentile) and the Cole-IOTF definition of obesity.

Weight based outcome data and quality of life data were available for all study participants, but for the baseline physical activity and sedentary behavior measurement, 20 data points **(19%)** were missing due to accelerometer failure and poor compliance with the accelerometry protocol.

Changes in weight status *within and between* groups

Table 3 provides data on change in weight and BMI. There were no statistically significant differences *within* the two groups over the 6 months for BMI z-scores and weight. There was no significant difference *between* the groups for the six-month changes in BMI z score, though six-month changes in weight differed significantly between groups, favoring the intervention (table 3).

Per-protocol analysis was also conducted as described above, comparing outcomes in the intervention group completers versus controls. **Changes in BMI z score over the 6 months were not statistically significant within the two groups, and did not differ significantly between intervention and control groups. Changes in body weight were significantly ($p<0.01$) reduced in the** intervention group (mean change +1.5kg, SD 2.4) **compared to the** control group (mean change +3.5, SD 2.0).

Changes in objectively measured habitual physical activity and sedentary behavior *within and between* groups

Table 3 gives changes in objectively measured physical activity and sedentary behavior within and between-groups over the six-month period. There was a statistically significant increase in the percentage of time spent in MVPA in the treatment group over the 0-6 month time interval ($p=0.01$), but no significant change in the control group. However, the difference in the change in MVPA between groups was not statistically significant**.** No other changes in physical activity and sedentary behavior within or between groups were statistically significant.

Changes in health-related quality of life *within and between* groups

Changes in quality of life between the two groups were not statistically significant, with the exception of the parent-reported total score (table 3)

Discussion

Main findings, study implications, and comparisons with other evidence

The present study suggests that conducting randomised controlled trials of obesity treatment interventions in Malaysia is feasible. An expansion of interventions to treat childhood obesity is required because most obese children now live in low-middle income countries (29). However, the recent Cochrane review of childhood obesity treatment RCT (9) **found no eligible RCT from low-middle income countries, with the sole exception of a study from China which was not directly comparable with the present study as it included 12-14 year olds and used an approach to treatment which was quite different.**

The present study found that changes favoring the treatment group were small: a reduced rate of weight gain; an improvement in MVPA (which, at just a few minutes per day, was probably not biologically significant); an improvement in parent-reported quality of life. The degree of change in body weight status which might be desirable in a childhood obesity treatment intervention is currently uncertain (11), **and would be a valuable direction for future research,** but improvements in cardiometabolic risk factors may require greater changes than were observed in the present study (30,31). Weight maintenance, or modest weight loss, is commonly recommended as the aim of childhood obesity treatment interventions (11,17-21), but this is rarely achieved by the majority of patients (9,13). In the present study 9/34 children in the treatment group maintained or lost weight over the 6-month period, 0/45 children in the waiting list control group did so. **Recent childhood obesity treatment RCT 's which involved longer term follow up provided some encouragement that treatment interventions which achieve modest improvements**

in BMI z score over 6-12 months might lead to improvements in weight status which are sustained for longer periods (32,33).

The present study was designed as a relatively low intensity (8 hour) intervention in order that it would be generalisable. Higher intensity childhood obesity treatment interventions usually have more marked effects on body weight status and other outcomes (9,16,**34**), but the higher the intensity of the intervention the less likely it is to be generalisable.

Levels of objectively measured physical activity of participating children were very low in the present study, with children typically spending only around 7 minutes/day in MVPA. Levels of objectively measured sedentary behavior (defined as no movement of the trunk; 22,23) were very high.

Health related quality of life of participating children was generally low relative to studies of healthy children (27,28), and this is also consistent with most of the literature on quality of life in pediatric obesity, all of which appears to have come from the western world to date (28). The modest improvements in quality of life associated with treatment which were observed in the present study have been reported elsewhere following a variety of different kinds of obesity treatment programs in children (13, 34)**.**

Study strengths and weaknesses

The principal strengths of the present study were: the high level evidence obtained, with adherence to the CONSORT statement on conduct and reporting of RCT (35); **the testing of a potentially generalisable intervention;** inclusion of a large number of study outcomes ; completing a challenging childhood obesity treatment RCT (36) in the novel setting of a low middle-income country.

Longer-term outcome measures would have been useful to assess the **sustainability of** intervention effects **on weight status, and longer-term follow up should be included in future trials**; an assessment of parent and child perspectives on the treatment program would have been desirable in order to inform future treatment interventions (37,38); **dietary assessment and assessment of cardiometabolic risk factors were not undertaken** - these were not feasible given resource constraints. The **trial was directed at parents who perceived their children's weight status as a problem, and treatment interventions aimed at parents who might not recognise that their children are obese, or that this is a problem, would be important in future. Future interventions might also find it useful to focus treatment at participating children, but this was not possible in the present study due to resource limitations**.

Conclusions

The present study suggests that a good practice intervention for treatment of childhood obesity in Malaysia **might have modest benefits which are** broadly comparable to those achieved by similar interventions in the developed world (13)**, though longer term follow up would be required to confirm whether or not the benefits persist.** The present study

could help inform the development of future treatments of childhood obesity in low and middle-income countries.

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Author contributions

Original concept: Reilly, Sharifah Wajihah Wafa.

Design of intervention: All authors.

Design of study: All authors.

Acquisition of data: Sharifah Wajihah Wafa

Interpretation of data: All authors.

Drafting and critical revision of manuscript: All authors.

Conflicts of interest: None.

Ethics Committee Approval: National University of Malaysia.

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Table 1 Components of the MASCOT treatment program

Session	Topic	Contents	Behavioural change technique(s)	Week
1	Wake up call	Risks of obesity The pros and cons of weight management Readiness to change	• Readiness to Change and Decisional Balance	1-2
2	Eat well, be well	Energy balance Healthy eating plan-Traffic Light Food composition	• Goal Setting, Contracting and Rewards • Self-Monitoring	3-4
3	Be active!	Increase physical activity Decreasing sedentary behavior	• Goal Setting, Contracting and Rewards • Self-Monitoring	5-6
4	Better eating	Family meals Fast food/snacks Label reading	• Problem-solving • Self-Monitoring	7-8
5	Parenting	Parenting skills How to be a good role model? Dealing with stress	• Problem-solving • Self-Monitoring	11-12
6	Let's cook together	Making foods together How to modify food in a healthy way		15-16
7	Problem solving; relapse prevention	Understanding relapse How to improve current diet and physical activity Tips maintaining a successful routine	• Problem-solving • Preventing Relapse	19-20
8	Long term goals; relapse prevention	Sharing tips with other parents Long-term Goal setting	• Goal Setting, Contracting and Rewards	23-24

Table 2. Characteristics of participating children at baseline

Characteristic	Full Sample n=107	Treatment Group n=52	Control group n=55
Male/Female	54/53	28/24	26/29
Age (years)	9.8 (1.5)	9.7 (1.4)	9.9 (1.6)
Anthropometric measurements			
Height (cm)	140.0 (10.2)	139.6 (9.8)	140.3 (10.7)
Weight (kg)	54.5 (13.1)	54.5 (12.1)	54.6 (14.0)
BMI (kg/m^2)	27.8 (5.5)	27.6 (3.4)	28.0 (7.0)
BMI z-score[1]	2.92 (0.61)	2.90 (0.49)	2.95 (0.60)
Habitual Physical Activity			
Total physical activity (cpm)	365 (143)	387 (140)	335 (144)
% monitored daytime			
Sedentary Behavior	89.1 (4.5)	88.5 (4.5)	89.8 (4.4)
Light Intensity Physical Activity	9.6 (4.7)	10.3 (4.7)	8.8 (4.7)
MVPA	1.0 (1.0)	0.9 (0.8)	1.0 (1.1)
Quality of Life			
Total: Child report	67.7 (14.5)	67.6 (13.6)	67.8 (15.4)
Total : Parent report	66.0 (16.4)	65.1 (15.7)	66.9 (17.2)

Footnotes:

No differences between the two groups significant at baseline

[1] z-score calculated relative to US reference data (12).

Table 3. Six- month changes in all outcome measures within and between-groups (n = 34 treatment group vs. 45 controls).

Outcome	Intervention Group Within-group change Mean (SD)	Control Group Within-group change Mean (SD)	Between-Group Difference, Mean (95% CI), P value
BMI z score	0.00 (0.72)	+0.10 (0.50)	-0.09 (-0.32, +0.30), 0.79
Weight (kg)	+1.5 (2.5)	+3.5 (2.0)	-1.9 (-0.8, -2.8), <0.01
Total physical activity (cpm)	+33 (133)	+16 (124)	+16 (-53, +86), 0.64
%of day time in Light intensity physical activity	+1.2 (5.0)	0.0 (3.6)	+1.2 (-1.0, +3.3), 0.40
Moderate-vigorous physical activity	+0.5 (1.0)*	0.0 (1.5)	+0.5 (-0.1, +1.2), 0.11
Sedentary behaviour	-1.3 (4.6)	-0.1 (3.4)	-1.2 (-3.3, +1.0), 0.29
Quality of life Parent-report:			
Psychosocial scale	+5.0 (19.0)	-1.9 (15.0)	+6.9 (-0.7, +14.5), 0.07
Physical scale	+0.7 (27.5)	-3.6 (22.9)	+4.3 (-7.0, +15.6), 0.45
Total	+3.9 (19.3)	-4.2 (15.5)	+8.0 (+0.3, +15.8), 0.04
Quality of life Child-report:			
Psychosocial scale	+6.0 (14.3)	-0.6 (16.0)	+6.6 (-0.3, +13.5), 0.06
Physical scale	+2.8 (18.6)	-3.3 (22.2)	+6.1 (-3 .3, +15.5),0.20
Total	+5.0 (11.6)	-1.4 (16.1)	+6.3 (-0.2, +12.7) 0.05

Flow of participants through the trial: Figure 1