Randomised Controlled Trial of a Good Practice Approach to Treatment of Childhood Obesity and Health-related Quality of Life and Habitual Physical Activity and Sedentary Behaviour of Obese Children in Malaysia

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ABSTRACT

Childhood obesity is a leading global public health issue. **Chapter One** of this thesis is a literature review of the evidence concerning the issue of childhood obesity and its management. The literature review describes this issue in terms of national and international prevalence and trends, health consequences and determinants. The literature review examines the evidence to guide effective management of childhood obesity. The role of parents in the management of childhood obesity has been identified as a promising area of research and specific attention is given to this issue.

This thesis examined the effect of a family-based behavioural treatment programme for obesity in 7-11 year olds (The Malaysian Childhood Obesity Treatment (MASCOT) Study). The intervention is presented in **Chapter Two**. Families of obese 7-11 year olds in Kuala Lumpur were randomised to either an intervention (treatment) or control (no treatment) group. The sample was characterised by BMI z-score, health related quality of life reported by participants and their parents (PedsQL questionnaire) and objectively measured habitual physical activity and sedentary behaviour (Actigraph accelerometry). The intervention was delivered over a six month period and between group differences in changes over the six month period were examined at this time point. The sample size (n=107) was calculated as sufficient to detect an estimated difference in the reduction in BMI z-score of-0.25 in over six months between groups and the SD of the change in BMI z-score of 0.21, allowing for dropout (and with power=90%, significance=95%). The primary outcome was change in BMI z-score. This chapter also describes how the MASCOT treatment

programme developed, and describes its content. 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 to11 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, covering topics on nutrition, physical activity and sedentary as well as parenting skills. All information was directed to parents, the main agent of change in which they were responsible for initiating and maintaining healthy lifestyle changes with their families.

Outcomes were recorded at baseline and six months, consisting of primary outcome indicators (body mass index (BMI) z-score) and secondary outcome indicators (weight changes, health-related quality of life (HRQoL) and, habitual physical activity and sedentary behaviour) **(Chapter Three)**. Analysis of the primary outcome found no significant group differences at the six month time point for BMI z-score (intervention: 0.0 (0.7) vs control: 0.1 (0.5), p=0.79). There were significant differences between the groups in favour of the intervention group in weight changes (intervention: 1.7(2.5) vs control: 3.5(2.0), $p<0.001$) and total parent score for HRQoL (intervention: 4.2(15.5) vs control -3.8(19.3), $p<0.05$).

This thesis also reports complementary studies that examined:

- the quality of life of obese children compared to pair-matched controls of healthy weight **(Chapter Four)** and

- the physical activity levels and sedentary behaviour of obese children in the MASCOT study versus healthy weight children **(Chapter Five)**

The study of quality of life **(Chapter Four)** found significant impairment in all HRQoL dimensions (Total score, Physical Health, Psychosocial Health) in the obese children compared to healthy weight children ($p<0.001$, respectively). In **Chapter Five** it was shown that obese children spent more time in sedentary behavior (intervention: 90.2% vs control: 87.5%, $p<0.001$) and less time in MVPA (intervention: 0.7% vs control: 1.2%, $p<0.001$) compared to healthy weight children.

Chapter Six concludes the thesis by summarising its results and highlighting how they have contributed to the evidence base. Study strengths and limitations are described and those weaknesses would be improved by suggesting a few changes in the MASCOT programme for future research.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

CHAPTER ONE: Literature Review

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AUTHOR'S DECLARATION

I declare that the work contained in the thesis is my original, and is the work of one author Sharifah Wajihah Wafa except otherwise stated. The information reported from other authors has been quoted with their names and source of publications. Aspects of the research have been supported by others, as indicated.

Development of programme - I developed and designed protocols for intervention content and programme materials used in the study alongside Hana Hamzaid (dietitian) and Professor John Reilly.

Recruitment - Along with NurHuda Razali (research assistant) I was jointly responsible for subject recruitment and retention, screening and baseline assessment and the consenting of each family into the study, adhering strictly to consent procedures.

Data collection - I was responsible for and carried out every aspect of data collection at baseline and the end of programme (6 month). The only exception is that some help with the hands on data collection was given by Nathirah and Hidayah (research assistants) for data collection in healthy weight children for quality of life's and physical activity and sedentary behaviour's studies (see Chapter Five and Six) (insufficient time spent in Malaysia for the PhD research made it impossible for me to carry out all of the data collection by myself for both additional studies).

Data analysis, Interpretation and Write-up - I have carried out all of the statistical analysis and interpretation of the data described in this thesis, and all of the writing is my own. I took advice from Professor John J McColl (statistician) on appropriate statistical tests and the use of SPSS. The writing is my own, but each chapter has been commented on by Professor John Reilly (supervisor).

LIST OF PUBLICATIONS

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LIST OF ABBREVIATIONS

BMI	Body Mass Index
CDC	Centers for Disease Control
CI	Confidence interval
CONSORT	Consolidated standards of reporting trials
CPM	Count per minute
CSA	Computer Science and Applications
FAO	Food and Agriculture and Organisation
FBBT	Family-based behavioral therapy
HRQoL	Health-related quality of life
IOTF	International Obesity Task Force
ITT	Intention-to-treat
IQ	Interquartile
LEAP	Live, Eat and Play
MASCOT	Malaysian Childhood Obesity Treatment
MEND	Mind, Exercise, Nutrition, Do it
MRC	Medical Research Council
MVPA	Moderate-vigorous physical activity

NICE	National Institute for Health and Clinical Excellence
RCT	Randomised Controlled Trial
PedsQL	Pediatric Quality of Life Inventory
SCOTT	Scottish Childhood Obesity Treatment Trial
SD	Standard deviation
SIGN	Scottish Intercollegiate Guideline Network
SPSS	Statistical Package for Social Science
TV	Television
UK	United Kingdom
USA	United States of America
WHO	World Health Organisation

CHAPTER ONE

Literature Review

1.1 Introduction

Childhood obesity is one of the greatest public health concerns of this generation and has implications for the health of children now and in the future [1]. The development of childhood obesity results from the interaction of a complex set of factors from multiple settings, acting in differing ways throughout a child's growth [2]. To tackle this problem, over recent years, a number of reviews and guidelines have been developed to guide the prevention and treatment of obesity in children. While prevention is very important, it does not deal with the issue of what can be offered for children already obese. The body of evidence on childhood obesity treatment is increasing [3], however, surprisingly there is no published evidence on childhood obesity treatment in Malaysia.

The MASCOT project was conceived to be an easily reproducible and generalisable treatment programme which might be adopted within the Malaysia Health system for primary school aged children. As one of the first reported RCTs on the treatment of childhood obesity outside the UK, US and, Australia and Europe, it is intended to address an important gap in the body of evidence on childhood obesity treatment.

1.2 Defining obesity in children

Obesity represents the most common chronic illness of children and adolescents. The World Health Organisation has declared obesity as a "worldwide epidemic" since the pattern has been repeated in developing countries combined with the increase in more developed nations [4]. Obesity in children arises when there is an excess of body fat, so ideally measures to determine body fatness should be used to diagnose obesity. However, direct measurement of body fatness is usually impractical and at present, there was no clinical method of measuring body fatness that has sufficient accuracy, thus, simpler proxies for excessive fatness are necessary, particularly in clinical practice [5]. Consistent evidence shows that body mass index (BMI) for age and sex is a suitable proxy or surrogate measure of fatness that meet two essential criteria: it can identify the fattest children adequately, with low–moderate false negative rate and a low false positive rate; children and adolescents at high BMI for age are at much greater risk of the co-morbidities of obesity [5]. Therefore, the BMI offers a reasonable measure of fatness in children and adolescents.

In adults, the universally recognised body mass index (BMI) cut-off point has been shown to be a good simple indicator of adiposity to define obesity. There is a wide body of evidence that links increasing BMI to increased risk of morbidity and mortality in adults [4]. Even though it does not differentiate between muscle and fat, BMI in adults correlates with more direct measures of fatness [5] and probably provides the best estimation of adiposity of all the calculated indices [6]. A BMI 25-29 defines overweight and a BMI of 30 or above defines obesity [4] in western adults. However there is much debate over the most appropriate BMI cut off points for this definition in Asian populations. In 2000, a

proposal was made to redefine the classification of obesity using BMI cut-offs for Asian populations (Table 1.1) as there was evidence showing that the risk of co morbidities occurs at a lower BMI in Asians [7]. A meta-analysis of population data from more than 10 countries showed that the proportion of Asian adults with a high risk of type 2 diabetes and cardiovascular disease is substantial at BMIs lower than the existing WHO cut-off point for overweight (25kg/m^2) [8].

Table 1.1: Classification of weight status according to BMI in Asian Adults

Classification	BMI (kg/$m^{2)}$	Risk of comorbidities
Underweight	< 18.5	Low (but risk of other clinical problems increased
Normal range	18.5 – 22.9	Average
Overweight:	> 23.0	Increased
At Risk	23.0 – 24.9	Increased
Obese class I	25.0 – 29.9	Moderate
Obese class II	> 30.0	Severe

Source: WHO [7]

Nevertheless, the WHO Expert Consultation [8] made no attempt to redefine BMI cut-off points for each population based on the body composition data and agreed that the WHO BMI cut-off points should be retained as international classification. The WHO Expert Consultation also suggested that lower BMI action points of 23 and 27.5kg/$m^{2,}$ which individual countries could use to define the cut-off points for increased risk of their population and to be added as points for public health action. The rationale for this approach was as follows:

1. The relationship between BMI and risk curves are continuous, hence all cut-off points based on risk are arbitrary;
2. Epidemiology "hard outcomes" such as defined disease were considered better than body composition and more meaningful to clinicians and policy makers and
3. BMI versus body composition varies substantially but the variation is not consistent across populations and within a given population under different social and lifestyle changes over time [8].

Therefore, the Committee recommended retaining the current WHO classification of BMI [4] for adults and at the same time there is a need to have the public health action points as recommended by WHO Expert Consultation [8]. (Table 1.2)

Table 1.2 Recommended BMI cut-off points for body weight classification and public health action for Malaysian adults

Body weight classification	BMI cut-off points definition (kg/m^2)[1]	Comorbidities risk	BMI cut-off points for public health action[2]
Underweight	<18.5		<18.5
Normal range	18.5 to 24.9	Low	18.5 to 22.9
Overweight	25.0		23.0 to 27.4
Pre-obese	25.0 to 29.9	Moderate	27.5 to 32.4
Obese class I	30.0 to 34.9	High	32.5 to 37.4
Obese class II	35.0 to 39.9	Very High	[3] 37.5
Obese class III	40.0		

[1]WHO [4]; [2]WHO [8]

Although the long-term effect of overweight and obesity on morbidity and mortality has not yet been well documented, a recent systematic review suggests that obesity in childhood is followed by increased risk of serious health consequences in adulthood [9]. In children, factors such as growth make definition of obesity more complex than adults, and obesity-mortality relationships are harder to detect in children than adults. As a result, childhood obesity has been defined in various ways in the literature (such as percentage of ideal weight, waist circumference, BMI centile and BMI z-score) leading to confusion on how to choose an appropriate reference population and how to select appropriate cut-off points for defining a child as obese. Moreover, it is difficult to directly compare the effectiveness of studies across countries, to compare obesity prevalence between countries and to conduct meta-analyses. Therefore, there is a need for a valid definition of childhood obesity urgently.

There are a plethora of reference data and charts for BMI in childhood, for example the 1990 UK reference, the 2000 CDC Growth Charts and the WHO charts. All the references are intended for clinical use in monitoring child's growth [10]. However, each of the references has different cut-off points to define obesity in children (Table 1.3).

Table 1.3 BMI cut-off points for obese children from various reference data

	Reference data	Cut-off points
1.	British 1990 Growth reference	95th centile for population monitoring, 98th centile for clinical assessment.
2.	World Health Organization (WHO) Child Growth Standard	z-score >3
3.	United States Centres for Disease Control and prevention (CDC) 2000 growth reference	>95th centile

The issues of using different definitions or cut-off points has been discussed extensively [10]. However, it is not clear yet that any definition is better than another although most definitions of childhood obesity are similar in that they are based on BMI relative to a reference distribution of BMI for age and sex.

In 1997, the International Obesity Task Force (IOTF) Childhood Obesity Working Group developed BMI centiles based on pooled data for children and adolescents aged 2-18 years from nationally representative surveys conducted in Brazil, Great Britain, Hong Kong, the Netherlands, Singapore and the USA [11] in order to facilitate global comparisons of trends in childhood and adolescent obesity rates [12]. These 'Cole-IOTF' international BMI for age reference data are practical for allowing obesity rates in different countries to be meaningfully compared. However, there is controversy about whether they should be used clinically to classify children and adolescents as overweight or obese [13]. There are strong arguments in favour of using national, rather than international, standards to define childhood and adolescent obesity clinically [13, 14].

For example, the Cole-IOTF international BMI reference curves were not sufficiently evaluated to determine their validity for obesity classification in children and adolescents, unlike national BMI reference data in the US and in the UK that have been around for much longer and have been well-evaluated [13, 15]. Furthermore, a recent systematic review appears to show that the sensitivity of the Cole-IOTF approach is lower than national reference data [5] (producing an underestimate of obesity prevalence compared to use of national reference data) and that sensitivity and specificity differ by sex in some countries [14]. The same systematic review also found that the use of BMI for age with national reference data and cut-off points was better than the Cole-IOTF approach for defining obesity based on BMI for age, with higher sensitivity (lower false negative rate) [5].

The use of the change in BMI z-score to define change in weight status in response to weight management was explored by Hunt et al. [16], who studied 92 obese children aged 7 to 19 years attending hospital weight management clinics, and measured BMI at two time-points (median interval 0.83 years) [16]. Percentage fat was measured via bio-electric impedance analysis as their 'gold standard' for fat loss. The study found that the change in BMI z-score was superior to BMI, weight (kg) and weight z-score in predicting changes in percentage fat, although for a given change in BMI z-score the range of percentage fat loss was wide [16]. A limitation of this study is its reliance on bio-electric impedance analysis as a 'gold standard'. The evaluation framework for obesity treatment interventions from the National Obesity Observatory similarly supports the use of the change in the BMI z-score to measure the change in a child's BMI [17].

1.3 Childhood obesity prevalence and trends

Prevalence and trends in childhood obesity – Malaysia

In Malaysia, no nationally representative survey has been carried out with the specific purpose of determining the prevalence of overweight and obesity amongst children or adolescents. However, many smaller scale studies have been reported. The earliest study (1993-1994) was conducted to determine the prevalence of obesity among school children in the state of Selangor involving a total of 28 rural and 24 urban primary schools [18]. The study reported that, among 2688 children aged 7 and 12 years old, the prevalence of obesity (using the National Centre for Health Statistics (NCHS) reference (WHO, 1983)) was 7.8%. The study also reported that the prevalence of obesity was significantly higher in urban schools (9.8%) compared to rural schools (6.1%) [18]. However, a study conducted in rural villages and estates in Peninsular Malaysia reported that the prevalence of obesity (using the National Centre for Health Statistics (NCHS) reference (WHO, 1983)) was less than 2% among 3000 rural children [19].

Another study among 6239 children and adolescents aged 7 to 16 years attending 22 primary and secondary schools in Kuala Lumpur found that the prevalence of obesity was 3.5% (using the National Centre for Health Statistics (NCHS) reference (WHO, 1983)) [20]. The study also reported that boys were more likely to be obese than girls. Possible small ethnic differences were also observed: 3.8% of the Indians were obese followed by Malays 3.6% and Chinese 3.4% but these differences were not significant [20]. A survey by Ismail and Tan [21] demonstrated the increase of obesity with increasing age: 6.6% among 7 year-olds, rising to 13.8% among 10 year-olds. Obesity among this 7 to 10 year-olds was higher among boys (12.5%) than girls (5.0%). However, ethnic differences in

this study were not similar to the study by Kasmini et al. [20]: among boys, 16.8% of Malays were obese compared to 11.0% of Chinese and Indians. Tee et al. [22] reported an obesity prevalence of 9.5% in boys and 5.2% in girls (based on >95th percentile of the BMI-for-age; WHO 1995) among 5,995 primary school children aged 7 to 10 year old in Kuala Lumpur.

Two separate studies, – survey I (2001/02) involving 11,264 and survey II (2007-08) involving 9987 were carried out among 6-12 year olds in four regions of Peninsular Malaysia [23]. The results showed that there was an increase in prevalence of obesity from 16.4% to 24% using IOTF cut-off [11] and from 20.7% to 26.4% using WHO reference [24]. Although these reports were not based on nationally representative data, it seems there is an apparent trend of a steady rise in prevalence of obesity among 6-12 year olds in Malaysia in recent years [23].

Prevalence and trends of childhood obesity in children- Worldwide

Overweight data (including obesity) for children from selected countries in each region are shown in Table 1.4. All the data are presented using the IOTF cut-off to define overweight and obesity. The data show that the highest prevalence estimates of overweight and obesity are found in the WHO Americas region with the lowest rates in the Africa region [25].

Table 1.4: Childhood prevalence (% of population) of overweight (including obesity) in selected countries, by WHO region using IOTF definitions

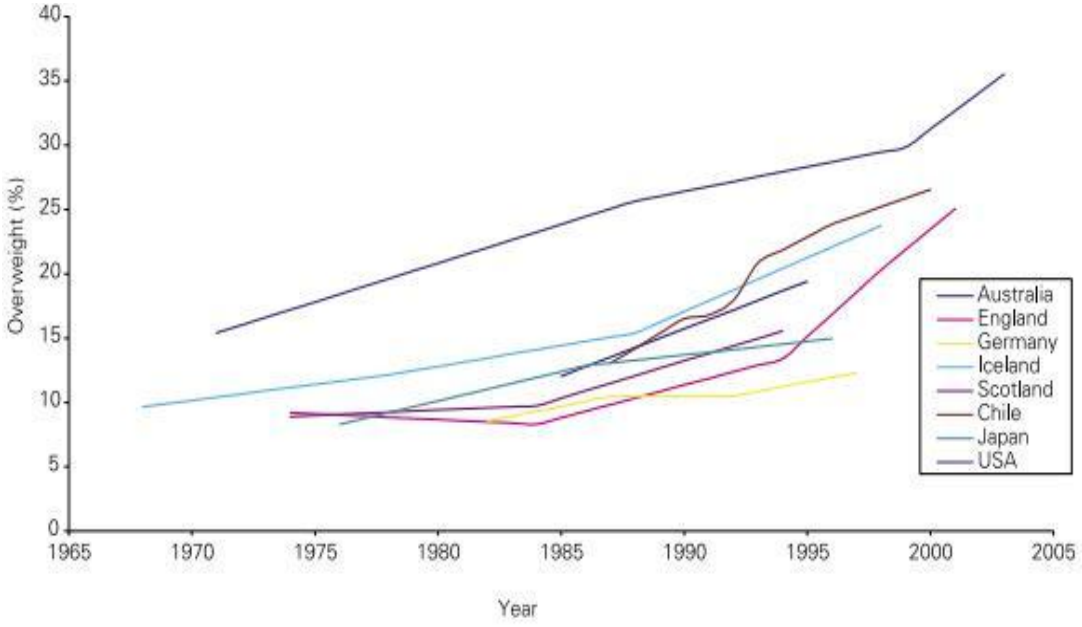
	Year of survey	Age (years)	Boys	Girls
WHO African region				
Algeria	2003	7-17	6.0	5.6
Mali	1993	5-17	0.2	0.5
South Africa	2001-4	6-13	14.0	17.9
WHO Americas region				
Brazil	2002	7-10	23.0	21.1
Chile	2000	6	26.0	27.1
USA	2003-4	6-11	31.7	37.5
WHO Eastern Mediterranean region				
Bahrain	2000	12-17	29.9	42.4
Iran	1995	6	24.7	26.8
Saudi Arabia	2002	5-17	16.7	19.4
WHO European region				
Czech Republic	2001	5-17	14.7	13.4
Portugal	2002/3	7-9	29.5	34.3
Spain	1998-2000	5-16	31.0	19.5
England	2001	5-17	21.8	27.1
WHO South-East Asia region				
India	2002	5-17*	12.9	8.2
Sri Lanka	2002	10-15	1.7	2.7
Thailand	1997	5-15	21.1	12.6
WHO Western Pacific region				
Australia	1995	7-17	21.1	21.3
China	1999-2000	11,15	14.9	8.0
Japan	1996-2000	6-14	16.2	14.3
New Zealand	2000	11,12	30.0	30.0
*5-15 for girls				

Source: Lobstein and Jackson-Leach [25]

Furthermore it has been shown that there is a worldwide trend of increasing prevalence of overweight amongst young people in selected developed countries, particularly since the 1990's (Figure 1.1). In England, there was a marked increase of childhood overweight and obesity to 25% in 2001, and

although the prevalence was not as high as in the USA in recent years, it was increasing faster than in the USA [25].

Figure 1.1 Prevalence of Children who are Overweight in Selected Countries in the World, from 1967 to 2005



Source: Lobstein and Jackson-Leach [25]

The global childhood obesity rates continued to increase until recent years, where a possible levelling off in prevalence has occurred more recently in some countries. The prevalence remains high, and a recent systematic review suggested that the 'levelling off' may be a pause in the childhood obesity epidemic [26] so childhood obesity represents a public health issue requiring urgent action, and for the children already obese, and for health professionals responsible for identifying and treating them, this is an important clinical issue.

1.4 The health consequences of childhood obesity

1.4.1 Introduction

There is now abundant evidence that childhood obesity adversely affects health. A systematic review of the health consequences of childhood obesity concluded that one of the most widespread and a significant immediate adverse effect of the condition is psychological morbidity [27]. Furthermore, persistence of obesity into adulthood is considered to be the most significant long term health consequence of childhood obesity that has contributed to increasing adult morbidity and mortality rates [27]. Other health consequences of childhood obesity (Table 1.5) have also been reported and are discussed in detail elsewhere [27]. This section will focus primarily on the health outcome data collected for the purpose of this thesis which includes psychological consequences of childhood obesity and the tracking of weight with age. A detailed review of other health consequences of childhood obesity is beyond of the scope of this section.

Table 1.5 Well-established health consequences of childhood obesity

Short term
Psychological co-morbidity
Cardiovascular risk factors
Asthma
Chronic inflammation
Long term
Persistence of obesity
Persistence of cardiovascular risk factors
Premature morbidity and increased risk of premature mortality

Source: Reilly et al. [27]

1.4.2 Psychological consequences of childhood obesity

Obesity in children is strongly associated with psychosocial morbidity [8]. Social and psychological consequences include stigmatisation, discrimination and prejudice. Child (and particularly adolescent) obesity has in general been linked to low self-image, low self-confidence and even depression in some obese children which may impact upon quality of life [28]. Negative influences on these aspects of health are experienced immediately and acutely by some obese children meaning they may be the most profound consequences of childhood obesity according to Griffiths et al. [28].

A number of psychosocial constructs have been studied in relation to childhood obesity. These include self-esteem, depression, social functioning, eating disorder psychopathology, quality of life, body dissatisfaction, and discrimination [28]. The study described in this thesis collected measures of children's quality of life because this is believed to be impaired in childhood obesity according to a recent systematic review [28], it may be a measure of possible adverse consequences of weight management therapy, and it can be measured fairly easily. The limited evidence reporting on this psychosocial outcome, particularly in Malaysia, is reviewed below. For completeness of this section, a short review reporting on self-esteem, a psychosocial health outcome which was not considered in this study but often included as a domain in studies of childhood obesity is also included.

1.4.2.1 Quality of life

According to the World Health Organisation (WHO), health is defined as "not merely the absence of disease, but complete physical, psychological and social

well-being" [29]. The WHO definition of "health" encompasses the definition of "quality of life". Specifically, quality of life is defined as a person's perception or satisfaction with their physical and general health and with the psychological, social and emotional aspects of their lives [29, 30]. According to Testa and Simonson [31], health- related quality of life (HRQoL) refers to the physical, psychological and social domains of health that are unique to each individual and each of these domains can be measured by the objective assessments of functioning or health status and the subjective perceptions of health. In other words, HRQoL reflects an individual's own judgment of his or her well-being and functioning within the context of day-to-day life [32]. A recent systematic review has shown that being obese can have a significant adverse effect on a child's quality of life [28]. It has been shown that the greater the severity of obesity, the poorer quality of life that child will experience [33].

Health-related quality of life (HRQoL) is becoming an important health outcome indicator among health professionals. Over the past decade, more and more research on the development of assessment tools of HRQoL has been reported to quantify the quality of life of healthy children as well as children with chronic diseases such as cancer, asthma, cystic fibrosis and obesity in order to characterise the global burden of the disease [34]. In young children, assessment of HRQoL is a challenge as the ability for children to respond to questionnaires, understand language, as well as use rating scales is limited due to their incomplete cognitive development [35]. Either because children are often regarded as unreliable respondents, or since their perspectives are important in their own right and distinct from their parents perspectives, separate instruments are needed that allow for both children and proxies (parents) as

respondents [35]. Children and parents may not share similar views about the impact of disease [33, 36-39] and when assessing children's quality of life, it is therefore preferable to involve both children and parents.

Systematic reviews have shown that paediatric obesity has adverse effects on health in both childhood and adulthood, suggests an increasing burden of future physical disorders such as diabetes, hypertension, and some forms of cancers [27]. There is a growing awareness of those long-term health complications among obese children but the more widespread psychosocial effects on obese children often go unaddressed by health professionals. Obesity is not only restricted simply to causing or exacerbating medical conditions but is also closely associated with development of adverse psychological and social conditions [27]. It has been shown that obese children commonly suffer discrimination and teasing from their peers which may affect their psychosocial health [27]. Thus, it is important to know more about quality of life in obese children in order to understand which impairments of function and well-being are associated with this condition.

Self-perceived health outcomes are most relevant and important to obese children and their parents because it captures the children's experiences and the parent's perspectives. Furthermore, assessment of changes in quality of life can be used as an outcome measure to evaluate the effectiveness of intervention programmes. So far, there have been a number of studies assessing HRQoL in obese children and these have been reviewed systematically [28]. It has been reported that there is strong evidence of negative effects of childhood

obesity on quality of life in clinical samples [36, 39, 40] but fewer studies in population-based community samples [33, 41].

In clinical studies on paediatric obesity, researchers have fairly consistently reported that obese children experience a lower quality of life than healthy (non-obese) children [28]. A recent systematic review found that four studies (two studies from Australia, one study each from US and UK) have examined child obesity and HRQoL using the Paediatric Quality of Life Inventory (PedsQL0 to assess self-report and parent-proxy report of HRQoL [33, 39, 42, 43]. The published studies are briefly discussed below and also summarised in Table 1.6.

Gibson et al. [42] conducted a study in a community sample in Australia in a group of 262 children- (158 healthy children, 77 overweight children and 27 obese children- defined as BMI in the 95th percentile of age and sex relative to US CDC reference aged 8-13 years old. The study reported impairment of quality of life associated with obesity- physical scale (obese: 78.7 vs non-obese 88.0), emotional scale (obese: 78.7 vs non-obese 88.0), social scale (obese: 73.7 vs non-obese 86.0) and school functioning scale (obese: 71.7 vs non-obese 78.6). In this study, the author compared the quality of life of obese children vs healthy weight children. Although the results showed that the scores were lower in all domains, the p-values were not reported in this study. However, the study reported a significant correlation between levels of depression and quality of life ($r=-0.70$, $p<0.01$) indicates that the lower the quality of life scores, the higher level of depression the children had.

In a community sample among 177 overweight and obese children (defined as BMI $\geq 85^{th}$ and $\geq 95^{th}$ percentile, respectively relative to US CDC reference) age 8-12 years old, Shoup et al. [43] demonstrated impairment of quality of life associated with obesity in all domains of functioning compared with the healthy sample reported in the Varni et al. [44]. The authors speculated that there are possible differences in quality of life between children who were obese and did not met the recommended guidelines for physical activity. Overweight and obese children who were not meeting recommended guidelines for physical activity reported significantly lower psychosocial quality of life than those who were meeting recommended guidelines [43] suggests that overweight and obese children may have better psychosocial quality of life if they are physically active.

Williams et al. [33] conducted a cross-sectional study of children from a community sample in Australia and showed that both parent-proxy report and child-self reported PedsQL decreased with increased child's weight. HRQoL (parent and child) for total, physical, psychosocial and social scores decline once child's weight above mean BMI and decline worsens with increasing BMI, so that scores lowest for obese children. Furthermore, the study also reported that overweight and obese children differed from healthy weight children most strongly on physical and social functioning scores. In this study, the authors demonstrated less impairment of quality of life associated with obesity in the community sample compared with the clinical sample reported in the Schwimmer et al. [36] study, suggested that severe impairment of quality of life associated with childhood obesity was mainly confined to obese children in obesity treatment clinics than in community samples.

Table 1.6 Summary of relevant studies assessing HRQoL in obesity children using PedsQL 4.0 questionnaires child and parent-proxy report

Publication details	Study and sample	General finding
Gibson et al. [42] Australia	• Cross sectional data of 262 children (158 normal weight, 77 overweight and 27 obese-(defined using CDC BMI for age $\geq 95^{th}$ percentile) aged 8-13 years old • Community-based sample	Obese children (n=27) had lower HRQoL than non-obese children (n=158) Increasing adiposity associated with increasing levels of psychosocial distress
Shoup et al. [43] USA	• Cross-sectional study of 92 overweight 85 obese children (overweight defined as $\geq 85^{th}$ percentile for age and obese defined as $\geq 95^{th}$ percentile for age relative to US CDC 2000) aged 8-12 years old • Community-based sample	Obese children had significantly lower HRQoL than overweight children
Williams et al. [33] Australia	• Cross-sectional data of 1456 children (1099 normal weight, 294 overweight and 63 obese- defined using both US CDC BMI for age criteria $\geq 95^{th}$ percentile and the Cole-IOTF definition of obesity) 9-12 years (n=1456) • Community-based sample	The study compared with clinical samples of overweight and obese children reported in the Schwimmer et al. [36] study. Clinical samples of overweight and obese children [36] had significantly lower HRQoL than population-based community samples [33]. Obese children had significantly lower HRQoL scores in the physical and social functioning than the healthy children
Hughes et al.[39] United Kingdom	• Cross-sectional study of 104 children (71 normal weight and 71 obese- defined as $\geq 98^{th}$ percentile relative to UK 1990 reference data) of 5-11 years • Clinical sample	Clinical samples of obese children had significantly lower HRQoL than lean children Parents of obese children perceived their child's HRQoL significantly lower than the children themselves

One study by Hughes et al. [39] from the UK examined HRQoL in a paediatric obese (defined as $\geq 98^{th}$ percentile relative to UK 1990 reference data) clinical sample –they found a significantly lower and marked decrease in HRQoL across all domains. The level of impairment of quality of life in this UK sample was worse than in US study by Schwimmer et al. [36]. Possible explanation for the lower scores could be cultural differences between the UK and the USA.

Since the recent systematic review by Griffiths et al. [28] found that all published studies of quality of life in obese children to date were from western societies and since the adverse impact of childhood obesity on quality of life may be culture-specific, there is a need to identify whether obesity has a significant adverse impact on quality of life in non-western societies. Successful interventions to manage obesity need to take account the cultural context in which obesity occurs, and thus studying obese children from non-western countries is important. No studies of quality of life in childhood obesity have taken place in Malaysia and so the MASCOT study provided an opportunity to test whether the apparently low quality of life described in obese children in Chapter Three was related to obesity or related to some other issue, such as the impact of Malaysian culture, attitudes, and beliefs, on child quality of life. Only one study of quality of life using the PedsQL has been carried out in Malaysian children:Ismail et al. [45] examined HRQoL in children with thalassaemia in Malaysia in Kuala Lumpur and found that the quality of life was significantly impaired in children with thalassaemia compared to healthy children. In summary, the limited evidence on quality of life in childhood obesity to date means that there is a need for more studies.

1.4.2.2 Self-esteem

Another frequently researched psychosocial variable in obese children is self-esteem. Self-esteem refers to "an individual's feelings of his or her self-worth and competence and is important marker of a child's well-being and mental health" [46]. Although the relationship between obesity and self-esteem in children is widely examined, the findings tend to be inconsistent. An early review on self-esteem and obesity in children indicated that there was no significant relationship between being obese and low self-esteem in 7-12 year old children [47]. On the other hand, a review of nine papers by Reilly and colleagues concluded that low self-esteem and behavioural problems were particularly commonly associated with obesity in children, though this seemed most likely in older obese children and obese adolescents [27]. The inconsistent findings may be due gender, ethnicity, whether the obese sample was recruited from the community (non-treatment seeking) or clinical (treatment seeking) samples, and the particular aspect of self-esteem measured [47, 48].

One of the most frequently used measures of self-esteem is the Self-perception Profile for children. It assesses five domains which are physical appearance, social competence, scholastic competence, athletic competence and behavioural conduct.

In summary, it can be concluded that aspects of quality of life and self-esteem tend to decrease with increasing weight status of children, but the evidence base is limited and mostly from western populations. This inverse relationship between weight and psychological aspects has been observed in clinical and community samples. Moreover, it is an important health outcome to monitor

within a child weight management intervention to ensure that no unintended harm is caused to those enrolled and to also identify any additional psychosocial benefits of involvement in such a programme.

1.4.3 Obesity persistence into adulthood

The biggest concern in the long-term consequences of childhood obesity is the persistence of obesity into adulthood. A systematic review by Singh et al. [49] considers the persistence or 'tracking' of childhood obesity into adulthood. The authors searched multiple electronic databases up to February 2007, and screened the reference lists of selected papers. Out of 25 articles, eighteen studies were included and all of them were longitudinal studies. The quality of studies was assessed and a narrative synthesis was provided. The authors did not carry out a meta-analysis due to heterogeneity between studies (e.g. definitions of obesity, length of follow-up).

All studies reported an increased risk for overweight and obese youth to be overweight or obese in adulthood. For the highest quality studies (based on a methodological quality assessment) [49], being overweight in childhood (<12 years) carried at least a two-fold risk of being overweight in adulthood, with the risk increasing further for those that were obese (rather than overweight). With increasing age of the youth, the tracking of obesity to adulthood is also higher. The tracking from being obese in childhood to being obese in adulthood ranged from 43% to 60% in children and from 47% to 90% in adolescents (>13 years), and when a study examined more than one age-group tracking increased with the age of the child [49].

Similarly, a previous systematic review, examining 7 studies estimated that 40% to 70% of obese pre-pubertal children become obese adults [50]. Reilly [50] indicates that these figures are likely to underestimate the current tracking of obesity from childhood into adulthood, because some of the studies are based on birth cohorts from the post 2nd World War era and not on cohorts growing up in the modern obesogenic environment where obesity persistence is more likely.

Reviews and studies from the UK and USA have found similar factors increase the risk of childhood obesity leading onto adult obesity. Persistence of obesity has been shown to increase consistently with the age of the child [33, 51, 52]; parental obesity [52, 53]; and the severity of obesity [33, 51]. Persistence may also increase with accelerated gain in BMI from age 7 to 11 [38] and vary by social class [54]. Interventions may need to target some of the above groups, in order to decrease tracking.

Only a few published studies [51, 52, 55-57] have provided longitudinal data examining the persistence of childhood obesity into adulthood and these are summarised in Table 1.7.

Table 1.7 Summary of the literature on the longitudinal data examining the persistence of childhood obesity into adulthood

Study (country)	Study design and sample	Age at measurement (yrs)		Definition of overweight/obese from BMI		Main findings
		Youth	Adult	Youth	Adulthood	
Power et al.[51] UK	Prospective longitudinal n=11212	7,11 and 16 years	33 years	$\geq 98^{th}$ centile	$\geq 30 kg/m^2$	Children obese at 7 years (males/females):43%/60% obese at age 33 Children obese at 11 years (males/females): 54%/57% obese at age 33 Children obese at age 16 years (males/females): 64%/72%
Laitinen et al. [55] Finland	Prospective longitudinal n=6280	Birth, 1 years and 14 years	31 years	$\geq 95^{th}$ centile	$\geq 30 kg/m^2$	Normal weight youth (males/females): 4%/4% became obese in adulthood Overweight youth (males/females): 56%/42% became overweight in adulthood; 25%/22% became obese in adulthood Obese youth (males/females): 4%/27% became overweight in adulthood; 47%/55% became obese in adulthood
Freedman et al. [56] US	Prospective longitudinal n=2610	2.5-17 years	18-37 years	$\geq 95^{th}$ centile	$\geq 30 kg/m^2$	Proportion of overweight that became obese in adulthood:- 2-5 years(males and females):83% 9-11 years (males/females): 76%/78% 15-17 years (males/females):86%/90%
Whitaker et al. [52] US	Retrospective n=854	1-2 , 3-5, 6-9, 10-14, 15-17 years	21-29 years	$\geq 85^{th}$ centile	males: $\geq 27.8 kg/m^2$ Females: $\geq 27.3 kg/m^2$	OR (95%CI) for being obese in adulthood (obese youth vc non-obese youth)- Age 1-2 years:1.3(0.6;3.0) Age 3-5 years:4.7(2.5;8.8) Age 6-9 years: 8.8(4.7;16.5) Age 15-17 years: 17.5(7.7;39.5)
Reilly et al. [57] UK	Prospective longitudinal n=5175	7 years	13 years	$\geq 85^{th}$ centile	$\geq 95^{th}$ centile	OR (95% CI) for being obese in adolescent for progression to obesity at age 13 for overweight age 7 was 18.1. 34% of overweight children at age 7 became obese by age 13 years

OR: odds ratio; CI: confidence interval.

Although the tracking of obesity from childhood to adulthood is an important consequence of childhood obesity, some studies have reported that at least half of obese adults were *not* obese as children or adolescents [51, 52, 57]. For example, a paper from the Bogalusa Heart Study in the USA reported that of the 581 adults who were obese only 144 (25%) had been obese in childhood / adolescence [56]. Furthermore, from the 1958 British birth cohort, Power et al. [51] report that most obese adults cannot be identified from childhood BMI, with only 40% of obese males at age 33 years being overweight or obese at age 16.

1.4.4 Impact of childhood obesity on mortality and morbidity in adulthood

A large body of evidence has demonstrated that overweight and obesity in childhood and adolescence have adverse consequences on premature mortality and physical morbidity in adulthood. A recent systematic review by Reilly and Kelly [9] considers the long-term impact of overweight and obesity in childhood and adolescence in childhood and adolescence on morbidity and premature mortality in adulthood. The authors searched multiple electronic databases up to June 2010, and screened the reference lists of selected papers. Out of 200 articles, 25 studies were included- 5 cohort studies of associations with premature mortality in adulthood [58-62], 11 studies of associations with cardiometabolic comorbidities of obesity in adulthood [63-73] and 9 studies of associations with a wide variety of other outcomes [74-82].

Four for the five cohort studies reported obesity and/or overweight in childhood-adolescence were associated significant with increased risk of premature mortality [58-61]. Furthermore, all studies reported a significantly association between child/adolescent overweight and obesity with increased risk of later

diabetes [63-65], stroke [66, 67, 69], coronary heart disease [66, 68, 69] and hypertension [70-73]. All the reported studies were from USA or Western Europe. Furthermore, three for the five studies reported on risk of cancer found significant relationships between recalled weight status and pre-menopausal breast cancer risk with the risk increasing when recalled/perceived weight status is low [75, 77, 82]. Other outcome measures of physical morbidity such as risk of asthma and atopy (1 study) [80], polycystic ovary syndrome (1 study)[81] and disability pension (a form of pension given to those people who are permanently or temporarily unable to work due to a disability)(2 studies) [78, 79] in adult life were also reported significant associations with overweight and obesity in childhood. Further studies are required to understand the impact of childhood obesity on mortality and morbidity in adulthood from other countries, outside the US or Western Europe.

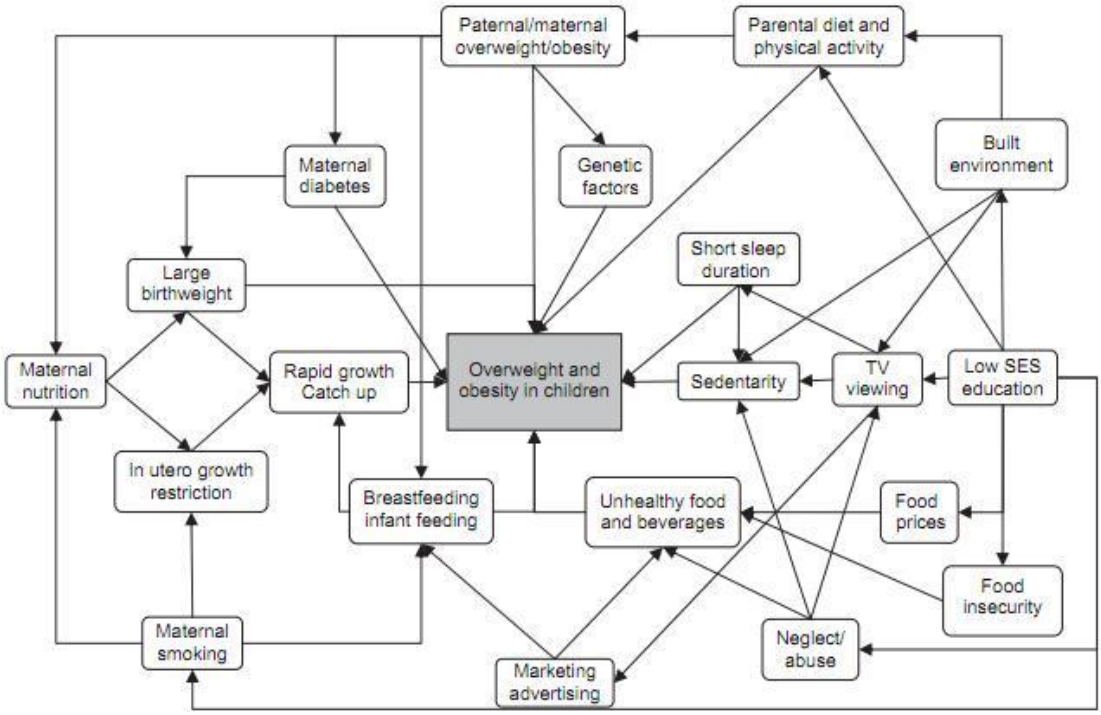
1.4.5 Summary of health consequences of childhood obesity

In summary, high prevalence of childhood obesity worldwide will increase the risk of immediate adverse health outcomes that potentially affect the child as well as future health consequences for adults, both physically and psychologically. A serious consequence of childhood obesity is that it persists into adulthood with the associated consequences to adult health, although it must be remembered that not all adults who are obese were obese as children. Therefore, it is important to have an early interventions, effective prevention and treatment strategies to halt the perpetuation of this major health issue. The key to design such strategies is to identify and understand the determinants of childhood obesity.

1.5 Determinants of childhood obesity

Obesity is caused by an imbalance in our energy intake versus our energy output, [83, 84] but the rise in childhood obesity is multi-factorial and complex. Figure 2 shows a model by Monasta et al.[85] that shows the complex web of potential determinants of overweight and obesity in children.

Figure 1.2 The complex web of potential determinants of overweight and obesity in children.



Source: Monasta et al. [85]

A large variety and number of risk factors have been identified for the development of obesity in childhood [84, 85]. These range from factors which would be difficult or impossible to modify, such as genes and ethnicity, to those which are potentially modifiable such as excessive hours of television viewing; low levels of physical activity; and dietary factors such as eating a diet high in

fat, carbohydrate and sugary drinks, missing breakfast and large portion sizes [84, 85].

Rising prevalence of childhood obesity could explain why environmental influences on obesity have gained a great deal of attention on contribution the development of childhood obesity. The determinants of childhood obesity and the current epidemic are without a doubt complex and multi-factorial, some of these issues are explored further below but a detailed discussion of aetiology of obesity would be beyond the scope of this thesis which has a focus on obesity treatment.

1.5.1 Genetics

Although mounting evidence suggests that the obesity epidemic is likely related to decreased habitual physical activity levels and changes in dietary nutrient intake as a result of environmental changes, there is strong evidence for a genetic component to the risk of obesity [86, 87]. Progress has been made in the last 15 years into the identification of possible genes that might influence obesity phenotypes in humans [88]. Many genes have been explored in order to identify their possible influence on the development of obesity and these include those genes that are implicated in food and energy expenditure regulation and lipid and carbohydrate metabolism. Genome-wide association studies (GWAS) have identified consistent associations with obesity and many genetic loci have been implicated for BMI, primarily in adults such as insulin-induced gene-2 (*INSIG2*) [89] and fat mass- and obesity-associated gene (*FTO*) [90].

However, to date, there have been only a few GWAS-related reports for childhood obesity specifically. A recent study conducted by Zhao and Grant [91] reported that a number of loci previously reported from GWAS analyses of adult BMI and/or obesity also play a role in childhood obesity. It is known that the *FTO* is the major contributor to polygenic obesity [92] and it has been shown that mice down or over-expressing *FTO* are resistant or prone to develop obesity [93, 94]. In human studies, the results also showed that the obesity predisposing *FTO* variant was associated with increased total and fat dietary intake in children [95, 96]. Additionally, the obesity risk variant was also associated with diminished satiety and/or increased feeling of hunger in children [97], increased snacking [98], decreased satiety [99], and increased total, fat and protein intake [98, 100]. In terms of physical activity, studies have reported an interaction between the *FTO* obesity risk genotype and physical activity on BMI variation or obesity risk in adults and adolescents [101].

Other than *FTO*, studies in polygenic and human obesity found that the obesity predisposing SNP variant near *MCR4* was associated with increased feeling of hunger [98, 99], increased snacking [98], decreased satiety[99] and increased total, fat and protein energy intake in children as well as adults [98, 100]. In 2009, Bauer et al. [102] discovered additional obesity genes (*SH2B1, KCTD15, MTCH2, NEGR1, BDNF*) identified by GWAS have an association with dietary intake and nutrient-specific food preference. Thus, by identifying common gene variants that predispose individuals to obesity, it is possible that subgroups of people could be targeted for a particular intervention before they become obese that may be possible to minimise risk by changing one's eating patterns and

being vigilant about food choices as well as adopting healthy lifestyle habits, like regular physical activity.

The role of monogenic or syndromic obesity has also been studied in obesity genetics research. Studies conducted by Farooqi and O'Rahilly [103] had identified seven monogenic genes that are involved in the regulation of appetite via the leptin-melanocortin pathway. Most of these have involved mutations in leptin production and its receptor, the α-melanocortin-stimulating hormone receptor (*MC4R)* and pro-opiomelanocortin (*POMC*) [104, 105]. It has been reported that the deficiencies in hormone leptin resulted in morbid obesity (usually from young age), increased appetite, hyperphagia and hypogonadotropic hypogonadism and it can be treated by injections of leptin [106]. Individuals with mutations in *MC4R* are reported as having severe obesity (particularly at an early age), hyperphagia, increased lean body mass as well as linear growth and hyperinsulinaemia [105, 106]. Mutations in *POMC* appear to result in severe obesity (from an early age), hyperphagia, altered pigmentation, usually red hair and adrenal insufficiency [104, 106]. A detailed review on polygenic and monogenic influences on the development of human obesity is beyond of the scope of this thesis.

Although genetic factors influence a child's likelihood of developing obesity, the expression of such a characteristic is reliant on a permissive environment and behaviours that promote excessive weight gain. As mentioned in section 1.1.2, global prevalence of childhood obesity has increased rapidly indicating the predominant role played by a changing environment on a stable genetic susceptibility [107]. An 'obesogenic environment' that describes current

lifestyle which encourage both foods high in energy density but low in nutrients (i.e fast foods) and decreased physical activity levels (i.e high car usage, TV watching, use of computers and playing video games) has probably led child populations to an excessive chronic positive energy imbalance.

1.5.2 Environmental factors

Changes in the environment have had a large part to play in the recent rise in obesity. There has been a shift towards an environment which promotes the intake of energy dense foods and one in with reduced opportunities for physical activity [108, 109]. The term 'obesogenic environment' has been used to describe a modern environment that fuels the obesity epidemic. In other words, the 'obesogenic environment' refers to an environment that contributes to obesity.

In 1999, Swinburn et al. [110] developed an ANGELO Framework (Analysis Grid for Environments Linked to Obesity) that has been used as an assessment tool for environmental determinants of obesity. This framework categorised various components of the obesogenic environment into two sizes of environment (micro/settings and macro/sectors) and four types of environments (physical, economic, political and socio-cultural), for measures related to obesity (i.e dietary behaviour, physical activity or weight)(see Table 1.8) [110]. Furthermore, the ANGELO framework is an efficient way on achieving an agreed plan for obesity interventions with diverse communities and it is also responsive to community needs to create stakeholder ownership of the action plan to combat the 'obesogenic environment [110]. Thus, focusing on modifying the

'obesogenic environment' that include access to healthy food and access to places to be physically active is important in tackling the rise in obesity.

Table 1.8 The Angelo Framework

Size	Type			
	Physical	**Economic**	**Politic**	**Socio-cultural**
Macro	Physical activity Diet weight/BMI	Physical activity Diet weight/BMI	Physical activity Diet weight/BMI	Physical activity Diet weight/BMI
Micro	Physical activity Diet weight/BMI	Physical activity Diet weight/BMI	Physical activity Diet weight/BMI	Physical activity Diet weight/BMI

Source:Swinburn et al. [110]

van der Horst et al. [111] reviewed 29 studies that used the ANGELO framework to identify a correlation between environment and obesity-related dietary behaviours in children. The results of this review of systematic reviews indicated that the most consistent association was found between parental intake and children's fat, fruit/vegetable intakes [111]. A less consistent but positive association also was found for availability and accessibility on children's fruit/vegetable intake. The review concluded that household socio-cultural factors e.g parental influences (parental intake) and household economic factors e,g parental education were the most extensively as potential environmental determinants that contribute to the obesity in children [111].

A recent systematic review by Monasta et al. [85] reviewed 22 systematic reviews to identify the early-life (from conception to 5 years of age) determinants of overweight and obesity. The quality of studies was assessed using Assessment of Multiple Systematic Reviews score [112]. The authors have reported that there was no review that can be classified as high quality, 11 as moderate and 11 as low quality studies [85]. A causal association between possible determinants and obesity, and the relative importance of each determinant were not carry out in the review as the determinants can be both a cause and consequence of overweight or obesity. The results of this review of systematic reviews indicate that breastfeeding may be a protective factor for later overweight and obesity, while obesity in infancy, rapid infant growth, maternal diabetes, maternal smoking, short sleep duration, less than 30 min of daily physical activity and consumption of sugar-sweetened beverages may be considered as risk factors [85].

Furthermore, it is well-recognised that children and adolescents are at higher risk of obesity if one of the parents is obese and at an even of higher risk if both parents are obese [52]. Nevertheless, it is quite difficult to determine whether this is due to genetic or familial environment factors or it might be a combination of both factors.

1.5.3 Familial influences

Evidence suggests that obesity clusters in families. Children of obese parents probably live in an 'obesogenic' family environment and so are at increased of being obese and maintaining their obesity. The Health Survey for England in 2007

has shown that the prevalence of obesity amongst children aged 2 to 15 years is higher where the parent(s) in the household are obese (i.e. both parents are obese or where the single parent as obese) compared with households with 'normal/underweight parent(s)'[113]. Clearly, children share the same environment with their families and many aspects of this environment are controlled by parents rather than children, in many ways such as food purchasing, food preparing and activity behaviours that influence the development of obesity in children.

There are numerous systematic reviews that examine the role of the parent in the aetiology of overweight and obesity in children namely in feeding [114-116], physical activity [117, 118] and screen time [119, 120].

1.5.3.1 Parental feeding

In 2004, Faith et al. [114] carried out a systematic review on the relationship between parental feeding styles and their relationship to child eating (energy intake) and weight. The author had identified 22 studies of which 19 were cross-sectional and only 3 studies were longitudinal. Selected studies were then sub-divided into those that examined general feeding control (8 studies) and those that examined feeding restriction by parents (e.g. restriction of snack foods) (9 studies). The results of the eight studies focusing on general feeding control were not consistent, showing equal reporting of positive associations (three studies) [121-123], no association (three studies) [124-126] and negative associations (two studies) [121, 127] between parental feeding styles and energy intake and/or weight status in children. However, of the nine studies that looked at feeding restriction, eight studies reported positive associations

between feeding restriction and child outcome [128-135], suggesting that a high level of feeding restriction by parents is associated with increased energy intake and/or increased weight in children.

A more recent systematic review by Clark et al. [115] examined the relationship between parental feeding behaviours and dietary intake and weight of children. The search was restricted to publications from 1996 to 2006 and 26 selected studies (11 cross-sectional, 6 longitudinal, 4 experimental, 2 observational, 2 qualitative, 1 retrospective) were identified. The authors concluded that the most consistent evidence is that parental restriction of snack foods is associated with 'uninhibited eating (when outside of parental control) and weight gain, particularly for girls', with nine studies showing positive associations [129-131, 133, 134, 136-139]. It has been shown that longitudinal designs provide a better evidence for causality [140]. Four of the studies on restriction were longitudinal [130, 136-138], thus providing some evidence for a causal relationship, in which parental restriction was associated with high fat intake [137], high snack intake [130], higher BMI [136] and eating in the absence of hunger [138]. The evidence for other parental behaviours such as parental monitoring or pressure to eat was inconsistent.

Both systematic reviews are consistent in their findings that restriction of 'snack' foods may be unlikely to work in obesity treatment interventions in children. Only 3 of the 22 studies in Faith et al. [114] review and 6 of the 26 studies in Clark et al. [115] review were longitudinal studies. Many of the included studies were cross-sectional, making it impossible to determine

whether the parent's feeding behaviour influences overweight or obesity in children, or vice versa.

1.5.3.2 Physical activity

Principally, weight gain results when energy intake is higher than energy expenditure, causing chronic energy imbalance. Energy intake is solely dependent on dietary consumption while energy expenditure depends on several components and physical activity is the major modifiable aspect for this. Thus, high dietary intake and low physical activity have been widely assumed to be causally involved in the development of obesity [83]. Obesity might also be maintained by a low level of physical activity. Most studies of habitual physical activity in children suggest that the overweight and obese are less active [141, 142] and have poorer fundamental movement skills than their normal-weight peers [143]. A meta-analysis also reported that there is consistent evidence that boys are more habitually active than girls [119] and that obese children favour participation in sedentary behaviours.

Given the scope for decreased physical activity among obese children, and the fact that increased physical activity is regarded as a cornerstone of childhood obesity treatment [3, 144, 145], several recent trials for treatment of obesity in children have reported on objectively measured physical activity [146-148]. Numerous interventions that include physical activity element in treatment designed to change physical activity behaviours in obese children. A recent systematic review by Cliff et al.[149] concluded that studies on the effect of child obesity treatment trials on physical activity of obese children were limited in quantity and quality: only three child studies were defined as high quality,

two from clinical settings [146, 150] and one from a community setting [148]. Furthermore, the correlates of parental factors and physical activity in children and adolescents have been previously explored in systematic reviews by Gustafson et al. [117] and Van Der Horst et al. [118].

A systematic review by Gustafson and Rhodes [117] identified 34 studies (5 longitudinal, 29 cross-sectional) published from 1985 to 2003 from five electronic databases. Twenty-four of the 34 studies examined the association of parents' physical activity level with their children's physical activity level (20 cross-sectional, 4 longitudinal). Only 6 studies measured physical activity objectively using accelerometers, 6 studies used validated questionnaires and 12 studies used non-validated questionnaires, highlighting a problem of validity with the measurements. Only 14 studies were summarised. The authors reported that associations between parents' and children's physical activity levels were inconsistent, showing equal reporting of positive correlations (6 studies) [151-156] and no association (7 studies)[157-163], and one further study found an inverse correlation [164]. Furthermore, the review also reported a strong positive relationship between parental support and children's physical activity levels from 18 studies (16 cross-sectional, 3 longitudinal) [117]. The authors stated that encouragement, involvement and facilitation were the three key forms of parental support which increased the likelihood of children engaging in physical activity [117].

A recent systematic review examines the correlates both of physical activity and sedentariness in youth [118]. This review was conducted and included studies published between January 1999 and January 2005. The 60 reviewed papers in

the recent review showed that for children aged 4-12 years, parental physical activity (for boys) and parent support were positively associated with physical activity but not for adolescents (age range 13-18) [118]. Both systematic reviews are consistent in their findings that parental support for physical activity is a key correlate of children's physical activity behaviour [117, 118].

In addition to the potential benefits of physical activity on energy balance in childhood obesity treatment, higher levels of physical activity would also have many other positive outcomes for the child's health[165], including improved cardiovascular risk factors [166, 167], and mental health and well-being including the promotion of self-esteem in children and adolescents [168].

1.5.3.3 Sedentary behaviour

It has been suggested that increased use of information and communication technology particularly TV viewing, playing video games and computers are critical sedentary factors affecting childhood obesity prevalence [119].

A systematic review with a meta-analysis included 30 studies (52 independent samples) on the relationship of TV viewing and body fatness and 24 studies (39 independent samples) on the relationship between TV viewing and physical activity showed positive statistically significant relationship between TV viewing and body fatness, and small negative relationship with TV viewing and physical activity among children and adolescents [119]. However, the review concluded that the relationships were too small to be of clinical significance, and that media-based inactivity was unfairly implicated in the rise in childhood obesity [119]. Furthermore, most studies in this meta-analysis were cross-sectional

studies and did not control for confounding factors; therefore they are unable to prove a relationship of cause and effect. It has been shown that cross sectional designs is the weakest evidence for causality as the findings can only show associations but not direction of influence [140].

However, findings from a birth cohort supported the fact that watching television in childhood is associated with an increased BMI, adding evidence for an association of cause and effect between television viewing and overweight or obesity [169]. Massive non-core food advertising (defined as high in undesirable nutrients or energy) particularly during children's peak viewing times could explain why TV viewing influences of obesity have gained a great deal of attention on contribution the development of childhood obesity [170].

Another recent systematic review conducted a review included published studies January 1990 to April 2007 [120]. Seventy-one selected studies (46 cross sectional, 28 longitudinal and 4 intervention studies) were identified. The authors concluded that the most consistent evidence recommends a limit to the time spent watching TV especially for younger children [120].

Most of the reported studies from both systematic reviews were from developed countries. With dramatic increases in the TV viewing and computer ownership documented in developing countries, it is likely that similar increases in sedentary behaviour will be seen there as well [170].

Jordan and Robinson [171] have reviewed the evidence around screen time (particularly TV viewing, playing video games and computers) and identified 5

promising interventions with the first three of which involve parents directly: eliminate TV from bedrooms; monitoring screen time at home; no TV whilst eating family meals; school curriculum based intervention; and training of health professionals [171]. While findings from aetiological studies are not the same as findings from treatment studies, a family-based treatment intervention probably needs to include reducing the time children spend in front of a screen as one of its component parts and this is discussed further in this thesis where treatment evidence is considered (Section1.5).

Furthermore, a systematic review on limiting sedentary behaviour to reduce childhood obesity also concluded that decreasing sedentary behaviours is an effective intervention to control weight in children and adolescents [172]. Successful interventions on reduce childhood obesity have focused on limiting time spent in TV viewing. Several mechanisms for the link between TV viewing and obesity have been suggested in children and adolescents. TV viewing can impact on energy balance through decreased energy expenditure (less time being physically active), possible reduction in resting metabolic rate [173] and increased energy intake (overeating while watching TV and children to food advertisements promoting unhealthy food i.e fast foods) [174, 175].

Reducing TV viewing represents a potentially important goal in childhood obesity prevention and treatment, and most recent evidence based guidelines for the treatment of childhood obesity have regarded the reduction of sedentary behaviour as a cornerstone of treatment [3, 144, 145]. Some obesity treatment trials have examined the potential benefit of reducing sedentary behaviour for weight management in children, particularly the work of Epstein's

group in the US. For example, as far back as the 1990's Epstein reported that obese children targeted for reduction in sedentary behaviours had a greater decrease in percentage overweight at 1 year than children targeted for being more active [176]. However in a later study, the same research team in 2000 reported that targeting either decreased sedentary behaviours or increased physical activity was associated with significant decreases in per cent overweight and body fat and improved aerobic fitness [177]. Decreasing sedentary behaviours therefore might be equally as effective as increasing physical activity in reducing childhood overweight.

Promoting increased physical activity and decreased sedentary behaviour is widely regarded as an important element of childhood obesity treatment, with favourable impacts on body composition and metabolism [178-180]. Changes in physical activity levels and sedentary behaviours are recommended by all international guidelines on the treatment of childhood obesity [144, 145, 181], most recommending at least 60 minutes MVPA per day , every day, and to decrease screen-based sedentary behaviours to no more than 2 hours per day of screen time.

1.5.4 Summary of determinants of childhood obesity

Behaviours that protect against obesity such as diets low in fat and sugar, control of portion size, and regular physical activity with lower sedentary behaviour are becoming difficult to control and maintain in the current environment. The influence of environment on the tendency for a child to gain weight excessively is almost impossible to separate from other influences on the development of childhood obesity. Furthermore, parents play an important role

in the aetiology of childhood obesity around the restriction of food, lack of support for physical activity and excessive screen time. Consideration of the family environment therefore is crucial as a strategy to manage the obesity epidemic particularly for young children, and this is discussed below in the sections on obesity treatment evidence.

1.6 Evidence for treatment strategies

1.6.1 Introduction

Over recent years, a number of reviews (systematic and narrative) have reported on evidence to guide the treatment of obesity in children. In addition, clinical practice guidelines rooted in those reviews were developed by various professional organisations, in a systematic way, synthesising the scientific literature into recommendations for best practice. Thus, this section provides a recent review from reviews on the management of childhood obesity. Additionally, two Clinical Practice Guidelines are examined in Section 1.6.3.

1.6.2 Systematic review- Cochrane Review, 2009 [3]

The 2009 Cochrane Review of interventions for treating obesity in childhood provides a transparent and systematic explanation of its methodology. Only RCTs were included in this review and were identified through searching from CENTRAL on the Cochrane Library Issue 2 2008 (including MEDLINE, EMBASE, CINAHL, PsycINFO, ISI Web of Science, DARE and NHS EED) from 1985 to May 2008. Only randomised controlled trials that observed subjects for a minimum six months follow up were included. Criteria regarding the type of participants, interventions and outcome measures were also provided. After screening inclusion criteria for the papers, there is an additional of 46 RCTs from a

previous Cochrane review, making a total of 64 RCTs (5230 participants) in the recent Cochrane systematic review.

Of the 64 trials, 10 (1424 participants) focused on anti-obesity drugs in adolescents (i.e. metformin, orlistat, sibutramine) and 54 (3806 participants) focused on lifestyle changes. Of the 54 RCTs focusing on lifestyle, 36 focused on behavioural oriented treatment programmes aiming to change diet, physical activity and sedentary behaviours (ranging from family-based therapy, cognitive-behavioural treatment, problem solving, and multi-component behavioural therapy); 12 focused on physical activity / sedentary behaviour only; and 6 focused on diet. For inclusion, the studies had to include a baseline and post intervention measurement of height and weight, with BMI z-score or percentage overweight as the primary outcome. A range of secondary outcomes were also considered, including a focus on adverse outcomes. The authors divided the 54 lifestyle studies for the purpose of analysis by the age of the child: 37 studies (4 dietary, 9 physical activity, 24 behavioural interventions) comprised children with a mean age <12 years and 17 studies (2 dietary, 3 physical activity, 12 behavioural interventions) comprised children with a mean age >12 years (i.e. adolescents).

A narrative synthesis and a meta-analysis are presented in the Cochrane review to ascertain the effect of behavioural family programmes on the change in BMI z-score compared with standard or minimal care. Only four of the 24 behavioural interventions in children <12 years fulfilled the criteria to be pooled, with 16 studies excluded from the meta-analysis as the studies had not been analysed using intention-to-treat principles. The Forest plot combining the remaining four

studies showed that the mean difference between the groups in BMI z-score favoured the behavioural intervention over standard care at the 6-month follow-up (-0.06, 95% CI -0.12 to -0.01) (Figure 1.3). However, the authors reported that there was no benefit at 12- months follow-up (-0.04, 95% CI -0.12 to 0.04) in behavioural interventions in children <12 years old.

Overall, the authors of the review admit that there is still limited data to ascertain which intervention is more effective in childhood obesity treatment but concluded that there is more than adequate evidence to support the effectiveness of a combination of four cornerstones to weight management (diet, physical activity and sedentary behaviour, behaviour modification and family-based therapy) in childhood obesity treatment. Furthermore, parental involvement was identified as being particularly useful in children < 12 years.

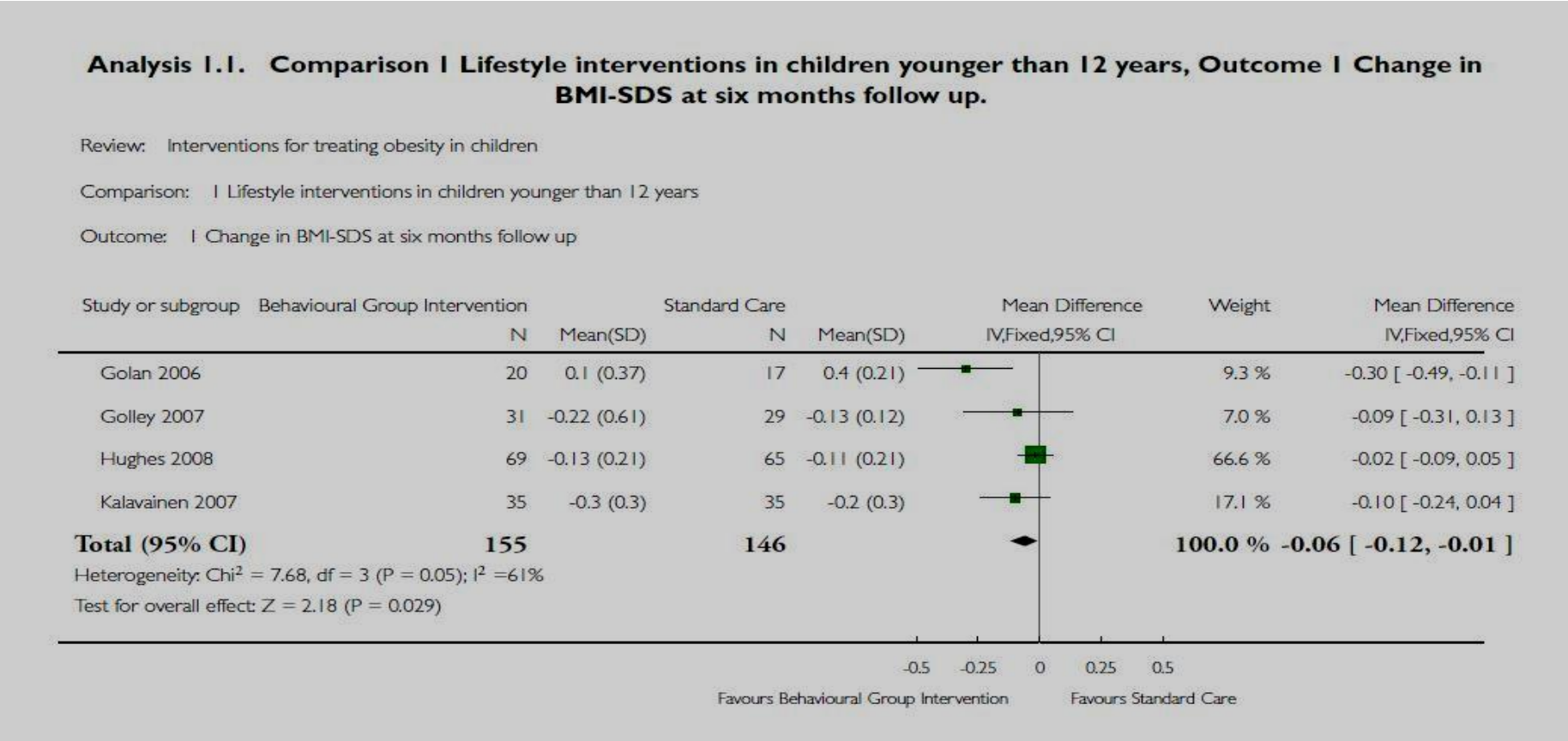
1.6.3 Clinical Practice Guidelines

NICE 43 Guidelines 2006-UK [144]

In England, guidelines for the management of obesity were developed by the National Institute of Clinical Excellence (NICE) in December 2006. The evidence for the NICE guidance was partially based on an earlier Cochrane review (100), but also included evidence from controlled clinical trials and controlled before-and-after studies, as well as evidence published since the Cochrane review of 2003. The guidelines addressed both clinical and public health recommendations, and for the purpose of this thesis, the clinical recommendations relating to the management of obesity in childhood will be reviewed. The guidelines were developed in accordance with the methods set out by the NICE in 'Guideline Development Process- Information for National

Figure 1.3 Forest Plots on the Treatment of Obesity in children under 12, 6 months follow-up from the Cochrane Systematic Review

(a) Behavioural interventions in children < 12 years – 6-month follow-up



Source:Oude Luttikhuis, Baur [3]

Collaborating Centres and Guideline Development Groups. The specific search strategies undertaken for the development of these guidelines are reported in Section 4.4 of the Full Guidelines.

Most of the evidence used to inform these clinical recommendations was ranked 1++ and 1+, indicating that it was sourced from well-conducted meta-analysis and systematic reviews with low risk of bias. The highest level of evidence (1++) is available for the following interventions in specialist weight management programmes:-

- Physical activity and diet combined are more effective in weight management in children aged 4-16 years, than diet alone
- Behavioural treatment combined with physical activity and/or diet is effective in children/adolescents aged 3-18 years
- Behavioural treatment can be more effective if parents, rather than children (aged 6-16 years), are given the main responsibility for behaviour change.

SIGN 115 Guidelines, 2010- Scotland [145]

The most recent guidelines for the management of obesity in Scotland were developed by The Scottish Intercollegiate Guidelines Network (SIGN) in February 2010 by the Academy of Royal Colleges and their faculties in Scotland. The Guidelines were based on a systematic review of evidence and the strength of the evidence was determined using the US Agency for Health Research and Quality, (AHRQ) appraisal method. The specific search strategies undertaken for the development of these guidelines are reported in SIGN 50: A Guideline Developer's Handbook (available at www.sign.ac.uk/pdf/sign50.pdf).

Similar to NICE Guidelines, most of the evidence used to inform these clinical recommendations was ranked 1++ and 1+, indicating that it was sourced from well-conducted meta-analysis, RCT, and systematic reviews with low risk of bias. The SIGN 115 guideli**ne** recommended that treatment strategies should be family based approaches targeting changes in diet, physical activity and sedentary behaviours [145]. The guideline also highlights that treatment should be behavioural in nature, and used the NICE 43 (2006) guideline's definition of what made a behavioural treatment. Behavioural modification techniques (such as goal setting, use of rewards and self-monitoring) were recommended, as part of a multi-component intervention. SIGN 115 did not however describe how treatment strategies should be implemented to make those behaviour changes [145].

In the UK, these two clinical practice guidelines for childhood obesity management have been developed to respond to the recent increases in rates of childhood obesity. The evidence informing the development of such guidelines and subsequent recommendations is consistent. Both clinical practice guidelines agree that an intervention is more likely to be effective if it promotes a healthy eating plan, encourages lifestyle physical activity and aims to reduce sedentary behaviours and takes a whole family approach.

1.6.4 Summary of evidence for treatment strategies

There is strong support for inclusion of the modalities of diet, activity, behaviour modification and parental involvement and support in a multi-component family-focused intervention for the effective management of childhood obesity. A

summary of the consensus from systematic review and guidelines would appear to be that the 'best bets' for treating childhood obesity are as follows:

- treatment should combine changes in diet plus changes in physical activity and/or reduction in sedentary behaviour (e.g. TV viewing);
- behavioural change and motivational techniques should be incorporated into the treatment programme and.
- treatment should directed at the entire family rather than just the obese child .

All international guidelines agree that treatment should be family based and only undertaken when the family [182], in particular at least one parent, is willing to engage in treatment and it should be integrated and be multi component, i.e. target diet, physical activity and sedentary behaviour. In other words, effective management strategies to promote those behaviours must occur within a family context to address modifiable behaviours that promote and maintain excessive weight gain. In the final stages of writing of this thesis, Shrewsbury et al. [182] published a systematic review which suggested that the importance of involving parents or the families in paediatric overweight and obesity treatment. The evidence base for family-based programmes to treat childhood obesity (aged 7 to 12), is reviewed in the following section.

1.7 Evidence-base for family-based programmes

Epstein et al.[183]

For some years research on paediatric obesity management has continued to grow. One of the major researchers and proponent of treatment programmes is

Len Epstein. Over a number of years, the research carried out by Epstein's group has indicated that an intensive intervention which uses targeted lifestyle changes (targeting changes in diet, physical activity and sedentary behaviour) along with the monitoring of lifestyle and the use of rewards can be successful in paediatric obesity management. His studies showed the importance of the programme and all the lifestyle changes being family-based with the support of the parents and family fundamental to any success. However although Epstein's studies were claimed as the ' best bets' for the treatment of childhood obesity [176, 177, 183-185], the treatments used in the various studies by Epstein have not been described in detail in any of his publications and no treatment manual is generally available, and so the treatment techniques cannot be easily replicated by other practitioners and researchers. One recent publication from the UK has used an adapted version of the Epstein treatment manual, in collaboration with Epstein, but did not publish the treatment manual [186].

Twelve of the studies in the Cochrane review [3] and 15 of the studies in the NICE guidance [144] were from Epstein's group, thus contributing considerably to the evidence base. He has been emphatic about the importance of the programme and all the lifestyle changes being family based with the support of the parents and family fundamental to any success. In 1994, this group evaluated A 'Family-Based Behavioural Therapy' (FBBT) programme, examining different lifestyle combinations, behaviour management approaches and/or target groups, delivered to groups over 8-12 weeks [183]. The FBBT programme used the Traffic Light Diet, which is a calorie based-food exchange system, with foods colour coded with red (foods particularly high in energy and thus should be

restricted/avoided), amber (foods are to be taken with caution) and green (foods that can be eaten freely).

In a ten-year follow-up of 'Family- Based Behavioural Therapy' in 77 families comprising obese parents and obese children, long-term changes in per cent overweight were best if the parent and child were targeted together (-11.2% at 5 years, -7.5% at 10 years). This result was compared with targeting the child alone (+2.7% at 5 years, +4.5% at 10 years) and a group where neither child nor parent were specifically targeted (+7.9%, +14.3%).[185] Their programme provides evidence that parents should be involved in the therapy process in order to sustain change.

Hughes et al. [187]

A more recent randomised controlled trial study used in the conception of the MASCOT programme was the SCOTT study which involved an individualised behavioural-based intervention with 134 obese children of primary school age (5-11 years old) randomised to either the SCOTT group (intervention) or a standard care group (control) in Glasgow and Edinburgh, Scotland. The intervention group involved an evidence-based novel dietetic treatment (eight dietetic interviews) over 6-months with a 5 hour 'dose' of treatment and used family-centred behavioural change techniques while the control group received 1.5 hours of 'typical' dietetic weight management delivered in a traditional (educational) manner, ie families were instructed what to do. The SCOTT study was closest in design to the MASCOT project. It was loosely based on Epstein's work, used the traffic light diet scheme, self-monitoring goal setting and relapse prevention, and the SCOTT treatment protocol has also been published [188].

Golan and Crow [189]

Golan and Crow's research has added to the evidence of the effectiveness of family-based interventions, but with an emphasis on parents as the main or only target of treatment. The authors reported a 7 year follow-up of a randomised controlled trial of 60 obese children aged 6-11 years with parents or children targeted as the exclusive agents of change. Per cent obesity was calculated using formula: 100 [actual weight - desirable weight)/desirable weight (based on the 50th percentile weight for a particular age, sex, and height according to the National Centre for Health Statistics growth charts)]

Parents attended a 14 session group therapy with total 'dose' of treatment of 14 hours consisting of eating and activity behaviour modification; decreasing stimulus exposure, parental modelling, and parents were encouraged to practice 'authoritative' parenting. On the other hand, the children attended 30 1-hour group sessions and they were prescribed with a diet, and discussions on physical activity, eating behaviour modification, stimulus control, self-monitoring, nutrition education, problem solving, and cognitive restructuring. The study reported that the mean reduction in percentage obese was superior for the parent group (29%) compared with the child group (20%) ($p<0.05$).

A further study was carried out by the same author in 32 families with obese children (BMI for age and sex >85th percentile) aged 6-11 years who were randomised either to treatment of parents exclusively (intervention group) *or* treatment of parents with the obese child [190]. Both groups received a 6-month educational and behavioural programme for a healthy lifestyle. With respect to changes in degree of overweight, significant reductions in percentage

overweight and BMI z-score were observed only for the parent-group (-12%; p=0.05 and -0.5; p=0.03, respectively), whilst non-significant increases were reported for outcomes in the parent and child group (+0.4% and +0.1, respectively), suggesting that interventions delivered to parents alone may be more effective and that the obese child could be omitted from active participation in treatment.

Golley et al. [191]

Golley et al. [191] have examined the effects of 'Triple P' Positive Parenting Program in the treatment of childhood obesity. The programme has been developed which combines parenting skills training using Triple P with healthy lifestyle information among 111 pre-pubertal overweight/obese children aged 6 to 9 years, in a clinical setting. Families were randomly assigned to three groups: 1) parenting skills alone 2) parenting skills plus lifestyle education (4 two hour group sessions on parenting followed by 7 sessions on lifestyle) and 3) waiting list control group. The intervention was only delivered to groups of parents – children did not attend any sessions, and parents were encouraged to deliver change at the level of the family rather than the individual child. Although there was no significant difference in BMI z-score between three groups, after a 12 months intervention programme, the study showed that there was a reduction of approximately 10% of BMI z-score in the parenting-skills training plus intensive lifestyle education compared to the parenting-skills training alone or waiting list for intervention (only reduction of approximately 5% in BMI z-score in both groups). This indicates that parenting programmes delivered alongside lifestyle components may be a more effective approach for weight management than programmes that focus on parenting alone. The study

also reported a greater reduction in BMI and waist-circumference z-scores in boys and suggested that the intervention programme would be more effective in boys than girls. A limitation is that the study did not have a traditional family-based 'lifestyle' programme arm without the parenting aspects, in order to assess the benefit of adding parenting skills to the treatment of obesity with lifestyle change.

Sacher et al. [192]

The Mind, Exercise, Nutrition, Do it (MEND) Program is a multi-component community-based childhood obesity treatment intervention. Participants were randomised to intervention or waiting list control group: 116 participants were recruited from five UK sites that includes children aged 8-12 years old, classified as (BMI ≥ 98th percentile, UK 1990 reference data). The primary outcome measure was change in waist circumference from baseline to 6 months. Changes in BMI and percentage of body fat were also measured as secondary outcomes.

Parents and children attended eighteen 2-hours group educational and physical activity sessions held twice weekly in sports centres and schools, followed by a 12-week free family swimming pass over 6 months. Children were then followed up 12 months from baseline. At 6 months, there were significant between-group differences in waist circumference z-score and BMI z-score in favour of the intervention group. Similarly at 12 months, children in the intervention group had reduced their waist and BMI z-scores by 0.47 ($p < 0.0001$) and 0.23 ($p < 0.0001$), respectively.

West et al. [193]

This study is a parent-centred intervention for childhood obesity that involves 101 participants with overweight and obese (using IOTF definitions) 4- to 11-year-old children who participated in an intervention or wait-list control condition. The primary outcome measure was BMI z-score, measurements were taken at 12 weeks. Similar with the Golley et al. [191] study, the parenting skills programme was based on the Positive Parenting Programme, 12-week intervention that consists of nine 90-min group sessions and three 20-min telephone sessions.

The 12-week intervention was associated with significant reductions in child BMI z-score and weight-related problem behaviour. There was a reduction in mean BMI z-score in the first 12 weeks of in the intervention group compared to no change in the wait-list control condition. For the intervention group the mean BMI z-score changed from 2.15 (0.43) at baseline to 2.04 (0.44) at 12 weeks and after 1 year follow-up, the mean BMI z-score decreased significantly to 1.96 (0.46).

1.7.1 Summary of evidence-base for family-based programmes

To summarise, there are a number of childhood obesity treatment interventions which now suggest that a family-based treatment of childhood obesity with parents as agent of change is an effective alternative to child group treatment. Indeed, Golan et al. [190] states that the parents-only approach was more effective. In the current study, the MASCOT programme was delivered as a family-based intervention, with both parents and children attending the group-based programme separately but parents were considered to be the 'agents of

change' to bring about the required changes in lifestyle. The treatment programme and its development are discussed in detail in Chapter Two and the full treatment programme is given in Appendix Seven.

Up to now, there has been no research activity in Malaysia on interventions to treat childhood obesity. It is pertinent to review the background and the issue of childhood obesity in Malaysia.

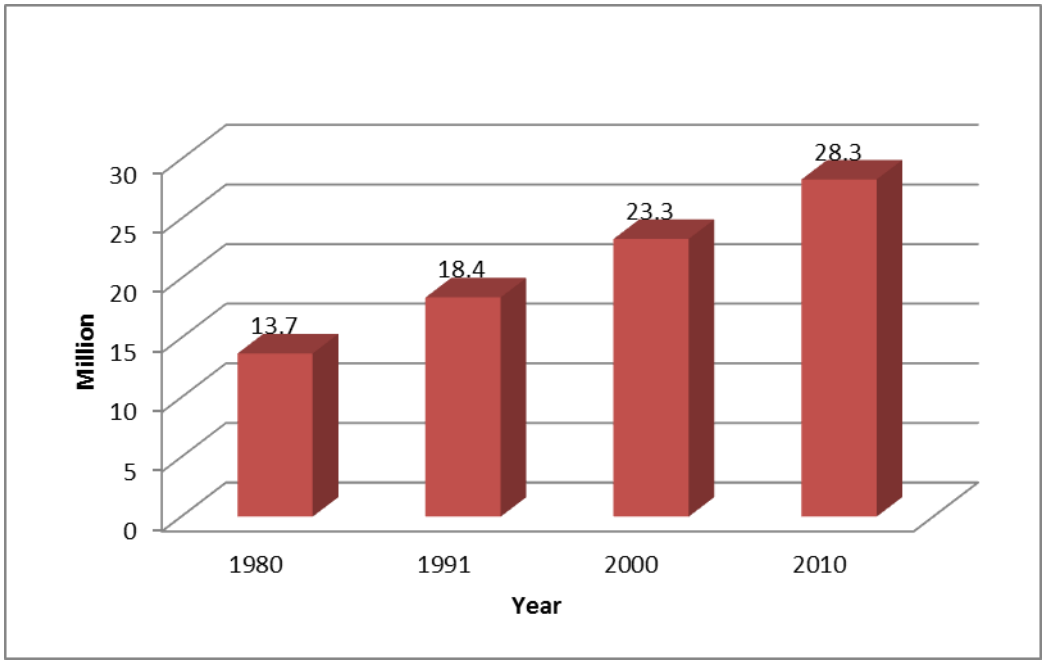
1.8 Malaysia in context

Malaysia has experienced rapid industrialisation and urbanisation since the country's independence in August 1957. Stability in economic growth and political development has resulted in improvements in mortality and morbidity in Malaysia. According to the recent 'Population Distribution and Basic Demographic Characteristic Report, Population and Housing Census Malaysia, 2010, total population of Malaysia was 28.3 million compared to 23.3 million in 2000 and consists of the ethnic groups Malays (67.4%), Chinese (24.6%), Indians (7.3%) and others (0.7%) [194]. Urbanisation has increased from about 25% of the population in 1960 to 71% in 2010 [194]. Based on poverty line income of US$1 per day, the prevalence of poverty decreased from 17% in 1990 to below 4% in 2009 [195].

Kuala Lumpur is the capital and the largest city in Malaysia with population of 1.6 million as of 2010 [193]. Kuala Lumpur and its surrounding urban areas form the most industrialised and economically, the fastest growing region in Malaysia with 100% urbanisation [193]. The economic transition and population growth, together with changes in lifestyle to one of urbanisation in have led to profound

shifts in dietary and physical activity behaviours among Malaysians , a 'westernisation' of lifestyle. Furthermore, the accelerated socioeconomic development in the past several decades in Malaysia has resulted in major changes beginning with a demographic transition to urbanisation , shifting occupations from physically active rapidly towards sedentary. Dietary changes also appear to be shifting towards a diet dominated by a higher intake of animal and lower intake of fibre. In other words, Malaysia is now experiencing a nutrition transition [195]. What was once a problem of developed countries is now affecting developing countries including Malaysia.

Figure 1.4 Total population of Malaysia from 1980 to 2010

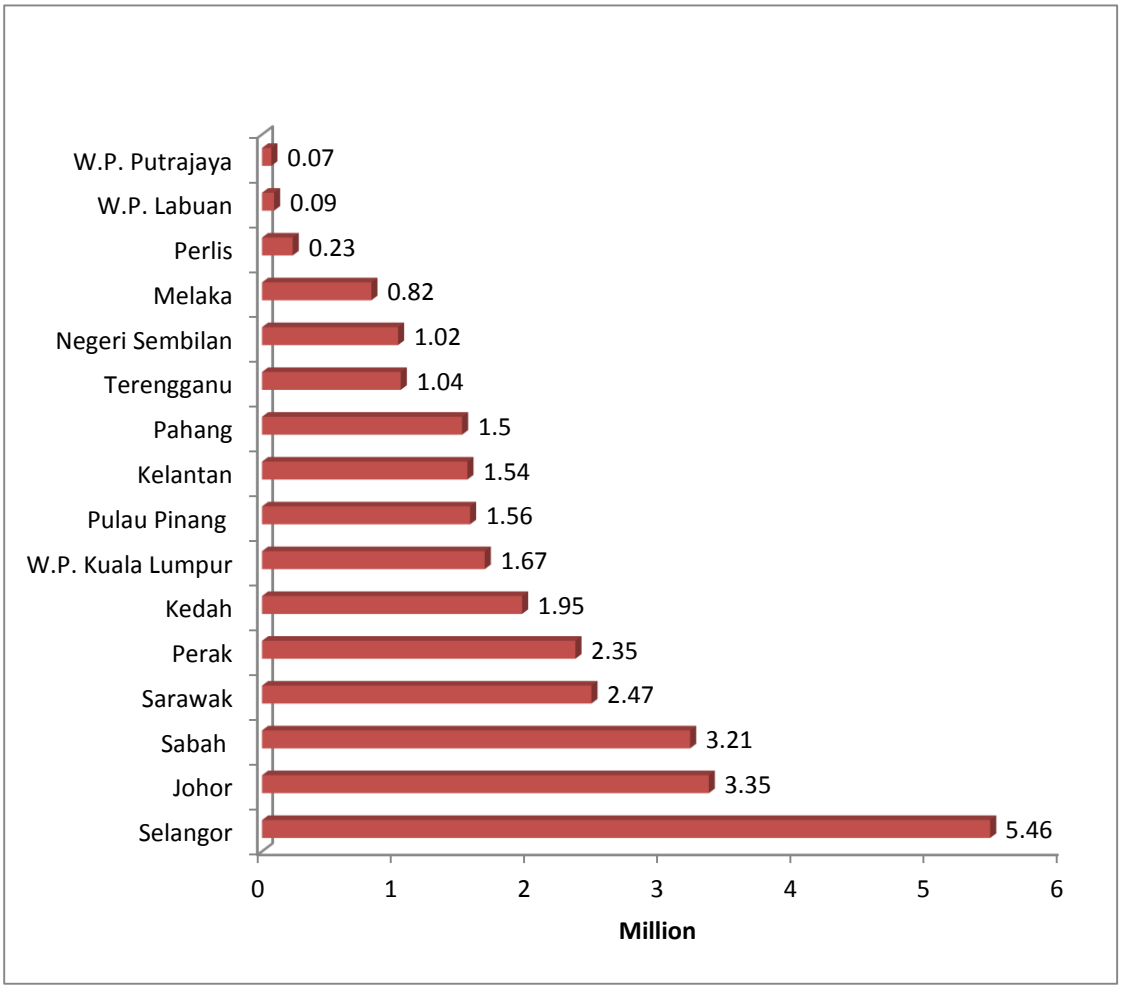


Source: Department of Statistics Malaysia (75)

The evolution in the lifestyle and dietary habits towards higher consumption of animal source foods, added sugar and fats and lower intakes of fruits and vegetables have been implicated in the increasing rate of obesity and nutrition-related non-communicable diseases in Malaysia [196]. In the absence of

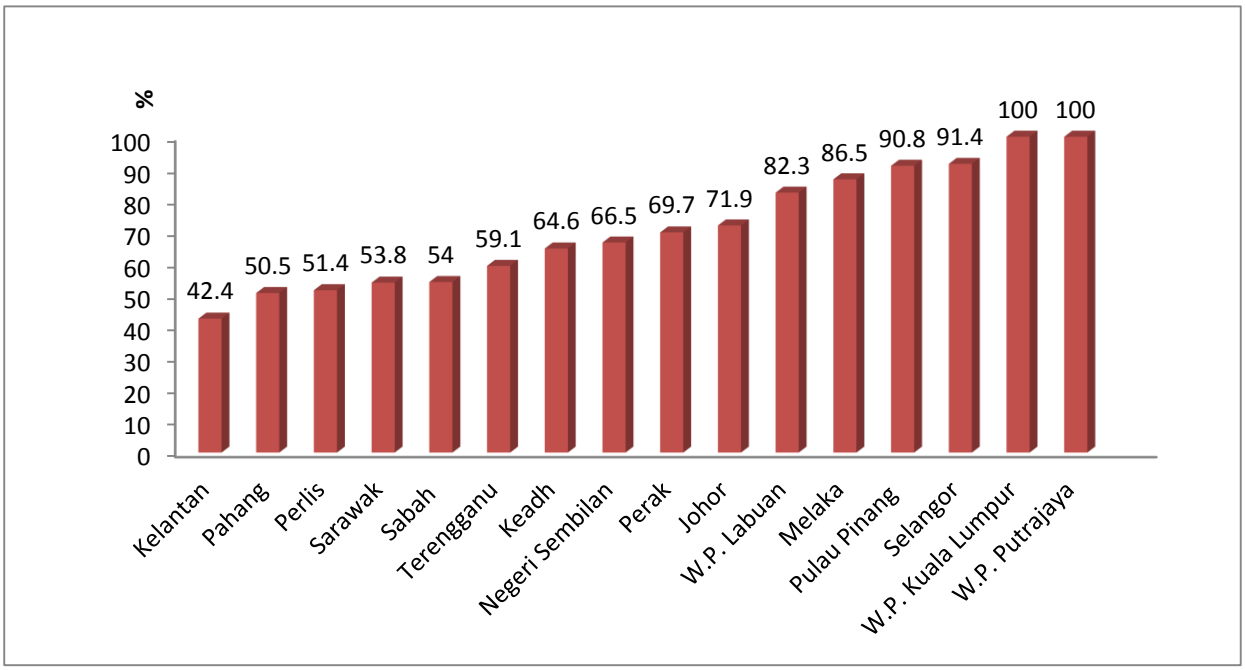
nationwide food consumption survey on dietary intake, the food balance sheet data provides some useful information on the trends in dietary intake of Malaysian people [197]. The food balance sheet data show that the energy intakes of Malaysian adults increased on average by 23% (2343kJ/day). Absolute fat and protein intakes also increased from 49g per person per day to 87g per person per day and from 49g per person per day to 61g per person per day, on average, respectively. These increases in total energy, fat and protein intake resulted from increased consumption of meat, fish, eggs, sweeteners, oil and fats (Figure 1.7)[197].

Figure 1.5 Population distributions by state, Malaysia, 2010



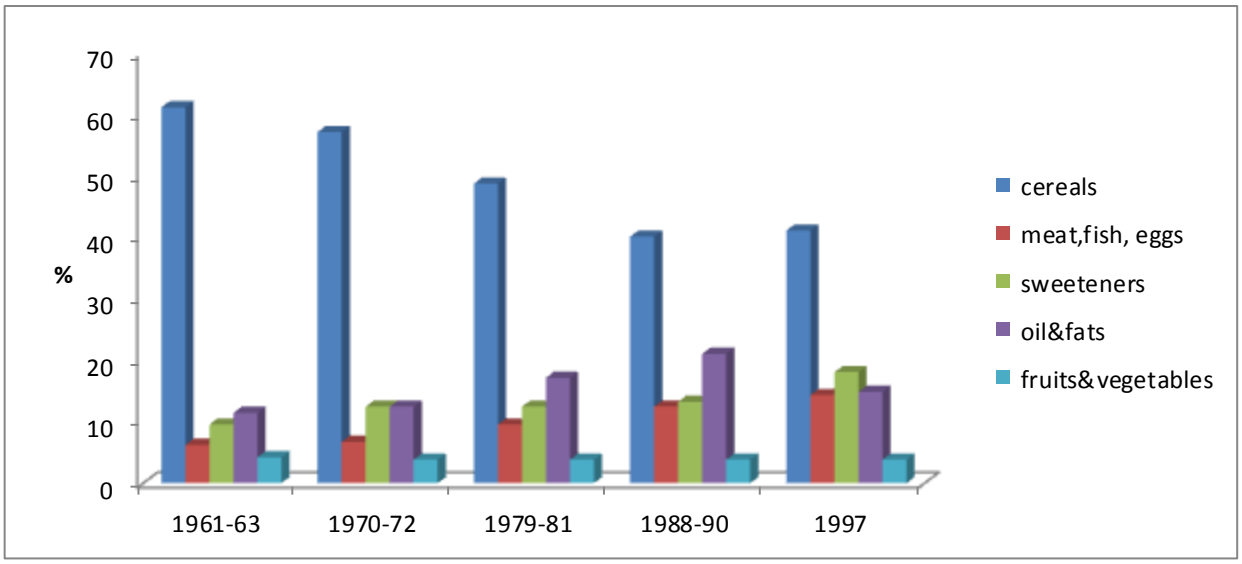
Source: Department of Statistics, Malaysia [194]

Figure 1.6 Level of urbanisation in Malaysia according to state, 2010



Source: Department of Statistics Malaysia [194]

Figure 1.7 Changes in sources of calories in Malaysia, 1961-1997



Source: FAO. Food Balance Sheet, 1961-1997[197]

Although these data are not specific to dietary intake of Malaysian children, a small study showed that the energy intake of 11-15 years old girls overweight children and adolescents is higher (2138kcal/day) than normal weight children

and adolescents (1903kcal/day)[198]. The study also reported that fat intake provides on average 30% of the total energy intake in this sample.

Furthermore, fast food is a growing component of the Malaysian diet. The growth of the fast food industry in Malaysia has increased dramatically since 1990s and it has been reported that total sales were RM 1 billion (£204 million) in 1997 increasing to RM 1.3 billion (£266 million) in 2000 [199].

Another concern is that a pilot study of physical activity and sport in Malaysian children reported that children showed a strong preference for sedentary pursuits, rather than sport or activity games in their leisure time [200], which may increase risk of the development of obesity in children. Watching television and/or video was the most popular leisure activity undertaken during the school week and at the weekend (97%) and video games were seen by 56% of boys compared to girls (25%)[200].

Childhood obesity research in Malaysia is very much in its infancy. Furthermore, as Malaysia progresses rapidly towards developed economic status, national strategies need to be developed to tackle both dietary and activity contributors to the excess weight gain in children.

In 2003, the Ministry of Health Malaysia and Academy of Medicine Malaysia developed clinical practice guidelines on the management of obesity in adults and children [201]. The guidelines were based on a systematic review and reports of other relevant expert working groups. Most of the evidence used to inform these clinical recommendations was ranked C, indicating a lack of

evidence from a large number of high quality RCTs to inform the guidelines for the Management of Obesity in Children and Adolescents. The Malaysian guideline recommended the following components in the management obesity of children and adolescents:-

- Reduction of energy intake by dietary modification, and using conventional foods
- Increase energy expenditure by increasing physical activities and decreasing physical inactivity
- Behaviour modification associated with eating habits and activity pattern
- Involvement of the family in the process of change.

All those components were included in the present study. At the time of starting the MASCOT project, no RCT on a childhood obesity treatment programme had been carried out in Malaysia. The recent and rapid increases in rate of childhood obesity internationally suggest a need for weight management programmes. Therefore, a well-designed programme on childhood obesity weight management should be developed in Malaysia based on recent evidence and guidelines.

1.9 Conclusion: Thesis aims and hypothesis

1.9.1 Thesis aims

As described in Section 1.6, the recent systematic review and the UK guidelines revealed a number of promising strategies for the successful management of childhood obesity. These strategies targeted parents as an agent of change to modify behaviour changes in physical activity, sedentary behaviour and diet. This thesis study therefore aims to address the primary research question:

"Does a family-based behavioural programme for the management of obesity (MASCOT) improve the BMI z-score of 7-11 year old children in Malaysia?"

The aims of the thesis study are:

- To address the primary research question, the MASCOT programme was compared with a no treatment control group. The study's primary outcome was change in BMI z-score at 6-months. The study also aimed to investigate a number of secondary outcomes namely change in quality of life, physical activity and sedentary behaviour, height and weight at 6-months **(Study Methodology- Chapter Two)**

- To examine the differences in health-related quality of life between obese children and healthy weight children **(Health-related Quality of Life- Chapter Four)**

- To examine the differences in physical activity and sedentary behaviour between obese children and healthy weight children **(Physical activity and Sedentary Behaviour- Chapter Five)**

1.9.2 Thesis hypothesis

The study research will test the hypothesis that:

"A 'good practice' intervention for the treatment of childhood obesity would have a greater effect on primary outcome (change in BMI z-score at 6-months) and secondary outcomes (change in physical activity and sedentary behaviour, height and weight at 6-months) than allocation to a no treatment control group."

CHAPTER TWO

Study Design and Methodology of the Randomised Controlled Trial of MASCOT (Malaysian Childhood Obesity Treatment) Programme

2.1 Introduction

This chapter outlines the design and methodology of the MASCOT intervention study which assessed the efficacy of the family-focused weight management programme (intervention) relative to no treatment group (control) of obesity in 7-11 year old school children. A full description of the MASCOT study is also given in this chapter and the treatment protocol is described in detail in Appendix Seven. The intervention programme was delivered for six months between November 2008 and April 2009 at primary schools in Kuala Lumpur and the outcome measurements were taken at baseline and six months. The MASCOT research team consisted of a dietitian, two physiotherapists as well as a psychologist based at the Universiti Kebangsaan Malaysia, Kuala Lumpur.

2.2 Ethical Approval

Ethics approval was granted by the Medical Research & Ethics Committee, Faculty of Medicine, Universiti Kebangsaan Malaysia, Kuala Lumpur.

2.3 Study design and reporting

2.3.1 Design

The MASCOT study was a single-blinded randomised controlled trial of a dietetic treatment for childhood obesity in children of primary school age. The trial was to be registered, conducted and reported in accordance with CONSORT

guidelines [202]. Compliance with CONSORT is essential to ensure our study has high methodological quality. The study also used an 'intention to treat' analysis on the conduct and reporting of RCTs. Intention to treat analysis (ITT) is a method of analysis for randomised trials where all subjects assigned to one of the treatments were analysed together regardless of whether or not they completed or received the treatment [203]. According the CONSORT statement [202], authors require to indicate whether analyses were performed on an ITT basis, however it does not outline how ITT should be approached. As outlined in Section 1.9.2, the study tested the hypothesis that obese children from a treatment group have no significant difference in change in BMI z-scores at 6 months compared to the no treatment (control) group.

The study did not compare the intervention group with standard care treatment in Malaysia because there is no or only minimal treatment available for obese children in the health care system in Malaysia. Obesity treatment in Malaysia at present has focused its attention on treating obese adults, not children. In view of the fact that this was a first study conducted in Malaysia and the lack of treatment given by the standard care system, the no treatment arm acted as a control group. The present study did not have the resources to offer a waiting list control, or to offer some form of control group which involved treatment.

2.3.2 Target patients

2.3.2.1 Justification

Study eligibility criteria were set out to ensure that 1) primary school children (aged 7-11 years old) recruited required weight management, 2) the degree of "obesity" was not such that the children were likely to have serious

comorbidities (many will have had comorbidities but not serious ones requiring urgent treatment) requiring specialist paediatric interventions and 3) the intervention programme would be appropriate for the child's development. Therefore, the inclusion and exclusion criteria for this study are noted below:

2.3.2.2 Study inclusion criteria

Children were eligible for the study if they were;

1. aged between 7 and 11 years old and attending primary school,
2. had a BMI $\geq 95^{th}$ centile (CDC reference)[204] and
3. had at least one parent willing to take part in the study

2.3.2.3 Study exclusion criteria

Children were ineligible to enrol in the study if they;

1. had an obvious underlying medical cause of obesity,
2. had serious co-morbidity requiring urgent medical or surgical attention,
3. had attended any dietetic clinic in past 12 months.

2.4 Study procedure

2.4.1 Recruitment

Subjects were recruited between July 2008 and November 2008 in Kuala Lumpur. 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. Potentially suitable children (considered to be overweight or obese by their class teacher) were assessed for eligibility by the author using BMI. Of 500 potentially eligible children identified

by teachers, 365 were confirmed as obese according to BMI (BMI $\geq 95^{th}$ centile). All of these 365 children were provided with study information sheet and the details of the study to be given to their parents (Appendix Two).

2.4.2 Consent

Following recruitment at the schools, the researcher then telephoned the families to inquire if they were interested in taking part in the study. The researcher ensured that the child was eligible for the study (see 2.3.2.2 for inclusion criteria). If the child was eligible and the family willing to take part in the study then they were invited to come to the university where all the baseline measurements were taken. At this point, the study was explained in detail to the parent and child.

If families were allocated the intervention group, the dietitian then sent a weight management programme timetable to the families and telephoned two days before the first class to confirm attendance. Additionally, all parents and children were assured that they could withdraw from the study at any time without consequence. Informed consent was obtained from parents (for their own participation and that of their child) and child assent was obtained from those eligible and interested.

2.4.3 Randomisation and concealment

Participating families attended a weight management centre where all baseline measures were taken, and then the researcher 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 (Prof.

JH McColl) at Glasgow University who produced a computer generated randomisation list which allocated participants to treatment or control group so that groups were balanced in blocks of 20. The group randomisation was stratified for gender. After the randomisation, the statistician sent (by email) the dietitian the study code and group allocation.

2.4.4 Blinding

All the outcome measurements taken at baseline and six months were measured by the main researcher (author) who remained blinded to group allocation throughout the study. The dietitian, physiologist, psychologist and the families were for obvious reasons not blinded to group allocation. The children and families were reminded regularly not to tell the main researcher which group they were in.

2.4.5 Delivery of interventions

2.4.5.1 Intervention group

The intervention was intended as a relatively low intensity (8 sessions, 8 hour contact time, delivered as group sessions) programme, delivered over a 26-week period largely by a dietitian who led every session. Input from a clinical psychologist supported the work of the dietitian outside treatment sessions, and provided support to parents directly during one session. This input helped ensure that the programme 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).[187] The treatment

programme involved greater contact time than SCOTT and was delivered as a group intervention targeting the parents only, unlike SCOTT [187]. Modifications to the 'SCOTT' treatment programme were made in order to use the parents as the main agents of change, a successful approach in some studies [189, 190], 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 [188] and 'Bright Bodies' childhood obesity treatment RCT [205]. The full description of the programme is discussed next (Section 2.5). The primary aim of the intervention was weight maintenance allowing the child to 'grow into their weight', ideally until their BMI was within normal centile ranges [145, 206].

2.4.5.2 Control group

Children who were allocated randomly to the control group did not receive treatment.

2.5 Study full description

2.5.1 Behavioural targets

The MASCOT treatment focused on change in three key behaviours recommended as the principal targets of obesity treatment by systematic reviews [3] and recent evidence based clinical guidelines [144, 145]: reductions in sedentary behaviour, particularly screen-time; increases in physical activity; changes in diet. The parents were targeted as the main agents of lifestyle change as recommended by recent systematic reviews [3] and clinical guidelines [144,145]

and the work of Golan etal. [190] which concluded that combined behavioural lifestyle interventions which are family centred are most likely to produce significant and clinically meaningful reductions in BMI z-score in obese children. Most lifestyle changes in the MASCOT treatment programme were intended mainly for the obese child, but to achieve such a change would require changes in lifestyle by the entire family, and so treatment efforts in MASCOT were directed largely at the parents.

Our MASCOT treatment programme therefore focused on bringing about sustained changes in dietary intake, increasing physical activity, reducing sedentary behaviour in children of primary school age, 7 to 11 years old, who are obese ($\geq 95^{th}$ centile for age relative to CDC reference [204] and above the obesity threshold from the Cole et al. method [11] in which the parents would be largely responsible for inducing changes in lifestyle.

2.5.2 Dose of treatment and method of delivery

The rationale for the treatment in MASCOT was that it should be relatively 'low dose' and so reasonably generalisable, and it was also felt that an eight group session intervention (with a total dose of patient contact of around 8 hours) would be more generalisable than the more intense and longer duration interventions which have been described in the US literature [183, 205] many of which require much greater patient contact over a much longer period. The programme was facilitated by a dietitian, psychologist and physiotherapist.

The Parent-Only group attended classes included nutrition education, exercise and behavioural modification topics facilitated by the dietitian and psychologist

of 60 minutes each. Parents were provided with treatment hand-outs that were modified from SCOTT materials [188] and Bright Bodies materials [205] supplemented with additional self-developed material (Appendix Seven). The content of each session in the MASCOT treatment programme is outlined in Table 2.1.

Concurrently, the children in the intervention arm of the MASCOT trial participated in a physical activity class facilitated by an exercise physiologist. Most sessions consisted of a warm-up, exercise and a cool down aimed to develop children's motor skills and to motivate them to increase physical activity.

2.5.3 Behavioural theory and behaviour change techniques

As noted above, the MASCOT treatment was intended as a family-centred approach based on heavily adapted version of treatments used in two (SCOTT and Bright Bodies Treatment Programme) recent childhood obesity treatment RCT [187, 205]. Considerable evidence from clinical trials shows that behavioural family-based treatment approaches are the most effective options for the management of childhood obesity [207]. The intervention employed a number of behavioural change techniques underpinned by two well recognised theories of behavioural change, the transtheoretical model [208] of change and the social cognitive theory [209, 210]. The use of these techniques was pioneered in childhood obesity treatment by Epstein and colleagues [183, 184, 211] and the techniques are becoming increasingly common in childhood obesity treatment and prevention trials [3, 144, 145, 187, 205]. Various behavioural change techniques were employed in the MASCOT treatment intervention in order to:

assist the parent and child in raising their awareness of their lifestyle; help them focus on the aspects of their lifestyle which require changes; to motivate the child and family to make lifestyle changes; to 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 [212]. These techniques are described in brief below.

2.5.3.1 Readiness to change and decisional balance

Motivation and readiness to change were explored in depth in the first appointment in the MASCOT treatment programme (Session 1, see Table 2.1). Assessment and reflection on readiness to change is an established part of 'good practice' management of a number of chronic paediatric diseases [213, 214] and was considered by the authors to be an important part in this programme to assess a parent's willingness or readiness to change the child's lifestyle. The MASCOT intervention programme used a Readiness-to-Change scale to determine where families were on the continuum between "not prepared to change" and "prepared to change". The parents were asked to mark on a scale 0 to 10 their current position in the change process, 0 indicating not prepared to change and a score above 5 suggesting that that the parent is willing to consider lifestyle change.

The parent was then asked to complete a 'decisional balance chart' which considers the 'pros and cons' scale sheet in order to help the parent to identify the pros (benefits) and cons (costs) of changing behaviour [187, 188]. Firstly, the parent was asked to write down the benefits of making the changes and also the

costs of making those changes. Then, the parent was asked to consider whether the pros outweigh the cons or the pros outweigh the cons. If the pros outweigh the cons, it should help motivate families to make behavioural changes. Open questions were also used as part of the decisional balance, to prime the parent to think about ways to overcome identified barriers to lifestyle change and actions that might be taken to overcome these barriers.

2.5.3.2 Goal setting, contracting and rewards

Setting realistic behaviour change goals is an established element of behaviour change techniques in the management of a number of other chronic paediatric diseases [215] which depend on lifestyle change in management [214-216], and is increasingly being used in the management of childhood obesity, and widely recommended by recent guidelines on childhood obesity treatment (SIGN 115)[145] and by the recent Cochrane review [3].

In the MASCOT treatment programme, goal-setting was used and was intended to encourage behavioural changes, and to help increase and maintain the child's and family's motivation for behaviour change [187, 212]. In the context of MASCOT, the parent was asked to identify the lifestyle changes his or her child can make and parents were asked to consider how to make them and think about the problems which might arise when making lifestyle changes and how to overcome these. In other words the MASCOT treatment programme was 'family centred'. In contrast, more traditional management of childhood obesity and other chronic disease is less family centred, and it would be typical for the health professional (e.g. the dietitian) to simply give out a set of instructions (e.g. a diet sheet) or for the dietitian to set behaviour change goals for the child

or the family, or in some more traditional treatment programmes no specific behaviour change goals would be set.

Even though the parent was asked to set the goals, they have to make sure that the goals can be achieved and agreed by his or her child. The dietetic professional in our programme assisted participating parents in creating "SMART" goals (ie, small, measurable, achievable, realistic and timely) [144, 184] which is regarded as being very important for accomplishing the goals. In MASCOT, parents were asked to set the goals that were based on the information that had been given in session 2 (nutrition education) and session 3 (physical activity and sedentary behaviour) (see Table 2.1). Parents were initially asked to choose behaviour change goals at those sessions and asked to set three goals to be kept until session 7.

Behavioural contracting is being used increasingly in 'good practice' in the management of childhood obesity and was used many years ago in the childhood obesity treatment programmes by Epstein [176, 177, 183-185]. In recent years, behavioural contracting has been used in a few childhood obesity treatments RCT [144, 217-219]. The signing of a 'contract' between the child, parents and health professional may help the parents to assist their children to maintain focus on specific behavioural goals that the parents have set in the allocated time period. In the MASCOT study participating parents and children agreed on a reward for the child achieving 100% of the goals which was then signed as a 'contract' between the child and parent and this was supported by the dietitian.

Besides that, in order to reinforce the commitment to meeting the lifestyle change goals, every time the child achieved one of the goals, the parent would put a colourful sticker on a "Goal Puzzle Chart" distributed to families (Appendix Eight). For a total of three stickers accumulated, he or she was entitled to the agreed reward. Counting the number of stickers was intended as a source of motivation for the child to make the lifestyle changes because that would mean he or she was getting closer to the reward. Children were allowed to choose a reward for achieving the agreed on lifestyle change goals and the rewards should be inexpensive, non-food items, such as a book or a family trip [188, 212]. Studies have shown that behavioural rewarding has been helpful as reinforcement to the setting and attainment of goals [183, 220, 221]. At the end of the MASCOT intervention programme at session 8, the parents were asked to set their children long-term goals (as part of relapse prevention) and these were recorded on a new goal sheet.

2.5.3.3 Self-monitoring as used in the MASCOT treatment programme

Many psychologists believe that self-monitoring is an essential strategy in behavioural change interventions in order to help people change their lifestyle [222, 223]. Self-monitoring of lifestyle has been used in 'good practice' management of a number of chronic paediatric diseases [214, 216], and is being used increasingly in childhood obesity management in RCT [3]. Since extensive, detailed diaries were likely to present an adherence problem, in the MASCOT treatment programme, we utilised much simpler and more focused self-monitoring diaries that could be kept by the children. It was emphasised as essential to parents that their children's diaries should be based on the child's personal goals and targeted behaviours. For example, if increasing vegetable and

fruit intake was one of the behaviour change goals, then daily intake of these foods would be recorded.

In the MASCOT treatment programme, families were encouraged to self-monitor their lifestyle in general, and the behaviours set as goals in particular, by keeping a simple lifestyle diary, in which parents guide their children to write down everything they eat, drink, recording the type of daily exercise and the time as well as the amount of TV viewing. From the second session until third session of the programme (see Table 2.1), the parents have to monitor their children to keep a lifestyle diary in which diet, physical activity, and sedentary behaviours were recorded each day for one month. During the parent sessions 4 and 5, the dietician reviewed the lifestyle diaries, in order to help encourage parents to help their children to keep the diaries, and to help highlighted progress towards the behavioural goal. After the review by the dietitian, parents and children were encouraged to continue with self-monitoring throughout the programme, and to use self-monitoring to assess whether goals have been achieved.

Table 2.1 Components of the MASCOT treatment programme (see Appendix Seven for programme details)

Session	Topics	Contents	Behavioural change technique	Week
1	Wake up call	Risky Life The benefits and sacrifice 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 reference guide	Goal Setting, Contracting and Rewards Self-Monitoring	3-4
3	Be Active!	How to motivate child to initiate physical activity How to decrease sedentary behaviour	Goal Setting, Contracting and Rewards Self-Monitoring	5-6
4	Make a Better Life	Eating a daily breakfast Family meal Fast food Label reading	Problem-solving Self-Monitoring	7-8
5	I Feel Good	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	Simply the Best	Understand a relapse How to improve current diet and physical activity Tips maintaining a successful routine	Problem-solving Preventing Relapse	19-20
8	Sharing is Caring	The most admirable family of the program Sharing tips with other parents Long-term Goal setting	Goal Setting, Contracting and Rewards	23-24

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

2.5.3.4 Problem- solving and preventing relapse

Problem-solving techniques, and relapse prevention, are increasingly being regarded as being of crucial importance to behaviour change in 'family centred' chronic disease management [224, 225]. In the MASCOT treatment programme problem solving techniques were encouraged, and families were advised to use them particularly when the child and/or the parent had difficulties in changing the behaviour which had been set as a goal. Since our MASCOT treatment programme was group-based, a 'brainstorming' approach was used in order to encourage parents to highlight likely problems which would arise, and then to generate a number of ideas from the group members for solutions to these problems during parent's session 4, 5 and 7 after the dietician reviewed the lifestyle diaries during the previous sessions (see Table 2.1). During discussion of problems and problem solving it was considered essential for the dietetic professional to use open questions and allow the parents to find appropriate solutions to the problems and share it with other parents.

In order to avoid lapses in behaviour change becoming long term relapses, relapse prevention was the focus of session 7, towards the end of the treatment programme to ensure that the child maintain behaviour or lifestyle changes in the long-term. During this session, the parent were asked to identify possible 'high risk' situations where sticking to goals could be difficult for their children [144]. For example, participating parents were asked to think of difficult situations that make it difficult to achieve the child's goals on a 'Tricky Situation' sheet. Questions were asked such as '*How do you deal with achieving your goal when someone invites you to a birthday party?*

2.5.4 Intervention content and timing

The treatment programme was held separately for parents and children as noted above, except one joint session of cooking (session number 6, Table 2.1). The first four sessions were held every 2 weeks and the next four sessions were held every one month for 4 months (Table 2.1). There were four groups, each consisting of approximately thirteen children and their parents. Treatment sessions were directed at parents only and were facilitated largely by a dietitian (7 hours), though with some input from a psychologist (present for 1/8 hours). Parents were provided with treatment handouts that were modified from SCOTT materials [188] and published Bright Bodies materials [205] supplemented with additional self-developed material. The content of each session is outlined in Table 2.1 and described in brief below.

2.5.4.1 Nutrition education component

A wide range of evidence-based guidelines and expert committee statements on treatment suggest that dietary change is an essential element of childhood obesity treatment. However, there is lack of evidence to inform what dietary modification (eg. prescriptive approach (Traffic Light Diet) vs structured meal approach (dieting) would be most effective. For the purpose of the MASCOT treatment programme, we used a non-diet approach which the quantity, quality and frequency of dietary intake are determined by parents. A non-diet approach is an educational process that involves learning better food choices and using moderate portion sizes that should prove to be more beneficial long term [226, 227]. When Savoye et al. [226] compared dieting vs non-dieting approaches to obesity treatment in adolescents they found that the non-dieting group showed improved long-term results. Furthermore, Field and colleagues have compared

dieting vs non-dieting approaches to obesity treatment in preadolescents and adolescents and demonstrated that not only was dieting ineffective for weight control but it may have promoted weight gain [227].

For the purpose of MASCOT, we used simplified a 'Traffic Light Diet' in order to teach parents and subsequently their children which foods should be avoided/reduced and which could be consumed freely [188]. The traffic light diet scheme did not require 'calorie counting', and used three categories: red foods (high-energy foods and should be avoided/greatly restricted), amber foods (high in energy, but also high in nutrients, take in moderate quantities) and green foods (have plenty of nutrients for only a low amount of energy, consume freely). The MASCOT nutrition education content (Table 2.1) also included teaching the concept of energy balance, and appropriate food label reading, and encouragement for more modest portion sizes.

2.5.4.2 Physical activity and sedentary behaviour component

All recent clinical guidelines and systematic reviews have recommended the inclusion of physical activity and reduction in sedentary behaviours in a multi-component programme for children's weight management [3, 144, 145]. There is widespread agreement in evidence-based guidance on a target to increase moderate to vigorous intensity physical activity to at least 60 minutes per day [144, 145]. For the purposes of MASCOT, while parents attended the healthy lifestyle classes; children participated in a supervised physical activity session. The sessions consisted of aerobic, treasure hunting and non-competitive, fun games to improve children's fundamental movement skills and aerobic capacity and at the same time to increase their confidence to participate in physical

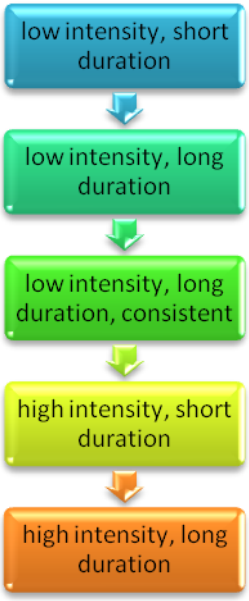
activity. Sessions used minimal space and equipment so that the children might continue participation in the activities that are easily transferable to the home environment.

Besides that, parents also targeted sedentary behaviour change. Sedentary behaviour refers to activity in which the work of the large skeletal muscles involved in habitual movement and postural control is very limited, for example sitting [228]. Furthermore, sedentary behaviour is not just a lack of physical activity, but is the purposeful engagement in behaviours with low energy expenditure such as TV viewing [229]. The parents were advised to self-monitor their and their children's screen time, and to work towards a goal of limiting time spent in screen time to no more than two hours per day or 14 hours per week [144, 145]. Targeting of both physical activity and sedentary behaviour began during MASCOT session 3 (see Table 2.1). Parents were responsible for setting activity goals at home for their children supported by a hand-out outlining the type of physical activity and how much they had spent on sedentary behaviour (screen time).

The children were encouraged to do different types of physical activities until they find those that they feel comfortable, fun and able to help them to achieve the desired goal. Parents were reminded to help make small incremental changes to the children's physical activity since their children would probably have been very inactive for some time and may also have lacked physical education which has a low priority in Malaysian schools. Therefore, in the transformation towards a healthier lifestyle by increasing physical activity, it was important for children in the MASCOT programme not to over-exert

themselves. This recommendation reflected a physical activity model (Figure 2.1) encouraging a low intensity and short duration of activity at the beginning of behavioural change, but gradual increase in the moderate-vigorous intensity activity levels to 60 minutes per day as a long term aim after they feel comfortable and confident with physical activities.

Figure 2.1: Physical activity model provided to parents to guide the achievement of MASCOT programme physical activity goals.



2.6 Retention

Participation retention in child weight management studies range from 10-50% [180]. Poor retention rates have implications for intention to treat analysis (see section 2.11) and can mean that studies are underpowered so every effort was taken to limit attrition. For example, scheduling of intervention sessions was flexible and timing and date was arranged between the dietitian and the parents.

Since our treatment was delivered as a group intervention, the dietitian tried to make sure that in each group more than 75% of the families attended intervention- she telephoned the parents two days before the intervention session as a reminder and tried to be flexible about intervention sessions where this was possible. The dietitian also kept information on a database on whether the subjects attended or failed to attend their sessions. Families were expected to attend 8 classes over 6 months. If a family failed to attend two consecutive classes, they were considered to be a non-completer of treatment. As noted, subjects were analysed within the groups to which they were randomly allocated i.e an 'intention to treat' analyses.

Furthermore, scheduling of the outcome measurement sessions was also flexible and where necessary individual appointments, home or school visits were offered. Additionally, families were provided with RM10 (approximately £2) following attendance at class and measurement sessions to assist with petrol costs.

2.7 Pilot study

The dietitian and psychologist carried out a small pilot study of the treatment protocol in Kuala Lumpur in May 2008. Due to the time constraints on the project the pilot involved a condensed version of the treatment protocol with the subjects attending four sessions over a month- period.

Session 1 and session 3 were given in their entirety (60 minutes in each session) in a first and third week of the pilot study. In second week, third session was conducted that consists of a 30-minute version of Session 2 followed by a 30

minutes version of Session 4 (see Table 2.1) and fourth session. In fourth week, 30 minute version of Session 7 followed by a 30 minute version of session 8 was conducted (see Table 2.1). All the new printed materials produced for the study were used in the pilot (see Appendix Seven).

Five children and families were enrolled into the pilot study. Prior to starting the pilot study all the children were screened for eligibility for the study and had all baseline measurements taken by the researcher (author) (as described in section 2.7). All five families completed the pilot study. At the end of the pilot study, the parents were asked to comment on the treatment and printed materials using structured questions (see Appendix Nine for these questions). All comments were very positive and there were no changes in the treatment protocol as a result of the pilot.

2.8 Outcome measurements

Baseline data were taken by the main researcher at baseline (2 weeks prior to the first class session) and six months after the first dietetic appointment (25 to 27 weeks). The main researcher followed standard written protocols for the measurements. As previously discussed (see section 2.4.4), the main researcher remained blinded to group allocation throughout the study and until the six-month study were statistically analysed and was not involved in delivery of the treatment programme.

The primary aim of present study was to test the hypothesis that a 'good practice' intervention for the treatment of childhood obesity would have a greater effect on primary and secondary outcomes than allocation to a no

treatment control group. While the primary outcome of the MASCOT trial was BMI z-score, in common with most other childhood obesity RCT [3], it is also important to test whether an obesity treatment intervention has any effects on other variables ('secondary outcomes'), including possible adverse effects. Childhood obesity impacts upon other aspects of health beyond weight and health and encompasses effects on physical, emotional, mental and spiritual health [83], therefore secondary outcomes that represent broader health outcomes were also assessed in the MASCOT study, and these were measures of physical activity, sedentary behaviour and psychosocial health (quality of life), weight and height.

2.8.1 Height, weight and BMI

Child's height was measured using the Leicester height measure (Chasmors, London, United Kingdom). The child was measured in light clothing with socks and shoes removed. Children stood barefoot with feet together on the centre base plate, the head was in the horizontal Frankfurt plane position and that they were standing up straight. To ensure accurate measurements were taken, height was measured 2-3 times for each subjects and the mean was recorded. Height was measured to the nearest 1mm.

Child's weight was measured using a Tanita electronic scale model WB-100MA (Chasmors, London, United Kingdom), with children lightly clothed and without shoes. To ensure accurate measurements were taken, height was measured 2-3 times for each subjects and the mean was recorded. Weight was measured to the nearest 0.1 kg.

Values for height, weight and BMI were converted to a decimal age and gender specific BMI z-score using a LMS method that was developed by Professor Tim Cole[http://www.healthforallchildren.com/index.php/shop/product/Software/Gr5yCsMCONpF39hF/0].

2.8.2 Habitual physical activity and sedentary behaviour

Habitual physical activity and sedentary behaviour were measured objectively 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). This accelerometer is small, lightweight and practical for use with children [230, 231]. 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 physical activity and sedentary behaviour [232, 233]. 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 behaviour. Accelerometry counts per minute (cpm) were used as a measure of total volume of physical activity. Accelerometry data were also summarised using cut-points to define time spent in sedentary behaviour (<1100cpm) [230] light intensity physical activity (1100-3200 cpm), and moderate to vigorous intensity physical activity (MVPA) (>3200cpm) [234] these are all empirically determined cut-off points based on previous paediatric validation studies [230, 234]. All monitors were routinely calibrated before use.

Participants were instructed to wear the accelerometer around the waist on an adjustable elastic belt and worn over the right hip under clothing as described previously [146] and a hand-out was given that illustrates on how to wear the activity belt correctly (see Appendix Four). They also recorded the time the monitor was attached in a diary (see Appendix Five) and removed each day and also other times that the monitor was removed during the day, for example, swimming. Data were downloaded and handled manually and no standard rule was applied to exclude strings of zeros as non-wear time: non-wear time was identified by visual inspection of accelerometer output combined with parental and child log sheets which recorded periods of non-wear time.

2.8.3 Health-related quality of life

The PedsQL™ Pediatric Quality of Life Inventory (Malay) version 4.0 questionnaires were used to measure the quality of life of obese children [44]. The PedsQL™ 4.0 is a 23-item child HRQoL measure consisting of four components-physical functioning (8 items), emotional functioning (5 items), social functioning (5 items) and school functioning (5 items) (see Appendix Six). For the purpose of the present study we used the self-reporting and parent proxy questionnaires for the 5-7 and 8-12 year olds. These four questionnaires are translated to Malay Language with kind permission of Prof. J. Varni (Professor of Research, Texas A&M University, Texas, USA). As recommended by Varni the questionnaires were completed before any other measurements were taken. The researcher (author) administered the questionnaire of the young children verbally and if it was felt appropriate the questionnaire for the older children was self-administered by the child [44].

Parents and children aged 8 and above were asked to answer to each item of the PedsQL 4.0 (see section 3.2.3.3) using a five-point response scale (0= never a problem, 1= almost never, 2= sometimes, 3= often and 4= almost always). In PedsQL 4.0, children age 5-7 years old are classified as younger children and a three-point scale was used instead of five responses (0= not at all a problem, 2= sometimes and 4= a lot) and each response was tied to a happy to sad face scale (Appendix Six). Responses to PedsQL questionnaire were reverse and linearly transformed to a 0-100 scale: 0= 100, 1= 75, 3= 25 and 4= 0, so that higher scores indicate better quality of life. The questionnaires were self-administered for parents and for children aged 8-12 years and interview (main researcher read the question and asked the subjects to point to either a smiling, middle or frowning face) administered for children aged 7 years.

An overall total score was derived from all the questions answered. The scale produces a Physical Health Summary Score (the total of the physical functioning subscale) and a Psychosocial Health Summary Score (from the mean of emotional, social and school functioning subscales) which add to give a Total Score.

2.8.4 Socio-demographic information

A questionnaire written in the national language (Malay) was designed to collect data for socio-demographic profile of the families (Appendix Three) during the first appointment with the main researcher (see section 3.3.3). The questionnaire asked parents to record information about their working situation, household size and household income. Because all the questionnaires were distributed and collected on the same day, there was a 100% response rate.

2.9 Data analysis

2.9.1 Sample size calculation

The present RCT study was powered using BMI data from the Scottish Childhood Obesity Trial (SCOTT) RCT [187] since the methods that were used in the present study were similarly with SCOTT study. Our statistician Prof JH Mc Coll (University of Glasgow) confirmed that 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 therefore intended that around 100 children would be entered into the trial to allow for sample attrition during the 6-month study. All the data within this chapter are reported as mean and standard deviation as changes in outcome measures were tested for normality and were normally distributed.

2.9.2 Quantitative analysis

All statistical analysis presented in this thesis were carried out by the author. Data were analysed using Statistical Package for Social Science (SPSS) version 16.0, a full description of the statistical analysis is given in section 3.4.2.1.

2.9.2.1 Primary analysis- Intention to treat (ITT) analysis

As mentioned in Section 2.1.1, for the purpose of this thesis, ITT analysis was conducted in which mean that all study subjects were retained in the groups to which they were originally allocated and no subjects were removed from the analyses by the researchers. 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).

2.9.2.2 Primary analysis- Paired t-test and independent sample t-test

The study was powered to establish the significance of the difference between groups in change in BMI z-score following the completion of the 6 month intervention programme. Therefore, independent sample t-test was conducted to examine the significance of any *between* group differences at the six-month time point (intervention end).

Changes in outcome variables *within* each group (intervention and control) between baseline and 6 month follow up are also presented, and the significance of within group (within participant) changes analysed by paired t-test.

2.9.2.3 Secondary analysis- Per protocol analysis

A pre-planned secondary analysis was also conducted using the 'per-protocol' approach and involved participants who attended at least 75% of scheduled sessions ($\geq$ 6/8 sessions) defined as 'completers'; participants who attended<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.

2.10 Discussion

2.10.1 Strengths of the MASCOT treatment programme

The present study is the first to describe a 'good practice' protocol for the treatment of childhood obesity in Malaysia, and, to our knowledge, is the first description of an obesity treatment protocol intended for any setting outside the

western world. The main strength of the present study was its novelty- no studies of this kind have been undertaken in Malaysia or in Asia more generally. The treatment programme which is described should be generalisable, and so 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 programs might produce greater improvements in weight status [3], but such interventions are much less likely to be practical [205].

Additionally, the lifestyle behaviours promoted in the MASCOT treatment programme are reflective of the recommendations made about treatment in recent systematic reviews [3] and concur with recent clinical practice guidelines [144, 145] for the management of obesity in children. The nutrition education component of the MASCOT programme was underpinned by the promising treatment offered by Bright Bodies programme [205]: it found that a non-diet approach (as defined above) seemed to be more beneficial for long-term success. In addition, the physical activity and sedentary behaviour recommendations promoted within the MASCOT treatment programme were based on current evidence-based guidelines and systematic reviews [3, 144, 145]. Furthermore, in the MASCOT treatment programme the children were encouraged choose their own activities by doing different types of physical activities until they find those that they feel comfortable, fun and able to help them to achieve the desired goal. Children are probably more likely to continue being active over time if they have the opportunity to choose their own activities [221]. A further strength of the treatment programme was the inclusion of behavioural change techniques such as decisional balance, goal

setting, self-monitoring, problem-solving and rewards [212] as recommended by recent NICE [144] and SIGN guidelines [145] in the UK.

Furthermore, a number of design features should help contribute to enhanced generalisability of the MASCOT treatment programme. The MASCOT treatment programme was designed to be less intensive compared to some US treatment interventions [205] with a total dose of treatment of approximately 8 hours per parent which should hopefully make the programme more widely applicable in other settings. In addition, the group delivery method in this programme would provide improved service efficiency over the current routine UK practice of individualised counselling for weight management [187]. One study has shown that a potential benefit of group programmes was that being part of the group, the children were more motivated to attend treatment sessions and enjoyed the support and interaction provided by the group setting [221]. Another strength of the MASCOT treatment programme was the involvement of parents in the treatment as described above. The parents were targeted as the main agents of change in the programme as they influence their children's environments and behaviours and involvement of parents would help the children to maintain their weight [235].

2.10.2 Limitations of the MASCOT treatment programme

Systematic reviews have suggested that longer and more intensive treatment programmes would probably produce greater effects on body weight and energy balance and long-term maintenance [180]. The MASCOT programme is a relatively low intensity intervention programme compared to many other treatment intervention programmes [205] that might be seen as a weakness.

However, the limited ‘dose’ of treatment in the MASCOT treatment programme was considered as strength because it should make the treatment programme more widely applicable. In addition, the publication of the MASCOT treatment programme in some detail should enable direct replication of the intervention in other settings, further increasing its generalisability.

2.11 Conclusion

In summary, this chapter provides key features of the RCT design that were required ensuring robustness of study findings that conducted and reported in accordance with CONSORT guidelines that are summarised in Table 2.1. These findings are presented in Chapter Four which report on the study outcomes and are summarised in the final chapter. Furthermore, the detailed description of the MASCOT treatment programme here should enhance the extension of obesity treatment, particularly if the intervention is successful. A detailed description of a treatment programme will also assist in development of other treatments in future, even if the intervention is revealed in the RCT to be unsuccessful. The description of physical activity, sedentary behaviour, and quality of life in the present study also provides important contextual information on obese children in Malaysia which should also assist future treatment programmes.

Table 2.2 Summary of the CONSORT criteria reported in this chapter

Criteria	Reported in thesis
Eligibility criteria for participants	Section 2.3.2.2
Details of the intervention	Section 2.5
Specific objectives and hypotheses	Section 1.9.1 and Section 1.9.2
Clearly defined primary and secondary outcome measures	Section 2.8
Sample size	Section 2.9.1
Randomisation	Section 2.4.3
Allocation concealment	Section 2.4.3
Implementation	Section 2.4
Blinding	Section 2.4.4
Statistical methods	Section 2.9.2

CHAPTER THREE

Results of the MASCOT Randomised Controlled Trial*

3.1 Statistical analysis and power

Data were analysed using SPSS version 14.0. All the analysis presented in this thesis was independently carried out by the author. Statistical analysis was carried out with the advice of Prof J. Mc Coll, Department of Statistics, University of Glasgow.

As discussed in Chapter Two, section 2.8.2.1, the primary outcome for the study was change in BMI z-score from baseline to six months and the study had been powered for 30 participants in each arm at 6 months with a change in BMI z-score of -0.25 at six months between groups giving 90% power and 0.05 significance (see Chapter Two section 2.8.1)

The baseline characteristics of the 107 participants were described as a group. Primary and secondary outcome findings were then reported using the analysis described in Chapter Two, section 2.8. All the data within this chapter are reported as mean and standard deviation as changes in outcome measures were tested for normality and were normally distributed.

Outcomes were analysed in two ways. First, changes in outcome variables *within* each group (intervention and control group) between baseline and 6 month follow up are presented, and the significance of within group (within participants) changes analysed by paired t-tests. Second, the issue of whether

*This chapter has been published in International Journal of Paediatric Obesity (see Appendix Ten)

changes in outcome variables differed significantly between groups (intervention versus control) was examined using independent sample t-tests. A p-value was less than 0.05 was taken to indicate statistical significance.

For the purpose of this thesis, intention to treat (ITT) analysis was conducted- this involved including in the analysis all subjects for whom data were available on the basis of the group they were allocated regardless of their adherence to the protocol (i.e. attendance) (as described in Chapter 2 section 2.3.1). Missing data were not imputed, therefore the outcome status of participants that were lost to follow up could not be accounted for and they were excluded from the analysis.

A pre-planned secondary analysis was also conducted using the per-protocol approach and involved participants who attended at least 75% of scheduled sessions ($\geq$ 6/8 sessions). The highest level of adherence was calculated to be attendance for at least 75% of scheduled sessions ($\geq$6/8 sessions- considered 'good' in this thesis) and less than six scheduled sessions were defined as 'poor' adherence. A planned per protocol analysis was performed for BMI z-score and weight for the completers (see section 2.9.2.3) in order to carry out a preliminary analysis to test whether adherence to the treatment programme (as indicated by attendance, a proxy measure of adherence) had any impact on outcomes.

3.2 Results

3.2.1 Subject recruitment and group allocation

365 families were assessed for eligibility for the present study as described in Chapter Two, section 2.3.2.1; 15 families did not meet study inclusion criteria due to weight status, medical history and age and another 233 families with eligible children refused to participate due to a lack of interest and time. In addition, five families were unable to be contacted due to providing incorrect contact numbers during the recruitment stage and five families failed to attend baseline assessment and were not enrolled in the study. Therefore the final sample size of 107 families represented 31% of enquiries from eligible families; 55 participants were randomised to no treatment (control group) and 52 to treatment (intervention group).

Of the 107 participants entered at baseline, 79 (74%) of participants (45 control; 34 intervention) attended the six-month follow-up. The expected drop out rate used in original power calculations was 30%; however, the actual dropout rate for the present study was 26% at six months. Figure 4.1 describes the flow of participants throughout the study in accordance with the CONSORT statement [202].

3.2.2 Adherence to treatment and study protocols

Programme session attendance was used as a proxy measure of adherence to the study protocol. Greater adherence to treatment has been associated with improved clinical outcomes and prevention or reduction of complications in some studies [236, 237]. Two categories (Figure 4.1) were used to represent different levels of adherence to treatment for participants in the treatment

group. Of the 52 intervention group participants, 25 (48%) participants attended 75% of their scheduled sessions (completers) and 27 (52%) participants attended less than 75% (non-completers). Analysis had been pre-planned to be carried out for analysis of completers as described above.

Figure 3.1 presents the number of participants analysed for the primary outcome at the point six-months after baseline. At six months, a total of 28 participants (26%) were lost to follow-up (no treatment (control): 10/55, treatment (intervention): 18/52). Thus, the overall retention rate at six months was 74%. The outcome status of participants lost to follow up cannot be accounted for and they were excluded from the intention-to-treat analyses.

3.2.3 Socio-economic status of MASCOT families at baseline

Table 3.1 presents the distribution of parent's working situation, household income and household size of the participants in the study. The working situation of parents was used as the indicator of the socioeconomic status of the family in the present study (as described in Chapter Two section 2.7.1). Table 3.1 shows that the study families had come from a range of socioeconomic backgrounds. Fifty per cent of the fathers worked at the private sector as well as the mothers (43%). In this sample, the mean monthly household income was RM4270.77 (GBP1 = RM5.3) with the majority of families (76%) in the study trial consisting of more than five people. There was no statistically significant difference in household income between intervention and control groups.

Figure 3.1 Flow of participants through the trial

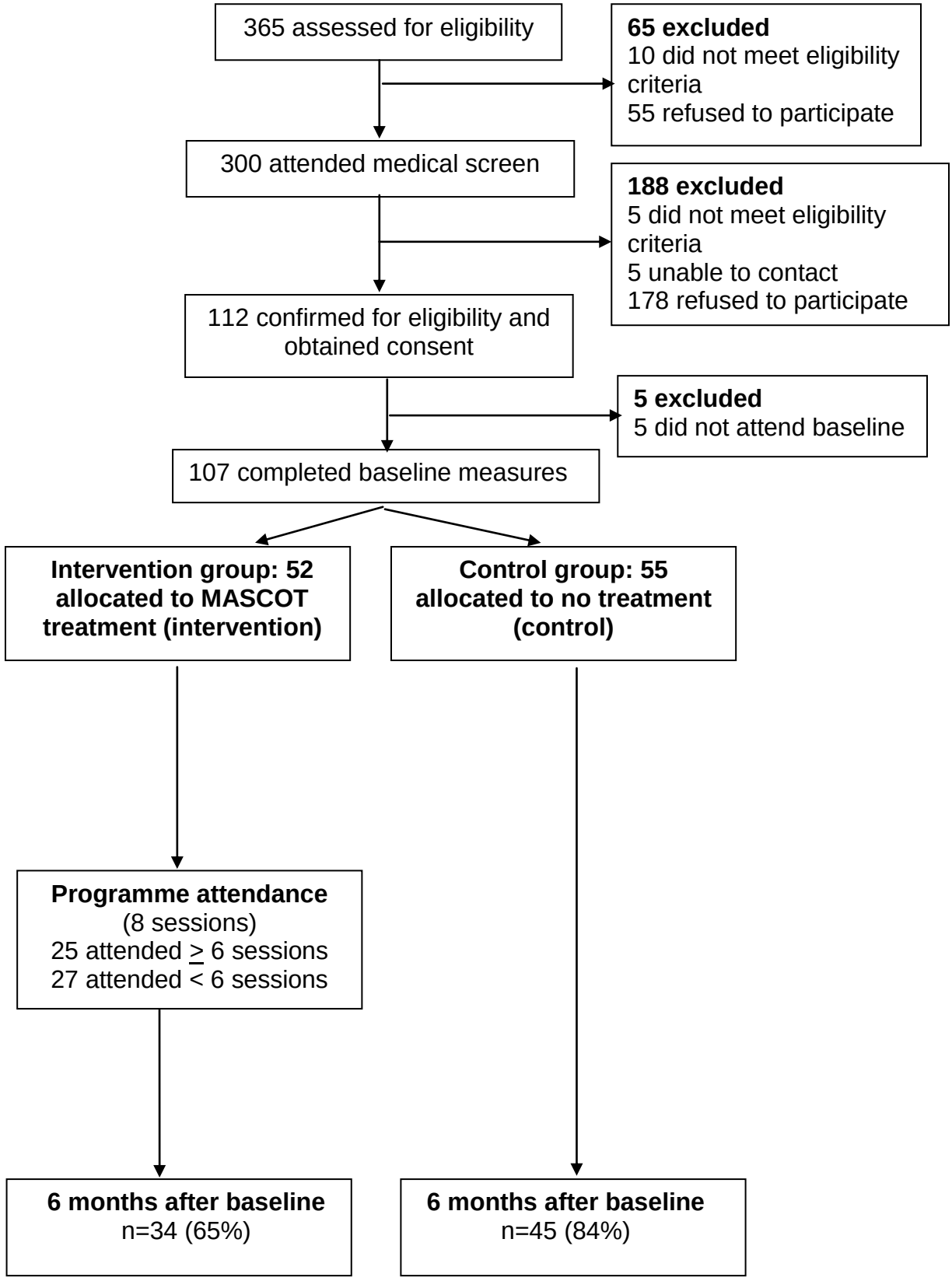


Table 3.1 Socio-economic status of MASCOT families at baseline

	Full sample (n=107)	Intervention group (n=52)	Control group (n=55)
	n(%)	n(%)	n(%)
Working situation			
Father			
Not working	2 (2)	3(5.8)	3(5.4)
Government sector	24(22)	14(26.9)	12(21.8)
Private sector	53(50)	22(42.3)	29(52.7)
Own business	24(22)	13(25.0)	11(20.0)
Mother			
Not working	28(26)	10(19.2)	20(36.3)
Government sector	23(22)	17(32.7)	6(10.9)
Private sector	46(43)	18(34.6)	28(50.9)
Own business	8(8)	7(13.5)	1(1.8)
Household income (RM)			
1- 750	3(3)	2(3.8)	1(1.8)
751- 2000	21(21)	8(15.4)	11(20.0)
>2000	75(76)	39(75.0)	38 (69.1)
	mean(SD)= RM4270 (3085)	mean(SD)= RM4748(3435)	mean(SD)= RM4492(5714)
Income per capita (RM)			
1-143	4(4)	3(5.8)	1(1.8)
144- 286	9(10)	3(5.8)	4(7.3)
>286	79(86)	41(78.8)	40(72.7)
Household size			
1-4	23(25)	14(26.9)	9(16.4)
5-7	63(69)	30(57.7)	33(60.0)
>7	6(7)	3(5.8)	3(5.5)

All differences between intervention and control groups non significant (chi squared tests)

3.2.4 Child characteristics at baseline

3.2.4.1 Baseline anthropometric measurements

The anthropometric measures and weight status of the two study groups were similar with an almost equal proportion of boys to girls (Table 3.2). There were 26 boys and 29 girls in the control group with 28 boys and 24 girls in intervention group. There were no significant differences between groups for child age, anthropometric measures and weight status. The absence of significant differences between intervention and control groups at baseline suggests that the randomisation successfully controlled for baseline differences between intervention and control groups.

Table 3.2 Baseline mean (SD) anthropometric measures and weight status of children enrolled in the MASCOT study

	intervention group	control group	p value[1]	Full sample
n	52	55		107
Male/Female	28/24	26/29	-	54/53
Age	9.7 (1.4)	9.9 (1.6)	0.62	9.8 (1.5)
Height (cm)	139.6 (9.8)	140.3 (10.7)	0.74	140.0 (10.2)
Height z-score	0.5 (0.9)	0.4 (1.0)	0.92	0.5 (0.9)
Weight (kg)	54.5 (12.1)	54.6 (14.0)	0.98	53.9 (13.1)
Weight z-score	2.6 (0.6)	2.5 (0.8)	0.67	2.5 (0.7)
BMI (kg/m2)	27.6 (3.4)	28.0 (7.0)	0.77	27.8 (5.5)
BMI z-score	2.9 (0.6)	3.0 (0.5)	0.40	2.9 (0.6)

[1]Independent t-test by group

3.2.4.2 Baseline habitual physical activity and sedentary behaviour

At the baseline measurement, 20 data points were missing due to accelerometer failure and poor compliance with the accelerometry protocol and therefore only 87 data points are presented in this study from the 107 study participants at baseline.

The accelerometer was worn over 5 days on average for a mean of 13 waking hours per day at baseline. The results showed that there were no significance differences between groups for overall habitual physical activity levels and levels of sedentary behaviour (Table 3.3). This suggests that the randomisation successfully controlled for baseline differences.

Table 3.3 Baseline mean (SD) physical activity and sedentary behaviour levels of children enrolled in the MASCOT study

	Group			
% monitored daytime	**Intervention (n=50)**	**Control (n=37)**	**p-value[1]**	**Full Sample (n= 87)**
Total activity (cpm[2])	387 (140)	335 (144)	0.91	365 (143)
% of day time :				
Sedentary behaviour	88.5 (4.5)	89.8 (4.4)	0.89	89.1 (4.5)
Light intensity activity	10.3 (4.7)	8.8 (4.7)	0.74	9.6 (4.7)
MVPA	0.9 (0.8)	1.0 (1.1)	0.09	1.0 (1.0)

[1]Independent t-test by group
[2]cpm= count per minute
*p-value <0.05

3.2.4.3 Baseline health-related quality of life scores

Baseline data from the two groups are shown in Table 3.4. At baseline, parents reported their child's physical scale quality of life was lower than their child perceived it to be on physical scales of the PedsQL^{TM} 4.0 (p=0.04), but there were no significant differences between parent and child reports for the other quality of life subscales or total scores. Table 3.4 presents this difference. There were no significant differences in quality of life for either child or parents report according to group at baseline, showing the randomisation to have been effective in this case.

Table 3.4 Baseline mean (SD) health-related quality of life scores for children (C) and parents (P) enrolled in the MASCOT study

	Full sample (n=107)	Intervention group (n=52)	Control group (n=55)	p-value
Psychosocial child	66.9 (15.3)	66.2 (15.3)	65.2 (15.5)	0.70
Psychosocial parent	65.7 (16.3)	67.3 (15.4)	66.2 (17.1)	0.74
	(p=0.41)			
Physical child	70.0 (18.6)	70.2 (16.5)	69.9 (20.6)	0.93
Physical parent	65.6 (19.7)	64.7 (19.8)	66.5 (19.9)	0.61
	(p=0.04)			
Total child	67.7 (14.5)	67.6 (13.6)	67.8 (15.4)	0.93
Total Parent	66.0 (16.4)	65.1 (15.7)	66.9 (17.2)	0.57
	(p=0.26)			

[1] Health-related quality of life scores measured using the Peds QL 4.0 where a higher score indicates a better quality of life.
[2] Independent sample t-test, significant differences presented in bold font (p<0.05)

It was considered relevant to look for any baseline differences between completers (attendance for at least 75% of scheduled sessions) (n=25) with non-completers (n=27). At baseline, parents reported their child's psychosocial scale HRQoL in non-completers group was significantly lower than completers group (p=0.01), but there were no significant differences between completers and non-completers for any of the other variables (Table 3.5)

Table 3.5: Baseline mean (SD) BMI z-score, habitual physical activity and sedentary behaviour and health-related quality of life between completers vs non-completers

Variable	Completers (n=25)	Non completers (n=27)	p-value[1]
BMI z-score	3.0(0.8)	2.8(0.5)	0.52
% monitored daytime			
Total activity (cpm[2])	400(153)	374(129)	0.54
% of day time :			
Sedentary behaviour	88.3(5.1)	88.8(3.8)	0.69
Light intensity activity	10.5(5.3)	10.0(4.1)	0.72
MVPA	1.0(1.0)	0.9(0.7)	0.61
Health-related quality of life			
Psychosocial child	71.7(14.9)	61.0(14.0)	0.01*
Psychosocial parent	69.4(15.8)	61.3(14.4)	0.06
Physical child	68.3(17.9)	72.0(15.3)	0.42
Physical parent	67.2(19.1)	62.3(20.4)	0.38
Total child	68.7(15.1)	61.8(15.7)	0.14
Total Parent	69.4(15.1)	61.8(15.7)	0.11

[1]Independent t-test by group; [2]cpm= count per minute; *p-value <0.05

Besides that, in order to look for differences at baseline for participants who attended the six-month follow-up (n=79) compared to participants who dropped out from the study (n=28), a statistical analysis was done for all variables. Table 3.6 shows that, there were no significant differences between participants who attended the six-month follow-up vs participants who dropped out from the study for all variables.

3.2.5 Changes in primary outcome (BMI z-score) between groups (intervention versus control comparisons)

3.2.5.1 Intention-to-treat-analysis

As described in section 1.5.1, the aim of the MASCOT study was to test for changes in BMI z-score from baseline to six months and the study had been powered on a change in BMI z-score of -0.25 at six months. Table 3.7 shows the changes in BMI z-score from baseline to six months (independent sample t-test) compared between the intervention and control groups. The primary analysis was conducted for all subjects with measures at six months post-baseline (intervention: 34, control: 45). There was no significant difference in the between group change in mean BMI z-score at six months intervention (p=0.79), difference -0.04 (95% CI -0.33, 0.25).

Table 3.6: Baseline mean (SD) BMI z-score, habitual physical activity and sedentary behaviour and health-related quality of life between participants who attended the six-month follow-up vs participants who drop out from the study.

Variable	Attend 6-months follow-up (n=79)	Drop out (n=18)	p-value[1]
BMI z-score	2.9(0.6)	2.9(0.5)	0.97
% monitored daytime			
Total activity (cpm[2])	370(146)	345(134)	0.50
% of day time :			
Sedentary behaviour	88.9(4.6)	89.8(4.1)	0.38
Light intensity activity	9.8(4.8)	9.0(4.5)	0.52
MVPA	1.0(0.6)	1.0(0.5)	0.10
Health-related quality of life			
Psychosocial child	68.1(15.0)	63.2(15.7)	0.15
Psychosocial parent	66.5(15.9)	63.5(17.3)	0.41
Physical child	70.9(18.4)	67.5(19.3)	0.40
Physical parent	65.8(19.3)	65.0(21.2)	0.86
Total child	68.7(14.0)	64.6(15.8)	0.20
Total Parent	66.8(16.0)	63.9(17.8)	0.43

[1]Independent t-test by group
[2]cpm= count per minute;
*p-value <0.05

Table 3.7 Change in BMI z-score from baseline to six months compared between groups, mean (SD)

Period	Intervention group (n=34)	Control group (n=45)	Between group Change *(95% CI)	p-value
0 to 6 months	0.0 (0.7)	0.1 (0.5)	-0.0 (-0.3, 0.3)	0.79

[1]Independant sample t-test
*95%CI: 95% confidence interval

3.2.5.2 Per-protocol analysis

Per-protocol analysis of BMI z-score (n= 70, intervention: 25, control: 45) conducted with participants who attended at least 75% of scheduled sessions revealed no significant group difference between the completers (for intervention group) and control group for the changes in BMI z-score using independent sample t-test at six months intervention difference 0.01 (95% CI -0.33, 0.34). (Table 3.8)

Table 3.8 Changes in BMI z-score compared between groups from baseline to six months for completers (treatment group) versus control group, mean (SD)

Period	Intervention completers (n=25)	Control group (n=45)	Between group Change *(95% CI)	p-value[1]
0 to 6 months	0.1 (0.8)	0.1 (0.5)	0.0 (-0.3, 0.3)	0.97

[1]Independant sample t-test
*95%CI: 95% confidence interval

3.2.6 Changes in primary outcome *within* groups (changes *within* the intervention group, changes *within* the control group)

3.2.6.1 Intention-to-treat-analysis

As described in section 2.8.2.1, the primary study outcome of the MASCOT study was BMI z-score. The analysis was conducted for all subjects with measures at six months post-baseline (intervention: 34, control: 45). Table 3.9 shows the mean and standard deviation of the BMI z-scores over time. There was no statistically significant difference within each group for BMI z-scores at any measurement points.

Table 3.9 BMI z-score over time compared within groups, mean (SD)

	Baseline	Six months	p-value[1]
Intervention (n=34)	3.0 (0.5)	3.1 (0.6)	0.96
Control (n=45)	2.8 (0.6)	2.9 (0.7)	0.53

[1]Paired t-test by group

3.2.6.2 Per-protocol analysis

Per-protocol analysis was also conducted with participants who attended at least 75% of scheduled sessions – known as the completers in a pre-planned analysis as noted in section 3.2.2. Twenty five (48%) of the intervention group and 45 (82%) of the control group were analysed for the primary outcome changes in BMI z-score (Table 3.10). There was no statistically significant difference within each group for BMI z-scores.

Table 3.10 BMI z-score within groups over time for completers versus controls, mean (SD)

	Baseline	Six months	p-value[1]
Intervention (n=25)	3.1 (0.4)	3.1 (0.6)	0.73
Control (n=45)	2.8 (0.6)	2.9 (0.7)	0.53

[1]Paired t-test by group

3.2.7 Secondary outcomes- Objectively measured habitual physical activity and sedentary behaviour

Levels of habitual physical activity and sedentary behaviour were measured at the two measurement stages as explained in Chapter Two section 2.7.3. At the 6 months measurement more data were missing due to poor compliance with the accelerometry protocol and the raw data available were difficult to interpret, therefore only data from only 55 (28 interventions; 27 controls) were analysed in this thesis.

3.2.7.1 Changes in habitual physical activity and sedentary behaviour compared between groups (intervention versus control comparisons)

Independent t-tests did not reveal any statistically significant between group differences (Table 3.11). This indicates that the MASCOT intervention did not improve habitual physical activity or sedentary behaviour relative to the control group.

3.2.7.2 Changes in habitual physical activity and sedentary behaviour *within* groups (changes *within* the intervention group, changes *within* the control group)

Table 3.12 shows the mean and standard deviation of total physical activity time that is defined as the accelerometer counts per minute (cpm), percentage of time in sedentary behaviour, light intensity activity and moderate to vigorous physical activity (MVPA) for both groups over time. There was a statistically significant increase in the percentage of time spent in MVPA in the intervention group over the 0-6 month time interval (p=0.01) (Table 3.12), but no significant change in the control group. No other changes within groups were statistically significant (Table 3.12).

Table 3.11 Changes in habitual physical activity and sedentary behaviour from baseline to six months by group, mean (SD)

	Intervention group (n=28)	Control group (n=27)	Between group Change *(95% CI)	difference p-value[1]
Total activity (cpm^2)	33 (133)	16 (124)	16 (-53,86)	0.64
% of monitored time				
Sedentary behaviour	-1.2 (4.6)	-0.1 (3.4)	-1.2 (-3.3,1.0)	0.29
Light intensity Activity	1.0 (5.0)	0.0 (3.6)	1.0 (-1.4, 3.4)	0.40
MVPA	0.5 (1.0)	0.0 (1.5)	0.5 (-0.1-1.2)	0.11

[1]Independant sample t-test
[2]cpm= count per minute
[*]95%CI: 95% confidence interval

Table 3.12 Habitual physical activity and sedentary behaviour *within* group change over time, mean (SD)

Measurement (group)	Baseline (intervention:27; control:28)	Six months (intervention:27; control:28)	p-value[1]
Total activity (cpm[2])			
Intervention	394 (147)	426 (141)	0.21
Control	340 (126)	357 (118)	0.50
% monitored time:			
Sedentary behaviour			
Intervention	88.3 (5.0)	87.0 (4.7)	0.17
Control	89.5 (3.8)	89.4 (3.4)	0.91
Light intensity activity			
Intervention	10.5 (5.2)	11.6 (4.7)	0.29
Control	9.1 (4.1)	9.1 (3.4)	0.99
MVPA			
Intervention	1.0 (0.9)	1.5 (1.3)	**0.01***
Control	1.1 (1.1)	1.1 (1.2)	0.98

[1]Paired t-test by group
[2]cpm= count per minute
*p-value <0.05

3.2.8 Secondary outcomes- Health-related quality of Life

As outlined in Chapter Two section 2.7.4, health-related quality of life (HRQoL) as measured by the PedsQL^{TM}4.0 was included as a secondary outcome of the MASCOT study. The questionnaire had a total quality of life score as well as separate sub-sections on physical, emotional, and social and school functioning. The 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. This outcome gives an indication of the potential benefits of involvement with respect to broader health outcomes, and might also be considered as a test of adverse effects of the intervention.

3.2.8.1 Changes in health-related quality of life scores between groups (intervention versus control comparisons)

Although there were improvements in quality of life in the intervention group, examination of the changes in child-reported HRQoL at the six month time point via Independent sample t-test between groups did not reveal any statistically significant group differences. As described in Section 2.9.1, the sample size calculation was based on 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. A post-hoc power calculation was conducted with the actual group differences achieved and the actual baseline HRQoL produced a required sample size of 90 subjects per group for the psychosocial child domain, 92 subjects per group for psychosocial parent domain and about 85 subjects per group for total child domain to achieve 90% power at the 0.05 significance level [238]. In all cases the calculations suggest that the study was probably slightly underpowered to detect a difference between groups for these dimensions of HRQoL, but these were secondary outcomes and the trends suggest that HRQoL improved in the treatment group relative to the control group.

An examination of the parent-reported HRQoL measures by the six month time point revealed a significant difference between groups for the parent proxy Total Scale Scores in favour of the intervention. Parents of intervention group scored significantly higher than control group for Total Scale Scores ($p=0.04$).

Table 3.13 Change in health-related quality of life scores from baseline to six months by group, mean (SD)

	Intervention group (n=34)	Control group (n=45)	Between group Change *(95% CI)	difference in p-value[1]
Psychosocial child	6.0 (14.3)	-0.6 (16.0)	6.6 (-.1,13.5)	0.06
Psychosocial parent	5.0 (19.0)	-1.9 (15.0)	6.9 (-0.7,14.5)	0.07
Physical child	2.8 (18.6)	-3.3 (22.2)	6.1 (-3.3,15.5)	0.20
Physical parent	0.7 (27.5)	-3.6 (22.9)	4.3 (-7.0, 15.6)	0.45
Total child	4.9 (11.6)	-1.4 (16.1)	6.3 (-0.2,12.7)	0.06
Total parent	4.2 (15.5)	-3.8 (19.3)	8.0 (0.3,15.8)	**0.04**

[1]Independant sample t-test, significant differences presented in bold font (p>0.05)

3.2.8.2 Changes in health-related quality of life scores *within* groups (changes *within* the intervention group, changes *within* the control group)

Table 3.14 shows mean and standard deviation of child self-reported and parent reported HRQoL measures over the 0-6 month time interval. There were no significant differences in the mean *within* group change of parent reported HRQoL measures (Total Score, Psychosocial sub-score and Physical sub-score) in both groups.

Unlike the parent -reported measures, there were significant improvements in the mean *within* group change for intervention group for the child reported Psychosocial sub-score and Total Scale from baseline to 6 months (paired t-test, p=0.02, respectively) (Table 3.14) but no changes *within* groups were significant for the control group.

Table 3.14 Health-related quality of life *within* change group over time, mean (SD)

Measurement (group)	Baseline (intervention:34; control:45)	Six months (intervention:34; control:45)	p-value[1]
Psychosocial child			
Intervention	67.7 (15.7)	73.6 (12.9)	**0.02**
Control	68.5 (14.6)	67.9 (15.8)	0.80
Psychosocial parent			
Intervention	66.8 (15.5)	71.8 (14.8)	0.13
Control	64.1 (16.9)	62.7 (13.2)	0.40
Physical child			
Intervention	68.2 (17.0)	71.0 (18.2)	0.39
Control	72.6 (19.4)	69.2 (17.9)	0.33
Physical parent			
Intervention	64.8 (18.4)	65.5 (22.7)	0.88
Control	66.5 (20.2)	62.9 (19.6)	0.30
Total child			
Intervention	67.8 (13.8)	72.7 (13.3)	**0.02**
Control	69.4 (14.2)	68.0 (14.7)	0.57
Total parent			
Intervention	66.3 (14.9)	70.1 (15.3)	0.25
Control	67.2 (16.9)	63.0 (14.4)	0.08

[1]Paired t-test, significant differences presented in bold font (p>0.05)

3.2.9 Secondary outcomes- Changes in weight

Although looking at BMI z-score and gives an indication of obesity level, in guideline recommendations and clinical practice the aim of intervention is weight maintenance [145, 206]. It is therefore of potential clinical significance to review the changes in weight.

3.2.9.1 Changes in weight between groups (intervention versus control comparisons)

3.2.9.1.1 Intention-to-treat-analysis

Table 3.15 shows the changes in weight from baseline to six months (independent sample t-test) compared between the intervention and control groups. The primary analysis was conducted for all subjects with measures at six months post-baseline (intervention: 34, control: 45). The change in weight in both groups over time shows that there was a significant difference between the groups using an independent t-test, with a mean weight gain of 1.7kg in the intervention group and 3.5kg in the control group.

Table 3.15 Change in weight from baseline to six months compared between groups, mean (SD)

Period	Intervention group (n=34)	Control group (n=45)	Between group Change (95% CI)	p-value
0 to 6 months	1.7 (2.5)	3.5 (2.0)	1.8 (0.8, 2.8)	<0.001

[1]Independent sample t-test

The primary aim for the intervention was weight maintenance; it was therefore considered important to look at the number of children who had achieved weight maintenance or weight loss compared to those who had gained weight. In the intervention group, 27% (9 out of 34) had maintained or lost weight from baseline to six months but none (0%, 0 out of 45) of the participants in the control group had maintained or lost weight.

3.2.9.1.2 Per-protocol analysis

Per-protocol analysis for weight change (n= 70, intervention: 25, control: 45) conducted with participants who attended at least 75% of scheduled sessions revealed a statistically significant difference in weight increase between the completers (for intervention group) and control group for the changes in weight at six months intervention in favour of the control group (control) (p=0.00) with a mean weight gain of 1.5kg in the intervention group and 3.5kg in the control group (3.16)

Table 3.16 Change in weight compared between groups from baseline to six months for completers (treatment group) versus control group, mean (SD)

Period	Intervention group (n=25)	Control group (n=45)	Between group Change (95% CI)	p-value[1]
0 to 6 months	1.5 (2.4)	3.5 (2.0)	2.0 (1.0, 3.1)	0.00

[1]Independant sample t-test

3.2.9.2 Changes in weight *within* groups (changes within the intervention group, changes within the control group)

3.2.9.2.1 Intention-to-treat-analysis

The analysis was conducted for all subjects with measures at six months post-baseline (intervention: 34, control: 45). Table 3.17 shows the mean and standard deviation of the weight over time within group. Weight significantly increased over time within the two groups ($p<0.001$, respectively) using a paired sample t-test (Table 3.17).

Table 3.17 Weight over time compared within groups, mean (SD)

	Baseline	Six months	p-value[1]
Intervention (n=34)	55.4 (11.6)	57.1 (11.5)	<0.001
Control (n=45)	53.5 (11.9)	57.0 (12.3)	<0.001

[1]Paired t-test by group

3.2.9.2.2 Per-protocol analysis of within group change in weight

Per-protocol analysis was also conducted for weight with participants who attended at least 75% of scheduled sessions (n= 70, intervention: 25, control: 45). Weight significantly increased over time within the two groups using a paired sample t-test (Table 3.18).

Table 3.18 Weight within groups over time for completers versus controls, mean (SD)

	Baseline	Six months	p-value[1]
Intervention (n=25)	57.8 (11.9)	59.3 (11.7)	0.01
Control (n=45)	53.5 (11.9)	57.0 (12.3)	0.00

[1]Paired t-test by group

3.2.10 Secondary outcomes- Changes in height

3.2.10.1 Changes in height between groups (intervention versus control comparisons)

Examination of change in height from baseline to six months revealed no significant difference between the groups (p=0.76) (Table 3.19) results from an Independent t-test, indicates that children in both groups continued to grow in height at a similar and expected rate over the study period.

Table 3.19 Changes in height from baseline to six months compared between groups over 6 months, mean (SD)

Period	Intervention group (n=34)	Control group (n=45)	Between group Change (95% CI)	p-value
0 to 6 months	2.6 (1.8)	2.7 (1.3)	0.1 (-0.6, 0.8)	0.76

[1]Independant sample t-test

3.2.10.2 Changes in height *within* groups (changes within the intervention group, changes within the control group)

Height growth was tested as a potential adverse effect of the intervention by comparing the change in height over time between the groups. Both groups showed a *within* group significant increase in height from baseline to six months (p=0.00, respectively), (Table 3.20), suggesting that children continued to grow at the expected rate after the MASCOT intervention (Chapter 7). Thus, there was no adverse effect detected on linear growth.

Table 3.20 Height over time compared within groups, mean (SD)

	Baseline	Six months	p-value[1]
Intervention (n=34)	140.3 (9.3)	142.9 (8.9)	<0.001
Control (n=45)	140.3 (10.1)	143.0 (10.1)	<0.001

[1]Paired t-test by group

3.3 Discussion

3.3.1 Study feasibility

As is obvious from the text above, the MASCOT RCT was feasible in Kuala Lumpur. The study had originally been powered for a total of 60 participants at 6 months, however, in the present study, 79 participants actually attended for outcome measures at 6 months. A total of 233 eligible families did not consent to participate in the study though. The main reasons given by parents for declining to enrol in the study were lack of interest and time, inconvenience of the location and transportation difficulties. Anecdotal comments from enrolled families suggested that parents may have preferred a child-centred approach

which may explain the lack of interest in enrolling in a present study that focused on a parent-centred approach. Another likely reason for eligible families declining to enrol in the present study was unawareness of parents regarding their child's weight status. It appeared that most of the parents are more concerned for their child's academic performance rather than their child's health as, anecdotally, many eligible families declined to participate in the study because they felt that it would compete with extra classes which are taken after school by many Malaysian children (e.g. after school classes in English and Religious studies are common) and some school activities that were conducted during the day. The use of anecdotal evidence from enrolled families has limitations, and the fact that the thesis did not include a qualitative study is a weakness in the study and this is discussed further in Chapter Six. A qualitative study, can help the researcher to understand and present the experiences and actions of study participants [238]. Furthermore, qualitative research data give researchers a better understanding of the social and personal factors that influence the management of a health condition, providing a real-world or human aspect to research findings [239]. Despite the limitation of using anecdotal data, these data were used in only a very restricted way, and the comments from the parents contribute by adding very slightly to a very limited evidence base on the feelings and influences of the parents of obese children in treatment programmes.

3.3.2 Baseline characteristics of study participants

Overall, the mean monthly household income in the sample recruited to the present study was lower than the average household income reported for Kuala Lumpur citizens (RM5011) by the Malaysian Department of Statistics [204]. Taking the gross poverty line income in Kuala Lumpur as RM713 for a household

of five persons (approximately RM143/person as noted by the Malaysian Department of Statistics [240] there were only 4% of the families (4 out of 107) in the present study living under the poverty line. However, this percentage of people living below the gross poverty line income may be overstated due to possible underreporting of the actual incomes by the participating families. According to the Malaysian Department of Statistics report [240], the average household size in Kuala Lumpur was 3.9. However, in the present study sample the mean household size was slightly higher than the census report for Kuala Lumpur [5.4 (1.7)] with the majority of families (76%, 69 out of 107) in the MASCOT trial consisting of more than five people.

There were no significant differences at baseline between groups according to child anthropometric measures, weight status (Table 4.2), and quality of life (Table 4.10) and physical activity and sedentary behaviour (Table 4.7). This suggests that the randomisation used in the present study was successful in avoiding any significant between -group differences at baseline.

3.3.3 Implications of findings

Evidence-based guidelines on childhood obesity treatment have repeatedly emphasised the importance of involving parents specifically those who are willing to make lifestyle changes and the parents and children perceive obesity as a problem [3, 144, 145]. Even though families recruited in the present study were perceived to be motivated, our findings to be show that the numbers that attended all the appointments were possibly lower than might have been hoped. Only 48% of the intervention group attended at least 75% of scheduled sessions.

The main reasons reported anecdotally by parents for not attending sessions were related to factors external to the intervention, mainly commitment towards jobs, suggesting that aspects of the programme were possibly not a major cause for non-attendance. Non-attendance might also reflect a poor time management or a lack of prioritisation of weight management from the parents. Families were provided with study programmes (see section 2.3.2) which detailed treatment sessions well in advance of each session, and they were reminded two days before each session. In addition, monetary incentives (reimbursement of travel costs) which could enhance attendance were used. Relatively few studies have focused on reasons for non-attendance in childhood weight management, and no studies have focused on this question in low –middle income countries such as Malaysia. One study in the US reported that 25% of parents cited time and location as the most important barrier to attending an individualised behavioural weight management clinic [241]. This is consistent with the anecdotal reports of parents in the present study and it suggests that these inhibitive factors may affect the programme. More detailed studies, using qualitative methods [212] might be useful in understanding why parents did not attend more sessions, and why they were possibly less engaged with the MASCOT intervention than would have been ideal.

Examination of the changes in BMI z-scores at six months via Independent t-test revealed no significant difference between the intervention and control groups ($p=0.79$) from baseline to six months. The present study therefore failed to show that the more intense intervention could improve the primary treatment outcome more than the control group.

Although mean BMI z-scores were essentially unchanged from baseline after 6 months in both groups, weight increased significantly in both groups. However, it is worth noting that the weight increase in the intervention group was significantly smaller compared with the control group from baseline to six months.

Another way of considering the success or failure of a childhood obesity treatment intervention is to consider the extent to which weight was maintained or lost. Weight maintenance is widely recommended as an important aim of childhood obesity treatment [145, 206] but this is rarely achieved by the majority of patients [187]. In the present study 27% (9 out of 34) of those in the intervention group maintained or lost weight from baseline to six months but none (0%, 0 out of 45) of the participants in the control group had maintained or lost weight. This indicates, together with the significant difference in weight change between groups that children in the intervention group probably responded better than children in the control group with regards to this outcome.

The degree of change in body weight status which might be desirable in a childhood obesity treatment intervention is currently unknown [3], and would be a valuable direction for future research, but improvements in cardio metabolic risk factors may require greater changes than were observed in the present study [16, 242]. Some authors [16] have suggested that the intervention should reduce BMI z-score by at least 0.5 units before the intervention can be considered successful in terms of improving cardiovascular risk factors such as measures of fasting glucose and blood lipids. Unfortunately, in the present study reductions in BMI z-score of 0.5 or greater by the 6 month outcome

measures were achieved by only 24% (8 out of 34) of the intervention group and 16% (7 out of 45) of the control group.

For the participants in the present study, the proportion of monitored time spent in sedentary behaviour was very high at about 89% of time during the day, equivalent to about 12 hours per day sedentary, defined as no movement of the trunk when measured as in the present study, based on the validation and calibration study by Reilly et al. [243](Table 4.7). Participation in MVPA was extremely low in both groups with a mean time spent in MVPA at baseline of 1% of daily time equivalent to about 8 minutes per day (Table 4.7). International recommendations for school age children are that they should accumulate at least 60 minutes every day of MVPA [144, 145], so the amount of time spent in MVPA by the children studies in MASCOT was well below recommended amounts. Achieving the recommended amount of MVPA in obese children in Malaysia will be a substantial undertaking which requires future research, and might also need a specific intervention.

Overall measurement of habitual physical activity and sedentary behaviour showed that there were no significant differences between groups from baseline to six months in the present study. These results appear to be showing that the intervention group did not improve habitual physical activity or sedentary behaviour relative to the control group. Despite the lack of between group differences, a significant increase in the percentage of time spent in MVPA was observed in the intervention group during the six month intervention period but no significant change in control group. The biological significance of this improvement in the intervention might be quite limited though; an improvement

of 0.5 % of monitored time during the day is equivalent to an 'extra' amount of MVPA of only about 4 minutes/day.

The present study findings suggest that the MASCOT intervention programme study did not negatively impact upon the health-related quality of life (HRQoL) of participants and in fact increased levels of child report and parent proxy report HRQoL were observed. At baseline, parents reported significantly lower QoL physical scores than the child for themselves. Similar discrepancies between parent and child reported HRQoL have been reported elsewhere [36, 37, 187], highlighting the differences in perception of quality of life indicators emphasising the importance of measuring both child- reported and parent-proxy HRQoL.

Children's changes in self-reported HRQoL did not differ significantly between groups from baseline to six months. However, psychosocial and total QoL scores from the children did increase significantly over the time period between baseline and 6 months in the intervention group and the control group did not show significant improvements. The *within* group increase in child reported HRQoL scores for the intervention group in the present study may or may not be clinically important- the author is not aware of research on minimum clinically important differences in quality of life changes in childhood obesity. There was a significant increase in parent proxy quality of life Total Scale Scores from baseline to six months in the intervention group compared to the control group.

A planned per-protocol analysis for BMI z-scores showed that the intervention group had no significant improvement relative to control participants from baseline to six months. This would indicate that attending at least 75% of

scheduled sessions had no clinical benefit. However, it is worth noting that the per-protocol analysis for weight change showed that the intervention group had a significantly smaller weight increase compared with the control group from baseline to six months with a mean weight gain of 1.5kg, and with 24% of the intervention group either maintaining or losing weight over the six months compared to 0% of the control group, as described above.

3.3.4 Comparison with SCOTT study

As mentioned in Chapter Three, the MASCOT project was based on the SCOTT project [188] while attempting to make it appropriate to the setting in Malaysia. Therefore, it is useful at this point to briefly compare the results from the present MASCOT project and SCOTT study in UK. More details of these comparisons with more global and international focus are further discussed in Chapter Six.

Table 3.21 shows a comparison of the MASCOT study results with SCOTT study. In order to enable comparison between MASCOT and SCOTT study in, the author has-

1. taken the mean of the change in BMI SD score, physical activity levels and quality of life over time in the Hughes, Stewart [187] study [this particular Hughes et al. [187] study reported the changes as median and not mean. The mean results were reported in the thesis of Stewart [244]]
2. shown results reported at 6-months (end of the treatment) only from SCOTT study [the SCOTT study [187] reported the outcomes at 6-months

of intervention and 12-months of intervention (6- months follow-up after intervention)]

Based on both studies results, we can say that there are similarities in BMI z-score changes, physical activity level changes and quality of life changes between MASCOT obese children and SCOTT obese children who received the treatment after 6 months of the intervention programme. In contrast, the control group (obese children who received standard care treatment) in the SCOTT study became less active, leading to significant differences in total physical activity and percentage of time in MVPA between novel treatment group and standard care group in SCOTT. The significant outcomes of Hughes et al. [187] compared to the present study are further discussed in Chapter Six.

Table 3.21 Comparison of the present MASCOT results with SCOTT study

	MASCOT	SCOTT [186]
Participants	7-11 years old Kuala Lumpur, Malaysia n= 107 randomised, 79 complete (74%) Intervention: n= 52; 6 months n=34 (65%) Control: n= 55; 6 months n= 45 (82%)	5-11 years old Scotland, UK n= 134 randomised, 97 complete (72%) SCOTT treatment: n= 69; 6 months n= 48 (70%) Standard care: n= 65; 6 months n= 49 (75%)
Primary outcome measure	Changes in BMI z-score at six months (end of treatment)	Changes in BMI SD score at six months (end of treatment)
Secondary outcomes	Total activity + time in sedentary behaviour, light intensity + MVPA at six months (end of treatment) Measures of quality of life at six months (end of treatment)	Total activity + time in sedentary behaviour, light intensity + MVPA at six months (end of treatment) Measures of quality of life at six months (end of treatment)
Primary outcome: Change in BMI z-score	Intervention= 0.1(0.5) Control= 0.0(0.7)	SCOTT treatment= -0.1 (0.2) Standard care= -0.1 (0.2)
Change in Physical activity levels	**Cpm**[1] Intervention: 33(133) Control: 16(124) **Sedentary behaviour** Intervention:-1.2(4.6) Control: -0.1(3.4) **Light intensity** Intervention : 1.0(5.0) Control : 0.0(3.6) **MVPA**[2] Intervention : 0.5(1.0) Control : 0.0(1.5)	**Cpm**[1] SCOTT treatment: 18 (163) Standard care: -98 (165) **Sedentary behaviour** SCOTT treatment: 0.1 (5.6) Standard care: 3.8 (5.3) **Light intensity** SCOTT treatment : -0.6 (4.6) Standard care : -3.3 (4.1) **MVPA**[2] SCOTT treatment : 0.5 (2.1) Standard care : -0.4 (1.8)
Secondary outcome: Change in Quality of Life	**Total child** Intervention : 4.9 (11.6) Control : -1.4 (16.1) **Total parent** Intervention :4.2(15.5) Control : -3.8 (19.3)	**Total child** SCOTT treatment : 3.7 (12.6) Standard care : 6.9 (13.5) **Total parent** SCOTT treatment : 3.3 (9.1) Standard care : 5.2 (9.8)

[1]cpm= count per minute
[2]MVPA= moderate-vigorous physical activity

3.4 Conclusion

Results from the present study showed that the hypothesis of the present study was rejected: obese children who participated in a six month family-based behavioural weight management programme did not have improved BMI z-scores at 6 months when compared with obese children who did not receive any treatment. However, examination of primary and secondary outcomes of the present study suggested that a good practice intervention for treatment of childhood obesity in Malaysia might have modest benefits which may be broadly comparable to those achieved by similar interventions in the developed world such as SCOTT [3, 187]. Furthermore, the persistence of a high prevalence of childhood obesity suggests there may be a need for continued weight management support following intervention end. Unfortunately, the design of the MASCOT study is unable to explore this. Wilfley et al. [245] have suggested that 'maintenance' approaches to childhood obesity treatment might be valuable, with treatment being extended over many years.

In Chapter Four and Chapter Five of this thesis, secondary outcomes from baseline data in the present study are compared with healthy (non-obese) children in Kuala Lumpur –these might help to provide a better understanding of how to design future childhood obesity treatment interventions in Malaysia.

CHAPTER FOUR

Health-related Quality of Life (HRQoL) of Obese Children in Malaysia Compared to Pair-Matched Controls of Healthy Weight Status*

4.1 Introduction

As discussed in section 3.3.3, the HRQoL of obese children participating in the MASCOT treatment programme was generally low (67.7±14.5) relative to other studies [36, 38-40]. Despite this, studies of among obese children all appear to have come from the western world to date and those findings may not generalise to other cultures. It is possible that obesity-related impairment of quality of life might be better or worse in Malaysian children than in western children, Therefore, the main aim of this chapter is to compare quality of life between obese children and matched children of healthy weight status in Malaysia in order to test whether or not the apparently low quality of life of obese children participating in MASCOT is specific to obesity or whether it is related to some other aspect of being a child in Malaysia.

4.2 Methods of health-related quality of life

The measurement of quality of life has become an important health outcome indicator as it provides information about the impact of the clinical condition of patient's lives and can target clinical management public policies that seek to improve the quality of life. There are a number of condition specific tools available to measure HRQoL in obese adults [246] and for children with various chronic illnesses. Nevertheless, no obesity specific tool exists for children.

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Obesity related quality of life in children is assessed using generic instruments to measure global HRQoL such as the PedsQL™ 4.0 and the Child Health Questionnaire-Parent Form 5.0 (CHQ-PF50). The PedsQL™ 4.0 was the tool used to measure HRQoL in this thesis study-see Chapter Two.

4.2.1 Participants of the health-related quality of life (HRQoL) study

Obese children in the present study were participants in the Malaysian Childhood Obesity Treatment Trial (MASCOT), which is described in detailed in Chapter Two. Obesity was defined based on body mass index (BMI) with both the Cole-IOTF definitions [11] and BMI ≥95th percentile on age and gender-specific US reference data [204]. In total, 107 children participated in the MASCOT study. HRQoL, weight and height were recorded at baseline (pre-treatment) and 6 months after the start treatment. The baseline data were used in the present study. HRQoL data were successfully obtained from all children and their parents.

Children with healthy weight status were recruited from primary schools in the same areas of Kuala Lumpur as controls (see Chapter Two, section 2.3.1). Anthropometric assessment was done prior to recruitment to identify children with healthy weight status (BMI below the 85th percentile; relative to US reference data) [204]. Initially we recruited 100 children; however 10 were excluded as they were unable to complete the HRQoL questionnaire. The final sample consisted of 90 healthy control children who were closely-pair matched for gender, age (same school year), and ethnicity with 90 children from the obese group (from MASCOT study), following the approach described by Hughes

et al. [39]. All participating children were from the majority (Malay) ethnic group.

The study was approved by the National University of Malaysia (UKM) research ethical committee, and written informed consent was obtained from parents, assent from the children.

4.2.2 Health-related quality of life questionnaire

As described in Chapter Two section 2.8.3 of this thesis, the best known, most widely used and validated generic non-disease specific HRQoL instrument for children is the Paediatric Quality of Life Inventory (PedsQL) that was used in the present study. HRQoL was measured using the Paediatric Quality of Life Inventory (UK) version 4.0 (PedsQL TM 4.0), translated into Malay. The PedsQL was chosen due to its ability to provide both parent-proxy and child self-report measures and the evidence that it is both valid and reliable as described in sections 2.4.3 and previous study [44]. A full description of the PedsQL questionnaire is given in Chapter Two, Section 2.8.3.

In brief, the PedsQL is both a child self-report and a parent proxy-report scale consisting of 23 items; physical functioning (eight items), emotional functioning (five items), social functioning (five items) and school functioning (five items). The items are reverse-scored and linearly transformed to a 0–100 scale, so that higher scores indicate better quality of life [39, 44]. An overall total score was derived from all the questions answered (mean of all 23 items). The physical health summary score (eight items) is the same as the physical functioning subscale. Psychosocial health summary score was derived from the mean of

emotional, social and school functioning items [39, 44]. The questionnaire was self-completed by parents and by children aged 8-12 years. For children aged 7 years the PedsQL was administered by the researcher who read the questions and the pupils completed the appropriate symbol on the PedsQL as described in section 2.8.3.

4.2.3 Anthropometric measurements

Height was measured using the SECA Body Meter to the nearest 0.1 cm. Weight was measured to the nearest 0.1 kg using scales (TANITA) with children in light indoor clothing. BMI was calculated as weight (kg)/height (m^2). BMI was expressed relative to CDC 2000 reference data as a standard deviation score (SDS). Obesity was defined as BMI $\geq 95^{th}$ percentile on age and gender-specific US reference data [204].

4.2.4 Statistical analysis and study power

Sample size for the study was based on previous study that used PedsQL^{TM} 4.0 to compare HRQoL between obese children and healthy controls in Scotland, UK [39]. With the paired design, the present study had >90% power at the 5% significance level to detect mean differences of total scale score of a magnitude (13.4; sd 18.8) reported previously [39] with around 40 paired comparisons. In order to consider the sexes separately if required, it was decided to recruit healthy controls until around 40 paired comparisons were available for both boys and girls. Recruitment stopped when 90 healthy weight controls were recruited and all 90 could be matched with obese participants in MASCOT.

All statistical analyses were conducted using Statistical Package for Social Science (SPSS) version 16.0. All the data within this chapter are reported as median and interquartile range (IQR) as changes in outcome measures were tested for normality and were normally distributed; therefore, Wilcoxon signed-rank tests were used to test the significance of differences between healthy weight and obese groups.

4.3 Results of the health-related quality of life (HRQoL) study

4.3.1 Characteristics of study participants

Table 4.1 summarises the demographic variables of the 90 obese children and healthy children, respectively. The mean age for healthy children was 10.0 y (IQR 9.9, 10.2). The median age of the obese children was 9.9y (IQR 9.4, 10.1).

As expected, the obese group had significantly higher weight, BMI and BMI z-scores relative to CDC 2000 population reference data compared to healthy children.

Table 4.1 Characteristics of the obese and healthy weight groups in the health-related quality of life (HRQoL) study (median, IQR) (n=180)

Variable	Obese group (n=90)	Healthy weight group (n=90)	Difference (95% CI)	p-value
Median age (years)	9.9(9.4,10.1)	10.0(9.9, 10.2)	0.2(-0.7,0.0)	0.06
Gender (M/F)	41/49	41/49	NA	NA
Median weight (kg)	53.8(51.4, 56.9)	28.9(28.5,30.5)	24.7 (27.6, 21.8)	<0.001
Median BMI (kg/m^2)		15.9(15.8, 16.4)	-13.2 (-12.9, -13.5)	<0.001
Median BMI z-score	2.9(2.8,3.0)	-0.4(-0.5,-0.2)	3.3 (3.5,3.0)	<0.001

Abbreviations: BMI, body mass index, 95%CI: 95% confidence interval
p-value <0.05

4.3.2 Health -related quality of life of obese children

Health-related quality of life (HRQoL) data are shown in Table 4.2. HRQoL was measured in 90 obese children (41 boys, 49 girls) median age 9.9y (IQR 9.4, 10.1), median BMI z-score was 2.9 (relative to CDC 2000 reference data).

HRQoL scores for the child self-report and parent-proxy report in the obese children are shown in Table 4.2. Median scores for the parent-proxy report ranged from 57 to 76 out of possible score of 100 (i.e best possible health). Median total score for parent-proxy report was 65.2 (inter-quartile (IQ) range

57.3-76.1). For the child self-report, median scores ranged from 51 to 74 and total score was 60.9 (IQ range 50.8-73.9).

There was no significant difference between parent-proxy reports and child self-reports in the obese group for total score and psychosocial score. However, the physical health score reported by child self-report was significantly higher than parent-proxy reports (p= 0.02).

Table 4.2 Health-related quality of life scores, median and IQR from the child report and parent-proxy report for the obese group (n=90)

	Boys (n=41)	Girls (n=49)	Total
Child self-report			
Total score	56.6 (50.6, 69.6)	64.1 (50.6, 82.4)	65.2 (57.3, 76.1)
Physical health	68.8 (57.9, 79.7)	65.6 (61.0, 82.9)	67.2 (59.4, 81.3)*
Psychosocial health	60.0 (52.5, 72.5)	65.0 (55.0, 76.8)	62.5 (53.3, 75.4)
Parent-proxy report			
Total score	63.0 (54.4, 75.6)	66.3 (58.2, 78.8)	60.9 (50.8, 73.9)
Physical health	59.4 (45.4, 75.0)	68.8 (46.9, 82.9)	61.0 (46.9, 78.1)
Psychosocial health	55.0 (50.9, 69.2)	61.7 (51.7, 76.7)	58.3 (51.7, 75.0)

**p-value<0.05*

4.3.3 Health -related Quality of Life of healthy weight children

Healthy weight children quality of life variables are given in Table 4.3. Median age was 10.0 y (IQR 9.9, 10.2), median BMI z-score was -0.4 (relative to CDC 2000 reference data).

HRQoL scores for the child self-report and parent-proxy report in the healthy weight children are shown in Table 4.3. Median scores for the parent-proxy report ranged from 48 to 79 out of possible score of 100 (i.e best possible health). Median total score for parent-proxy report was 59.3 (inter-quartile (IQ) range 47.8-79.4). For the child self-report, median scores ranged from 64 to 85 and total score was 76.1 (IQ range 64.1, 84.8).

The HRQoL child self-reports were significantly higher than the parent-proxy reports for total score, physical health and psychosocial health ($p<0.001$, respectively).

Table 4.3 Health-related quality of life scores, median and IQR from the child report and parent-proxy report for the healthy weight group (n=90)

	Boys (n=41)	Girls(n=49)	Total
Child self-report			
Total score	75.0 (63.0, 85.9)	76.1 (64.1, 84.3)	76.1 (64.1, 84.8)*
Physical health	81.3 (59.4, 90.6)	84.4 (70.4, 90.6)	82.9 (65.7, 90.6)*
Psychosocial health	73.3 (63.3, 83.3)	73.3 (65.0, 83.3)	62.5 (53.3, 75.4)*
Parent-proxy report			
Total score	56.5 (47.8, 71.2)	68.5 (50.0, 80.4)	59.3 (47.8, 79.4)
Physical health	50.0 (40.6, 70.4)	62.5 (48.4, 86.0)	57.9 (43.8, 77.1)
Psychosocial health	60.0 (52.5, 75.0)	68.3 (50.9, 80.9)	61.7 (43.8, 84.4)

**p-value <0.05*

4.3.4 Formal paired comparison of HRQoL between obese and healthy control children in the entire sample (n=90 paired comparisons)

Table 4.4 summarises the paired comparisons of child self-report and parent-proxy report scores of HRQoL for the obese and healthy weight groups. For the parent-proxy scores, none of the differences between obese and healthy weight groups were statistically significant in all HRQoL domains. However, child-self report scores were significantly higher in the healthy control group compared to the obese group.

Table 4.4 Paired comparisons of health-related quality of life (median IQR) for the healthy weight group vs obese group.

Variable	Healthy weight group (n=90)	Obese group (n=90)	p-value	Thaalassaemia clinical sample (151)
Child self-report				
Total score	76.1 (64.1, 84.8)	65.3 (57.3, 76.1)	< 0.001	68.9 (12.1)
Physical health	82.9 (65.7, 90.6)	67.2 (59.4, 81.3)	< 0.001	69.2(16.5)
Psychosocial health	73.3 (64.4, 83.3)	62.5 (53.3, 75.4)	< 0.001	67.6 (12.8)
Parent-proxy report				
Total score	59.3 (47.8, 79.4)	60.9 (50.8, 73.9)	0.464	Not measured
Physical health	57.9 (43.8, 84.4)	61.0 (46.9, 78.1)	0.319	Not measured
Psychosocial health	61.7 (51.7, 77.1)	58.3 (51.7, 75.0)	0.765	Not measured

**p-value <0.05*

4.3.5 Formal paired comparison of HRQoL between obese boys and healthy weight boys (n=41 paired comparisons)

The results of the gender-matched analysis for boys (n=82, ie 41 pairs) demonstrated that obese boys reported significantly lower for child-self report in HRQoL scores on all domains of the PedsQL (total scale score, physical health and psychosocial health) compared to the matched healthy weight sample ($p<0.05$) (Table 4.5). However, there were no significant differences for parent-proxy report for all domains between obese and healthy weight boys.

Table 4.5 Paired comparisons of health-related quality of life (median IQR) for the healthy weight boys vs obese boys (n=82)

	Healthy(n=41)	Obese (n=41)	p-value
Child self-report			
Total score	75.0 (43.5, 91.3)	63 (37.0,84.1)	<0.01*
Physical health	81.3 (57.9, 79.7)	68.8 (31.3, 93.8)	<0.01*
Psychosocial health	73.3 (52.5, 72.5)	60.0 (36.7, 87.5)	<0.01*
Parent-proxy report			
Total score	56.5 (34.8, 84.8)	56.6 (34.8, 84.8)	0.95
Physical health	50.0 (28.1, 96.9)	59.4 (28.1, 87.5)	0.48
Psychosocial health	60.0 (38.3, 91.7)	55.0 (35.0, 90.0)	0.29

**p-value <0.05*

4.4.6 Formal paired comparison of HRQoL between obese girls and healthy weight girls (n=49 paired comparisons)

For girls (n=98, ie 49 matched pairs), the obese girls group reported significantly lower HRQoL scores on all domains of child-self report HRQoL compared to healthy control girls ($p<0.05$) (Table 4.6). No significant differences in parent-proxy report were found between obese girls and lean girls.

Table 4.6 Paired comparisons of health-related quality of life (median and IQR) for the healthy weight girls vs obese girls (n=98)

	Healthy (n=49)	Obese (n=49)	p-value
Child self-report			
Total score	76.1(53.3, 94.6)	66.3 (30.4,88.0)	<0.05
Physical health	84.4 (43.8, 96.9)	65.6 (25.0, 100)	<0.01
Psychosocial health	73.3 (48.3, 96.7)	65.0 (33.3, 90.0)	<0.05
Parent-proxy report			
Total score	68.5 (32.6, 100)	64.1 (42.7, 92.4)	0.88
Physical health	62.5 (21.9, 100)	68.8 (34.4, 100)	0.81
Psychosocial health	68.3 (33.3, 100)	61.7 (41.7, 95.0)	0.47

**p-value <0.05*

4.4 Discussion

The present study supports the hypothesis that obese children of primary school age in Malaysia have impaired health related quality of life compared to their healthy weight peers. The findings are consistent with other studies [42, 43, 144] using a community-sample that also found significant impairment in all HRQoL dimensions in the obese participants compared to non-obese controls. However, the present study also indicated that the impairment of quality of life

associated with obesity in Malaysian children is evident from child-reports, not from parent-proxy reports.

Furthermore, in the present study there was no evidence that impaired quality of life was gender-specific. This is line with previous studies by Schwimmer et al. [36], Williams et al. [33], Hughes et al. [39] and Riazi et al. [40] suggests that the impact of obesity is not necessarily gender-specific. However, Wake et al. [247] found gender specific differences in the extent of the impairment of quality of life associated with obesity in Australian children, but the recent systematic review by Griffiths et al. [28] found that few studies have examined the question of whether quality of life impairment in obesity is gender-specific. In the adolescents' obesity study, Swallen et al. [248] reported gender to be significantly associated with HRQoL in obese compared to normal weight adolescents. It is possible that gender differences in HRQoL associated with obesity are small in childhood, but emerge or increase in adolescence.

The assessment of quality of life in obese children is particularly important as it is related to the most common short-term consequences of paediatric obesity, ie psychological problems often related to discrimination and/or teasing [27]. The recent systematic review by Griffiths et al. [28] identified an impairment of quality of life as being typical of obese children, but it should be noted that only six studies of children were eligible for this review and all were from the western world.

The use of self-reported health-related quality of life questionnaires in the assessment of obese children can help identify the impact of being obese from

the children's perspective. There have also been discussions about the importance of children's perspectives on their own health [249]. One study found that children as young as six years old can adequately understand and accurately report their own health and well-being [250]. Carr et al. [251] stressed that any measurement of the quality of life of children should include questions on physical, social and psychosocial functioning of a child from the child's perspective.

The parent perspective on quality of life is also important [252]. A systematic review emphasised the value of obtaining perspectives on quality of life from both parents and children where possible [252]. Some studies have suggested that parent-perceived impairments in quality of life might be a more important driver of health care utilisation and treatment-seeking for childhood obesity than child-perceived impairment [39, 247], and parent perceptions may also influence the extent to which family lifestyle changes might be made in response to obesity treatment interventions.

Though the present study was consistent with studies from the western world which have shown that childhood obesity is associated with impairment in quality of life, and this might suggest that cultural differences might not matter to the influence of obesity on quality of life of obese children, subtle culture-specific differences in quality of life associated with childhood obesity might still be present. For example, Hughes et al. [39], compared quality of life between obese and healthy weight children of similar age to the present study in Scotland using identical study design and methods. Hughes et al. [39] found, in contrast to the present study, that impaired quality of life in obese children was much

more evident and more marked when parent reported quality of life was used than when child self-reports were used. In the present study the impairment of quality of life associated with obesity was most marked when viewed from the child's perspective and was not present when viewed from the parent's perspective. The reasons for this are not clear and need further research but might be related to cultural differences between the western world and Malaysia. In the present study the parent reported quality of life for the healthy controls was very low, and this might explain why in the parent reports childhood obesity was not associated with significant impairment of quality of life.

Statistically significant obesity related impairment of quality of life was observed in the present study, when child reports of quality of life were used, but the 'biological significance' of such impairment is unclear-in other words it is not clear if the impairment is enough to cause psychological harm or suffering to obese children. Previous studies in western societies have generally found that childhood obesity is associated with PedsQL total scale scores which lie among the scores for children with other chronic and disabling conditions [28, 44, 253]. The HRQoL total scores from obese children in the present study lie at the lower end of the range described previously for children with other chronic and disabling conditions from western societies [28, 44, 253].

Only one previous study of quality of life using the PedsQL has been carried out in Malaysian children. Ismail et al. [45] tested the hypothesis that quality of life was impaired in children with thalassaemia from Kuala Lumpur, and reported a mean child-specific total score of 68.9 for thalassaemia patients and 79.8 from

healthy controls. The present study median total score of 60.9 for the child reports from the obese children in Kuala Lumpur was well below the values reported for thalassaemia patients in the same city by Ismail et al. [45].

There is some research to date suggesting that there are differences in HRQoL among obese children depending on how they are sampled. Firstly, it has been suggested that impairment of quality of life might be worse in clinical samples than community samples that are obese [33]. Williams et al. [33] used the PedsQL 4.0 to assess HRQoL in a community-based sample of obese children in Australia, and observed significantly lower scores for total score, physical health and social functioning in obese children compared to controls, but the impairment of quality of life was apparently not as marked as that described in studies which recruited clinical samples of obese children. This led Williams et al. [33] to suggest that childhood obesity need not impair quality of life but quality of life impairment was most likely in clinical samples. At the moment there is probably not enough evidence to be sure if clinical samples have poorer quality of life than community samples of obese children. In the present study, the obese sample was from the community setting – they might be described as 'treatment seeking' by the time their quality of life was measured however as they had agreed to take part in the MASCOT RCT (and their agreement included consent to be allocated to treatment if that was the outcome of the randomisation)- the present study sample was therefore not quite a clinical sample nor quite a community sample.

The main strengths of the present study were homogenous sample of community sample studied, adequate power and the pair-matched design which allowed key

variables (age and gender) to be controlled. Another strength of the study lies in the use of a valid and reliable instrument for assessment of HRQoL that is valid across different cultures [28, 33, 43] and so which allows a cross-cultural comparison of the impact of childhood obesity on quality of life. Furthermore, this was only the second study to examine health-related quality of life in children in Malaysia.

A number of study limitations should be noted. While no significant impairments of quality of life with obesity were observed using parent reports, it is possible that impairments are present, but these are of very small magnitude and so would require much larger samples in order to detect. Further research would also be needed to examine specific domains in quality of life in more detail, and to examine age effects (eg in adolescents the effect of obesity on quality of life might be different) and within-country effects, in other parts of Malaysia or in other ethnic groups within Malaysia for example. Further studies are needed in other samples and settings to confirm the generalisability of our findings and to address other issues such as the influence of culture on HRQoL in childhood obesity and the influence of obesity treatment on changes in quality of life.

4.5 Conclusions

The present study shows an impaired HRQoL in obese children from Malaysia. Impairment in HRQoL was very similar in both boys and girls. The degree of impairment is likely to be greatest when assessed using the child perspective rather than the parent perspective. Impaired quality of life appears to be associated with childhood obesity in Malaysia, as in western countries. Therefore, the widespread existence of quality of life impairment in childhood

obesity in Malaysia provides an additional argument that it should be taken seriously by health professionals.

CHAPTER FIVE

Habitual Physical Activity and Sedentary Behaviour of Obese Children in Malaysia Compared to Pair-Matched Controls of Healthy Weight Status

5.1 Introduction

As discussed in Section 2.8.2, the physical activity levels of obese children participating in the MASCOT treatment programme were extremely low relative to recommendations for physical activity [254, 255]. A growing body of evidence has found lower levels of objectively measured physical activity in obese children and adolescents relative to their lean counterparts [146, 256-260]. However, results have been inconsistent and this may be partly dependent on whether clinical samples of obese children are studied or whether community samples of obese children are studied [146, 258]. Despite this, studies of physical activity among obese children all appear to have come from the western world to date and those findings may not generalise to other cultures. It is possible that the physical activity levels of obese children in Malaysia might be worse than in western children, and that difference between obese and healthy weight children might be larger or smaller in Malaysia than in other cultures.

This chapter therefore aimed to (1) measure habitual physical activity and sedentary behaviour of Malaysian obese children aged 7-11 years; (2) test the hypothesis that obese Malaysian children are less physically active than their peers by comparing results between obese children and a sample of age- and sex- matched healthy weight children.

5.2 Methods of the habitual physical activity and sedentary behaviour study

To date, a wide range of methods have been used to measure physical activity levels in obese children. These are categorised into two types of measurement: subjectively measured (self-report questionnaires) and objectively measured (heart rate monitor, accelerometer, and pedometer). Self-report questionnaires are the most commonly used method due to their low cost and ease of administration. However, this measure has limitations, given that self-reports are subject to considerable recall bias and have limited validity and reliability among children [261, 262].

To avoid limitation of self-report, a number of studies have utilised objective measures to examine levels of physical activity in obese children. To date, few studies have utilised accelerometers to assess obesity-related differences in physical activity in children, comparing the obese and non-obese. These devices can detect and record magnitude of movement on a real-time basis and can overcome some of the limitations of self-report questionnaires, including the avoidance of bias in measurement of the level of physical activity. Accelerometers also provide reliable information about the frequency, duration and intensity of physical activity within a given day or several days or even a week enabling patterns of movement or inactivity to be assessed [263]. Besides, they are capable of providing estimates of percentage of time spent at levels of light, moderate and vigorous intensity physical activity [264].

As noted above, several studies have used accelerometers to assess the habitual physical activity of obese children objectively. The published studies are briefly discussed below and also summarised in Table 5.1.

In 2001,Trost et al. [141] reported a significantly lower total volume of physical activity, and MVPA in a group of 54 obese children (defined as BMI > 95th centile) compared with 33 non-obese children (mean age of 11.4±0.6) in a community sample in the USA. In this study, the authors also found that, obese children reported significantly lower levels of physical activity self-efficacy and were involved in significantly fewer community organisations promoting physical activity.

Similar to the findings of Trost et al. [141], a study among 133 children age 8-18 years from community and clinical settings in UK demonstrated that obese children spending less time in MVPA than the non-obese children [258]. The authors also put forward the suggestion that the home environment is closely associated with reduced levels of physical activity obese children may typically have better levels of physical activity during school day [258] and this supports the use of family-based intervention to promote physical activity in the families of obese children [183, 189, 191].

Another UK study found that obese children spent on average 80.4% of their monitored time in sedentary behaviour and only 2.5% of their monitored time in moderate-vigorous physical activity (MVPA) [146], equivalent to about 20 minutes per day in MVPA. This cross-sectional study of obese children from a clinical sample reported that the total volume of activity and MVPA were significantly higher in the non-obese group than the obese group. However, the study also reported that time spent in sedentary behaviour of obese children was similar to their non-obese peers [146].

One study by Riddoch et al. [259] examined the level and patterns of physical activity in a large contemporary cohort of 11 year old children- the Avon Longitudinal Study of Parents and Children (ALSPAC). The study also confirmed that activity levels are lower in overweight and obese children compared to normal weight children [259], though the ALSPAC participants who were obese represent a community sample rather than a clinical sample of obese children.

All of the above published studies of physical activity in obese children to date were from western societies and since the physical activity levels associated with childhood obesity may be culture-specific, there is a need to identify whether obesity has a significant association with low physical activity levels in non-western societies. Successful interventions to manage obesity need to take account the cultural context in which obesity occurs, and thus studying obese children from non-western countries is important. No studies of objectively measured physical activity and sedentary behaviour of children have taken place in Malaysia and so there is a need to collect data on these important variables in Malaysia children. In addition, the MASCOT study could be enhanced by the inclusion of a comparison of physical activity and sedentary behaviour between obese and healthy weight children, providing an opportunity to test whether the apparently low physical activity and high sedentary behaviour described in the MASCOT obese children in Chapter Four was obese-specific or whether it was more related to the Malaysian setting.

Table 5.1 Summary of relevant studies assessing physical activity levels in obese children using accelerometer

Publication details	Study and sample	General findings
Trost et al. [141] **United States**	Cross-sectional study of 213 children (133 non obese vs 54 obese-defined as 95th percentile relative to CDC US reference data) Community sample	Compared to non-obese children, obese children had significantly lower:- Total counts per day :28.3 x 10^4±2.01 x 10^4 vs 37.7 x 10^4 ±1.41 x 10^4 MPA :62.6±4.5 vs 78.2±3.2 min/day VPA :7.1±1.3 vs 13.5±0.9 min/day
Page et al. [258] **United Kingdom**	Cross-sectional study of 133 children (108 non obese vs 25 obese-defined as >99th percentile using Cole-IOTF definition of obesity) Clinical sample	Compared to non-obese children, obese children had significantly lower:- Total counts per hour: 31 844±13200 vs 41844±10430 Moderate or greater intensity PA: 9.9±3.9 vs 12.9±4.2 min/hour
Hughes et al. [146] **United Kingdom**	Pair-wise comparison for age and gender of 53 obese children (defined as >98th percentile relative to 1990 UK reference data) matched with 53 non obese children Clinical sample	Compared to non-obese children, obese children had significantly lower:- Total activity (c.p.m): 648±196 vs 729±228 MVPA: 2.4% vs 3.9%
Riddoch et al. [259] **United Kingdom**	Cross-sectional study of 5595 children (4335 normal vs 941 overweight vs 253 obese-defined using both 1990 UK reference data) Community sample	Activity levels (c.p.m) were lower in both the overweight and obese children Normal: 590.6 (IQ 484.4-721.1) Overweight: 542.7(IQ 454.4-673.1) Obese: 520.0(IQ442.6-625.4)

In summary, the limited evidence on habitual physical activity and sedentary behaviour in childhood obesity to date means that there is a need for more studies, particularly from outside the western world, and particularly using objective methods. The present study therefore aimed to test whether physical activity levels were lower in obese children than non-obese children in Malaysia.

5.2.1 Participants in the habitual physical activity and sedentary behaviour study

Obese children in the present study were participants in the Malaysian Childhood Obesity Treatment Trial (MASCOT), which is described in detail in Chapter Two. In total, 107 children, 54 boys and 53 girls, participated in the baseline stage of the MASCOT study. Physical activity, sedentary behaviour, body mass and height were recorded at baseline and 6 months after the start of the treatment. However, for physical activity and sedentary behaviour, 20 participants were excluded as data points were missing due to accelerometer failure, poor compliance with the accelerometry protocol (see section 2.4.3) and monitors were lost. Therefore, only 87 of the 107 obese children in MASCOT were successfully measured for physical activity and sedentary behaviour at baseline.

Children with healthy weight status (defined as BMI <85th percentile on age and gender-specific US reference data) were recruited from primary schools in the same areas of Kuala Lumpur as the MASCOT sample. The sample in present study was not the sample as reported in Chapter Four. Since physical activity might vary by age and gender, in the present study obese children and non-obese children were pair-matched by gender and age. The final sample consisted of 86

healthy weight children who could be closely pair-matched for age and gender with 86 children from the obese group.

The study was approved by the National University of Malaysia (UKM) research ethical, and written informed consent was obtained from parents, assent from the children.

5.2.2 Objectively-measured physical activity and sedentary behaviour

As described in Chapter Two section 2.8.2 habitual physical activity and sedentary behaviour were measured objectively over five days-during the waking hours (except during bathing and other water activities) using a GT1M accelerometer (The Actigraph, Fort Walton Beach, Florida, USA. In brief, the children were instructed to wear the activity belt and it should be fitted in the child's hip and keeping a diary for 5 day. The accelerometers were set to record activity in one minute epochs; these counts per minute (cpm) were used as a measure of total volume of physical activity [230, 231, 265]. The percentage of time spent in sedentary behaviour, light intensity activity and moderate to vigorous physical activity (MVPA) were determined from the accelerometer readings by use of agreed cut-off points based on previous validation studies. The cut off points in the proposed study are as follows [234, 243]:

<100 cpm – sedentary behaviour [243]

1100-3200 cpm – light intensity activity

>3200 cpm – moderate to vigorous physical activity [234]

5.2.3 Anthropometric measurements

Height was measured using the SECA Body Meter to the nearest 0.1 cm. Weight was measured to the nearest 0.1 kg using scales (TANITA) with children in light indoor clothing. BMI was calculated as weight (kg)/height (m^2). BMI was expressed relative to CDC 2000 reference data as a standard deviation score (SDS). Obesity was defined as BMI ≥95^{th} percentile on age and gender-specific US reference data.

5.2.4 Statistical analysis and study power

Sample size for the present study was based on a previous study which found a statistically significant difference in total physical activity between obese and non-obese children of the same age [146]. We calculated that a minimum of 40 pairs, with 20 pairs of boys and 20 pairs of girls were required to have a >90% power at the 5% significance level to detect a mean difference of 100 accelerometry counts/min/day (a measure of total volume of physical activity, and this difference is roughly equivalent to the difference between boys and girls in most previous studies) [259] in each sex. All statistical analyses were conducted using Statistical Package for Social Science (SPSS) version 16.0.

Data were checked for normality before analysis using descriptive statistics and Kolmogrov-Smirnov normality test. As obese and non-obese children were matched for age and sex, paired tests were used to analyse the significance of differences between groups. Total physical activity, total hours monitored and percentage of monitored time spent in sedentary behaviour, light intensity activity and MVPA were not normally distributed. Therefore, Wilcoxon-signed

rank tests were used to test the significance of differences between obese and non-obese groups.

5.3 Results of habitual physical activity and sedentary behaviour study

5.3.1 Characteristics of study participants

Descriptive characteristics of the 86 obese and 86 healthy weight participants are shown in Table 5.2. The median age for healthy children was 10.0 y (IQR 9, 10). The median age of the obese children was 9.5y (IQR 8,11).

As expected, the obese group had significantly higher weight, BMI and BMI z-scores relative to CDC 2000 population reference data compared to healthy children.

Table 5.2 Characteristics of the pair-matched obese and healthy weight groups (n=172), median (IQR)

Variable	Obese group (n=86)	Healthy weight group (n=86)	Difference (95% CI)	p-value
Median age (years)	10.0 (8.0, 11.0)	10.0 (9.0, 10.0)	9.5, 9.8	0.45
Gender (M/F)	41/45	41/45	NA	NA
Weight (kg)	53.8 (45.0, 62.6)	28.9 (26.7, 32.8)	39.6, 44.3	< 0.001
Height (m)	137.5 (133.8, 147.0)	135.0 (130.0, 139.5)	136.0, 136.7	< 0.001
BMI (kg/m^2)	26.9 (24.9, 29.0)	15.9 (15.7, 17.3)	20.8, 22.7	< 0.001
BMI z-score	2.9 (2.5, 3.3)*	-0.3(-.8, .4)	1.1, 1.6	< 0.001

Abbreviations: BMI: body mass index.

5.3.2 Habitual physical activity and sedentary behaviour of obese children

Objectively measured habitual physical activity and sedentary behaviour data are shown in Table 5.3. Physical activity was measured in 86 obese children (41 boys, 45 girls) median age 9.5y (IQR8,11), median BMI z-score was 2.9 (relative to CDC 2000 reference data).

The proportion of monitored time spent in sedentary behaviour was high in the obese children, median of 90% (range 71.8, 97.0) of the waking day (about 12 hours) (Table 5.3). Participation in moderate to vigorous physical activity was extremely low in this group at a median of 0.7% (range 0.0, 4.5) of monitored time during the day, equivalent to about 5 minutes per day.

Table 5.3 Habitual physical activity and sedentary behaviour, median (IQR) for the obese group (n=86)

	Boys (n=41)	Girls (n=45)	Total
Total physical activity (cpm)	356 (50-835)	307 (134, 629)	336(50,835)
% of monitored time			
Sedentary behaviour	88.9 (71.8, 97.0)	91.0(80.6,95.8)	90.2 (71.8, 97.0)
Light intensity physical activity	9.69 (1.1, 26.8)	7.4 (2.5, 19.2)	8.3 (1.1, 26.8)
MVPA	0.8 (0.0, 4.5)	0.6 (0.08, 3.32)	0.7 (0.0, 4.5)

Abbreviations: c.p.m/ count per minute; MVPA, moderate to vigorous physical activity;
[a]Sedentary behaviour <1100 counts/min, light intensity activity 1100-3200 counts/min, MVPA >3200 counts/min

5.3.3 Habitual physical activity and sedentary behaviour of healthy weight children

Habitual physical activity and sedentary behaviour of healthy weight children are given in Table 5.4. Median age was 10.0 y (IQR 9.0, 10.0), median BMI z-score was -0.3 (relative to CDC 2000 reference data).

The proportion of monitored time spent in sedentary behaviour was also high in the non-obese children, median of 88% (range 73.0, 95.9) of the waking day (about 12 hours). Participation in moderate to vigorous physical activity was extremely low in this group at a median of 1.2% (range 0.0, 7.7) of monitored time during the day, equivalent to about 9 minutes per day (additional 4 minutes compared to the obese group).

Table 5.4 Habitual physical activity and sedentary behaviour, median (IQR) for the healthy weight group (n=86)

	Boys (n=41)	Girls (n=45)	Total
Total physical activity (cpm)	380 (167-712)	371 (142, 851)	380 (145,851)
% of monitored time			
Sedentary behaviour	87.0 (73.0-93.6)	87.6(74.5,95.9)	87.5 (73.0, 95.9)
Light intensity physical activity	10.9 (4.9-20.9)	9.9 (2.3,21.7)	10.5 (2.3, 21.7)
MVPA	1.3 (0.1, 7.7)	1.0(0.0,7.0)	1.2 (0.0, 7.7)

Abbreviations: c.p.m/ count per minute; MVPA, moderate to vigorous physical activity;
[a]Sedentary behaviour <1100 counts/min, light intensity activity 1100-3200 counts/min, MVPA >3200 counts/min

5.3.4 Formal-paired comparison of habitual physical activity and sedentary behaviour between obese and healthy weight children in the entire sample (n= 86 paired comparisons)

Table 5.5 shows total hours monitored total physical activity, and the percentage of monitored time spent in sedentary behaviour, light intensity physical activity and MVPA in the obese and healthy weight groups. The median total physical activity (cpm) was 336 in the obese group and 380 in the healthy weight group, with no significant between-group difference (Z = -1.655, p=0.098). Time spent in sedentary behaviour was significantly higher in the obese group compared to the healthy-weight group (Z = -3281, p=0.001). Light intensity physical activity was similar in obese and healthy weight groups (Z= -1.626, p=0.104). Participation in MVPA was significantly higher in the healthy weight group vs. the obese group (Z= -3.555, p< 0.001). Obese children spent 0.7% (range 0.0, 4.5) of their monitored time in MVPA (equivalent to approximately 5 mins/day) compared to 1.2% (range 0.0, 7.7) in the non-obese group (equivalent to approximately 8-9 mins/day).

Table 5.5 Paired comparisons of habitual physical activity and sedentary behaviour (median and IQR) in obese vs non-obese children

Variables	Obese group (n=86)	Non-obese group (n=86)	p-value
Total physical activity (cpm)	336 (50,835)	380 (145,851)	0.098
% of monitored time			
Sedentary behaviour	90.2 (71.8, 97.0)	87.5 (73.0, 95.9)	**<0.001**
Light intensity physical activity	8.3 (1.1, 26.8)	10.5 (2.3, 21.7)	0.104
MVPA	0.7 (0.0, 4.5)	1.2 (0.0, 7.7)	**< 0.001**

Abbreviations: CI, confidence interval; c.p.m/ count per minute; MVPA, moderate to vigorous physical activity
[a]Sedentary behaviour <1100 counts/min, light intensity activity 1100-3200 counts/min, MVPA >3200 counts/min

5.3.5 Formal-paired comparison of habitual physical activity and sedentary behaviour between obese boys and healthy weight boys (n= 41 paired comparison)

The results of the gender-matched analysis for boys (n=82, 41 pairs) demonstrated that obese boys had lower time spent in MVPA compared to the matched healthy weight controls ($p<0.05$) (Table 5.6). Time spent in sedentary behaviour was significantly higher in the obese group compared to the healthy weight group ($p<0.001$).

Table 5.6 Paired comparisons of habitual physical activity and sedentary behaviour (median IQR) for the healthy weight boys vs obese boys (n= 82)

Variable, Median and range	Healthy weight (n=41)	Obese (n=41)	p-value
Total physical activity (cpm) (range)	380 (167-712)	356 (50-835)	0.325
% of monitored time			
[a] Sedentary behaviour (range)	87.0 (73.0-93.6)	88.9 (71.8, 97.0)	0.05*
Light intensity physical activity (range)	10.9 (4.9-20.9)	9.69 (1.1, 26.8)	0.425
MVPA (range)	1.3 (0.1, 7.7)	0.8 (0.0, 4.5)	<0.001*

Abbreviations: c.p.m/ count per minute; MVPA, moderate to vigorous physical activity
[a] Sedentary behaviour <1100 counts/min, light intensity activity 1100-3200 counts/min, MVPA >3200 counts/min
*p-value <0.05

5.3.6 Formal-paired comparison of habitual physical activity and sedentary behaviour between obese girls and healthy control girls (n= 45 paired comparison)

For girls (n=90, 45 matched pairs), the obese girls had significantly lower time spent in MVPA (p=0.03) and significantly higher time spent in sedentary behaviour (p=0.01) compared to healthy weight girls (Table 5.7).

Table 5.7 Paired comparisons of habitual physical activity and sedentary behaviour (median IQR) for the healthy weight girls vs obese girls (n=90)

Variable, Median and range	Healthy weight (n=45)	Obese (n=45)	p-value
Total physical activity (cpm) (range)	371 (142, 851)	307 (134, 629)	0.149
% of monitored time			
[a] Sedentary behaviour (range)	87.6(74.5,95.9)	91.0(80.6,95.8)	0.01*
Light intensity physical activity (range)	9.9 (2.3,21.7)	7.4 (2.5, 19.2)	0.132
MVPA (range)	1.0(0.0,7.0)	0.6 (0.1, 3.3)	0.03*

Abbreviations: c.p.m/ count per minute; MVPA, moderate to vigorous physical activity
[a] Sedentary behaviour <1100 counts/min, light intensity activity 1100-3200 counts/min, MVPA >3200 counts/min
p-value <0.05

5.4 Discussion

Participants in the MASCOT study spent about 12 hours per day sedentary (defined as no movement of the trunk when measured as in the present study, based on the accelerometry validation and calibration study by Reilly et al. [243].This definition of sedentary includes both sitting and standing (standing but with no trunk movement). Participation in MVPA was extremely low in obese children in the present study with a median time spent in MVPA equivalent to only about 5 minutes per day. Recent WHO recommendations on physical activity for health for children and adolescents age 5-17 years state that they should accumulate at least 60 minutes every day of MVPA [254], and the same recommendation has been made in obesity management guidelines for children [144, 145, 181], thus the amount of time spent in MVPA by the obese children

studied in MASCOT was well below recommended amounts. This large gap between the MVPA undertaken and the amount recommended is a major challenge for childhood obesity treatment.

In the present study, we expected that obese children would be less active than healthy weight children. In contrast to our hypothesis, total volume of physical activity (as measured by accelerometry count per minute) was not significantly different between groups. On the other hand, we found that participation in moderate vigorous physical activity was significantly lower in obese children compared to non-obese children. However, this difference in MVPA (median of -0.5% of monitored time, equivalent to only around 4-5 minutes per day) between the obese and non-obese groups was small. Although our findings show that obese children spent significantly more time in sedentary behaviour compared to their lean counterparts, this difference was also small (equivalent to a median difference between groups of only 2.5 % of monitored time, or approximately about 20 minutes per day).

We analysed the physical activity levels by gender, as it was possible that the effect of obesity on level of habitual physical activity might differ between boys and girls. After we analysed separately for obese vs healthy weight boys and for obese vs healthy weight girls, we found that time spent in sedentary behaviour was significantly higher in both obese boys and obese girls compared to control boys and control girls, respectively. Similarly, there was a significant between group difference in MVPA within boys and within girls. The present study, therefore, found no evidence that differences in physical activity and sedentary behaviour associated with obesity was gender-specific. A preliminary conclusion

would be that childhood obesity is associated with reduced physical activity and increased sedentary behaviour in Malaysia, but that these obese specific differences apply in both sexes. Many studies have found gender differences in children's physical activity, with boys typically showing greater levels physical activity than girls [266-268].

Our findings appear to be show that the obese children in Malaysia have extremely low habitual MVPA. Low levels of physical activity are a risk factor for excessive positive energy balance, and important in maintenance of obesity [269]. Although MVPA was lower and sedentary behaviour was higher in obese children compared to healthy weight children in the present study, both groups did not achieve the current MVPA recommendation and their levels of physical activity were extremely low. Hence, we suggest that low physical activity observed in the present study may not be an obesity-specific problem in Malaysia.

Our results were consistent with Malaysian National Centre for Chronic Disease Prevention and Health Promotion report which stated that young Malaysians are increasingly inactive, unfit and overweight [270]. A study conducted among Malaysian adolescents reported that among the factors restricting their involvement in physical activity were time constraints, lack of companions, facilities and motivation [271]. However, the reasons for such low levels of MVPA in both obese and control groups in the present study are unclear. Many researchers have focused on the role of environment plays in decreasing energy expenditure, particularly the built environment. It has been shown that the built environment plays an important role in influencing obesity by creating a climate

that promotes a reduction in energy expenditure that has come to the forefront of public health research. A systematic review by Davison and Lawson [272] has reviewed 33 studies on the relationship between the environment and child and adolescent physical activity, ages 3 to 18 years old. The review found that participation in physical activity is positively associated with publicly provided recreational infrastructure (access to recreational facilities and schools) and transport infrastructure (presence of sidewalks and controlled intersections, access to destinations and public transport). Conversely, transport infrastructure (number of roads to cross and traffic density/speed) and local conditions (crime, area deprivation) are negatively associated with participation in physical activity. Furthermore, studies have found the characteristics of 'obesogenic' environment that includes macro (i.e transport, the built environment, health care services and a wide range of government services and policies) and micro environments (i.e family home, school and local neighbourhood) are hypothesised to be direct determinants of children's physical activity [272, 273]. Environmental factors might have resulted in low physical activity levels in the present study. Therefore, identifying factors that affect physical activity levels of children is an essential step toward developing effective interventions for reducing obesity.

Some other studies have also used objective physical activity measures and concluded that physical activity levels are typically very low in obese children, particularly in clinical samples [146]. The present study was consistent with studies from the western world which have shown that childhood obesity is associated with low MVPA and high sedentary behaviour levels, and this might suggest that cultural differences might not influence differences in habitual

physical activity and sedentary behaviour between obese and non-obese children very much. Hughes et al.[146] compared habitual physical activity and sedentary behaviour in a clinical sample of obese children with healthy weight children of similar age to the present study in Scotland using identical study design and methods to those used here, including the same accelerometers and same accelerometry cut-points. Hughes et al. [146] found, similar to the present study, that her sample of obese children were significantly less physically active than non-obese children. Nevertheless, the percentage of time spent in MVPA in this UK clinical sample of obese children was higher than present study (difference approximately 13 mins/day) though both studies reported lower than recommended daily amounts of MVPA.

The present study had a number of strengths. The methods were objective, validated and the sample was adequately powered. In addition, this was the first study to use objective measures of physical activity in children in Malaysia, and one of only a handful to measure physical activity objectively in children from low-middle income countries.

There are several limitations to be noted. The present study included a sample of obese children recruited to an obesity treatment trial [274] and it is not clear if they would be representative of obese children from community samples. This study used a single, waist-mounted, uniaxial accelerometer with measures movement predominantly in the vertical plane. Triaxial accelerometers are considered preferable by some authors, but studies have shown that there is little difference in accuracy of physical activity measurements from uniaxial versus biaxial or triaxial devices [260, 275], and a recent systematic review by

De Vries et al. [276] found high validity for the uniaxial accelerometer used in the present study.

The cut-point values chosen for moderate and vigorous activity and sedentary behaviour used in the present study were based on previous validation studies. One recent study reported that the cut-point for MVPA suggested by the study of Evenson et al. [277] provided the most acceptable classification among children of all ages. Use of an alternative cut-point for MVPA or sedentary behaviour would not have altered the between group comparisons in the present study, but would have altered the absolute amounts of MVPA measured. For example, for illustration applying the Evenson et al. [277] cut point to the obese sample in the present study produced estimates of the median time spent in MVPA of 1.2 (IQR 0.6, 5.1). The issue of using accelerometry cut points to define MVPA remains highly controversial [278], and at present it is probably best to simply use the same cut points for both groups when between group comparisons are being made, as in the present study.

It is also worth noting that accelerometer count per minute –a measure of total volume of physical activity which is unaffected by cut points chosen-was very low compared to other studies of children of a similar age. For example, Basterfield et al. [232] recently used identical methods to the present study in a representative sample of 7-9 year old children in England and reported a mean accelerometer cpm of 643 in the 9 year olds, much higher than that measured in the healthy weight group in the present study. Indeed a study conducted in highly obesogenic environment (highest prevalence of childhood obesity in England) reported a mean accelerometer cpm of 694 in the 9-10 year olds [266]

much higher than in the present study. Given that the sample studied in Basterfield et al. [232] study characterised by low levels of physical activity and in McLure et al. [266] study conducted in highly obesogenic environment, the observation that levels of physical activity in Malaysian children of similar age was much lower gives cause for concern.

5.5 Conclusions

The present study supports the view that obese children in Malaysia have very low MVPA levels and very high levels of sedentary behaviour. The study also suggests that obese children are not strikingly more sedentary or much less physically active than healthy children though, but that levels of physical activity and sedentary behaviour are slightly more favourable in the healthy weight than in the obese.

CHAPTER SIX

Overall Discussion and Conclusions

6.1 Introduction

As described in Chapter One, there are now many studies on the treatment of childhood obesity but mostly from the western world. The original purpose of the MASCOT research project was to test a group family-based treatment, which incorporated good practice as outlined in evidence-based systematic reviews and treatment guidelines, compared to a no treatment control in Malaysia. The present research project was the first RCT on the treatment of childhood obesity in the Malaysian population.

In addition to the MASCOT RCT, the thesis included two studies that examined the physical activity and sedentary behaviour and quality of life of obese children compared to pair-matched controls of healthy weight children. These two additional studies were of benefit in complementing the results from the main MASCOT study. It was not clear without examining the objectively measured physical activity and sedentary behaviour and quality of life of obese children whether or not these variables would be better or worse in obese Malaysian children than in obese western children. In addition, differences between obese and healthy weight children for variables such as physical activity and quality of life might be larger or smaller in Malaysia than in other cultures. The data which emerged from these two additional studies on obese and non-obese children in Malaysia should help to build up a body of evidence and point to future areas of possible research in childhood obesity treatment.

This final chapter reiterates the main findings of this thesis study and further outlines a number of issues regarding the MASCOT programme that are pertinent to be expanded. A difference in treatment outcomes between other childhood obesity treatment studies is also discussed in detail in this chapter. Study strengths and weaknesses then are identified and discussed. Finally, those weaknesses which would be improved by suggesting a few changes in the MASCOT programme for future research are outlined at the end of this final chapter.

6.2 Reiteration of key findings of MASCOT

The key findings of the PhD were I) no significant between-group difference observed for the primary outcome of BMI z-score at the six month time point II) weight change data in favour of the intervention group III) secondary outcomes quality of life and physical activity were improved at 6 months and IV) significant differences in physical activity levels and quality of life between obese children and healthy weight children from the two additional studies.

Non-significant between group difference observed for the primary outcome of change in BMI z-score at the six month time point

There was no group difference for BMI z-score at the six month time point, indicating that the family-based behavioural intervention did not improve the management of obesity in 7-11 year old children and the possible reasons for this were presented in Section 6.6.

According to Reinehr and Andler [242], a reduction of at least 0.5 BMI z-score is required before the change has clinical significance. In the intervention group,

only eight of the 34 obese children (24%) achieved a 0.5 reduction in BMI z-score. The modest change of BMI z-score observed in the MASCOT study perhaps suggest that interventions should be longer term and more intense and this is discussed below in Section 6.3.

Weight maintenance in favour of the intervention group

It has been suggested by guideline recommendations and clinical practice that the aim of intervention in childhood obesity treatment is weight maintenance [145, 206]. Although the present study did not show any significant difference between the treatment group and no treatment group in terms of changes in BMI z-score, 27% (9 out of 34) of those in the intervention group maintained or lost weight from baseline to six months but none (0%, 0 out of 45) of the participants in the control group had maintained or lost weight, indicating that children in the intervention group probably responded better than children in the control group with regards to this outcome. It is, however, questionable whether the weight change is a better indicator or not of success in the intervention programme. According to Summerbell et al. [180] the use of weight change as a primary indicator of effectiveness in child weight management programmes may be inappropriate.

Secondary outcomes of quality of life and habitual physical activity and sedentary behaviour improved at 6 months

A recent systematic review [3] suggested that future trials of obesity treatment should report potential for harm of interventions and three aspects were identified for exploration: linear growth, psychological well-being and eating disorders. The first two have been examined and discussed in Chapter Three.

With regards to psychological well-being, the total score for children's quality of life from the parents' perspective in intervention group improved significantly at the end of the MASCOT programme at 6 months (Chapter Three). From the children's perspective, the total score and the psychosocial functioning domain of quality of life improved significantly at the end of the programme in the intervention group. However, there was no significant difference in these variables between groups. Overall, the present study shows no adverse effect on psychological well-being of the MASCOT intervention.

Although there were no significant differences in habitual physical activity and sedentary behaviour between treatment and no treatment groups at 6 months, time spent in moderate vigorous physical activity in the treatment group increased significantly over time, though the increase was very small.

Significant differences in physical activity levels and quality of life between obese children and healthy weight children

The study in Chapter Four found significant impairment in all HRQoL dimensions in the obese children compared to healthy weight children. As presented in Chapter Four, the impairment of quality of life associated with obesity in Malaysians children is evident from child-reports, not from adult-reports.

In Chapter Five it was shown that obese children were significantly less physically active compared to healthy weight children, but the amount of time spent in MVPA in both groups was well below recommended amounts.

6.3 The MASCOT programme

There are two main issues regarding the MASCOT treatment programme that are pertinent to be expanded on in this final chapter and these are discussed below. : 1) the length and intensity of treatment and 2) the use of parents as agent of change

At the time of the MASCOT treatment's conception (2007/2008), the treatment was considered low-moderate intensity in comparison to the some recent US treatment programmes such as the Bright Bodies programme [205]. The present study was intended to be of similar low-moderate intensity to recent UK treatment programmes such as SCOTT [187] that had been used in the process of developing the MASCOT intervention programme (see Chapter Two). In the low-moderate intensity treatment provided by SCOTT, scheduled patient contact time was 5-6 hours and individual families attended an office based dietitian for nutrition and behaviour modification sessions over 6 months. At the end of the 6 month intervention, those undertaking the intervention had a median increase in weight of 3.2 kg [187]. Even the high intensity Bright Bodies intervention also achieved fairly modest changes in weight after 12 months of intervention with a scheduled total patient contact time of approximately 110 hours: those undertaking the intervention had a mean increase in weight of 0.3kg [205].

Since the MASCOT study was the first childhood obesity treatment programme to be tested in Malaysia, and since resources for obesity treatment are likely to be limited in future in this healthcare system, the MASCOT treatment was designed to be a low-moderate intensity intervention. It was to be undertaken by an

integrated multi-disciplinary team that involved a dietitian, psychologist and physiologist with scheduled patient contact time of 8-9 hours (additional 3 hours compared to the time spent with families in the SCOTT study) as this was seen as the most cost effective way to deliver such a programme within Malaysian healthcare system constraints. Although the present study showed slightly lower mean increases in weight after the end of 6 months treatment (1.7kg) compared to the SCOTT study (3.2kg), the programme was not sufficient to produce decreases in BMI z-score in the magnitude of -0.25 or more. As the study was sufficiently powered for a -0.25 decrease in BMI z-score (see Chapter Two, Section 2.9.1) this would imply that programmes successful in significantly reducing BMI z-scores probably require being more intensive than the MASCOT programme. A few intervention treatment programmes that offer higher-intensity and longer-tem have intervention reported promising results in change in BMI-z score in overweight and obese children (see Section 6.4.2).

In contrast, Reinehr et al. [279] reported that the lifestyle intervention "Obeldicks light" that are less intensive (6-months programme) were more effective than "Obeldicks" (1-year-programme) for obese children and adolescents [280]. However, it should be noted that the "Obeldicks Light" study was conducted in overweight children but the "Obeldicks" study was conducted in obese children. According to Schaefer et al. [280], the intervention is likely to be more effective in overweight but not obese, showing that in this case, the intensity of the programme might not explain differences in treatment outcomes.

Recent systematic reviews [3] and guidelines [144, 145] suggested that interventions to treat childhood obesity should involve the family. To date, state-of-the-art of childhood obesity programmes that are family based usually involve both the obese child and at least one parent. However, the child's degree of involvement, together or separately with parents and their children, varied between previous treatment trials. Some studies indicate that when parents and children are targeted for behaviour change with information given in separate group condition [211, 281], outcomes usually improve compared to child alone condition [282, 283]; but others have not reported this finding.[189, 190] It has been suggested by Israel [284] that children are less inhibited, better controlled and participate more actively in treatment when they were treated separately from their parents. Anecdotally, the dietitian in the present study reported that the parents were more open to discuss about their children's behaviour in the programme if the children were not in the same group with them.

At the start of the MASCOT project, the common practice in the literature was individual treatment with the children and the parent (usually the mother) serving as a helper. However, the work of Golan et al. [190] showed that targeting the parents as the exclusive agents of change might be superior to the approach using children as agent of change. For the MASCOT project purposes, the Golan conceptual model on familial approach to treatment of childhood obesity was used, with parents as the sole agent of change [189]. The dietitian and psychologist who were involved in the MASCOT treatment both felt the Golan model was very helpful and useful for them to apply in the treatment programme. Although there were no qualitative study interviews in the present

study, to obtain the views of children or parents taking part in MASCOT, a questionnaire given to parents after end of the treatment programme suggested that parents felt more confident to change their children's eating and physical activity behaviour and they would have been likely to engage in further treatment episodes if these had been available. One parent suggested that the programme should have used joint sessions with parents and children together. This particular parent felt that, children would listen more seriously to a health professional's advice rather than to the same advice when given by parents, and this parent also felt that some of the questions raised by children could not be answered by the parents but would have been answered easily by the health professionals. This suggestion might be useful for future research on childhood obesity treatment in Malaysia, and it might be helpful to have parent-targeted versus family targeted treatment arms in future trials. Although the Golan et al. [190] study showed the benefit of targeting only parents for the management of childhood obesity, cultural differences may give different results in different studies.

6.4 Comparisons with highly relevant other work

6.4.1 Hughes et al.[187]

The SCOTT project had a major influence on the MASCOT treatment protocol, namely in the use of the traffic light diet plan, the use of behavioural change techniques, involvement of the family, targeting of sedentary behaviour as well as physical activity levels, the intention to use a low or modest intensity intervention, The present study was also similar to the SCOTT study in the inclusion of secondary outcomes such as physical activity, sedentary behaviour, and quality of life. It therefore seems appropriate to compare the results of the

MASCOT intervention with Hughes work on SCOTT in some detail. In summary, the SCOTT studies carried out by Hughes reported similar outcomes to the MASCOT project.

The SCOTT study used a family-centred approach with participants randomised to either behavioural programme group, a family-centred counselling and behavioural strategies to modify diet, physical activity and sedentary behaviour or a 6-month standard care group: 134 participants were recruited in two study centres in Scotland, UK. The children were aged 5-11 years old, classified as "overweight" (BMI $\geq 98^{th}$ centile relative to UK 1990 reference data). The primary outcome measure was BMI z-score, measurements were taken from baseline to six and 12 months. Objectively measured physical activity and sedentary behaviour and quality of life were also measured as secondary outcomes.

The SCOTT programme consisted of 8 appointments (7 outpatient visits and 1 home visit) during 26 weeks with a total patient contact time of ~5 hours. The programme used various behavioural change techniques: exploring motivation to make changes, exploring pros and cons of change, identifying barriers to change, problem-solving barriers, goal-setting, rewards, self-monitoring, social support and preventing relapse. The standard care group had minimal contact (~1.5 hours as dietetic outpatients) over the 6 months.

The intervention group in SCOTT had no significant effect relative to standard care on BMI z-score from baseline to 6 months but both groups had significantly decreased BMI z-score from baseline to 6 and 12 months. For participants who complied with treatment in the intervention group, the weight increase was

significantly smaller than that of control group from baseline to 6 months. There were also significant between group differences in changes in total physical activity, percentage of time spent in sedentary behaviour and light-intensity physical activity in favour of the intervention group in SCOTT. For the intervention group, the median percentage of day time spent in sedentary behaviour decreased from 81.8 at baseline to 81.2 at 6 months, however, in the standard care group, the median percentage of day time in sedentary behaviour was increased from 80.7 at baseline to 84.4 at 6 months. Although parent-reported QoL scores significantly improved from baseline to 6 months in both groups, there were no significant between-group differences for changes in QoL scores for the child self-report or parent proxy report from baseline to 6 months.

In the SCOTT project, one to one time spent with a single health professional was used although family lifestyle changes were constantly emphasised and one parent was required to attend all sessions the intervention was targeted at the obese child. This compares to the 8 hours of group sessions with multi-disciplinary health professionals in the MASCOT project. The MASCOT intervention had no timetabled individual time, but during sessions parents were able to discuss and support each other in the group as well as exchange the ideas and opinions with the dietitian and psychologist. Having a one to one option (ie 1 dietitian and saw 1 family) in one of the sessions in the programme could have helped families ask something privately and this may have helped in making the child's behaviour changes.

There was generally quite a similar compliance with the intervention in both the SCOTT project and MASCOT project, with 71% and 65% completing the treatment

phase, respectively (defined as participants who attended at least 75% of scheduled sessions/appointments). Participants in both projects received funding of their travel expenses that probably helped with retention to treatment programmes.

6.4.2 Obesity treatment study with long-term intervention or long-term outcome measures

Assessment of long term outcome measures (at least one year; preferably longer) is important in order to assess sustainability of the programme outcomes. Much of the current evidence is based on findings from short term studies with outcomes of less than 12 months, including MASCOT. However, there has been lack of long-term intervention ($\geq$ 1 year) RCTS of childhood obesity treatment reported to date [3]. According to the recent systematic review, only two studies lasted more than 1 year for weight management programme aged below 12 years.

There is a recent German study, the 'Obeldicks', looking at the effects of lifestyle intervention reported promising results after 1 year of intervention [285]. Details of the study are discussed below.

Reinehr et al. [285]

The study recruited 663 obese children and adolescents aged 4 to 16 years from 4 different outpatient centres in Germany during the years 1999-2006. The 1-year 'Obeldicks' treatment programme was based on physical exercise, nutrition education, and behaviour therapy and the programme was divided into 3 phases. During the first 3 months (first phase-intensive phase), the participants took part

in a nutritional and eating behavioural course for 1.5 hours in each 6 group sessions followed by monthly sessions (30 mins/month) in the establishing phase (second phase) for 6 months. During this phase, the participants were provided with systematic and solution-focused theories followed by 3 months of further individual care in the last phase. The participants also took exercise therapy once a week throughout the entire 1 year. The primary outcome measurement was change in BMI SD score measured at baseline, 1 year, 2 years, 3 years, 4 years and 5 years of follow-up.

At 12 months, the mean BMI SD score had reduced significantly from 2.46 at baseline to 2.10 with mean reduction 0.36 (95% CI: 0.33, 0.39) and 0.46 (95%CI: 036, 0.55) at 4 years after the intervention. The study also reported that the youngest children (<8 years at the onset of intervention) had significantly highest decrease in BMI SD score over 5 years than the oldest children (>13 years) ($p<0.05$), suggesting the possible benefit of an early intervention in childhood obesity treatment.

The 'Obeldicks' treatment programme involved more than one health professional in the programme targeted at changes in diet, physical activity and sedentary behaviour, as well as all involving some elements of behavioural change techniques similar to SCOTT study. However, one possible explanation as to why Reinehr's intervention was apparently more successful than the MASCOT intervention is that the treatment was more intense and longer term than in the MASCOT intervention.

Results from Reinehr's study demonstrates the importance of a treatment programme that offers high-intensity and longer-tem intervention involving highly motivated obese children or families if larger changes in BMI-z score are to be achieved. With more intense and longer-term interventions, better outcomes can probably be achieved and the results might be more marked and last longer than those observed in the MASCOT study.

6.4.3 Study with no treatment as control group

It is also noteworthy that the MASCOT study used a no treatment control group. It was not possible to have a treated control group in Malaysia and not practical within the resource limitations of PhD (discussed further in Section 6.7). Some previous childhood obesity treatment trials have involved comparison of intervention with a treated control group, [187] others with a no treatment control. A study conducted by Wake et al. [286] has shown a similar result with MASCOT study when a control group for the treatment did not receive any treatment.

The LEAP study by Wake et al. [286] compared an intervention over 12 weeks targeting change in diet, physical activity and sedentary behaviour with a control group who received no intervention. 258 children aged 5 years, classified as overweight or obese (using IOTF cut off points) but with a BMI SD score of < 3 SD took part in GP surgeries across Melbourne, Australia. The primary outcome measure was BMI and measurements were reported at 6 and 12 months after randomisation. Objectively measured physical activity and sedentary behaviour, nutrition score and quality of life were also reported as secondary outcomes. At 6 months the mean BMI had changed for the intervention group from 20.2 (2.3)

at baseline to 20.5 (2.6) as well as for the control group from 20.3 (0.9) to 20.6 (2.2). There was no significant difference for the BMI between the two groups at 6-months measurement point (−0.12; 95% CI −0.40 to 0.15, P=0.4). This was broadly similar to the MASCOT project in which there was no significant difference for the BMI change between the intervention and no-intervention (control) groups at 6 month (-0.06; 95% CI −0.16 to 0.04, P=0.2).

6.5 Main strengths of the present study

The MASCOT study set out to be a well conducted RCT with a robust study protocol that followed the CONSORT guidelines. Randomised controlled trials are considered the "gold standard" for treatment and intervention studies. This study's randomisation was carried out remotely using a computer-generated sequence by a statistician who knew only the study code, age and gender and was unaware of any clinical details. In addition, randomisation was stratified by age and gender- reducing the risk of confounding due to these factors. Examination of key characteristics and confounders at baseline found no significant group differences, indicating that the randomisation process was successful. The author who undertook all the outcome measurements were blinded to group allocation and sample size was identified to increase the chances that the trial would be sufficiently powered, using BMI data from the Scottish Childhood Obesity Trial (SCOTT) RCT.

Furthermore, MASCOT was a 'good practice' treatment as it incorporated the evidence-based recommendations that are summarised in Table 6.1. A number of design features hopefully contributed to enhanced generalisability of the study. The use an internationally recognised measure (CDC, 2000) [205] of

childhood obesity and validated tools [44, 276] to measure the outcomes improve the accuracy and relevance of study reporting. Generalisability is further addressed by the intervention being designed to be suitable for inclusion in current treatment service delivery models in Malaysia health system. Indeed, the group delivery method would provide improved service efficiency over the routine practice in Scotland (and reflected in the SCOTT study) of one-to-one individual counselling for weight management [187].

In the health-related quality of life study, a major strength was the use of a valid and reliable instrument for assessment of HRQoL that is valid across different cultures [33, 36, 39, 40, 287] and so which allows a cross-cultural comparison of the impact of childhood obesity on quality of life by comparing quality of life deficits with obesity in Scotland to those in Malaysia. Similarly in the physical activity study, the method used was objective (accelerometry) and validated and this was the study was the first study to use objective measures of physical activity in children in Malaysia, and one of only a handful to measure physical activity objectively in children from low-middle income countries

Table 6.1 Summary of key features of obesity treatment recommended by good practice recommendation (SIGN 2010, NICE, 2006)

Treatment recommendation	Reported in thesis
Treatment should only be directed to motivated parents and those willing to make lifestyle change	Section 2.5.3.1
Treatment should be family-based, involving at least one parent	Section 2.5.3.1
Treatment should be combined decreasing overall dietary energy intake, increasing physical activity and decreasing sedentary behaviour	Section 2.5.4.1 & section 2.5.4.2
Treatment should use behavioural change techniques as an integral part of treatment programme	Section 2.5.3
Weight maintenance is an acceptable goal of treatment	Section 3.2.9.1

6.6 Main weaknesses of the present study

The present study did not find any statistically significant difference between the intervention and control group at the six month time point for the primary outcome. The absence of a significant effect on the primary outcome is worthy of further research but may be due to 1) limited long-term follow-up 2) limited power 3)limitations of the methodology used 4) lack of training or competence in the dietitian, psychologist and physiologist who delivered the treatment 5) absence of outcome measures which would have been useful and which might have changed even in the absence of major changes in anthropometry, e.g. dietary intake and cardio metabolic risk assessments. These possibilities are outlined in more detail below.

Clinical guidelines [145] and systematic reviews [3] suggest that intervention studies need to be conducted in duration of at least 12 months, including the intervention and follow-up period. Long-term follow-up evidence is necessary to understand the sustainability of any interventions [3,145]. There are an increasing number of childhood obesity treatments RCT which now report outcomes at 12 months after the start of the intervention [3]. However, it was beyond the scope of this thesis to report findings beyond the six month post-intervention end time point. There are a number of explanations for the relatively short term follow up, including practical limitations, such as the particular nature of research project funding arrangements. Funding for the present study was not allowed for MASCOT intervention to be conducted over longer periods, or longer term follow-up, and data collection in Malaysia was to be restricted to a one year period to comply with University of Glasgow degree

regulations. Undoubtedly, the evaluation component of the research in longer term is important but cost can be substantial. For example, the cost for the SCOTT project was £192,677 (not including the qualitative study in SCOTT) compared to only £6010 for the MASCOT project. Although this cost comparison makes the SCOTT project 32 times more expensive than the MASCOT project, it should be noted that there are similarities in BMI z-score changes, physical activity level changes and quality of life changes [187].

Despite achieving the calculated sample size, it is possible that the present study was underpowered to show statistically significant differences between groups. As described in 2.9.1, the sample size calculation was based on a reduction in BMI z-score of 0.25 from baseline to the six month time point for the intervention group and was powered using BMI data from the Scottish Childhood Obesity Trial (SCOTT) RCT [187] since the methods that were used in the present study were similar to the SCOTT study. The present study was testing the efficacy of the intervention- that is the effect of the intervention in an ideal setting. For example, subjects were purposefully provided with regular reminders to attend session. However, given that the intervention was occurring in an obesogenic environment and families may have identified more barriers than facilitators to the achievement of programme goals, the full potential of the intervention may not have been realised. This may be a possible reason for lack of statistical significance by group in the present study.

A limitation of methodology was another weakness in the present study. It is possible that in the novel treatment employed in the present study, there were too many concepts and strategies implemented in the MASCOT group thus the protocol was not adequately followed as described. There were a variety of behavioural change techniques were employed as well as the use of the traffic light diet scheme in the present study. All of these techniques and approaches were new, particularly in Malaysia. There is a possibility that lack of experience in the use of behaviour change techniques, and /or lack of skills might have affected the MASCOT treatment intervention.

It was very important for those delivering the MASCOT intervention that they followed the treatment programme schedule and used the behavioural change techniques consistently. In order to ensure the dietitian was well-prepared to manage the programme, skills training in the behavioural change techniques was conducted. This training was done in the present study but with limited time and resources. Acquiring expertise in behavioural change techniques and parenting skills may also provide the dietitian with a useful age-appropriate child behaviour modification approach to address family-lifestyle and weight-related behaviour [288].

A number of measurements such as body fat makers, arm to waist ratio and skinfold thicknesses were not used as outcome measurements in this study. Initially, the original intention of the present study was to carry out some of these measurements as an attempt to give an indication in changes in estimated body fat or body fat

distribution in addition to BMI z-score which is a proxy for body fat. At the time of starting the study, the equipment that available to be used to estimate the total body fat mass was Tanita Body Fat analyser model TBF 300. Unfortunately, no validated equation to estimate body fat in children using the Tanita machine was available. Although the use of arm to waist ratio is not expensive, it is difficult to replicate the findings as the measurement is not widely used. Although skinfold thickness are usually more accurate than BMI at predicting body fat [289], the measurement is not recommended for clinical use [290, 291]. Furthermore, there is a large number of skinfold prediction equations available that require the selection of the most appropriate, based on its validity within the population under study and the validity of any of the equations to Malaysian children was unclear [291]. Thus, it is difficult to assess body fat of children in clinical and community settings, and time consuming. As a result of the doubts of the Tanita estimates of fat mass the arm to waist ratio and the skinfold thicknesses, these measurements were not included in the present study. However, these assessments may give a fuller picture of the possible overall health benefits of treatment [297]. Total body fat can be successfully measured using DEXA scan and other techniques which are laboratory based that would enhance the result from the present study but this was not feasible given resource and funding constraints.

Moreover, measurement of changes in the child and family dietary intakes were not undertaken in the present study. The lack of information on dietary changes has been a criticism made in a recent systematic review of dietetic interventions in childhood

obesity treatment [292]. The lack of attention to measurement of dietary data is likely due to the challenges of measuring dietary intake, particularly in children and adolescents [293]. There are number of issues relating to dietary assessment, mainly the problem of "under reporting". A completed Food Standards Agency (FSA) funded study reported that there is a change in eating behaviour when individuals are asked to record their intake (observation effect) and that individuals may misreport their changed eating behaviour (reporting effect) that may lead to the problems of "under reporting" [294]. In fact, the misreporting effect was more marked when the measurements were carried out in the individual's own homes compared to a controlled laboratory so dietary intake measurements are difficult to interpret [294]. A recent systematic review identified deficiencies in the quality of dietary intake methods reporting in child obesity studies [295]. The review reported that only 3 out of 31 selected studies were rated as 'excellent' in the quality of dietary intake methods reporting and 15 studies were rated as 'poor'. To overcome the issues, Burrows et al. recommended the use of dietary intake methods reporting checklist that may help other researchers to replicate study methodology and can evaluate the quality of dietary intake results [295]. Inclusion of such information may provide interesting data on changes in dietary habits during the intervention.

6.7 Challenges of research in the MASCOT study

Conducting research with humans in a free-living environment has many recognised challenges. There were four main specific challenges to child weight management

experienced by the author subject recruitment, subject retention; allocation of adequate funding; time constraints. All these challenges are discussed in brief below.

The recruitment of families into child weight management interventions is often difficult [296] and was a challenge experienced by the author. Recruitment of the 107 families (29.3% from 365 eligible for the study) took four months starting July 2008 until November 2008. The sample consisted of volunteers from the community, and recruitment relied on parental identification of obesity in the child. It is likely that poor parental perception of and concern regarding childhood obesity reported elsewhere [297-299] were present in the target populations and contributed to the low levels of enquiry regarding the study. In addition, the effectiveness of school as a recruitment channel was overestimated. Most of the schools just gave permission to the author to recruit the school children but refused to give any cooperation to encourage the families to join the programme and saw the problem of childhood obesity was beyond the school's control. A reluctance of school management to raise the sensitive issue of childhood weight with parents is a likely reason for poor identification and referral to the MASCOT study.

In recognition of the poor retention rates experienced by previous child weight management interventions, a number of strategies were implemented in the MASCOT study to minimise attrition. These included the provision of RM10 (approximately £2) at measurement sessions to reimburse petrol and other travel costs and the availability of reduced assessment options for families who were reluctant to attend

full measurement sessions ie. self-report packs provided with a self-addressed, stamped envelope or home visits. These strategies resulted in a 35% attrition rate at 6 months, less than the upper limit of 42% reported elsewhere [3]. The challenges of subject retention must be recognised and accepted by researchers so that strategies to minimise attrition are included in the logistical and financial planning of child weight management trials.

Another challenge of research in the MASCOT study was inadequate research funding and time constraints. Adequate funding is required to ensure that the important outcomes are evaluated over an adequate time frame in order to determine long-term efficacy. Such a time frame was beyond the scope of the present study and this would be true of most PhD research periods which are typically three years in duration. Budget restraints may result in limited evaluation of interventions given the expense associated with the inclusion of additional outcomes, particularly those concerned with qualitative evaluation. Therefore, funding bodies need to provide more resources if a broad range of study outcomes are to be included, over a longer period, including qualitative aspects of the study.

6.8 Suggested changes to MASCOT studies for future research

It was a learning experience for those involved in the MASCOT project as it was the first childhood obesity treatment study conducted in Malaysia. There are a number of aspects that could have been carried out differently and these are discussed in brief below.

6.8.1 The pilot study

Piloting of an intervention is needed prior to proceeding to a definitive RCT. An 'exploratory trial' or pilot (feasibility) RCT is indicated by the UK MRC framework [300]. However, the pilot study for MASCOT was conducted as a short version of the MASCOT treatment protocol and ran for one month only with 5 families due to overall time constraints and lack of project funding. This proceeded with the intervention team and the author. It would have been more satisfactory if the pilot study had involved the full MASCOT treatment with 8 sessions and had involved more families. The pilot study was intended to identify changes that could be made to this family-based programme, to make it more acceptable to families and/or to make it more effective, in accordance with the MRC framework [300]. The MASCOT treatment programme was developed based on other previous interventions though, especially SCOTT [187] and Bright Bodies [206] and so to some extent the piloting had been done by other authors, though not in a Malaysian context and not by the study team involved in MASCOT.

6.8.2 Training for health professionals

A number of commentators described that the possibility of errors in study outcomes using behavioural change techniques is being due to insufficient training and skills of the interviewers [301]. Therefore, skilful health professionals are essential for the optimum delivery of the MASCOT treatment programme. To further this, all health professionals involved in the future need to have adequate training and possibly greater experience in the use of behaviour change techniques.

6.8.3 Structure of the MASCOT protocol

There are a number of points in the structure of the MASCOT treatment programme that could have been changed to improve the programme. As described in Chapter Two, the treatment sessions were directed at parents only and the children participated in a physical activity class. However, Golan and Crow [188] indicated that treating the parent alone leads to better outcomes for the children's BMI than treating both the parent(s) and child. The author's conclusion may have not have been ideal for the Malaysian setting and there is a possibility of cultural differences that may influence the efficacy of the programme. Therefore, it is beneficial to have some joint sessions that would meet parents' desires for some sessions with children and parents together in one group, although keeping the majority of the sessions as separate groups.

The cooking session in MASCOT was an interesting session and from the dietitians' point of view it was extremely enjoyable to see the family cooking together and applying what they learned in the class. This session was the only joint session in the MASCOT treatment programme. Cooking together was educational for the child and parent, allowing them to discuss and prepare a meal in a healthy way. In addition to cooking session, a visit to a supermarket could allow the children and parents to have the same discussion with the additional opportunity of good discussing on green, amber and red foods and food labels before the they purchase the food for cooking class session.

Due to the funding limitations, Glasgow University regulations on the time spent outside of Glasgow during a PhD (maximum 12 months), and time constraints, the MASCOT project was only able to take outcome measurements up to 6 months from baseline. However as childhood obesity is a chronic condition, follow up and monitoring is important to help and support children and families in keeping them to lifestyle changes, and as noted above some studies with long term follow up have suggested that benefits of treatment can be maintained well beyond the end of a treatment programme. On-going brief weighing sessions that include encouragement to continue with lifestyle changes may also enhance any programme and could be carried out by the school or even by telephone.

6.8.4 Qualitative study

Quantitative methods alone will not help answer the questions that influence the behaviours of individuals. It would have been of great value to this MASCOT project if qualitative research had been also conducted. The combination of quantitative methods and qualitative methods would provide more evidence for the effectiveness of behavioural interventions. Inclusion of qualitative research methods within interventions was another research recommendation made by the Cochrane review of interventions for treating obesity in children [3] and is recommended as part of health interventions by the UK MRC [300]. The qualitative study allows an insight into the lived experience of study participants – an aspect that is crucial when examining a condition as deeply contextual as the family management of childhood overweight, in

accordance with the MRC framework [300]. Following the MRC Framework may be helpful in future obesity treatment interventions.

It would have been valuable for the researchers to get the parent's views and feedback from the programme beyond just the simple questionnaire which were used. It would have been very useful in helping to tease out how the MASCOT treatment was considered by the parents and children.

6.8.5 Outcome measurements

No body fat measurement was carried out in the present study that was discussed in Section 6.6. Although BMI z-score is a proxy for body fat, it is not a measure of body fatness. Waist circumference measurement is a useful tool in children and adolescents for measuring fat distribution and particularly for identifying central fatness [302, 303] but it is possible that it may not add to the information obtained from BMI in children [304, 305].

6.9 Possible future research

The results described in this thesis have indicated several areas of possible future research. Although the MASCOT treatment programme has started from the points of view of what the health professional and 'experts' consider to be the most relevant for successful treatment programme, the present treatment programmes do not appear to be meeting the needs and requirements of obese children and their parents.

The development of obesity in childhood involves interactions among multiple factors that are personal (dietary and physical activity patterns, taste and physical activity preferences), environmental (home, school, and community), societal (food advertising, social network, and peer influences), healthcare-related (access and provider counselling) and physiological (intrauterine and early life "programming," appetite and satiety mechanisms, and genetic predisposition) [306]. Therefore, a well- conducted needs assessment prior to developing an intervention that collects information and community input on the needs that relate to obesity in children and which factors that may contribute to the obesity problem seems pertinent in order to design improved obesity treatment in future.

Furthermore, studies have shown that frequency of attendance to sessions is related to successful weight management [307], thus maximising attendance to each sessions of treatment is desirable and designing interventions with a variety of delivery modes that better "fit" participants may be one way to achieve this. As discussed in Section 3.3.1, one the main reasons given by parents for declining to enrol in the MASCOT study was lack of interest and time and it is common barrier for parental attendance at sessions [308]. Taking into account of this problem, future research needs to be aware of the perceived barriers of behaviour change in order to enhance the programme attendance as well as the efficacy of the treatment programme. To further this, screening questionnaires issued to participants prior to enrolment could enhance recognition of potential barriers to change the motivation of the individual to engage in behaviour change. Since the study is a parent-led, family-based

treatment, the questionnaires should be targeted at parents as it would help to ensure the attendance for both parents and the children to session is successful. One childhood obesity treatment study was carried out in the UK which employed such a strategy, which required parents to complete a questionnaire to assess their motivational level in order to be admitted to their treatment programme [286]. This strategy could assist with the identification of subjects most likely to engage and consequently succeed in the programme, ultimately improving its overall efficacy. The result from this screening tool could identify the suitability of a treatment programme for potential subjects, opportunities for tailoring of the programme to suit individual participant needs or the usefulness of pre-intervention motivational strategies to progress individuals to a stage of action. Such a strategy could help to identify factors beyond the health sector that influence lifestyle. These are considerations which are largely unanswered by the literature [179] and also present major design and funding challenges if conducted in an RCT.

Although the MASCOT project targeted parents as the primary agents of change, the study did not produce substantial changes in the primary outcome. It is probably because there is a lack of supportive environment that is essential to support healthy lifestyle initiatives that may be occurring in the home or school. It has been shown that a supportive environment for healthful behaviours is a requisite component of individual action [309]. As children spend more time at school compared at home during weekdays, it is essential to create a supportive school environment to ensure that the canteen supply a healthy food and also the management of the schools have

to mandate inclusion of physical activity in the curriculum to support healthy lifestyle choices driven by parents at home.

Another key issue in the present study is time barriers and this is likely to be the most important barrier to overcome when supporting parents to create healthful family environment [310]. The time limitations created by our modern, nuclear family environment is experienced by author and parents alike, however up to now there is no research available to support this phenomenon in order to provide impetus for societal change around this dynamic. The government needs to be aware the need for environmental change in order to support healthy lifestyle choices by creating a *social policy* approach to healthy lifestyles rather than the current *health policy* approach [311]. Although this approach is not an easy approach, but certainly addressing this obstacle is an essential task for the research field over the coming decade.

6.10 Conclusions

The 6-months findings of the MASCOT RCT in this thesis indicates that obese children in a family behavioural weight management programme have no significant difference in BMI z-scores at 6 months when compared with obese children who did not receive any treatment. However, changes in body weight, physical activity levels and quality of life favoured the intervention group at 6 months. The MASCOT project was the first treatment of childhood obesity to be conducted and reported in Malaysia, and outside the UK, US, Europe and Australia. Thus, the MASCOT study helps add to the evidence base on childhood obesity treatment by providing evidence from Malaysia. The

MASCOT treatment programme is a novel childhood obesity intervention in Malaysia which has the potential to make a difference to help families with children who are obese, impacting on obesity and other health outcomes. The programme seems to have modest benefits for treatment of obese children which at least last in the short term (up to six months), similar to other childhood obesity treatment interventions in the UK [187]. This programme warrants further follow-up sessions that may improve the programme's efficacy on childhood obesity treatment, and further research on how to improve outcomes of childhood obesity treatment.

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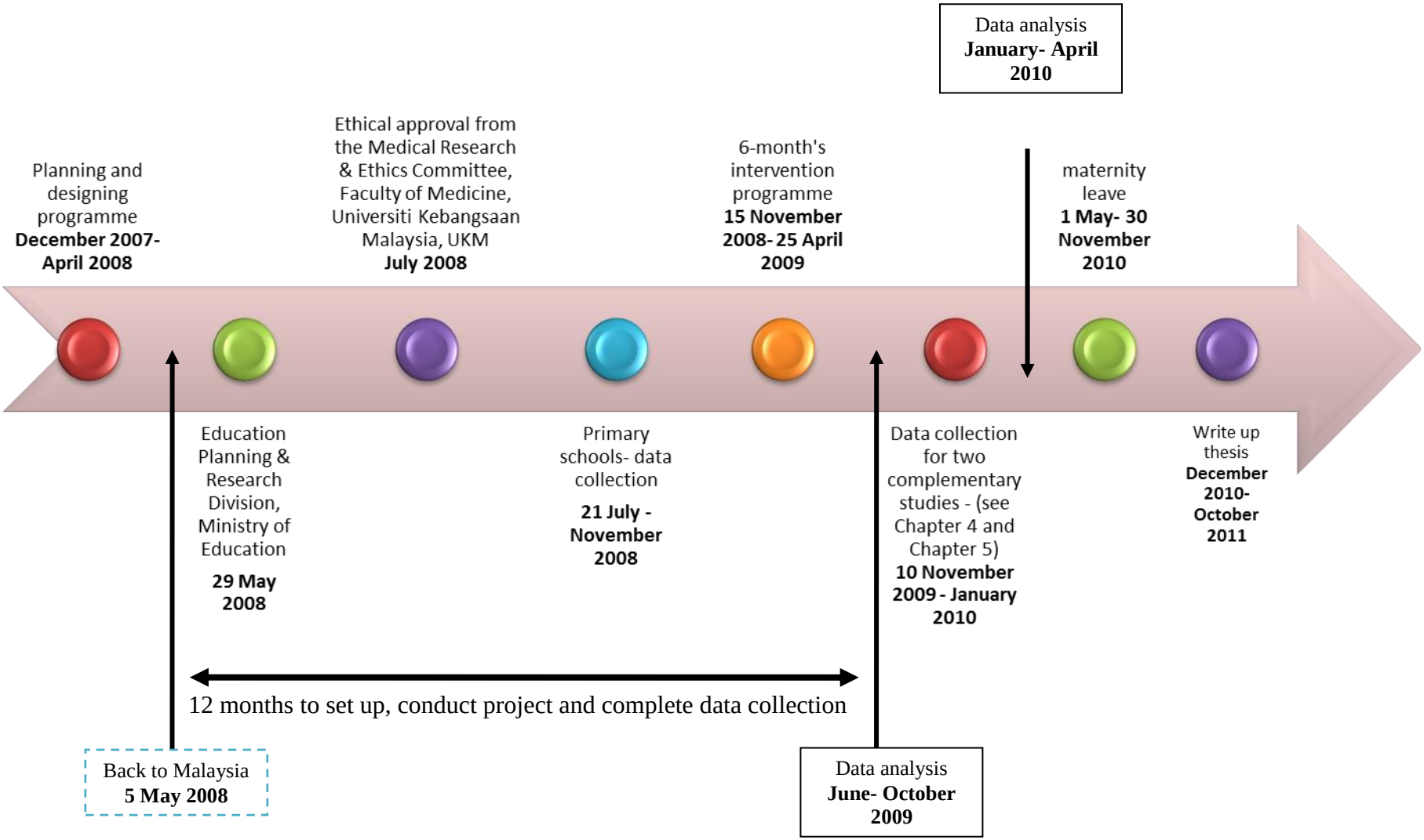
8.0 List of appendices

APPENDIX ONE



INFORMATION FOR PARENTS

CONFIDENTIAL

INFORMATION SHEET

Trial for evaluating childhood obesity treatments
You are being invited to take part in a research study. Before you decide whether you would like to take part, it is important for you to understand why the research is being done and what will involve. Please take time to read this information sheet carefully and discuss it with others if you wish. If there is anything that is not clear, or if you like to know more information, please do not hesitate to contact Miss Wafa on the telephone number at the end.

The aim of the study
The aim of this study is to investigate a new treatment for childhood obesity. The treatment is a family-based group program which has been developed in America and United Kingdom. Up until now, it has not been available for families in Malaysia.

Why is the study being done?
There are very few services available for obese children and their families in this country. We would like to find out if this new program is helpful to children and families in Malaysia.

What will happen if we take part?
The treatment is being tested as part of a large research trial. If you are agreeing to be referred to this trial, you will be sent an initial appointment to come and meet us. At this appointment, we will ask you and your child to fill in some questionnaires and have some measurements taken (weight, height and waist circumference). We will repeat all of these measures at the final session (6 months after the first appointment) and 12 months later. Taking part in the trial will not mean extra tests or procedures above those done as usual clinical care, but we would like to use the information from them for our study. During the treatment, your child will be weighed regularly.

Sometimes, because we do not always know whether this treatment is the best way of treating patient, we need to make comparisons. After our initial meeting, provided the study is considered to be suitable for your child, you will be either being offered the treatment, or not received the treatment. The option that you are offered will be chosen by a computer which has no information about individual families- i.e., it will be selected by chance. This means that we can compare the effectiveness of the group program to what happens without treatment for the same period of time. This will help us to know exactly how effective the group treatment program is.
The program is outlined in more detail below. It will be run by a dietitian who has experience working with children and families.

Family-based behavioral treatment
Treatment is a group program; your child would be part a group with other children attending an exercise class, while you would meet with other parents. The aim of the parent's group is to teach you how to make a healthy food choices, increase physical activity and decrease sedentary behaviors. You and your child would need to come to group sessions fortnightly to start with, reducing in frequency to monthly sessions over a total of 6 months. The groups will be run after school/on Saturday morning at Physiology Department, Universiti Kebangsaan Malaysia, Chow Kit and each session will last for 1 hour.

What are the potential benefits?
We anticipate that your child will benefit from the treatment. We hope that, following the study, similar treatments will be made widely available on the Ministry of Health of Malaysia so that other children too can benefit

What are the risks and discomfort?
No risk to you or your child can be foreseen.
Do I have to take part in this study?
It is up to you and your child to decide whether or not to take part. If you decide to take part you will be asked to sign a consent form. If you decide, now or at a later stage, that you do not wish to participate in this research project, that is entirely your right. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

If I decide I would like to take part in this study, what is the next step?
Once you decide to take part in this study, you will be sent an appointment to see our dietitian for a few measurements and you will meet the research team.

Who is organizing and funding the study?
The study is being jointly organized by University of Glasgow and Universiti Kebangsaan Malaysia.

Is there any payment if I join the program?
There will be no payment for taking part in this study. However, you will be offered travelling expenses for all journeys from your home to UKM.

Who will access to the research records?
All information which is collected about you and your child during the course of this research will be kept strictly confidential. As a parent only you have the right to know the results of the analysis

Who do I speak to if problems arise?
If you have any complaints about the way in which this research project has been, or is being conducted, please, in the first instance, discuss them with the dietitian whom you are in contact. If the problems are not resolved, or you wish to comment in any other way, please contact the Chairman of the Research Ethics Committee, by phone via 03-91703795/3772/313, and the committee administration will put you in contact with him.

How to contact the researchers:

Prof Madya Dr. Ruzita Abdul Talib,
Department of Nutrition and Dietetics,
Faculty of Allied Health Sciences,
Jalan Raja Muda Abdul Aziz, 503000
Kuala Lumpur.
Tel 019-2756497

Sharifah Wajihah Wafa,
Department of Nutrition and Dietetics,
Faculty of Allied Health Sciences,
Jalan Raja Muda Abdul Aziz, 503000
Kuala Lumpur.
Tel 012-6911510

Should you decide to take part in this research study, you will be given a copy of this information sheet for your records and asked to sign a consent form.

CONSENT FORM FOR A RESEARCH PROJECT

Title of project:
Childhood Obesity Treatment in Malaysia- An exploratory Randomised Controlled Trial (MASCOT)

Consent:
I have read the information of the research project stated above and understand its contents. I have had the nature and purpose of the research project, so far as it affects me and my son/daughter, fully explained to my satisfaction by the information letter and telephone. My consent is freely given. I also understand that while information gained during the research project may be published in the form of a report or a journal article, my personal results will not be identified in any way in those publications. I also have the right to withdraw from the research project at any stage.

I _____
(phone Number :_____) of_____
_____ (address) hereby consent to **take part/do not want to take part** in this research project with my son/daughter _____ (name)

Signature: _____ Date: _____

Witness

Name :
IC :
Signature :
Date :

Dietitian

Name :
IC :
Signature :
Date :

APPENDIX THREE

Code | | | |

UNIVERSITY of GLASGOW

Malaysian Childhood Obesity Treatment

MALAYSIAN CHILDHOOD OBESITY TREATMENT

All information given will be kept strictly private and confidential.

Demographic Profile

Parent's name: _____

Children's name: _____

Address: _____

_____

_____

Phone no. (House): _____

Date of birth: ___/___/____

Working situation:

Father: □ Not working

□ Government sector

□ Private sector

□ Own business

Mother: □ Not working

□ Government sector

□ Private sector

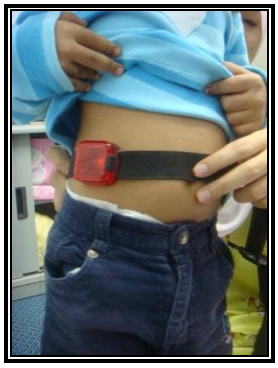
□ Own business

Household size: _____

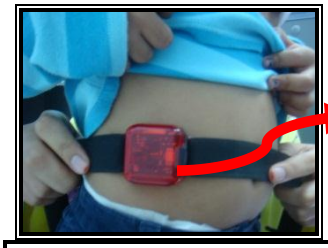
Household income: RM_____

APPENDIX FOUR

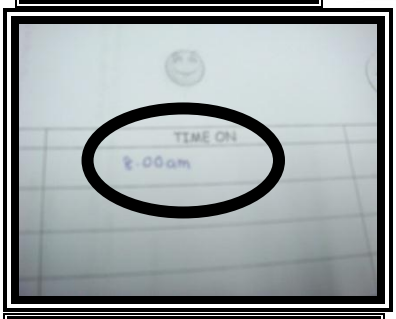
HOW TO WEAR ACCELEROMETER



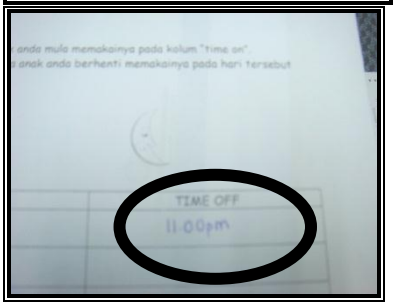
1. Be sure the activity monitor in the right side of your child's waist
2. Activity belt worn under clothing



3. Keep ACTIGRAPH logo at the bottom and not reversed



4. Note the time your child starts to wear a seat belt in the ACTIVITY DIARY in column "ON TIME".
EXAMPLE: 8:00 am



5. Remove the belt and record the activity before bed time your child stop wearing belt on the activity in column "TIME OFF".
EXAMPLE: 11.00pm

ACTIVITY BELT DIARY

Name: _____

School: _____

Wear the belt in the morning and make a note when your child starts to wear on the column "time on". Remove the belt at bedtime and make a note when your child stops wearing it on that column "time off"

HARI	TIME ON	TIME OFF

ID# _____

Date:_____

PedsQL™

Senarai Semak
Kualiti Hidup Pediatrik

Versi 4.0 – Bahasa Melayu

LAPORAN KANAK-KANAK (UMUR 5-7)

Arahan untuk penemuramah:

Saya akan menanyakan beberapa soalan kepada anda tentang perkara yang mungkin menjadi masalah kepada beberapa kanak-kanak. Saya ingin tahu berapa kerap masalah yang mungkin anda alami bagi perkara-perkara berikut.

Berikan templat kepada subjek dan tunjukkan kepada respon ketika anda membacakannya.

Jika ia <u>tidak pernah</u> menjadi masalah bagi anda, tunjukan jari anda pada muka senyum

Jika ia <u>kadangkala</u> menjadi masalah bagi anda, tunjukkan jari anda pada muka biasa

Jika masalah <u>selalu</u> berlaku, tunjukkan jari anda pada muka masam

Saya akan membacakan setiap soalan.Tunjukkan pada gambar-gambar yang menunjukkan berapa kerap masalah ini kepada anda. Mari kita cuba terlebih dahulu

	Tidak pernah	Kadangkala	Selalu
Adakah anda sukar memetik jari	☺	😐	☹

Arahkan subjek cuba memetik jari untuk membuktikan sama ada mereka menjawab soalan dengan betul. Ulang soalan jika subjek memberikan respon berlainan dengan tindakan mereka memetik jari.

Cuba fikirkan bagaimana keadaan anda pada beberapa minggu yang lepas. Sila dengar baik-baik bagi setiap ayat yang dibacakan dan beritahu saya berapa kerap ia menjadi masalah kepada anda

Selepas membaca satu ayat, telunjukkan pada templat. Jika subjek segan atau tidak faham bagaimana menjawab soalan, bacakan pilihan respon ketika tunjuk pada muka-muka.

FUNGSI FIZIKAL *(masalah dengan…)*	**Tidak pernah**	**Kadangkala**	**Selalu**
1. Adakah anda sukar untuk berjalan	0	2	4
2. Adakah anda sukar untuk berlari	0	2	4
3. Adakah anda sukar bersukan atau bersenam	0	2	4
4. Adakah anda sukar mengangkat barang besar	0	2	4
5. Adakah anda sukar mandi sendiri	0	2	4
6. Adakah anda sukar melakukan aktiviti harian (seperti mengemas barang mainan)	0	2	4
7. Adakah anda berasa sakit atau luka (di mana?_____)	0	2	4
8. Pernahkah anda berasa terlalu penat untuk bermain	0	2	4

Ingat, beritahu saya berapa kerap masalah berikut terjadi pada anda beberapa minggu yang lepas.

FUNGSI EMOSI *(masalah dengan…)*	**Tidak pernah**	**Kadangkala**	**Selalu**
1. Adakah anda berasa takut	0	2	4
2. Adakah anda berasa sedih	0	2	4
3. Adakah anda berasa marah	0	2	4
4. Adakah anda sukar untuk tidur	0	2	4
5. Adakah anda risau apa akan terjadi pada diri anda	0	2	4

FUNGSI SOSIAL *(masalah dengan…)*	**Tidak pernah**	**Kadangkala**	**Selalu**
1. Adakah anda sukar bergaul dengan rakan-rakan	0	2	4
2. Pernahkah rakan-rakan lain tidak mahu bermain dengan anda	0	2	4
3. Pernahkah rakan-rakan lain mengejek anda	0	2	4
4. Bolehkah rakan-rakan lain melakukan perkara yang anda tidak boleh lakukan	0	2	4
5. Adakah sukar untuk anda terus bermain apabila bermain dengan rakan-rakan	0	2	4

FUNGSI SEKOLAH *(masalah dengan…)*	**Tidak pernah**	**Kadangkala**	**Selalu**
1. Adakah anda sukar menumpukan perhatian di sekolah	0	2	4
2. Adakah anda pelupa	0	2	4
3. Adakah sukar untuk sentiasa menyiapkan kerja sekolah	0	2	4
4. Adakah anda tidak ke sekolah kerana tidak sihat	0	2	4
5. Adakah anda tidak ke sekolah kerana perlu berjumpa doktor/ke hospital	0	2	4

Berapa kerap masalah ini kepada anda?

Tidak pernah

Kadangkala

Selalu

ID# _____

Date:_____

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LAPORAN IBUBAPA untuk **KANAK-KANAK** (umur **5-7**)

ARAHAN

Mukasurat seterusnya mempunyai senarai perkara-perkara yang mungkin menjadi masalah kepada anak anda. Sila beritahu kami **berapa kerap** masalah bagi setiap perkara-perkara berikut anak anda alami pada **BULAN LEPAS** dengan membulatkan:

0 jika **tidak pernah** bermasalah
1 jika **hampir tidak pernah** bermasalah
2 jika **kadang-kala** bermasalah
3 jika **selalu** bermasalah
4 jika **hampir sentiasa** bermasalah

Tiada jawapan yang betul atau salah.
Jika anda tidak faham soalan, sila minta bantuan.

*Pada **BULAN LEPAS**, berapa kerap anak anda mengalami **masalah** berikut …*

FUNGSI FIZIKAL ***(masalah dengan…)***	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Berjalan lebih dari satu blok bangunan	0	1	2	3	4
2. Berlari	0	1	2	3	4
3. Menyertai aktiviti sukan atau bersenam	0	1	2	3	4
4. Mengangkat sesuatu yang berat	0	1	2	3	4
5. Mandi sendiri	0	1	2	3	4
6. Melakukan aktiviti harian di sekeliling rumah	0	1	2	3	4
7. Mengalami luka atau sakit	0	1	2	3	4
8. Rendah tahap tenaga/cepat letih	0	1	2	3	4

FUNGSI EMOSI ***(masalah dengan…)***	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Berasa takut	0	1	2	3	4
2. Berasa sedih/murung	0	1	2	3	4
3. Berasa marah	0	1	2	3	4
4. Kesukaran untuk tidur	0	1	2	3	4
5. Risau apa akan terjadi kepada mereka	0	1	2	3	4

FUNGSI SOSIAL ***(masalah dengan…)***	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Bergaul dengan kanak-kanak lain	0	1	2	3	4
2. Kanak-kanak lain tidak mahu berkawan dengannya	0	1	2	3	4
3. Diejek oleh rakan-rakan	0	1	2	3	4
4. Tidak boleh melakukan sepertimana kanak-kanak sebaya mereka yang lain mampu lakukan	0	1	2	3	4
5. Sentiasa kekal bermain dengan rakan-rakan lain	0	1	2	3	4

FUNGSI SEKOLAH *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Memberi tumpuan di dalam kelas	0	1	2	3	4
2. Pelupa	0	1	2	3	4
3. Menyiapkan kerja/tugasan sekolah	0	1	2	3	4
4. Tidak hadir ke sekolah kerana tidak sihat	0	1	2	3	4
5. Tidak hadir ke sekolah kerana berjumpa doktor/ke hospital	0	1	2	3	4

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LAPORAN KANAK-KANAK (umur **8-12**)

ARAHAN

Mukasurat seterusnya mempunyai senarai perkara-perkara yang mungkin menjadi masalah kepada anda. Sila beritahu kami **berapa kerap** masalah bagi setiap perkara-perkara berikut anda alami pada **BULAN LEPAS** dengan membulatkan:

0 jika **tidak pernah** bermasalah
1 jika **hampir tidak pernah** bermasalah
2 jika **kadang-kala** bermasalah
3 jika **selalu** bermasalah
4 jika **hampir sentiasa** bermasalah

Tiada jawapan yang betul atau salah.
Jika anda tidak faham soalan, sila minta bantuan.

*Pada **BULAN LEPAS**, berapa kerap anda mengalami **masalah** berikut …*

KESIHATAN DAN AKTIVITI SAYA *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Sukar untuk saya berjalan lebih dari satu blok	0	1	2	3	4
2. Sukar untuk saya berlari	0	1	2	3	4
3. Sukar untuk saya melakukan aktiviti sukan atau	0	1	2	3	4
4. Sukar untuk saya mengangkat sesuatu yang berat	0	1	2	3	4
5. Sukar untuk saya mandi sendiri	0	1	2	3	4
6. Sukar untuk saya melakukan aktiviti harian di sekeliling rumah	0	1	2	3	4
7. Saya merasa sakit atau luka	0	1	2	3	4
8. Saya mempunyai tahap tenaga yang rendah/ cepat	0	1	2	3	4

PERASAAN SAYA *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Saya berasa takut	0	1	2	3	4
2. Saya berasa sedih/murung	0	1	2	3	4
3. Saya berasa marah	0	1	2	3	4
4. Saya mengalami kesukaran untuk tidur	0	1	2	3	4
5. Saya risau apa akan terjadi pada diri saya	0	1	2	3	4

BAGAIMANA SAYA BERGAUL DENGAN ORANG LAIN *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Saya mengalami masalah untuk bergaul dengan kanak-kanak lain	0	1	2	3	4
2. Kanak-kanak lain tidak mahu berkawan dengan saya	0	1	2	3	4
3. Kanak-kanak lain mengejek saya	0	1	2	3	4
4. Saya tidak dapat melakukan perkara-perkara seperti mana rakan-rakan sebaya saya mampu lakukan	0	1	2	3	4
5. Susah untuk saya sentiasa bermain dengan kawan – kawan saya	0	1	2	3	4

SEKOLAH ***(masalah dengan…)***	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
1. Sukar untuk menumpukan perhatian di dalam kelas	0	1	2	3	4
2. Saya pelupa	0	1	2	3	4
3. Saya mengalami masalah menyiapkan tugasan	0	1	2	3	4
4. Saya tidak ke sekolah kerana tidak sihat	0	1	2	3	4
5. Saya tidak ke sekolah kerana ber jumpa doctor/ke	0	1	2	3	4

ID# _____

Date:_____

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LAPORAN IBUBAPA untuk **KANAK-KANAK** (umur **8-12**)

ARAHAN

Mukasurat seterusnya mempunyai senarai perkara-perkara yang mungkin menjadi masalah kepada anak anda. Sila beritahu kami **berapa kerap** masalah bagi setiap perkara-perkara berikut anak anda alami pada **BULAN LEPAS** dengan membulatkan:

0 jika **tidak pernah** bermasalah
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2 jika **kadang-kala** bermasalah
3 jika **selalu** bermasalah
4 jika **hampir sentiasa** bermasalah

Tiada jawapan yang betul atau salah.
Jika anda tidak faham soalan, sila minta bantuan.

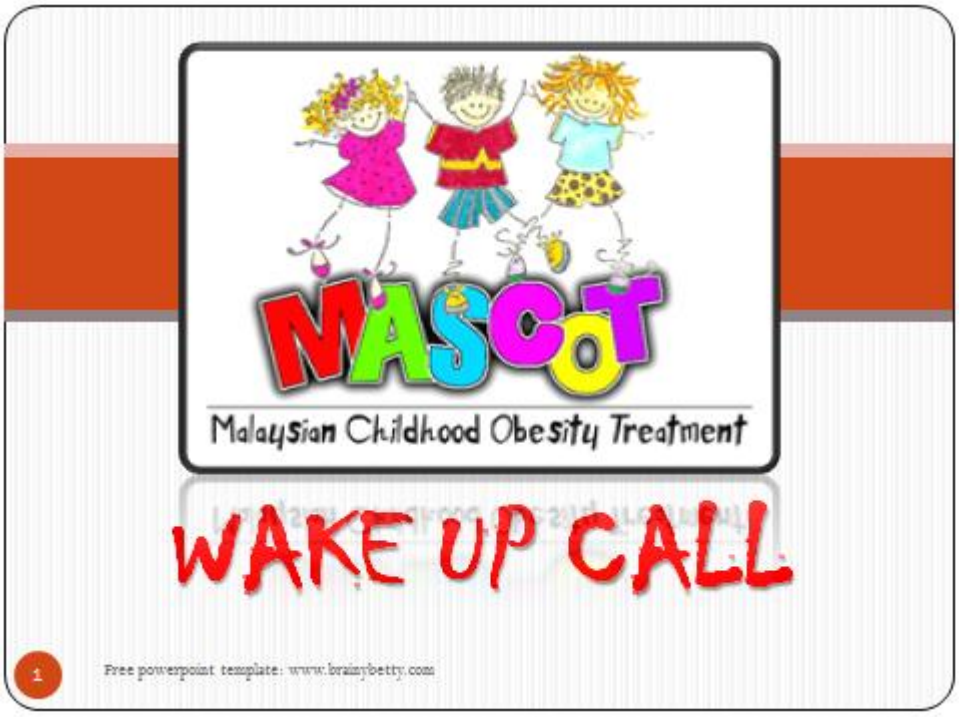
*Pada **BULAN LEPAS**, berapa kerap anak anda mengalami **masalah** berikut …*

FUNGSI FIZIKAL *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
9. Berjalan lebih dari satu blok bangunan	0	1	2	3	4
10. Berlari	0	1	2	3	4
11. Menyertai aktiviti sukan atau bersenam	0	1	2	3	4
12. Mengangkat sesuatu yang berat	0	1	2	3	4
13. Mandi sendiri	0	1	2	3	4
14. Melakukan aktiviti harian di sekeliling rumah	0	1	2	3	4
15. Mengalami luka atau sakit	0	1	2	3	4
16. Rendah tahap tenaga/cepat letih	0	1	2	3	4

FUNGSI EMOSI *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
6. Berasa takut	0	1	2	3	4
7. Berasa sedih/murung	0	1	2	3	4
8. Berasa marah	0	1	2	3	4
9. Kesukaran untuk tidur	0	1	2	3	4
10. Risau apa akan terjadi kepada mereka	0	1	2	3	4

FUNGSI SOSIAL *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
6. Bergaul dengan kanak-kanak lain	0	1	2	3	4
7. Kanak-kanak lain tidak mahu berkawan dengannya	0	1	2	3	4
8. Diejek oleh rakan-rakan	0	1	2	3	4
9. Tidak boleh melakukan sepertimana kanak-kanak sebaya mereka yang lain mampu lakukan	0	1	2	3	4
10. Sentiasa kekal bermain dengan rakan-rakan lain	0	1	2	3	4

FUNGSI SEKOLAH *(masalah dengan…)*	**Tidak pernah**	**Hampir tidak pernah**	**kadang kala**	**Selalu**	**Hampir sentiasa**
6. Memberi tumpuan di dalam kelas	0	1	2	3	4
7. Pelupa	0	1	2	3	4
8. Menyiapkan kerja/tugasan sekolah	0	1	2	3	4
9. Tidak hadir ke sekolah kerana tidak sihat	0	1	2	3	4
10. Tidak hadir ke sekolah kerana berjumpa doktor/ke hospital	0	1	2	3	4


MASCOT
Malaysian Childhood Obesity Treatment
WAKE UP CALL
1
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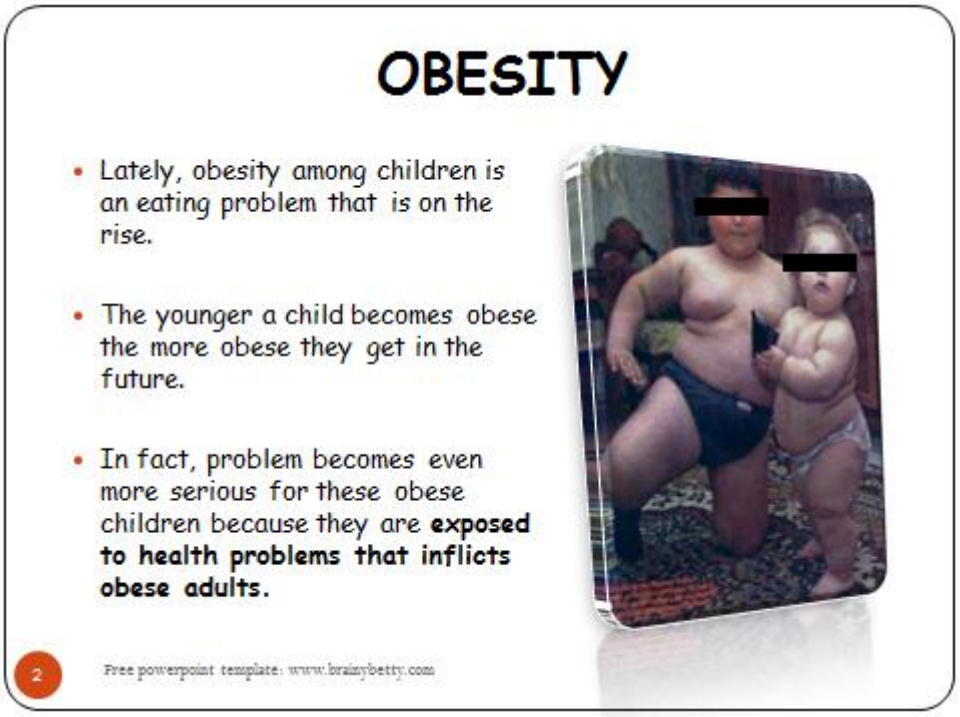
OBESITY
Lately, obesity among children is an eating problem that is on the rise.
The younger a child becomes obese the more obese they get in the future.
In fact, problem becomes even more serious for these obese children because they are exposed to health problems that inflicts obese adults.
2
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EFFECTS OF OBESITY

- High blood pressure
- Type 2 Diabetes
- Coronary Heart Disease
- Cancer
- Psychological effects

3

Diabetes

- Those over the age of 50 are especially more prone to have Type 2 Diabetes. However, in the past few decades, more and more overweight children have Type 2 Diabetes.
- The percentage of children with diabetes in the US is very high. This is a result of a fast food diet and playing computer games frequently as a daily routine.

4

Coronary Heart Disease

- A research conducted in the US found overweight children to have a **permanent risk** to have coronary heart disease in their life span.
- Overweight children should be careful with their food intake as they already have a **risk factor for coronary heart disease even if they manage have normal weight later on in adult life.**

The Overweight Children's Psychology

- Self-loathing and feels rejected by people
- Low self-esteem
- Assume self to be dense
- **Overweight children's quality of life is as hard as that of those having cancer**

Kanak-kanak gemuk cenderung bunuh diri

Berita Harian, 13 Jul 07

Mangsa dianggap bodoh, hodoh oleh rakan sebaya

Psikologi budak gemuk

Obesity: Does Your Child Have A High Risk?

- Obesity is defined as having excess weight compared to an individual's body size according to the calculation of the Body Mass Index (BMI).

$$BMI = weight(kg) / height\ (m)^2$$

- BMI will be plotted against a specific growth chart according to age and gender. If the BMI value is over the 95th percentile, your child is categorized as obese.

7

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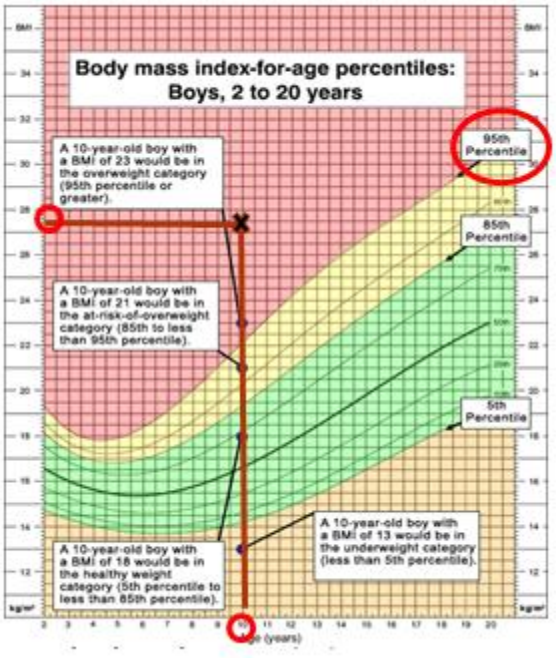

Ali, age 10 years old, weight 80 kg and height 170 cm.

BMI = 80kg / 1.7 x 1.7
= 80/ 2.89
= **27.7**

The BMI will be plotted against the specific growth chart which correlates with your child's age and gender.

If the BMI value is over the 95th percentile, your child is categorized as obese.

8

How can I help my child?

- Parental support is an important aspect in this program.
- Family is the major motivator for children to change for a healthier lifestyle.
- Numerous studies have shown children to be **more successful in weight management when there is active parental involvement.**

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Benefits of weight management

- Reduced weight
- Better appearance
- Healthy body
- Prevent disease
- Boosts confidence
- More active
- No longer teased by friends

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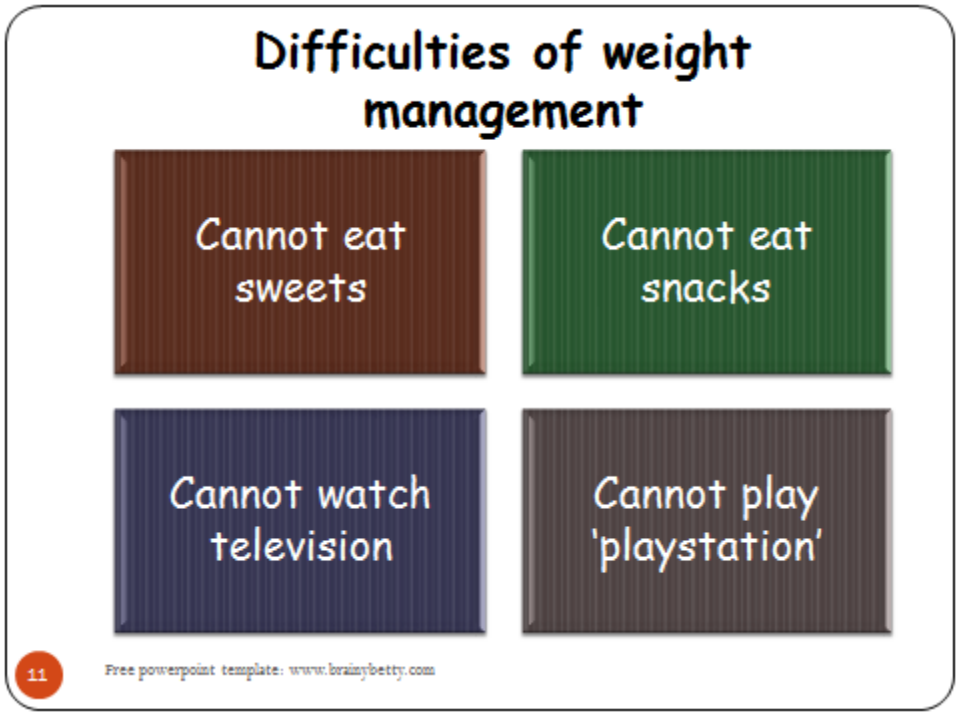
Difficulties of weight management
Cannot eat sweets
Cannot eat snacks
Cannot watch television
Cannot play 'playstation'
11
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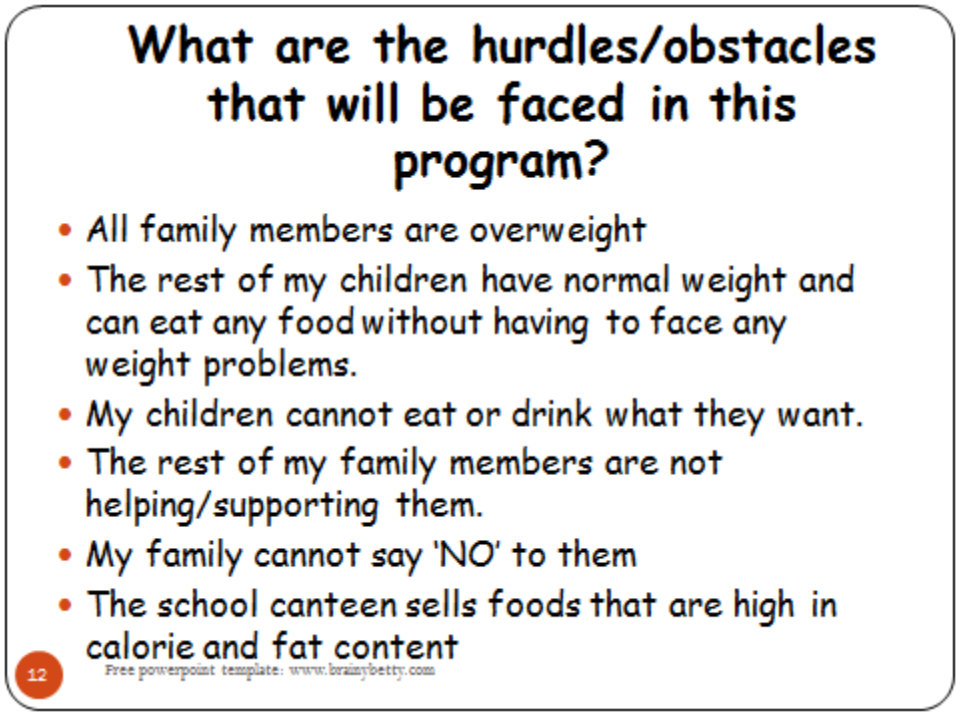
What are the hurdles/obstacles that will be faced in this program?
All family members are overweight
The rest of my children have normal weight and can eat any food without having to face any weight problems.
My children cannot eat or drink what they want.
The rest of my family members are not helping/supporting them.
My family cannot say 'NO' to them
The school canteen sells foods that are high in calorie and fat content
12
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Addendum..

- I do not have the financial means to buy healthy food.
- I am too busy to prepare healthy meals
- My children likes to spend time watching TV
- My children likes to play 'video games' and computer
- My children does not eat properly
- My child likes to skip breakfast
- My child prefers to lounge than being active or in sports

13

How do you control your child's weight in a more planned manner?

Change has to be done in an unhurried manner and moderately

Start with things that are easy to be changed

DO NOT stop your children from eating their favourite meal BUT control the intake and its portion

14

Continuation..

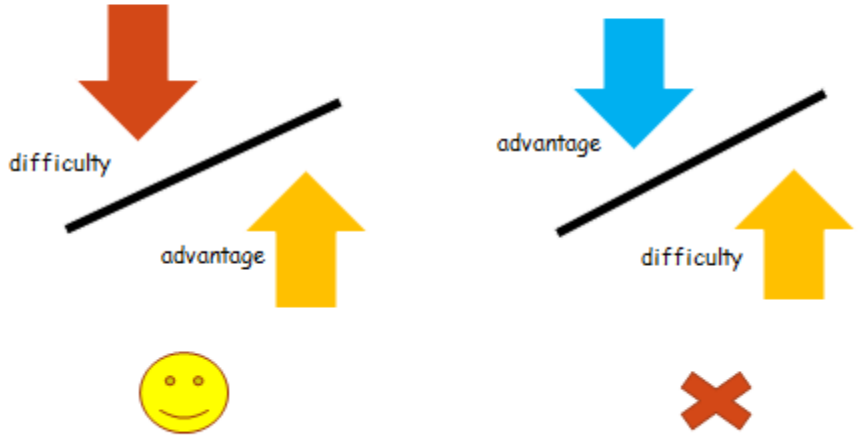
They can watch their favourite TV shows but reduce the time.

Make sure the objective of the family's behavioural transformation is achievable

REMEMBER!! A SMALL change can generate a significant difference

15

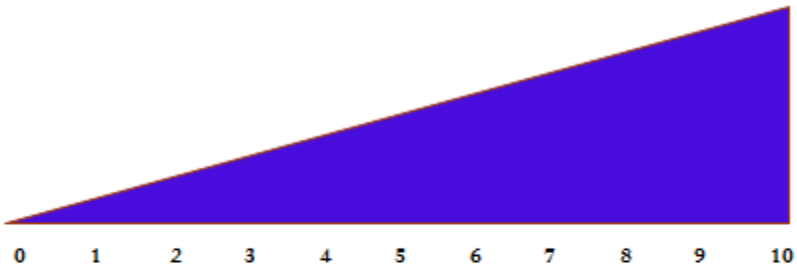
Consider.....



16

XXX

Are you ready to help your child?



0: Not ready…… 10: very ready

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List at least 3 goals that your child aspire to achieve in this program. If they are successful in realizing their listed goals, reward them and set a new goal.

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Goals

Example:

1. Increase vegetable/fruit portion
2. Increase physical activity
3. Reduce watching TV

19

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EAT WELL, BE WELL

20

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ENERGY BALANCE CONCEPT

- An individual's weight is a balanced product between the total energy obtained and the total energy produced.
- If an individual constantly have excess energy that is unused, then, this will result in excess weight.

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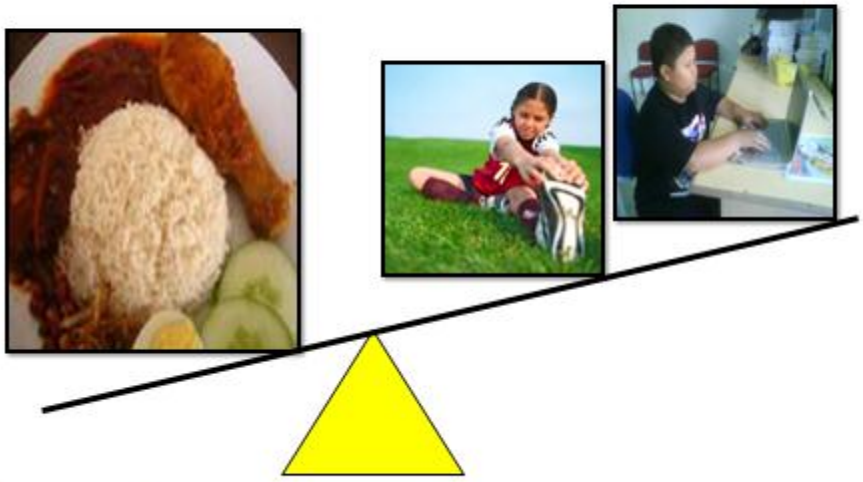
Energy Intake > Energy Expenditure



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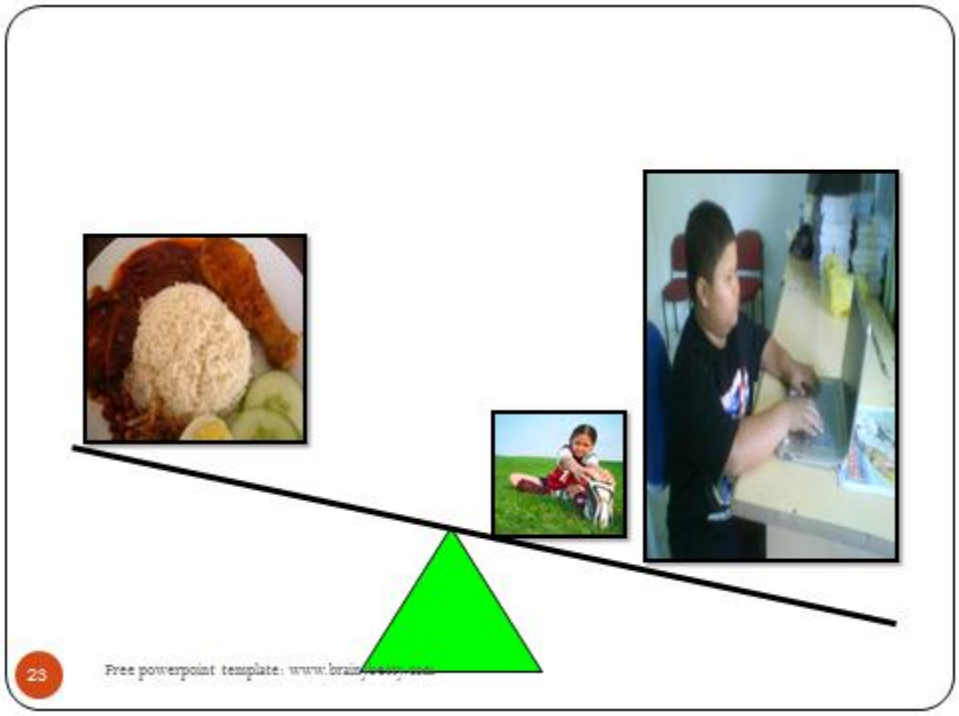
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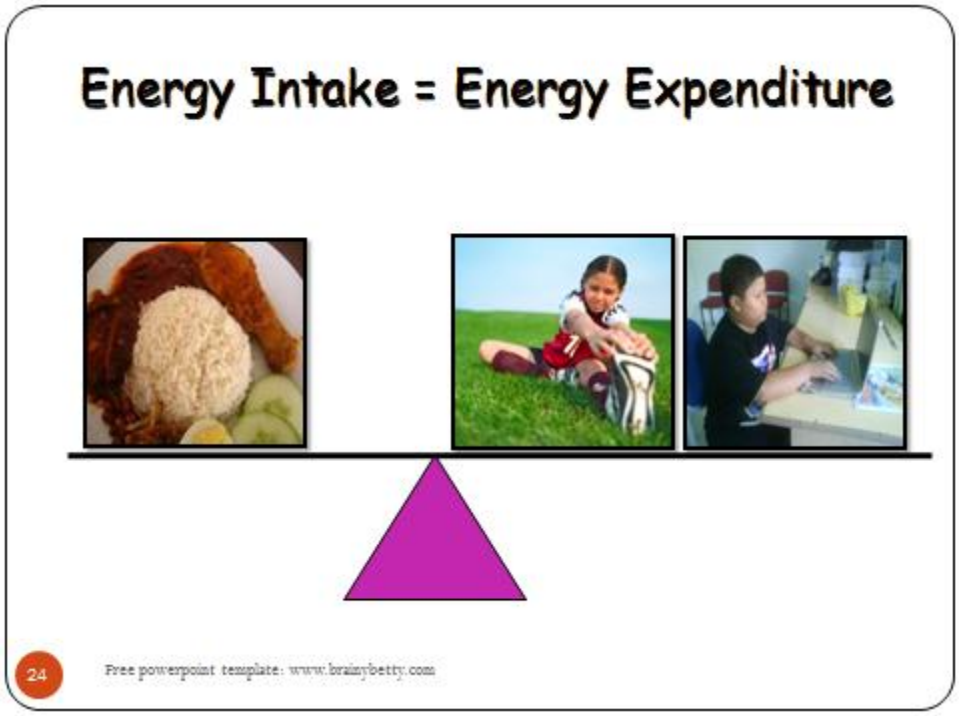
Energy Intake = Energy Expenditure
24
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Choosing healthy foods

- Trying to choose healthy foods that have little association with illness for children is not easy.
- Nowadays, there are various light snacks and pre-cooked meals readily available in grocery stores and supermarkets.
- As parents or guardians, it is our responsibility to monitor and control our children's choice of meals.

- A research by Mindy Hermann, R.D., a dietitian, finds that children's food regime and most types of food consumed by children nowadays are more likely to **generate ill effects for growth**. Parents and guardians should choose foods that are truly essential for children's healthy development.

- Children should be avoided from taking snacks which do not provide any benefits towards their growth development.

MAIN FOCUS

- High fat foods
- High sugar foods

27

Various foods that should be taken as minimal as possible

Donut

Each Donut contains 200 to 300 calories and is mostly packed with a lot of fat and trans-fatty acid that can clog up the arteries.

Chicken Nugget

This food is full of fat. The nugget and its sauce contains sodium which may result in elevated blood pressure for adults.

28

French fries

It usually contains a significant amount of fat and only contain a low amount of vitamin. It is best for children to eat it in moderation; they can be given this once in a while but in a small portion.

Chips or crisps

There are a variety of chips or crisps in the market such as potato chips, prawn crisps, corn crisps and even Cheese puff. It mostly contains fat, sodium, and empty calories. Children should be controlled from consuming a lot of this food.

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- **Carbonated drinks**

  Almost 10 spoons of sugar is in a bottle or tin of a carbonated drink. Sugar can cause people to be overweight and teeth to decay. Children who prefers to drink soft drinks that are claimed to contain milk in fact do not obtain enough calcium for bone growth.

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Have you ever asked your child to go on a diet?

- Eat only a few types of food at certain times → reduced weight
- HOWEVER, with this type of diet, it usually BEGINS well and ENDS without a consistent effect
- Dieting is only guided by printed papers with an organized list of foods that only needs one to follow its regime without knowing why..

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Non-diet approach

Non-diet approach is where <u>teach your child to learn about making the right decision</u> <u>on food selection</u> by providing essential information which can always be used as a guide for both you and your children

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- Non-diet approach will take time and requires more effort
- Nevertheless, when you have gained all information that you have learnt and practiced together with your children, then you and your children will be able to face any obstacles. This would eventually result in your child's capability to make a better decision on food.
- It would also help your child to be more flexible and realistic in determining the objective of their weight management.

Dieting vs Non-dieting

Diet

- A specified time. Some may start and end if dieting on a short term basis. ???
- Providing information without educating
- There is weight loss but it will return to previous weight after diet ends.
- No change in behaviour

Non-diet

- Change is in stages to encourage long term behavioural change
- Educate towards a healthy lifestyle
- Better food selection
  - Preparing low fat milk
  - Selecting low calorie food
  - Drink plain water instead of sugar-containing and high-calorie drinks
- Reduce size of meal portion

Healthy Eating Plan

Only 3 words

GREEN

AMBER

RED

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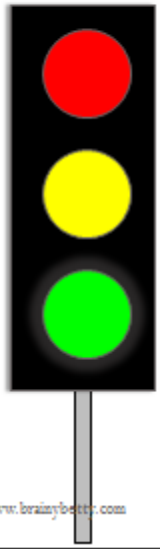
THE TRAFFIC LIGHT DIET



Stop & think

Go carefully

Go

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Green Foods

- Foods that contain low content of fat and sugar
- Rich in vitamins and minerals
- Your children have to take it without limit every day
- This type of food is best taken as snack whenever your child is hungry or even after meal time

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Amber Foods

- It is important to maintain a healthy body and helps a balanced growth
- Take this food TWICE DAILY and try to maintain intake while dining
- Chicken and meat roasted, stewed, cooked in microwave or oven rather than fried.

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Red Foods

- Unhealthy foods as they contain high fat and sugar while having a low level of vitamins and minerals.
- Avoid over-indulgence as best as possible
- It should only be taken once daily, if feasible.

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Better food selection : PRACTICE

- 4 omelettes
- 1 tablespoon butter
- 1 glass of full fat milk
- 4 slices of white bread

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PRACTICE

1. List out all the foods/drinks that your child consumed at breakfast/lunch/dinner. Note down meal size and preparation method.
2. Cross out foods/drinks that are not a good choice
3. Write down the better food choice next to the crossed out list of foods
4. Circle out foods that were not prepared more healthily and low fat
5. Write down a better food preparation

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continuation...

7. Look at the meal size. Circle out those that you think is too many/big

8. Write out a more suitable meal size next to the circle

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CONGRATULATIONS!!!

You have just used a non-diet approach! The following day, try making a better decision on food and take a smaller meal size. Thereafter, practice this approach for the whole week.

REMEMBER,
a small change can generate a significant difference!!!

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You can help your child by...

- Following a healthy eating plan with your children - Traffic Light Diet
- Buying more 'green' foods and reduce buying 'red' foods.
- Dining together as a family
- Thinking positively for every change that is being done

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continue...

- Giving rewards:
  - Taking your child to the cinema or the park
  - Buying books, games or comic books
  - Organizing a sleepover for your child and their friends

45

You Can Change!!

There are often obstacles that may hinder you from progressing forward towards a new change. However, there are ways beyond measures. For example: you want to cross a river. You are given the choice of whether to swim or to take a boat. It requires a great deal of effort to overcome this obstacle and yet you keep on moving forward towards your goal.

46

The following are examples of hindrances to providing a healthy meal for your children and the necessary measures to overcome it

Barrier	Measures to overcome
• Your child likes/always think of food	• Make sure first with **whom?when?where?** does your child always wants to eat. Is it when they are out with grandmother? Or after dinner? Or eating in front of the TV; better known as the CRITICAL TIME/SITUATION
• Your child goes to the kitchen and sees carbonated drinks in the refrigerator	• Be certain that you buy healthy foods, encourage other family members who have high awareness for health to buy groceries. Be sure that there are no unhealthy snacks in the house- you have saved a lot of money

47

Barrier	Measures to overcome
• Eating in the bedroom • Eating while watching TV	• Make a rule for your child to eat in the kitchen/dining area only • Do not eat while watching TV, restrict your child's allocated time to watch TV, play computer games, remove TV from the bedroom
• Your child gets angry/throws a tantrum/rebellious	• Express your concerns about your child's health to them. Try to understand what made them eat unhealthily and unable to change

48

GOAL

- Should be 'SMART'

Specific
Measurable
Achievable
Realistic
Timeline

49

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Be Active!!

50

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HOW WE MOTIVATE OUR CHILDREN TO INITIATE PHYSICAL ACTIVITY

"Active people feel better
&
are in more control"

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Motivation

- Parents should not assume that their children would be able to transform themselves easily when their children have been **inactive all this while and lacking formal basic physical education**. In order to change their lifestyle, children needs encouraging words from their parents to motivate them.
- Children who are inactive should be informed about the advantages of physical activities.

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Benefits

- PSYCHOLOGICAL EFFECTS

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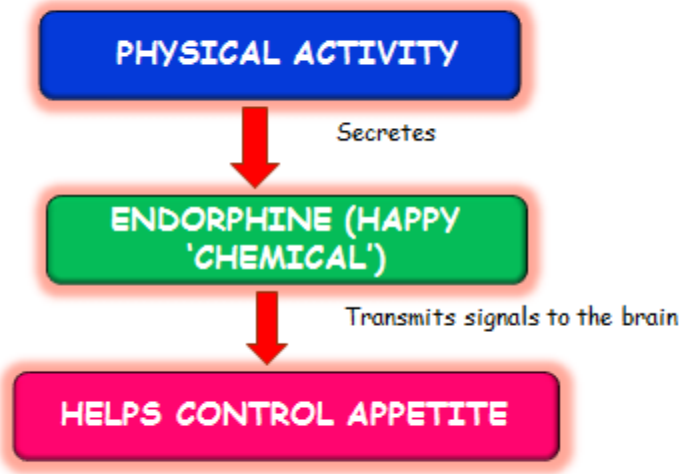
- CONTROL APPETITE



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- MAINTAIN WEIGHT

  - Doing more physical activities can help maintain weight and prevent excess weight gain.

"A FEW LIFESTYLE CHANGES, MANY BENEFICIAL DECISIONS"

- Small changes:
  - Exercising **2 days/week for 20 minutes** is easier than exercising **3 days/week for 1 hour.**

In the transformation towards a healthier lifestyle, it is imperative for children with sedentary lifestyle not to over-exert themselves when exercising

tips

Do different types of physical activities until your child find those that they feel COMFORTABLE , FUN and able to help them achieve the desired GOAL.

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Daily Activities

Climbing stairs

Gardening

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Exercise

treadmill

aerobic

walk

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Sports

football

netball

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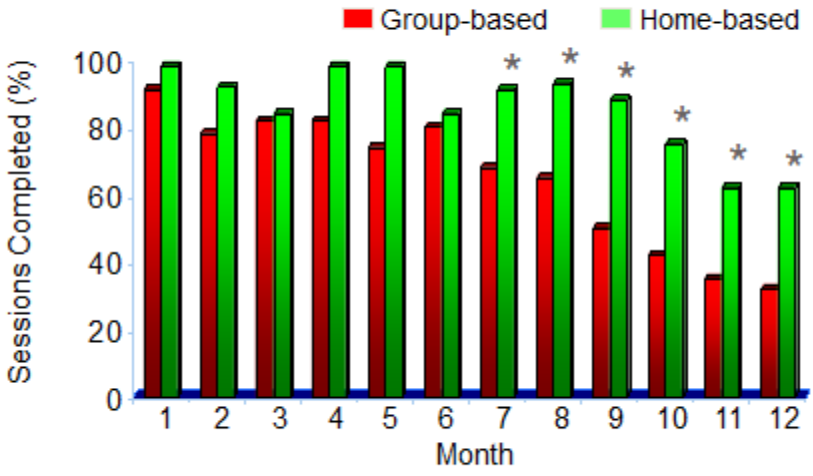
Compliance is GREATER with home based versus group-based activity



63 Ferri et al. *J Consult Clin Psychol* 1997;65:278.

Sedentary Behaviour

64

SEDENTARY BEHAVIOUR

- It is much more effective to reduce children's sedentary behaviour than encouraging them to adopt a more active lifestyle
- Reduce sedentary behaviour (watching TV and playing computer games) to <2 hour a day or 14 hours a week in overall.

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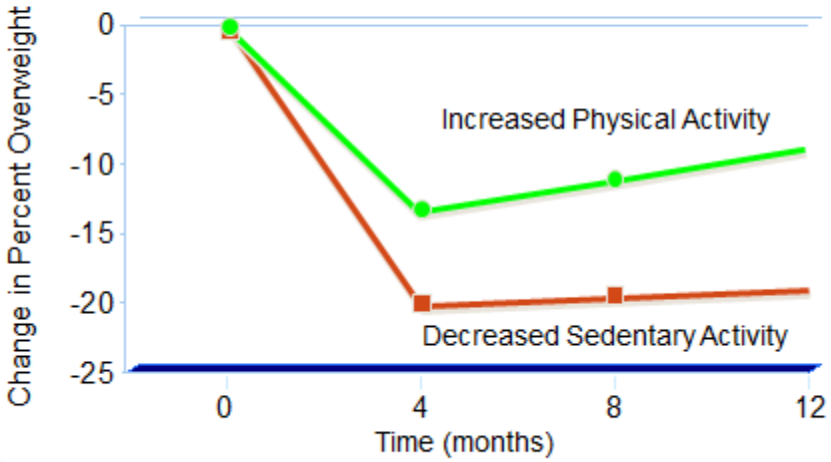
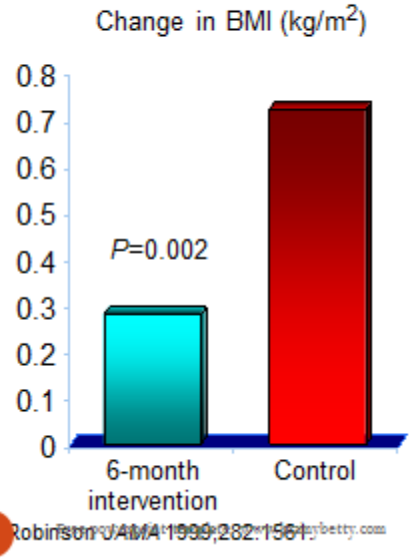
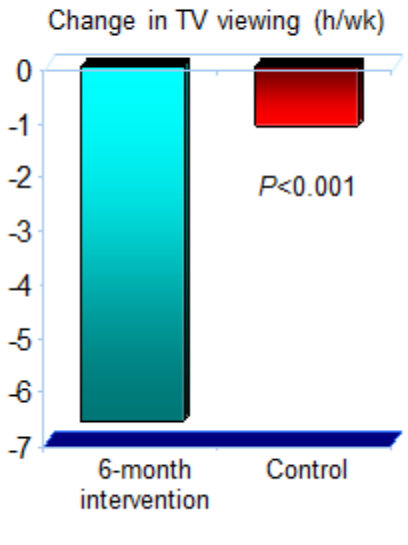
Effect of Decreasing Sedentary Activities vs Increasing Physical Activities on Body Weight in Children 6-12 Years Old



66 *Epstein et al. Health Psychol 1995;14:109*

Decreasing television viewing leads to improved BMI in children





67 Robinson JAMA 1999;282:1561.

CONCLUSION

- Active children feel better and are in more control
- Exercise helps reduce appetite
- Physical activity can help maintain weight and prevent excess weight gain
- Increase daily physical activity (walking) to a minimum of 30 minutes every day
- Reduce sedentary behaviour to 2 hours daily or 14 hours a week

68

Make a better life

Why Skip Breakfast?

- In a hurry.
- Mom did not cook.
- No appetite in the morning.

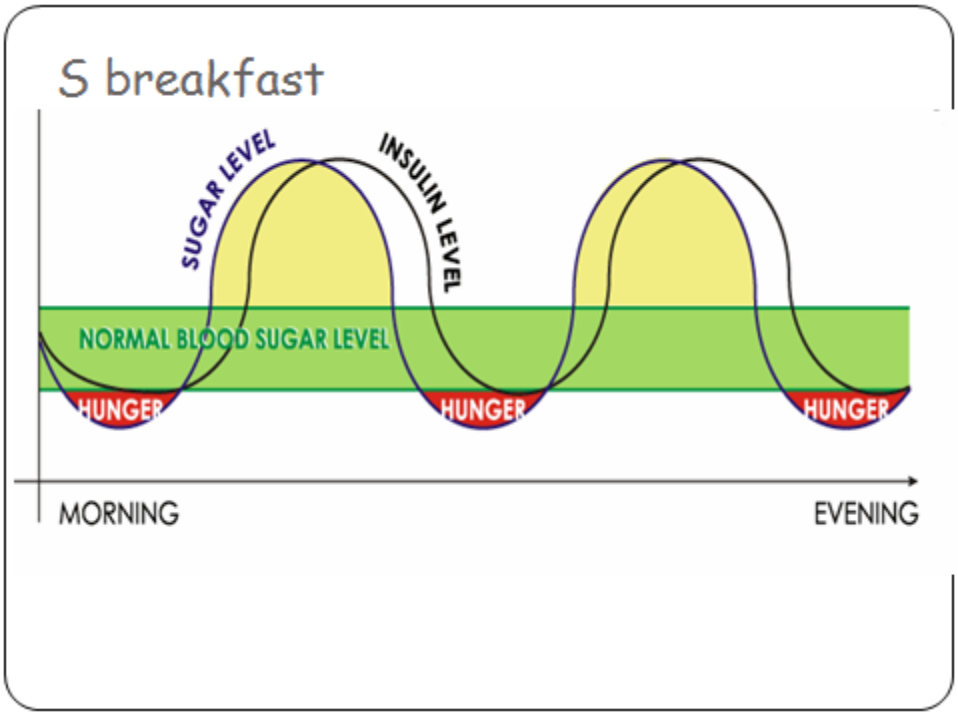
Do You Know?

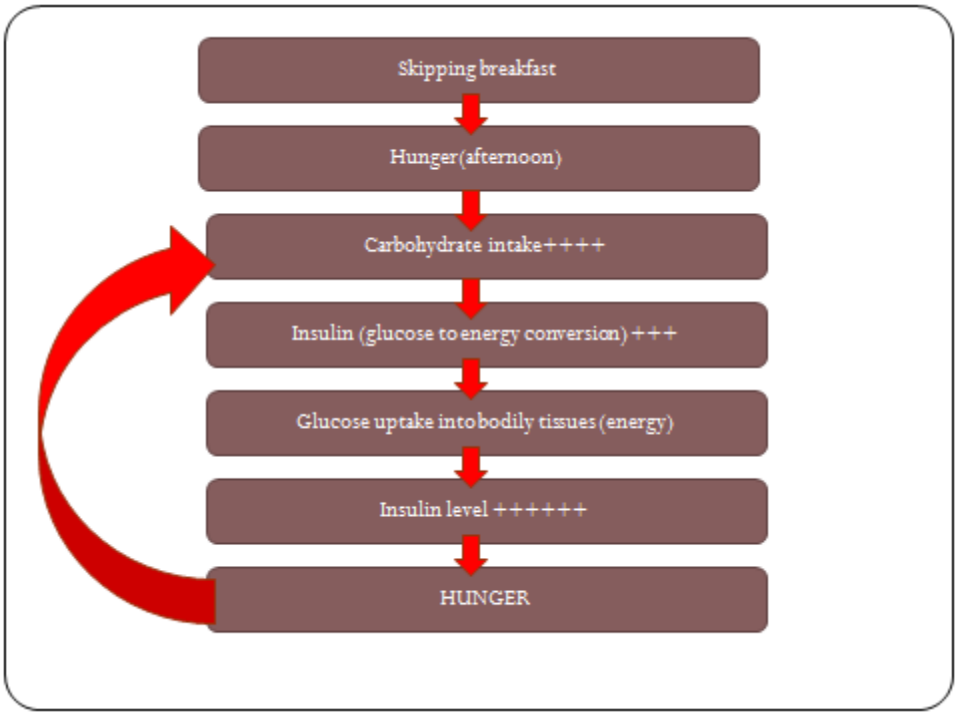
If you want your children to start off the day well, have enough energy to study as well as be able to think smart, be alert, productive, and always at the forefront, then what you should do is make sure they **EAT BREAKFAST**

"Breakfast is the most important meal of the day"

- Children who skip breakfast have excess weight (Boutelle et al. 2002; Dwyer et al. 2001; Sjoberg et al. 2003; Keski-Rahkonen et al. 2003, Ma et al. 2003).

- Not eating breakfast correlates with increasing obesity risk


S breakfast
SUGAR LEVEL
INSULIN LEVEL
NORMAL BLOOD SUGAR LEVEL
HUNGER
HUNGER
HUNGER
MORNING
EVENING


Skipping breakfast
Hunger(afternoon)
Carbohydrate intake++++
Insulin (glucose to energy conversion) +++
Glucose uptake into bodily tissues (energy)
Insulin level ++++++
HUNGER

Family meals

- Eating together as a family is the best time to keep tabs with loved ones
- If possible, try eating at home because this can allow you to prepare meals that can satisfy your children's and your dietary needs

- Let your children eat a healthier meal when dining with family members as it can discourage them from eating unhealthy snacks (kids food), some of which are processed foods.
- The best time for dinner is at least 4 hours before sleep.

- Eating with family encourages children to feel appreciated (have a sense of belonging) as it depicts a clear picture of what a family unit is.
- Children who frequently eats with their family have a normal weight because this allowed self-observation on their adult's food choices and portion size.

Read Food Labels

Did you know that you could choose foods that can satisfy your dietary needs by reading the food label on the packaging?

See Food Information Panel

Food Information Panel enlists the total content of energy and nutrient.
The following is one of the example:

FOOD INFORMATION		
Serving Size: 5 pieces(20g) Total serving for each packet: 5		
Nutrient	**per 100g**	**per serving (20g)**
Energy, kcal	**525**	**105**
Carbohydrate, g	**56.2**	**11.2**
Protein, g	**8.0**	**1.6**
Fat, g	**29.8**	**6**

Comparing food values in different brands for the same product

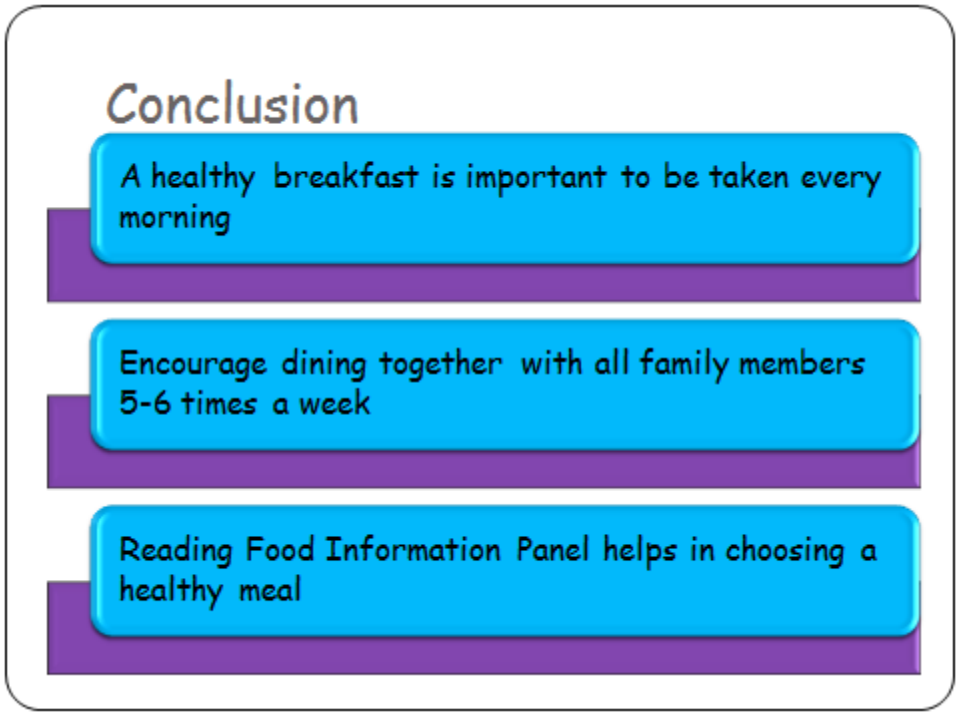
A

Serving Size: 200ml. Total Serving: 5		
Nutrient	per 100 ml	per serving (200ml)
Energy, kcal	125	250
Carbohydrate, g	12	24
Sugar, g	0	6
Protein, g	8	16
Fat, g	5	10

B

Serving size: 250ml. Total Serving: 4		
Nutrient	per 100 ml	per serving (250ml)
Energy, kcal	82	205
Carbohydrate, g	11	27.5
Sugar, g	2	5
Protein, g	5	12.5
Fat, g	2	5


CHECK!!!!
Each serving's calorie content
Each serving's total fat content
Total saturated fat
Total cholesterol
Total sodium
Total carbohydrate
Total dietary fiber
Each serving's sugar content


Conclusion
A healthy breakfast is important to be taken every morning
Encourage dining together with all family members 5-6 times a week
Reading Food Information Panel helps in choosing a healthy meal

MASCOT

Malaysian Childhood Obesity Treatment

I Feel Good

Avoid threats

Focus on the positive aspect and encourage self capability

Issues

- Obesity rate among children in Malaysia have almost doubled (NHMS-III, 2006)
- Sedentary lifestyle among children - TV, computer, activities at home – increase likelihood of gluttony
- "Fast food + junk food" culture
- Lack of parental supervision

Risks

- Physical health – an early start
  - Diabetes
  - Coronary Heart Disease
  - Arthritis
- Mental health
  - Self esteem
  - Depression
  - High risk behavior

Weight Management

- Energy balance

Management :

- Eating
- Physical activity

BOTH OF WHICH ARE BEHAVIOURAL

Correlating factors

- Emotion
- Thoughts
- Physiology
- Physical environment
- Social environment

Factor management leads to behavioural management

Teaching Method

- Modeling
  - Teaching by example
- Encouraging and reducing
  - With the pros and cons after eating
- By association
  - Healthy food = fun

BEHAVIOURAL MANAGEMENT

- Understanding behaviour:
  - Encouraging factor
  - Maintenance factor
- Functional analysis – behavioural function
  - Antecedent
  - Behaviour
  - Consequences

Encouraging behaviour

- Behaviour → good outcome= high probability of recurrence
- Good outcome =
  - Reward
  - Associate with fun
- Social influence
  - Model
  - Trend vs. Unique

Behavioural Modification Method

- Giving rewards to desired behaviour
- Changing undesired behaviour
- Forming behaviour in stages (familiarization)
- Overt correction
- Time out
- Reducing special privilege
- Advise

Character and behavioural transformation

- Model
  - Who?
- Classical generalization
  - Sign and reminder for a healthy practice
- Instrumental generalization
  - Healthy = reward, ill = punishment
- Familiarization
  - Let healthy practice in life become a daily routine/remind health requirements

Character and behavioural transformation

- Get attention with fun
- Friendliness
- Associate with model and advantages of healthy lifestyle
- Encourage self confidence and positive attitude for healthy lifestyle
- Start with small and easy steps
- Social affirmation - GREAT!

Simply the best

Relapse

- "relapse" is defined as a resumption of old behaviors.
- What are the causes of relapse?
  - stress or more correctly, distress, anxiety, or depression.
- focusing on child's attitudes and beliefs, set achievable goals, and assist in modifying behaviors.
- discuss the child's thoughts, beliefs, assumptions and his/her expectations.
- bring the child to adopting realistic perceptions and assumptions, forming a reasonable plan, and setting achievable goals.
- looking at reinforcing appropriate behaviors, learning a skill set which will contribute to increasing appropriate behaviors, and rewarding helpful behaviors and extinguishing non-helpful behaviors.

Problem-solving model

- (a) Orientation (developing an appropriate coping perspective) -- Problems are a normal part of managing your child's weight, but they can be dealt with effectively.
- (b) Definition or specifying the problem and goal behaviors -- What is the particular problem facing your child right now? What is your child's goal in this situation?

- (c) Generation of Alternatives (i.e., brainstorming potential solutions) -- The greater the range of possible solutions you consider, the greater your chances of developing an effective solution.

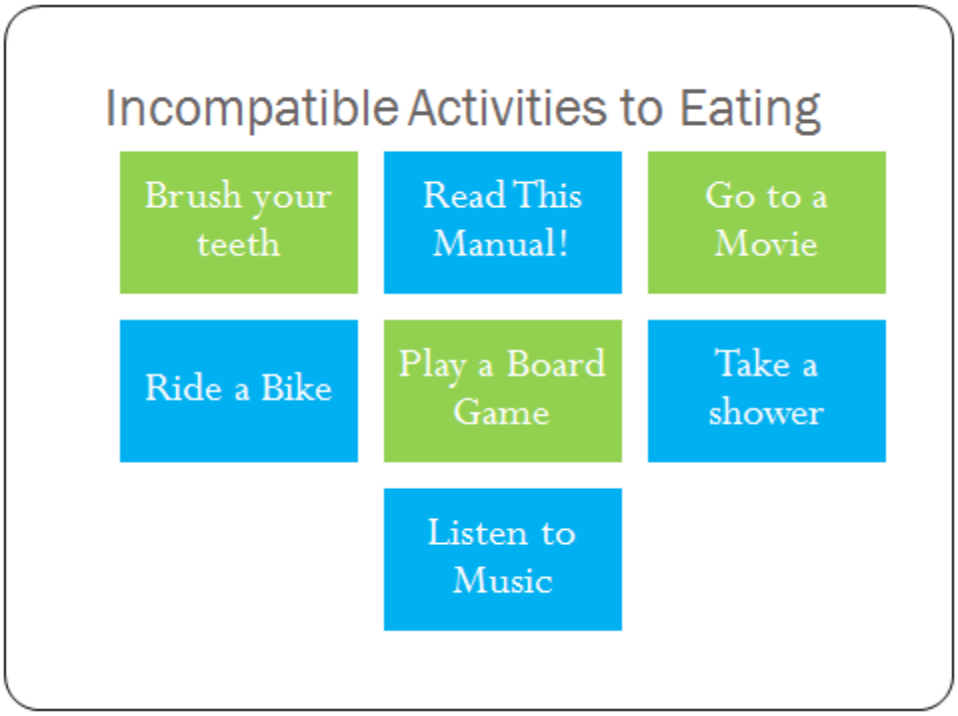
- (d) Decision Making (i.e., anticipating the probable outcomes of different options) -- What are the likely short- and long-term consequences of each of your options?

- (e) Implementation and Evaluation (i.e., trying out a plan and evaluating its effectiveness) -- What solution plan are you going to try and how will you know if it works?

Remember!

"Making mistakes is part of the learning process"

- The essential point is to not blame your child yet help them take responsibility for their own health.
- not be judgmental and notes that the obese deal with harsh vocabulary which often equates obesity with sinfulness, and blames the child for yielding to temptation and indulgence.


Incompatible Activities to Eating
Brush your teeth
Read This Manual!
Go to a Movie
Ride a Bike
Play a Board Game
Take a shower
Listen to Music


Coping With Lapse
Step 1: Stop, Look, and Listen
Step 2: Stay Calm
Step 3: Renew Diet Goals
Step 4: Analyze the Lapse
Step 5: Take Charge Immediately
Step 6: Ask For Help

Tips maintaining a successful routine

- **Don't blame your child if he/she isn't perfect.** If your child once fail at he/she attempts to curtail his/her overeating, it doesn't mean he/she is a failure at weight control and that he/she should just give up. Accept that he/she made a poor choice, but don't let that poor choice influence the rest of his/her plan. The same holds true with physical activity. Skipping a few workouts doesn't mean he/she can't get back on track. Weight control does not involve making perfect choices all the time, rather it's about attempting to make good choices more often than poor ones.

- **Avoid surroundings where you know your child tempted to make poor food choices.** Everyone has a time when we're most likely to overeat ie birthday party. Try to plan other activities or distractions for those times, or plan in advance how you're going to handle them and stick to it.

- **Decide on some nonfood rewards for your child when he/she reaches interim goals.** For examples, at the end of the first week of healthy eating or after the first 5 pounds lost, buy your child a new DVD or book.

- **Stock your pantry and refrigerator with healthy foods.** Get rid of the high-calorie, low-nutrition snacks like chips and candy. But don't forget to have plenty of healthier options available as well, such as low-fat cheese and yogurt, fruit, instant cocoa without added sugar, sugar-free popsicles or puddings, or whatever appeals to your child when they are hungry for a snack.

- **Set small goals and focus on these rather than the "big picture."** remember SMART GOAL

MULA

1

2

3

NAME:

APPENDIX NINE

Post pilot semi structured questionnaire

1. In general how did you feel about the program – overall impression?

_____

2. Your expectations before the start

_____

3. How did it compare with your expectations? Worse or better?

_____

4. How did you find the written materials?

_____

5. Goal setting was it useful / difficult?

_____

6. Diary keeping was it helpful / easy to do?

_____

7. Did rewards help you to meet your goals?

_____

8. Number of sessions, were they easy to attend / too many / too few?

_____

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The Malaysian Childhood Obesity Treatment Trial (MASCOT)

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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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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.controlled-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	• Readiness to change and decisional balance	1-2
2	Eat well, be well	Energy balance Healthy eating plan-Traffic Light Diet Food reference guide	• Goal setting, contracting and rewards • Self-monitoring	3-4
3	Be active!	How to motivate child to initiate physical activity How to decrease sedentary behaviour	• Goal setting, contracting and rewards • Self-monitoring	5-6
4	Make a better life	Eating a daily breakfast Family meal Fast food Label reading	• Problem-solving • Self-monitoring	7-8
5	I feel good	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	Simply the best	Understand a relapse How to improve current diet and physical activity Tips maintaining a successful routine	• Problem-solving • Preventing relapse	19-20
8	Sharing is caring	The most admirable family of the programme Sharing tips with other parents Long-term goal setting	• Goal setting, contracting and rewards	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 ≥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 $2.9 \pm 0.6 kg/m^2$. Mean height's score relative to US-CDC reference data was 0.5 (SD0.9).

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

Table 2. Baseline characteristics of children (mean and SD) enrolled in the MASCOT trial

Characteristics	*Full Sample*	*Treatment Group*	*Control group*
Male/Female	54/53	28/24	26/29
Age	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)
Height z-score[1]	0.5(0.9)	0.5(0.9)	0.4(1.0)
Weight (kg)	53.9(13.1)	54.5(12.1)	54.6(14.0)
Weight z-score	2.5(0.7)	2.6(0.6)	2.5(0.8)
BMI (kg/m2)	27.8(5.5)	27.6(3.4)	28.0(7.0)
BMI z-score[1]	2.9(0.6)	3.0(0.5)	2.9(0.6)
Habitual Physical Activity (n=87)			
% monitored daytime:			
Total activity (cpm)	387(140)	335(144)	365(143)
Sedentary Behavior	89.1(4.5)	88.5(4.5)	89.8(4.4)
Light Intensity 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[2]			
Psychosocial scale : Child	66.9(15.3)	66.2(15.3)	67.3(15.4)
: Parent	65.7(16.3)	65.2(15.5)	66.2(17.1)
Physical scale : Child	70.0(18.6)	70.2(16.5)	69.9(20.6)
: Parent	65.6(19.7)	64.7(19.8)	66.5(19.9)
Total score : Child	67.7(14.5)	67.6(13.6)	67.8(15.4)
: Parent	66.0(16.4)	65.1(15.7)	66.9(17.2)

[1] Relative to US CDC reference 2000; [2] in table ???????

of 1% of monitored time during the day, equivalent to about 8 minutes per day, on average.

Health related quality of life of study participants

Health related quality of life data are given in Table 2. Mean total score based on child self-report was 67.7 (SD 14.5), and mean total score based on parent-proxy report was 66.0 (SD 16.4). Overall, the HRQOL scores for the child self-report and parent proxy report were low. There were no significant differences between parent and child reports for total scores.

DISCUSSION

This study is the first to describe a protocol for the treatment of childhood obesity in Malaysia, and, to our knowledge, is the first description of a treatment protocol intended for any setting outside the western world, based on a recent systematic review (Luttikhuis *et al.*, 2009). The study is also the first quantitative characterisation of quality of life, and of objectively measured habitual physical activity and sedentary behaviour among obese children outside the western world.

Objectively measured physical activity was very low among obese children, averaging only around 8 minutes per day. Achieving the clinical and public health target for MVPA suggested by childhood obesity treatment guidelines of 60 minutes per day is therefore likely to be extremely difficult. Future treatment interventions will therefore need large effects to get obese children to recommended levels of physical activity. The results of the present study are similar to a recent study that used objective

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 on-going 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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ORIGINAL ARTICLE

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 (RCTs) 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- to 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 six 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 (+1.5 kg vs. +3.5 kg, 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.

Key words: *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 randomized controlled trials (RCT) of treatment interventions from the developing world, with the exception of one single study from China. As a result, the generalizability 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,

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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 aged 7–11 years had to be obese (BMI above the 95th percentile relative to US reference data) (12), and 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.

Randomization 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 randomization 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 sessions, 8-hour contact time, delivered as group sessions) program, delivered over a 26-week period largely by a dietician (HH) who led every session. Input from a clinical psychologist (LN) supported the work of the dietician 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 dietician 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 13 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 I.

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: (i) exploration of the pros and cons of changes in diet, physical activity, and sedentary behavior; (ii) exploration of motivation to change diet, physical activity, and sedentary behavior; (iii) 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); (iv) identifying the main barriers to behavior change and problem solving in relation to these barriers; (v) goal setting in relation to diet, physical activity, and sedentary behavior and behavioral contracting; (vi) use of appropriate rewards for achieving diet goals, physical activity goals, and sedentary behavior goals; and (vii) 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 six months had elapsed, after the study had ended.

Table I. Components of the Malaysian Childhood Obesity Treatment Trial (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

Outcome measures and blinding

Outcome measures were made at baseline and again at six 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 0.1 kg in light indoor clothing with children not wearing shoes, and height was measured to 0.1 cm 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-sec epochs, collapsed to 1 min when cut-off 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 summarized using cut-off points as percentage of the time spent in sedentary behavior (<1100 cpm; 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 six 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 six-month study.

Outcomes were analyzed in two ways. First, changes in outcome variables *within* each group (intervention and control) between baseline and six-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 II). 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

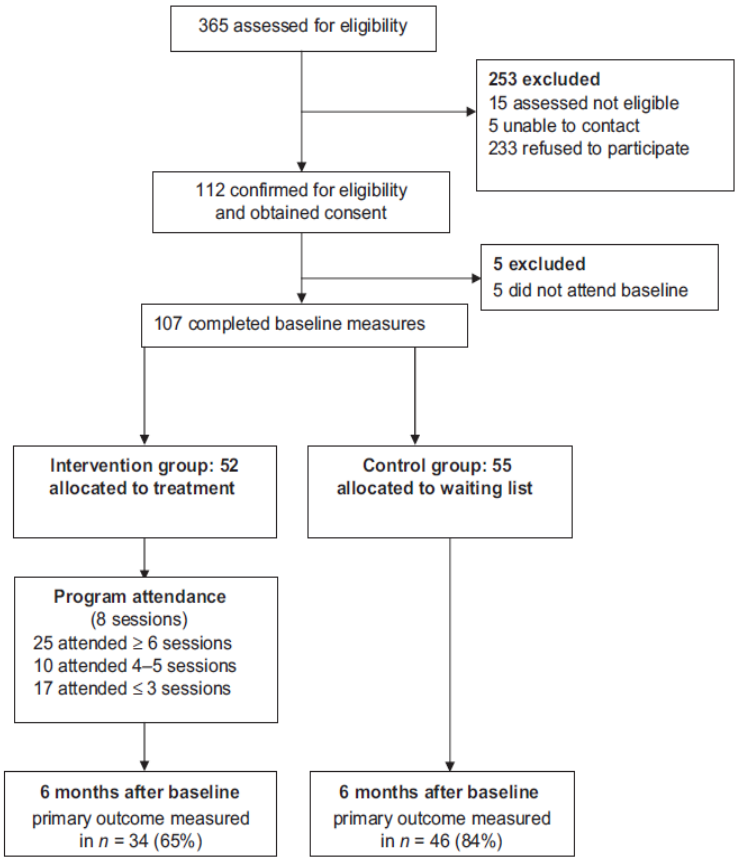

Figure 1. Flow of participants through the trial.

Table II. 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)

No differences between the two groups significant at baseline. [1]z-score calculated relative to US reference data (12).

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 III provides data on change in weight and BMI. There were no statistically significant differences *within* the two groups over the six 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 III).

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 six 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 +1.5 kg, 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 III 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 III).

Discussion

Main findings, study implications, and comparisons with other evidence

The present study suggests that conducting randomized 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- to 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

Table III. 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

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 six-month period, 0/45 children in the waiting list control group did so. Recent childhood obesity treatment RCTs 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 generalizable. 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 generalizable.

Levels of objectively measured physical activity of participating children were very low in the present study, with children typically spending only around 7 min/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 generalizable intervention; inclusion of a large number of study outcomes; and 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 recognize 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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ORIGINAL ARTICLE

Quality of life of obese children in Malaysia

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Abstract

Background. Quality of life (QoL) is impaired in childhood obesity, but the literature on this is all from Western countries. *Aim*. To test for impairment of QoL in obese children in Malaysia, using parent-reported and child-reported QoL. *Methods*. Health-related Quality of Life was measured using the Paediatric Quality of Life Inventory version 4.0. Comparison of QoL between a community sample of 90 obese children (as defined by US CDC and Cole-IOTF definitions), median age 9.5 y (interquartile range [IQR] 8.6, 10.5 y) and 90 control children of healthy weight (BMI less than the 85th centile of US reference data), median age 10.0 y (IQR 9.6, 10.5 y). Children were matched pair-wise for age, gender, and ethnic group, and controls were recruited from schools in the same area as obese participants. *Results*. For child self-report, the healthy weight group had significantly higher QoL for the physical (median 82.9, IQR 65.7, 90.6), and psychosocial domains (median, 73.3, IQR 64.4, 83.3), and total QoL (median 76.1, IQR 64.1, 84.8) compared to the obese group (median 67.2, IQR 59.4, 81.3; median 62.5, IQR 53.3, 75.4; median 60.9, IQR 50.8, 73.9; all $p < 0.001$). There were no significant differences between the obese and healthy weight group for parent-reported physical health, psychosocial health, or total QoL. *Conclusion*. Obese children in Malaysia have markedly poorer QoL than their peers, but this is not evident when parent reports of QoL are used.

Key words: *Quality of life, Malaysia, child, adolescent, overweight, obesity*

Introduction

Prevalence of childhood obesity continues to rise dramatically in the Asia-Pacific area, including Malaysia (1). Quality of life (QoL) in childhood chronic disease, including obesity, is of increasing interest (2,3). A recent systematic review in this journal, *International Journal of Pediatric Obesity* (4), found 'strong evidence that pediatric obesity impacts negatively on quality of life'. However, the systematic review found only six eligible studies of children (4). Furthermore, all of the eligible studies were from the Western world. Cultural differences might mean that childhood obesity may have a greater or lesser impact on QoL in non-Western societies, but to address such questions requires a widening of the evidence base on QoL. The present study therefore aimed to test the hypothesis that health-related QoL is impaired in obese Malaysian children, by comparing QoL between obese children and matched control children of healthy weight status. In addition, since parent-reported and child-reported child QoL may not always be concordant (5), a secondary aim was to test the hypothesis using both child-reported QoL and parent-reported QoL.

Methods

Participants

Parents gave informed written consent, and the study was approved by the University Kebangsaan Malaysia (UKM) research ethical committee. Obese children in the present study were participants at the baseline stage of the Malaysian Childhood Obesity Treatment Trial (MASCOT), which is described

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elsewhere (6). In brief, MASCOT was a single-blinded randomized controlled trial of a dietetic treatment for childhood obesity in children of primary school age in Kuala Lumpur, Malaysia. Obesity in MASCOT was defined using BMI with both the Cole-IOTF definitions (7), and BMI ≥ 95th percentile on age and gender-specific US reference data (8). Height was measured using the SECA BodyMeter to the nearest 0.1 cm. Weight was measured to the nearest 0.1 kg using scales (TANITA) with children in light indoor clothing. In total, 107 children, 54 boys and 53 girls, participated in the baseline stage of the MASCOT study.

Children with healthy weight status were recruited as controls from two primary schools in the same areas of Kuala Lumpur used to recruit the sample to the MASCOT study. Anthropometric assessment was performed prior to recruitment to identify children with healthy weight status (BMI below the 85th percentile; [8]) and the assessment identified 90 eligible control participants, all 90 of whom consented to participation (41 boys and 49 girls aged 8–11 years). Since QoL might vary by age, gender, and ethnicity, in the present study obese children and those of healthy weight status were pair-matched by gender, age (same school year), and ethnicity, following the approach described by Hughes et al. (5), giving 90 pairs for inclusion in the present study. All participating children were from the majority (Malay) ethnic group.

Health-related quality of life

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 (2). Participating children completed the PedsQL at school in the presence of a researcher. Parents completed the PedsQL at home. In brief, the PedsQL is both a child self-report and a parent proxy-report scale consisting of 23 items made up of physical (eight items), social (five items), emotional (five items) and school functioning (five items) components (5). The items are reverse-scored and linearly transformed to a 0–100 scale, so that higher scores indicate better QoL (2,5). A total scale score, from all 23 items, was calculated to provide an overall measure of the QoL (2,5), and two domains were calculated, for physical health (from the sum of the physical components) and psychosocial health (from the sum of the social, emotional, and school functioning components [2,5]).

Statistical analysis and study power

Sample size for the present study was based on previous studies (5,9) of differences in QoL between obese children and healthy controls. With the paired design (5) the present study had >90% power at the 5% significance level to detect mean differences of total scale score of a magnitude reported previously (5) with around 40 paired comparisons. In order to consider the sexes separately if required, it was decided to recruit matched controls of healthy weight status until at least 40 paired comparisons were available for both boys and girls.

All statistical analyses were conducted using Statistical Package for Social Science (SPSS) version 16.0. Data were checked for normality before analysis using descriptive statistics and Kolmogorov-Smirnov normality test. The QoL data were not normally distributed. Therefore, Wilcoxon signed-rank tests were used to test the significance of differences between healthy weight and obese group.

Results

Characteristics of study participants

Healthy control participant QoL variables are given in Table I. Median age was 10.0 y (interquartile range [IQR] 9.6, 10.5). Median total QoL score for child-self report was 76.1 (IQR 64.1, 84.8). For parent proxy-report, median total score was 59.3 (IQR 47.8, 79.4). The QoL child self-reports were significantly higher than parent-report for the physical domain and psychosocial domain, as well as total scores ($p < 0.05$).

QoL summary data for the obese children are given in Table II. Median age was 9.5 y (IQR 8.6, 10.5 y), and mean BMI z score was 2.90 (SD 0.60). Median total QoL score for child-self report was 60.9 (IQR 50.8, 73.9). Median total QoL score for parent proxy-report, was 65.2 (IQR 57.3, 76.1).

Formal paired comparisons of QoL between obese children and healthy weight control children

Table III gives paired comparisons of QoL between the obese and healthy weight groups. For the child self-report, total, physical and psychosocial subscale scores were all significantly lower in the obese group than the healthy weight control group ($p < 0.001$ in all cases). For the parent-proxy QoL reports, none of the differences between obese and healthy weight groups were statistically significant.

Table I. Health-related Quality of life scores, median and interquartile range (IQR), for the healthy weight controls, for both child self-report and parent-proxy report.

	Boys ($n = 41$)	Girls ($n = 49$)	Total ($n = 90$)
Child self-report			
Total score	75.0 (63.0, 85.9)	76.1 (64.1, 84.3)	76.1 (64.1, 84.8)*
Physical scale	81.3 (59.4, 90.6)	84.4 (70.4, 90.6)	82.9 (65.7, 90.6)*
Psychosocial scale	73.3 (63.3, 83.3)	73.3 (65.0, 83.3)	62.5 (53.3, 75.4)*
Parent-proxy report			
Total score	56.5 (47.8, 71.2)	68.5 (50.0, 80.4)	59.3 (47.8, 79.4)
Physical scale	50.0 (40.6, 70.4)	62.5 (48.4, 86.0)	57.9 (43.8, 77.1)
Psychosocial scale	60.0 (52.5, 75.0)	68.3 (50.9, 80.9)	61.7 (43.8, 84.4)

*Significant difference ($p < 0.05$) between child self-report and parent-proxy.

Discussion

The present study supports the hypothesis that obese children in Malaysia have impaired health-related quality of life compared to their healthy weight peers. However, the present study also indicates that the impairment of QoL associated with obesity in Malaysian children is evident from child-reports, not from parent reports. There was no evidence that impaired QoL was gender-specific. Wake et al. (10) found gender specific differences in the extent of the impairment of QoL associated with obesity in Australian children, but the recent systematic review by Griffiths et al. (4) found that few studies have examined the question of whether QoL impairment is gender-specific.

A systematic review emphasized the value of obtaining perspectives on QoL from both parents and children where possible (11). The clinical implications of impaired QoL in childhood obesity may depend on whether or not the impairment is most marked from the child or the parent perspective. Parent-perceived impairments in QoL might be a more important driver of healthcare utilization and treatment-seeking for childhood obesity than child-perceived impairments (5,10), since the decision to seek treatment for obesity usually lies with the parent rather than the child. Engagement of parents with treatment is likely to be an important influence on treatment outcome (12), and engagement may be enhanced if parents perceive an impairment of QoL in their children, or if they perceive that QoL is improving in response to treatment (13,14). The child perspective on QoL is important in its own right though (5,11).

Statistically significant obesity-related impairment of QoL was observed in the present study, but the 'biological significance' of such impairment is unclear. Previous studies in Western societies have generally found that childhood obesity is associated with Peds QL total scale scores which lie among the scores for children with other chronic and disabling conditions (2,4,15). The QoL total scores from obese children in the present study lie at the lower end of the range described previously for children with other chronic and disabling conditions from western societies (2,4,15). Only one previous study of QoL using the Peds QL has been carried out in Malaysian children. Ismail et al. (16) tested the hypothesis that QoL was impaired in children with thalassaemia from Kuala Lumpur, and found a mean child-reported total score of 68.9 for thalassaemia patients and 79.8 from healthy controls. The present study median total score of 60.9 for the child reports from the obese children in Kuala Lumpur was therefore well below the values reported for patients with thalassaemia in the same city by Ismail et al. (16), and this also supports the view that the obese children in the present study were experiencing impairment of QOL which might also be 'clinically' significant.

Table II. Health-related QoL scores, median and IQR, from both child report and parent proxy report, for the obese group.

	Boys ($n = 41$)	Girls ($n = 49$)	Total ($n = 90$)
Child self-report			
Total score	56.6 (50.6, 69.6)	64.1 (50.6, 82.4)	65.2 (57.3, 76.1)
Physical scale	68.8 (57.9, 79.7)	65.6 (61.0, 82.9)	67.2 (59.4, 81.3)
Psychosocial scale	60.0 (52.5, 72.5)	65.0 (55.0, 76.8)	62.5 (53.3, 75.4)
Parent-proxy report			
Total score	63.0 (54.4, 75.6)	66.3 (58.2, 78.8)	60.9 (50.8, 73.9)
Physical scale	59.4 (45.4, 75.0)	68.8 (46.9, 82.9)	61.0 (46.9, 78.1)
Psychosocial scale	55.0 (50.9, 69.2)	61.7 (51.7, 76.7)	58.3 (51.7, 75.0)

Table III. Paired comparisons of health-related QoL (median and IQR) for the healthy weight group vs. obese group.

Variable	Healthy weight group ($n = 90$)	Obese group ($n = 90$)	95% CI for difference	p-value
Child self-report				
Total score	76.1 (64.1, 84.8)	60.9 (50.8, 73.9)	(−16.0, −7.6)	<0.001
Physical scale	82.9 (65.7, 90.6)	67.2 (59.4, 81.3)	(−14.5, −4.5)	<0.001
Psychosocial scale	73.3 (64.4, 83.3)	62.5 (53.3, 75.4)	(−13.0, −5.2)	<0.001
Parent-proxy report				
Total score	59.3 (47.8, 79.4)	65.3 (57.3, 76.1)	(−3.2, 6.3)	0.464
Physical scale	57.9 (43.8, 84.4)	61.0 (46.9, 78.1)	(−5.6, 7.6)	0.319
Psychosocial scale	61.7 (51.7, 77.1)	58.3 (51.7, 75.0)	(−7.8, 2.3)	0.765

Hughes et al. (5) compared QoL between obese and healthy weight children of similar age to the present study in Scotland, UK, using identical study design and methods. Hughes et al. (5) found that impaired QoL in obese children was much more marked when parent-reported QoL was used than when child self-reports were used, in contrast to the present study. The reason for this difference is unclear, but cultural differences might be important. Child self-reported QoL from the healthy weight controls in the present study, those studied by Hughes et al. (5), and the healthy controls from Malaysia by Ismail et al. (16) were very similar. However, in the present study parent-proxy reported QoL values for the healthy controls were much lower than those reported by parents in studies of healthy children from Western societies (5). Further research will be required in order to understand the nature and origin of differences in QoL between Western and non-Western nations, and differences within non-Western nations.

The present study matched obese children and controls of healthy weight status for age, gender, and ethnicity. All participants attended public primary schools in the same area of urban Kuala Lumpur and the range of socio-economic status was narrow. The sample had slightly lower reported family income than is typical for Kuala Lumpur. The present study had some limitations. While no significant impairments of QoL were observed using parent reports, it is possible that impairments are present, but these are of very small magnitude and so would require much larger samples in order to detect. Similarly, subtle gender differences in the extent and nature of QoL impairment might be present but undetectable without much larger studies designed specifically on this question. Previous literature on impairment of QoL in obese children has generally failed to find marked age or gender differences in the impairment (4,17–20), with a few exceptions (10).

Conclusion

The present study supports the view that obese children in Malaysia have impaired quality of life compared to children of healthy weight. The study also suggests that identification of impairment in QoL should consider both the child and parent perspective on QoL.

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