Randomised controlled trial of the MEND programme: a family-based community intervention for childhood obesity

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Thesis submitted for the degree of Doctor of Philosophy

August 2013

In memory of my much loved grandparents

Barney and Cecile Abramowitz

Author's declaration

I, Paul Manfred Sacher confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed: ______________________

Abstract

Background and aims Childhood obesity is a serious global public health issue. The number of children affected has increased dramatically in recent years, and despite extensive research in this field, no effective generalisable prevention or treatment interventions have been achieved as yet. The aim of this randomised controlled trial (RCT) was to evaluate the efficacy of the Mind, Exercise, Nutrition, Do it (MEND) programme, a multicomponent community-based childhood obesity intervention.

Methods One hundred and seventeen obese children were randomly assigned to intervention or waiting list control (6-month delayed intervention) groups. Parents and children attended eighteen 2-hour group educational and physical activity sessions held twice weekly in sports centres and schools, followed by provision of a 12-week free family swimming pass. Waist circumference, BMI, body composition, physical activity level, sedentary activities, cardiovascular fitness and self-esteem were assessed at baseline, 3, 6, 9 and 12 months.

Results Participants in the intervention group exhibited reduced waist circumference *z*-score (−0.37; $p < 0.0001$, n = 81) and BMI *z*-score (−0.24; $p < 0.0001$, n = 82) at 6 months, compared to the control subjects. Significant between-group differences were additionally observed in cardiovascular fitness, physical activity, sedentary behaviours, and self-esteem. Mean attendance for the MEND programme was 86%, with a drop-out rate of 4%. At 12 months waist and BMI *z*-scores of children in the intervention group were reduced by 0.47 ($p < 0.0001$) and 0.23 ($p < 0.0001$), respectively, along with sustained benefits in cardiovascular fitness, physical activity levels, and self-esteem.

Conclusions The MEND programme had beneficial effects on physical and psychological outcomes (anthropometry, cardiovascular fitness, physical activity habits, self-esteem), which were sustained at 12 months from baseline. The high attendance and low drop-out rates suggest that families found this intensive community-based intervention acceptable. Further studies are currently underway to confirm the promising findings of this trial.

Acknowledgements

I am extremely grateful to my PhD supervisors, Professor Atul Singhal, Dr. Margaret Lawson and Professor Tim Cole, for providing support and guidance throughout the PhD process.

Much gratitude goes to Maria Kolotourou, a very dear friend and the trial research assistant, for her dedication, tireless work, support and encouragement.

I wish to express a special acknowledgement to David Hodgson and the rest of my family who provided emotional support and motivation to continue with my studies.

I would also like to extend my gratitude to Harry MacMillan and other colleagues at MEND for their continued support and for allowing me to have some time out of the office to dedicate to the completion of this thesis.

Many thanks go to Vanessa Shaw for approving my secondment from Great Ormond Street Hospital for Children NHS Trust to the MRC Childhood Nutrition Research Centre UCL Institute of Child Health to conduct the RCT.

The MEND RCT was gratefully supported by a Researcher Development Award in 2004 from the National Institute of Health Research. Additionally, financial and non-financial support (e.g., staff and venues) were provided by the following organisations: Sainsbury’s Supermarkets Ltd., Bromley Mytime, Bromley Primary Care Trust (PCT), Great Ormond Street Hospital for Children NHS Trust, London Borough of Lewisham, MEND Central Ltd., New Cross Gate New Deal for Communities, Parkwood Leisure, Southwark PCT, The Lewisham Hospital NHS Trust, UCL Institute of Child Health, and Waveney PCT.

Ultimately, this trial could not have been completed without the participating families. I would like to personally thank all the children and parents for their time, patience and enthusiasm.

This thesis is dedicated to my Grandparents who sadly passed away before completion of my PhD. I know they would be proud of me.

Glossary of abbreviations

ADA	American Dietetic Association
BF%	Body Fat percentage
BIA	Bioelectrical impedance analysis
BME	Black and Minority Ethnic
BMI	Body Mass Index
bpm	beats per minute
CDC	Centers for Disease Control and Prevention
CI	Confidence Interval
cm	centimetres
COMA	Committee on Medical Aspects of Food Policy
CVD	Cardiovascular Disease
d	day
DEXA	Dual-energy X-ray absorptiometry
DH	Department of Health
DISC	Dietary Intervention Study in Children
DRV	Dietary Reference Values
EAR	Estimated Average Requirement
EFSA	European Food Safety Authority
ERV	Energy Reference Value
FAO	Food and Agriculture Organisation
FBBT	Family-Based Behavioural Treatment
FDA	Food and Drug Administration
FSA	Food Standards Agency
FFM	Fat-Free Mass
FM	Fat Mass
GP	General Practitioner

HD	High Density Lipoprotein
HFFM	Fraction of FFM that is water
hr	hour
HSE	Health Survey for England
IASO	International Association for the Study of Obesity
ICER	Incremental Cost-Effectiveness Ratio
IOTF	International Obesity Taskforce
kcal	kilocalories
kg	kilograms
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LDL	Low-Density Lipoprotein
LEAP	Live, Eat and Play
m	metre
m^2	square metre
MEND	Mind, Exercise, Nutrition, Do it!
mg	milligrams
MK	Maria Kolotourou
ml	millilitres
mmHg	millimetres of Mercury
mmol	millimoles
MREC	Metropolitan Multi-Centre Research Ethics Committee
MORI	Market and Opinion Research International
n	sample size
NAO	National Audit Office
NCMP	National Child Measurement Programme
NDNS	National Diet and Nutrition Survey
NHLBI	National Heart, Lung and Blood Institute

NHMRC	National Health and Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
Ob gene	Obese gene
OECD	Organisation of Economic Co-operation and Development
P	p-value
PCT	Primary Care Trust
PE	Physical Education
PS	Paul Sacher
QALY	Quality Adjusted Life Year
R&D	Research and Development
RCT	Randomised Controlled Trial
SCOTT	Scottish Childhood Overweight Treatment Trial
SD	Standard Deviation
SEC	Socioeconomic Circumstances
SEP	Socioeconomic Position
SHA	Strategic Health Authority
SIGN	Scottish Intercollegiate Guidelines Network
SOP	Standard Operating Procedures
TBW	Total Body Water
TG	Triglycerides
TV	Television
UCL	University College London
UK	United Kingdom
WHO	World Health Organisation

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Chapter 1 Background and Introduction

1.1 Background

Childhood obesity is one of the most serious public health issues currently facing society. The number of affected children has dramatically increased over recent years, and despite extensive research in this field, no effective solutions have been found to date.

The current trial was motivated by a private ambition to tackle this growing problem, owing to a personal history of childhood obesity. I decided to train as a dietitian, and spent 11 years in the NHS working with individual children and their parents. Owing to the scale of the childhood obesity epidemic, a new approach was required. As an example, assuming 4 million (based on 30% of children in the UK) (Bridges and Thompson 2010) overweight and obese children are offered individual consultations for 30 minutes per month over the period of one year, three million days of consultations would be required, a service that would require 14,000 professionals working full-time. Individualised treatment is therefore not feasible, and with this in mind, I devised a group-based intervention in an effort to develop a scalable childhood weight management programme.

The MEND[1] programme was specifically created in 2001 to determine whether a scalable, community-based, multicomponent lifestyle intervention is effective in improving health outcomes in obese children. At the time of initial development (2001), no published national guidelines for the management of paediatric obesity were available.

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[1]MEND is an acronym and was originally developed in 2001. MEND stood for Mind, Exercise, Nutrition and Diet but due to feedback from children in this trial who felt uncomfortable with the word “Diet” printed on their t-shirts and programme resources, the word “Diet” was subsequently changed to “Do it!”

I developed the MEND concept, and acted as the Chief Investigator for both the feasibility and randomised controlled trials. The curriculum for the MEND intervention was developed by a multidisciplinary team, led by myself. Appendix 1 summarises my contributions to the field of childhood obesity.

This thesis provides a critical appraisal of the relevant childhood obesity literature and describes how the MEND intervention was developed, evaluated in the form of a feasibility trial and RCT, and subsequently implemented in diverse communities in the UK.

1.2 Introduction

Obesity is a complex disease caused by a wide range of factors. At a basic level, people gain weight by consuming more calories than expended over a prolonged period of time. Excess calories accumulate and are stored by the body as fat, leading to overweight and obesity. Several variables, including biological, behavioural and societal influences, increase the likelihood of excessive weight gain. Childhood obesity is currently a major public health issue, as evident from the numerous academic and governmental publications related to this topic and reports of its frequent occurrence in the media and press. Effective, replicable and scalable interventions are thus urgently required to treat the millions of children affected by this serious medical condition.

Data on the prevalence and future projections of the childhood obesity epidemic are presented in the next section.

1.3 Prevalence and future projections

1.3.1 Prevalence

International

The prevalence of overweight and obesity is escalating worldwide in both developed and developing countries. A recent analysis of the global (144 countries) prevalence of overweight and obesity in preschool children (< 5 years) showed that in 2010, 43 million children (35 million from developing countries) were estimated as overweight and obese, while 92 million were at risk of overweight. The prevalence of preschool childhood overweight and obesity increased from 4.2% (95% CI: 3.2%, 5.2%) in 1990 to 6.7% (95% CI: 5.6%, 7.7%) in 2010 (de Onis, Blossner *et al*. 2010).The worldwide childhood obesity problem varies significantly across countries, owing to the different characteristics of populations, lack of data and methodological issues (Wang and Lobstein 2006). Interesting illustrations of the increasing global prevalence of overweight in children and adolescents have been published by the International Association for the Study of Obesity (IASO) (shown in Figures 1-6). Recent evidence additionally indicates that that while childhood obesity rates are plateauing, the rates and numbers of affected children remain alarmingly high (Rokholm, Baker *et al*. 2010; Olds, Maher *et al*. 2011).

Figure 1. Global prevalence of overweight in boys (prior to 1990)

Image removed for copyright reasons

Source: www.iaso.org/publications/trackingobesity/global-trends-childhood-overweight. Accessed in November 2012.

Figure 2. Global prevalence of overweight in boys (1990-1999)

Image removed for copyright reasons

Source: www.iaso.org/publications/trackingobesity/global-trends-childhood-overweight. Accessed in November 2012.

Figure 3. Global prevalence of overweight in boys (2000-2006)

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Source: www.iaso.org/publications/trackingobesity/global-trends-childhood-overweight. Accessed in November 2012.

Figure 4. Global prevalence of overweight in girls (prior to 1990)

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Source: www.iaso.org/publications/trackingobesity/global-trends-childhood-overweight. Accessed in November 2012.

Figure 5. Global prevalence of overweight in girls (1990-1999)

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Source: www.iaso.org/publications/trackingobesity/global-trends-childhood-overweight. Accessed in November 2012.

Figure 6. Global prevalence of overweight in girls (2000-2006)

Image removed for copyright reasons

Source: www.iaso.org/publications/trackingobesity/global-trends-childhood-overweight. Accessed in November 2012.

In a recent publication by the Organisation of Economic Co-operation and Development (OECD), the estimated prevalence of overweight and obesity among children aged 5-17 years (based on the IASO definition for overweight/obesity) varied from 4.5% (Chinese girls) to 45% (Greek boys) (Figure 7). The report additionally revealed that one in five children across all countries were affected by excess adiposity, and in most countries (with some exceptions, including the UK), higher rates were observed in boys than girls (OECD 2011).

Figure 7. Latest available estimates of overweight and obese children aged 5-17 years

Image removed for copyright reasons

Source: OECD 2011

United Kingdom (UK)

Currently, the two most widely available sources of data in the UK for the calculation of childhood overweight and obesity prevalence are the Health Survey for England (HSE) and National Child Measurement Programme (NCMP). Both datasets use the 85^{th} (overweight) and 95^{th} (obese) BMI percentiles of the 1990 reference population (Cole, Freeman *et al*. 1995) (see Section 1.5) for classification of overweight and obese, respectively.

Health Survey for England (HSE)

The HSE presents a cross-sectional survey of health and health-related behaviours in adults and children in England. Since 1993, HSE datasets have been produced annually. HSE comprises a series of core elements that are included every year and specific topics that are included in selected years. Core childhood topics include general health, fruit and vegetable consumption, height and weight (BMI).

According to the most recent Health Survey for England (HSE 2010) (Bridges and Thompson 2010), mean BMI was similar for boys and girls (18.2 kg/m^2 and 18.3 kg/m2, respectively), while 17% boys and 15% girls aged 2-15 were classified as obese, and 31% of boys and 29% of girls as either overweight or obese (Figure 8). Older children (11-15 years of age) were more likely to be obese, compared to younger age groups (2-10 years).

Figure 8. Mean BMI for children aged 2-15 in relation to age and gender

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Taken from the Health Survey for England (2010) publication (Bridges and Thompson 2010).

Children aged 11-15 years (20% boys and 17% girls) were more likely to be obese than those aged 2-10 years (15% boys and 14% girls) (Figure 9).

Figure 9. Overweight and obesity prevalence of children aged 2-15 in relation to age and gender (1995-2010)

Image removed for copyright reasons

Taken from the Health Survey for England (2010) publication (Bridges and Thompson 2010).

Figure 9 depicts the trends in mean BMI and the prevalence of overweight and obesity between 1995 and 2010 for children aged 2-15 in the UK. For boys, mean BMI increased by 0.5 kg/m^2 (from 17.7 kg/m^2 to 18.2 kg/m^2). Among girls, mean BMI in 2010, recorded as 18.3 kg/m^2, was not significantly different from that in 1995, although increases were recorded in the intervening period.

Figure 10. Overweight and obesity prevalence of children aged 2-15 in relation to age and gender (1995-2010)

Image removed for copyright reasons

Taken from the Health Survey for England (2010) publication (Bridges and Thompson 2010).

As depicted above (Figure 10), between 1995 and 2010, obesity in boys increased from 11% to 17% and that in girls from 12% to 15%. However, the pattern of increase was not uniform over this time. The period until 2004 and 2005 saw steady increases in the prevalence of obesity, followed by differences for boys and girls. Among boys, the obese proportion remained between 16% and 19% from 2001 onwards. Among girls, the pattern was slightly different, with a significant decrease in obesity between 2005 and 2006 and similar levels between 2006 and 2010.The lack of significant changes in the proportion of obese children over the last four to five years suggests that the trend in obesity may be stabilising.

Similarly, a study in the USA reported no significant changes in the prevalence of high BMI for age among children and adolescents between 2003-2004 and 2005-2006 (Ogden, Carroll *et al*. 2012).The authors of the HSE have highlighted the importance of monitoring trends in the future using HSE data to confirm that this is a continuing pattern in England, and not just a plateau within a longer-term trend of a more gradual increase.

Analysis of the HSE 2010 data additionally revealed differences in the proportion of obese children when adjusted for equivalised household income. Children in the highest income quintiles were the least likely to be obese (14% in the highest two quintiles for boys and 12%-13% in the highest three quintiles for girls), and obesity was most likely in children in the lowest quintiles (20% in the lowest quintile for boys and 17%-18% for girls).This is a common finding, consistent with earlier studies showing that childhood obesity is more prevalent among older children and lower income households(HSE 2006; Stamatakis, Zaninotto *et al*. 2010; El-Sayed, Scarborough *et al*. 2011; van Stralen, te Velde *et al*. 2012).

Earlier analysis of HSE data (2008) focusing on physical activity and fitness revealed that physical activity levels decrease with age and no more than 45% of the population at any age achieved the government recommendations for physical activity, with more boys meeting this target for all age groups (Figure 11). The average time spent on physical activity was higher for boys than girls (10.8 hr/week for boys versus 8.7 hr/week for girls), and this discrepancy was more obvious with increasing age, as activity time was significantly reduced in girls. Girls were found to walk more, while boys participated in more informal activities (90% for boys and 86% for girls) and formal sports (49% for boys and 38% for girls).

Figure 11. Proportion of children meeting government recommendations for physical activity in relation to age and gender

Image removed for copyright reasons

Source: HSE 2008

In 2010, the National Observatory for Obesity (NOO) published a recent report on physical activity as a determinant of childhood obesity using data from the HSE 2008, National Travel Survey, Annual PE and Sport Survey, and the School Census (NOO 2010). This report additionally highlighted the direct relationship between physical activity and social class, as indicated by household income. Specifically, children from poorer households appear to spend less time on physical activity, compared to their counterparts from households of higher income. Data from objectively measured physical activity (based on 7-day accelerometry), shown in Figure 12, further supported the gender differences in physical activity levels as well as the alarming failure to meet the government's recommendations for physical activity with increasing age.

Figure 12. Objective summary of activity levels (children aged 4-15 years) with 7 days valid accelerometry

Image removed for copyright reasons

Source: NOO 2010

Another interesting finding was the steep increase in sedentary activities with increasing age, starting at 2 years and peaking at 15 years, whereby 30% of children spent 6 h/day or more in sedentary activities on weekdays and 40% on weekends. Finally, promising results from the PE and Sport Survey showed that the percentage of children participating in at least 120 minutes of PE per week gradually doubled from 44% in 2003/4 to 86% in 2009/10 (Figure 13). Another encouraging finding from HSE 2007 was that a significant percentage of children aged 11-15 years, especially girls, expressed a wish to increase their levels of physical activity during the day (NOO 2010).

Figure 13. Proportion of children in Years 1-11 (aged 5-16) participating in at least 120 minutes of curriculum PE per week (2003/4 to 2009/10)

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Source: PE and Sport Survey 2008/09, 2009/10. Department of Children, Schools and Families.

National Child Measurement Programme (NCMP)

NCMP is an annual programme that measures the heights and weights of children aged 4-5 years (Reception) and 10-11 years (Year 6) in England. The 2010/11 NCMP represents the fifth year of assessment after incorporation of this system (DH 2011), and contains the largest number of child measurements collected to date by the programme, specifically, 1,036,608 measurements of children from state-maintained schools. Overall participation in NCMP was 92.6% in 2010/11, which was the highest ever achieved. This high rate of participation dramatically narrowed the confidence intervals, thus minimising the chance of potential errors in prevalence rates. However, it should be noted that there is a high risk of bias due to the issue of selective opt-out. Overweight and obese children are more likely to be self-conscious about their weight and therefore sensitive to the measurement process. In addition, parent's may fear upsetting their children by allowing school nurses to weigh them, or may not be ready to face the issue that their child is either overweight or obese. For these reasons, it is possible, that the 7.4% of missing data may consist of a higher proportion of overweight and obese children therefore skewing the overall prevalence rates downwards at both Reception year and Year 6. Further efforts should be made to ensure that all children are measured as part of the NCMP in order to obtain accurate prevalence rates. Accurate NCMP prevalence rates will provide much needed data to establish yearly changes in UK childhood overweight and obesity levels.

According to this study, the combined prevalence of overweight and obesity at Reception year was 22.6% (around one in five children) and 33.4% at Year 6 (around one in three children). The prevalence of obesity in Year 6 was over twice that in Reception (19% versus 9.4%). A higher number of boys than girls were classified as obese in both year groups.

Another interesting observation was that in the Reception year, prevalence of overweight was higher than that of obesity (13.2% for Reception versus 9.4% for Year 6), whereas in Year 6, the converse was observed (14.4% for Reception versus 19% for Year 6). More girls than boys were classified as healthy weight among both Reception (77.9% girls versus 66.6% boys) and Year 6 children (75% girls versus 64% boys). In terms of location, South Central Strategic Health Authority (SHA) had the lowest prevalence of obesity (8.1% and 16.5% for Reception and Year 6, respectively), while London SHA had the highest prevalence (11.1% and 21.9% for Reception and Year 6, respectively). Similar trends were observed for urban areas, which had higher obesity rates, compared to town and village areas. Interestingly, HSE 2010 revealed no differences in children across different SHAs in terms of prevalence of obesity or BMI (Bridges and Thompson 2010).

As expected, more deprived areas were associated with greater prevalence of obesity, and the discrepancy was more pronounced among the older children (Reception year: 12.1% in the most deprived areas versus 6.9% in the least deprived areas; Year 6: 23.7% in the most deprived areas versus 13.8% in the least deprived areas). Ethnicity additionally affected the prevalence of obesity. In particular, significantly higher rates of obesity were recorded in children from the "Asian or Asian British", "Any other ethnic group", "Black or Black British" and "Mixed" groups, compared to the national average.

Comparison of NCMP 2010/2011 data with earlier years

The gender-specific prevalence of overweight and obesity and mean BMI z-scores by year of measurement in Reception and Year 6 are compared in Figures 14 and 15 respectively. The most significant finding was that the prevalence of overweight and obesity in Reception year was lower in 2010/2011 (22.6%), compared to 2009/2010 (23.1%) and 2006/2007 (22.9%). In Year 6, the proportion of obese children was higher in 2010/2011 (19%), compared to 2009/2010 (18.7%) and 2006/2007 (17.5%). Finally, the prevalence of combined overweight and obesity was similar to that in 2009/2010 (33.4% in both years) and higher than 2006/2007 (31.6%) (Figure 16).

Figure 14. Prevalence of obesity (with 95% confidence limits) in relation to year of measurement, school year and gender

Image removed for copyright reasons

Taken from NOO NCMP: Changes in children's BMI between 2006/07 and 2010/11(DH 2011).

Figure 15. Mean BMI z-score (with 95% confidence limits) in relation to year of measurement, school year and gender

Image removed for copyright reasons

Taken from NOO NCMP: Changes in children's BMI between 2006/07 and 2010/11 (DH 2011).

Figure 16. Prevalence of underweight, overweight, obese, and combined overweight and obese children in relation to NCMP year and school year

Image removed for copyright reasons

Taken from NOO NCMP: Changes in children's BMI between 2006/07 and 2010/11 (DH 2011).

1.3.2 Future projections

According to the Foresight Report, around 14% of the under 20s in the UK are predicted to be obese by 2025, which should increase to 25% by 2050 (Figure 17) (DH 2011). A recent publication indicates that if the current trends persist, the percentage and numbers of overweight and obese children in the UK will considerably increase by 2015,with further widening of the gap between manual and non-manual classes (Stamatakis, Wardle *et al*. 2010). Globally, for preschool children, this prevalence of obesity is expected to reach 9.1% (95% CI: 7.3%, 10.9%) or 60 million by 2020 (de Onis, Blossner *et al*. 2010). However, despite the observed plateau in the prevalence of childhood overweight and obesity in many countries, there are no signs of reversing of the epidemic, and rates remain extremely high (DH 2011).

Figure 17. Forecast trend in the proportions of overweight and obese adults and children from 1993 to 2050

Image removed for copyright reasons

Taken from the Cross-Government Obesity Unit publication (DH 2011).

Conclusions

The current escalating prevalence of childhood obesity and alarming future projections underline the urgent need for effective solutions for this serious public health issue.

1.4 Definition of obesity

Obesity is defined as the condition of excessive accumulation of fat to the extent where it impairs health by increasing the risk of morbidity and/or mortality (Reilly 2005).

Fat accumulation occurs with positive energy balance, i.e., when energy intake exceeds energy expenditure. This condition can result from increased energy intake, reduced energy expenditure or a combination of the two factors. Positive energy balance does not have to be considerable to lead to weight gain. Accumulation of small daily positive balances causes an increase in body weight over time.

For instance, in theory, increasing daily energy intake by 100 kcal (e.g., eating an extra slice of bread per day) can cause an increase in body weight of approximately 4.5 to 5 kg over a year if dietary intake and physical activity levels remain unchanged. Therefore, prolonged small positive energy balance, especially in combination with decreased physical activity, rapidly leads to increased body weight, and eventually, obesity (Maffeis 2000).

Different measures for assessing obesity have been suggested. Weight, percentage above ideal weight, body mass index (BMI), waist circumference and body fat percentage are the most widely used adiposity indicators to date. Among these, BMI is the most common tool, providing a reliable measure for assessing weight status in both adults and children.

1.5 Measures of weight status and body composition

1.5.1 Body mass index (BMI)

In adults, BMI values between 25 and 29.99 kg/m^2 indicate overweight, while those above 30 kg/m^2 signify obesity. BMI values between 30 and 34.99 kg/m^2, 35 and 39.99 kg/m^2 and above 40 kg/m^2 are grouped as Class I, II and III obesity, respectively. These cut-off values are lower for specific ethnicities, such as Asians, where metabolic syndrome has been reported at a lower BMI, relative to Caucasian populations.

1.5.2 BMI, BMI growth charts and z-scores in children

BMI provides an easy-to-measure indication of a child's weight status, similar to adults, and is used in clinical practice to categorise individuals as underweight, healthy weight, overweight or obese. BMI is used in preference to weight alone, since at any given age, it takes into account (effectively removing) variations in weight attributable to differences in height. BMI is also a valuable tool for short-term evaluation following childhood weight management programmes where only small changes are likely to occur as a result of growth.

To assess BMI status when monitoring children over the long-term, it is important to take into account their age, gender and natural growth patterns. Consequently, BMI growth charts have been developed. The expected changes in BMI or weight for a child according to age and gender can be predicted by examining the respective growth charts.

Each country should apply BMI charts constructed using data from their own representative paediatric population, since different populations have different growth patterns. The most commonly used growth charts and cut-offs for the assessment of childhood obesity include:

World Health Organisation (WHO) BMI growth charts (de Onis, Onyango *et al*. 2007) published in 2007. The representative sample included children from Brazil, Ghana, India, Norway, Oman and the United States for the 0-5 year growth charts. For the 5-19 year growth charts, data from the National Centre for Health Statistics (USA) were used. The cut-offs used to define overweight and obesity are the 85th and 95th centiles, respectively.

Centre for Disease Control (CDC) BMI growth charts (Kuczmarski, Ogden *et al*. 2002) published in 2002. The sample consisted of children participating in national US surveys. The cut-offs used to define overweight and obesity are the 85th and 95th centiles, respectively.

International Obesity Task Force (IOTF) BMI growth charts (Cole, Bellizzi *et al*. 2000). These growth charts introduced international cut-offs for obesity that facilitated cross-country comparison of obesity prevalence. The cut-offs for overweight and obesity were devised to correspond to the adult cut-off points of 25 kg/m^2 and 30 kg/m^2 at 18 years.

UK BMI growth charts (Cole, Freeman *et al*. 1995) based on a national UK sample. In this case, the cut-offs used to define overweight and obesity in clinical practice are the 91st and 98th centiles, respectively. The corresponding percentiles for epidemiological use are 85th and 95th to define overweight and obesity, respectively.

1.5.3 Adjusting for changes in BMI due to natural growth over time

The natural pattern of growth for a child is to continue along the same percentile for BMI, i.e., we would expect a child at the 50th percentile at age 7 years to remain at this centile at 10 years of age.

Increases in BMI and weight over time represent changes that occur due to natural growth. However, it is important to note that the magnitude of BMI and weight changes that represent natural growth differ over time, depending on the age, gender and weight status (percentile) of a child. Consequently, monitoring weight status using raw BMI or weight values will not provide a true indication of the success of a childhood weight management programme or allow meaningful interpretation of changes between individuals and groups.

The z-score[2] presents an appropriate tool to measure the long-term effects of child weight management programmes. BMI z-score is a preferable measurement to weight z-score, as it accounts for differences attributable to increase in height. The z-scores effectively provide a unit to represent the percentile on growth charts, e.g., 50th percentile equals a z-score of 0 units, 70th percentile a z-score of 0.524 units, and 95th percentile a z-score of 1.645 units. In the UK, the BMI z-score cut-offs are 1.33 and 2 for overweight (91st centile) and obesity (98th centile) (Cole, Freeman *et al*. 1995), and values above 3.5 and 4 are classified as severe and extreme obesity, respectively (SIGN 2010). The

[2] A z-score (or standard deviation score) indicates the distance (measured in standard deviations) a data point is from the mean of the reference population for their age and gender.

corresponding figures for WHO and CDC growth charts are 1.036 for overweight (85^{th} centile) and 1.645 (95^{th} centile) for obesity.

The key to understanding z-scores is based on two main principles:

1. If the BMI of a child increases at the rate expected due to growth for their gender, age and weight status, i.e., continuing along the same percentile, z-scores remain the same. For example, if a boy displays increased BMI but stays at the 95^{th} percentile at 9, 10 and 11 years of age, his BMI z-score would be 1.7 at all time-points.

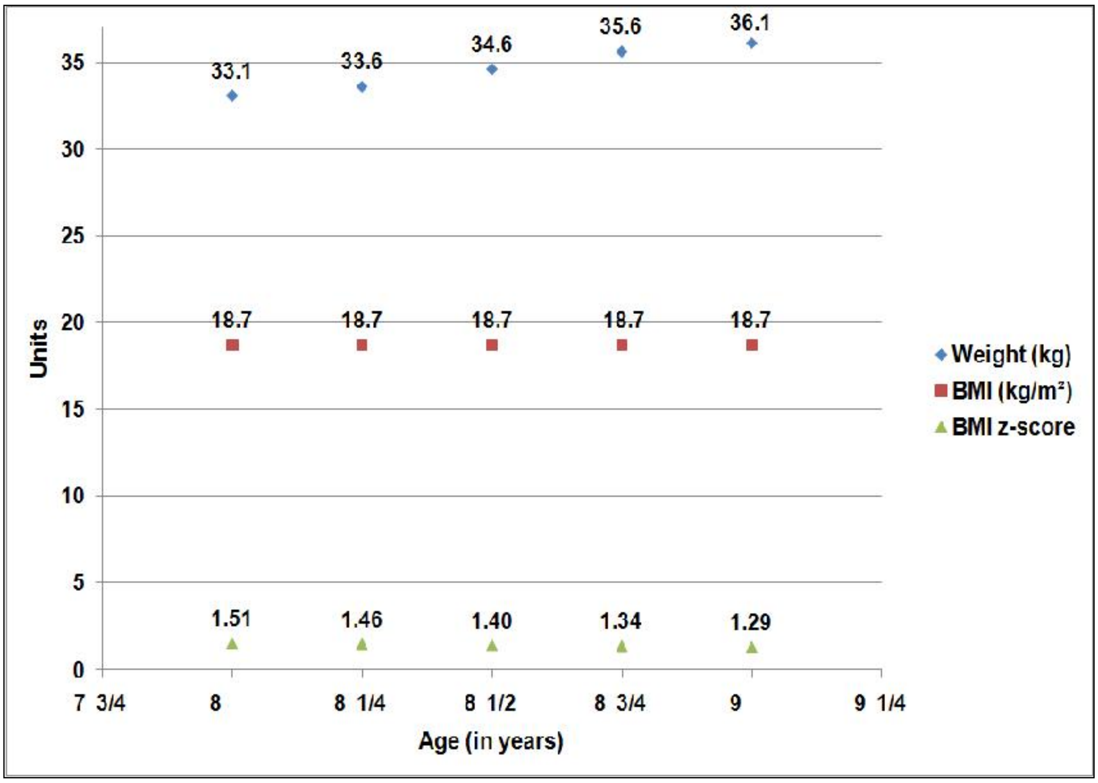
2. The z-score for a child of any given age or gender remains the same if they are at the same percentile. For example, the BMI of a 7-year old boy at the 98^{th} percentile is 19.5 kg/m^2 and that of a 9 year old girl at the 98^{th} percentile is 22.2 kg/m^2. Although these two children have different BMI values, ages and genders, their BMI z-scores are similar (i.e. 2.1).

Therefore, z-scores allow the meaningful evaluation and comparison of both individual and groups of children of different genders and ages. The utility of z-scores when monitoring a child participating in a weight management programme is clearly evident when considering the example presented in Figure 18.

In this case, changes over a one-year period for an 8-year old boy participating in a weight management programme are presented. His weight increased by 3 kg over the year, but his BMI remained constant, because his height also increased by 6 cm. These data do not represent a true indication of changes in his weight status or the success of the programme, since weight and BMI do not take into account changes that occur during growth.

The BMI z-score enables us to determine the rate of BMI change, taking into account what would normally be expected due to growth for gender, age and weight status. In this instance, the BMI z-score of the boy is reduced at each measurement point. The decrease in the BMI z-score indicates that his BMI has decreased in relation to the expected increase due to growth, and thus the programme has been successful in improving his weight status.

Figure 18. Changes in weight, BMI, and BMI z-score over a one-year period for a fictitious eight-year old boy participating in a weight management intervention



Based on unpublished work by Radley et al. (2010).

The issue of assessing change in weight status is further complicated and Cole *et al.* have suggested that for younger children the use of raw BMI is a better tool for assessing short term changes in adiposity compared to BMI z-score or percentage BMI. This is due to the fact that BMI units for obese children result in larger percentage changes compared to leaner individuals and centile curves are further apart for higher centiles due to the skewness of the BMI distribution (Cole, Faith *et al.* 2005). For older children, Hunt *et al.* have suggested that changes in BMI z-score may better reflect percentage fat loss compared to raw BMI (Hunt, Ford *et al*. 2007). However, according to a summary of evidence for the US Preventive Services Task Force conducted by Whitlock *et al.*, although BMI is recognised as a relative measure of weight rather than body fat, it remains the recommended method to determine overweight among children and adolescents. Despite the lack of data to determine clinically significant levels of overweight and obesity, BMI is recommended as the best adiposity proxy currently available for children of all ages due to the fact that it tracks reasonably well from childhood to adolescence and from adolescence to young adulthood. (Whitlock, Williams *et al.* 2005).

1.5.4 Clinical application of BMI

BMI is a useful substitute for total adiposity and an easy, rapid and cost-effective form of measurement. Indeed, for the general population, BMI adequately represents total body fat (Pietrobelli, Faith *et al*. 1998; Phan, Maresca *et al*. 2012). However, this index is not as sensitive for children who are overweight or obese, and does not provide an indication of body fat distribution and abdominal fat (Savva, Tornaritis *et al*. 2000; Brambilla, Bedogni *et al*. 2006).

Central adiposity is more strongly related to cardiovascular disease and metabolic risk factors in children than total adiposity (Savva, Tornaritis *et al*.

2000; Janssen, Katzmarzyk *et al*. 2004; Rudolf, Greenwood *et al*. 2004; Janssen, Katzmarzyk *et al*. 2005; McCarthy, Cole *et al*. 2006).

Moreover, over the past two decades, visceral obesity, measured using waist circumference, among British children has increased to a greater extent compared to BMI, suggesting that BMI measurements alone are insufficient for assessment of obesity (McCarthy, Ellis *et al*. 2003; Rudolf, Greenwood *et al*. 2004).

1.5.5 Waist circumference and waist circumference z-score in children

Waist circumference is a cost-effective, practical and easy-to-measure indicator of abdominal fat (Rudolf, Greenwood *et al*. 2004; Ness-Abramof and Apovian 2008), although its use as a practical tool for this purpose is controversial. However, encouraging evidence associating waist circumference with several cardiovascular disease and metabolic syndrome risk factors (Leibowitz, Moore *et al*. 2009; l'Allemand-Jander 2010) has resulted in the development of waist circumference growth charts for several populations (Schwandt, Kelishadi *et al*. 2008; Galcheva, Iotova *et al*. 2009; Poh, Jannah *et al*. 2011), including children in the UK (McCarthy, Jarrett *et al*. 2001).

In both research and clinical practice, a combination of waist circumference and BMI is currently considered the best method to assess children's weight status, as the combined measurement provides information on overall adiposity status and indication of abdominal fat (Savva, Tornaritis *et al*. 2000; McCarthy, Jarrett *et al*. 2001; Janssen, Katzmarzyk *et al*. 2004; Rudolf, Walker *et al*. 2007; Aeberli, Gut-Knabenhans *et al*. 2012). The purpose of performing both measurements is to identify children at risk due to increased adiposity and optimise assessment of the effectiveness of obesity treatment programmes (Janssen, Katzmarzyk *et al*. 2005; McCarthy, Jarrett *et al*. 2005).

The issue of how waist circumference can be measured accurately (especially in severely obese individuals) is under debate (Reilly, Kelly *et al*. 2010), and other concerns regarding the use of appropriate cut-off points according to different populations and ethnicities have been highlighted (SIGN 2010; Glasser, Zellner *et al*. 2011). In addition, waist circumference measures subcutaneous rather than intra-abdominal fat, raising doubts about its suitability for use in paediatric populations (Bosy-Westphal, Booke *et al*. 2010). Despite these issues, waist circumference remains a practical anthropometric measurement before and during weight loss treatment, as it provides a proxy measure of abdominal fat and is easily obtained (NHLBI 1998; Chiavaroli, Giannini *et al*. 2012).

A recent study by Ross and colleagues showed that the measurement protocol for waist circumference does not substantially affect its association with all - cause and cardiovascular disease mortality and diabetes (Ross, Berentzen *et al*. 2008). However, earlier investigations suggest that the protocol followed and its standardisation influences research findings and affects results, particularly in women (Mason and Katzmarzyk 2009; Mason and Katzmarzyk 2009). As long as the protocols are carefully selected and implemented, individuals performing the measurements are meticulously trained, and standard operating procedures are always followed on site, it appears unreasonable to exclude a measure that can easily and inexpensively provide supplementary information on body composition in children.

For this reason, an increasing number of paediatric obesity interventions have started to include the waist circumference measurement, (NHMRC 2003; McCarthy 2006; Benfield, Fox *et al*. 2008). Another notable point is that discrepancies in measurements in children have a relatively small impact on the corresponding z-scores due to the inherent characteristics of waist circumference growth charts. More precisely, higher centiles of waist circumference growth charts are further apart, compared to lower centiles, resulting in small differences for larger discrepancies among children with increased waist circumference (Rudolf, Walker *et al*. 2007).

A study has reported that monitoring waist circumference in addition to BMI z-score provides a useful tool for assessing children and adolescents at increased risk for cardiovascular disease risk factors (Tybor, Lichtenstein *et al*. 2011). Therefore, close adherence to a well-designed protocol and proper training (ideally, performance of measurements by the same individual) can minimise variability in waist circumference data, facilitating its application as an effective measurement of obesity (Rudolf, Walker *et al*. 2007).

1.5.6 Other methods of measuring body composition

Skinfold thickness measurement

Skinfold thickness has been used over a long period of time for the assessment of body composition. The advantages of the method include ease of use once training is complete, low cost, rapidity and non-invasiveness. Moreover, skinfold callipers are small, light and portable. The disadvantages include technical errors, especially when different people perform the measurements, unsuitability for use in very lean or obese individuals, and the fact that the method mainly provides a measure of subcutaneous fat, leaving visceral fat out of the equation. No scientific evidence is available supporting its validity as a predictor of body fat in children when BMI for age is known. Use of triceps and subscapular skinfold thickness and plotting on relevant growth charts is more often performed as a result of clinical judgment and expert panel recommendation. However, published evidence indicates that the use of skinfold thickness measurement is inappropriate and does not provide any additional information, compared to BMI percentiles, especially in overweight and obese children (Freedman, Wang *et al*. 2007; Mei, Grummer-Strawn *et al*. 2007; Semiz, Ozgoren *et al*. 2007).

Underwater weight measurement

Underwater weighing is based on the Archimedes principle assuming that muscles and bones are denser, whereas fat is less dense than water and therefore "floats" in it. The purpose is to assess body density and subsequently derive body composition using specific equations. The subject needs to be fully covered by water for the test to be performed. The volume of water displaced, combined with the weight of the subject, is used to derive values for fat and fat-free mass. Due to its accuracy at the time of conception, this technique was considered the "gold standard" for body composition assessment, even though it is only based on the two-component model. Recent advances in technology have allowed the development of more sophisticated methods. Some significant disadvantages of the procedure include the requirement for special equipment that takes up considerable space, its long duration, dependence on cooperation from understudy subjects and experience of the person delivering the test (Ellis 2000).

Air displacement plethysmography (Bod Pod)

Air displacement utilises the same principles as underwater weighing, but uses air instead of water. This is an advancement on the previous method, and body density is defined and used to calculate body composition. The procedure is better tolerated by subjects, less invasive, quicker and easier to implement, and applicable to a variety of subjects, including obese children, but still requires expensive, bulky equipment (Lee and Gallagher 2008).

Dilution techniques

According to this method, body weight is divided into fat-free and fat mass, and changes in total body water affect body composition. The method assumes that fat-free mass in healthy individuals is 73% water. Therefore, using a tracer dose of labeled water (tritium, deuterium, or oxygen-18) and collecting body fluid samples (blood, urine or saliva), the excretion rate of the tracers/isotopes after equilibration time can be employed to estimate body composition. As the more hydrated compartment, fat-free mass is initially estimated, and fat mass subsequently derived by subtracting fat-free mass from total body weight (Ellis 2000; Lee and Gallagher 2008).

Bioelectrical impedance analysis (BIA)

Bioelectrical impedance is used to estimate body composition based on the two-component model. The method involves measurement of body's impedance after transmitting a low voltage electric current. The underlying principle is that the body's two components manifest different impedance to current, i.e., fat-free mass has more water and is therefore a better conductor of electricity, whereas fat mass is less hydrated and a poorer conductor of electricity, with the basic assumption that 73% of body's fat-free mass comprises water. The main advantages of the method are that the equipment is portable, simply and rapidly performed, and requires minimal training, along with being relatively low-cost and safe for most individuals. The major disadvantage is that successful implementation of the method depends on individual compliance with specific guidelines that need to be followed prior to measurement (no food and fluid consumption hours before measurement, and no caffeine, alcohol intake and exercise 8-12 hours before measurement) and may be affected by diseases or other factors that influence body hydration (Lee and Gallagher 2008). Over the years, a number of studies have confirmed that when using the appropriate equations, BIA provides an effective means to assess body composition in overweight and obese children (Hosking, Metcalf *et al*. 2006; Wright, Sherriff *et al*. 2008; Haroun, Taylor *et al*. 2010).

Dual-energy X-Ray absorptiometry (DEXA)

DEXA assumes the body has three components: fat mass, bone-free fat mass and bone minerals. The method uses low radiation (1-10% of a chest X-ray) to estimate these three components for the whole body or partially for specific regions, and is the gold standard for assessing bone density. Additionally, DEXA is widely used for body composition assessment. The method has better accuracy than the two-component model methods (underwater weighing, Bod Pod, BIA) and good reproducibility, and can be used on a variety of subjects with exposure to only a very small amount of radiation. However, limitations include the requirement for large and expensive equipment and fact that the subject needs to stand still during the procedure (Lee and Gallagher 2008).

Other methods for body composition assessment

Other less frequently used procedures for body composition assessment include total body potassium method, neutron activation analysis, magnetic resonance imaging and computed tomography, applied occasionally in specialty centres mainly for research purposes (Ellis 2000).

Conclusions

The above sections provide a summary of the different methods employed for measuring body composition in children. Thus, in general, obesity in children is assessed using a variety of methods ranging from simple and inexpensive measurements applicable in community settings, such as BMI and waist circumference, to more sophisticated procedures, including DEXA, air displacement plethysmography, BIA and dilution techniques.

1.6 Causes of childhood obesity

The 2007 Foresight report on obesity by the Government Office for Science provides a comprehensive summary on the causes of obesity (Finegood, Merth *et al*. 2010).

The report suggests that obesity simply results from energy intake exceeding energy expenditure over a sustained period of time. However, this energy imbalance does not have a simple explanation, since there are many complexities in the ways people acquire and use energy. For the general population, the report argues *"…it is now generally accepted by health and other professionals that the current prevalence of obesity in the UK population is primarily caused by people's latent biological susceptibility interacting with a changing environment that includes more sedentary lifestyles and increased dietary abundance."* In theory, obesity results from an imbalance between energy intake and energy expenditure. However, the exact mechanisms underlying this process remain unknown. In fact, obesity reflects complex interactions between genetic, metabolic, cultural, socioeconomic and behavioural factors. The environment contributes significantly to these interactions and seriously affects eating and activity habits, owing to the ready availability of abundant food with low nutritional value, discouragement of physical activity and encouragement of sedentary activities, such as watching television or playing on computer games. Additionally, economic and cultural factors, perinatal development and practices are important contributors to the obesity epidemic (summarised in Table 1).

Table 1. Causes of obesity identified in research

Biology
- Humans have a powerful ‘hunger drive’ (a biological compulsion to search out food), and limited ‘sensitivity to abundance’ (feeling of having ‘had enough’ easily overridden by the sight or taste of food). - Genetic: a number of specific genes associated with obesity have been identified. However, evidence indicates no physiological differences between the slim and the obese, suggesting that biology is not the root cause of obesity.
Early life and growth patterns
- Higher weight gain soon after birth is associated with obesity in later life. - Breastfed babies have slower weight gain and are less likely to be obese.
Behaviour
- There is evidence of long-term reduction in energy expenditure: for adults because of employment patterns, car ownership and labour-saving devices; for children due to reduced walking and cycling to school and parental fears of outside play.
- Sedentary behaviours, in particular TV viewing, are a particular risk factor for obesity. - Consumption of energy-rich, high-fat and low-fibre food and sugar-rich drinks is a significant risk factor for obesity. - Complex psychological reasons underlie people’s food and activity-related behaviours. For instance, people form habits that are often triggered by environmental cues. There is reduced motivation to acquire new information that is inconsistent with habitual behaviour.

- Organisation cultures, social processes and the media play a significant role in cuing individual behaviour. For instance, organisations are responsible for the food available in the workplace or provide incentives for particular means of travel.
The living environment
- Advances in technology have tended to engineer physical activity out of the environment, for instance, decreasing the need to walk and undertake household labour, although no direct link to obesity has been shown. - Evidence of a relationship between physical activity and perceptions of our physical environment in terms of safety, aesthetics, and convenience has been reported. Residents of 'walkable' neighbourhoods tend to be more active and weigh less in general. - Food and drink access: some studies show that limited availability of high-quality, affordable 'healthy' food in a neighbourhood is associated with poor diet and obesity.
Economic drivers
- The price of food and drink frames the context in which consumer choices are made. Studies have shown that fruit and vegetables have increased as a component of food budgets, while fats and oils, starches and sugars have decreased. - Working practices: for adults, a correlation between longer working practices and higher obesity prevalence has been reported.

Taken from Tipping the Scales (2011).

Evidently these factors do not manifest collectively in every obese individual. Each person has their own circumstances and causal pathways that lead to increased body weight. Identification of the specific factors for individuals is the job of researchers and health professionals, as the only way to effectively combat the condition is to specify the underlying causes, which often constitute the starting point that can lead to a feasible solution. However, given the complexity of the factors involved and their interrelationships, the puzzle of obesity aetiology is often difficult to assemble for each individual, and even when deciphered successfully, the route leading to its solution can prove highly challenging.

1.6.1 Genetic factors

In 1994, identification of the obese gene (ob gene) and its protein product, leptin, resulted in the early hypothesis that defects in this gene are responsible for the obesity epidemic (Zhang, Proenca *et al*. 1994). Leptin is a hormone produced mainly by adipose tissue that acts in the brain by suppressing appetite, and consequently, food intake. However, leptin deficiency is a relatively rare condition, with very few reported cases (Bell-Anderson and Bryson 2004).

Since 1994, several obesity-related genes have been identified. In general, the condition seems to be polygenic, i.e., several genes act synergistically to increase the risk for obesity (Speiser, Rudolf *et al*. 2005; Wardle 2005), and only in exceptional cases, body weight is the result of a defect in a single gene (monogenic obesity). According to the most recent human obesity gene map, 460 genes, markers and chromosomal regions are associated with human obesity, supporting the multifactorial nature of the condition (Perusse, Rankinen *et al*. 2005). Additionally, recent studies have shown that that apart from effects on weight regulation and energy balance, genes indirectly influence the weight status by manipulating behaviour and leading to dietary or activity habits that promote weight gain, and ultimately, obesity (Wardle 2005).

Thus, genetics certainly plays a role, but this factor alone is unlikely to explain the current epidemic. A genetic predisposition to increased adiposity is relevant, but does not necessarily mean that the individual is destined to become or remain obese. This is particularly true for children, where weight management programmes are very important, as these can effectively help in the maintenance of healthy weight, regardless of their genetic background.

1.6.2 Diet and physical activity

Broadly speaking, the main environmental factors associated with obesity are diet and physical activity. These two elements represent the two sides of the energy balance equation, i.e., energy intake (diet) and energy expenditure (physical activity).

Diet

Diet becomes a factor in the equation of childhood obesity well before the child is even born. There is growing evidence that eating habits in pregnancy, *in utero* exposure to flavours, maternal weight before conception, weight gain during pregnancy and other factors, e.g., gestational diabetes, breastfeeding practices and introduction of solid foods, constitute important parameters affecting the risk of an individual becoming overweight or obese in childhood (Robinson and

Godfrey 2008; Kim, England *et al*. 2011; Martinez, Cordero *et al*. 2012; Oddy 2012; Spencer 2012; Trout and Wetzel-Effinger 2012).

During growth, the dietary factors resulting in childhood obesity relate to food quantity and quality. In particular, the shift towards large-portion high-calorie foods and drinks, which are abundantly available, encourages the consumption of energy-dense diets (Powell and Nguyen 2012). Furthermore, children have more unstructured eating patterns in the current times, due to increased home snacking and access to more money than in the past. The increased consumption of fast food, ready meals and the availability and/or price of healthy foods in supermarkets are believed to have a significant contribution to the high prevalence rates of childhood obesity (Wang, Ludwig *et al*. 2009; Lamichhane, Puett *et al*. 2012). Sugar-sweetened beverages and fruit juice are also a contributory factor to the increase in calorie intake, and hence increased weight, leading to suggestions for their replacement with water and whole fruits (de Ruyter, Olthof *et al*. 2012; Powell and Nguyen 2012; Wilson 2012).

On the other hand, measuring dietary intake in children is inherently complicated and the real overall picture of diet in children remains unknown (Lambert, Agostoni *et al*. 2004). Even with the numerous technological advances, there is no consensus on the best methodology that facilitates accurate reporting of children's eating habits. Diet records, 24-hour recalls, and food frequency questionnaires have specific advantages and disadvantages. Therefore, it is up to the individual researchers to decide which technique is best suited for their study population. However, the differential use of tools across studies makes it difficult to compare results, and consequently, draw conclusions on the real scenario. In fact, it is practically impossible to measure children's dietary intake under real-life conditions with no errors, especially in obese populations that are more prone to misreporting (Collins, Watson *et al*. 2010).

It is well established that measurement of dietary intake in children has serious misreporting implications. Under the age of 12, parents are the main source of information on children's eating habits. However, employment and everyday commitments often reduce parental control of food intake in children and undermine the accuracy of their reports. Furthermore, as children grow older, dietary intake remains unsupervised in many cases owing to increasing purchasing power and out-of-house food consumption, and is consequently unreported by parents (Livingstone, Robson *et al*. 2004; Collins, Watson *et al*. 2010). This, in turn, reduces the accuracy of dietary assessment in children, leading to significant misreporting of dietary intake. The situation becomes more complicated for obese children, as this group is characterised by higher rates of underreporting (Bandini, Schoeller *et al*. 1990; Fisher, Johnson *et al*. 2000; Lambert, Agostoni *et al*. 2004).

However most available evidence suggests that the energy and/or macronutrient composition of children's diet does not play an important role, as different combinations of macronutrient breakdown do not appear to have an effect on weight status (Rodriguez and Moreno 2006; Collins, Watson *et al*. 2010; Agostoni, Braegger *et al*. 2011; Elliott, Truby *et al*. 2011). Some studies have indicated benefits of macronutrient manipulation in obese children with metabolic syndrome, mostly as a result of reduction in total and saturated fat, free fructose and increase in antioxidants (Zimmermann and Aeberli 2008; Aeberli, Spinas *et al*. 2009).

The prevailing lack of association between diet and weight status may be masked by the known problem of increased underreporting among overweight and obese children, compared to their healthy weight counterparts, combined with the inherent issues in measuring dietary intake. However, despite these limitations, specific characteristics in children's diet appear to correlate with healthier weight status. For instance, increased intake of dietary fibre and slow-release carbohydrates and reduction in simple sugars, as well as structured eating patterns, age-appropriate portion sizes, regular family meals and limitation of fast food and frequent snacking may enable the maintenance of healthy weight in paediatric populations (Agostoni, Braegger *et al*. 2011).

Dietary assessment tools

Dietary assessment tools can be qualitative or quantitative and prospective or retrospective. The most commonly used tools for dietary assessment at present are 24-hour recalls (retrospective quantitative), food diaries (prospective quantitative) and food frequency questionnaires (retrospective qualitative), as summarised below.

Twenty-four hour recall

Twenty-four hour recalls are retrospective tools for assessing dietary intake. This method requires a trained interviewer to obtain information about all the foods and drinks consumed by the subject during the previous day. Multiple recalls (3 or 4 days, including weekdays and weekends) are considered good tools for the assessment of habitual dietary intake (Holmes, Dick *et al*. 2008). Single recalls are used in epidemiological studies with large samples, but are insufficient to assess individual dietary intake. Repeated dietary recalls provide detailed, qualitative information about the foods consumed, and since they are retrospective and relatively rapid, the method does not alter eating habits or require literacy from the subject. However recalls have certain disadvantages, as they rely on the subject's memory, portion estimation is not as precise as in weighed records, and the interviewers need to be sufficiently trained to ask all the necessary questions in a neutral way without directing the subject towards specific answers (Trabulsi and Schoeller 2001). It is suggested that the cognitive level in children does not allow them to effectively recall all the foods consumed on the previous day, especially before 8 years of age (Baranowski and Domel 1994; Livingstone, Robson *et al*. 2003). However, a recent review of the literature found that for children aged 4-11 years, 24-hour multiple pass recalls conducted over at least a 3-day period (including weekdays and weekends) using parents as proxy reporters of children's intake were the most accurate in estimating total energy intake in children (Burrows, Martin *et al*. 2010).

<u>Food diaries</u>

Food diaries are prospective quantitative tools used to assess individual habitual dietary intake. The individual is required to record all food and drink at the time of consumption. These diaries have been traditionally used in the United Kingdom for the assessment of dietary intakes in national surveys (e.g., National Diet and Nutrition survey) (Gibson 2010). Food diaries can be weighed or based on household measures (estimated) and last from a few days to a full week or more.

The 7-day weighed food diary was considered the gold standard method of dietary assessment until the doubly labelled method in 1990 revealed the problem of underreporting (Livingstone, Prentice *et al*. 1990; Schoeller 2002). Food diaries are beneficial in that they do not rely on memory, provide better measures of portions than recalls and record foods and drinks in considerable detail, allowing better estimates of energy and other nutrients. However, food records are time-consuming and subject to reporting bias, as individuals may alter their habits to complete the diary more easily or to generate more desirable results, particularly overweight or obese people. Moreover, this method requires literacy, motivation and compliance (Trabulsi and Schoeller 2001). Food diaries are still considered a good estimate of children's diet when completed by both the parents and children, depending on age (O'Connor, Ball *et al*. 2001; Burrows, Martin *et al*. 2010).

Food frequency questionnaires

Food frequency questionnaires are qualitative or semi-quantitative retrospective tools used for assessing food patterns. These surveys report the frequency of consumption of foods from a list over specific time-periods, both of which vary considerably. The method is quick and easy to complete, highlights infrequently consumed foods, and can target specific foods to provide information on micronutrient intake. Questionnaires are often used to investigate relationships between diet and disease, for e.g., extensive use has been recorded in the EPIC (European Prospective Investigation into Cancer and Nutrition) study (Ocke, Larranaga *et al*. 2009). Their use is more related to groups than individuals, as they allow response ranking but do not provide exact quantities of foods or nutrients (Andersen, Tomten *et al*. 2003). Moreover, this method relies on memory and retrospective portion estimation, grouping of foods can be problematic when analysing data, consumption of composite foods can affect the responses in some cases, and since the questions are closed and the list is limited, individuals may not be able to correctly translate their actual intake under the questionnaire's structure (Trabulsi and Schoeller 2001). In children, food frequency questionnaires have been successfully applied to estimate diet quality (Huybrechts, Vereecken *et al*. 2010), but not habitual intake (Burrows, Martin *et al*. 2010; Kobayashi, Kamimura *et al*. 2011).

<u>Physical activity and sedentary behaviours</u>

Apart from its contribution to energy balance for the maintenance of healthy weight, physical activity in youth is essential for overall health and wellbeing, and has a considerable impact on physical, social and emotional development.

Recent observations suggest that decreased physical activity levels in children substantially exceed the potential decrease in dietary energy intake. Therefore, a major cause of the observed childhood obesity epidemic may be physical inactivity, rather than increased energy intake (Livingstone and Robson 2000; Molnar, Torok *et al*. 2000; Sallis and Glanz 2006). This theory is reinforced by the proportion of children failing to achieve the recommended physical activity (60 minutes of moderate to vigorous activity per day) (NICE 2009).

As with diet, reduced physical activity in children starts early. Available evidence indicates that toddlers are significantly less active than those a few generations ago. This finding justifies the increased prevalence of overweight and obesity in preschoolers, which provides the basis for subsequent obesity maintenance or deterioration (Reilly 2008; Cox, Skouteris *et al*. 2012). Obesity established at such a young age persists easily as the child grows, leading to childhood, adolescent and adult obesity, along with all the potential co-morbidities. Moreover, growing children tend to maintain their eating and activity habits, and therefore, if reduced physical activity is present in the preschool period, the odds are that physical activity will become even more limited with age (Janz, Kwon *et al*. 2009). Indeed, research on the UK population has shown a continuous reduction in the physical activity of growing children to alarmingly low levels, particularly in adolescent girls (HSE 2008; NOO 2010).

Several, and in some cases, interrelated underlying factors contribute to low physical activity levels. For instance, increased time spent in sedentary activities (television viewing and computer use), automation (e.g., elevators, cars) and parental child safety and accessibility concerns are likely to have contributed to decreased physical activities among children over the years. In addition, given the overall low levels of physical activity, peer pressure to be active is particularly low, compared to playing video games or watching television (NICE 2009). Additionally, apart from the direct effect of physical activity on energy expenditure, children who exercise regularly tend to have better and more structured eating habits (Nelson, Stovitz *et al*. 2011), further supporting the link between low physical activity levels and childhood obesity (Sallis and Glanz 2006; Cox, Skouteris *et al*. 2012; De Craemer, De Decker *et al*. 2012). In practice, if a child stays at home for many hours sitting, studying, watching television or playing on the computer, opportunities to reach for food are inevitably increased. Boredom is often a trigger for increasing snacking on unhealthy foods, which links to comfort eating and all the associated implications on body weight and psychology. Physical activity helps the child to maintain insulin and glucose levels, thereby eliminating food cravings and allowing better control of glucose levels throughout the day (Tompkins, Moran *et al*. 2011).

Psychology is another area suggested to affect physical activity levels in youth (NICE 2009). Children with increased body weight often have low self-esteem, which discourages play with their healthy weight counterparts. Their perception of physical appearance and athletic competence can lead to abstinence from activities owing to fear of being bullied (Mitchell, Moore *et al*. 2012). Thus, these factors often prevent children from participating in free-living physical activities (Guinhouya 2012). Moreover, the increase in built-up environments has severely reduced opportunities for children to be physically active, compared to the past, including minimisation of basic activities, such as walking, taking the stairs, cycling or playing in the neighbourhood (Saelens, Sallis *et al*. 2003; Frank and Kavage 2009). These factors collectively create a vicious cycle that feeds low physical activity and fitness levels in youth and increases the rates of total and abdominal obesity (Ortega, Ruiz *et al*. 2010).

However, scientific evidence validating a decreasing trend in physical activity levels among children remains controversial. This is mainly attributed to the different methodologies used, such as self-reports and questionnaires versus accelerometry. Indeed, several studies have implemented different methods to assess physical activity levels, which, by design, require considerable input and cooperation from parents, and after a certain age, the child involved.

Accelerometry is currently considered the most accurate and objective method to measure physical activity, but is relatively expensive (although the prices have decreased over the last few years). Moreover, interpretation of accelerometry results can prove challenging and the method relies on full compliance of the participants with wearing the device at all times and places, which can prove difficult for children (NICE 2009; Ekelund, Tomkinson *et al*. 2011).

On the other hand, questionnaires and recalls have more limitations, as they rely on self-reporting and categorised sports, thus failing to capture daily or common unstructured activities. These methods rely on memory, which can be a serious burden, owing to inaccurate event recall and time estimates (Ekelund, Tomkinson *et al*. 2011). Additionally, the historical focus on moderate to vigorous physical activity has drawn attention to specific types of activities, leaving out of the equation important features of lifestyle activities in everyday life that may contribute importantly to weight status in children, such as light activities that can be performed more easily and are more sustainable than higher-level activities (Belanger, Gray-Donald *et al*. 2009; Marshall 2009).

Sedentary activities comprise the other part of the energy expenditure equation that contributes to the onset and maintenance of childhood obesity. The majority of studies refer to sedentary activity in terms of the time spent in front of the television, but other activities, such as studying, computers and video games, additionally take considerable time in the daily routines of children and should not be neglected. Television viewing and computer usage have been reported as factors that contribute to obesity in youth, both directly by promoting sedentary behaviour and indirectly by encouraging the consumption of large-portion, high-energy foods (Goran and Treuth 2001; Matheson, Killen *et al*. 2004; Buijzen, Schuurman *et al*. 2008; Pearson and Biddle 2011).

An additional indirect effect of television on energy balance is the impact of food advertisements on children’s nutritional intake, as the multicolour alternation of images promoting certain products, combined with the use of specific role models popular among the audience, make the products highly desirable (Guran and Bereket 2011). Parents often decide to give in to their children's demands for such products for various reasons, including lack of knowledge, pressure of peer consumption, or potential guilt for the limited time spent with their children as a result of work and other commitments.

The amount of food consumed has also been shown to increase after exposure to food-related advertisements (Halford, Boyland *et al*. 2008), and a considerable proportion of the daily energy intake in children occurs during screen time (Matheson, Killen *et al*. 2004). Indeed, 90% of the food advertisements relate to foods that are high in fat, sugar or salt (Guran and Bereket 2011). This observation, coupled with the finding that children are exposed to an estimated 10,000 advertisements per year (among which around 95% promote "junk food"), provides further support of links between television viewing and the escalating prevalence of childhood obesity (Schwartz and Puhl 2003; Guran and Bereket 2011).

Television viewing, computer usage and video games take up time that may be otherwise engaged in sports, active play or other more physical pursuits (Lambiase 2009). Television viewing has additionally been associated with reduced resting metabolic rate (Klesges, Shelton *et al*. 1993).However, these findings have not been confirmed by more recent studies (Cooper, Klesges *et al*. 2006; Jackson, Djafarian *et al*. 2009).

As both diet and physical activity are difficult to assess accurately, their precise roles in the aetiology of childhood obesity remain unknown. Indications of poorer diet quality and reduction in total energy expenditure provide a plausible explanation for the childhood obesity epidemic, although the underlying mechanisms are complex and multi-factorial.

1.6.3 Other suggested factors

Apart from the obvious contributions of diet and physical activity on weight status in children, additional risk factors associated with obesity in children are specified below.

Perinatal nutrition

Nutrition during pregnancy, *in utero* nutrition and early infant feeding practices contribute to the nutrition programming of obesity. There is growing evidence that perinatal nutrition is a serious risk factor for the development of childhood obesity. Interventions are therefore needed to target maternal obesity and the early years (Plagemann 2006; Das 2008).

Adiposity rebound

Adiposity rebound is the period around 6 years of age when BMI begins to increase after reaching its lowest point. Early adiposity rebound has been linked with greater risk for development of obesity in adolescence and early adulthood. Addressing obesity in the early years, before the adiposity rebound, may be an effective strategy for preventing later obesity (Williams and Goulding 2009; Campbell, Williams *et al*. 2011; Boonpleng, Park *et al*. 2012).

Socioeconomic circumstances (SEC)

The patterns of socioeconomic distribution of obesity mainly depend on the social structure and developmental status of the country. In developed countries, children from low socioeconomic circumstance (SEC) families are more prone to obesity, while childhood obesity is less common in families of higher SEC where parents are better educated and aware of the negative health and psychosocial consequences of excessive body weight for their children. In the Health Survey for England (2008) children from lower-income households were more likely to be obese. Twenty percent of boys in the lowest income quintile were obese, compared to 12% of boys in the highest income quintile (HSE 2008).

In contrast, in countries undergoing nutrition transition where under nutrition is traditionally the major cause of morbidity and mortality, the opposite trend is observed, as obesity and westernised lifestyles constitute symbols of wealth and well-being and their negative health effects are not generally known or given much consideration (Popkin and Gordon-Larsen 2004).

Ethnicity

Similar to adults, obesity in childhood differs among ethnic groups. According to the most recent NCMP results (2010/2011), certain ethnicities are clearly associated with higher obesity rates (Figures 19 and 20). More precisely, black, Asian and mixed race children had higher levels of obesity, while the lowest prevalence was observed among white children and Indian girls (DH 2011). The reasons behind these discrepancies may be attributable to parental obesity status, i.e., if parents are overweight or obese, the chance of children in the family "inheriting" increased weight is higher. Socioeconomic and cultural influences on body image, eating and activity habits also appear related to the observed ethnic discrepancies. Lastly, genetic variations attributed to ethnicity may play an important role in the obesity phenomenon, but have not been studied in detail (Misra and Khurana 2009; Sealy 2010; Misra and Khurana 2011; Mushtaq, Gull *et al*. 2011).

Figure 19. Prevalence of underweight, overweight and obesity in Reception year in relation to ethnic group

Image removed for copyright reasons

Source: NOO 2011

Figure 20. Prevalence of underweight, overweight and obesity in Year 6 in relation to ethnic group

Image removed for copyright reasons

Source: NOO 2011

Parental obesity

Family is increasingly recognised as an important contributory factor to the growing problem of childhood obesity (Patrick and Nicklas 2005). Family appears to play equally important roles in influencing diet and physical activity, especially at younger ages (Maffeis 2000). Children are likely to adopt parental eating habits as a result of environmental exposure rather than heredity of ‘food choice genes’ (NICE 2006).

Parental overweight and obesity increases the risk of childhood obesity (Keane, Layte *et al*. 2012). The risk of childhood obesity doubles if a child has one overweight or obese parent. If both parents are overweight or obese, the risk of a 2 to 15 year-old boy or girl becoming overweight or obese almost triples (Table 2).

Table 2. Child overweight or obesity incidence according to parental weight status

	Boys (2-15 years) % overweight or obese	Girls (2-15 years) % overweight or obese
No overweight/ obese parents	16	13
One overweight/ obese parent	31	28
Both overweight/ obese parents	46	45

Source: Zaninotto, Wardle et al. 2006

Parental obesity more than doubles the risk for adult obesity among both obese and normal weight children (Zaninotto, Wardle *et al*. 2006). This association appears age-dependent, i.e., the younger the child, the greater the effect of parental obesity on their weight status (Whitaker, Wright *et al*. 1997). Parental disordered eating may additionally be associated with increased body weight in children (NICE 2006).

Therefore, interventions to address childhood obesity should include strategies for the entire family to address dietary intake and physical activity levels.

Medical disorders and/or drugs

Certain diseases, such as Prader-Willi or Down's syndrome, and the use of drugs, such as steroids or antiepileptic medications, can contribute to the onset of obesity by affecting appetite and weight regulation, leading to weight gain (Lobstein, Baur *et al*. 2004).

Conclusions

All the evidence presented in this section indicates that the causes of childhood obesity are multifactorial and complex. Knowledge of the exact mechanisms leading to increased body weight in the young is essential to facilitate the design of effective solutions for this serious public health issue.

1.7 Consequences of childhood obesity

Childhood obesity is a global public health epidemic with many serious consequences both in childhood and adulthood. Indeed, its short and long-term effects on physical and psychological health, including a potential decrease in life expectancy, have made prevention and treatment of childhood obesity a national and international priority (NICE 2006; Barlow 2007; SIGN 2010).

1.7.1 Short-term consequences

The short-term (within childhood) effects of increased body weight on children's health include respiratory and orthopaedic problems as well as gastroenterological, endocrine and cardiovascular complications (Figure21). Furthermore, obesity in children is often associated with a number of cardiovascular disease (CVD) risk factors, such as sub-clinical dyslipidaemia, insulin resistance, high blood pressure and low fitness levels (Batch and Baur 2005).

Figure 21. Consequences of childhood obesity

Image removed for copyright reasons

Taken from Batch and Baur 2005

In a study conducted by Freedman *et al*. (1999), 58% of overweight children had at least one cardiovascular (CVD) risk factor and 25% had two or more CVD risk factors (Freedman, Dietz *et al*. 1999). In another study, 29% of obese adolescents were diagnosed with metabolic syndrome, compared with 0.1% healthy weight children of similar ages (Cook, Weitzman *et al*. 2003). The rise in prevalence of impaired glucose tolerance and type 2 diabetes among children and adolescents is another serious recent phenomenon associated with obesity in childhood (Amed, Daneman *et al*. 2010).

In addition to the above physiological consequences, obesity probably has the most widespread impact on psychological status in children (Reilly and McDowell

2003). The psychosocial effects of childhood obesity include peer discrimination, body dissatisfaction and low self-esteem (Strauss 2000; Zametkin, Zoon *et al*. 2004; Puhl and Latner 2007). Low self-confidence and fear of being bullied can prevent obese children from participating in sports, often leading to a vicious cycle of inactivity that further exacerbates weight gain (Strauss, Rodzilsky *et al*. 2001; Trost 2001). Psychosocial development of children may thus be impaired as a result of obesity (Must and Strauss 1999). Self-esteem is a commonly used measure of this impairment (Strauss 2000). However, inconsistent data suggesting moderate or no differences in self-esteem between obese and healthy weight children have additionally been reported (Zametkin, Zoon *et al*. 2004). This discrepancy has been attributed to the fact that obese children use compensatory methods to protect against low self-esteem (Manus and Killeen 1995). Poor body image, usually as a result of peer teasing or parental concerns, is a more consistent finding in obese children, leading to body dissatisfaction, depression and increased risk for future onset of eating disorders (Ricciardelli and McCabe 2001; Zametkin, Zoon *et al*. 2004). Recent studies have shown that weight management interventions for overweight and obese children have a positive effect on their psychological status (SIGN 2010).

The most consistent finding is negative body image, which is more pronounced among females, possibly due to differences in their physical appearance in relation to the prevailing standard of the socially acceptable slim female (Zametkin, Zoon *et al*. 2004). The features of negative psychology due to body dissatisfaction among obese children are associated with anxiety, depression, problematic eating behaviours and unhealthy eating habits that often persist into adulthood, and lead to psychosocial dysfunction and social isolation (Kelly, Ricciardelli *et al*. 1999; Lobstein, Baur *et al*. 2004).

Stigmatisation is another consequence of childhood obesity. Bullying is often a problem, and increased body weight can seriously affect relationships of children with their peers (Eisenberg, Neumark-Sztainer *et al*. 2003). School is the most common environment where obese children receive negative comments and rejection due to their weight. Worrying reports suggest that healthy weight children perceive their overweight peers as mean, stupid, ugly, unhappy, lazy, selfish, stupid, dishonest and unpopular (Wardle, Volz *et al*. 1995). Notably, even teachers and parents can have negative attitudes and beliefs relating to childhood obesity (Wardle, Volz *et al*. 1995).

Unfortunately, children often do not have the skills or maturity to effectively cope with such negative life experiences, and the same often applies to parents who are frequently criticised with regard to their children's weight status. Consequently, parents of overweight and obese children commonly experience guilt, helplessness and anger (Schwartz and Puhl 2003).

1.7.2 Long-term consequences

Childhood obesity is an independent risk factor for adult obesity (Biro and Wien 2010; Lloyd, Langley-Evans *et al*. 2010; Vamosi, Heitmann *et al*. 2010; Lloyd, Langley-Evans *et al*. 2012). The risk of overweight children maintaining their weight status into adulthood is at least twice that of healthy weight children. This means that most overweight and obese children will maintain their increased body weight in adulthood. The risk is higher for adolescents and children with obese parents (Singh, Mulder *et al*. 2008).

While most adults with obesity were not obese as children, the majority of obese children appear to retain their excess weight as adults (Singh, Mulder *et al*. 2008; Herman, Craig *et al*. 2009; Craigie, Lake *et al*. 2011). The risk of persistence of increased body weight from childhood into adulthood is associated with parental obesity, and increases with age, severity and duration of obesity (Reilly 2005; Herman, Craig *et al*. 2009). In other words, a morbidly obese adolescent carrying excess weight from an early age with obese parents has a significantly higher risk of remaining obese as an adult, compared to a moderately obese 5-yearold with no family history of obesity (Whitaker, Wright *et al*. 1997).

Overweight and obese children additionally have a higher risk of developing serious health problems in later life, including coronary heart disease and stroke, type 2 diabetes, eating disorders, bowel cancer and high blood pressure (Flynn, McNeil *et al*. 2006; Barlow 2007). United States researchers have estimated the prevalence of obese 35-year olds in 2020 on the basis of adolescent overweight and historical trends regarding overweight adolescents who become obese adults. Based on computer modelling analysis, the group estimated that adolescent overweight will increase the prevalence of obese 35-year olds in 2020 to between 30 to 37% in men and 34 to 44% in women. As a consequence, an increase in the total number of coronary heart disease events and deaths is projected to occur in young adulthood (Bibbins-Domingo, Coxson *et al*. 2007).

Moreover, in another study, higher BMI at 18 years of age was found to be independently associated with premature mortality (Reilly 2005). Obesity in childhood additionally has social consequences in adulthood, as overweight adolescents complete fewer years in education, are less likely to get married, and are more affected by poverty than their healthy weight peers (Gortmaker, Must *et al*. 1993).

Finally, childhood obesity has significant direct and indirect economic consequences. The primary care costs for the treatment of obese children are reported to account for 2-7% of total health care costs. This excludes the long-term costs of associated medical conditions, such as diabetes, cancer and cardiovascular disease (Daviglus, Liu *et al*. 2004; Lobstein, Baur *et al*. 2004).

Indirect costs associated with decreased productivity are also considerable, but their magnitude is difficult to assess (Reilly and McDowell 2003). In 2005, the UK Government requested Foresight to carry out a review of obesity. Foresight concluded that without action, obesity-related diseases would cost an additional £45.5 billion per year (Kopelman, Jebb et al. 2007; Finegood, Merth et al. 2010).

Conclusions

In summary, childhood obesity is associated with several serious short- and long-term health and psychosocial problems, as well as significant mounting economic costs. Consequently, its prevention and treatment has become a serious public health priority.

Chapter 2 Childhood obesity prevention

Childhood provides an important opportunity for obesity prevention, as diet and activity habits adopted during this period are likely to persist in adulthood. Childhood obesity prevention programmes should aim to targ*et a*ll children from birth, particularly the younger groups and those with risk factors, since once established, increased adiposity is significantly more difficult to overcome.

Over the past 10 years, considerable research and multiple publications have focused on identifying the features of a successful childhood obesity prevention programme. Policy-makers and practitioners addressing childhood obesity require this evidence to aid in making informed decisions. This is mainly done once target behaviours are identified, but most importantly, when implementation within the family context proves successful (Barlow 2007).

Ideally, evidence on whether the intended results are obtained, which parts of the population benefit or not, the underlying reasons for success or otherwise, and whether any negative side-effects deserve attention is additionally required. However, a review of the existing literature reveals a striking contrast between the high prevalence and consequent importance of addressing obesity and the paucity of knowledge to facilitate prevention efforts, despite the large number of studies. A body of intervention research on policy and environmental approaches for evidence-based obesity prevention efforts is largely absent in the literature (Making and Medicine 2010).

Reversal of the childhood obesity epidemic requires several interventions that span multiple levels and are sustained for many years, including changes in individual behaviour, schools, homes and workplaces, and sectors within agriculture, food services, education, transportation, as well as urban planning. While there is overwhelming evidence on the need to reduce obesity, the consensus on effective policies or programmatic strategies is less clear (Gortmaker, Swinburn *et al*. 2011).

As discussed (Section 1.6), the causes of obesity are multiple and interrelated. Obesity can occur as a result of a wide variety of 'causal pathways', which differ between individuals and change over the course of life. Correspondingly, this variability of causal pathways highlights a need for a range of different solutions to treat obesity. All childhood obesity interventions, targeted at either healthy weight or overweight and obese children, aim to avoid, halt or reverse obesity, and are therefore classified as prevention. The ultimate aim of childhood obesity prevention is to reduce the number of overweight and obese children as well as healthy weight children progressing to overweight or obese adolescents and adults. There are four categories of prevention, which are discussed below.

2.1. Categories of prevention interventions

Prevention activities at the system level

In 2010, an Institute of Medicine committee for obesity prevention in the USA recommended that researchers, government, educators and journal editors incorporate systems thinking to guide the development of environmental and policy interventions and study design (Making and Medicine 2010).

Examples of prevention activities at the systems level include changes to the built environment (infrastructure), increased facilities for outdoor physical activity, reduction in fast food outlets, financial subsidies for healthy foods (economic) such as fruit and vegetables, banning of food marketing to children (media), and taxation of energy-dense foods and drinks, including alcohol.

A good example of such an initiative is "Ensemble Prévenons l'Obésité Des Enfants: (EPODE, Together Let's Prevent Childhood Obesity), a large-scale, coordinated, capacity-building approach for communities to implement effective and sustainable strategies to prevent childhood obesity. Since 2004, the EPODE methodology has been implemented in more than 500 communities over six countries. The programme is focused on children aged 0-12 years of age and their families (micro-environment), as well as local stakeholders (macro-environment) (Figure 22). This is a long-term project aiming to promote healthy lifestyles in a sustainable manner on multiple levels. While the initial results of this effort have been encouraging, further data are required to validate its effectiveness (Borys, Le Bodo *et al*. 2012).

Figure 22. Outline of Ensemble Prévenons l'Obésité Des Enfants (EPODE) stakeholders at central and local levels

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Taken from Borys, Le Bodo et al. 2012.

Primary prevention

Primary prevention refers to preventive strategies aimed at limiting the incidence of disease by controlling the factors identified as being causes and/or risk factors for a specific condition. In this case, the target population consists not only of selected risk groups, but also the general population, including healthy individuals (Beaglehole, Bonita *et al*. 2003). For the purposes of this publication, primary prevention includes all interventions aimed at stopping children from becoming overweight or obese and is reviewed further in Section 2.1.1.

Secondary prevention

Secondary prevention aims to cure patients and reduce the more serious consequences of disease through early diagnosis and treatment. This intervention is directed at the period between onset of the disease and the time when symptoms emerge. Secondary prevention aims to reduce the prevalence of disease (Beaglehole, Bonita *et al*. 2003). For the purposes of this publication, secondary prevention refers to all interventions aiming to improve the health and weight status of overweight or obese children and is reviewed further in Section 2.1.2.

Tertiary prevention

Tertiary prevention aims at reducing the progress or complications of established disease, and is an important aspect of therapeutic and rehabilitation medicine

(Beaglehole, Bonita *et al*. 2003). Tertiary prevention is reviewed further in Section 2.1.3.

2.1.1 Primary prevention

Governments worldwide are being urged to take action to prevent childhood obesity and address underlying determinants of the condition. Strong evidence indicates that once established, obesity is difficult to reverse (Barlow 2007). Successful prevention interventions are desperately required to reduce the current childhood obesity epidemic (Summerbell, Waters *et al*. 2005). Effective prevention would ensure that the “conveyor belt” effect leading to childhood and subsequent adult obesity is terminated. However, prevention of childhood obesity remains a considerable challenge. Evaluation of primary prevention studies is fraught with difficulties (Bautista-Castano, Doreste *et al*. 2004; Waters, de Silva-Sanigorski *et al*. 2011), and therefore, well-designed population-based studies are essential to develop effective public health strategies for childhood obesity prevention.

In 2004, a group of 65 physicians and other healthcare professionals representing nine countries convened in Israel to review the available evidence and develop a consensus statement on childhood obesity (Speiser, Rudolf *et al*. 2005). As part of this process, prevention strategies during the life-course were examined. Although 8 years old now these options presented in the form of suggestions are still relevant (Table 3).

Table 3. Options for prevention of childhood obesity

Pregnancy	- Achieve normal BMI before pregnancy - Do not smoke - Engage in moderate exercise (as tolerated)
Lactation/ weaning	- Exclusive breastfeeding for a minimum of 6 months - Delay introduction of solids and sweet liquids
Family	- Eat as a family in a fixed time and place - Do not skip meals, especially breakfast - Turn off the television during meals, keep it off in children's bedrooms and restrict times for television, video and computer usage - Use small plates and keep serving dishes away from the table - Avoid sweet or fatty foods and soft drinks
Schools	- Review policies and procedures to promote healthy eating - Set a curriculum for nutrition education - Educate teachers about basic nutrition and the benefits of physical activity - Provide facilities for physical activity - Establish minimum standards for physical education - Review content of vending machines, substitute unhealthy with healthy choices
Community	- Provide family-friendly playing facilities for all age groups - Provide nutrition education on healthy shopping and offer healthy versions of cultural-specific foods
Healthcare professionals	- Provide accurate and appropriate information to the public with respect to the obesity issue - Emphasise the extent and importance of the obesity epidemic
Industry	- Introduce age-specific nutrition labelling for products advertised to children

Taken from Speiser, Rudolf et al. 2005.

All the strategies listed in Table 3 aim to modify behaviours, with a view to improving nutrition and physical activity levels at the individual, family, community and societal levels. Evidence at the time suggested that inclusion of the entire family is a crucial factor in the prevention of childhood obesity (Bautista-Castano, Doreste *et al*. 2004).

Generic systematic reviews on childhood obesity prevention

In 2005, Summerbell and co-workers conducted a Cochrane systematic review of studies to prevent childhood obesity, with the main objective of determining the effectiveness of educational, health promotion and/or psychological/family/ behavioural therapy/counselling/management interventions that focused on diet, physical activity or lifestyle support or both in preventing obesity. Twenty-two controlled trials were included, of which 10 were long-term (at least 12 months) and 12 were short-term (12 weeks to 12 months). All studies included children aged 18 years or younger, and the majority of studies were conducted in school settings. Only two studies were family-based interventions targeting non-obese children of obese or overweight parents (Summerbell, Waters *et al*. 2005).

The authors noted methodological weaknesses in all 22 studies, but reported greater than 74% follow-up data. Intervention components included dietary education alone, physical activity alone and combined diet and physical activity. The results of these studies indicated no significant impact on children’s weight status, and the review concluded that there was no evidence of effective strategies to prevent childhood obesity. The underlying reasons included a lack of well-designed long-term studies and coordination among sectors affecting aspects of children's lives (food industry and marketing, schools, media, environmental factors) that influence areas directly related to the risk for obesity development. It is worth noting at the time the significant mismatch between the severity and prevalence of child obesity and evidence base to inform policy and wider preventative initiatives (Summerbell, Waters *et al*. 2005).

Recently, the Cochrane systematic review examining interventions for preventing childhood obesity, referred to above, was updated (Summerbell, Waters *et al*. 2005; Waters, de Silva-Sanigorski *et al*. 2011). An additional 36 studies (55 in total, as 3 were excluded from previous review) were included in the update, with the majority focusing on children aged 6-12 years. Twenty-six studies were conducted in the USA, 6 in the United Kingdom, and the remainder in other countries. Among the 55 studies included, 50 were set in high-income countries and therefore the results were potentially applicable to a UK setting. The majority (75%) of the studies lasted for 12 months or less, and 30 had high risk of bias for one or more domains (selection, blinding, attrition, performance and detection).

Thirty-nine studies targeted children aged 6-12 years. However, according to the authors, only 27 provided appropriate BMI or BMI z-score data for inclusion in the meta-analysis. Interestingly, only seven of the 39 studies were conducted outside of an education setting. Results of the meta-analysis revealed a statistically significant mean effect size in BMI or BMI z-score of -0.15 (95% CI: -0.23 to -0.08) (Waters, de Silva-Sanigorski *et al*. 2011).

Physical activity was assessed using a variety of measures and indicators. Overall physical activity-related factors were shown to improve in the majority (21) of studies. A forest plot of changes in BMI or BMI z-score revealed that physical activity interventions (16 studies) resulted in a significant difference of -

0.11 (95% CI: -0.19 to -0.02), while dietary interventions (6 studies) led to a non-significant difference of -0.12 (95% CI: -0.28 to 0.05). Combined physical activity and dietary interventions resulted in a significant difference of -0.18 (95% CI: -0.27 to -0.09).

Eight studies reported the impact of the interventions on cardiovascular risk factors. Four of these showed beneficial effects on blood pressure, heart rate, blood lipids and cardiovascular fitness. Results based on gender depicted an inconclusive picture, with some studies showing an influence and others indicating no effect. Analyses performed relative to duration revealed a significant mean effect size in BMI or BMI z-score of -0.17 (95% CI: -0.25 to -0.09) for duration ≤12 months, and a corresponding mean effect size of -0.12 for studies lasting for >12 months (95% CI: -0.21 to -0.03).

The authors concluded that the best estimate of effect on BMI was a 0.15 kg/m^2 reduction, corresponding to a small but clinically important shift in population BMI if sustained over several years. However, they highlighted that due to the heterogeneity of the observed effects, potential attrition bias in many studies and likelihood of small study bias, findings should be interpreted with caution. Another potential bias suggested is evidence of under-reporting of small studies with negative findings in the published literature, which could inflate the effect sizes. The strongest evidence of effectiveness was found in 6-12 year olds, but the finding was primarily attributed to the larger number of studies performed in this age group. As 75% of studies lasted for 12 months or less, no conclusions could be reached in terms of sustainability of health outcomes.

The authors concluded that some support is now available to determine the effectiveness of obesity prevention interventions in children. Importantly, few minor adverse outcomes were reported. For the first time, a systematic review of childhood obesity prevention interventions provided evidence that interventions aimed at all children can successfully reduce BMI. However, further research is required to determine whether these interventions are generalisable and effective when delivered at scale.

An earlier systematic review and meta-analysis examined behavioural interventions to prevent childhood obesity (Kamath, Vickers *et al*. 2008). In contrast to previous systematic reviews, the approach of the authors was to examine the extent to which preventive interventions affected lifestyle (physical activity and dietary) behaviours as outcomes, and not focus on obesity as a direct outcome.

Twenty-nine RCTs (children aged 2-18 years) were included with complete datasets for at least one of the behavioural outcomes. Interventions caused minor changes in the respective target behaviours, but had no significant effect on BMI, compared to controls. As expected, results were similar to those reported in the earlier Cochrane review (Summerbell, Waters *et al*. 2005), but dissimilar to the most recent Cochrane review (Waters, de Silva-Sanigorski *et al*. 2011). This finding suggests that either the recent trial has more positive effects on BMI or increased power provided by the larger number of studies (55 versus 29) allows the detection of smaller changes.

In conclusion, recent reviews and meta-analyses have started to report optimistic results from interventions aiming at reducing the risk for obesity in childhood. However, methodological issues pose a serious problem, as they are responsible for significant heterogeneity among studies, making it difficult to assess effectiveness. Future research should shed more light on the features associated with success, given the importance of early obesity prevention.

Prevention studies in schools

Considerable research in the field of prevention of childhood obesity has focused on school-based interventions. In 2009, a meta-analysis of trials examining the effect of school-based physical activity interventions on body mass index was conducted (Harris, Kuramoto *et al*. 2009). Eighteen randomised and non-randomised controlled studies involving 18,141 children were included. BMI did not improve following school-based physical activity interventions (weighted mean difference -0.05 kg/m^2 (95% CI: -0.19 to 0.10). Moreover, no consistent changes in other measures of body composition were observed, despite positive changes in eating habits in children. These results were analogous to those reported from a systematic review (Waters, de Silva-Sanigorski *et al*. 2011) .

A research team from Australia conducted a review of existing systematic reviews and meta-analyses of school-based behavioural interventions for preventing obesity (Khambalia, Dickinson *et al*. 2012). Studies were included, based on the following selection criteria: (i) participants were school-based children, (ii) the study design had to be a review with sufficient reporting of methodological details to allow critical appraisal of data quality (preferably a systematic review or meta-analysis, and (iii) reviews considered individual studies examining behavioural interventions for preventing overweight or obesity, including physical activity, dietary behaviours, modifying exercise or dietary behaviours or a combination of these approaches.

A total of 8 reviews (3 meta-analyses, 5 qualitative systematic reviews) met the inclusion criteria, and as observed with previous systematic reviews, the differences in methodology, results and interpretation made comparisons difficult. Intervention components in the school setting associated with significant weight reduction in children included long-term programmes with combined diet and physical activity and a family component. As established previously, no single intervention will fit all schools and populations, and therefore, further high-quality research focusing on identifying specific programme characteristics predictive of success is essential.

Owing to the increasing percentage of both parents being in full-time employment, children spend more time in schools. In the USA, 8.4 million children participate in some form of after-school programme (Branscum and Sharma 2012). The aim of these programmes is to provide a safe and structured environment for children after school hours, and offer an opportunity to promote health-based interventions for preventing childhood obesity. In another study, researchers conducted a comprehensive review of after-school obesity prevention interventions between 2006 and 2011 (Branscum and Sharma 2012). Twenty-five studies (7 RCTs) were included in this review, the majority of which were USA-based. Overall, the group concluded that these types of interventions have a low impact on outcomes, but outlined a number of recommendations for future after-school programme trials.

Thus, evidence on the effectiveness of school-based and after-school interventions for the prevention of childhood obesity is still inconclusive. Despite the lack of significant findings with regard to adiposity, school-based physical activity remains a crucial area that is reported to have considerable benefits on health, and linked to reduced blood pressure, improved lean muscle mass, bone mineral density, aerobic capacity and flexibility (Harris, Kuramoto *et al*. 2009). However, given the lack of conclusive evidence, efforts should be made to obtain generalisable positive data to support decisions by policy-makers promoting school-based physical activity as a central component of the strategy to reduce childhood obesity.

Conclusions

Most of the available primary prevention studies are school-based, and those combining diet and physical activity appear the most effective. However, results obtained from reviews supporting protective effects of specific interventions are inconsistent, and further investigation is required (Summerbell, Waters *et al*. 2005; Kamath, Vickers *et al*. 2008; Khambalia, Dickinson *et al*. 2012).

Although primary prevention of childhood obesity is more cost-effective than secondary prevention, the lack of successful primary prevention strategies combined with the escalating prevalence of obesity necessitates the simultaneous development of strategies aimed at both primary and secondary prevention (Gortmaker, Swinburn *et al*. 2011). Primary prevention is always preferable to secondary and tertiary prevention. However, we cannot neglect overweight or obese children by focusing mainly on primary prevention strategies. With current childhood obesity rates at their highest levels in human history, effective joint primary and secondary prevention interventions are urgently required to manage this devastating epidemic. Up-to-date evidence shows that the impact of current primary prevention interventions on reducing childhood obesity, their mechanism of action, and safety remain poorly understood, impeding assessment of their effectiveness.

2.1.2 Secondary prevention

The primary purpose of secondary prevention interventions (childhood weight management interventions) is to support and promote behavioural modifications to improve nutritional intake and increase energy expenditure. This allows normal growth to continue with little risk of impaired growth and future eating disorders (Kirk, Zeller *et al*. 2005; Hunt, Ford *et al*. 2007). Consequently, results are more likely to be sustained in the long-term (Batch and Baur 2005; Williamson, Han *et al*. 2011).

Many combinations of strategies are incorporated into multicomponent child weight management interventions. The majority include lifestyle interventions consisting of behavioural modifications focused on diet and physical activity. Dietary interventions are included in most multicomponent interventions, and many types have been trialled, varying from brief advice to intensive and structured dietary management by a dietitian. Physical activity interventions may be used to improve treatment success. These interventions also vary in nature from brief lifestyle advice provided by a health care professional to structured physical activity supervised and delivered by an exercise professional.

Differences in the health care and non-health care settings in which multicomponent interventions are conducted and variations in terms of views regarding what constitutes an effective approach to weight management contribute to the variability observed across weight management trials. Evidence regarding the type and number of individual interventions included in a weight management multicomponent programme is difficult to obtain. Instead, data may be obtained from each component supporting its effectiveness for incorporation into a "best practice" multicomponent intervention, depending on the area of delivery, target population and available resources, such as skills and venues. Individual strategies and published evidence supporting the efficacy of individual strategies are discussed in the following sections.

Study design and multicomponent interventions

Several study designs have been employed to evaluate the effectiveness of multicomponent interventions for childhood weight management. The majority of these are non-controlled, which may result in overestimation of intervention effectiveness. Most studies are undermined by high levels of drop-out or loss of follow-up of participants, resulting in increased selection bias that limits the generalisability of findings.

Goals of multicomponent interventions

The most commonly cited goal for multicomponent interventions is to achieve improvements in anthropometry (Oude Luttikhuis, Baur *et al*. 2009). The outcomes targeted in children's weight management interventions generally include objectively measured markers of body composition, such as BMI (adjusted for age and gender), and less commonly, waist circumference. Secondary goals commonly include a wide range of other outcomes (clinical, e.g., blood pressure, lipids, cardiovascular fitness, time spent in physical or sedentary activities, and psychosocial, e.g., self-esteem and quality of life). In some trials, parental outcomes are included as markers for entire family lifestyle change.

Effectiveness of dietary interventions

Successful treatment of childhood obesity requires a sustained negative energy balance, which may be achieved by modification of dietary intake. This section focuses on interventions with a strong dietary modification component.

A systematic review examined the effectiveness of dietetic interventions for treatment of childhood obesity (Collins, Warren *et al*. 2006). Thirty-seven RCTs met the inclusion criteria, and 17 of which contained sufficient information for meta-analysis of the standardised effects. Owing to the various combinations of treatments, including a dietary intervention and variable composition of the control groups, a meta-analysis to ascertain the effectiveness of dietetic interventions *per se* was not possible. However, a meta-analysis was performed on the subset of studies (n=8) including both a dietary intervention component and adequate control group. Limited studies have evaluated dietary intervention as the sole component of treatment and compared this with a non-intervention control group. The authors stressed that caution should be taken when interpreting the results, as only a small number of studies were included in the meta-analysis and diet was only a single component of the interventions, making its contribution difficult to evaluate.

The results suggest that interventions containing a dietary component are effective in achieving relative weight loss in overweight or obese children (pooled standardised mean difference, -1.82, 95% CI: -2.40 to -1.23) (Collins, Warren *et al*. 2006). Only four studies had follow-up data, and meta-analysis of the outcomes indicated a diminishing effect of the intervention over time (pooled standardised mean difference, -0.64, 95% CI: -0.89 to -0.39). Sixteen studies used the Traffic Light Diet (or a variation) for intervention. Five studies included a food or calorie exchange programme, while only one compared two different dietary interventions (low-fat versus low carbohydrate). Reports on dietary compliance were extremely poor in the majority of studies. The authors concluded by reiterating that due to the lack of quality research in this area, results need to be interpreted with caution. Thus, application of this research is challenging, as while interventions including dietary treatments clearly achieve weight loss, it is difficult to establish conclusions about details or particular features. As the majority of internationally available childhood weight management programmes contain a dietary component, further research would be invaluable to determine the most effective dietary treatment.

In the most recent Cochrane review on childhood obesity management (Oude Luttikhuis, Baur *et al*. 2009), four studies were categorised as dietary interventions. Only two (Nova, Russo *et al*. 2001; Epstein, Paluch *et al*. 2008) of these studies fulfilled all the criteria for pooling in a meta-analysis, but involved different comparisons.

One investigation was of particular interest, as it compared the effect of targeting increased consumption of healthy foods (fruits, vegetables and low-fat dairy) versus reducing intake of high energy-dense foods within the context of a family-based behavioural weight management programme in the USA (Epstein, Paluch *et al*. 2008). Traditionally, the approach of lowering energy intake has centred on reducing energy-dense, low nutrient-dense foods. Epstein hypothesised that an alternative or complementary approach may be to target increased consumption of healthy foods, thereby leading to a reduction in energy intake. Forty-one obese children (>85th BMI centile) aged between 8 and 12 years (mean BMI z-score = 2.3) were randomly assigned to the 24-month intervention study.

In Epstein's approach, the Traffic Light Diet, the most commonly reported dietary intervention strategy (Collins, Warren *et al*. 2006), was used to decrease energy intake and promote healthy eating habits for children and their parents. Traffic Light Diet foods are categorised as Green, Yellow, and Red, based on amounts of fat and sugar per serving. Green foods are high in nutrient density and low in energy density (fat = 0-1 g or sugar <10% calories/serving). Most Green foods belong to the fruit and vegetable groups. Yellow foods are higher in energy density than Green foods (fat = 2-5 g or sugar 10-25% calories/serving), while Red foods are higher than Yellow or Green foods (fat > 5 g or sugar > 25% calories/serving). Red foods are usually derived from fats, oils, and sweets, and should be consumed sparingly. Modified foods from the fat, oil, and sweet groups are considered Red foods, even if their fat and/or energy levels are low. These food types contribute few nutrients to the diet and compete with healthier food consumption. In addition to the Traffic Light Diet, participants were instructed to consume between 1,000 and 1,500 calories per day, but the way in which this was achieved is unclear. Families were additionally educated on the merits of reading food labels and healthy shopping.

Both groups were instructed to follow the Traffic Light Diet to reduce energy intake, and provided with information on the positive effects of physical activity. Parents and children were additionally awarded points for meeting dietary goals as a method of positive reinforcement. Additional points could be earned for parent weight loss of 1 pound per week and child weight loss of ½ a pound per week. The goal for normal weight parents was to maintain their weight within a 5 pound range. Parents and children were instructed to weigh themselves at home (Epstein, Paluch *et al*. 2008).

The intervention between groups differed in a number of respects. One group was instructed to replace energy-dense foods with fruits, vegetables and low-fat dairy (Group A). The second group focused on meeting the calorie goal and decreasing Red foods by at least two a day below their normal consumption (Group B).

No significant differences in obesity reduction were observed between the two groups. The mean age of children in the study was 10.5 years. Children in Group A displayed reduced BMI z-scores by -0.25 (±0.09), -0.26 (±0.15) and -0.27 (±0.41) at 0-6, 0-12 and 0-24 months, respectively. The BMI z-scores of children in Group B were reduced by -0.31 (±0.05), -0.21 (±0.17) and -0.11 (±0.21) at 0-6, 0-12 and 0-24 months, respectively. Between-group differences were significant ($p < 0.001$) at 12 and 24 months. Children from both groups showed a significant ($p < 0.05$) reduction in consumption of red foods up to one year, with better long-term maintenance in Group A. Between-group differences were observed only at 24 months ($P = 0.03$). No significant changes in low-fat dairy consumption were observed. Older, female children with lower baseline BMI z-scores assigned to Group A displayed greater sustained reductions in BMI z-score over the two years than children assigned to Group B. Parent BMI changes showed a similar linear pattern to that observed in children, with Group A parents displaying significant linear reductions in BMI ($P < 0.05$). Significant between-group differences in parental BMI were observed at 24 months (P = 0.017) (Epstein, Paluch *et al*. 2008).

Epstein and colleagues concluded that in the context of a comprehensive family-based behavioural weight management programme that encourages reduction in energy intake, increase in physical activity and changes in parenting behaviour, targeting an increase in fruit and vegetable intake and low-fat dairy products is associated with significantly greater reduction in BMI z-score over two years for both children and parents than focusing on reducing energy-dense foods. Interestingly, Group A was associated with no relapse in weight regain from 6 months of treatment through the 2-year follow-up. However, no details were available in terms of actual intensity of the treatment and follow-up. Moreover, no information about the qualifications of the research team delivering the intervention was provided, although previous Epstein studies have employed highly specialised health care professionals. A limitation of this study was the use of questionnaires to measure dietary intake, which may not have been sufficiently accurate or sensitive to detect changes in diet between groups, particularly as the numbers in each group were small (Group A, n= 21, Group B, n=20). A significant loss in the number of subjects at 24 months was additionally reported (Group A, n= 14, Group B, n=13). Due to these low numbers and methods of dietary assessment, conclusive results were not obtained from this study. However, the data indicate that improvement in healthy eating habits is an important target in childhood weight management programmes (Epstein, Paluch *et al*. 2008).

In summary, dietary recommendations for the management of childhood obesity support the promotion of a healthy diet within a multicomponent intervention, but do not advocate any particular dietary approach alone, given the lack of strong evidence to date (NICE 2006; SIGN 2010).

Effectiveness of physical activity interventions

Engaging in regular physical activity during childhood is widely accepted as an effective preventive measure for a variety of health risk factors across all ages, genders, ethnic and socioeconomic groups (Jannsen 2010). However, across all age groups, levels of physical activity remain low (HSE 2008), while obesity rates continue to rise (Bridges and Thompson 2010). Increasing energy expenditure while maintaining or decreasing energy intake is the mainstay of any successful childhood weight management programme. In this section, we specifically examine interventions with a focus on increasing physical activity levels and/or decreasing sedentary activities.

An Australian research team conducted a systematic review examining the efficacy of exercise for treating overweight in children and adolescents (Atlantis, Barnes *et al*. 2006). This report was the first aiming to establish the isolated effects of exercise on obesity among children and adolescents. Studies were only included if the specific effects of exercise could be determined. In total, 14 studies were examined, including a pooled sample of 481 boys and girls with a mean age of 10.9 ±1.5 years. Exercise led to a significant reduction in percent body fat in obese boys and girls aged 12 years. The investigators additionally noted that the current recommended doses of exercise/physical activity for treating overweight in children published by several expert committees (30-60 minutes/day at moderate intensity, most days of the week: 210-360 minutes/week) (Daniels, Arnett *et al*. 2005; NICE 2006) are substantially higher than those tested in RCTs of obese children. In fact, no randomised trial prescribed a dose of more than 200 minutes per week of aerobic exercise to obese children. These findings suggest that significant effects on percent body fat are achievable with a lower dose of prescribed exercise than that currently recommended.

The Cochrane review (2009) on childhood obesity management identified nine studies focusing mainly on the physical activity component of a childhood obesity intervention. Only four of these studies fulfilled the inclusion criteria, but were not pooled for meta-analysis due to non-comparable study designs and interventions (Oude Luttikhuis, Baur *et al*. 2009).

A study by Gutin and colleagues in the USA comparing the effects of physical training intensity on cardiovascular fitness, percentage body fat and visceral adipose tissue in obese adolescents was included in the review (Gutin, Barbeau *et al*. 2002). Eighty 13-16 year olds were assigned to 8 months of either: i) lifestyle education plus moderate-intensity physical training, ii) lifestyle education plus high-intensity physical training or iii) lifestyle education only. Physical training was offered 5 days per week, with target energy expenditure of 250 calories per day for all subjects in physical training groups.

The investigators reported an increase in cardiovascular fitness in the high-intensity physical training group, but not the moderate-intensity group, which was considerably greater than that in the lifestyle education only group. No other significant differences were evident among the three groups. Adolescents attending physical training for 2 or more days per week showed marked improvements in cardiovascular fitness, as well as reduction in percentage body fat and visceral adipose tissue. Although the study was only conducted in adolescents, the results demonstrated that high-intensity physical training is more effective than moderate-intensity training in enhancing body composition (Gutin, Barbeau *et al*. 2002). This may also be relevant for younger children, as high-intensity physical activity is known to be more effective in reducing adiposity by promoting fat burning and cardiovascular fitness improvement.

The review did not include the study by Owens and co-workers in the USA, as body composition was selected as primary outcome versus BMI. This analysis provided important information on the role of physical activity alone in improving body composition in obese children. The researchers assessed the effects of physical training without dietary intervention on visceral adipose tissue and percentage body fat in obese children (Owens, Gutin *et al*. 1999). Seventy-four obese 7-11 year-old children were randomly assigned to physical training and control groups. The intervention involved 4 months of controlled physical training, 5 days per week for 40 minutes per session. The estimated energy expenditure was 220 calories per training session. The physical training group showed a significant decrease in percentage body fat and increase in fat-free mass, compared to the control group. Moreover, the increase in visceral adipose tissue was markedly lower in the physical training group. The authors concluded that regular exercise induces a significantly greater decline in adiposity, compared to the control group, after 8 months of intervention.

Another group of investigators in the USA examined the use of resistance training to treat pre-adolescent obese children (Sothern, Loftin *et al*. 2000). This older study was additionally excluded in the review (Oude Luttikhuis, Baur *et al*. 2009), as it did not meet the inclusion criteria, but nevertheless, provides a useful insight into the roles of different types of exercise on programme retention. In this study, 19 subjects (7-12 years of age) were enrolled in a 10-week weight management programme, which included diet, behaviour modification, and aerobic and flexibility exercises. An additional 48 control subjects participated in diet, behaviour modification, and a walking programme three times a week. Fifteen treatment subjects completed the 10-week programme (retention rate = 79%). BMI was reduced at 10 weeks, and did not increase significantly at one-year follow-up in both treatment and control groups. In the treatment group, percent body fat was considerably decreased, but no changes in fat-free mass were observed. The authors concluded that the addition of specific exercise regimes, such as resistance training, improves programme retention, particularly in severely obese children (Sothern, Loftin *et al*. 2000).

Sedentary and physically active behaviours are the principal options for leisure time activities (Epstein, Paluch *et al*. 2000). Adiposity is likely to result in cases where inactive pursuits predominate. Westernised lifestyles are associated with an increase in sedentary behaviour, and consequently, higher obesity rates. The incorporation of physical activity into daily life is important for many reasons. Physical activity is crucial to produce greater energy expenditure than energy intake, and should include both organised and incidental activities (NICE 2006).

In order to prevent children from perceiving exercise as an unpleasant experience, fun, non-competitive activities are encouraged. Moreover, beneficial effects on energy expenditure can be achieved by providing trivial everyday opportunities for activity, e.g., walking (Levine 2004).

Despite the finding that exercise does not seem to have significant effects on weight reduction (Jakicic and Otto 2005), the overall associated health benefits necessitate its incorporation in childhood weight management interventions (Summerbell, Ashton *et al*. 2003). The proven benefits of physical activity in the prevention of weight gain, along with its positive effects on psychology and self-esteem further support its inclusion in programmes to control obesity (ADA 2006; NICE 2006; SIGN 2010).

Reduction in sedentary activities, such as time spent watching television or playing computer games, can also have beneficial effects on weight control. A recent systematic review examined the effect of sedentary behaviour and health indicators in school-aged children (Tremblay, LeBlanc *et al*. 2011). Based on this review of 232 studies, sedentary behaviour (primarily TV viewing) for more than 2 hours per day was associated with unfavourable body composition, decreased fitness, lower self-esteem and decreased academic achievement in children aged 5–17 years. This finding was true for all study designs and across all countries. The authors concluded that reducing sedentary behaviour can improve body composition. Moreover, both increased physical activity and reduced sedentary activities are necessary to improve health outcomes in children (Tremblay, LeBlanc *et al*. 2011).

To date, interventions aimed at reducing sedentary behaviours have generally been more successful than those promoting physical activity (Epstein, Paluch *et al*. 2000; Ritchie, Welk *et al*. 2005; Salmon, Ball *et al*. 2005). This finding highlights the importance of targeting sedentary habits, rather than focusing solely on promotion of physical activity.

In conclusion, there is sufficient evidence to support the routine recommendation of increased physical and decreased sedentary activities within childhood obesity weight management interventions. However, it is not clear whether inclusion of actual physical activity sessions within the intervention offers any benefit over education to increase physical activity or reduce sedentary behaviours outside of the intervention.

Effectiveness of behavioural interventions

Behavioural counselling has been advocated as an important element of child obesity treatment since 1987 (Epstein and Wing 1987). In the Cochrane review, 24 studies incorporated interventions with a large behavioural component, but only 8 reported analyses based on intention-to-treat principles (Oude Luttikhuis, Baur *et al*. 2009). Of these, 4 (Golan, Kaufman *et al*. 2006; Golley, Magarey *et al*. 2007; Kalavainen, Korppi *et al*. 2007; Hughes, Stewart *et al*. 2008) meeting all the criteria were pooled in meta-analysis aiming to establish the effect of a behavioural family programme, compared to standard or minimal care, on changes in BMI z-score. The meta-analysis of 301 participants revealed a small positive change of -0.06 (95% CI: -0.12 to -0.01) on BMI z-score in the parent-focused behavioural group intervention, compared to standard care.

Golan and colleagues in Israel examined the reduction in overweight and changes in eating-related behaviours in 60 obese 6 to 11-yearolds subjected to a family-based approach (Golan, Weizman *et al*. 1999). Children were randomly assigned to one of two groups. The intervention group used parents as the agents of change (a family-based health-centred approach), whereas in the control group, children acted as their own agents. All children were followed up for one year from baseline. Parents received 14 one-hour support/educational sessions from a dietitian, whereas children in the control group received 30 sessions. Individual sessions were also held for members of both groups where necessary.

Significant differences were evident between the two groups in terms of reduction of exposure to food stimuli and changes in eating habits (eating while standing, watching television, reading or doing homework, following stress and between meals). Mean weight reduction (by percentile only) was significantly greater in the intervention group, compared to the control group.

The researchers concluded that treatment of childhood obesity with parents as the exclusive agents of change promotes greater behavioural changes and weight loss than using children as their own agents. However, it must be noted that the group did not compare parents alone with parents and children together as agents of change (Golan, Weizman *et al*. 1999)

A 7-year follow-up study of the children from the previous investigation where only parents were targeted, compared with a control intervention solely focusing on children as targets, was performed (Golan and Crow 2004). Fifty of 60 children that had participated in the study 7 years previously were located, and their weights and heights re-measured. At the 7-year follow-up period, children were 14 to 19 years of age. Mean reduction in overweight was greater at all follow-up points in children of the parent-only group, compared with those of the children-only group. Seven years after the original programme was terminated, mean reduction in children's overweight was 29% in the parent-only group versus 20.2% in the children-only group ($p < 0.05$) (Golan and Crow 2004).

An Israeli research team conducted a RCT to evaluate the relative efficacy of treating childhood obesity via a family-based health-centred intervention targeting parents alone versus parents and obese children together (Golan, Kaufman *et al*. 2006). Thirty-two families with obese children 6 to 11 years of age were randomised into groups, whereby participants were provided with a 6-month comprehensive healthy lifestyle educational and behavioural programme. In both groups, parents were encouraged to foster authoritative parenting styles. The intervention aimed at parents only resulted in a significant reduction in BMI z-score at the end of the programme (-0.4, $P < 0.05$) as well as one-year follow-up (-0.5, $P = 0.025$), compared with that aimed at parents and children. The differences between the groups at both times were significant ($P < 0.05$). In both groups, the parents' weight status did not change. These results suggest that omitting obese children from active participation in the health-centred programme may be beneficial for weight loss and promotion of a healthy lifestyle.

Golan's research suggests that parent-only treatment of childhood obesity is more effective than combined parent and child treatment (Golan, Kaufman *et al*. 2006). A possible reason for these findings is that many topics, including parenting skills, are sensitive subjects that are not appropriate for discussion in front of children. If parents and children are always together during the intervention, the topics of discussion are limited. However, another interesting comparison is the evaluation of a parent-only versus parent and child intervention that includes parent-only periods, for example, where children are provided exercise time while their parents discuss sensitive or adult-focused issues. Using this approach, both types of intervention could be incorporated and subsequently evaluated.

In Australia, a research team compared parent-centred with child-centred lifestyle therapy in 165 participants aged 8 years (BMI 24.4 to 25.2) (Okely, Collins *et al*. 2010). The parent intervention focused on diet and the child intervention on physical activity. All groups received 10 weekly face-to-face sessions, followed by three-monthly relapse-prevention phone calls to 12 months post-intervention. The mean reduction in BMI z-score at 12 months was 0.4 in the parent group (95% CI: 0.3 to 0.5), 0.2 in the child group (95% CI: 0.1 to 0.3) and 0.3 in the combined intervention group (parent + child) (95% CI: 0.2 to 0.4). This trial demonstrates that all three combinations of parent only, child only and parent and child interventions are effective. A parent skills training component may have provided a useful addition to the parent only and parent and child interventions to determine whether additional benefits are achievable over diet and activity alone.

An Australian RCT evaluating the relative effectiveness of parenting skills training as a key strategy for the treatment of overweight children was published (Golley, Magarey *et al*. 2007).This study included 111 parents of overweight pre-pubertal children (aged 6 to 9 years) assigned to parenting skills, parenting plus intensive lifestyle intervention or a waiting list control. After 12 months, the BMI z-score of children in the parenting skills plus lifestyle intervention group was reduced by 10%, compared to 5% reported in the group with parenting skills alone and 5% reduction in wait list controls.

Hughes *et al*. (2008) conducted a UK RCT with 134 children aged 5 to 11 years that assessed a family-centred counselling and behavioural therapy program to modify diet, physical activity and sedentary behaviour, compared with standard care (Hughes, Stewart *et al*. 2008). After 12 months, the median BMI z-score decreased in both groups (intervention = -0.07, 95% CI: -0.22 to -0.04; control =

-0.19, 95% CI: -0.26 to -0.08). No significant differences in BMI reduction were observed between the two groups.

In the USA, Kalarchian *et al*. (2009) conducted a RCT with 192 children aged 8 to 12 years (BMI ≥ 97th centile) who participated independently in the parent and child group, and involved individual behaviour therapy and lifestyle coaching that focused on calorie control, increased physical activity and reduced sedentary behaviour (Kalarchian, Levine *et al*. 2009). In contrast, the control group only received brief advice. After 18 months, the intervention was associated with a non-significant 1.2% decrease in child percent overweight, compared with 0.2% reduction in the control group (p = 0.62).

A RCT in Finland comparing family-based group treatment with routine counselling in 70 participants aged 7 to 9 years with weight for height >115% was reported (Kalavainen, Korppi *et al*. 2007). The family-centred group programme included diet, physical activity and reduction in sedentary behaviour. Parents received the programme intervention, while the control group received a brief intervention and written advice. The intervention resulted in a loss of weight for height of 7% at 6 months, compared with a corresponding loss of 2% in the control group. At 6 months after the programme had ended, percentage weight loss was 3% in the intervention group, compared with a gain of 2% in the control group.

The USA Dietary Intervention Study in Children (DISC) was a multi-centre, collaborative, randomised trial involving 663 8 to 10-year old children (363 boys and 300 girls) with elevated low-density lipoprotein cholesterol (1995). The investigation was designed to test the efficacy and safety of dietary and behavioural interventions to lower saturated fat and cholesterol intake while promoting a healthy eating pattern.

Children were randomised into intervention and usual care groups. The study aimed to promote adherence to a healthy diet using intervention strategies based on social-learning theory and social-action theory constructs, according to which children learn behaviours through observation and imitation of models, such as parents, siblings, other family members, peers, and celebrities. Intensive intervention included 6 weekly sessions during the first 6 months, followed by 5 biweekly group sessions led by nutritionists and behaviourists during which dietary information and practical tips for following the diet were provided. Group sessions were followed by two individual sessions with the nutritionist.

During the subsequent 6-month period, 4 group and 2 individual sessions were additionally held. These relatively intensive intervention sessions were followed by maintenance sessions 4 to 6 times per year during the second and third years, with monthly telephone contacts between group sessions. The usual care group was provided with publications on healthy eating and assessed annually.

At 3 years, dietary total fat, saturated fat, and dietary cholesterol levels had decreased significantly in the intervention group, compared with the usual care group (-4.2%, -2.1%, -18.1 mg for % total dietary fat, % saturated fat and mg of dietary cholesterol, all $P < 0.001$). These results indicate that a behavioural approach to dietary modification leads to sustainable changes in dietary intake in 8 to 10-year old children.

In the US, researchers randomised 67 obese children into 3 groups receiving a 6-month family-based behavioural weight control programme alone or with parent or child problem-solving (Epstein, Paluch *et al*. 2000). All 3 groups showed significant BMI z-score decreases at 2 years. Almost 50% of the children in the standard group displayed marked (> 1.0) BMI z-score decreases. Across all groups, mean BMI z-score was reduced from 2.7 to 1.9 at 2 years. However, to date, no other group has managed to replicate Epstein's interventions or findings.

In the meta-analysis by Oude Luttikhuis *et al*. (2009), the intervention target was the family or the child with a parent in 40 of the 64 studies, while the rest examined either the child alone, parent alone (1 study) or the effects of different levels of parent and/or child participation. In children less than 12 years of age, parent-focused lifestyle interventions were more effective than standard care in reducing BMI z-score at 6 months (effect size -0.06, 95% CI: -0.12 to -0.01), but this reduction was non-significant by 12 months (effect size -0.04, 95% CI: -0.12 to 0.04).

Family involvement is generally the core element of a successful weight management programme, as the main aim of intervention is adoption of healthy lifestyle habits for the whole family. The behavioural change component needs to involve the whole family in order to achieve successful changes, provide support, and be sustainable and applicable to the child. Targeting lifestyle treatments for the parent or parent and child appear more effective than targeting the child alone. Parental involvement in treatment of children with overweight or obesity increases the likelihood of improvements in anthropometry (Oude Luttikhuis, Baur *et al*. 2009). This is not surprising, since parents serve as role models and determine their children's physical and social environments (Ritchie, Welk *et al*. 2005). Depending on the age of the child, parents can be more or less involved in the programme. For instance, programmes aimed at preschool and pre-pubertal children should focus on parents, as they constitute the primary agents of change within a family. Conversely, for pubertal and adolescent groups, parents and children can attend common and/or separate sessions, but it is important for the children to be engaged and actively involved in the process.

Peer contribution becomes central in adolescence, although school and friends are also important for younger children. However, pre-adolescent children are primarily influenced by their family in terms of behaviour and attitude. As many parents of obese children are overweight or obese themselves, they may have a history of repeatedly making unsuccessful attempts to change their own behaviour. These factors make parental inclusion challenging for those designing and delivering childhood obesity programmes.

Consequently, inclusion of parents is essential for a successful childhood obesity intervention programme, especially for younger children (ADA 2006; NICE 2006; SIGN 2010). Although crucial, parental involvement requires motivation and commitment, which may not be present.

In summary, current recommendations state that there is limited evidence to support the use of behavioural counselling alone for reducing overweight in children or adolescents. However, there are sufficient indications to routinely recommend the inclusion of a behaviour modification component within a multicomponent, family-based group intervention, along with dietary counselling and physical activity for reducing overweight in school-aged children.

Effectiveness of multicomponent interventions

Interventions that address all three key lifestyle areas related to obesity, specifically, nutrition, physical activity and behaviour, are more effective than those that address only one or two of these areas (Oude Luttikhuis, Baur *et al*. 2009).

In 2008, a meta-analysis of RCTs assessed the efficacy of treatments for childhood obesity (McGovern, Johnson *et al*. 2008). The study revealed short-term efficacy of pharmacological interventions for Sibutramine (which is no longer available in the UK) and Orlistat (only prescribed in adolescents). In addition, a moderate treatment effect of physical activity on adiposity, but not BMI, and a small to moderate effect of combined lifestyle interventions targeting families on BMI was reported (Figure 23). The authors did not observe significant interactions between age of participants and effect of lifestyle interventions with parental involvement, but a trend towards a larger treatment effect was observed in children aged 8 years or less (-0.70; 95% CI: -1.0 to -0.40).

Figure 23. Summary of meta-analysis results from RCTs of treatments for paediatric obesity

Image removed for copyright reasons

Taken from McGovern, Johnson et al. (2008). Plot shows meta-analytic point estimates (■) and 95% CI (horizontal lines). SMD, standardised mean difference

A US evidence report analysed 20 studies conducted in children aged between 4 and 18years (Whitlock, O'Connor *et al*. 2008). Their results demonstrated that comprehensive lifestyle interventions that included nutrition, physical activity and behavioural components produced short-term improvements in weight. BMI reduction of 1.9 to 3.3 kg/m^2 over 6 to 12 months, respectively, was achieved, compared with control group participants.

The most recent meta-analysis of childhood obesity interventions included trials that specifically evaluated any combination of lifestyle (dietary, physical activity, behavioural therapy), drug or surgical intervention, compared with no treatment (Oude Luttikhuis, Baur *et al*. 2009). RCTs specifically designed to treat obesity in children less than 18 years of age and included at least 6 months of follow-up were included. The rationale for introducing this criterion arose from the observation that many interventions appear effective in the short term (up to 3 months), but not the long term (Glenny, O'Meara *et al*. 1997). However, as obesity is a chronic condition, evaluation of longer-term effectiveness is crucial.

The lifestyle interventions ranged in duration from 1 to 24 months, with 14 having a duration of less than 6 months. The majority (29) of studies occurred in the USA, while only 2 of the 54 were conducted in the UK. Thirty-seven studies were conducted in children with a mean age less than 12 years, while the rest focused on adolescents. Fifty-four lifestyle interventions were further subdivided into 3 categories: activity-based, dietary interventions and behavioural.

In children under 12 years, family-targeted behavioural lifestyle interventions led to a greater reduction BMI z-score than standard care at 6 months follow-up. The effect size was small (-0.06, 95% CI: -0.12 to -0.01), but statistically significant, and possibly clinically relevant. In children 12 years and older, lifestyle interventions were more effective than standard care in reducing BMI z-score at 6 and 12 months (effect size -0.14, 95% CI: -0.17 to -0.12 at 6 months and effect size -0.14, 95% CI: -0.18 to -0.10 at 12 months).

This review highlighted the importance of a combined dietary, physical activity and behavioural approach in pre- and post-adolescent weight management interventions. One-third of the lifestyle intervention studies included in the review reported measures of harm. However, no adverse effects on linear growth, eating behaviour or psychological well-being were noted.

Influence of intensity of intervention in multicomponent interventions

The intensity of interventions, including the duration over which the intervention is provided and frequency of contact between provider and participants, appears to influence the success of childhood weight management programmes.

A meta-analysis of 20 studies in children showed that programmes incorporating medium-intensity (26 to 75 contact hours) or high-intensity (over 75 contact hours) intervention achieved greater BMI reduction than those with lower intensity (Whitlock, O'Connor *et al*. 2008).

A similar meta-analysis of studies aimed to assess lifestyle interventions in the management of overweight and obese adolescents (Collins, Warren *et al*. 2006). Daily versus weekly frequency of contact between the provider and caregiver was compared. Daily contact was associated with significantly greater weight reduction than weekly contact at 6 months follow-up (average of 9% versus 5% weight reduction, respectively).

A systematic review of 17 studies in 3,086 children and adolescents that assessed the components of primary care interventions to treat childhood overweight and obesity was recently conducted (Sargent, Pilotto *et al*. 2011). In eight of the 17 studies, positive changes in anthropometry were observed, including reduction in BMI between 0.8 kg/m^2 and 3.3 kg/m^2 and reduction in BMI z-score between 0.10 and 0.11. The monthly rate of contacts in effective interventions ranged from 0.2 (one contact in 6 months) to 11.3 (34 contacts in 3 months). The six interventions with a contact rate of monthly or less (rate < 2) reported one to three significant outcomes in either anthropometry or behaviour change. In contrast, each of the six effective interventions with higher intensity (at least one contact every 2 weeks) reported two or more significant outcomes.

Overall, it appears that greater intervention intensity is likely to be an important factor for predicting success following a childhood weight management intervention. Unfortunately current evidence does not provide accurate guidance on intensity of interventions.

Influence of the role of health education in multicomponent interventions

The majority of studies aiming to treat obese children incorporate a health education component designed to promote understanding of the role of specific elements of obesity management or teach children and/or their parents or carers specific prevention and/or treatment strategies. Common topics include nutrition, increasing physical activity, reducing sedentary behaviour and behavioural change components.

The majority of studies have been conducted in clinic-based or community settings, for e.g., schools and leisure centres (Oude Luttikhuis, Baur *et al*. 2009; Sargent, Pilotto *et al*. 2011). In the clinic-based setting, health education is generally delivered face-to-face to the parent or child with or without inclusion of the child, with written materials used to reinforce key messages. In the school setting, the child is usually the recipient of group-based face-to-face health education. This may be supplemented with written material, including pamphlets or a workbook. Health education can be provided by a broad range of health care professionals, including dietitians, clinicians (e.g., GPs), school or practice nurses, psychologists and teachers (including physical education teachers).

A systematic review of 22 school-based intervention studies (16 RCTs and 6 controlled clinical trials) involved over 6,997 participants (Li, Li *et al*. 2008). In total, 17 studies were conducted among overweight and/or obese Chinese children aged between 3 and 19 years. The majority of studies focused on improving the level of knowledge, physical activity levels, and/or diet of overweight children and adolescents. Four studies used an intervention focusing on health education, two on health education and physical activity, seven on health education, physical activity and diet, three on physical activity alone, and the remaining six on physical activity and diet. The majority of investigations reported improvement in one of many outcomes. However, there were major methodological weaknesses that did not allow direct comparisons, as different measures for intervention effectiveness were used across studies (Li, Li *et al*. 2008).

Another meta-analysis that included a number of primary studies assessing health education was performed in the US in 2007 (DeMattia, Lemont *et al*. 2007). The first study reported the results of a RCT testing a 2-year curriculum to promote healthy eating and limit television watching in preschool children. BMI decreased in the intervention group and increased in the control group. Point estimates were not provided. However, the differences did not reach statistical significance. Television viewing decreased by 24% and increased by 12% in the intervention and control groups, respectively. A second study reported the results of an 18-lesson, 6-month classroom curriculum for 8 to 10-year olds to reduce screen time. At follow-up, BMI of the treatment group increased by 0.3 kg/m^2 versus 0.7 kg/m^2 in the control group. A third study provided health education over 2 years in students from Grades 6 to 7. Excess body weight decreased from

24% to 20% in the intervention group and increased from 22% to 24% in the control groups.

In summary, these studies collectively demonstrate that the degree to which the health education component is responsible for improvements in outcomes of multicomponent interventions is uncertain. As a stand-alone intervention, patient education is not usually associated with significant weight reduction. Currently, insufficient evidence is available to recommend a specific type of education or provide guidance on the most effective setting or format for education or frequency of sessions.

Influence of parental involvement in multicomponent interventions

Despite the well-reported positive effects of parental involvement in childhood obesity treatment programmes, more recent research has begun to incorporate parental perception of child overweight as a key variable in determining the family's readiness to modify the child's environment and lifestyle (Doolen, Alpert *et al*. 2009; Tschamler, Conn *et al*. 2010).

In younger age groups, increased weight is often dismissed by parents who believe that the child is either well-fed or will grow leaner with age. At a young age, weight management is more preventive than interventional. However, the need exists for establishing healthy eating and activity habits as early as possible, as habits acquired at a young age tend to persist in later childhood and adolescence. Parents of overweight and obese children commonly underestimate their child's weight status. This is especially true for at-risk populations and boys, possibly due to social norms that "allow" males to be larger than females, but require females to be slim to gain social acceptance (Doolen, Alpert *et al*. 2009).

The underlying reasons of this phenomenon have not yet been specified, and most available evidence is based on theory, rather than solid scientific data. In a study, results from a focus group were assessed in an effort to understand the causes underlying the observed discrepancy between perceived and actual weight status of children. Possible reasons include parental mistrust of growth charts, often perceived as having little relevance to their child, limited understanding of the real definition of overweight (for instance, the belief that only severely obese children belong to this category), and fear of being judged as bad parents or their child being stigmatised and labelled as "fat" (especially for younger ages) (Jain, Sherman *et al*. 2001). Another possible explanation is that the increasing prevalence of childhood obesity has caused confusion in terms of what may be normal and higher than normal, hence leading parents to judge their overweight child as 'normal' by comparison to their (also overweight) counterparts (Young-Hyman, Herman *et al*. 2000). Parental denial, "optimistic bias" (i.e., the tendency to view things more optimistically than one should), cultural beliefs, and low education and/or socioeconomic status are additionally thought to contribute to this phenomenon (Doolen, Alpert *et al*. 2009).

Screening programmes organised to identify at-risk children at schools often do not communicate the message of childhood overweight and obesity in a culturally appropriate way, therefore failing to increase awareness in ethnic minority groups that are disproportionally affected by increased adiposity (Fitzgibbon and Beech 2009).

Influence of group versus individual treatment

Another important consideration when developing childhood weight management interventions is group versus individual treatment, which has been extensively researched (Braet and Wydhooge 2000; Kalavainen, Korppi *et al*. 2007; Garipagaoglu, Sahip *et al*. 2009).

Group interventions have more therapeutic benefits and are more cost-effective than individual treatments (Barlow 2007). For this reason, this model is widely used in research-based childhood obesity treatments (Braet and Wydhooge 2000; Goldfield, Epstein *et al*. 2001; Epstein, Paluch *et al*. 2007; Kalavainen, Korppi *et al*. 2007; Garipagaoglu, Sahip *et al*. 2009).

Community group interventions have also been shown to be effective in the treatment of other childhood problems, such as disruptive behavioural disorders (Cunningham, Bremner *et al*. 1995). Importantly, group-based interventions not only improve outcomes on target variables, but also have the potential to provide additional therapeutic outcomes (Robinson 1999; Barlow 2007).

More precisely, community group interventions are more beneficial in a number of areas, since they: i) provide greater access to families from minority groups, as venues are more convenient and travel expenses for attending are reduced, ii) counter the stigma and participation barriers often associated with individual sessions in a hospital, iii) extend limited resources, and therefore have the potential to reach a greater number of children, and iv) facilitate improved outcomes and maintenance of behaviours (Cunningham, Bremner *et al*. 1995).

A review of behavioural treatments for childhood and adolescent obesity showed that group treatments are more effective than individual treatment sessions.

Group interventions were established as being more efficient, providing greater therapeutic interactions between participants, improved attendance rates, and higher cost-effectiveness (Robinson 1999; Goldfield, Epstein et al. 2001).

Interestingly, a recent study examining whether individualised counselling by a dietitian trained in behavioural changes aids in managing childhood obesity disclosed no effects on BMI reduction (Hughes, Stewart *et al*. 2008).

The clinical benefits of community groups include group discussion of problem-solving processes, which enhances understanding of management of the presenting problem, group discussion of goals and homework improving adherence (Meichenbaum 1987; Pedrosa, Oliveira *et al*. 2011), and the development of social support networks (i.e., links with other families and community resources), which can be utilised after programme completion (Cunningham, Bremner *et al*. 1995).

However, group-based treatment may not be appropriate for all obese children. Some children may have complex medical and/or psychosocial needs, which cannot be adequately dealt with in a group environment. These types of families require specialist individualised care and support. In addition, some childhood obesity interventions are provided directly to families by non-specialist staff, for e.g., health trainers with no specialist medical or psychosocial knowledge or treatment skills (Rudolf, Christie *et al*. 2006). Moreover, some families prefer the privacy afforded by individualised treatment and fail to engage with group-based interventions.

In conclusion, both group-based and individualised treatment options should be available to meet the needs of all families with overweight or obese children.

Influence of the role of GP delivery in multicomponent interventions

In a study published in BMJ, an Australian research team conducted a GP-delivered intervention programme. This RCT with 258 paediatric participants (aged 5 to 9 years, BMI z-score < 3) assessed a GP-based family orientated lifestyle intervention for weight loss (Wake, Baur *et al*. 2009). GPs attended two 2½-hour group training sessions for instruction in stages of change and training in brief, solution-focused family therapy, and received a 30-minute DVD, which role-modelled scenarios using solution-focused therapy in consultations. Each GP conducted two simulated patient sessions appraised by an actor playing the role of the 'parent'. GPs who did not receive a pass grade were offered additional training. The intervention involved four standard consultations over 12 weeks targeting changes in lifestyle, supported by purpose-designed written materials. Control group participants did not receive any intervention. Subjects in both groups did not display reduced BMI or improvement in anthropometric indices. After 12 months, adjusted mean difference in BMI between intervention and control groups was -0.11 kg/m^2 (95% CI, -0.45 to 0.22).

Another RCT involved 163 participants aged 5 to 9 years (BMI z-score < 3) randomised to education materials and four standard GP consultations over 12 weeks targeting nutrition, physical activity and sedentary behaviour or a control group (McCallum, Wake *et al*. 2007). GPs received an education package regarding delivery of the intervention, comprising three evening group sessions on brief solution-focused therapy techniques. This approach was used by GPs to set and record appropriate, healthy lifestyle goals with the family, assisted by a written, personalised 20-page behaviour change resource designed at a 12-year old reading level. However, the intervention did not result in weight loss in either the intervention or control groups. BMI z-score from baseline to 15 months decreased by 0.03 (95% CI: -0.17 to 0.10).

Studies examining the role of GPs are important, as doctors are responsible for the primary health care of children and potentially play a very important role in effective management of the childhood obesity epidemic. Therefore, the GP practice is the most sensible place to assess children's weight status in the presence of parents (McCallum, Wake *et al*. 2007; Wake, Baur *et al*. 2009). Parents often seek or accept advice from their doctor and take their opinions seriously. Accordingly, doctors need to be appropriately trained to assess childhood obesity and communicate with families in order to offer feasible solutions (Lumeng, Castle *et al*. 2010). Another limitation of the GP-led approach is that GP practices often lack the resources to provide systematic and multi-disciplinary support to families with obese children. However, with appropriate networking, GPs may be able to liaise with other health or non-health professionals to offer solutions that effectively help families address weight problems in their children. As a stand-alone intervention, clinician education does not appear to significantly improve patient outcomes, and remains an important area for further research.

Effectiveness of UK multicomponent trials

Four RCTs have been conducted in the UK to evaluate the effects of 4 different interventions for treating childhood obesity (Hughes, Stewart *et al*. 2008; Ford, Bergh *et al*. 2009; Sacher, Kolotourou *et al*. 2010; Croker, Viner *et al*. 2012). Three of these will be reviewed in detail, and the fourth presented and discussed as part of this PhD thesis (Sacher, Kolotourou *et al*. 2010). An additional intervention, designated WATCH IT, has been developed and assessed in the form of a process evaluation, with a future RCT planned (Rudolf, Christie *et al*. 2006).

A number of investigators aimed to test the generalisability of the most widely cited intervention (FBBT: Family-Based Behavioural Treatment) originally developed in the USA to target families with obese 8 to 12-year olds (Epstein, Valoski *et al*. 1994; Croker, Viner *et al*. 2012). The generalisability of the efficacy of FBBT is uncertain, as previous studies have been conducted in academic settings and no other RCTs are available for FBBT evaluation. Therefore, Croker and co-workers examined the acceptability and effectiveness of FBBT in an ethnically and socially diverse group of children in a UK children's hospital (Great Ormond Street Hospital for Children NHS Trust).

FBBT is a structured intervention comprising advice on whole family lifestyle change with a behavioural weight control programme for the obese child. Children attend with one parent or carer, with a maximum of 8-10 families per group. The aims of FBBT are to reduce fat and energy intake, increase physical activity and change parent-child interactions. The behavioural programme is based on the social learning theory and employs behaviour modification techniques, such as self-monitoring (daily food and activity diaries), goal setting, positive reinforcement, stimulus control, and relapse prevention. In the study by Crocker *et al*. (2012), parents were instructed in behaviour management principles to support their child's behaviour change and make changes to the home environment to encourage family-wide uptake of healthy lifestyle behaviours. Cognitive components of the programme included advice on managing teasing and general problem-solving. The key dietary targets were to follow a regular eating pattern, reduce snacking to no more than two occasions per day, and consume a balanced diet (as described in Section 3.5.1, the ‘Eatwell plate’) (DH 2011) and the ‘Traffic Light’ system (Epstein 1996) in appropriate quantities. Key physical activity targets were to reduce time spent in sedentary behaviours and increase time spent in lifestyle or structured activity, in keeping with the current UK recommendation of 60 minutes a day (O’Donovan, Blazevich *et al*. 2010). The authors delivered the FBBT as described by Epstein and colleagues, with minimal adaptation for use with British families (Epstein 1996).

The intervention consisted of 15 x 1.5 h sessions delivered over 6 months (10 weekly, 3 fortnightly, 2 monthly). Children and parents were split into two groups. Interventions to the parent groups were delivered by clinicians with experience working with parents and families (psychologist, family therapist or experienced dietitian) and to the children’s groups by a dietitian experienced in working with children as well as a research assistant.

The primary outcome of the trial was BMI z-score at 6 months. Secondary outcomes included waist circumference z-score, body composition and self-esteem. Children in the treatment group only were followed up at 12 months. Thirty-seven children (mean BMI z-score = 3.2 ± 0.6) were allocated to the intervention group. However, 15 (41%) of the children dropped out and were lost to follow-up. Overall, 43% of children were non-white, with significantly more girls than boys (70:30). The median number of sessions attended was 9 (IQR 10.5). No significant differences were recorded between groups for BMI z-score, waist circumference z-score, cardiovascular or psychosocial outcomes. Within-group analysis revealed marked reductions in BMI z-score for both groups (intervention: -0.11, control: -0.10). No overall change in BMI z-score at 12 months follow-up was observed, possibly due to significant weight gain between 6 and 12 months (+5.7 kg). These results are inconsistent with the conclusions of the Cochrane review, which showed a significant pooled treatment effect of -0.06 BMI z-score from behavioural interventions, compared to controls (Oude Luttikhuis, Baur *et al*. 2009). The author's explanations for the reduced effect of the intervention, compared to other evaluations of FBBT, included minor changes to the programme, for e.g., elimination of daily weighing, replacement of calorie goals with those on food types and portion size and lack of incentives for participation. The group additionally suggested that some differences can be explained by ethnically diverse samples and the clinical setting, in comparison to many of the other academic settings. The results of this trial raise issues over the generalisability of FBBT and the use of expensive treatment when other less expensive options are available.

Researchers at the Bristol Care of Childhood Obesity Clinic (COCO) evaluated the effect of a novel eating device, known as the Mandometer, compared with standard care in the clinic in children aged 9 to 17 (Ford, Bergh *et al*. 2009). The Mandometer was developed at the Section of Applied Neuroendocrinology and Mandometer Clinic, Karolinska Institutet, Stockholm, Sweden. This is a portable weighing scale connected to a small computer that can generate a graph representing food removal from the plate. The user puts a measured portion of food determined by a therapist on the scale and the computer records and displays weight loss from the plate as the user eats in real-time graphics. Removal of food from the plate generates a gradually developing line on a screen that can be compared and matched to a pre-set eating line displaying the speed at which the therapist wants the user to eat. Deviation from the training line by eating too quickly or slowly elicits a spoken request from the Mandometer to slow down or eat faster. At regular intervals, a rating scale appears on the screen, and the user rates their level of fullness from 0 (no satiety) to 100 (maximum satiety), which yields "development of satiety" curve and allows comparison of the development of fullness to a "normal" fullness curve again pre-set on screen. During training, the user gradually adopts a more normal pattern of eating and satiety by following these training lines and curves. The Mandometer was originally developed for treating eating disorders, such as anorexia and bulimia nervosa, but in this publication, it was evaluated as a method for increasing satiety by reducing eating speed and therefore decreasing energy intake.

Children above the 95th BMI centile with no underlying medical problems were eligible for the study. Children in the intervention group saw a specialist Mandometer nurse once a week for 6 weeks, every second week for a further six weeks, and once every sixth week thereafter (a total of 15 individual appointments). In addition, the research nurse telephoned the children to offer support and encouragement every second week from week 12 onwards. Children also received four dietetic consultations from a paediatric dietitian plus 3 clinician visits. Children in the control group were offered four appointments with a multidisciplinary team consisting of a clinician, paediatric dietitian and an exercise specialist. The primary outcome was change in BMI z-score at 12 months, with further follow-up at 18 months (no contact with clinical staff between 12 and 18 months). The study was powered for 40 children in each group, and 106 participants were recruited. Mean age at baseline was 12.7 years (±2.2) and mean BMI was 34.4 (range: 24.2 to 46.6) (BMI z-score not provided).

Ninety-three of the children were classified as white. Assessment of 91 children at 12 months revealed that those in the intervention group had a significantly lower mean BMI z-score (-0.27, 95% CI: -0.14 to -0.41). This significant difference was sustained at 18 months (BMI z-score -0.27, 95% CI: -0.11 to -0.36). Children in the intervention arm reduced their speed of eating by 11%, compared to a gain of 4% in the control group. Measures of quality of life improved in both arms of the study, with no reported adverse events. Mean attendance of the 15 appointments was 83% for children in the intervention group, with 86% retention at 12 months.

The positive effects of the study suggest that modification of eating behaviours offers additional benefits to standard lifestyle modification in treating childhood obesity. However, it is worth noting that there was significant contact time between research and/or clinical staff and participants. Some evidence suggests that treatment intensity affects outcomes in weight loss interventions (Digenio, Mancuso *et al*. 2009). Another important consideration not discussed in the publication is the cost-effectiveness of this intervention using novel technology. It is assumed that the cost of clinical care plus the Mandometer may not allow this type of clinical intervention to be offered to many obese children considering the current financial climate in the UK, but nonetheless, provides an innovative promising approach.

Hughes and colleagues (2008) designed a behavioural intervention based on recommendations from systematic reviews and expert committee guidance (Barlow and Dietz 1998; Hughes, Stewart *et al*. 2008). The intervention was designed to treat obese children within a UK health care setting (Royal Hospitals for Sick Children in Glasgow and Edinburgh) with limited resources (e.g., staff and time) using a family-centred approach combined with behaviour change techniques. The trial, designated SCOTT (Scottish Childhood Overweight Treatment Trial), was the first RCT in the UK to implement best practice recommendations in a relatively low-intensity office-based setting using a single health professional.

The study was designed to test the efficacy of the intervention, compared to standard dietetic care (control group), in reducing BMI z-score in obese children between 5 and 11 years of age. The intervention was delivered individually to families by an experienced paediatric dietitian trained in behaviour change counselling. Families received 8 appointments (7 outpatient visits and 1 home visit) over 26 weeks, with a total patient contact time of 5 hours. The programme included dietary advice using a modified traffic light diet and guidance on how to increase physical activity and restrict sedentary behaviours. Full details of the intervention have been published previously (Stewart, Houghton *et al*. 2005). Table 4 provides a summary of the intervention, compared to control (standard care).

Table 4. Comparison of best-practice individualised behavioural intervention with standard dietetic care used in the SCOTT trial

Image removed for copyright reasons

Taken from Hughes, Stewart et al. (2008)

One hundred and thirty-four children (BMI z-score = 3.3, IQR: 2.8 to 3.6) were randomly assigned to the intervention or control group (powered for 34 per group, based on a between-group difference of -0.25 in primary outcome, i.e., BMI z-score at 6 months). Overall, 72% of children were measured at 6 months and 64% at 12 months. A proportion (68%) of participants assigned to the intervention group complied with the treatment, which was defined as attendance at ≥ 75% of appointments. Moreover, 70% of those assigned to the control group attended ≥ 75% of their appointments. BMI z-score decreased significantly within groups from baseline to 6 months (intervention: 95% CI: -0.18 to -0.07; control 95% CI: -0.16 to -0.03) and baseline to 12 months (intervention: 95% CI: -0.22 to -0.04; control: 95% CI: -0.26 to -0.08). There were no significant differences between groups for BMI z-score at 6 (0.03, 95% CI: -0.05 to 0.11) and 12 months (-0.04, 95% CI: -0.17 to 0.07). Analysis of secondary outcomes revealed no significant between-group changes for waist circumference at 6 or 12 months, compared to significant between-group differences for physical activity levels and sedentary behaviours at 6 months only. Changes in quality of life scores for the child self-report and parent proxy report were not significantly different.

Results from this study highlighted that when treatment for childhood obesity is provided individually in a clinical setting using well-trained staff, outcomes are unsatisfactory. Clinical settings, such as hospitals, may medicalise the problem and therefore disempower families from making the necessary lifestyle changes. Similar results were obtained with the LEAP trial in Australia when GPs provided advice on nutrition, physical activity and sedentary behaviours (McCallum, Wake *et al*. 2007). These studies highlight the need for more intensive, group-based interventions that may be more suitably delivered in non-medical settings.

Rudolf and co-workers (2006) conducted an evaluation of the WATCH IT intervention in a socially disadvantaged areas of Leeds, UK (Table 5) (Rudolf, Christie *et al*. 2006). The WATCH IT intervention is a multicomponent lifestyle programme including counselling (motivational and solution-focused approach), provision of physical activity, reduction of sedentary behaviours, healthy eating advice and appetite regulation. The programme has three components: weekly individual family appointments (30 minutes) for encouragement, support and motivational counselling, weekly one-hour group physical activity sessions (it is unclear whether parents are included), and group parenting sessions (presumably while children are exercising alone). Parents are a key target of the intervention, which lasts for 3 months to 1 year. The intervention was delivered by health trainers with ongoing support and supervision from a multidisciplinary team, including a dietitian and psychologist.

Ninety-four children participated in the intervention. Pre- and post-longitudinal data were available for 68 (72%) children at 3 months and 48 (51%) children at 6 months. At 3 months, 54% children, and at 6 months, 71% children displayed a decrease in BMI z-score. Change in mean BMI z-score at 3 months was -0.01 (SD 0.12, $p > 0.05$). By 6 months, mean BMI showed a significant decrease (mean change -0.07, SD 0.16, $p = 0.01$). The mean change in BMI z-score at 6 months was greater for girls (-0.07, SD 0.14, $p = 0.02$) and participants aged 13 years or over (-0.13, SD 0.14, $p = 0.01$). The authors confirmed that funding was available to conduct a randomised controlled trial, which is crucial for determining the efficacy of this intervention.

In summary**,** systematic reviews (Collins, Warren *et al*. 2006; Whitlock, O'Connor *et al*. 2008; Oude Luttikhuis, Baur *et al*. 2009; SIGN 2010) demonstrated that earlier RCTs evaluating childhood obesity trials had methodological flaws, such as small sample sizes, high dropout rates, short-term follow-up, lack of detail about the randomisation process, lack of blinding, and failure to use intention-to-treat analysis. Intensive behavioural treatment programs have proved successful in clinical studies from one centre in the USA (Epstein, Valoski *et al*. 1994). However, these interventions were intense, requiring a number of specialist health professionals, and therefore may not be generalisable to all health care systems. Importantly, a specialist multidisciplinary team recently failed to replicate these findings in a UK setting (Croker, Viner *et al*. 2012). Another UK trial has also failed to show significant reductions in childhood weight status (Hughes, Stewart *et al*. 2008), and therefore, high-quality studies that establish more generalisable interventions to treat childhood obesity are urgently required.

Table 5 provides a summary of selected UK and international interventions and additional trial details.

Table 5. Comparison of childhood obesity weight management interventions

Organisation, country, study design	Target group, attendance and retention	Format / intervention design, intensity	Delivery details: Skill level	Delivery details: Number of staff	Delivery details: Delivery site	Content / professional time	Comprehensiveness and outcomes / evidence
PEACH (Parenting, Eating and Activity for Child Health) Sydney and Adelaide, Australia RCT comparing parenting skills plus healthy lifestyle education versus healthy lifestyle education alone. (Golley, Magarey *et al*. 2007)	5 – 9 years overweight or obese (exclusion BMI z-score >4) N = 111 12 – 14 parents per group 83 - 69% retention rate at 12 and 24 months.	'Parents only' intervention. Nutrition information, problem solving approach for the whole family, not individual child. Children offered supervised physical activity (PA) as a childcare option but not considered part of intervention. Healthy Lifestyle (HL) + Parenting 4 x 2 hours (hrs) healthy lifestyle sessions + 8 parenting sessions 90 min. fortnightly then tapered to monthly over 7 months. + 4 telephone support calls per child Total time = 20 hrs + phone calls HL only 8 sessions 90 min fortnightly then tapered to monthly over 6 months + 4 x15 min support calls per child Total time = 12 hrs + phone call	Conducted by dietitians who had completed accredited parenting skills training in Triple P. Triple P training consists of 3 day course. Dietitians, no further training required.	1 – 2 per programme (+ PA leaders for child care)	Paediatric unit of Flinders Medical Centre + Westmead Hospital, Sydney. Space donated by the hospitals.	Content time 20 hrs + phone calls OR 12 hrs + phone calls Professional Time 40 hrs or 24 hrs + PA leaders time + Triple P training time + phone calls Intensity level of intervention: Moderate intensity.	BMI Z score results: HL + Parenting 2.77±0.58 at baseline 2.48±0.70 at 6 months 2.46±0.65 at 12 months 2.38±0.67 at 24 months HL only 2.68±0.65 at baseline 2.46±0.70 at 6 months 2.44±0.71 at 12 months 2.26±0.84 at 24 months 10% relative weight loss achieved and maintained at 2 years for the HL + P programme. **BMI z-score change: -0.09**

Organisation, country, study design	Target group, attendance and retention	Format / intervention design, intensity		Delivery details			Content / professional time	Comprehensiveness and outcomes / evidence
				Skill level	Number of staff	Delivery site		
HIKCUPS Hunter & Illawarra Kids Challenge using Parent Support Newcastle and Wollongong in NSW, Australia RCT comparing 3 formats of delivery. PRAISE vs. SHARK vs. combination of both. (Okely, Collins *et al.* 2010)	6 – 9 years overweight or obese (exclusion BMI z-score >4) Total sample 216 children at initial, 165 at 12 months. 108 per site, 36 children per group. 64% retention rate at 12 months	PRAISE –Positive Reinforcement and Incentives for Smart Eating. - Parent centered dietary modification programme - Parent only - 26 week programme + follow-up (F/U) 10 week core curriculum – 2hrs sessions 16 week follow up curriculum, parent led at home. 2 x 2 hrs sessions at 26 weeks and 2 months with facilitator Telephone follow up calls monthly, 3 months post 26 weeks.	SHARK – Skills Honing & Active Recreation for Kids. - Child centered physical activity - Skill development programme Child only - 26 week programme + F/U 10 week core curriculum – 2hrs sessions + weekly homework challenge 16 week follow up curriculum, parent led at home. 2 x 2 hrs sessions at 26 weeks and 2 months with facilitator Telephone follow up calls monthly, 3 months post 26 weeks.	In RCT PRAISE sessions led by dietitians and SHARK PA leaders were PE teachers. 5 day training required to qualify as session leaders.	2 leaders per programme. 1 x trained facilitator 1 x physical activity specialist	University campuses of Newcastle and Wollongong. But programme designed for implementation in community settings such as schools, health and leisure centres.	<u>Content Time</u> Combined programme SHARK + PRAISE = 44 hrs + phone calls. <u>Professional Time</u> 88 hours of direct professional time. + 5 day training time <u>Intensity Level of Intervention:</u> Moderate intensity	Baseline to 12month published results. Results across all groups at 12 months: BMI z-score decreased 2.81±0.71 to 2.45±0.69 ($p < 0.001$) Energy intake decreased 261±108 kJ/kg to 204±69 kJ/kg ($p < 0.001$) LDL/HDL decreased 2.08±0.64 to 1.99±0.64 (NS) Waist circumference no change (76.6±9.4cm to 76.2±9.7cm ($p = 0.11$) No significant difference between the 3 formats. **BMI z-score change: -0.32**

Organisation, country, study design	Target group, attendance and retention	Format / intervention design, intensity	Delivery details			Content / professional time	Comprehensiveness and outcomes / evidence
			Skill level	Number of staff	Delivery site		
Golan *et al*. Israel. Parent only sessions vs. parents and their child. (Golan, Kaufman *et al*. 2006)	6 – 11 years 32 families BMI >85th percentile. Retention not reported	16 x 1 hour education sessions Initially weekly for 10 weeks, then 4 sessions delivered fortnightly, the last 2 sessions once per month. + 40 – 50 min. one to one appointments held monthly for each family. Total intervention time 6 months Both programmes covered same content, but parent + child programme was adapted to include child in activities. Family based, but with parents providing authoritative direction. Content emphasized healthy eating habits, and increased PA and a decrease in sedentary activities.	Dietitian Family therapist	2 per session	Unknown	Content Time 24 hours Professional Time 46 hours Intensity Level of Intervention : Low intensity	Results published at 6, 12, 18 months Parent only group: mean BMI z-score change of -0.4 (P <0.05) 9.5% reduction in overweight. Parent and Child group: mean BMI z-score change of 0.1 (NS) 2.4% reduction in overweight. **BMI z-score change: -0.30**
Traffic Light Diet RCT comparing Parent only (PO) vs. Parent + Child (P+C) Minneapolis and San Diego, USA (Boutelle, Cafri *et al*. 2011)	8 – 12 yrs 80 families across 5 groups BMI >85th percentile. PO retention at 6 months 60%; P+C retention at 6 months 70%	Based on behavioral treatment intervention developed by Epstein *et al*.(Traffic Light Diet) Total intervention time 5 months Parent and Child – 2 x 1hr sessions delivered to child and parent separately. + weekly 10 minutes per family one to one sessions for goal planning Parent only – 1 hour sessions Group sizes 6 -10 participants	Clinical psychologists or advanced clinical psychology students. All leaders completed 3 day behavioral intervention training.	2 per session	University of Minnesota and University of California	Content Time 30 hours Professional Time 60 hours Intensity Level of Intervention : Moderate intensity	Parent only results for BMI z-score Baseline 2.29±0.38 5 months 2.16±0.54 11 months 2.10±0.68 Parent + child results for BMI z-score Baseline 2.25±0.34 5 months 2.06±0.40 11 months 2.08±0.41 **BMI-Z change: -0.17**

Organisation, country, study design	Target group, attendance and retention	Format / intervention design, intensity	Delivery details			Content / professional time	Comprehensiveness and outcomes / evidence
			Skill level	Number of staff	Delivery site		
Lifestyle Triple P Positive Parenting Programme The University of Queensland. RCT in 2003-06 compared 12 weeks of intervention with control group. (West, Sanders *et al*. 2010)	5 – 10 yrs (RCT sample were 4-11 yrs old, 101 families in total). Self-referral Retention not reported	Parents only intervention/ prevention programme Total intervention time 4 months. 16 sessions – 10 group sessions of 90 mins. delivered weekly, followed by 6 telephone sessions with 15-30mins individual phone calls, fortnightly. Children attend session 1 and 16 for measurements, PA focused games are played at these two sessions. Group sizes 8 – 10 families Informative presentations centered on new nutritional knowledge and parenting skills are delivered, followed by group discussion, role plays, group problem solving and role modeling exercises.	Sessions delivered by a clinical psychologist with Triple P training. Proposed delivery team of health professionals with Triple P training, with support staff with nutrition, PA background. Moderate – high skill level	1 main facilitator plus support staff.	RCT sites used were primary schools, teaching hospital, and university clinic.	Content Time 18 hours Professional Time 45 hours Intensity Level of Intervention : Low intensity	Measurements taken at baseline, 12 weeks and 12 month follow up. Other outcomes; self-reported checklists measured parenting skills and self-efficacy, as well as lifestyle behavior scale **BMI z-score change: -0.19**
Watch it Leeds, UK Evaluation of pilot phase, prior to RCT to assess clinical effectiveness. (Rudolf, Christie *et al*. 2006)	8 – 16 yrs, mean age 12.2 94 children BMI >98th percentile Self-referral or health professional referral. 77% retention at 3 months.	Community based 'clinics', across 8 sites. Developed from HELP programme. Weekly individual appointments, 30mins with child and parent – using HELP manual. + weekly group sessions for 60 mins. + weekly parent only group sessions (implemented later) + weekly 60 mins. physical activity sessions. Total intervention time 3 months, with option to renew each 3 months for one year.	"Trainers" no professional qualifications but trained HELP content. Recruited for personal qualities and communication skills. Supervised by dietitian and psychologist monthly, and input for a paediatrician as needed.	Minimum of 2 per clinic time + PA trainers.	Local sports and community centres, after school. Available 4 days a week 3.30 – 6.30pm	Content Time Minimum of 30 hours Professional Time 72 hours Intensity Level of Intervention : Moderate intensity	Qualitative outcomes; Evaluation by surveying staff and conducting a focus group discussion with user families. Quantitative outcomes; change in BMI Z score. Baseline 3.09±0.45 3 months 3.08±0.12 (NS) 6 months 3.02±0.16 (p <0.001) **BMI z-score change: -0.07 (6 months)**

Organisation, country, study design	Target group, attendance and retention	Format / intervention design, intensity	Delivery details			Content / professional time	Comprehensiveness and outcomes / evidence
			Skill level	Number of staff	Delivery site		
Reinehr *et al*. Investigating the changes in weight status (BMI z-score) and CVD risk factors, 12 months post intervention. Germany (Reinehr, Temmesfeld *et al*. 2007)	6 – 14 yrs 203 children BMI >97th percentile. 86% retention	Obeldicks outpatient programme. 3 phases of intervention; Intensive phase – 3 months, 90 mins. sessions fortnightly over 6 sessions, child only. Nutrition and behavior change focus. + parents attended 6 x parent only sessions. Total intervention time 12 months. + Weekly exercise sessions Establishing phase – 6 months, 6 x 30 mins. individual psychology sessions, 1 per month. + weekly exercise Weekly exercise sessions then continued for the entire 12 months. Total intervention time 12 months.	High level of skill required.	Unknown	Hospital outpatient department	Content Time 52 hours Professional Time 52 hours Intensity Level of Intervention: Moderate intensity	BMI z scores Baseline 2.4 12 months 2.1 24 months 2.1 Change -0.3 and maintained over 2 years. Also measured systolic and diastolic BP, lipid profile, glucose and insulin levels. **BMI z-score change: -0.30**

Effect sizes required for clinical significance

While the core elements of successful childhood obesity interventions are generally agreed on (ADA 2006; NICE 2006; SIGN 2010), there is less consensus about the parameters by which such interventions should be judged as clinically effective. Since childhood obesity affects several body functions and systems, markers that reflect this diverse range should be applied for evaluation of interventions. Apart from anthropometry, the most common markers relate to cardiovascular health (e.g., lipid profile, blood pressure), metabolic functioning (e.g., insulin resistance), psychological wellbeing (e.g., self-esteem) and behaviour (e.g., diet and physical activity).

As discussed, anthropometric measures, such as BMI z-score and waist circumference, are reliably associated with adiposity and other indices of obesity-related health impairment, and therefore widely used to evaluate the impact of childhood obesity interventions. Associations between the degree of BMI z-score change and markers of metabolic and cardiovascular health have been examined in an attempt to establish thresholds at which an intervention can be claimed as clinically effective (Reinehr and Andler 2004; Reinehr, de Sousa *et al*. 2006; Hunt, Ford *et al*. 2007; Ford, Hunt *et al*. 2010). Reinehr *et al*. (2004) showed that weight loss following an outpatient childhood weight management programme in Germany was associated with improvement in the atherogenic profile and insulin resistance when BMI z-score decreased by at least 0.5 over a one-year period. In the UK, Ford and colleagues reported similar results, but also found significant improvements in body fat and insulin sensitivity at a lower BMI z-score reduction (-0.25). The group further suggested the use of this score as the minimum threshold for evaluating clinical effectiveness (Ford, Hunt *et al*. 2010).

The BMI z-score is undoubtedly valuable and constitutes an important tool for the assessment of childhood obesity interventions. However, the reliability of a BMI z-score threshold as a sole measure of an intervention's effectiveness may be unsatisfactory. The threshold of -0.25 was primarily defined by association with metabolic health parameters, which while important, represent only one of many body systems affected by obesity. Several interventions in the published literature have reported smaller BMI z-core reductions and achieved significant improvements in other parameters, such as quality of life, behaviour, self-esteem and physical activity levels (Hughes, Stewart *et al*. 2008; Farpour-Lambert, Aggoun *et al*. 2009). Indeed, additional health benefits affecting children's eating and activity habits, psychology and family functioning have been observed in individuals who do not achieve greater than -0.25 BMI z-score changes (Kirk, Zeller *et al*. 2005; Nowicka, Pietrobelli *et al*. 2007; Cummings, Henes *et al*. 2008; Kolsgaard, Joner *et al*. 2012).

Guidelines for management of childhood obesity

Evidence-based guidelines are crucial for the management of childhood obesity. Treatment of obesity in childhood shares the same fundamental principle as that for adult obesity, i.e., decrease in energy intake and increase in energy expenditure.

However, the primary goal of treatment (i.e., weight reduction or deceleration of weight gain) and recommended mode of intervention are variable, dependent on the child's age and initial level of overweight, amongst other considerations.

To assist clinicians in determining the most appropriate form of treatment, paediatric weight management guidelines exist in many countries, with a view to promoting best practice. However, at present, many of these recommendations are based on low-grade scientific evidence (Oude Luttikhuis, Baur *et al*. 2009).

Comprehensive international paediatric weight management guidelines have only been published in recent years (NICE 2006; Barton 2010; SIGN 2010), and recommend multicomponent interventions. Prior to 2006, the only guidelines available in the UK were those published by the Royal College of Paediatrics and Child Health, in collaboration with the National Obesity Forum and the Scottish Intercollegiate Guidelines Network (SIGN 2010). However, these were based mainly on best practice and not evidence, and provided very little practical guidance.

UK guidelines

Clinical guidelines for the prevention, identification, assessment and management of overweight and obesity in adults and children have been produced for England and Scotland (NICE 2006; SIGN 2010).

The National Institute for Health and Clinical Excellence (NICE) guidelines

The National Institute for Health and Clinical Excellence guidelines have been developed using a complex and comprehensive methodology involving experts in the topic, systematic reviews and public consultations. In 2006, NICE produced a guidance document entitled “Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children.” The aim of these guidelines was to present the first comprehensive and integrated approach to prevention, treatment and maintenance, and provide preliminary national recommendations for the management of childhood obesity in England and Wales.

Safety and effectiveness are the cornerstones of paediatric weight management programmes. In contrast to adults, weight reduction in children is not the ultimate objective. In children, the aim is weight maintenance (for BMI ≥ 91^{st} centile) or weight loss between 0.5 and 1 kg per month (for BMI ≥ 98^{th} centile) (Cole, Freeman *et al*. 1995). Greater weight reduction may be considered in cases of serious health problems or severe obesity, provided the child is closely supervised by an appropriately trained health professional (NICE 2006).

NICE recommended multicomponent interventions as the treatment of choice, and stipulated that weight management programmes should include behaviour change strategies to increase children's physical activity levels or decrease inactivity, improve eating behaviour and quality of diet, and reduce energy intake (NICE 2006).

The Scottish Intercollegiate Guidelines Network (SIGN) guidelines

SIGN produced the first set of UK guidelines on the management of obesity in 2003, which was subsequently updated in 2010 (SIGN 2010). SIGN guidelines were produced using standard methodology, including systematic reviews and gradation of evidence.

SIGN guidelines recommend treatment of childhood obesity in subjects with BMI values ≥ 98^{th} centile, family-based approaches targeting changes in diet, physical activity and sedentary behaviours, and use of behavioural change tools within childhood weight management programmes. SIGN highlights that lifestyle interventions, compared to standard care or self-help, can produce significant and clinically meaningful reductions in overweight and obesity in children and adolescents. Generally, the most effective weight management treatments for young people are both intensive and long-lasting, with an intervention period of at least six months. They also raise the concern of parents and health professionals that treating childhood obesity increases the risk of developing eating disorders. However, this has been discounted in the most recent Cochrane review (Oude Luttikhuis, Baur *et al*. 2009). SIGN additionally highlights that quality of life and self-esteem are improved in children and young people participating in weight management programmes. Finally, the guidelines recommend that treatment programmes for managing childhood obesity should incorporate behaviour change components and be family-based involving at least one parent/carer, and aim to change the whole family's lifestyle. Programmes should promote a decrease in overall dietary energy intake, increased levels of physical activity and reduced time spent in sedentary behaviours (screen time). Furthermore, staff involved with management of childhood obesity should undertake training on the necessary lifestyle changes and use of behavioural modification techniques.

Conclusions

Current guidelines are based on low-grade scientific evidence, as the majority of studies for the treatment of childhood obesity have several biases or do not report long-term results (Summerbell, Ashton *et al*. 2003; Oude Luttikhuis, Baur *et al*. 2009). These limitations pose a serious practical problem for families seeking effective local treatments, and thus represent an important focus for future research.

However, guidelines consistently state that interventions for school-aged children should include parental involvement, nutrition education, increased physical activity, decreased sedentary behaviours and behavioural modification.

In conclusion, features of a successful childhood obesity intervention have been specified, based on research findings and best-practice recommendations. However, there is an urgent need for the development of a uniform, flexible treatment programme that incorporates all these features for successful management of the alarmingly high rates of childhood obesity in the UK and universally.

Other methods used for the secondary prevention of childhood obesity

Residential weight loss camps

Weight loss camps are generally suitable for adolescents and not younger children. However, due to high running costs, these types of interventions are generally not available for the majority of obese adolescents.

Currently, no RCTs supporting the effectiveness of residential programmes for childhood obesity management in reducing adiposity are available (NICE 2006; SIGN 2010).

Non-randomised studies assessing the effectiveness of such camps for obese children have shown that these interventions are successful in reducing adiposity during the supervised period, but children regain the weight lost in the long-term (Gately, Cooke *et al*. 2000; Christiansen, Bruun *et al*. 2007).

A possible reason for unsuccessful long-term weight loss is that these interventions are intensive and the residential environment very well-controlled and thus effective in the short-term. However, adolescents need additional support back in their home environment where the problem arises in the first place.

2.1.3 Tertiary prevention

Pharmacotherapy

Previous studies have suggested the use of drugs and surgical approaches as possible solutions in the management of childhood obesity (Treadwell, Sun *et al*. 2008; Wald and Uli 2009). The most well-characterised pharmacological agents used to treat childhood obesity include:

Orlistat: Orlistat can be used for children above 12 years and has modest effects in BMI reduction, ranging from 0.6 to 0.7 kg/m^2 (Oude Luttikhuis, Baur *et al*. 2009). Safety concerns include fat-soluble vitamin deficiencies due to steatorrhoea (Wald and Uli 2009). Another consideration is the psychosocial effects of this medication, which may induce incontinence if a low-fat diet is not followed. Thus, in general, this medication is not employed due to side-effects.

Sibutramine: Sibutramine was initially approved for children above the age of 16 years under supervised conditions (Wald and Uli 2009). However, the drug has recently been withdrawn from the market, owing to significant safety concerns (FDA 2010).

Metformin: Metformin is only approved for children aged 10 and above with diabetes or insulin resistance (FDA 2010).

Thus, only a couple of anti-obesity medications are currently available for older obese children. The problem with pharmacological agents is that the positive effects are modest and short-term, and no long-term data are available on their efficacy and safety in children. Therefore, the use of these agents should be limited, and suitable candidates for obesity drug-therapy cautiously selected and rigorously monitored (Wald and Uli 2009).

Given that all drugs have side-effects and are only effective if combined with a healthy diet and physical activity, which, on their own, can be sufficient to cause BMI reduction, the overall benefit of pharmacological treatments on childhood obesity is questionable.

Bariatric surgery

Similar to pharmacological treatment, surgery for the management of childhood obesity should be seriously considered. Firstly, as with any surgery, there are potentially serious post-surgical complications, including death in severe cases. Secondly, children rarely have the decisional capacity to provide informed consent about whether they want to undergo surgery or not. Thirdly, there is no confirmed evidence that bariatric surgery operations do not affect maturation and growth in children. Finally, compared to adults, children comply very poorly with post-operative instructions (including diet, activity advice, and vitamin and mineral prescription). Therefore, the success of surgery is greatly jeopardised, while at the same time, there are concerns about the post-operational nutritional status of these patients, since in most cases, the capacity of the gastrointestinal system to digest and absorb nutrients is reduced (Treadwell, Sun *et al*. 2008). The NICE guidelines for the management of childhood obesity do not recommend bariatric surgery in children or young people (NICE 2006).

Conclusions

The findings of studies to date indicate that residential weight loss camps, pharmacotherapy and bariatric surgery are not effective long-term strategies for managing childhood obesity.

Chapter 3 Development of the MEND intervention

The UK Medical Research Council (MRC) document ’A Framework for the Development and Evaluation of Randomised Controlled Trials for Complex Interventions’ was used as a basis for the development, evaluation and implementation of the MEND intervention (Craig, Dieppe *et al*. 2008).

3.1 Defining MEND as a complex intervention

Complex interventions are built up from a number of components, which may act both independently and interdependently. The components usually include behaviours, parameters of behaviours (e.g., frequency, timing), and methods of organising and delivering those behaviours (e.g. type(s) of practitioner, setting and location) (May, Mair *et al*. 2007).The MRC framework for the development and evaluation of RCTs for complex interventions argues that "the greater the difficulty in defining precisely what the ‘active ingredients’ of a therapeutic healthcare intervention are, and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention" (Craig, Dieppe *et al*. 2008).

Owing to little clarity on the precise definition of a ‘complex intervention’, these interventions can be defined as educational or psychosocial aimed at changing knowledge, beliefs or behaviours (Redfern, McKevitt *et al*. 2006).

Based on these definitions, the MEND intervention can be defined as a complex intervention, due to the following factors: (i) MEND is a multicomponent intervention, based on the best evidence available. However, the outcomes influenced by components, are unclear, e.g., is BMI influenced by changes in diet, physical activity or both? (ii) Different families respond in different ways to the same intervention. (iii) MEND is an educational and behaviour change programme aimed at improving dietary, physical activity and sedentary behaviours. (iv) Factors, such as intensity, delivery staff, venues and financial resources needed for effective provision of the programme add to the complexity of MEND.

3.2 The MRC complex intervention process

The MRC has developed a framework for complex interventions, which incorporates key elements of the development and evaluation process. The four stages are: development, feasibility/piloting, evaluation and implementation (Figure 24).

Figure 24. Key elements of the MRC development and evaluation process

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Taken from Craig, Dieppe et al. 2008.

Interventions should be developed systematically using the best available evidence and appropriate theory, and subsequently tested with a carefully phased approach, starting with a series of pilot studies targeted at each of the key uncertainties in design and progressing to an exploratory, and subsequently, definitive evaluation. Results should be disseminated as widely and persuasively as possible, and further research performed to assist and monitor the process of implementation (Craig, Dieppe *et al*. 2008).

3.3 Development of the intervention

According to the MRC framework, prior to undertaking a thorough evaluation, an intervention should be developed to the point where it is reasonably expected to have a positive effect (Craig, Dieppe *et al*. 2008). The MRC identifies the following three steps for the development of a complex intervention: (i) identification of the evidence base, (ii) identification/development of the appropriate theory, and (iii) modelling process and outcomes.

The evidence and theories underpinning child obesity interventions have been presented in Section 2.1.2. It is important to note that the majority of this evidence was not available prior to the MEND feasibility trial in 2002. Therefore, development of the MEND intervention has been an iterative process, with continual evolvement from conception to evaluation and implementation. This is a positive process, as it has ensured constant improvement of the curriculum in order to reflect feedback from participants and delivery staff as well as emerging research and Government guidelines. The current MEND curriculum is the 7th edition and has undergone significant refinement since its initial development in 2001.

However, closer reflection of the changes within the curriculum reveals that the core intervention has remained largely the same as that used in the RCT. Changes to the curriculum have generally occurred due to the inclusion of additional supportive information (e.g., sleep, bullying) and not major changes to the structure, intensity, underlying behaviour change theories or dietary principles.

The third step in the development stage is the modelling process and outcomes. This step was not included in the development of the MEND intervention, as modelling is a sophisticated form of statistical analysis and not deemed necessary for the relatively straightforward feasibility and RCT evaluations.

However this process is currently being utilised to determine the population-level effects of the UK implementation of the MEND programme (Section 8.9.2) (Law 2010). It is possible that findings from this research will lead to further refinement of the programme content, for e.g., additional supportive material for specific cultures, particularly black and minority ethnic (BME) groups or operational methods of delivery.

Goals of the intervention

The aims of the MEND intervention were to promote a mild negative energy balance by reducing energy intake and/or increasing energy expenditure in a way that would support children's growth covering their nutritional needs. To this effect, efforts were made to enhance dietary and physical activity behaviours, thereby improving measures of anthropometry and psychosocial outcomes.

3.3.1 Dietary component

Successful treatment of childhood obesity requires a sustained negative energy balance. Modification of dietary intake is one method to achieve this goal. The majority of childhood weight management interventions documented in the literature contain a dietary component. A systematic review by Collins *et al*. (2006) on the role of dietary intake in children's weight management interventions concluded that reduction in total energy intake is necessary for effective weight loss to occur in obese children. However, no evidence was obtained to suggest that any particular dietary or macronutrient manipulation, e.g., low carbohydrate or high protein, is more effective.

A number of studies have demonstrated that a structured dietary management component is effective when provided as a single component within a multicomponent weight management programme (Epstein, Myers *et al*. 1998; Epstein, Paluch *et al*. 2007; Oude Luttikhuis, Baur *et al*. 2009). However, there is insufficient evidence to recommend one particular dietary approach over another.

In children, severe restriction of food intake is prohibited for physiological and psychological reasons. A considerable reduction in energy and nutrient intake can adversely affect growth in children. Therefore, since for some children, weight maintenance has similar effects on weight status to weight reduction with increasing height, this approach is considered safer and more preferable. Evidently, this also depends on the child's age and initial BMI, as there are occasions where weight reduction is essential to gradually reduce adiposity, especially in older children with very high BMI or those with co-morbidities, such as insulin resistance and hypertension.

However, even in these occasions, weight reduction should only occur under supervised conditions by implementing a mildly hypocaloric healthy balanced diet, increased physical activity and reduced sedentary behaviours. For younger children who are overweight or marginally obese, weight maintenance or small weight reduction (0.5-1kg per month) that allows gradual reduction in BMI velocity is recommended. In older and more obese children and adolescents, routine weight reduction should be around 1-2 kg per month and the maximum weight loss in the severely obese should not exceed 1 kg per week (Barlow 2007). In all scenarios, periodical measurement of children's weight status for 6 months or more is highly recommended in order to assess progress and long-term compliance of newly adopted eating and activity habits (NICE 2006; SIGN 2010).

Concerns about the establishment of eating disorders or other negative effects on children's psychological wellbeing in weight management have been raised. According to the most recent Cochrane review on childhood obesity treatment, the majority of studies reported no or very few adverse effects of the intervention, such as disordered eating, anxiety and depression (Oude Luttikhuis, Baur *et al*. 2009). Furthermore, the benefits of the interventions outweighed any mild adverse effects. All interventions involved gradual changes within the family context and advocated the adoption of healthy eating habits without focusing on weight loss or quick changes in body image. The golden rule in weight management is to implement SMART (Specific, Measurable, Achievable, Realistic, Time-limited) goals that improve children's eating and activity habits, allowing them to acknowledge small victories without becoming hungry or obsessed with the scales.

The ultimate aim of weight management is long-lasting results, which requires time. A restrictive diet directly opposes this aim. In contrast, a gradual balanced approach is sustainable, and provides positive messages around healthy eating and activity patterns. The child needs to understand that in practice, the lifestyle advice provided should be the same for all children, regardless of weight status, and is applicable for the rest of their life. The only difference is that for overweight and obese children, this approach also results in amelioration of their weight status.

In conclusion, restrictive diets are strictly prohibited in children and adolescents, as these can impair growth and psychological wellbeing. The appropriate approach should advocate healthy eating and activity habits without focusing on weight loss. The health professional is responsible for periodically assessing and providing feedback on weight status in a way that prioritises behaviour changes and only monitors weight loss as an additional tool.

National healthy eating guidelines for children have been designed to improve the general nutrition and health of the population. It should be noted that these guidelines are not specifically aimed at managing childhood obesity in children. The Eatwell Plate is a recent policy tool devised by the UK Department of Health (DH), with a view to helping the public follow a healthier diet (Figure 25) (DH 2011). It adheres to the government's recommendations for healthy eating and provides a visual representation of the proportions of foods needed daily for a healthy, balanced diet. The Eatwell Plate consists of five food groups: bread, rice, potatoes, pasta and other starchy foods (33% of plate size), fruit and vegetables (33% of plate size), milk and dairy foods (15% of plate size), meat, fish, eggs, beans and other non-dairy sources of protein (12% of plate size), and foods and drinks high in fat and/or sugar (8% of plate size).

Figure 25. The Eatwell plate

Image removed for copyright reasons

Source: DH 2011

The Eatwell plate applies to adults and children above the age of two years from all ethnic and cultural groups. The relative contribution of each food group is presented in a visual way, with each part of the pie displaying the appropriate size and a different colour. It is important to highlight that the Eatwell Plate does not refer to a particular meal, but an overall healthy balanced diet.

Frequency of servings and portion sizes are deliberately omitted, as individual requirements vary. The only exceptions are the 5-a-day recommendation (for fruit and vegetables) and the 2-a-week recommendation for fish (one of which needs to be oily). Health professionals are advised to tailor portion sizes and frequency to individual patient needs.

The current recommendations for the management of childhood obesity include promotion of a healthy diet within a multicomponent intervention, but do not advocate the sole use of specific dietary approaches (NICE 2006; SIGN 2010). Therefore the aim of dietary treatment within a multicomponent childhood obesity intervention should be promotion of healthy eating using appropriate health education methods and behaviour change techniques.

MEND dietary component

Based on the available evidence and current national healthy eating guidelines, the MEND dietary component was designed to steer families towards a healthier, more balanced diet. A 'non-dieting' philosophy was advocated throughout the intervention. Therefore, children were discouraged from weighing themselves and encouraged to make lifestyle changes to improve health, rather than achieve rapid weight loss (Summerbell, Ashton *et al*. 2003; Oude Luttikhuis, Baur *et al*. 2009).

The nutrition component of the MEND programme was designed to raise awareness and educate parents and children to encourage healthier daily choices. Nutrition sessions were devised for delivery to both children and parents, and suited to the reading and comprehension ages of primary school children.

Nutrition sessions consisted of healthy eating advice for obese children and their families, and included simple healthy eating tips in the form of achievable weekly targets (nutrition targets), education on reading and understanding "back of pack" food and drinks nutrition information, fat and sugar cut-offs, differences between refined (processed) and unrefined (unprocessed) carbohydrates, portion sizes, and other simple advice aimed at producing gradual improvements in dietary intake and habits. In addition, families participated in practical sessions involving a guided supermarket tour, cooking of healthy recipes and learning coping strategies to deal with birthday parties, school meals, eating out, holidays and other special occasions (Table 6, nutrition sessions are italicised).

Table 6. MEND programme curriculum (theory sessions only)

Session (week)	**Session title**	**Summarised content**
1(1)	Introduction	Introduction to trainers, ice-breaker, what happens at each session, MEND health and safety rules and procedures.
2 (1)	*Food groups and healthy eating*	*The causes and consequences of being overweight with an introduction to dietary guidelines and healthy eating.*
3 (2)	Goals and rewards (parents only)	Basic concepts and effective behaviour modification techniques showing parents how to set goals and give rewards as a way to motivate their children to develop healthier eating and activity patterns.
4 (2)	*Refined versus unrefined carbohydrates*	*The benefits and importance of following a diet high in unrefined carbohydrates.*
5 (3)	Goals and rewards	Children learn how to set purposeful goals to help improve their dietary and physical activity behaviours.
6 (3)	*Fats and sugars*	*Parents and children learn about the harmful short- and long-term effects of diets high in saturated and hydrogenated fats and added sugars e.g. glucose and sucrose.*
7 (4)	External triggers (parents only)	Parents shown that certain triggers in their children's environment encourage the consumption of unhealthy foods and inactivity.
8 (4)	*Food labels and portion sizes*	*The group learns how to read and understand food and drink nutrition labels. Portion sizes are also examined.*
9 (5)	Modelling (parents only)	Parents learn how to identify some of their own behaviour patterns that could be preventing their children from achieving their goals.

10 (5)	*Menu planning*	*Practical ideas for menu planning. Simple suggestions for healthy meals.*
11 (6)	Internal triggers (parents only)	Parents learn how internal triggers (feelings, hunger, thoughts and cravings) can cause their children to overeat.
12 (7)	*Supermarket tour*	*The group tests their practical skills at picking healthy foods off the shelf and attends a fruit and vegetable preparing and tasting session.*
13 (7)	Internal Triggers – "who wants to be a healthionnaire?"	Game-based session designed to help children identify their internal triggers and means to deal with them.
14 (7)	*Food presentation and tasting*	*Parents and children cook and sample a variety of healthy meals.*
15 (8)	Problem solving (parents only)	An open forum designed to allow parents to discuss and identify any problem areas they may be experiencing.
16 (8)	*Eating out, parties and other tempting occasions*	*Families learn effective ways to follow healthy guidelines at the most tempting of times e.g. birthday parties, holidays, eating out and at school.*
17 (9)	Improving self- esteem	Self-esteem and confidence building session.
18 (9)	Farewell	Summing up, farewell, certificates of achievement.

Note: five of the behaviour modification sessions were delivered to parents only while children participated in an exercise class.

The aim of the nutrition sessions was to support families in modifying their diets and eating habits in an achievable and sustainable manner. Creation of a nutritional rationale that accommodates exact classification for all foods and drinks is a dietetic challenge. The nutrition guidelines of MEND were based on a combination of healthy eating dietary principles. More specifically, the curriculum promoted increased consumption of unrefined carbohydrates and dietary fibre and reduced saturated and hydrogenated fatty acids and added sugars. Foods were grouped to create a child- and family-friendly system that encouraged healthier food choices. The nutrition guidelines were designed to be simple and practical for families to adopt. Application of these principles thus allowed children and families to make informed dietary decisions in a simple and effective way[3].

No foods or drinks were classified as ‘forbidden’, ‘good’ or ‘bad’ during the intervention, as this type of practice does not encourage long-term eating habits, reduces adherence, and stigmatises the ‘forbidden’ or ‘bad’ items, making them more desirable to children (Wardle 2005). Instead, the terms “MEND-Friendly” and “MEND-Unfriendly” were used to guide families toward dietary components that met healthy eating criteria.

A third category was included, which allowed the classification of foods and drinks that did not strictly fit into either the healthy or unhealthy category (MEND-Friendly*). Inclusion of a third dietary classification category is quite common in dietary management approaches for children, including the Traffic Light Diet that

[3]At the time of the feasibility trial and RCT, national healthy eating guidelines incorporated the “Balance of Good Health – Food Standards Agency” which has subsequently changed to “EatWell Plate – Department of Health.

has green, orange and red categories, and the USA National Heart, Lung and Blood Institute's "Go, Slow, Whoa" dietary classification system (NHLBI 2012). Table 7 summarises the dietary classification system of MEND.

Table 7. Summary of MEND's dietary classification system

MEND-Friendly	MEND-Unfriendly	MEND-Friendly*
1. Whole grains (containing all parts of the grain). 2. Unprocessed (or restored grains). 3. Processed or convenience foods, snacks and drinks (low in fat and/or added sugar i.e. ≤ 5 g/100 g).	1. White grains (parts of grain removed). 2. Processed (parts of grain removed). 3. Processed or convenience foods (high in fat and/or added sugar i.e. > 5 g/100 g).	1. Nutritious foods which naturally contain higher amounts of healthy fats and natural sugars, e.g., nuts and dried fruit. 2. Meets MEND fat and sugar cut-offs but less nutritious than MEND-Friendly foods, e.g., snack foods, such as baked crisps, rice cakes and popcorn. 3. Contains low-calorie sweeteners.

Although there is no evidence to support the use of one dietary approach over another, consumption of foods and drinks low in sugar and fat and high in dietary fibre is an effective way to reduce energy intake via decreasing energy density (Johnson, Mander *et al*. 2008). During the MEND programme, families were encouraged to swap MEND-Unfriendly foods and drinks with MEND-Friendly alternatives, and instructed to aim for a maximum of five MEND-Unfriendly "treats" per week. This technique helped children and parents to incorporate small amounts of unhealthy "treat" foods/snacks within a healthier balanced diet, supporting the 'no forbidden foods' philosophy (Wardle 2005).

Over the course of the programme, families were educated on the different types of fat, i.e., monounsaturated and polyunsaturated fats were classified as MEND-Friendly, whereas saturated and hydrogenated fats were MEND-Unfriendly. Thus, consumption of healthy fats was encouraged in a way that was easy for families to understand and implement in everyday life.

Prior to the MEND feasibility trial, I developed a nutrition label reading method to enable children and parents to easily read and understand "back of pack" nutrition information (Sacher, Chadwick *et al*. 2005). This method was designed to support families in making appropriate choices and additionally allowed nutrition comparison between products.

In the UK, back of pack nutrition information is standardised, whereas front of pack information varies with respect to the food manufacturer and retailer. This method was tested prior to and during the feasibility trial using focus groups and questionnaires, and generated highly positive feedback from dietitians, members of the public, children and parents. On average, the system could be introduced and explained to children (7 years and above) and parents within 5 minutes. Over 95% participants were able to correctly differentiate between a selection of MEND-Friendly and MEND-Unfriendly food and drink products (unpublished data).

The system was further refined, standardised and incorporated into the intervention utilised in RCT. This simple technique for label reading combining the fat, sugar and ingredient list aimed to help families develop new nutritional skills and use simple tools to make informed choices (Table 8).

Table 8. MEND label reading rules

Step 1: Look at back of pack	Per 100 g column
Step 2: Check fat	Total fat less than 5 g per 100 g
Step 3: Check sugars	Total sugars less than 5 g per 100g
Step 4: Check ingredients	Is sugar high, because of natural or added sugars?

<u>Low-calorie sweeteners</u>

Food Regulations describe sweeteners as “food additives that are used or intended for us either to impart a sweet taste to food or as a table-top sweetener. Table-top sweeteners are products that consist of or include, any permitted sweeteners, and are intended for sale to the ultimate consumer, normally for use as an alternative to sugar.” The use of sweeteners to replace sugar is justified for the production of energy-reduced foods, non-cariogenic foods (unlikely to cause tooth decay), extension of shelf-life through replacement of sugar, production of dietetic products, or foods with minimal effect on blood sugar (most sweeteners produce a very small glycaemic response due to non-carbohydrate structure, partial metabolism or use in very small quantities).

Low-calorie sweeteners can be divided into two broad categories.

1. Non-nutritive, high-intensity sweeteners. These are used in very small quantities, as their sweetening effect is very strong and caloric value negligible. The most well-known of these products include aspartame, saccharin, cyclamate, sucralose, acesulfame K and stevia. Currently, the majority of organisations (national and international) approve their use as sweeteners (FSA, FDA, JECFA, FAO). However, the previous UK Food Standards Agency advised parents to give young children no more than three beakers (180ml each) a day of dilutable soft drinks or squash containing cyclamate in order to avoid exceeding the acceptable daily intake.
2. Reduced-calorie bulk sweeteners. These are sugar alcohols (polyols) that sweeten with less energy per gram, compared to table sugar (approximately 2 kcal/g, relative to 4 kcal/g for table sugar). Examples of polyols include erythritol, mannitol, xylitol, sorbitol, isomalt and hydrogenated starch hydrolysates. Since these compounds are not fully absorbed from the gut, polyols are less available for energy metabolism. However, they are used in similar amounts as sugar, in contrast to intense sweeteners that are used in very small quantities, thus adding bulk and texture to food. Excessive intake of polyols (>50 g/day of sorbitol, >20 g/day of mannitol) may cause diarrhoea, which is indicated on the packs by law.

The safety of low-calorie sweeteners is a matter of debate, mainly due to their previous link to some types of cancer (in most cases in experimental animals rather than humans) and other diseases (e.g., autism). No sound scientific evidence has been obtained to validate the above theories, despite extensive research. Nevertheless, some members of the public are highly concerned about the potential negative effects of low-calorie sweeteners on current and future health. Notably, before authorisation for use in food or drink, all sweeteners are extensively investigated by The Joint FAO/WHO Expert Committee on Food Additives (JECFA) at the international level, the European Food Safety Authority (EFSA) at the European level, and national agencies (previously the Food Standards Agency in the UK).

Despite the apparent safety of low-calorie sweeteners, the British Dietetic Association states that "in the UK, the consumption of intense sweeteners is monitored to ensure that typical intakes do not exceed safe levels. Their use is not permitted in foods specifically prepared for babies and young children, and as a precautionary measure, the diets of healthy children should not contain large quantities of foods containing artificial sweeteners".

Justification for the use of low-calorie sweeteners as part of the dietary component of the MEND intervention

Consumption of sugar-sweetened beverages, which include soft drinks, fruit drinks, energy drinks and flavoured and vitamin waters has increased worldwide (Malik, Popkin *et al*. 2010). Strong evidence has been obtained showing that consumption of 1-2 servings per day of sugar-sweetened beverages is associated with weight gain, dental caries in children and adults, metabolic syndrome and type 2 diabetes (Malik, Schulze *et al*. 2006; Dubois, Farmer *et al*. 2007; Malik, Popkin *et al*. 2010). Moreover, recent research supports the use of artificially sweetened soft drinks as an effective tool in reducing obesity and preventing dental caries (Bellisle and Drewnowski 2007; de Ruyter, Olthof *et al*. 2012).

The health of obese children is far more likely to suffer in the long-term due to regular consumption of added sugars and subsequent increase in energy intake, compared to regular intake of low-calorie sweeteners. In view of the recognition that the optimal beverages for children's health are water, low-fat milk and small quantities of pure fruit juice, combined with the lack of long-term studies evaluating the effects of low-calorie sweetener intake in children, guidelines for the inclusion of artificially sweeteners were temporary, applied only for the duration of programme, and excluded healthy weight siblings. Families were instructed to gradually wean their children off low-calorie sweeteners after completion of the programme. Unfortunately, intake of low-calorie sweeteners was not measured as part of the feasibility or RCT dietary evaluation, and therefore no conclusions can be reached in terms of family compliance with these recommendations.

In summary, sugar-sweetened beverages are linked to obesity and other negative health outcomes. There is strong evidence that replacement of sugar-sweetened with sugar-free beverages can reduce obesity, and no links between consuming low-calorie sweeteners and health risks have been established to date. Therefore, substitution of sugar with low-calorie sweeteners was recommended as part of the MEND dietary component as a temporary aid to reduce energy intake.

3.3.2 Behaviour modification component

The use of behaviour modification techniques is effective as part of a multicomponent intervention (Section 2.1.2) (NICE 2006; Oude Luttikhuis, Baur *et al*. 2009). The behavioural part of the MEND programme included techniques designed to involve the whole family and help parents to improve their children's overall dietary habits, activity patterns and self-confidence (Table 9).

These protocols followed the principles of cognitive behaviour therapy, and aimed at gradual, permanent changes in the children's lifestyle habits (Epstein, Myers *et al*. 1998; Cole, Waldrop *et al*. 2006). Behaviour modification sessions consisted of eight sessions designed by Dr. Paul Chadwick, as presented in Table 6 (not italicised).

Table 9. Behaviour modification principles used in the MEND programme

Behaviour modification principle	MEND programme
Positive parenting	Positive parenting themes run throughout, e.g., setting boundaries, consistency, behaviour management.
Habit development (goals)	Nutrition theory sessions: families received 2 weekly nutrition targets at each session (16 nutrition targets in total). Behaviour theory sessions: families set two individualised weekly goals focused on both nutrition and physical activity.

Learning theory – triggers	Two parent workshop discussions covered internal and external triggers.
Learning theory – rewards	Using praise & attention (informal rewards) to reward positive behaviour was incorporated in parent's session. A goals and reward star chart (formal rewards) was operated throughout the programme. Children also received both an individual reward (agreed with and provided by their parent), as well as a group reward at the end of the programme.
Social learning theory	An entire parent's session was dedicated to role modelling.
Problem solving	Parents were encouraged to solve problems during parent-only sessions. In addition, an entire session was dedicated to the topic of problem solving.
Monitoring	Parents were encouraged to monitor their children's weekly goals and the MEND Leaders monitored group goals and rewards using a star chart.
Motivation	Peer group support, goals & rewards and information provision collectively promoted parent and child motivation.

Taken from Baur and O'Connor (2004); Berkel, Poston et al. (2005) and Wardle and Cooke (2005)

3.3.3 Physical activity component

As noted in Section 2.1.2, systematic reviews of child obesity exercise/physical activity interventions has confirmed that regular physical activity is associated with reduction of adiposity in overweight and obese children and adolescents (Atlantis, Barnes *et al*. 2006; Collins 2007). Physical activity is undoubtedly important, since decreased activity in children and consequent energy expenditure are major factors in the development of obesity (NICE 2009).

Health benefits of increasing the level of physical activity in childhood include effective weight control, lower blood pressure and improved psychological wellbeing (NICE 2009). Data from a large sample of men and women showed that physical activity levels in primary school years have a significant long-term effect on the activity habits of women (Trudeau, Laurencelle *et al*. 1999).

Healthy levels of physical fitness (4 to 5 times per week) require regular participation in activities that generate significantly higher energy expenditure than the resting level (DH 2011). Thus, strategies to promote physical activity in children and adolescents should be incorporated into all child obesity interventions (Goran and Treuth 2001).

Unstructured moderate-intensity activities facilitate the majority of disease-preventing and health-promoting benefits of exercise in obese children (Sothern, Loftin *et al*. 2000). Physical activity can be increased in different ways, for instance, by increasing active pursuits and/or decreasing sedentary behaviours, such as watching television, internet and computer games. An increase in lifestyle physical activity levels, such as walking to school, has been shown to have a better long-term effect on weight than structured exercise (Whitlock, O'Connor *et al*. 2010). Unfortunately, no precise guidelines on the type, dose and intensity of physical activity required to manage childhood obesity are available at present.

Pre-adolescent children find periods of defined exercise (aerobic classes or videos, stationary bicycles or treadmills) boring or punitive (Barlow and Dietz 1998), which has presented a major obstacle in other childhood obesity management programmes, resulting in poor attendance and retention rates.

Additionally, there is no consensus on whether childhood obesity interventions should include an exercise component as part of the programme or simply promote lifestyle activity or a combination of both. The only recommendations available are the current UK government guidelines for the general childhood population, which stipulate at least 60 minutes of physical activity per day (NICE 2006).

Based on the lack of clear recommendations, a multi-pronged approach was used for the formulation of the MEND physical activity component. Four strategies comprised the physical activity component of the intervention: (i) moderate to vigorous physical activity provided at each session (60 minutes, twice per week), (ii) behaviour change strategies for parents to increase their own children's physical activity levels in everyday life, (iii) encouragement of parents to become more effective role models by participating in physical activity with their children, and (iv) strategies for parents and children to reduce screen time and other common sedentary behaviours (ADA 2006; NICE 2006; Barlow 2007; SIGN 2010; DH 2011).

The MEND programme exercise sessions comprised alternating land and water-based multi-skills activities, which focused on non-competitive group play previously shown to facilitate safe and effective weight management in obese children (Sothern, Loftin *et al*. 2000). The 18 physical activity sessions consisted of fun activities and group play, both on land and water, to increase strength, fitness, balance, agility and coordination. Sessions were graded, structured and non-competitive.

Experts in the field of child physical activity designed and implemented a physical activity curriculum that was not only fun but also specifically designed for overweight and obese children and reinforced the nutrition and behaviour modification principles from the theory sessions.

3.3.4 Maintenance phase

Whilst it is widely recognised that ongoing support is required for successful behaviour change in paediatric obesity treatment (NICE 2006), limited information is available on how to help families maintain behavioural changes and sustain improvements in weight status following initial treatment (Oude Luttikhuis, Baur *et al*. 2009).

A RCT conducted in 2007, included 150 paediatric overweight and obese participants aged 7 to 12 years and aimed to assess the efficacy of maintenance treatment approaches for childhood overweight (Wilfley, Stein *et al*. 2007). All participants initially received a 5-month weight loss treatment that focused on dietary modification, increased physical activity and behaviour change skills. Participants were subsequently randomised to either weight maintenance via behavioural skills maintenance (BSM), social facilitation maintenance (SFM) or no intervention control. BSM was a family-based, cognitive-behavioural approach that emphasised self-regulation behaviour and relapse prevention. SFM helped parents develop child peer networks that supported healthy eating and physical activity. Both BSM and SFM were delivered as 16 weekly sessions. The weight loss intervention resulted in a BMI z-score reduction of 0.22 (SD 0.17). BSM and SFM interventions promoted improved weight maintenance, relative to the controls, at 2 years follow-up. Mean changes in BMI z-score were -0.04 (BSM), -0.04 (SFM) and 0.05 (control). The authors concluded that the addition of maintenance-targeted treatment improves the short-term efficacy of weight loss treatment for children, relative to no maintenance treatment (Wilfley, Stein *et al*. 2007).

An analysis of 20 studies on paediatric patients (aged 4 to 18 years) showed limited evidence of treatment maintenance in behavioural intervention trials (Whitlock, O'Connor *et al*. 2010). Multicomponent interventions that included behaviour therapy were associated with BMI or weight change improvement over 48 months and for at least 12 months after completion of the intervention. To date, the majority of childhood obesity interventions have focused on relatively short-term follow-up, i.e., 12-24 months (Oude Luttikhuis, Baur *et al*. 2009). Limited studies have evaluated the effects of different weight maintenance strategies on long-term outcomes. Available evidence suggests that multicomponent interventions that include behavioural components promote maintenance of BMI reduction at 2 years follow-up. Moreover, continuation of increased physical activity levels post-intervention leads to longer-term weight maintenance (DH 2011).

In the absence of specific guidelines on types of effective support following a childhood weight management intervention, no maintenance support was offered to families attending the MEND feasibility trial. For families participating in the MEND RCT, free swimming passes were provided during the post-intensive phase. Specifically, after the intensive phase, participants received a 3-month free family swim pass at the leisure centre where the programme was delivered, with the aim of promoting sustainability of increased physical activity behaviours for the whole family. Families were only allowed to use the swimming pool, as children less than 16 years of age were not permitted access to the gym. Frequency of visits was self-monitored using a provided diary.

Chapter 4 Feasibility and piloting methods

Introduction

The feasibility and piloting methods stages of the MEND intervention (Appendix 2) (Sacher, Chadwick et al. 2005) were used to inform the MEND RCT evaluation described in Chapter 6. It should be noted that the feasibility trial was conducted in 2002, prior to my registration to undertake a PhD. Rigorous methodology was not employed for the formulation and completion of the feasibility trial.

MRC guidance on assessing feasibility and piloting methods

According to the MRC framework for developing and evaluating complex interventions, the feasibility and piloting stage includes testing procedures for acceptability, estimating the likely rates of recruitment and retention of subjects, and calculation of appropriate sample sizes. Evaluations are often undermined due to problems of acceptability, compliance, delivery of the intervention, recruitment and retention and smaller-than-expected effect sizes that could be anticipated by effective piloting. Pilot study results should be interpreted cautiously when making assumptions for larger-scale evaluations. A combination of qualitative and quantitative methods may be needed, for example, to understand barriers to participation and estimate response rates (Craig, Dieppe *et al*. 2008).

4.1 MEND feasibility and piloting methods trial

The MEND feasibility and piloting methods trial (hereafter referred to as the MEND feasibility trial) was an uncontrolled, pre-post design study. The aim of the MEND feasibility trial was to assess its acceptability, feasibility and compliance in a small group of obese children and their families (Appendix 2). A secondary aim was to pilot the methods employed in the delivery of the MEND intervention and to provide data for calculation of the RCT sample size.

4.1.1 Methods

The MEND intervention was designed as a programme for 7-12 year-old obese children and their families, aimed at promoting the development of healthy lifestyle patterns and managing excessive weight gain. The programme focused on five key areas: parenting, emotional well-being, eating behaviours, physical activity and nutrition, as described in Section 3.3.

In 2001, prior to developing the intervention, a thorough literature review was undertaken to collect evidence of factors related to the development of childhood obesity and approaches to managing this condition. The literature revealed limited high-quality and many international studies with heterogeneous design, often uncontrolled, and with small sample sizes. Review of these studies provided little generalisable data.

One sole systematic review was available at the time, which focused on childhood obesity prevention and management programmes. The review concluded that “there is a lack of good quality evidence on the effectiveness of interventions on which to base national strategies or inform clinical practice." In general, family-based programmes that involve parents, increase physical activity, provide dietary education and target reduction in sedentary behaviour were found to be the most promising strategies to reduce childhood obesity (NHS Centre for Reviews and Dissemination & The University of York 2002).

In addition, the Royal College of Paediatrics and Child Health and the National Obesity Forum produced guidelines for the management of childhood obesity in primary care, stating that rapid weight loss and strict dieting were not appropriate for children (Royal College of Paediatrics and Child Health 2002). The majority of the scant evidence used to develop the original MEND intervention has been superseded by more recent literature, as described in Section 2.1.2.

In order to ascertain perceptions and views concerning effective childhood weight management, semi-structured interviews were conducted with parents, academics and health care professionals (including dietitians, an eating disorder specialist and clinical psychologist, school nurses and GPs).

Once the above stages above were complete, Dr. Paul Chadwick and I devised the contents of the curriculum based on the limited available evidence, combined with best clinical practice. A draft manual was developed which included a session outline for each of the nutrition and behavioural modification sessions. The session outline included topics for discussions, activities and timings for each component. This manual was further developed and standardized in preparation for the RCT as described in Section 6.2 and 6.5.

Although the feasibility intervention was devised by a specialist clinical team including a dietitian and psychologist, due to the scale of the childhood obesity epidemic and knowledge that specialist health care professionals were under resourced, the aim from the outset was to develop a generalisable intervention that could be delivered by a wide range of non-specialists.

4.1.2 Recruitment

Obese children aged 7–11 years were recruited through local professional networks in primary and secondary care. An information pack was designed for health care professionals (GPs, dietitians and school nurses) working in a 1-2 mile radius of the trial venue (London Boroughs of Camden and Islington). Packs contained BMI charts, parent and child information sheets and referral letters for use by GPs, dietitians and school nurses. In addition, posters were produced for placement in GP practice waiting areas. I attended health care professional meetings to present the aims and details of the trial in order to raise awareness.

A further recruitment strategy included use of the media and internet. An advertisement was placed in a local newspaper, which provided brief details of the trial and a request for participants. An additional advertisement was placed on the website of Great Ormond Street Hospital NHS Trust. A local radio interview was conducted by myself, discussing the issues of childhood obesity and details of the trial, with a contact number for interested parents.

There were no inclusion criteria apart from child's age range (7-11 years) nor where there any exclusion criteria. All families who self-referred were requested to seek a referral from their GP to ensure that the intervention was properly integrated within their health care. Referred children were asked to bring their health care professional referral form. All families were invited to an assessment appointment with the trial researchers.

4.1.3 Assessment

The main aims of the assessment were to provide the families with further information about the study, assess motivation and practicalities for attending (e.g., travel, care for other children), establish eligibility (as per the inclusion criteria), and collect baseline anthropometric, medical and psychometric data. Families in receipt of state benefits were reimbursed travel expenses for assessment appointments and treatment sessions. Once the assessments were completed, the eligible families were invited back for the baseline measurement session.

4.1.4 Intervention

The MEND intervention consisted of 20 twice-weekly sessions, each lasting up to 2 hours, over 3 months (included additional assessment and measurement sessions). All sessions were group-based, and consisted of eight nutrition-focused, eight behavioural modification, 18 physical activity and 2 measurement sessions (Table 6).

Nutrition and behavior modification sessions alternated weekly, so that families were provided with one nutrition and one behavior modification session per week. Five of the behavior modification sessions were designed specifically to allow delivery to parents without the children being present due to the adult nature of the topics. All sessions were prepared in advance and recorded on a voice recorder for transcription purposes. The physical activity sessions alternated between land- and water-based activities.

The programme was held in the early evening (5-7pm) on Monday and Wednesday at a central London sports centre (Oasis Sports Centre, 32, Endell Street, Covent Garden, London, WC2H 9AG). The intervention was delivered by a paediatric dietitian (Paul Sacher), a clinical psychologist (Dr. Paul Chadwick) and a physiotherapist (Lisa Hogan).

4.1.5 Outcomes

The primary outcome measure was waist circumference z-score, and secondary outcomes included BMI z-score (see Section 6.9.6), diastolic blood pressure (see Section 6.9.8) and self-esteem (see 6.9.10). Results of a step test were reported in the publication of this trial, but have not been included, since the test was not validated (Sacher, Chadwick *et al*. 2005). Where possible, the weights and heights of parents were measured, and BMI calculated (see Section 6.9.6). Assessments were carried out at baseline, 3 and 6 months. Attendance was also taken during the programme sessions.

4.1.6 Results

All families assessed were eligible for the trial. Eleven subjects (6 girls) with a mean age of 9.6 years consented to participate in the trial. Medical histories and health care professional referrals noted no evidence of illness or comorbidities.

Parents self-classified all children as white ethnicity, and parental SES was not assessed. One child was referred by a hospital paediatrician, five by school nurses, and the rest were self-referred. Baseline demographics and anthropometry are presented in Table 10.

Table 10. Baseline characteristics of the MEND feasibility trial participants (n=11)

	Intervention
Gender – female	60% (6)
Ethnicity – white	100% (11)
Age (years)	9.6 (1.6)
BMI (kg/m²)	26.6 (2.3)
BMI z-score	2.86 (0.42)
Waist circumference (cm)	83.0 (7.3)
Waist circumference z-score	2.96 (0.58)
Maternal BMI (kg/m²)	35.4 (9.2)

Data are presented as means (SD) or % (n), BMI: Body mass index

One participant dropped out after the baseline assessment session due to family illness, and was therefore excluded from all further analyses. Among the 17 parents assessed, seven were classified as obese (BMI ≥ 30) and 8 overweight (BMI ≥ 25) at baseline.

Waist circumference, waist circumference z-score, BMI, BMI z-score, diastolic blood pressure and self-esteem were significantly improved following the 3-month intervention (see Table 11). Benefits were sustained in the succeeding 3-month follow-up period. However, significance was not maintained for BMI and waist circumference z-score. Mean programme attendance was 78% (range, 63–88%), with a 100% retention rate.

Table 11. Summary of feasibility trial results at baseline (0 months), end of intervention (0-3 months) and follow-up (0-6 months)

Outcome	0 months (n=10)	3 months (n=10)	6 months (n=7)	0-3 months difference	0-6 month difference
BMI (kg/m2)	26.4 (3.4)	25.6 (3.5)	25.4 (3.7)	-0.9(0.8)*	-0.8 (1.2)
BMI z-score	2.86 (0.4)	2.59 (0.5)	2.59 (0.5)	-0.21(0.18)*	-0.21 (0.2)*
Waist circumference (cm)	82.9(12.1)	80.7(11.2)	82.1(11.4)	-2.2 (2.6)*	-3.4 (2.0) *
Waist circumference z-score	2.92 (0.6)	2.72 (0.6)	2.65 (0.7)	-0.20(0.2)*	-0.36 (0.2)
Diastolic BP (mmHg)	90 (6)	81 (6)	73(7)	-8(5) **	-19 (8) *
Self-esteem score (range: 36-144)	97 (9)	112 (12)	115(7)	15(8) **	13 (8) *

*Results are presented as mean (SD).*Paired t-test ≤ 0.05; **paired t-test ≤ 0.005.*

4.1.7 Discussion

The purpose of this small-scale feasibility trial was to pilot the MEND intervention, and not obtain generalisable results. The uncontrolled trial was undertaken to assess the feasibility and acceptability of implementing the intervention in a non-clinical setting. The intention at the outset was to recruit a sample size between 1 to 15 children and their families. Eleven children participated in the trial, suggesting reasonably successful recruitment. All families invited to participate in the trial consented.

Considering the intensity of the programme sessions (20 sessions over 10 weeks), the high attendance (mean sessions attended: 78%) and retention (percentage of participants who finished the intervention: 91%) rates demonstrated high acceptability of the delivery format, intensity and content of the programme. In addition, all parents who were offered the opportunity to participate accepted, suggesting a willingness to commit to the intervention and make an investment for their children's health. Ideally, qualitative evaluation should have been included in order to draw firm conclusions, particularly to clarify the barriers to participation and how families regarded the programme content. Additionally, it would have been useful to determine which components of the intervention families felt were most helpful and how they viewed the level of information provided. Unfortunately, no formal process evaluation or qualitative feedback was obtained due to lack of resources and time. Notably, this trial was not undertaken as part of my PhD. All three researchers were engaged in full-time employment at the time and conducted the feasibility trial outside of formal working hours.

At 3 and 6 months from baseline, all outcomes changed in a positive direction, and unexpectedly, given the small sample size, reached statistical significance in most cases (Table 11). As this was a small trial and not powered to achieve statistical significance, these changes suggested an association with improvements in weight status and health. BMI z-score was reduced by 0.21 at 3 months, which was maintained at 6 months. This magnitude of change is 3.5 times that recorded in the Cochrane review of parent-focused lifestyle interventions (effect size at 6 months -0.06, 95% CI: -0.12 to -0.01) (Oude Luttikhuis, Baur *et al*. 2009).

Waist circumference z-score was also reduced at 3 and 6 months. A decreased waist circumference indicates reduced intra-abdominal fat, associated with improvements in metabolic complications of obesity and cardiovascular risk (Shelton, Le Gros *et al*. 2007; Hughes, Stewart *et al*. 2008). Other interesting findings were improved diastolic blood pressure, which was unexpected, as all children were normotensive at baseline. Reduction in diastolic blood pressure provides some indication that the physical activity component of the intervention may improve cardiovascular fitness (Kirk, Zeller *et al*. 2005; Farpour-Lambert, Aggoun *et al*. 2009). Finally, the observed improvements in self-esteem, a risk factor for the development of impaired psychological status in obese children, suggested that the programme also improves psychological health (Griffiths, Parsons *et al*. 2010).

As stated earlier, statistically significant findings were unexpected due to the small sample size, but suggested potential for the intervention if replicated when delivered at scale. However, without a control group, it is not possible to attribute any of these improvements to the programme, as simply participating in the trial itself may produce positive findings. The trial also provided data that were used to inform the power/sample size calculation for the RCT.

The initial small trial had significant limitations, including uncontrolled study design, lack of blinding, small sample size and lack of qualitative process evaluations. Furthermore, the intervention was delivered by a specialist clinical team, which provided no indication of whether analogous results could be obtained when delivered by other non-specialist professionals. As all parents classified their children as white ethnicity, the sample did not reflect the ethnic diversity of the UK population.

Our preliminary findings warranted further investigation to determine whether similar results could be achieved under controlled trial conditions, and the trial was subsequently used to inform the MEND RCT (Appendix 3).

4.2 Findings that informed the MEND RCT

Evaluation of the feasibility of this novel intervention, as well as piloting its methods provided useful findings that were incorporated in the planning of the controlled trial.

Some of the lessons learnt included the realisation that there was a lack of solid evidence on which to base childhood weight management interventions, and that close attention to the emerging literature was important. Another positive outcome that aided in continuation of the development and evaluation process was that the feasibility trial provided some indication of potential benefits associated with a multicomponent, community-based approach. No UK-based evidence was available showing that this type of combined, multidisciplinary approach could be successful at the time, and historically, many studies have focused on only one or two components, i.e., nutrition and/or physical activity and/or behavioural modifications (Summerbell, Ashton et al. 2003; Summerbell, Waters et al. 2005). This presented the opportunity to continue development of the intervention and conduct an adequately powered, controlled trial.

The MEND feasibility trial provided an opportunity to pilot methods and outcomes for evaluation of the RCT. The following outcomes and their methods proved feasible and provided valuable data for analysis: BMI (children and mothers), BMI z-score, waist circumference, waist circumference z-score, blood pressure and self-esteem. These outcomes and their methods were then considered for evaluation of the RCT.

The method for conducting the step test proved feasible. However, the method for measurement of recovery heart rate itself, following the step test, was not validated in a paediatric population. For this reason, results of the step test were not included in this thesis. However, the methods for conducting the step test proved feasible in a community-setting and were therefore considered for inclusion in the RCT.

Another positive finding of the feasibility trial was that the intervention, although not well explored, appeared acceptable to families and produced significant improvements in health outcomes. Thus, no fundamental changes were made to the core structure of the programme. Use of the core structure, experience of delivering the feasibility intervention, transcripts of the sessions, and a professional writer's skills and experience facilitated manualisation of the programme, leading to publication of the 1st edition of the MEND Programme Manual (Section 6.5).

An observation during the feasibility trial was that obese children thoroughly enjoyed both the land- and water-based physical activity sessions. It was important to evaluate whether obese children engage and participate in twice-weekly physical activity sessions, in view of earlier evidence demonstrating that obese children are typically less active than their healthy weight peers (HSE 2008; NICE 2009; DH 2011). In addition, other multicomponent approaches to child weight management have not provided/incorporated physical activity sessions within the interventions (Hughes, Stewart *et al*. 2008; Ford, Bergh *et al*. 2009; Oude Luttikhuis, Baur *et al*. 2009; Croker, Viner *et al*. 2012). The high attendance and retention rates, combined with the observed improvements in cardiovascular fitness, supported the maintenance of this component in the RCT.

4.3 Reflection on the research process

This small, uncontrolled trial was designed to assess the feasibility of implementing an intensive community-based intervention for the management of childhood obesity. On reflection, although the selected study design was appropriate for this stage of evaluation, additional validated quantitative and qualitative outcomes would have provided richer data. Use of non-validated tools is not recommended when alternatives exist. The step test conducted by our physiotherapist was not validated, and therefore did not allow sound conclusions on changes in cardiovascular fitness. Fortunately, blood pressure data provided an indication that cardiovascular fitness had indeed moved in a positive direction.

Other useful outcomes would have included a reliable measure of dietary intake (Section 1.6.2) and physical activity levels (accelerometers). Unfortunately, at the time of the trial, accelerometers were scarce, impractical, bulky and very expensive, and therefore not employed. Alternatively, questionnaires may have provided some information on physical and sedentary activity behaviours, but validated and accurate questionnaires for measuring physical activity in children were not available at the time of the intervention development (Reilly and McDowell 2003; NOO 2011).

Additionally, qualitative evaluation would have provided valuable information regarding children and parent acceptability and perceptions of the intervention, along with feedback on logistical issues, such as timing, venues, length of sessions as well as programme content.

Follow-up was reasonably short, and ideally, would have extended to at least 12 months from baseline in order to provide insights into the sustainability of the outcomes noted at 3 and 6 months. However, there were insufficient resources to conduct the follow-up study.

Despite methodological flaws, the trial provided some useful outcomes to support the application of funding for conduction of a larger controlled trial. Feasibility was also invaluable for developing and trialling the actual intervention, and provided data for the RCT power calculation.

Chapter 5 Hypotheses and aims

5.1 Trial hypotheses

The trial hypotheses were as follows:

5.1.1 Hypothesis 1

The MEND programme will reduce waist circumference and BMI z-scores by clinically significant amounts at 6 and 12 months in a group of obese 8-12 year old children, thereby improving their weight status.

5.1.2 Hypothesis 2

Levels of self-esteem will improve as body composition and cardiovascular fitness improve.

Secondary hypothesis

A secondary hypothesis, which was not conducted formally as part of my PhD, but which has been included for completeness was:

5.1.3 Hypothesis 3

Outcomes of the MEND trial will be similar to those achieved when the MEND intervention is implemented under service-level conditions across the UK.

5.2 Aims

The aims of the trial were:

1. To undertake a randomised, controlled, clinical trial to evaluate the MEND childhood obesity intervention.

2. To compare changes in primary and secondary outcomes at 6 months between groups.

3. To determine if waist circumference and BMI z-score changes at 6 and 12 months were clinically significant, compared with other childhood weight management interventions.

4. To compare intra-participant changes in primary and secondary outcomes for determining whether individual changes were sustained at one year from baseline

5. The aim of the secondary data analysis was to investigate physiological, behavioural and psychological benefits associated with different levels of BMI z-score in children who participated in the RCT.

6. The aim of further research following the trial was to determine if the MEND intervention was generalisable when implemented in diverse communities across the UK.

To achieve all the above aims and substantiate the trial hypotheses, a number of outcomes were collected. These included (i) anthropometrical indices: body weight, height, BMI waist circumference, (ii) body composition, (iii) cardiovascular health: fitness test, blood pressure, (iv) physical activity and sedentary behaviours, (v) self-esteem, (vi) dietary intake, (vii) socioeconomic and ethnicity data, (viii) puberty staging.

These outcomes and the methodologies implemented for assessment are explained in detail in the next Chapter.

Chapter 6 Methods

6.1 Identification of reviewed literature

The majority of literature searches used PubMed Central as the main portal. Google search was additionally utilised for the identification of governmental reports and/or national and international recommendations that were not published in peer reviewed journals. Books and manuals were used wherever applicable.

Publications on the background, introduction, prevention, management, development of the intervention, and Discussion chapters were included in preference if they were meta-analyses, systematic reviews, reviews, practice guidelines, RCTs or large clinical trials with objectives corresponding to the outline of each chapter or section, or with similar characteristics to the current trial when used for comparison purposes. Supporting literature was selected based on study design, sample size, journal impact factor, study research centre, and author reliability. All efforts were made to include the most recent available literature (after 2005 or 2000, depending on availability), with the exception of key references with multiple citations that are routinely used to justify specific statements (e.g., growth chart reference, dietary assessment tool description references). Wherever research findings were ambiguous or inconclusive, all scenarios were presented and referenced, and the findings critically appraised.

Small uncontrolled studies on populations with different profiles (e.g., those from developing countries and on pre-schoolers or children in late adolescence) were excluded from the literature search, along with non-English publications.

The following keywords were used to conduct the literature review:

Prevalence: childhood, obesity, overweight, prevalence, cost, review, parental obesity, maternal obesity, age, gender, ethnicity, social class, socioeconomic status, income, urban, rural, deprivation, physical activity, sedentary activity, transportation, international worldwide, Europe, United Kingdom, Health Survey for England, National Child Measurement Programme, obesity projections, obesity plateau, International Association for the Study of Obesity, developed countries, developing countries, future projections, forecast.

Assessment: childhood obesity, assessment, z-score, growth charts, BMI, waist circumference, body composition, assessment, validity, central adiposity, weight loss, childhood obesity screening, abdominal obesity, central obesity, adiposity in children, skinfold thickness, bioelectrical impedance, underwater weighing, Air Displacement Plethysmography, dilution techniques, doubly labelled water, Dual Energy X-Ray Absorptiometry.

Causes: childhood obesity, causes, aetiology, genes, genetic, medical disorders, drugs, parental obesity, parental eating behaviour, parental perception, family, dietary intake, physical activity, television, sedentary, computer, perinatal nutrition, pregnancy, gestational diabetes, breastfeeding, early feeding practices, nutrition programming, adiposity rebound, socioeconomic status, inactivity, psychology, self-esteem, depression, built environment, advertisements, role models, junk food, sugary drinks, soft drinks.

Consequences: childhood obesity, consequences, short-term, long-term, health, psychology, self-esteem, bullying, depression, body dissatisfaction, body image, eating disorders, metabolic syndrome, insulin resistance, diabetes, adult obesity, cardiovascular disease, risk factors, economic consequences, cost, health system, socioeconomic status.

Dietary intake: childhood obesity, diet, macronutrients, energy intake, energy expenditure, underreporting, misreporting, intervention, treatment, dietary assessment, dietary reference values, recommended nutrient intake, 24-hour recall, food diary, food frequency questionnaire.

Prevention: childhood obesity, prevention, schools, community, parents, family, health promotion, health promotion, health education, diet, physical activity, television, sedentary, inactivity, behavioural intervention, multi-disciplinary, multicomponent.

Management: childhood obesity, management, treatment, group treatment, individual treatment, intervention, recommendation, health education, best practice, diet, physical activity, television, sedentary, behavioural intervention, multi-disciplinary, multicomponent, bariatric surgery, pharmacological treatment, cardiovascular fitness, blood pressure, heart rate, physical activity, exercise, sedentary activities, inactivity, television, self-esteem, psychology, attendance, retention, dropout, effectiveness, effect size, follow-up, Traffic Light Diet, parents as exclusive agents, GP, doctor, weight loss camps.

The remainder of this chapter discusses the methods for evaluation of the MEND intervention informed by findings of the feasibility trial described in Chapter 4. It should be noted that the MEND RCT was conducted for the purposes of this PhD.

6.2 Standardisation

In 2003 to 2004, following the feasibility trial, Dr. Paul Chadwick and I standardised and manualised the programme to make it generalisable for delivery by other non-obesity specialist professionals in a variety of community settings.

6.3 Training

To ensure standardised delivery across multiple trial sites, all theory and exercise leaders received identical training (4 days) and materials, specifically, theory (nutrition and behaviour modification) and exercise manuals, children's handouts, programme resources, and teaching aids. The manuals contained detailed guidance for the delivery methods for all sessions (Section 6.5). The importance of standardised delivery of the intervention was highlighted throughout the training, and involved practical role plays to ensure effective and consistent delivery.

6.4 Intervention resources

A programme kit was created with the dual aim of standardising the intervention and supporting the leaders (Figure 26). The kit additionally contained resources for participants (backpack, binder and handouts). Resources were referenced in the manuals, and the leaders provided with detailed guidance on their usage to ensure the appropriate learning outcomes for each session. The kit was also intended to remove the burden from trainers by providing all the resources required to conduct the sessions available in a single portable container.

Figure 26. The MEND programme kit (2005)

6.5 Manualisation of the intervention

A professional writer was employed to compile the MEND Programme Manual. The writer had extensive experience in producing specialist manuals, writing for children and adults, including health professionals, and had a strong interest in childhood nutrition and health. During the feasibility trial, all sessions were recorded and transcribed in order to provide information for development of the manuals, with a view to ensuring standardised delivery of the MEND intervention. The manual content was provided by both myself and Dr. Paul

Chadwick in both written and verbal forms, which were combined with the transcripts of the feasibility trial to produce draft sessions. All draft sessions were reviewed and amended as necessary, until final approval from myself and Dr. Paul Chadwick.

The format and structure of the manual was developed by the writer, based on individual research and experience of the most effective formats for dissemination of a health education programme by a wide range of professionals aimed at families. The aim of the manual was to promote quality assurance and standardisation between research sites. A 216-page manual was produced after 14 months of consultations, discussions and development, consisting of the following sections: Introduction, 8 Mind (behaviour modification), 8 Nutrition, Farewell, and appendices containing sources of further reading, useful addresses, resources, and 25 healthy recipes. Each session contained supporting material for parents and children (handouts) written specifically to meet the reading requirements of the average age of primary school children. A separate exercise manual was compiled by Fitpro Ltd. to standardise the exercise sessions.

Manuals were written with the aim of being culturally appropriate, and this was primarily expressed by the inclusion of guidelines for eating during religious holidays, such as Ramadan, Christmas, Easter and Passover. During the manualisation process, feedback was obtained from a variety of professionals and incorporated into the final version. No formal evaluation or testing of the manuals was performed.

6.6 Intervention delivery teams and locations

A Principal Investigator was assigned for each research site, and provided guidance on selecting intervention delivery teams. Evidence suggests that the type of health professional providing advice to families is not critical, as long as they have the appropriate training and experience, are enthusiastic and able to motivate, and provide long-term support (NICE 2006).

A minimum of 3 trained professionals was required for each research site team. Teams comprised a nutrition theory leader, a behavioural theory leader, an exercise leader and an optional assistant. The nutrition and behavioural theory leader was the same person at all but one site. The professional backgrounds of the MEND leaders at each site are summarised in Table 12.

Table 12. Locations and professional backgrounds of MEND leaders

Location	Nutrition theory leader	Behavioural theory leader	Exercise leader	Assistant
Bromley PCT	Dietitian	Dietitian	Exercise trainer	Nutritionist
Lewisham PCT (1)*	Dietitian	Dietitian	Physiotherapist and Exercise trainer	Dietitian and Nutritionist
Lewisham PCT (2)	Dietitian	Dietitian	Exercise trainer	Nutritionist
Southwark PCT	Nutritionist	Nutritionist	Exercise trainer	Nutritionist

Waveney PCT	Dietitian	Social worker	PE teacher	Nutritionist

** Paul Sacher fulfilled the role of nutrition and behavioural theory leader at this site*

6.7 Training

Training for the intervention took place over 4 days, consisting of one day on nutrition, one day on behaviour modification, and two days on physical activity (one day of land- and one day of water-based activities). All training was developed specifically for this trial. I developed and delivered the first day of training, Dr. Paul Chadwick the second, and Fitpro Ltd. provided the third and fourth days of physical activity training.

Training took place at Ladywell Leisure Centre (261 Lewisham High Street, London, SE13 6NJ), and was attended by all teams, except Waveney PCT. Training for Waveney PCT took place in Suffolk due to the high costs associated with travel to London and accommodation.

The training modules were not designed as a general guidance for nutrition, behaviour modification and physical activity, but aimed to specifically instruct teams on delivering these components of the intervention using the trial resources provided (Figure 26).

Day 1 consisted of introduction to the trial and an overview of the research protocol. This included roles and responsibilities of the principal investigators and their respective delivery teams (i.e., theory and exercise leaders). Information was provided on the aims of the trial and the background for creation of the

MEND programme. Details of the structure of the programme and methods for delivery of all sessions were provided. Delivery teams were also instructed that this was a group-based intervention and no individualised advice was to be provided during the programme sessions. Teams were advised to report adverse events and refer back to the families' GPs in cases of medical concerns. The remainder of the day was spent discussing the nutrition component of the intervention in detail.

Day 2 consisted of an overview on the psychosocial consequences of childhood obesity, including self-esteem and eating disorders. Guidance on raising the weight issue and detailed discussions on effective delivery of the behaviour change sessions were included. The day ended with role plays to evaluate the competency of the theory leaders. There were opportunities throughout days 1 and 2 of training for issues, concerns and questions to be addressed. Qualitative feedback from training participants was obtained.

Days 3 and 4 consisted of land and water-based exercise training, which was delivered to both theory and exercise leaders. The training involved demonstrations of manualised exercise sessions plus education on physiological considerations when delivering physical activity to obese children.

In addition to the above training, I provided one-to-one training for principal investigators, which focused on their roles and responsibilities and recruitment strategies for individual research sites and programmes.

6.8 The MEND RCT intervention

The intervention consisted of two phases: intensive (0-9 weeks) and post-intensive (10-24 weeks). The intensive phase of the MEND intervention consisted of 18 group sessions delivered over 9 weeks. The sessions comprised an introductory meeting, 8 theory sessions focusing on behaviour modification, 8 theory sessions providing nutrition education, 18 physical activity sessions, and a final closing (graduation) session.

Weekly theory sessions alternated between nutrition and behaviour modification. Children participated in physical activity sessions twice weekly after the theory sessions, while parents participated in parent-only unstructured, facilitated, problem solving discussions. Table 6 provides details of the 18 sessions.

Group sessions lasted for 2 hours, and were held twice weekly in leisure centres and school venues. Each group consisted of 8-15 children plus an accompanying parent/carer. Sessions were delivered after school and work hours, typically from 5:30-7:30 p.m., with a view to improving attendance of both children and parents/carers.

The post-intensive phase consisted of the provision of a free pass for the entire family to attend a local leisure centre swimming pool. Ideally, the post-intensive phase of the trial would have included on-going structured physical activity sessions, similar to those provided during the programme, however resources did not allow for this. In addition, children were not allowed to exercise in the leisure centre gyms or classes as they were under the age of 16. We therefore aimed to evaluate whether provision of the free swimming pass would encourage families to exercise together and promote sustained physical activity behaviours.

6.9 Study design

6.9.1 MRC guidance on evaluating a complex intervention

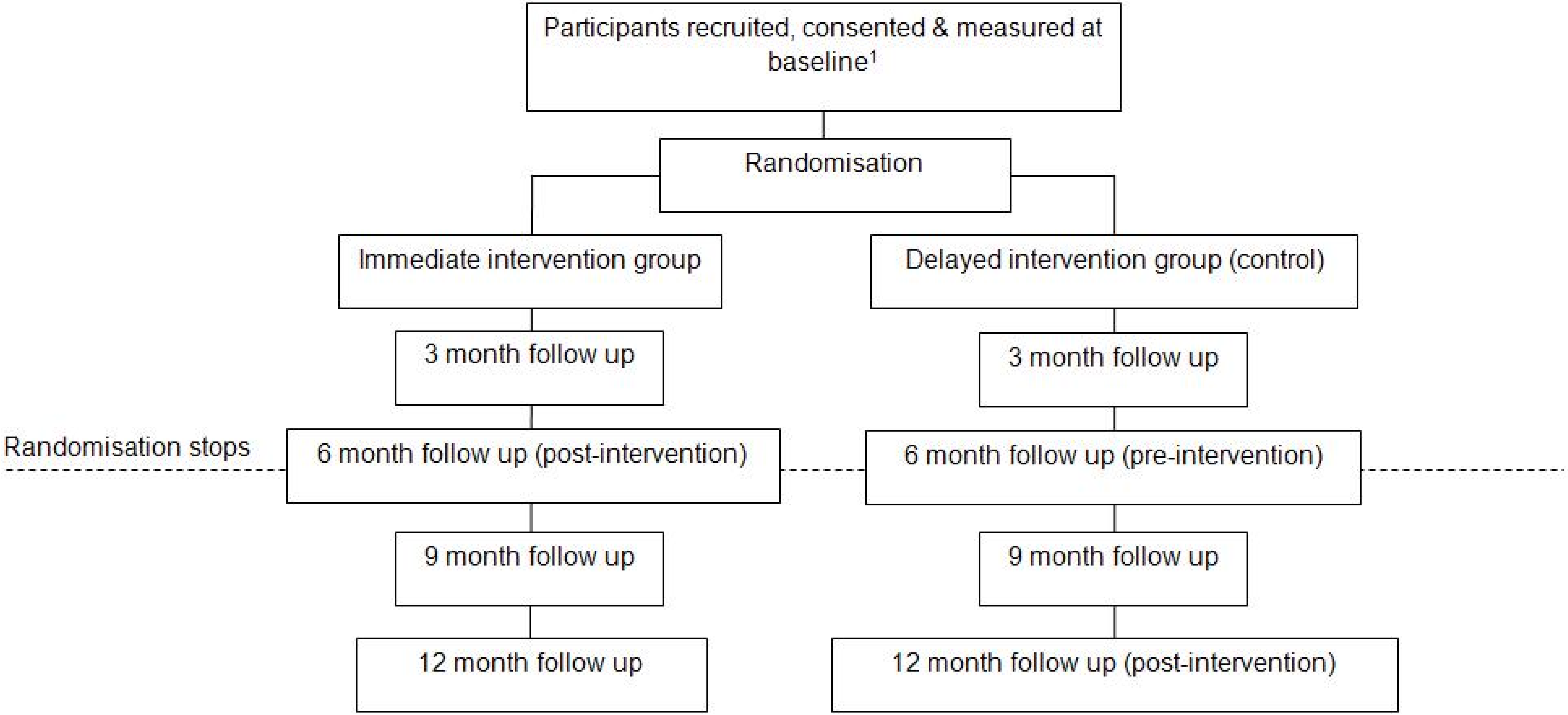
According to the MRC framework for developing and evaluating complex interventions, several study designs are available to assess different types of interventions, and randomisation should always be considered to avoid selection bias (Craig, Dieppe *et al*. 2008).

A RCT was selected as the most appropriate study design to evaluate the efficacy of MEND for the management of childhood obesity. This RCT was designed to assess the effectiveness of a 6-month intervention, compared to a delayed intervention group. The intervention was delivered at 5 separate community sites by teams with no previous experience of delivery. All eligible participants were assessed at baseline and randomly allocated to start the intervention (immediate intervention group) or receive the intervention 6 months later (control group or delayed intervention group).

Ideally, a period of 12 months would have been selected over 6 months for the delayed intervention group. However, the ethics committee approving this trial felt that it was not ethical to make treatment-seeking families wait longer than 6 months. In addition, it was hoped that offering the control group the intervention at 6 months from randomisation would aid in recruitment and retention.

Measurements were performed at baseline, 3, 6, 9 and 12 months from randomisation (Figure 27). It is important to note that baseline and 6 month measurements were performed before and after the intervention for the immediate intervention group. After 6 months, the control group received the (delayed) intervention. Therefore, for these children, 6 month and 12 month measurements were the ’before’ and ’after’ intervention measurements. In the within-subject analysis presented in the Results section, children from both groups were included.

Figure 27. Trial flow chart



Follow up periods in the above graph are months from randomisation

[1]Baseline measurements for the intervention group = pre-intervention

6.9.2 Participants

Eligibility criteria

The following inclusion and exclusion criteria were applied to select participants in the trial:

Inclusion criteria

1. Children referred by a health professional or self-referred.
2. Children between 8-12 years of age.
3. Obese, defined as BMI above the 98th centile on the BMI chart for boys/girls (UK reference data) (Cole, Freeman *et al*. 1995).
4. At least one parent or carer able to attend each session.
5. Clinically well with no chronic illness.

Exclusion criteria

1. Children with physical disabilities that would exclude their participation in exercise sessions.
2. Those with significant developmental delay or psychiatric diagnosis (children with these conditions need a more specific, tailored intervention, and are unlikely to obtain maximum benefit from the trial).
3. GP advised unsuitability for the trial.

4. Children with conditions that clinically cause obesity, e.g., steroid use, specific syndromes.

A letter was sent to the GPs of all children excluded from the trial, which included information on their weight status and reason for unsuitability, leaving clinical management at the discretion of the respective doctors.

Recruitment

Obese children were identified using two methods that had been successfully evaluated and refined in the feasibility trial (Sacher, Chadwick *et al*. 2005). Principal investigators were encouraged to develop an individualised recruitment strategy for their trial site with my support. The strategies varied among sites, depending on their experience and local networks and contacts. Each principal investigator had a local number for families to call where they could obtain more information on the locally delivered programme, e.g., time, day, and venue. In addition, all families were given a number on the information sheets for the researchers based at the Institute of Child Health, where they were provided with specific information verbally and by post.

Methods of recruitment were broadly divided into 2 categories.

1. Health professional referral: local paediatric dietitians, school nurses, GPs and paediatricians were informed of the trial by the Principal Investigators. These professionals were provided with trial information packs (boys and girls BMI charts, poster and leaflets, parent and child information sheets),

with a view to identifying families meeting the trial eligibility criteria and providing them with the information sheets (Appendix 4). In some cases, health professionals conducted a patient record review to identify suitable children for the study who were then sent a letter containing an introduction to the trial as well as the parent and child information sheets. Families interested in participating were provided with contact details to obtain further information. No personal data was provided to the research team from health professionals without the families' consent.

2. Self-referral: the trial was advertised in local newspapers (editorials and paid) and on the internet. The advertisement and editorials requested interested parents to contact a designated local telephone number or the Institute of Child Health for more information. The information sheets clearly stated that parents and children interested in participating in the trial should contact the research team via telephone. During the first call, parents were asked to provide the age and estimated height and weight of their child, along with information on any medical conditions, with the intention of pre-screening children who did not meet the inclusion criteria.

If children did not meet the inclusion and exclusion criteria (e.g., outside the age range and/or not above the 98th centile for age and gender (i.e., not obese) or with a medical diagnosis), they were not invited for baseline measurements. It was politely explained to parents or carers that their child was not eligible. Those who fulfilled the age and weight status criteria and had no medical conditions were offered an appointment for baseline measurements.

At the time of baseline measurement, all children meeting the eligibility criteria were invited to participate in the trial. Consent and assent forms (for parents and children, respectively) were signed by both researchers and families to confirm trial entry (Appendices 5 and 6). Both forms included permission for the researchers to contact the child's GP. Children who did not meet the inclusion criteria were not invited to participate, and permission from the parent was requested in order to notify their GP.

Families that were unsure about participation were given the forms to take home, along with a self-addressed, stamped envelope to return if they decided to participate. Once consent and assent forms were signed, letters were sent to the respective GPs informing them of patient inclusion in the trial and requesting contact in case there was any reason to preclude them from participation (Appendix 7). Participants were free to withdraw from the trial at any stage.

6.9.3 Randomisation

Participants were randomised by an independent researcher using a random permuted block design with size 6 blocks. The randomisation schedule was computer-generated. An administrative staff member notified the families of the group to which they had been assigned to ensure that the researchers collecting outcome data were blinded to group allocation. Following participant consent, it was explained that it was important not to reveal their group allocation to the researcher performing measurements.

However, owing to the delayed intervention and intensive interactions between families and researchers, and because participants were keen to discuss their measurements with the research team, blinding to the randomisation was not eventually possible.

6.9.4 Sample size

Based on the feasibility trial (Sacher, Chadwick *et al*. 2005), analysis of covariance (ANCOVA) was used to detect a 3 cm difference in waist circumference (primary outcome) between randomised groups. Assuming 5% significance and 80% power, 40 children needed to be recruited to each group. Taking into account 20% dropout (10% dropout during the feasibility trial), 48 children per group were required, making a total of 96. The trial also had 80% power to detect a 0.45 standard deviation change in individual subjects at 3, 6, 9 and 12 months from randomisation.

6.9.5 Outcome measurements

Data were collected at baseline, 3, 6, 9 and 12 months by two researchers (PS, MK) with the assistance of the local Principal Investigators. All measurements were observed or checked by the Principle Investigator at each site.

6.9.6 Anthropometry

Body weight was measured using electronic scales with an accuracy of ± 0.1 kg. Scales were positioned on a firm level surface away from any encumbrances and automatically calibrated. Subjects were asked to remove shoes and outer clothing and to stand on the centre of the scale, keeping still, while facing forwards with their hands at their sides. This procedure was repeated twice and weight was recorded in kilograms to one decimal place (Heyward 1998).

Standing height was measured to the nearest 1 mm using a stadiometer. Subjects were asked to remove shoes and outer clothing. Subjects stood straight with feet flat, back, shoulders, head, buttocks and calves against the stadiometer backboard, heels against the heel plate, and head in the horizontal Frankfurt (orbito-meatal) plane. Subjects were asked to breathe normally and remain still. The head-plate was then placed on top of subject's head and the measurement recorded in metres to two decimal places (Heyward 1998).

The above indices were measured for both children and parents, and subsequently used to calculate the BMI by dividing weight (kg) by height squared (m^2). Children were classified as obese at BMI $\geq 98^{th}$ centile for age and gender (Cole, Freeman *et al*. 1995). Parents with BMI values between 25 and 29.99 kg/m^2 were classified as overweight, while those with a BMI above 30 kg/m^2 were classified as obese (NICE 2006).

Waist circumference was measured by the same researcher using a non-flexible tape measure. Subjects were asked to stand straight. The researcher identified the narrowest girth of the waist, usually about 4 cm above the umbilicus. If this proved to be difficult then the subject was asked to bend to the side and the researcher then identified the point at which the trunk folded, and used this as the landmark. The waist circumference was then measured and recorded at this point with the tape horizontal (Rudolf, Walker *et al*. 2007).

Detailed description of the Standard Operating Procedures (SOP) for weight, height and waist circumference measurements are provided in Appendix 8 and 9.

6.9.7 Body composition

Body composition was based on the hydrometry two-component model. Total body water (TBW) content was measured via deuterium oxide dilution, with 2-hydrogen as the isotope of choice (deuterium) (Wells, Fuller *et al*. 1999).

According to this model, body weight is divided into fat-free mass (FFM) and fat mass (FM). FFM was calculated using the equation: FFM = TBW/H_{FFM}, whereby H_{FFM} represents the fraction of FFM that is water, according to the corresponding age- and sex-specific values.

Based on the principles of the two-component model and values for FFM, fat mass (FM) was calculated as follows: FM = wt – FFM. Body fat (BF%) was estimated using the equation: BF% = (FM/wt) x 100.

In order to prepare the deuterium, sample tubes and salivettes were labelled with subject reference details and the date. Deuterium doses according to body weight were prepared for each participant. On site, a saliva sample was obtained prior to dosing. The deuterium solution was then drunk by the subject. The dosing time was recorded and instructions provided to families which detailed procedures for obtaining a subsequent saliva sample and recording of fluid intake between samples. Samples were posted to the researcher’s address and analysed in the laboratory in order to derive FFM and FM. Detailed description of the SOP is provided in Appendix 10.

6.9.8 Cardiovascular health

Cardiovascular fitness was assessed based on the recovery in heart rate one minute after a validated 3-minute step test standardised for rate and height. Before conducting the test the platform height was adjusted according to the child's height. Resting pulse was recorded for 15 seconds followed by 3 minutes of stepping at the rate indicated by metronome. After 3 minutes, stepping ceased and the subject sat down on the step. The researcher then recorded immediate post-exercise pulse rate for 15 seconds. Following this, the subject remained resting for another minute and resting pulse rate was recorded for 15 seconds. (Francis and Feinstein 1991). The SOP for measurement of heart rate recovery following the step test is included in Appendix 11.

Systolic and diastolic blood pressures were measured in the supine position, from the left arm with an appropriately sized cuff and automated blood pressure monitor. Three blood pressure measurements were taken after a 10-minute rest, and the average of the last two measurements used for analysis (Sanchez-Bayle, Munoz-Fernandez *et al*. 1999). Detailed description of the SOP for measuring blood pressure is provided in Appendix 12. Blood pressures recorded above the 91st centile were reported to the respective GPs.

6.9.9 Physical activity and inactivity

Levels of physical activity and sedentary behaviours were assessed using a non-validated questionnaire adapted from Slemenda *et al*. (1991). This included the number and duration of physical education lessons, as well as time spent on different types of vigorous activities (e.g., sports) and sedentary activities (e.g., television, computer).

The procedure described below was used to complete the exercise questionnaire.

Parents and children were asked to provide information on:

1. How many Physical Education (PE) lessons they took part in per week. If the assessment took place during school holidays, children were asked about the number of PE lessons they participated in during the previous school term.

2. The duration of each PE lesson.

Parents were asked to estimate:

1. The number of hours per week their child spent watching TV and videos, on the computer and playing video games (school days and nights).

3. The number of hours their child spent watching TV and videos, on the computer and playing video games at weekends.

4. The number of hours per week their child spent on the following activities (excluding physical education): cycling, swimming, running, football, aerobics or dancing, gymnastics, walking, tennis or badminton, netball, hockey, basketball, rugby, skating or any other sport.

5. The total number of hours their child spent in vigorous activity (defined as activity leading to the child getting out of breath or sweating) per week.

6. Their child’s activity level, compared to peers, for classification as: significantly lower than peers, lower than peers, same as peers, more than peers, or significantly more than peers.

Time spent in each activity was summed up to generate total physical activity time per week. Time spent watching TV and videos, on the computer and playing video games on weekdays and weekends was summed up to derive sedentary activity time. A copy of the exercise questionnaire for children can be found in Appendix 13.

6.9.10 Self-esteem

Self-esteem was evaluated using the Harter Self-Perception Profile, a common assessment tool validated for UK children of this age group (Harter 1985). A modified version of the questionnaire was used for the current trial (Hoare, Elton *et al*. 1993) (Appendix 14). This questionnaire was completed by the child with the researcher’s assistance if needed, and consisted of 36 statements divided into the following categories: scholastic competence, social acceptance, athletic competence, physical appearance, behavioural conduct, and global self-worth.

Once completed, the questionnaire was checked for omissions and scored according to the author’s instructions. More precisely, the 36 questions corresponded to six sub-scales: global self-esteem, scholastic competence, social acceptance, athletic competence, physical appearance and behaviour. A score ranging from 1 to 4 was allocated to each response and the average score (score range 1-4) for each sub-scale was generated. For the purposes of the current study, only global self-esteem was used.

To minimise errors and facilitate data processing at follow-up, a system for rapid and safe scoring of the above questionnaire was developed. This system enabled the entry of raw data exactly as it appeared in the completed questionnaires. Subsequently, by running an appropriately developed SPSS syntax file, scores were automatically calculated, and children classified in the corresponding categories. The syntax file and commands were based on the scoring instructions in the questionnaire.

6.9.11 Dietary intake

The most common methods for assessing children's habitual dietary intake are dietary recalls and food diaries. Seven-day diet records are commonly assumed to provide accurate estimates of habitual energy intake. Three day diet records were selected as the method for assessing dietary intake in the RCT. Parents were asked to maintain a 3-day (two weekdays and one weekend day) diary of all foods and drinks consumed by their child.

The majority of records were completed by the parent, but in many cases, children contributed to the recording of their dietary intake. Parents and children were shown how to complete the diary by the two research dietitians (PS, MK).

The procedure below was followed to instruct families on how to complete the 3-day food diaries.

1. Participants were asked to record everything they had eaten and drunk for 3 days. They had to select 2 weekdays and one weekend day when the child was eating and drinking normally.

2. The importance of accuracy for the food diary was explained, and children and parents declared a ‘peace pact’ for the 3 days, whereby the child was encouraged to reveal all food and drink consumed over this period to parents without any repercussions.

3. Families were instructed to record all meals, snacks and drinks during the 3 days.

4. A completed example day was used to demonstrate how to record foods and drinks, as well as the amounts offered to children and left over.

5. Families were asked to weigh all foods and drinks, if possible, and failing that, use household measures to describe quantities. A diagram with household measures was used to explain this clearly.

6. Families were additionally requested to send food wrappers and packaging back to the research team to increase the accuracy of the analysis.

Data entry was performed by a trained dietitian and food selection was performed in an effort to match foods recorded as accurately as possible. In order to standardise the results, a “shopping list” was compiled of all unknown items from the food diaries, and details of these products obtained from supermarket visits. The data collected for each item included nutritional information (energy, carbohydrate, sugar and fat content) and packet weight and/or portion size to ensure selection of the most appropriate item available in the Microdiet database and enable future use of the list as a reference.

Recipes were also analysed and all ingredients included in the analysis. Once data entry was complete, the software generated daily energy, macronutrien and micronutrient results for each participant. These were subsequently used to derive the group daily averages.

6.9.12 Socioeconomic and ethnic group classification

Social classification was based on the occupation of the parent providing the main financial support for the family, in accordance with the UK Registrar General's Classification system. Ethnic background information was obtained from parents, based on the UK census categorization (1993). Families were grouped as social classes I, II, III (Manual and Non-Manual), IV, V or unemployed. A social data collection form was created to record the data (Appendix 15).

6.9.13 Puberty staging

A validated self-assessed Tanner line drawing puberty staging form was used (Bonat, Pathomvanich *et al*. 2002). All children over the age of 9 years completed a puberty staging questionnaire at each measurement session, following verbal permission from parents. Boys and girls were left alone to complete the form, which was returned in a sealed envelope to ensure privacy, as no physician was present to perform the Tanner stage assessment.

6.9.14 Attendance and retention

An accurate record of attendance for each child participating in the intervention was maintained. Individual attendance (%) was calculated for each participant by averaging the number of MEND sessions attended as number of sessions attended by the participant multiplied by 100 and divided by 18 (total number of MEND sessions).

Group attendance (%) was calculated by averaging the individual attendance for all participants receiving the intervention (immediate and delayed intervention group). Children who were invited and agreed to participate in the intervention but never attended any of the sessions or completed the intervention were defined as ’dropouts’.

Retention rate was calculated at each follow-up time-point to assess the percentage of children attending the measurement sessions. Retention rate was solely based on presence at the measurement and not intervention sessions. There was only one measurement opportunity for each family at all time-points, due to restrictions with regard to availability of the community venues used to perform the measurements.

Following the MEND programme, families were provided a free pass to attend their local leisure centre swimming pool, as well as an attendance diary to self-monitor the frequency of visits. Parents were asked to obtain a signature and date from the attending receptionist to validate attendance. Unfortunately, there was no mechanism to record whether parents and children or children alone actually swam. Families were asked to submit their paper-based card at the measurement session 3 months after receiving the swimming pass, once it had expired.

6.9.15 Data

Primary data analysis

All variables were assessed for normality using the One-Sample Kolmogorov-Smirnov non-parametric test. Randomised groups were compared at baseline, 3 and 6 months using an independent sample t-test for normally distributed variables and Fisher's exact test for categorical variables. Groups were analysed as randomised. Secondary analysis included adjustment of trial outcomes for differences between groups at baseline, i.e., follow-up measurements were subtracted from baseline measurements and the differences used in analysis. This was performed to eliminate baseline differences that may have influenced the unadjusted results.

Paired comparisons of data from children from both groups collected before the intervention and at 6 months were conducted using the appropriate measurement time-points (baseline and 6 months for the intervention group, and 6 and 12 months for the delayed intervention group). Paired comparisons between data obtained at baseline and 12 months to assess the effectiveness of the intervention were only conducted for subjects randomised to the (immediate) intervention group, as no 12-month follow-up was available for the control/ delayed intervention group (see also Section 6.9.1). Univariate analysis was used to check for associations between changes in BMI and waist circumference and their z-scores at 6 and 12 months and several predictors of success. The results did not indicate the need for further multivariate analysis.

Statistical significance was set at $p < 0.05$. All analyses were conducted using the SPSS 13.0 statistical software package for Windows (SPSS, Inc., Chicago, IL).

Secondary data analysis

Secondary data analyses were carried out on two sub-samples of children participating in the RCT. The first sub-sample consisted of a group of 71 participants from both arms from the original RCT who completed the 6-month intervention (Figure 35). The second included a group of 42 participants assessed at 12 months (6 months following the intervention). The delayed intervention design of the original RCT meant that only participants who initially received the intervention (arm 1 or immediate intervention group) were assessed at 12 months (Figure 35). Analyses were performed using available data, discarding records with missing measurements.

Data from 79 children from both groups were used in the analysis. Differences in outcomes after 6 and 12 months from baseline were investigated using a t-test.

Subjects were split into four subgroups on the basis of changes in the BMI z-score as follows:

- Group A: participants with an increase in BMI z-score of > 0
- Group B: participants with a decrease in BMI z-score of ≥ 0 to <0.25
- Group C: participants with a decrease in BMI z-score of ≥ 0.25 to <0.5
- Group D: participants with a decrease in BMI z-score of ≥ 0.5

For all BMI z-score subgroups and each outcome variable, pre-intervention levels and changes between ‘initial’ and ‘final’ measurements were summarised as mean values and standard errors.

Differences in outcomes across the four BMI z-score subgroups were investigated at two time-points, specifically, 6 and 12 months from baseline. For each time-point, analysis of variance (ANOVA) was performed to determine whether there were significant differences in the ‘initial’ means and mean change of outcomes across the four BMI z-score subgroups.

A test for linear trend in the change of outcome variables after baseline using linear regression was performed at 6 and at 12 months post-intervention to assess whether BMI z-score change as a continuous variable predicted outcome change. The test for linear trend at 6 months was adjusted for the randomisation group. Assumptions of normality and homogeneity were assessed post-hoc by examining QQ plots of the residuals of the fitted models. Statistical significance was set at $p < 0.05$ two-tailed. All analyses were conducted using SPSS 18.0 for Windows (SPSS, Chicago, IL).

Data handling

Apart from the dietary intake and self-esteem questionnaires, all other data were collated by scanning data collection forms using Teleform version 10.2 desktop software and reader. Details on dietary intake and self-esteem data handling are available in Sections 6.9.10 and 6.9.11.

Data cleaning

During form scanning or manual entry, data were assessed for obvious errors. In cases where data were clearly wrong, values were discarded and handled as missing. However, this occurred very rarely, as all measurements were double-checked by researchers and the Principal Investigator during data collection.

Data storage and protection

Participant records (measurement sheets and questionnaires collected for all visits) were grouped per site and stored in individual folders at the UCL Institute of Child Health in locked cabinets. The trial was covered by UCL Data Protection Registration (reference No Z6364106, section 19, research: health research).

6.9.16 Ethical, safety and other considerations

Ethical considerations

Ethical approval for this trial was obtained from the Metropolitan Multi-Centre Research Ethics Committee (MREC) on 2nd February, 2005 (Appendix 16). In addition, site-specific ethical approval was obtained for all trial sites. Each trial site had a Principal Investigator approved by MREC.

Local R&D approval was also required and therefore obtained for the Lewisham PCT, Waveney PCT and Southwark PCT trial sites.

The trial was officially concluded on 13th January, 2007, and the Southampton and South West Hampshire Research Ethics Committee (which replaced the Metropolitan Multi-Centre Research Ethics Committee on 12th September 2006) was duly informed (Appendix 17).

Safety considerations

Each venue of intervention delivery recorded incidents in an accident log book.

Insurance

No-fault compensation insurance cover was obtained for the trial (Appendix 18). In addition, all trial sites were required to hold their own public liability insurance, and copies of these were obtained for confirmation.

Trial registration

The trial was registered with the International Standard Randomised Controlled Trial Number Register (www.isrctn.org) (ISRCTN30238779).

Trial sponsors

Great Ormond Street Hospital for Children NHS Trust and UCL Institute of Child Health were the sponsors for the current trial.

Research staff involved in the trial

Paul Sacher was the Chief Investigator for this trial. Dr. Paul Chadwick, Professor Tim Cole, Dr. Jonathan Wells, Professor Atul Singhal, Professor Alan Lucas and Dr. Margaret Lawson approved the final RCT protocol. Professor Atul Singhal, a paediatrician, was responsible for the medical care of participants. Maria Kolotourou was the trial Research Assistant.

Chapter 7 Primary data analysis results

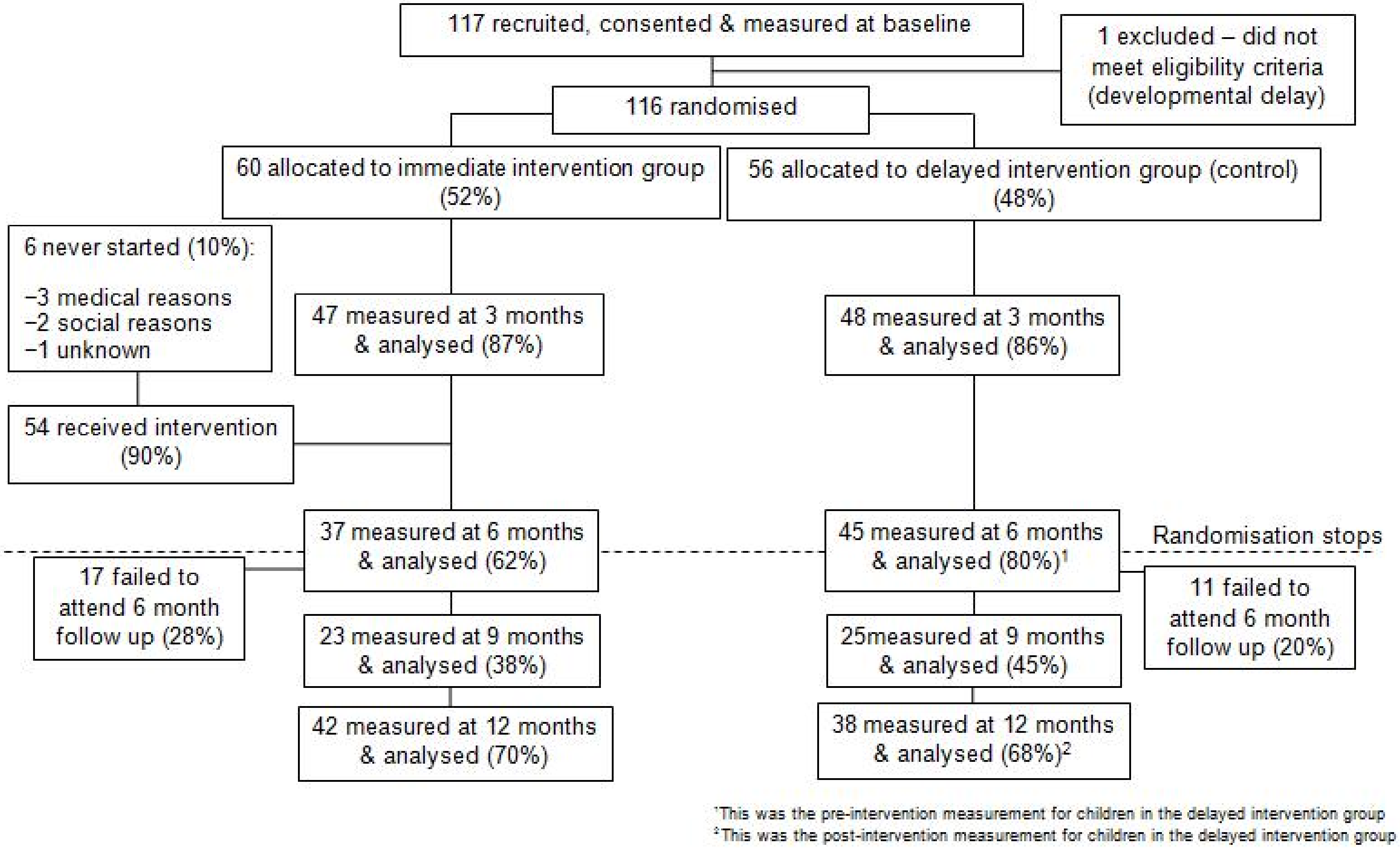
7.1 Trial flow chart

Figure 28 outlines the trial flow chart. One hundred and seventeen children were recruited, among whom 116 were randomised (60 to the intervention and 56 to the control group). Among the 60 children randomised to the intervention group, 54 completed the intervention. At 6 months, children in the control group received the 6-month intervention.

7.2 Dates of recruitment and follow-up

Recruitment took place between March 2005 and January 2006. Twelve month measurements were completed in January 2007.

Figure 28. Trial flow chart (with numbers)



7.3 Trial demographics

7.3.1 Baseline characteristics of the trial population

There were no significant differences in any of the variables between groups at baseline, apart from gender, as more girls were randomised to the intervention group ($p = 0.03$) (Table 13).

Fifty-four percent of the children included were girls, and 50% were white (Table 14 provides a breakdown of participant ethnicities). Occupation of the primary earner in the household was used to determine social class. The percentage of households where the primary earner had a manual occupation was 61% (Table 13). Average age was 10.2 years. Children as a group were moderately obese (as suggested by their mean BMI z-score of 2.8), with a mean waist circumference z-score of 2.8. On average, children had 39.5% body fat.

The majority of mothers (75%) were either overweight or obese (31% overweight, 44% obese). Figure 29 presents maternal BMI distribution. Paternal BMI was not reported, as the majority of children were accompanied at the measurement sessions by their mothers only.

Mean systolic and diastolic blood pressures were between the 75^{th} and 91^{st} centiles for the mean age of the group. Nine children had systolic blood pressures above 140 mmHg, but all were less than 150 mmHg. Diastolic blood pressure was less than 90 mmHg for all participants at baseline.

On average, children were doing one hour of physical activity per day (7.5 hours per week) and watching television or playing computer and video games for approximately 3 hours per day (20.9 hours per week).

Table 13. Baseline characteristics of the trial population

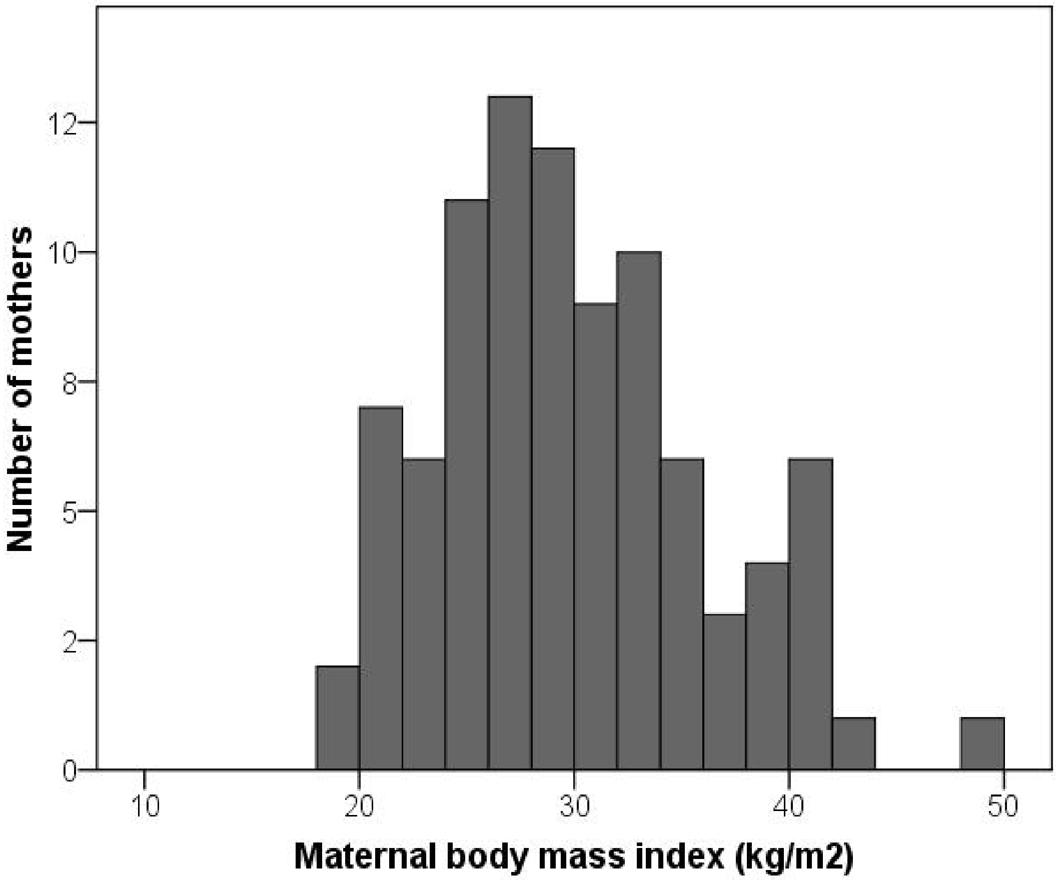
	n	Intervention	n	Control	n	Both groups	p-value
Gender - female	60	63% (38)	56	45% (25)	116	54% (63)	0.03
Ethnicity - white	60	50% (30)	56	50% (28)	116	50% (58)	0.6
Social class - manual	60	60% (24)	56	62% (21)	116	61% (45)	0.5
Age (years)	60	10.3 (1.3)	56	10.2 (1.3)	116	10.2 (1.3)	0.8
Weight (kg)	60	59.2 (12.5)	56	58.3 (14.8)	116	58.8 (13.6)	0.9
Weight z-score	60	2.58 (0.63)	56	2.53 (0.77)	116	2.6 (0.7)	0.5
Height (m)	60	1.47 (0.08)	56	1.46 (0.10)	116	1.5 (0.1)	0.5
Height z-score	60	1.08 (0.98)	56	1.07 (1.17)	116	1.1 (1.1)	0.6
BMI (kg/m²)	60	27.2 (3.7)	56	27.1 (4.9)	116	27.1 (4.3)	0.8
BMI z-score	60	2.77 (0.51)	56	2.76 (0.63)	116	2.8 (0.6)	>0.9
Waist circumference (cm)	60	81.8 (8.3)	55	80.3 (8.6)	115	81.1 (8.4)	0.4
Waist circumference z-score	60	2.89 (0.54)	55	2.70 (0.62)	115	2.8 (0.6)	0.08
Lean body mass (kg)	51	35.1 (6.2)	49	35.1 (7.7)	100	35.1 (6.9)	>0.9
Fat mass (kg)	51	23.3 (6.4)	49	23.8 (9.3)	100	23.6 (7.9)	0.8
Body fat (%)	51	39.6 (6.2)	49	39.4 (7.0)	100	39.5 (6.6)	0.9
Maternal BMI (kg/m²)	47	29.3 (6.2)	44	30.5 (6.5)	91	29.8 (6.3)	0.4
Systolic blood pressure (mmHg)	60	120.7 (13.4)	56	120.7 (11.7)	116	120.7 (12.6)	0.8
Diastolic blood pressure (mmHg)	60	65.8 (7.8)	56	66.7 (7.7)	116	66.2 (7.7)	0.6
Recovery heart rate (beats per minute)	59	96.6 (24.1)	55	96.0 (20.4)	114	96.3 (20.7)	>0.9
Physical activity (hours per week)	60	7.2 (4.6)	56	7.8 (4.6)	116	7.5 (4.3)	0.5
Sedentary activity (hours per week)	60	21.0 (10.5)	56	20.9 (8.8)	116	20.9 (9.7)	0.8
Global self-esteem score (maximum 4)	60	2.8 (0.6)	56	2.8 (0.6)	116	2.8 (0.7)	0.5

Data are presented as means (SD) or % (n), BMI: Body mass index, SD: Standard deviation

Table 14. Detailed ethnicity breakdown

	N	%
White	58	50%
Black caribbean	20	17%
Black african	6	5%
Black other	2	2%
Asian other	1	1%
Mixed race	23	20%
Other	3	3%
Refused	3	3%
Total	**116**	**100%**

Figure 29. Maternal BMI distribution at baseline



7.3.2 Baseline dietary intake

According to Table 15, children consumed a mean 1922 kcal/day at baseline. The macronutrient composition of children's diets was 53% carbohydrate (21% sugars, of which 14% non-milk extrinsic sugars), 15% protein, 36% fat (13% saturated fatty acids, 11% monounsaturated fatty acids and 6% polyunsaturated fatty acids). Sodium intake was 2659 mg/day. There were no significant differences in dietary data between groups at baseline. Table 15 presents the dietary reference values for children aged 10 years for comparison.

Table 15. Baseline dietary intake and Dietary Reference Values

							Dietary Reference Values for children aged 10 years*	
	n	**Intervention**	**n**	**Control**	**N**	**Both groups**	**Boys**	**Girls**
Total energy (kcal/day)	43	1908 (464)	38	1938 (391)	81	1922 (429)	1938†	1866†
Fluid (ml/day)	43	1242 (469)	38	1274 (474)	81	1257 (469)	1200‡	1200‡
Carbohydrate (g/day)	43	254 (69)	38	255 (62)	81	255 (65)	50% [a]	50% [a]
Total sugars (g/day)	43	111 (49)	38	111 (41)	81	111 (45)	< 11% [a]	< 11% [a]
Glucose (g/day)	43	20 (13)	38	18 (8)	81	19 (11)	n/a	n/a
Fructose (g/day)	43	23 (20)	38	19 (9)	81	21 (16)	n/a	n/a
Sucrose (g/day)	43	47 (23)	38	51 (29)	81	49 (26)	n/a	n/a
Lactose (g/day)	43	10 (7)	38	12 (9)	81	11 (8)	n/a	n/a
Protein (g/day)	43	70 (19)	38	71 (15)	81	70 (17)	73 [a]	70 [a]
Total fat (g/day)	43	75 (22)	38	77 (22)	81	76 (21)	35% [a]	35% [a]
Saturated fatty acids (g/day)	43	26 (8)	38	28 (9)	81	27 (9)	< 10% [a]	< 10% [a]
Monounsaturated fatty acids (g/day)	43	24 (8)	38	25 (7)	81	24 (7)	15% [a]	15% [a]
Polyunsaturated fatty acids (g/day)	43	12 (5)	38	12 (4)	81	12 (5)	6% [a]	6% [a]
Non starch polysaccharides (g/day)	43	12 (4)	38	12 (5)	81	12 (5)	18 [b]	18 [b]
Sodium (mg/day)	43	2693 (971)	38	2621 (775)	81	2659 (880)	1200[c]	1200[c]
Calcium (mg/day)	43	724 (231)	38	789 (254)	81	755 (243)	550[c]	550[c]
Iron (mg/day)	43	10 (2)	38	10 (3)	81	10 (3)	8.7[c]	8.7[c]

*Data are presented as means (SD).*The age of 10 years was selected to align with the trial population mean age at baseline. †Total energy values are based on SACN 2011 Energy Reference Values for children aged 10 years who are less active (SACN 2011).‡ Due to lack of data on children, Food Standard Agency recommendation for fluid intake in adults was used.[a] Due to lack of data on children, the figures were based on COMA 1991 adult population average of percentage of total energy intake (COMA 1991).[b] As recommended for obese children (NICE 2006). [c]Recommended Nutrient Intake (RNI), COMA 1991 (COMA 1991). n/a: Reference intake not available*

7.4 Comparison of randomised groups at 3 months

After adjusting for baseline values, the differences between groups for BMI and waist circumference and their z-scores were highly significant (p-value < 0.0001 for both variables) (Table 16).

Recovery heart rate and physical activity levels were improved in the intervention group, compared to controls (adjusted and unadjusted values). Moreover, the global self-esteem score adjusted for baseline was improved. All remaining variables were altered favourably in the intervention group, but this improvement did not reach statistical significance.

Table 16. Comparison of randomised groups at 3 months

	Intervention		Control		Difference (unadjusted for baseline)		Difference (adjusted for baseline)		
	n	**Mean (SD)**	**n**	**Mean (SD)**	**Mean (CI)**	***p***	**n**[2]	**Mean (CI)**	*p*
Waist circumference (cm)	47	78.5 (8.1)	48	81.7 (9.5)	-3.2(-6.8 to 0.3)	*0.08*	94	-4 (-5 to -2.9)	*<0.0001*
Waist circumference z-score	47	2.63 (0.54)	48	2.76 (0.63)	-0.13(-0.37 to 0.11)	*0.3*	94	-0.28 (-0.37 to -0.19)	*<0.0001*
BMI (kg/m²)	47	26.1 (3.4)	48	27.5 (5.3)	-1.4(-3.2 to 0.4)	*0.1*	95	-1 (-1.4 to -0.7)	*<0.0001*
BMI z-score	47	2.57 (0.49)	48	2.77 (0.64)	-0.2(-0.44 to 0.03)	*0.09*	95	-0.17 (-0.24 to -0.1)	*<0.0001*
Lean body mass (kg)	43	34.8 (7.4)	43	35.7 (7.1)	-0.8(-3.9 to 2.3)	*0.6*	81	-1.2 (-2.7 to 0.3)	*0.1*
Fat mass (kg)	43	22.1 (7.9)	43	23.6 (9.9)	-1.5(-5.3 to 2.4)	*0.4*	81	-1.1 (-2.7 to 0.5)	*0.2*
Body fat (%)	43	38.3 (9)	43	38.5 (7)	-0.1(-3.6 to 3.3)	*0.9*	81	-0.4 (-3.1 to 2.2)	*0.7*
Maternal BMI (kg/m²)	40	29.4 (5.7)	37	29.9 (6.8)	-0.5(-3.3 to 2.3)	*0.7*	77	-0.4 (-1.4 to 0.7)	*0.5*
Systolic blood pressure (mmHg)	47	113.8 (11.6)	48	115.4 (8.8)	-1.7(-5.9 to 2.6)	*0.4*	95	-1.7 (-5.9 to 2.6)	*0.4*
Diastolic blood pressure (mmHg)	47	63.7 (8.9)	48	64.5 (8.4)	-0.8(-4.3 to 2.7)	*0.7*	95	0.3 (-3.7 to 4.2)	*0.9*
Recovery heart rate (beats per minute)	45	97.4 (19.9)	48	121.6 (23.5)	-24.2(-33.2 to -15.2)	*<0.0001*	90	-28.6 (-40.5 to -16.7)	*<0.0001*
Physical activity (hours per week)	47	12.7 (5)	48	6.9 (3.8)	5.8(4 to 7.6)	*<0.0001*	95	6.9 (4.9 to 8.9)	*<0.0001*
Sedentary activity (hours per week)	47	17.9 (7)	48	21.1 (11)	-3.2(-7 to 0.6)	*0.1*	95	-2.8 (-6.7 to 1.1)	*0.2*
Global self-esteem score (maximum 4)	46	3.0 (0.6)	45	2.8 (0.6)	0.2 (-0.1 to 0.5)	*0.1*	91	-0.25 (0 to 0.5)	*0.05*

Data are presented as means (SD) or mean (CI) analysed with an independent sample t-test, CI: 95% Confidence Interval, [2] *Small loss of n for some variables*

Comparison of randomised groups at 3 months (dietary data)

Table 17 shows that total sugar, sucrose, total fat, saturated fat, monounsaturated fat, and polyunsaturated fat intakes were significantly reduced for the intervention group, compared to controls at 3 months, for both unadjusted comparisons and after adjustment for baseline variables.

Over this period, the dietary fibre intake (non-starch polysaccharides) was significantly increased among children in the intervention group, compared to controls. Protein, calcium and iron intakes were not significantly different between groups.

Table 17. Comparison of randomised groups at 3 months (dietary data)

	Intervention		Control		Difference (unadjusted for baseline)		Difference (adjusted for baseline)		
	n	**Mean (SD)**	**n**	**Mean (SD)**	**Mean (CI)**	***p***	**n[2]**	**Mean (CI)**	***p***
Total energy (kcal)	28	1461 (296)	28	1877 (535)	-417 (-650 to -184)	*0.03*	52	-330 (-627 to -33)	*0.001*
Fluid (ml/day)	28	1318 (549)	28	1685 (1871)	-367 (-1106 to 372)	*0.3*	52	-439 (-1265 to 386)	*0.3*
Carbohydrate (g/day)	28	202 (51)	28	251 (82)	-49 (-85 to -12)	*0.1*	52	-38 (-86 to 11)	*0.01*
Total sugars (g/day)	28	80 (39)	28	113 (43)	-32 (-54 to -10.4)	*0.01*	52	-37 (-67 to -8)	*0.005*
Glucose (g/day)	28	15 (11)	28	19 (8)	-5 (-10 to 1)	*0.1*	52	-7 (-15 to 1)	*0.09*
Fructose (g/day)	28	18 (12)	28	22 (12)	-4 (-11 to 2)	*0.05*	52	-11 (-21 to 0)	*0.2*
Sucrose (g/day)	28	30 (18)	28	50 (28)	-20 (-33 to -8)	*0.05*	52	-18 (-36 to 0)	*0.002*
Lactose (g/day)	28	9 (7)	28	11 (6)	-1 (-5 to 2)	*0.9*	52	0 (-5 to 5)	*0.4*
Protein (g/day)	28	64 (14)	28	67 (21)	-2 (-12 to 7)	*0.6*	52	3 (-8 to 15)	*0.7*
Total fat (g/day)	28	49 (14)	28	75 (26)	-25 (-36 to -14)	*0.001*	52	-23 (-36 to -9)	*<0.0001*
Saturated fatty acids (g/day)	28	14 (4)	28	27 (11)	-12 (-16.9 to -8)	*0.001*	52	-11 (-18 to -5)	*<0.0001*
Monounsaturated fatty acids (g/day)	28	15 (5)	28	24 (9)	-9 (-13 to -5.1)	*0.005*	52	-7 (-13 to -2)	*<0.0001*
Polyunsaturated fatty acids (g/day)	28	8 (4)	28	12 (4)	-4 (-6 to -2)	*0.02*	52	-4 (-7 to -1)	*0.001*
Non starch polysaccharides (g/day)	28	13 (4)	28	11 (3)	2 (0 to 4)	*0.009*	52	4 (1 to 7)	*0.03*
Sodium (mg/day)	28	2041 (573)	28	2711 (1020)	-670 (-1113 to -227)	*0.07*	52	-557 (-1170 to 56)	*0.004*
Calcium (mg/day)	28	644 (230)	28	712 (281)	-68 (-206 to 69)	*0.5*	52	53 (-122 to 228)	*0.3*
Iron (mg/day)	28	9.4 (3)	28	10.1 (4.5)	-1 (-3 to 1)	0.5	52	0.8 (-1.8 to 3.4)	0.5

Data are presented as means (SD) or mean differences (CI) analysed with the Independent Samples t-test, CI: 95% Confidence Interval [2]Small loss of n for some variables

7.5 Comparison of randomised groups at 6 months

Table 18 summarised the 6 month between group results. Overall, at 6 months, children in the intervention group displayed improvements in all trial variables, compared to controls (including anthropometry, body composition, cardiovascular health, activity patterns and self-esteem).

7.5.1 Anthropometry

The primary outcome (waist circumference at 6 months) was 4.3 cm (95 % CI: -7.8 to -0.8) lower in the intervention group, compared to the control group. Additionally, BMI was significantly lower in the intervention than the control group (-1.9 kg/m^2; $p = 0.05$ and -1.2 kg/m^2; $p < 0.0001$ for unadjusted and adjusted BMI, respectively).

Similar patterns were observed for adjusted BMI and waist z-scores (-0.24; $p < 0.0001$ and -0.37; $p < 0.0001$ for adjusted BMI z-score and waist z-score, respectively) and unadjusted BMI z-scores (-0.28; $p = 0.03$), but not for unadjusted waist z-score (-0.23; $p = 0.09$).

7.5.2 Body composition

There were no significant changes in body composition, with the exception of body fat mass adjusted for baseline, which was 2.4 kg less in the intervention group, compared to control ($p = 0.05$).

7.5.3 Cardiovascular health, physical and sedentary activity levels, and self-esteem

Cardiovascular health improved in the intervention group, as indicated by the differences in the recovery heart rate and diastolic blood pressure, relative to the control group. Activity patterns improved, as evident from the +3.9 and -5.1 hours/week between-group differences in favour of the intervention group for physical activity adjusted for baseline and sedentary behaviours, respectively. Global self-esteem was higher for the intervention group.

7.5.4 Swimming pass use

At the end of the intensive phase of the MEND programme, children were provided with a swimming pass lasting an additional 12 weeks. Results showed that 32% of the families used the free swimming pass for an average of 5 times in 12 weeks (i.e., 1-2 times a month).

Table 18. Comparison of randomised groups at 6 months

	Intervention		Control		Difference (unadjusted for baseline)		Difference (adjusted for baseline)		
	n	**Mean (SD)**	**n**	**Mean (SD)**	**Mean (CI)**	***p***	**n[2]**	**Mean (CI)**	***p***
Waist circumference (cm)	37	77.7 (7.2)	45	82.0 (8.6)	-4.3 (-7.8 to -0.8)	*0.02*	81	-4.1 (-5.6 to -2.7)	*<0.0001*
Waist circumference z-score	37	2.53 (0.58)	45	2.76 (0.61)	-0.23 (-0.50 to 0.03)	*0.09*	81	-0.37 (-0.49 to -0.25)	*<0.0001*
BMI (kg/m^2)	37	25.7 (3.3)	45	27.7 (5.2)	-1.9 (-3.8 to 0.0)	*0.05*	82	-1.2 (-1.8 to -0.6)	*<0.0001*
BMI z-score	37	2.47 (0.50)	45	2.75 (0.66)	-0.28 (-0.54 to -0.02)	*0.03*	82	-0.24 (-0.34 to -0.13)	*<0.0001*
Lean body mass (kg)	23	35.7 (5.9)	22	36.2 (7.4)	-0.5 (-4.5 to 3.5)	*0.8*	43	-0.8 (-2.6 to 0.9)	*0.3*
Fat mass (kg)	23	21.8 (4.5)	22	23.8 (9.7)	-2.1 (-6.7 to 2.6)	*0.4*	45	-2.4 (-4.8 to 0.0)	*0.05*
Body fat (%)	23	37.9 (4.8)	22	38.6 (7.7)	-0.7 (-4.6 to 3.1)	*0.7*	43	-1.6 (-5 to 1.9)	*0.7*
Maternal BMI (kg/m^2)	27	28.8 (5.6)	33	29.9 (6.8)	-1.1 (-4.3 to 2.2)	*0.5*	60	0.4 (-0.4 to 1.3)	*0.3*
Systolic blood pressure (mmHg)	36	111.1 (10.2)	45	112.5 (9.0)	-1.5 (-5.7 to 2.8)	*0.5*	81	-1.0 (-6.4 to 4.4)	*0.7*
Diastolic blood pressure (mmHg)	36	60.7 (7.9)	45	64.5 (7.8)	-3.9 (-7.4 to -0.4)	*0.03*	81	-3.9 (-8.1 to 0.4)	*0.07*
Recovery heart rate (beats per minute)	37	94.8 (16.9)	45	113 (28.7)	-18.2 (-28.8 to -7.5)	*0.001*	79	-20.3 (-33.9 to -6.6)	*0.004*
Physical activity (hours per week)	37	14.2 (8.2)	45	11.0 (7.8)	3.2 (-0.3 to 6.7)	*0.07*	82	3.9 (0.1 to 7.8)	*0.04*
Sedentary activity (hours per week)	37	15.9 (7.2)	45	21.7 (9.2)	-5.8 (-9.5 to -2.2)	*0.002*	82	-5.1 (-9.0 to -1.1)	*0.01*
Global self-esteem score (maximum 4)	37	3.2 (0.7)	44	2.9 (0.7)	0.3 (0.0 to 0.6)	*0.05*	81	0.3 (0.0 to 0.7)	*0.04*

Data are presented as means (SD) or means (CI) analysed using an independent sample t-test, CI: 95% Confidence Interval; [2]Small loss of n for some variables

7.5.5 Dietary data

According to Table 19, at 6 months differences in dietary data were not statistically significant.

Table 19. Comparison of dietary intake between randomised groups at 6 months

	Intervention		Control		Difference (unadjusted for baseline)		Difference (adjusted for baseline)		
	N	**Mean (SD)**	**n**	**Mean (SD)**	**Mean (CI)**	***p***	**n[2]**	**Mean (CI)**	***p***
Total energy (kcal)	25	1518 (384)	32	1565 (360)	-47 (-246 to 151)	*0.6*	50	44 (-245 to 333)	*0.8*
Fluid (ml/day)	25	1349 (534)	32	1331 (596)	18 (-287 to 322)	*0.9*	50	52 (-289 to 393)	*0.8*
Carbohydrate (g/day)	25	199 (58)	32	213 (57)	-14 (-45 to 17)	*0.4*	50	13 (-32 to 58)	*0.6*
Total sugars (g/day)	25	85 (46)	32	84 (37)	1 (-21 to 23)	*0.9*	50	11 (-22 to 43)	*0.5*
Glucose (g/day)	25	15 (12)	32	14 (8)	0 (-5 to 6)	*0.9*	50	3 (-6 to 12)	*0.5*
Fructose (g/day)	25	17 (14)	32	17 (10)	0 (-6 to 6)	*1.0*	50	7 (-4 to 19)	*0.2*
Sucrose (g/day)	25	35 (28)	32	34 (18)	1 (-11 to 13)	*0.9*	50	4 (-15 to 22)	*0.7*
Lactose (g/day)	25	10 (7)	32	11 (7)	-1(-4 to 3)	*0.7*	50	0 (-4 to 5)	*0.9*
Protein (g/day)	25	69 (19)	32	63 (14)	5 (-4 to 14)	*0.2*	50	-9 (-18 to 0)	*0.1*
Total fat (g/day)	25	55 (20)	32	57 (21)	-2 (-13 to 9)	*0.8*	50	3 (-13 to 20)	*0.7*
Saturated fatty acids (g/day)	25	19 (9)	32	19 (8)	0 (-4 to 4)	*1.0*	50	0 (-8 to 7)	*0.9*
Monounsaturated fatty acids (g/day)	25	18 (7)	32	18 (7)	0 (-4 to 3)	*0.9*	50	0 (-5 to 5)	*1.0*
Polyunsaturated fatty acids (g/day)	25	9 (3)	32	9 (4)	0 (-2 to 2)	*0.8*	50	2 (-1 to 4)	*0.3*
Non starch polysaccharides (g/day)	25	10 (4)	32	13 (7)	-2 (-5 to 1)	*0.1*	50	1 (-3 to 5)	*0.5*
Sodium (mg/day)	25	2133 (784)	32	2491 (675)	-359 (-746 to 29)	*0.1*	50	358 (-167 to 883)	*0.2*
Calcium (mg/day)	25	671 (294)	32	689 (262)	-18 (-166 to 130)	*0.8*	50	-52 (-225 to 122)	*0.6*
Iron (mg/day)	25	9.9 (3.7)	32	12.4 (20.8)	-2.6 (-11 to 5.9)	*0.5*	50	2 (-7.1 to 11.1)	*0.7*

Data are presented as means (SD) or means (CI) analysed with the independent samples t-test, CI: 95% Confidence Interval; [2]Small loss of n for some variables

7.6 Within-subject changes at 3 months from baseline

Waist circumference, BMI and z-scores were significantly reduced at 3 months. Maternal BMI was markedly reduced by 0.4 kg/m^2 ($p \leq 0.0001$). Systolic blood pressure was significantly reduced (-4.6 mmHg; $p \leq 0.0001$), while no notable changes in diastolic blood pressure were observed. Other measures of cardiovascular fitness that were significantly improved included recovery heart rate, physical and sedentary activity levels (Table 20).

Table 20. Within-subject changes in outcomes at 3 months from baseline

	Baseline (0 months)		At 3 months	Difference (0 – 3 months)	
	n[a]	Mean (SD)	Mean (SD)	Mean (CI)	*p*
Waist circumference (cm)	69	81.9 (7.7)	78.5 (8.3)	-3.3 (-3.9 to -2.8)	*< 0.0001*
Waist circumference z-score	69	2.90 (0.46)	2.58 (0.59)	-0.32 (-0.5 to -0.28)	*< 0.0001*
BMI (kg/m²)	70	27.1 (3.6)	26.2 (3.7)	-0.9 (-1.1 to -0.7)	*< 0.0001*
BMI z-score	70	2.74 (0.5)	2.54 (0.54)	-0.20 (-0.23 to -0.16)	*< 0.0001*
Lean body mass (kg)	62	35.2 (6.5)	35.3 (7.2)	0.1 (-0.8 to 0.9)	*0.9*
Fat mass (kg)	62	23.2 (7.1)	22.4 (8.2)	-0.8 (-1.7 to 0.1)	*0.1*
Body fat (%)	62	39.2 (6.1)	38.2 (8.5)	-1 (-2.5 to 0.5)	*0.2*
Maternal BMI (kg/m²)	46	30 (6.3)	29.6 (6.3)	-0.4 (-0.6 to -0.2)	*< 0.0001*
Systolic blood pressure (mmHg)	70	118.4 (12.9)	113.8 (10.7)	-4.6 (-7.2 to -2)	*< 0.0001*
Diastolic blood pressure (mmHg)	70	65.3 (8.5)	62.8 (8.4)	-2.5 (-4.7 to -0.3)	*0.03*
Recovery heart rate (beats/minute)	65	115.1 (28.1)	96.2 (19.9)	-18.9 (-26.4 to -11.4)	*< 0.0001*
Physical activity (hours/week)	70	7.5 (4.1)	12.7 (5.1)	5.2 (3.9 to 6.5)	*< 0.0001*
Sedentary activity (hours/week)	70	20.9 (8.4)	16.6 (7.1)	-4.3 (-6.3 to -2.3)	*< 0.0001*
Global self-esteem score (maximum 4)	46	2.9 (0.8)	3 (0.6)	0.1 (0 to 0.3)	*0.1*

Data are presented as means (CI) analysed with the paired t-test, CI: 95% Confidence Interval

[a]*Includes children from both groups (immediate and delayed) measured before and after the intervention (i.e., baseline and 3 months for the intervention group, 6 and 9 months for controls)*

7.7 Within-subject changes at 6 months from baseline

As shown in Table 21, all outcomes, except maternal BMI, were significantly improved at 6 months from baseline. Also, univariate analyses revealed that 6-month changes in BMI, waist circumference and their z-scores were not affected by gender, single parenthood, accommodation status (owned/rented), employment status and age. Ethnicity was the only parameter that influenced BMI change and its z-score at 6 month, with non-white children being more likely to do worse. More precisely, BMI was reduced on average by 1.5 units in white children and by 0.5 units in non-white children ($p = 0.06$) and BMI z-score was reduced by 0.38 in white children and by 0.21 in non-white children ($p = 0.01$) at 6 months.

Table 21. Within-subject changes in outcome variables at 6 months from baseline

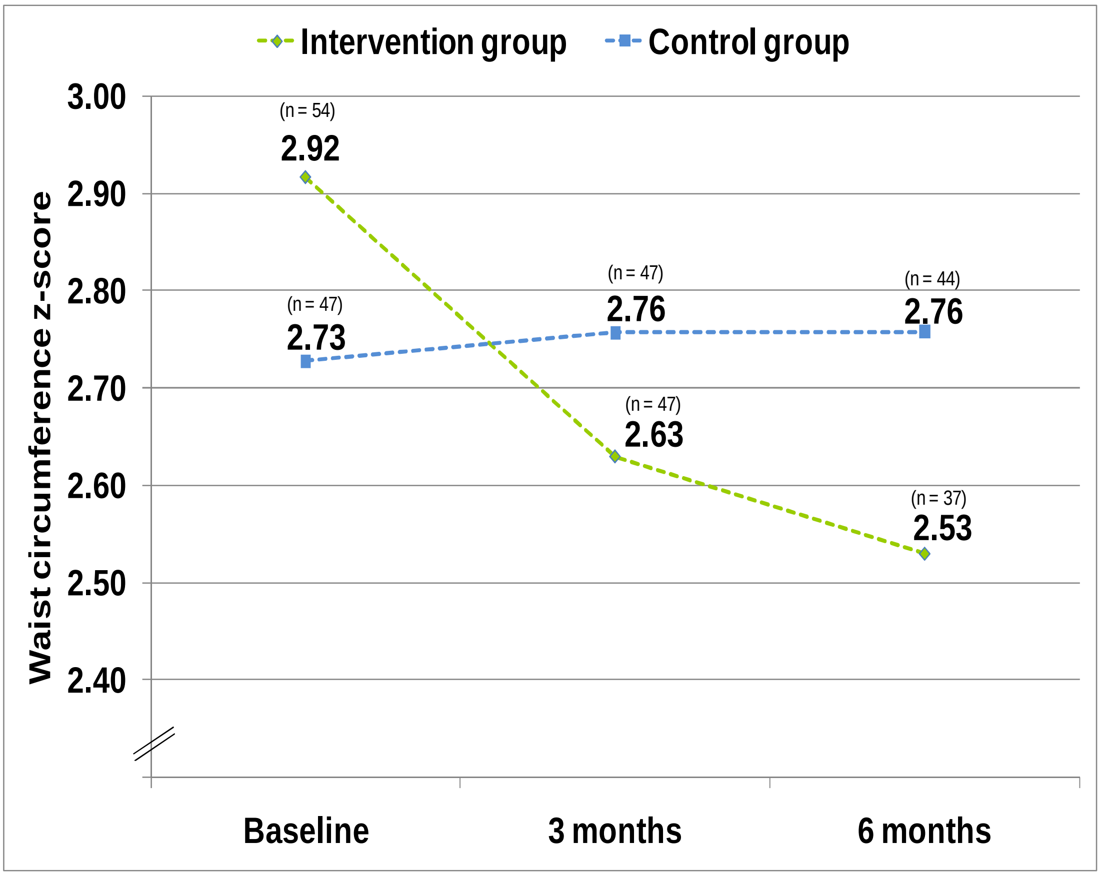
	Baseline (0 months)		At 6 months	Difference (0 – 6 months)	
	n[a]	Mean (SD)	Mean (SD)	Mean (CI)	*p*
Waist circumference (cm)	71	80.8 (7.6)	76.6 (8.1)	-4.2 (-5.1 to -3.4)	< *0.0001*
Waist circumference z-score	71	2.82 (0.54)	2.34 (0.74)	-0.48 (0.33 to 0.04)	< *0.0001*
BMI (kg/m²)	71	26.9 (4.3)	25.9 (4.6)	-1 (-1.4 to -0.6)	< *0.0001*
BMI z-score	71	2.7 (0.57)	2.41 (0.66)	-0.3 (0.29 to 0.03)	< *0.0001*
Lean body mass (kg)	22	34.7 (5.4)	36 (5.9)	1.3 (0.3 to 2.2)	*0.01*
Fat mass (kg)	22	23.4 (4.6)	22 (4.4)	-1.4 (-2.5 to -0.2)	*0.02*
Body fat (%)	22	40.2 (4.6)	38 (4.8)	-2.2 (-3.6 to -0.7)	*0.005*
Maternal BMI (kg/m²)	49	29.6 (6.4)	29.6 (6.5)	0 (-0.3 to 0.3)	*0.995*
Systolic blood pressure (mmHg)	70	116.8 (12.8)	111.8 (9.4)	-5 (-7.9 to -2.2)	*0.001*
Diastolic blood pressure (mmHg)	70	65.2 (8.5)	60.9 (8)	-4.3 (-6.6 to -2)	< *0.0001*
Recovery heart rate (beats/minute)	70	112.7 (25.5)	94.7 (19.2)	-17.9 (-24.7 to -11.2)	< *0.0001*
Physical activity (hours/week)	71	8.8 (5.4)	13 (7.2)	4.2 (2.2 to 6.2)	< *0.0001*
Sedentary activity (hours/week)	71	20.6 (8.3)	15.8 (7.7)	-4.8 (-6.8 to -2.9)	< *0.0001*
Global self-esteem score (maximum 4)	67	2.9 (0.7)	3.2 (0.7)	0.2 (0.1 to 0.4)	*0.007*

Data are presented as means (CI) analysed with the paired t-test, CI: 95% Confidence Interval
[a]*Includes children from both groups measured before and after the intervention (i.e., baseline and 6 months for the intervention group, 6 and 12 months for controls)*

7.8 Within-subject changes for waist circumference z-score and BMI z-scores at 3 and 6 months

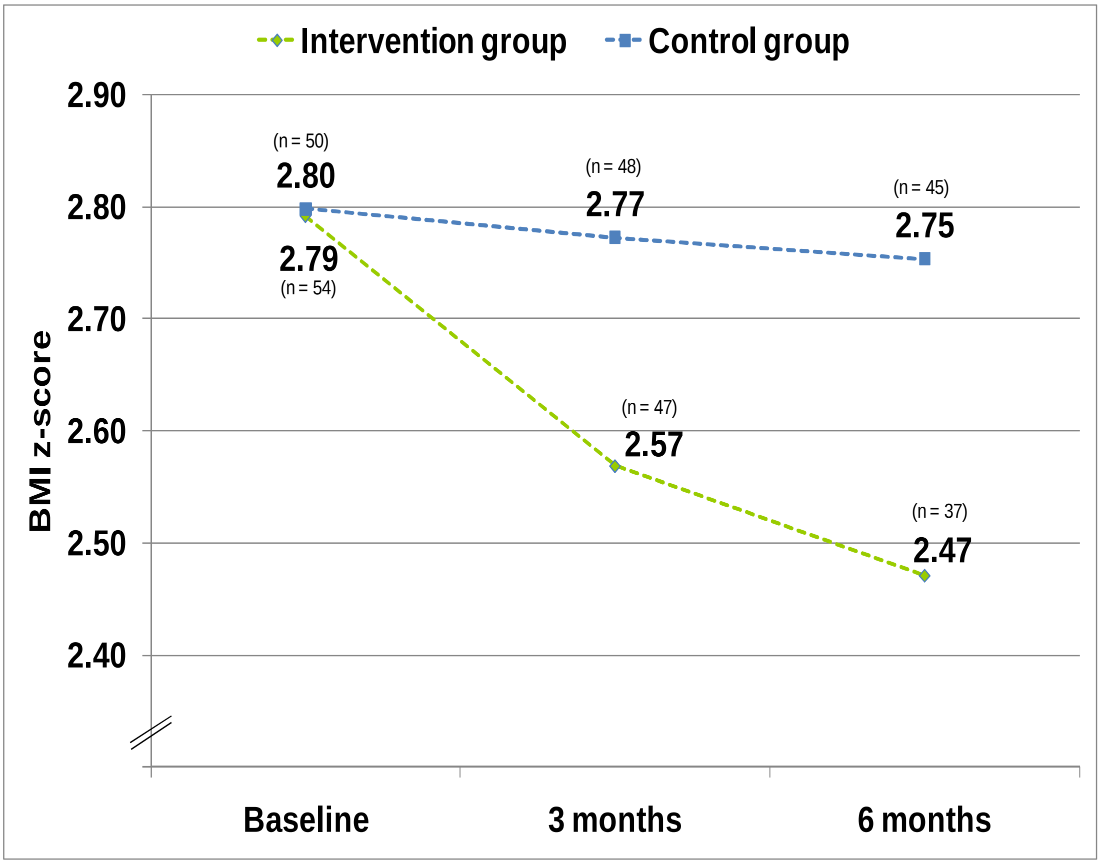
Figures 30 and 31 present the progressive changes in waist circumference and BMI z-scores from baseline to 3 and 6 months for the intervention and control groups, respectively. Waist circumference z-score was significantly decreased in the intervention group, but not the control group (Figure 30). A similar pattern was observed for the BMI z-score (Figure 31).

Figure 30. Within-subject changes for waist circumference z-score at baseline, 3 and 6 months



The intervention group in Figure 30 consists of children in the immediate intervention group only. Average z-scores are presented for all available children at each time-point (non-matched data).

Figure 31. Within-subject changes for BMI z-score at baseline, 3 and 6 months



The intervention group above consists of children in the immediate intervention group only. Average z-scores are presented for all available children at each time-point (non-matched data).

7.9 Within-subject changes at 12 months from baseline

Table 22 summarises the 12 month within-subject changes. Waist circumference and BMI z-scores were significantly ($p \leq 0.0001$) reduced at 12 months from baseline. Systolic blood pressure was reduced by 6.5 mmHg ($p \leq 0.004$), while diastolic blood pressure was not significantly affected.

Recovery heart rate and physical activity levels were markedly improved, whereas sedentary activities did not change significantly. Global self-esteem was significantly improved. Body composition data were not available at 12 months, due to lack of resources for sample analysis.

Similarly to 6-month results from univariate analyses, 12-month changes in BMI, waist circumference and their z-scores were not affected by gender, single parenthood, accommodation status (owned/rented), employment status and age. Ethnicity was the only parameter that affected BMI change at 12 month (but not its z-score), with non-white children being more likely to do worse. More precisely, BMI at 12 months was reduced by 0.7 units in white children and was increased by 0.4units in non-white children ($p = 0.04$).

Table 22. Within-subject changes in outcomes at 12 months from baseline

	Baseline (0 months)		At 12 months	Difference (0 – 12 months)	
	n[a]	Mean (SD)	Mean (SD)	Mean (CI)	*p*
Waist circumference (cm)	42	82 (7.5)	78.9 (7.8)	-3.1 (-4.6 to -1.6)	< *0.0001*
Waist circumference z-score	42	2.96 (0.44)	2.49 (0.63)	-0.47 (-0.56 to -0.36)	< *0.0001*
BMI (kg/m²)	42	27.2 (3.2)	27.1 (3.7)	-0.1 (-0.7 to 0.4)	*0.7*
BMI z-score	42	2.82 (0.46)	2.59 (0.53)	-0.23 (-0.33 to -0.13)	< *0.0001*
Lean body mass (kg)	n/a	n/a	n/a	n/a	n/a
Fat mass (kg)	n/a	n/a	n/a	n/a	n/a
Body fat (%)	n/a	n/a	n/a	n/a	n/a
Maternal BMI (kg/m²)	28	31.0 (5.7)	31.2 (5.8)	0.2 (-0.2 to 0.7)	*0.3*
Systolic blood pressure (mmHg)	41	121.3 (14.8)	114.8 (12.8)	-6.5 (-10.7 to -2.3)	*0.004*
Diastolic blood pressure (mmHg)	41	65.7 (8.9)	63.2 (7.9)	-2.5 (-5.6 to 0.6)	*0.1*
Recovery heart rate (beats/minute)	39	114.5 (29.2)	102.2 (20.1)	-12.4 (-21.6 to -3.1)	*0.01*
Physical activity (hours/week)	40	7.3 (4.1)	11.2 (7)	4 (1.9 to 6)	< *0.0001*
Sedentary activity (hours/week)	41	20.5 (8.4)	18.5 (8.3)	-2 (-4.3 to 0.4)	*0.1*
Global self-esteem score (maximum 4)	40	2.8 (0.8)	3.1 (0.7)	0.3 (0 to 0.5)	*0.03*

Data are presented as means (CI) analysed with paired t-test, CI: 95% Confidence interval

[a] *Includes children from the intervention group only*

n/a: Data not available due to lack of resources

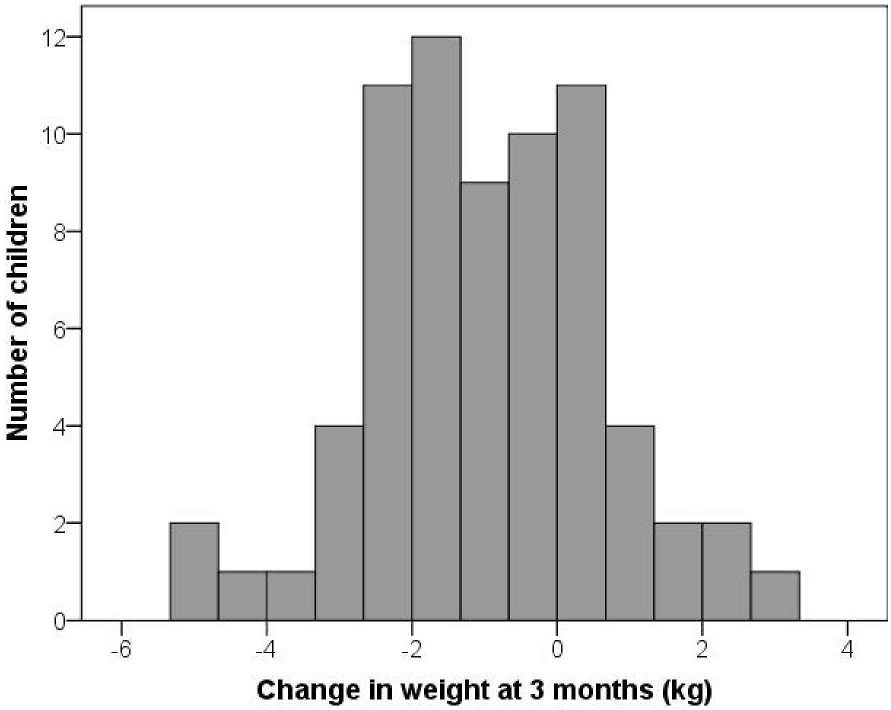
7.10 Changes in weight

Changes in weight at 3 months

The weight change spread occurring over the intensive phase of the intervention, i.e., the MEND programme, is graphically depicted in Figure 32. Children receiving the intervention (immediate or delayed) lost one kilogram on average during the 3-month period.

Overall, 6 children lost more than 3 kg at 3 months (more than the recommended 1 kg per month) (SIGN 2010), and the range of weight changes during this period was -5 kg to +3.3 kg.

Figure 32. Changes in weight (kg) at 3 months among participants receiving the intervention (n = 70)

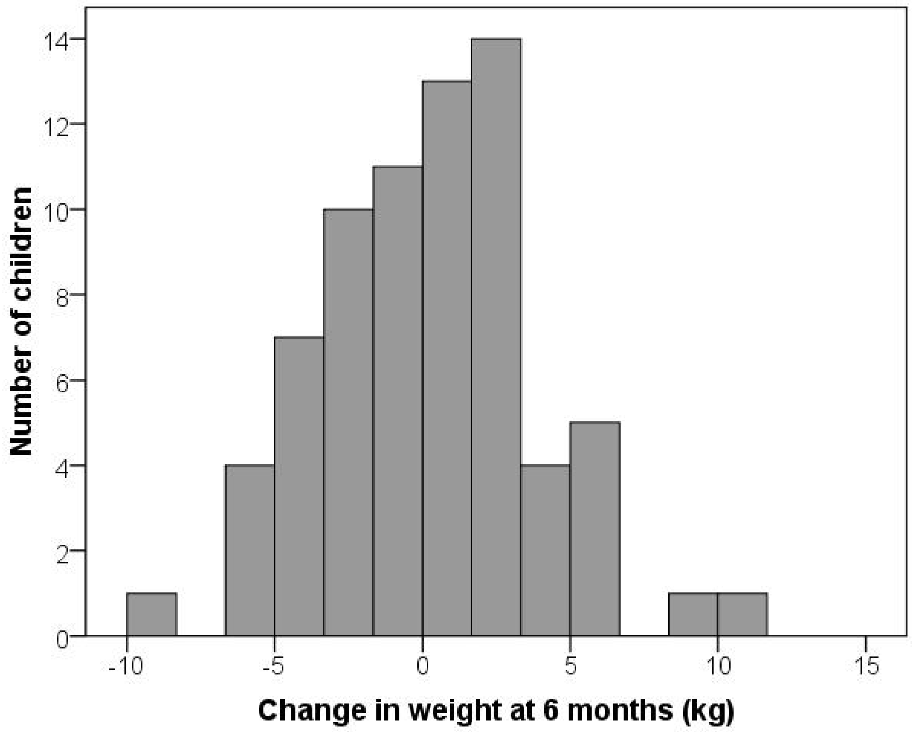


The graph above represents children from both groups measured before and after the intervention (i.e., baseline and 3 months for the intervention group, and 6 and 9 months for controls).

Changes in weight at 6 months

At 6 months, the average change in weight was +0.3 kg. The weight change range at 6 months was -9.8 kg to +11.3 kg, and 3 children lost more than 1 kg per month during this period (Figure 33).

Figure 33. Changes in weight (kg) at 6 months among participants receiving the intervention (n = 71)

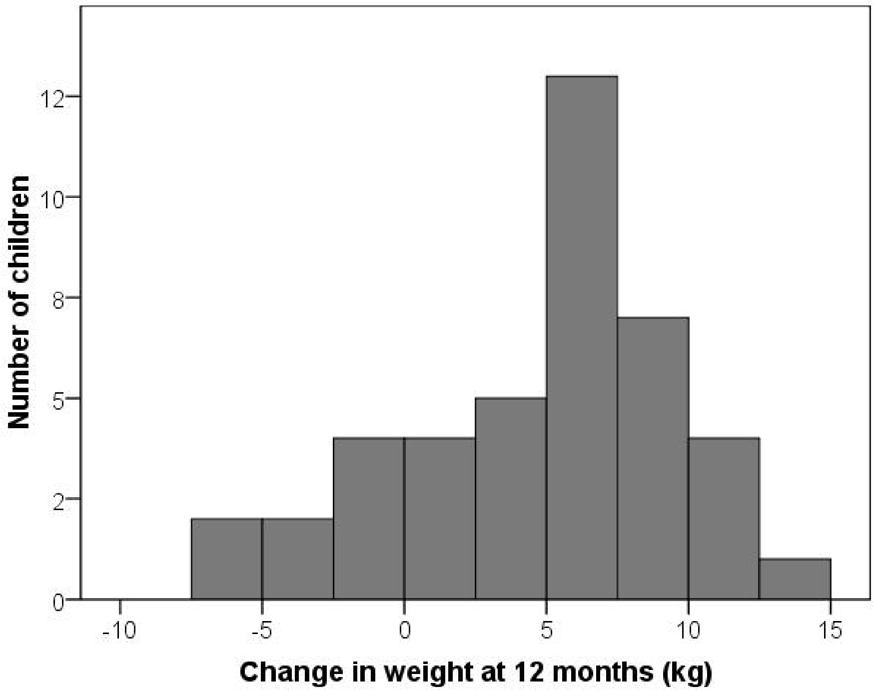


The graph above represents children from both groups measured before and after the intervention (i.e., baseline and 6 months for the intervention group, and 6 and 12 months for controls).

<u>Changes in weight at 12 months</u>

At 12 months, weight change was, on average, +4.9 kg, and the maximum weight reduction observed was -7.2 kg (range from -7.2 kg to + 14.5 kg) (Figure 34).

Figure 34. Change in weight (kg) at 12 months among participants receiving the intervention (n = 42)



The graph above represents children from the intervention group measured at baseline and 12 months.

7.11 Within-subject changes at 3 and 6 months from the start of intervention (dietary data)

According to tables 23 and 24, within-subject analysis at 3 and 6 months revealed that most dietary indices, including energy, total sugars, total fat, saturated fatty acids and sodium, were significantly reduced. Protein, calcium and iron intakes were not significantly changed. Finally, intake of monounsaturated and polyunsaturated fat was lower at 3 and 6 months from baseline.

Only 4 sets of dietary data were obtained at 12 months due to participant non-compliance with completion of food diaries. Owing to the small sample size, statistical analysis was not performed.

Table 23. Within-subject changes in reported dietary intake at 3 months from baseline

	Baseline		At 3 months	Difference (0 – 3 months)	
	n[a]	Mean (SD)	Mean (SD)	Mean (CI)	*p*
Total energy (kcal)	34	1855 (389)	1467 (325)	-388 (-549 to -226)	*< 0.0001*
Fluid (ml/day)	34	1279 (511)	1325 (511)	46 (-137 to 230)	*0.6*
Carbohydrate (g/day)	34	251 (65)	206 (52)	-45 (-71 to -19)	*0.001*
Total sugars (g/day)	34	116 (51)	83 (36)	-33 (-50 to -16)	*< 0.0001*
Glucose (g/day)	34	21 (13)	15 (10)	-6 (-12 to 0)	*0.04*
Fructose (g/day)	34	26 (22)	19 (11)	-7 (-15 to 1)	*0.1*
Sucrose (g/day)	34	48 (24)	31 (19)	-17 (-26 to -8)	*0.001*
Lactose (g/day)	34	10 (7)	10 (7)	-1 (-4 to 2)	*0.6*
Protein (g/day)	34	67 (15)	66 (14)	-1 (-7 to 6)	*0.9*
Total fat (g/day)	34	72 (17)	48 (16)	-24 (-32 to -16)	*< 0.0001*
Saturated fatty acids (g/day)	34	25 (8)	14 (5)	-12 (-15 to -8)	*< 0.0001*
Monounsaturated fatty acids (g/day)	34	23 (6)	15 (6)	-9 (-12 to -6)	*< 0.0001*
Polyunsaturated fatty acids (g/day)	34	12 (5)	8 (4)	-4 (-6 to -2)	*< 0.0001*
Non starch polysaccharides (g/day)	34	11 (4)	14 (3)	3 (1 to 5)	*< 0.0001*
Sodium (mg/day)	34	2516 (867)	1986 (580)	-530 (-892 to -168)	*0.01*
Calcium (mg/day)	34	709 (203)	657 (215)	-52 (-155 to 51)	*0.3*
Iron (mg/day)	34	9.3 (2.3)	9.8 (2.8)	0.4 (-0.7 to 1.5)	*0.4*

Data are presented as means (CI) analysed with the paired t-test, CI: 95% Confidence Interval
[a]Includes children from both groups measured before and after the intervention (i.e., baseline and 3 months for the intervention group, 6 and 9 months for controls)

Table 24. Within-subject changes in dietary intake at 6 months from baseline

		Baseline	At 6 months	Difference (0 – 6 months)	
	n[a]	Mean (SD)	Mean (SD)	Mean (CI)	*p*
Total energy (kcal)	30	1940 (402)	1485 (377)	-456 (-668 to -243)	*0.0001*
Fluid (ml/day)	30	1328 (492)	1343 (525)	15 (-232 to 262)	*0.9*
Carbohydrate (g/day)	30	263 (67)	194 (56)	-69 (-103 to -36)	< *0.0001*
Total sugars (g/day)	30	123 (52)	84 (42)	-39 (-64 to -14)	*0.003*
Glucose (g/day)	30	23 (14)	15 (11)	-8 (-15 to -2)	*0.02*
Fructose (g/day)	30	28 (22)	17 (13)	-10 (-20 to -1)	*0.03*
Sucrose (g/day)	30	51 (23)	36 (26)	-16 (-30 to -2)	*0.03*
Lactose (g/day)	30	11 (7)	10 (7)	-1 (-5 to 2)	*0.4*
Protein (g/day)	30	69 (17)	67 (19)	-2 (-10 to 6)	*0.6*
Total fat (g/day)	30	75 (18)	54 (19)	-21 (-32 to -10)	< *0.0001*
Saturated fatty acids (g/day)	30	27 (9)	18 (8)	-9 (-14 to -3)	*0.002*
Monounsaturated fatty acids (g/day)	30	24 (6)	18 (6)	-7 (-10 to -3)	< *0.0001*
Polyunsaturated fatty acids (g/day)	30	13 (5)	9 (3)	-4 (-6 to -2)	*0.001*
Non starch polysaccharides (g/day)	30	12 (4)	11 (4)	-1 (-3 to 0)	*0.1*
Sodium (mg/day)	30	2721 (935)	2125 (770)	-596 (-975 to -216)	*0.003*
Calcium (mg/day)	30	766 (249)	648 (298)	-119 (-266 to 28)	*0.1*
Iron (mg/day)	30	9.9 (2.4)	9.6 (3.6)	-0.3 (-1.7 to 1.2)	*0.7*

Data are presented as means (CI) analysed with the paired t-test, CI: 95% Confidence Interval
[a]*Includes children from both groups measured before and after the intervention (i.e., baseline and 3 months for the intervention group, 6 and 9 months for controls)*

7.12 Within-subject changes at 3 and 6 months (controls)

Tables 25 and 26 show that at 3 months, children in the control group displayed significantly reduced waist circumference, systolic blood pressure and physical activity levels, as well as increased lean body mass and recovery heart rate.

At 6 months, waist circumference was further decreased and lean body mass increased. Converse to the 3-month data, physical activity levels increased at 6 months from baseline for the control group.

Table 25. Within-subject changes in outcomes at 3 months from baseline (controls)

		Baseline	3 months	Difference (0 – 3 months)	
	n	**Mean (SD)**	**Mean (SD)**	**Mean (CI)**	***p***
Waist circumference (cm)	47	80.5 (8.8)	81.5 (9.5)	1 (0.2 to 1.8)	*0.01*
Waist circumference z-score	47	2.74 (0.59)	2.74 (0.62)	0 (-0.07 to 0.07)	*1.0*
BMI (kg/m²)	48	27.4 (5.2)	27.5 (5.3)	0.1 (-0.2 to 0.4)	*0.4*
BMI z-score	48	2.81 (0.64)	2.77 (0.64)	-0.04 (-0.09 to 0.02)	*0.2*
Lean body mass (kg)	41	34.6 (6.8)	36 (7.1)	1.3 (0.6 to 2.1)	*0.001*
Fat mass (kg)	41	24 (9.8)	23.9 (10)	-0.1 (-0.9 to 0.7)	*0.8*
Body fat (%)	41	39.8 (7.4)	38.7 (7.1)	-1.1 (-2.5 to 0.2)	*0.1*
Maternal BMI (kg/m²)	37	29.9 (6.7)	29.9 (6.8)	-0.1 (-1.1 to 1)	*0.9*
Systolic blood pressure (mmHg)	48	120.2 (11.4)	115.4 (8.8)	-4.8 (-7.5 to -2)	*0.001*
Diastolic blood pressure (mmHg)	48	66.6 (8)	64.5 (8.4)	-2.1 (-5 to 0.9)	*0.2*
Recovery heart rate (beats per minute)	46	108 (28.1)	120.8 (23.6)	12.8 (5.5 to 20)	*0.001*
Physical activity (hours per week)	48	8.2 (4.7)	6.9 (3.8)	-1.3 (-2.6 to 0)	*0.05*
Sedentary activity (hours per week)	48	21 (9.1)	21.1 (11)	0.2 (-3 to 3.4)	*0.9*
Global self-esteem score (maximum 4)	45	2.9 (0.6)	2.8 (0.6)	-0.1 (-0.3 to 0.1)	*0.3*

Data are presented as means (CI) analysed with the paired t-test, CI: 95% Confidence Interval

Table 26. Within-subject changes in outcomes at 6 months from baseline (controls)

		Baseline	6 months	Difference (0 – 6 months)	
	n	Mean (SD)	Mean (SD)	Mean (CI)	*p*
Waist circumference (cm)	44	80.4 (8.7)	81.7 (8.5)	1.3 (0.3 to 2.4)	*0.02*
Waist circumference z-score	44	2.72 (0.62)	2.74 (0.6)	0.01 (-0.07 to 0.09)	*0.8*
BMI (kg/m²)	45	27.3 (5.2)	27.7 (5.2)	0.3 (-0.1 to 0.7)	*0.1*
BMI z-score	45	2.79 (0.65)	2.75 (0.66)	-0.03 (-0.1 to 0.03)	*0.3*
Lean body mass (kg)	21	34.2 (7.3)	36.3 (7.5)	2.1 (0.5 to 3.7)	*0.01*
Fat mass (kg)	21	23.2 (8.6)	24.2 (9.8)	1 (-1.2 to 3.3)	*0.4*
Body fat (%)	21	39.6 (7.7)	38.9 (7.7)	-0.6 (-3.9 to 2.7)	*0.7*
Maternal BMI (kg/m²)	33	30.4 (6.8)	29.9 (6.8)	-0.5 (-1.2 to 0.1)	0.1
Systolic blood pressure (mmHg)	45	120 (11.4)	112.5 (9)	-7.4 (-10.7 to -4.2)	< *0.0001*
Diastolic blood pressure (mmHg)	45	66.3 (7.9)	64.5 (7.8)	-1.7 (-4.4 to 0.9)	*0.2*
Recovery heart rate (beats per minute)	43	107.1 (29.8)	111.8 (28.7)	4.7 (-5.9 to 15.2)	*0.4*
Physical activity (hours per week)	45	7.8 (4.6)	11 (7.8)	3.2 (0.5 to 6)	*0.02*
Sedentary activity (hours per week)	45	21.4 (9.3)	21.7 (9.2)	0.3 (-2.5 to 3.1)	*0.8*
Global self-esteem score (maximum 4)	44	2.9 (0.7)	2.9 (0.7)	0 (-0.2 to 0.2)	*0.9*

Data are presented as means (CI) analysed with paired t-test, CI: 95% Confidence Interval

7.13 Within-subject changes in reported dietary intake at 3 months from the start of intervention (controls)

Longitudinal analysis revealed no significant changes in reported dietary outcomes at 3 months, except for calcium, which was reduced by 123 mg/day (Table 27).

Table 27. Within subject changes in outcomes at 3 months from baseline (dietary data, controls)

		Baseline	At 3 months	Difference (0 – 3 months)	
	n	**Mean (SD)**	**Mean (SD)**	**Mean (CI)**	***p***
Total energy (kcal)	26	1949 (354)	1843 (537)	-106 (-335 to 123)	*0.4*
Fluid (ml/day)	26	1244 (443)	1724 (1938)	480 (-332 to 1292)	*0.2*
Carbohydrate (g/day)	26	260 (55)	247 (84)	-13 (-50 to 24)	*0.5*
Total sugars (g/day)	26	113 (41)	112 (44)	-1 (-23 to 20)	*0.9*
Glucose (g/day)	26	19 (9)	19 (8)	0 (-4 to 4)	*1.0*
Fructose (g/day)	26	20 (10)	22 (13)	3 (-2 to 7)	*0.3*
Sucrose (g/day)	26	52 (27)	50 (29)	-2 (-17 to 13)	*0.8*
Lactose (g/day)	26	12 (9)	10 (6)	-1 (-5 to 2)	*0.5*
Protein (g/day)	26	70 (13)	64 (18)	-6 (-15 to 3)	*0.2*
Total fat (g/day)	26	77 (19)	74 (26)	-4 (-14 to 7)	*0.5*
Saturated fatty acids (g/day)	26	28 (9)	26 (12)	-2 (-8 to 4)	*0.5*
Monounsaturated fatty acids (g/day)	26	25 (7)	24 (9)	-2 (-6 to 3)	*0.5*
Polyunsaturated fatty acids (g/day)	26	12 (4)	11 (4)	-1 (-3 to 1)	*0.6*
Non starch polysaccharides (g/day)	26	12 (5)	11 (3)	-1 (-4 to 1)	*0.2*
Sodium (mg/day)	26	2623 (596)	2678 (1045)	55 (-399 to 509)	*0.8*
Calcium (mg/day)	26	797 (240)	673 (249)	-123 (-246 to -1)	*0.05*
Iron (mg/day)	26	10.1 (3.7)	9.7 (4.4)	-0.4 (-2.7 to 1.8)	*0.7*

Data are presented as means (CI) analysed with paired t-test, CI: 95% Confidence Interval

7.14 Within-subject changes in reported dietary intake at 6 months from the start of intervention (controls)

At 6 months, a number of significant changes in the reported dietary intake were observed. Total energy, carbohydrate, total sugars, glucose, fructose, sucrose, protein, total fat, saturated, monounsaturated and polyunsaturated fat levels were decreased (Table 28). Total energy intake was reduced by 400 kcal ($p < 0.0001$).

Table 28. Within subject changes in outcomes at 6 months from baseline (dietary data, controls)

		Baseline	At 6 months	Difference (0 – 6 months)	
	n	**Mean (SD)**	**Mean (SD)**	**Mean (CI)**	***p***
Total energy (kcal)	27	1958 (351)	1557 (333)	-400 (-568 to -232)	< *0.0001*
Fluid (ml/day)	27	1257 (435)	1320 (595)	63 (-155 to 281)	*0.6*
Carbohydrate (g/day)	27	265 (58)	211 (53)	-55 (-78 to -31)	< *0.0001*
Total sugars (g/day)	27	113 (40)	82 (34)	-31 (-46 to -16)	< *0.0001*
Glucose (g/day)	27	19 (9)	14 (8)	-6 (-9 to -2)	*0.002*
Fructose (g/day)	27	20 (10)	16 (9)	-4 (-7 to 0)	*0.03*
Sucrose (g/day)	27	50 (28)	34 (18)	-16 (-25 to -6)	*0.002*
Lactose (g/day)	27	11 (9)	11 (7)	0 (-4 to 3)	*0.8*
Protein (g/day)	27	70 (13)	62 (11)	-9 (-14 to -4)	*0.002*
Total fat (g/day)	27	75 (17)	58 (21)	-18 (-29 to -6)	*0.004*
Saturated fatty acids (g/day)	27	28 (9)	19 (8)	-9 (-14 to -4)	*0.001*
Monounsaturated fatty acids (g/day)	27	25 (7)	18 (7)	-7 (-10 to -3)	< *0.0001*
Polyunsaturated fatty acids (g/day)	27	11 (4)	9 (3)	-2 (-4 to -1)	*0.005*
Non starch polysaccharides (g/day)	27	13 (5)	13 (7)	0 (-3 to 4)	*0.99*
Sodium (mg/day)	27	2675 (764)	2484 (614)	-191 (-564 to 181)	*0.3*
Calcium (mg/day)	27	795 (259)	670 (218)	-125 (-239 to -12)	*0.03*
Iron (mg/day)	27	10.7 (3.8)	12.8 (22.6)	2.2 (-6.7 to 11)	*0.6*

Data are presented as means (CI) analysed with paired t-test, CI: 95% Confidence Interval

7.15 Response rates

Response rate was calculated using the number of participants in each group (intervention or control) with valid data at each time point (3, 6 or 12 months) versus the number of participants with valid data at baseline.

At 3 months, response rates for the intervention group varied from 58% for the dietary data, to 76% - 85% for the remaining outcomes. The corresponding response rates for the control group varied from 80% to 88%.

At 6 months, the intervention group response rate was 45% for body composition and for the remaining outcomes varied from 59% to 63%. The corresponding figures for the control group were 45% for body composition and 75% to 84% for the remaining outcomes.

At 12 months when due to the study design only data for the intervention group were available, response rates varied from 60% to 70%, with the exception of dietary data as there were no data for this metric at 12 months.

7.1.6 Measurement retention and trial dropout rates

Overall, 62% children in the intervention group were measured at 6 months and 70% at 12 months. Measurements were performed on 83% of children of the intervention group at either 6 or 12 months. In the control group, 80% children were measured at 6 months and 68% at 12 months.

7.17 Programme attendance and dropout rates

Mean attendance for the MEND programme was 86% (including children from both immediate and delayed intervention groups), with 94% and 68% of children attending more than 9 and 15 of the 18 sessions, respectively. There were no dropouts in the intervention group and 2 (4%) in the control group.

7.18 Adverse effects

No adverse effects of the intervention were reported.

7.19 Secondary data analysis results

Table 29 summarises the pre-intervention variables for the 79 participants with either post intervention (groups 1 and 2, 6 months from pre-intervention, different time-points for each group) or 6 month post-intervention data (group 1 only, 12 months from baseline) (for more information on the sample definition, please see Table 29 footnote and Figure 35). Among these, 71 (90%) were followed up at 6 months and 42 (53%) (from arm 1 only) at 12 months (Figure 35). The mean BMI z-score reduction at 6 and 12 months was -0.30 and -0.23, respectively ($p < 0.001$) (Table 30). Over the 6-month period of the intervention, BMI z-scores were increased in 9 children, and reduced by ≥ 0 to < 0.25 in 29, ≥ 0.25 to < 0.5 in 17 and ≥ 0.5 in 16 children. The initial mean and mean changes 6 months after baseline for these subgroups are shown in Table 31. Among the 42 participants followed up 12 months after baseline, BMI z-score was increased in 9, and reduced by ≥ 0 to < 0.25 in 18, ≥ 0.25 to < 0.5 in 8 and ≥ 0.5 in 7 individuals. The corresponding initial mean values and mean changes 12 months after baseline in relation to subgroup are shown in Table 32.

Overall, changes over 6 and 12 months were significant for all variables except diastolic blood pressure and sedentary activities at 12 months (Table 30). Waist circumference and its z-score over 6 and 12 months showed significant differences between the four BMI z-score subgroups, and positive linear trends were observed between reduction and BMI z-score loss (Tables 31 and 32). However, for systolic and diastolic blood pressure, recovery heart rate, physical activity, sedentary activities and global self-esteem, no statistically significant differences or trends were evident across the BMI z-score subgroups at 6 or 12 months from baseline (Tables 31 and 32).

Table 29. Pre-intervention* variables

Variable	Pre-intervention*		
	n	Mean	(SD)
Age (years)	79	10.3	(1.3)
BMI (kg/m²)	79	27.1	(4.2)
BMI z-score	79	2.75	(0.56)
Weight (kg)	79	59.0	(13.7)
Weight z-score	79	1.11	(1.0)
Height (m)	76	1.47	(0.09)
Height z-score	79	2.56	(0.68)
Waist circumference (cm)	79	81.5	(8.0)
Waist circumference z-score	79	2.86	(0.53)
Systolic blood pressure (mmHg)	79	117.7	(13.0)
Diastolic blood pressure (mmHg)	79	65.2	(8.5)
Recovery heart rate (beats/minute)	78	115	(29)
Physical activity (hours/week)	79	8.8	(5.4)
Sedentary activity (hours/week)	79	20.4	(8.0)
Global self-esteem score (range 0-4)	78	2.9	(0.8)

SD: Standard deviation.
**These are measurements at 0 months for immediate intervention group and at 6 months for delayed intervention group.*

Figure 35. Delayed-intervention design from the MEND RCT (Sacher, Kolotourou *et al*. 2010)

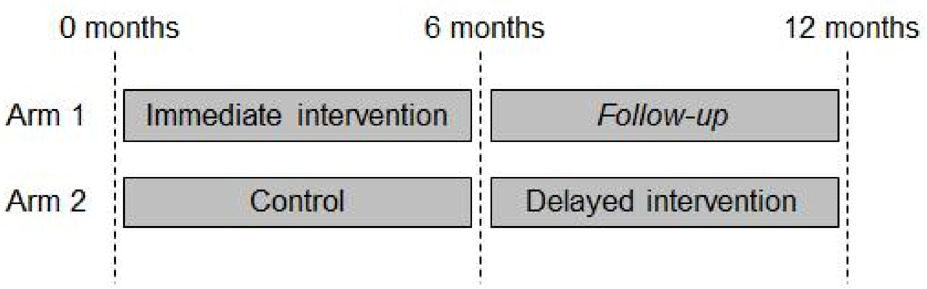


Table 30. Changes in BMI, waist circumference, blood pressure, fitness, activity and self-esteem over 6 and 12 months

	Change over 6 months				Change over 12 months			
	n	**Mean**	**(SE)**	**p-value**	**n**	**Mean**	**(SE)**	**p-value**
BMI (kg/m^2)	71	-1.0	(0.18)	<0.001	42	-0.11	(0.27)	0.7
BMI z-score	71	-0.30	(0.03)	<0.001	42	-0.23	(0.05)	<0.001
Waist circumference (cm)	71	-4.2	(0.4)	<0.001	42	-3.1	(0.7)	<0.001
Waist circumference z-score	71	-0.48	(0.04)	<0.001	42	-0.47	(0.06)	<0.001
Systolic BP (mmHg)	70	-5.0	(1.4)	<0.001	41	-6.5	(2.1)	0.004
Diastolic BP (mmHg)	70	-4.3	(1.1)	<0.001	41	-2.5	(1.5)	0.1
Recovery heart rate (beats/minute)	70	-18	(3)	<0.001	39	-12	(5)	0.01
Physical activity (hours/week)	71	4.2	(1.0)	<0.001	40	4.0	(1.0)	<0.001
Sedentary activity (hours/week)	71	-4.8	(1.0)	<0.001	41	-2.0	(1.2)	0.1
Global self-esteem score (range 0-4)	67	0.2	(0.1)	<0.001	40	0.3	(0.1)	0.03

SE: Standard error; p-values obtained from t-test

Table 31. Changes in BMI, waist circumference, blood pressure, fitness, activity and self-esteem with BMI z-score change over 6 months

	Change in BMI z-score over 6 months								Group	Test of
	Increased		BMI z-score Decrease >0 to <0.25		BMI z-score Decrease ≥ 0.25 to <0.5		BMI z-score Decrease ≥ 0.5		Comparison†	linear trend‡
n*	(n = 9)		(n = 29)		(n = 17)		(n = 16)			
	Mean	(SE)	Mean	(SE)	Mean	(SE)	Mean	(SE)		
BMI (kg/m^2)										
Initial Mean	28.6	(2.6)	27.2	(0.7)	26.3	(0.6)	25.9	(0.9)	0.5	
Mean Change	1.4	(0.3)	-0.3	(0.1)	-1.6	(0.1)	-3.0	(0.2)	<0.001 by design	<0.001 by design
BMI z-score										
Initial Mean	2.81	(0.28)	2.76	(0.11)	2.60	(0.11)	2.65	(0.13)	0.7	
Mean Change	0.08	(0.02)	-0.14	(0.02)	-0.37	(0.02)	-0.71	(0.05)	<0.001 by design	<0.001 by design
Waist circumference (cm)										
Initial Mean	80.4	(3.6)	82.0	(1.4)	80.3	(1.5)	79.4	(1.9)	0.7	
Mean Change	-2.4	(0.8)	-2.5	(0.5)	-4.9	(0.7)	-7.8	(0.7)	<0.001	<0.001
Waist circumference z-score										
Initial Mean	2.79	(0.24)	2.93	(0.09)	2.70	(0.12)	2.75	(0.13)	0.7	
Mean Change	-0.29	(0.07)	-0.31	(0.04)	-0.55	(0.08)	-0.82	(0.06)	<0.001	<0.001
Systolic BP (mmHg)										
Initial Mean	117.2	(4.3)	116.6	(2.7)	116.9	(2.6)	116.5	(3.2)	0.7	
Mean Change	-4.6	(2.7)	-5.7	(2.5)	-3.2	(2.7)	-6.0	(3.0)	0.9	0.4
Diastolic BP (mmHg)										
Initial Mean	66.9	(3.0)	66.1	(1.8)	65.3	(1.9)	62.9	(1.8)	0.6	
Mean Change	-5.3	(3.8)	-3.9	(2.1)	-2.2	(1.7)	-6.7	(1.9)	0.6	0.7

SE: Standard error
**n = maximum number of participants per subgroup*
†: p-value obtained from ANOVA.
‡: p-value obtained from linear regression model fitting BMI z-score change as continuous explanatory variable and adjusting for randomisation group.

Table 31 (continued)

	Change in BMI z-score over 6 months								Group	Test of
	Increased		BMI z-score Decrease >0 to <0.25		BMI z-score Decrease ≥ 0.25 to <0.5		BMI z-score Decrease ≥ 0.5		Comparison†	linear trend‡
n*	(n = 9)		(n = 29)		(n = 17)		(n = 16)			
	Mean	(SE)	Mean	(SE)	Mean	(SE)	Mean	(SE)		
Recovery Heart Rate (beats/minute)										
Initial Mean	125	(12)	111	(4)	115	(6)	107	(6)	0.99	
Mean Change	-28	(13)	-13	(5)	-19	(5)	-21	(7)	0.5	>0.9
Physical activity (hours/week)										
Initial Mean	8.8	(1.8)	7.8	(1.0)	11.4	(1.6)	8.1	(0.9)	0.2	
Mean Change	1.3	(2.1)	5.1	(1.5)	2.4	(2.3)	6.2	(1.8)	0.4	0.12
Sedentary activity (hours/week)										
Initial Mean	20.6	(2.4)	22.9	(1.5)	17.1	(1.8)	20.3	(2.2)	0.9	
Mean Change	-8.7	(2.2)	-4.9	(1.8)	-2.7	(1.8)	-4.8	(1.7)	0.4	0.3
Global self-esteem score (range 0-4)										
Initial Mean	2.8	(0.3)	2.8	(0.2)	3.2	(0.1)	3.0	(0.1)	0.7	
Mean Change	0.1	(0.3)	0.3	(0.1)	0.2	(0.2)	0.3	(0.2)	0.8	>0.9

SE: Standard error
**n = maximum number of participants per subgroup*
†: p-value obtained from ANOVA.
‡: p-value obtained from linear regression model fitting BMI z-score change as continuous explanatory variable and adjusting for randomisation group.

Table 32. Changes in BMI, waist circumference, blood pressure, fitness, activity and self-esteem with BMI z-score change over 12 months

	Change in BMI z-score over 12 months										Group	Test of
	Increased		BMI z-score Decrease >0 to <0.25			BMI z-score Decrease ≥ 0.25 to <0.5			BMI z-score Decrease ≥ 0.5		Comparison†	linear trend‡
n*	(n = 9)		(n = 18)			(n = 8)			(n = 7)			
	Mean	(SE)	Mean	(SE)	N	Mean	(SE)	N	Mean	(SE)		
BMI (kg/m^2)												
Initial Mean	27.5	1.4	27.4	0.8		27.4	0.9		26.4	0.6	0.9	
Mean Change	1.9	0.2	0.4	0.1		-0.9	0.2		-3.1	0.4	<0.001 by design	<0.001 by design
BMI z-score												
Initial Mean	2.71	(0.18)	2.82	(0.11)		3.01	(0.17)		2.75	(0.07)	0.6	
Mean Change	0.11	(0.03)	-0.11	(0.01)		-0.37	(0.02)		-0.81	(0.08)	<0.001 by design	<0.001 by design
Waist circumference (cm)												
Initial Mean	81.4	(2.0)	83.8	(2.2)	8	80.6	(2.0)	7	80.1	(2.5)	0.6	
Mean Change	-1.6	(1.1)	-2.2	(1.1)	8	-2.7	(1.7)	7	-7.9	(1.3)	0.02	<0.001
Waist circumference z-score												
Initial Mean	2.89	(0.12)	2.99	(0.12)	8	3.08	(0.14)	7	2.86	(0.16)	0.7	
Mean Change	-0.29	(0.08)	-0.36	(0.07)	8	-0.56	(0.11)	7	-0.92	(0.15)	0.001	<0.001
Systolic BP (mmHg)												
Initial Mean	117.7	(4.5)	120.9	(3.3)	8	126.3	(6.5)	7	121.5	(5.8)	0.7	
Mean Change	-9.3	(3.4)	-2.7	(3.5)	8	-5.7	(3.9)	7	-12.9	(6.2)	0.3	0.2
Diastolic BP (mmHg)												
Initial Mean	63.7	(3.9)	66.3	(1.9)	8	69.3	(3.2)	7	63.8	(2.5)	0.6	
Mean Change	-6.6	(4.9)	0.3	(1.9)	8	-3.8	(2.7)	7	-2.6	(3.2)	0.4	>0.9

SE: Standard error

**n = maximum number of participants per subgroup*

†: p-value obtained from ANOVA test.

‡: p-value obtained from linear regression model fitting BMI z-score change as continuous explanatory variable.

Table 32 (continued)

	Change in BMI z-score over 12 months										**Group**	**Test of**
	Increased		**BMI z-score Decrease >0 to <0.25**			**BMI z-score Decrease ≥ 0.25 to <0.5**			**BMI z-score Decrease ≥ 0.5**		**Comparison†**	**linear trend‡**
n*	(n = 9)		(n = 18)			(n = 8)			(n = 7)			
	Mean	(SE)	Mean	(SE)	N	Mean	(SE)	N	Mean	(SE)		
Recovery Heart Rate (beats/minute)												
Initial Mean	111	(8)	115	(8)	8	115	(6)	7	115	(12)	0.99	
Mean Change	-12	(10)	-14	(8)	7	1	(5)	7	-22	(11)	0.5	0.5
Physical activity (hours/week)												
Initial Mean	5.2	(0.8)	8.6	(1.1)	8	7.8	(1.6)	7	6.3	(1.2)	0.2	
Mean Change	3.2	(1.6)	3.7	(2.0)	7	3.9	(1.3)	6	6.1	(1.6)	0.9	0.5
Sedentary activity (hours/week)												
Initial Mean	21.1	(3.1)	21.2	(1.8)	8	18.8	(2.6)	7	21.0	(4.2)	0.9	
Mean Change	-1.4	(4.1)	-1.5	(1.2)	7	-1.6	(1.1)	7	-4.3	(3.4)	0.9	0.8
Global self-esteem score (range 0-4)												
Initial Mean	2.9	(0.3)	2.7	(0.2)	8	2.7	(0.3)	7	3.1	(0.2)	0.7	
Mean Change	0.3	(0.3)	0.4	(0.2)	7	-0.1	(0.3)	7	0.5	(0.2)	0.5	0.6

SE: Standard error
**n = maximum number of participants per subgroup*
†: p-value obtained from ANOVA test.
‡: p-value obtained from linear regression model fitting BMI z-scorechange as continuous explanatory variable.

7.20 MEND UK implementation (Roll-out) results

Between 2007 and 2010, 7-13 year old overweight and obese children participated in 2063 MEND programmes across the UK. The intervention was delivered by a wide range of professionals in community venues. Outcomes were assessed pre- and post-intervention. The baseline characteristics and pre-post analysis data are presented in Tables 33 and 35.

Demographics of the implementation phase revealed that 24% of families were BME (UK average: 7.9%) (Table 34), 34% were single parents (UK average: 24%) and 47% did not own their own home (UK average: 31%), a proxy for SEC (2011).

From 2010 onwards, parents attending the UK programmes were measured (height and weight) and their BMI calculated. The data revealed that at baseline, 0.4% of parents were classified as underweight (BMI ≤ 18.49 kg/m^2), 17.9% of parents were healthy weight (BMI 18.5-24.99 kg/m^2), 29.8% were overweight (BMI 25- 29.99 kg/m^2) and 52% were obese (BMI ≥ 30 kg/m^2). The BMI distribution for parents is depicted in Figure 36. The mean parental baseline BMI was 31.5 kg/m^2 (SD 7.2), and percentage weight change for all parents following the intervention was -1%.

Table 33. Baseline characteristics of participants (UK Roll-out data)

	N	Minimum	Maximum	Mean	SD
Age (years)	15457	6.5	14.0	10.4	1.8
Height (cm)	15457	103.0	192.0	146.0	11.5
Weight (kg)	15457	23.5	152.0	59.5	16.8
BMI (kg/m^2)	15457	17.8	89.6	27.4	4.9
BMI z-score	15457	1.33	5.67	2.77	0.63
Waist circumference (cm)	15319	40.0	158.0	87.0	12.5
Recovery heart rate (beats per minute)	13614	50.0	210.0	108.8	21.8
Physical activity (hours/week)	14290	0.0	50.0	10.5	7.2
Days doing physical activity (per week)	13689	0.0	7.0	1.7	1.7
Sedentary activities (days/week)	14124	0.0	80.0	15.9	10.9
Nutrition score (0-28)	14527	1.0	28.0	16.3	4.6
Total difficulties score (0-40)	14371	0.0	37.0	13.5	7.0
Body esteem (0-24)	12790	0.0	24.0	9.0	5.6
Rosenberg self-esteem (0-30)	9112	0.0	31.0	16.5	6.9

BMI: Body mass index, SD: Standard deviation,

Table 34. Ethnicity breakdown (UK Roll-out data)

Ethnicity breakdown	N	%
Asian	1024	10%
Black	861	8%
White	7892	76%
Mixed	429	4%
Other Ethnic Groups	147	1%
Total	10353	100%

Figure 36. Graph of parental BMI distribution (UK Roll-out data)

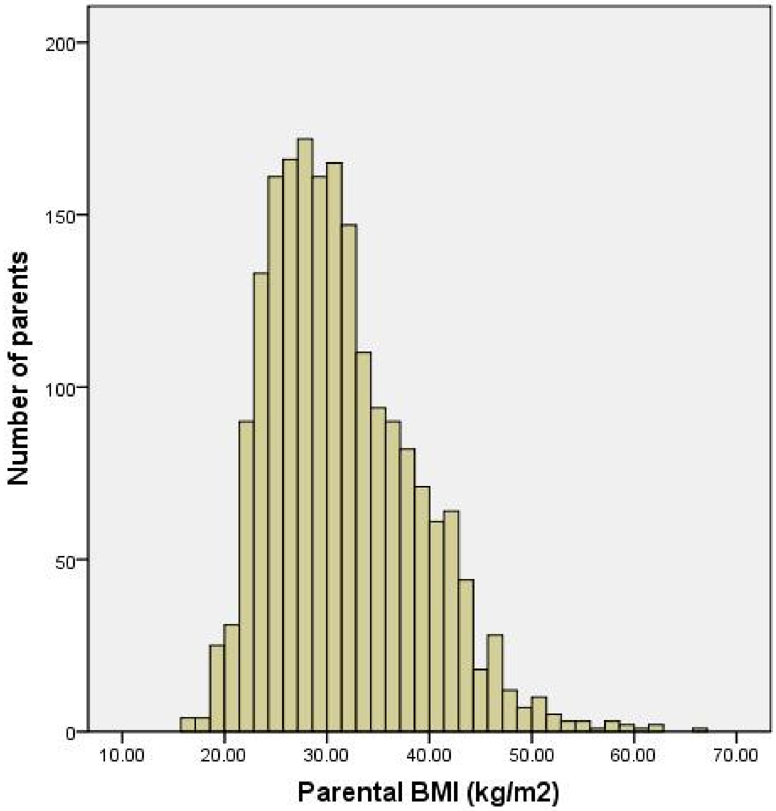


Table 35. **Within-subject analysis before and after the MEND programme (UK Roll-out data)**

		Before MEND		After MEND		Difference (Before vs. After MEND)			
	N	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**Lower CI**	**Higher CI**	**p-value**
BMI (kg/m²)	10173	27.2	4.5	26.4	4.5	-0.8	-0.8	-0.8	< 0.0001
BMI z-score	10173	2.76	0.61	2.58	0.67	-0.18	-0.18	-0.17	< 0.0001
Waist circumference (cm)	10155	86.6	11.8	84.1	11.7	-2.6	-2.6	-2.5	< 0.0001
Days doing physical activity (per week)	8453	1.7	1.7	2.9	1.7	1.3	1.2	1.3	< 0.0001
Physical activity (hours/week)	8784	10.4	6.9	14.0	7.6	3.6	3.4	3.8	< 0.0001
Sedentary activities (days/week)	8637	16.1	10.8	10.3	7.4	-5.8	-6.0	-5.6	< 0.0001
Recovery heart rate (beats per minute)	8935	108.5	21.3	99.9	20.2	-8.7	-9.1	-8.3	< 0.0001
Nutrition score (0-28)	9031	16.5	4.5	22.8	3.8	6.3	6.2	6.4	< 0.0001
Total difficulties score (0-40)	8839	13.2	6.9	10.3	6.5	-2.9	-3.0	-2.8	< 0.0001
Body esteem (0-24)	7701	9.0	5.7	13.1	6.4	4.1	4.0	4.2	< 0.0001
Rosenberg self-esteem (0-30)	5594	16.6	6.8	19.8	6.8	3.2	3.0	3.3	< 0.0001

Data are presented as means (CI) analysed with paired t-test, CI: 95% Confidence Interval

Chapter 8 Discussion

At the time of development and evaluation of the MEND intervention, no published childhood obesity intervention programmes that were both efficacious and generalisable in a UK community setting were available. However, a growing number of government initiatives to improve childhood health and prevent the increase in childhood obesity, e.g., the 'fruit at school' scheme and two hours of compulsory physical education for all children at school, were implemented. Although commendable, these initiatives were not evidence-based or specifically designed for the management of children who were already overweight or obese. At this time, interventions introduced in the school setting generally showed poor results in terms of reducing child BMI (Summerbell, Ashton *et al*. 2003).

The purpose of the development, evaluation and implementation of the MEND intervention was to determine whether: i) health and wellbeing could be improved in obese children attending a novel, multicomponent intervention outside of a clinical setting in the UK, ii) families would engage and attend an intensive programme, iii) the intervention was efficacious in a controlled trial when delivered by professionals other than the original specialist programme developers, iv) changes in anthropometry were clinically significant, and v) the intervention was effective when implemented under service-level conditions across the UK.

Thus, the primary aim of MEND RCT was to test the hypothesis that an intensive family-based programme of nutrition education, exercise and behaviour modification, followed by free access to swimming facilities, can improve anthropometry, cardiovascular fitness and self-esteem in obese school-aged children, compared to a waiting list control group. The secondary purpose of the trial was to evaluate whether positive health outcomes could be sustained at 12 months and replicated when implemented under service-level conditions across the UK.

8.1 Trial population baseline measures

8.1.1 Ethnicity and socioeconomic circumstances (SEC)

Ethnicity and SEC are relevant factors when developing and evaluating childhood weight management interventions, owing to known socio-demographic inequalities in the distribution of childhood overweight and obesity (El-Sayed, Scarborough *et al*. 2012). For example, studies over the past 20 years have shown reasonably consistent evidence that children in disadvantaged circumstances are more likely to be overweight or obese than their more advantaged peers (Shrewsbury and Wardle 2008). Ethnic minority children are at increased risk of adult obesity, cardiovascular disease risk and insulin resistance, and therefore present important targets for childhood obesity interventions (El-Sayed, Scarborough *et al*. 2012). Several studies have shown that children from ethnic minorities are generally more overweight than Caucasian children, with lower fitness levels, poorer diets, and higher levels of television viewing (HSE 2006; Singh, Kogan *et al*. 2008; El-Sayed, Scarborough *et al*. 2012). In the 2004 Health Survey of England (HSE) that focused on the health of ethnic minorities (HSE 2006), the proportion of overweight (including obese) children aged 2-15 ranged from 22% (Chinese boys) to 42% (Black African boys). Research suggests that this variation may be partly explained by some types of families (such as those with better SEC) being more likely to access services that support health and behaviour change (Marmot and Bell 2012).

Interestingly, in developed countries, children from lower SEC households appear more prone to increased body weight, whereas in developing countries, the opposite trend is evident (Wang and Lobstein 2006). An inverse association between low SEC in childhood and adult obesity, cardiovascular disease risk and overall mortality has been reported (Senese, Almeida *et al*. 2009). Additionally, children from lower SEC groups appear less physically active and fit, compared to their higher SEC counterparts, and these features persist into adulthood (Cleland, Ball *et al*. 2009).

The current trial was characterised by a high proportion of children from black and minority ethnic group (BME) backgrounds and low socio-economic circumstances (SEC). In total, 47% of children were classified as BME, compared to the overall UK population, which is predominantly white (national average, 91.9%) (Table 14) (2011). This was not unexpected, considering that 4 of the 5 trial sites were located in inner London areas containing higher proportions of non-white families.

In the present trial, the occupation of the primary earner of the child's household was used as an indicator of SEC. The primary earner had a manual occupation in 61% of participating families (Table 13), leading to the classification of many households as low SEC (1993).

8.1.2 Anthropometry and body composition

Height and weight measurements of children were used to calculate their BMI and corresponding weight status. In addition, waist circumference and body composition were evaluated. The majority of children were classified as moderately obese (BMI z-scores 2 to 3.5; mean, 2.8) (Table 13), 8 as severely obese (BMI z-scores 3.5 to 4) and 2 extremely obese (BMI z-score greater than 4) (SIGN 2010). Similar trials have reported BMI z-scores at baseline ranging from 2.0 (SD not reported) (Golan, Kaufman *et al*. 2006), 2.4 (SD 0.1) (Reinehr, de Sousa *et al*. 2006), and 2.75 (SD 0.52) (Golley, Magarey *et al*. 2007) to as high as 3.7 (SD 1.1) (Epstein, Paluch *et al*. 2007). Significant discrepancies in BMI z-score at baseline may not allow objective comparison of outcomes between studies. Moreover, for the development of a community-based intervention targeting the majority of children with increased adiposity, a moderately obese sample provides more generalisable results and expectations than an intervention addressing severely obese participants.

The mean waist circumference z-score in the current trial was above the 99.6th centile (McCarthy, Jarrett *et al*. 2001). Mean total body fat percentage was 39.5%, which is above the 98th centile for both genders for children between 8-12 years, according to the UK reference curves for body fat (McCarthy, Cole *et al*. 2006). Waist circumference is not commonly measured in other trials, particularly in the USA, where there are no reference values for childhood waist circumference.

Therefore, the current trial population was characterised by both general and central adiposity leading to increased risk of several health problems, both in the short and long term (Barlow 2007; Oude Luttikhuis, Baur *et al*. 2009).

8.1.3 Parental obesity

Weight and height measurements of parents were obtained to calculate BMI and weight status. The majority of children attended the baseline measurement sessions with their mothers. Overall, 75% of the parents were overweight or obese (Figure 29) with a mean BMI at baseline of 29.8 kg/m² (Table 13). This finding is similar to data from the feasibility trial (88% of overweight or obese parents), and strongly supports earlier literature linking parental and childhood obesity (Zaninotto, Wardle *et al*. 2006) (Table 2).

The proportions of overweight and obese parents have rarely been reported in similar trials, which is surprising, considering that family is increasingly recognised as an important contributor to the growing problem of childhood obesity (Patrick and Nicklas 2005; West, Sanders *et al*. 2010; Keane, Layte *et al*. 2012). Children are likely to adopt their parents' eating habits as a result of environmental exposure, rather than heredity of 'food choice genes'. In this way, obesity is passed from one generation to the next (Patrick and Nicklas 2005; NICE 2006).

The correlation between parental and child obesity necessitates the targeting of either parents alone or entire families with obesity interventions, and not just obese children. Accordingly, the current intervention trial included the obese child and at least one parent or carer.

8.1.4 Cardiovascular fitness

Cardiovascular fitness was measured using systolic and diastolic blood pressure and a non-validated step test method in the feasibility trial. This was addressed in the RCT as cardiovascular fitness, assessed using validated methods consisting of both recovery heart rate following a 3-minute validated step test as well as systolic and diastolic blood pressure. The mean recovery heart rate at baseline was 96.3 beats per minute (Table 13). Unfortunately, no reference values were available for children's recovery heart rates following the 3-minute step test, which would have facilitated comparisons and provided some indication of baseline fitness.

Blood pressure is an indicator of vascular health and cardiovascular fitness. Hypertension has been reported in obese children, and linked to subsequent cardiovascular disease (Stabouli, Papakatsika *et al*. 2011; Tybor, Lichtenstein *et al*. 2011). The majority of children in the trial population had blood pressure values at baseline within the normotensive range according to the UK blood pressure centiles (Jackson, Thalange *et al*. 2007).

Poor cardiovascular fitness is an important contributor to the development of co-morbidities in obese children (Reinehr, de Sousa *et al*. 2006). Recent evidence has shown that decreasing cardiovascular fitness from childhood into adulthood increases the risk of obesity and insulin resistance (Dwyer, Magnussen *et al*. 2009).

On the other hand, improving fitness early in life can help reduce cardiovascular disease risk factors (insulin resistance, abdominal obesity, blood pressure), even if the child remains within the overweight or obese category (Nassis, Papantakou *et al*. 2005; Ortega, Ruiz *et al*. 2010). Interventions aimed at improving cardiovascular fitness can potentially aid in preventing the onset of cardiovascular disease and type 2 diabetes in adults, as well as the persistence of obesity in later life (Nassis, Psarra *et al*. 2005; Dwyer, Magnussen *et al*. 2009).

For these reasons, children included in the trial intervention participated in twice-weekly exercise sessions in order to promote and evaluate effects on cardiovascular fitness. Earlier groups have evaluated parent-only interventions (Golan, Kaufman *et al*. 2006; Boutelle, Cafri *et al*. 2011) with positive weight status results but have rarely reported changes in children's cardiovascular fitness.

8.1.5 Physical and sedentary activity levels

In the current trial, the average time spent doing physical activity at baseline was 7.5 hours/week (Table 13). This level appeared to meet the current recommendation that children should participate in a minimum of one hour of physical activity per day (NICE 2009; DH 2011). However the figure was lower than the average physical activity levels reported in the most recent Health Survey for England (13.8 and 10.9 hours/week for boys and girls, respectively) (DH 2011). Generally, low physical activity levels are reported in obese children (Froberg and Andersen 2005), especially among older girls (DH 2011).

Time spent in sedentary activities was 50% higher than the current recommendation (3 hours/day vs. the recommended maximum of 2 hours/day (NICE 2006; Barlow 2007; SIGN 2010).

Accelerometers are the gold standard method for measuring physical activity (Rowlands, Stone *et al*. 2007). However, due to their high cost at the time of the trial, the appropriate resources were not available. Instead, a questionnaire assessing physical activity levels was used, based on the validated physical activity survey developed by Slemenda *et al*. (1991) (Appendix 13). Measurement of physical and sedentary activities using questionnaires is a common problem in childhood studies (Barton 2010), and the results are not always consistent, mostly due to the methodological limitations in assessing physical activity in the young (Dollman, Norton *et al*. 2005; NOO 2011). Accordingly, physical and sedentary activity results should be interpreted with caution.

8.1.6 Global self-esteem

In this study, global self-esteem at baseline was lower than that of the general population (2.8 vs. 2.9 – 3.1 in the current and general population, respectively) (Table 13). Low self-esteem values during childhood have been reported in obese populations (Strauss 2000). According to Wang and colleagues, obese children have almost twice the odds of low self-esteem, compared to healthy weight children (Wang, Wild *et al*. 2009).

Interestingly, no differences in global self-esteem scores were evident between boys and girls, in contrast to earlier literature showing that global self-esteem reduces with age to a greater extent for girls than boys (Hoare and Cosgrove 1998). Moreover, weight status has been reported to affect self-esteem in different UK ethnic populations. For instance, overweight or obese white and Bangladeshi boys have lower self-esteem, compared to other ethnicities, whereas in black boys and girls, this pattern of association is not evident (Viner, Haines *et al*. 2006). Here, we observed no differences in self-esteem at baseline in various ethnic groups.

8.1.7 Dietary intake

In the current study, the average energy intake of the trial population at baseline was 1922 kcal/day (Table 15). This figure is similar to the UK Energy Reference Value (ERV) of 1902 (average ERV for boys and girls aged 10 years with low physical activity levels) (Table 15) (SACN 2011). However, ERV is derived using median values for weight in the basal metabolic rate equation, and therefore, the current population would have higher values if increased (or corrected) weight is used. This creates a conflicting picture for energy balance in these children, as the issue of how this population is obese with such an energy intake is paradoxical. One explanation of this phenomenon is a potential lower activity level leading to lower energy requirements or high rate of underreporting (see Section 1.6.2), which is common among overweight and obese children and results in misleading low levels of energy intake (Fisher, Johnson *et al*. 2000; Bandini, Must *et al*. 2003; Lambert, Agostoni *et al*. 2004).

Underreporting of energy intake does not seem to be macronutrient-specific, i.e., children seem to equally underreport all macronutrients (Rodriguez and Moreno 2006; Collins, Watson *et al*. 2010; Agostoni, Braegger *et al*. 2011; Elliott, Truby *et al*. 2011). Therefore, the percentage of energy intake from macronutrients can be assessed with more confidence. In the current population, total carbohydrate and fat intake were close to the recommended levels (50% and 35%, respectively). However, saturated fat and non milk extrinsic sugar intake were higher in the current sample, as saturated fatty acids accounted for 13% of energy intake, relative to the recommendation of no more than 11% of total energy intake. Moreover, dietary fibre (non-starch polysaccharides) intake was 12 grams per day, similar to the individual minimum for adults recommended by COMA 1991, but lower than the recommendation for obese children (NICE 2006). Fluid, calcium and iron intake were found to be within the recommended levels. However, sodium intake (2659 mg/day) was significantly higher than the recommended 1200 mg per day. Sodium intake is often underestimated in dietary assessment (Koopman 1992), which is rather worrying in terms of children's health, given the well-known concerns about increased consumption of sodium (Morrison and Ness 2011; Stabouli, Papakatsika *et al*. 2011). In summary, even though energy intake in children appeared to fall within the recommended range, macronutrient quality indicated poor overall diet quality (Eisenberg, Neumark-Sztainer *et al*. 2003).

8.2 Changes in indicators of adiposity

Adiposity was measured using three separate parameters, specifically, waist circumference, BMI and body composition. Results at 3 and 6 months are based on controlled data**.** Due to the trial design, after 6 months, the control group received the intervention, and therefore, all future analyses became uncontrolled.

Sustainability of outcomes is crucial in assessing the success of a weight management programme. However, available literature for childhood obesity interventions with long-term (greater than 12 months) follow-up is limited (Oude Luttikhuis, Baur *et al*. 2009). Sustainability of outcomes in the current trial was evaluated by analysing the 12-month longitudinal data only in the intervention group (Figure 28 and Table 22).

8.2.1 Waist circumference and waist circumference z-score

Waist circumference was selected as the primary outcome measure, an unusual parameter of choice in child obesity intervention studies. Since the MEND intervention targeted both diet and physical activity, the primary outcome was selected in expectation of simultaneous changes in body fat and lean body mass, which could not be detected with routinely used BMI. As BMI does not distinguish between fat and lean mass, it would be possible for an increase in lean tissue to mask a fall in adipose tissue content. Waist circumference does not depend on lean mass, and is thus not susceptible to this limitation.

Waist circumference increases naturally with growth (McCarthy, Cole *et al*. 2006), and this parameter was thus adjusted for age and gender (z-score) to determine the true effects of the intervention. The exact clinical significance of reduced waist circumference in children is currently unknown, owing to the long period between its measurement and clinical manifestations of the disease. However, researchers currently encourage its application to better assess the effectiveness of obesity treatment programmes (Janssen, Katzmarzyk *et al*. 2005; McCarthy, Jarrett *et al*. 2005), given that excess abdominal fat in children is associated with several cardiovascular disease risk factors (McCarthy 2006).

At 3 and 6 months post-randomisation, waist circumference decreased by 3.2 cm (Table 16) and 4.3 cm (Table 18), respectively, among children in the intervention group, compared to controls. The corresponding figures for waist circumference z-score reduction were 0.13 and 0.23 at 3 and 6 months, respectively. The changes within groups for waist circumference z-score are presented in Figure 30.

These results compare favourably with those from two other randomised studies on multidisciplinary lifestyle intervention for paediatric obesity (Shelton, Le Gros *et al*. 2007; Hughes, Stewart *et al*. 2008) and three studies on the effects of pharmaceutical management of obesity (Chanoine, Hampl *et al*. 2005; Klein, Cottingham *et al*. 2006; Srinivasan, Ambler *et al*. 2006).

At 12 months, waist circumference and waist circumference z-score were reduced by 3.1 cm ($p < 0.0001$) and 0.47 ($p < 0.0001$), respectively, compared to baseline (Table 22). The decrease in waist circumference z-score was larger than 3-month and similar to 6-month results (Table 18). This finding indicates a sustained reduction in waist circumference z-score from the end of the intervention (6 months) until 12 months post-randomisation.

Determination of the precise elements of the intervention that led to sustained reduction in waist circumference z-score at 12 months is difficult. One possible factor is the increased cardiovascular fitness (as indicated by increased physical activity levels and reduced recovery heart rate and systolic blood pressure) observed at both 6 and 12 months. A number of studies have disclosed lower levels of visceral adiposity in overweight and obese children and adolescents who exercise (Gutin, Barbeau *et al*. 2002; Nassis, Papantakou *et al*. 2005; Nassis and Sidossis 2006).

To date, few childhood obesity interventions have employed waist circumference as a complementary index for assessing effectiveness, despite increasing evidence supporting the advantages of its inclusion in trial protocols (Rudolf, Greenwood *et al*. 2004; Tybor, Lichtenstein *et al*. 2011), making comparisons difficult.

In adults, large waist circumference (men > 102 cm, women > 88 cm) is associated with 20% increased mortality risk (Koster, Leitzmann *et al*. 2008) and its reduction with significant health benefits (Han, Richmond *et al*. 1997; de Koning, Merchant *et al*. 2007).

A study by Schmidt *et al*. (2010) showed that elevated waist circumference in childhood is a strong predictor of metabolic syndrome in adulthood. Moreover, the effects are mostly associated with increased triglyceride and glucose levels and higher blood pressure (Schmidt, Dwyer *et al*. 2011).

Shalitin and co-workers (2009) additionally revealed favourable effects of modest waist circumference reductions following a 12-week intervention period. The authors reported improvements in a variety of biochemical markers, including LDL cholesterol, HDL cholesterol, triglyceride and insulin levels (Shalitin, Ashkenazi-Hoffnung *et al*. 2009). This is particularly important for overweight and obese children with increased central adiposity, as visceral fat is highly correlated with decreased insulin sensitivity (Krekoukia, Nassis *et al*. 2007), and in particular, waist circumference is a predictor of insulin resistance (Manios, Moschonis *et al*. 2008).

Overall, the potential advantages of waist circumference may outweigh the known disadvantages, such as greater measurement error and variability over time, compared to BMI (Rudolf, Walker *et al*. 2007).

8.2.2 BMI and BMI z-score

In view of the limitations of waist circumference, BMI was used as a secondary outcome measure. Similar to waist circumference, BMI naturally increases over time in children due to growth (Cole, Freeman *et al*. 1995). Accordingly, z-scores were used to adjust for age and gender when assessing changes in BMI.

Positive health outcomes have been obtained following BMI reduction. Shalitin *et al*. (2009) reported a positive correlation between BMI z-score reduction and improvements in LDL cholesterol and insulin sensitivity in their sample of obese pre-pubertal children (Shalitin, Ashkenazi-Hoffnung *et al*. 2009). Studies have shown that insulin sensitivity is substantially improved with weight loss in obese children, consequently reducing the risk of complications, such as type 2 diabetes and liver fat accumulation (Reinehr, de Sousa *et al*. 2006; Savoye, Shaw *et al*. 2007; Ben Ounis, Elloumi *et al*. 2008).

In the current trial, at 3 and 6 months post-randomisation, BMI decreased by 1.4 kg/m^2 (Table 16) and 1.9 kg/m^2 (Table 18), respectively, among children in the intervention group, compared to controls. The corresponding figures for BMI z-score reduction were 0.2 and 0.28 at 3 and 6 months, respectively. BMI z-score was reduced by 0.23 at 12 months, compared to baseline (Table 22).

BMI z-score is an indicator of treatment effectiveness, as it allows for comparisons despite age and gender variations. Notably, in the current trial, the BMI z-score change in favour of the intervention group occurred in the absence of an expected increase in the control group (Tables 25 and 26) (Nader, O'Brien *et al*. 2006).

A few studies have attempted to quantify the magnitude of BMI z-score reduction required to positively influence metabolic health in obese children (Reinehr, de Sousa *et al*. 2006; Hunt, Ford *et al*. 2007; Ford, Hunt *et al*. 2010). Reinehr and colleagues published results suggesting that a 0.5 BMI z-score reduction is required for improved metabolic health (systolic and diastolic blood pressure, LDL and HDL cholesterol, triglycerides, insulin resistance) one year after an obesity intervention (Reinehr and Andler 2004).

A UK research team subsequently examined the effects of different levels of BMI z-score reduction on several cardiovascular disease risk factors in obese children (Ford, Hunt *et al*. 2010). The group observed metabolic benefits for insulin sensitivity, TC/HDL cholesterol ratio and blood pressure with a BMI z-score reduction of only 0.25 units (less than Reinehr's cutoff), suggesting that 0.25 is the minimum for metabolic benefits.

Very few multicomponent lifestyle interventions have achieved BMI z-score reductions at the levels recommended by Reinehr (2004) and Ford *et al*. (2010). Some trials have led to a reduction in BMI z-score by ≥ 0.25 (Golan, Kaufman *et al*. 2006; Reinehr, de Sousa *et al*. 2006; Okely, Collins *et al*. 2010) recommended by Ford *et al*. (2010), but less than Reinehr's recommendation of 0.5 (Reinehr and Andler 2004). In the most recent Cochrane review on childhood obesity treatment, four studies (Golan, Kaufman *et al*. 2006; Golley, Magarey *et al*. 2007; Kalavainen, Korppi *et al*. 2007; Hughes, Stewart *et al*. 2008) were included in the meta-analysis for BMI z-score at 6 months post lifestyle intervention in children younger than 12 years (Oude Luttikhuis, Baur *et al*. 2009). The mean difference in BMI z-score for the four studies was -0.06 (95% CI: -0.12 to -0.01). Three studies (Golley, Magarey *et al*. 2007; Kalavainen, Korppi *et al*. 2007; Hughes, Stewart *et al*. 2008) were included in the meta-analysis for BMI z-score at 12 months, with a mean difference of -0.04 (95% CI: -0.12 to 0.04) (Oude Luttikhuis, Baur *et al*. 2009).

The observed BMI z-score reduction of 0.23 in the current trial is almost six-fold higher than the average decrease of 0.06 observed for lifestyle interventions (Oude Luttikhuis, Baur *et al*. 2009). It is difficult to establish the reasons for the differences in BMI z-score changes between different childhood weight management interventions (Table 36). Even when sufficient levels of BMI z-score reduction are achieved, one cannot assume that these results are generalisable to different countries or populations. One example is the Traffic Light Diet intervention, whereby significant variations in BMI z-score change have been observed upon delivery by different groups: -1.07 (Epstein, Paluch *et al*. 2007), -0.17 (Boutelle, Cafri *et al*. 2011) and -0.11 (not significant between groups) upon replication in the UK (Croker, Viner *et al*. 2012). Consequently, our understanding of the effects of childhood weight management interventions on changes in the BMI z-score remains poor.

Table 36. Comparison of BMI z-score at 12 months

Intervention	**12 month BMI z-score change**
Australia: HICKUPS (diet and physical activity) (Okely, Collins *et al*. 2010)	-0.32
Israel: Parent-only treatment (Golan, Kaufman *et al*. 2006)	-0.30
Germany: Obeldiks (Reinehr, de Sousa *et al*. 2006)	-0.30
UK: MEND (Sacher, Kolotourou *et al*. 2010)	**-0.23**
Australia: Lifestyle Triple P (West, Sanders *et al*. 2010)	-0.19
USA: Bright Bodies (Savoye, Shaw *et al*. 2007)	-0.18
USA: Traffic Light Diet, parent plus child arm (Boutelle, Cafri *et al*. 2011)	-0.17
UK: Traffic Light Diet (Croker, Viner *et al*. 2012)	-0.11
Finland: Parent and child (separate groups) (Kalavainen, Korppi *et al*. 2007)	-0.10
Australia: PEACH (Golley, Magarey *et al*. 2007)	-0.09
UK: B'Active (Hughes, McLaughlin *et al*. 2007)	-0.02

For more detail on these interventions see Section 2.1.2 and Table 5

Despite these interesting, albeit inconclusive findings, research in this area is limited. It appears premature to recommend BMI z-score thresholds to define intervention effectiveness, especially in light of several studies suggesting that improvements in glucose and lipid profile and positive metabolic effects can be achieved with smaller reductions or even maintenance of the BMI z-score (Kirk, Zeller *et al*. 2005; Nowicka, Pietrobelli *et al*. 2007; Cummings, Henes *et al*. 2008; Hughes, Stewart *et al*. 2008; Farpour-Lambert, Aggoun *et al*. 2009; Pedrosa, Oliveira *et al*. 2011; Kolsgaard, Joner *et al*. 2012).

Another important point is that while BMI and BMI z-score are simple and convenient tools to assess the effectiveness of childhood obesity interventions, they have several limitations. These indices do not take into account body composition or provide information about other aspects of health, behavioural change and psychology (Janssen, Craig *et al*. 2004; McCarthy, Cole *et al*. 2006). For instance, in interventions with an exercise component, small reductions in BMI z-score may be masked due to positive changes in body composition, for e.g., increased lean body mass (Lazaar, Aucouturier *et al*. 2007; Farpour-Lambert, Aggoun *et al*. 2009).

8.2.3 Body composition

Measurement of body composition using deuterium dilution was a third mode of evaluation of the intervention effects on adiposity. No significant changes were observed at either 3 or 6 months, except for adjusted fat mass, which was markedly reduced at 6 months (-2.4 kg; $p \leq 0.05$) (Table 18). Fat mass reduction was supported by decreased waist circumference observed in the intervention group at 6 months. This is significant, given that visceral fat, which is more accurately predicted from waist circumference (Brambilla, Bedogni *et al*. 2006), is the tissue associated with cardiovascular disease risk factors in children (Savva, Tornaritis *et al*. 2000).

We observed no significant reduction in body fat (%), in accordance with the findings of Hunt *et al*. (2007), who showed that due to wide variations in body fat (%) loss, a BMI z-score reduction greater than 0.5 is required for definite body fat (%) reduction, mainly representing loss of subcutaneous rather than visceral fat (Hunt, Ford *et al*. 2007).

Body fat re-distribution and reduction in abdominal fat that did not result in total body fat decrease may explain the lack of significant changes in overall body composition, which may need more time to appear in a moderately obese population (Nassis and Sidossis 2006).

Unexpectedly, children in the control group displayed increased lean body mass, which may further complicate our interpretation of body composition data (Tables 25 and 26). This increase is possibly linked to the higher physical activity levels in the control group at both 3 and 6 months. Unfortunately, body composition was not assessed at 12 months, owing to a lack of resources.

8.2.4 Weight loss

As children are growing, change in weight is not used as an outcome to assess the effectiveness of childhood obesity interventions. Rapid weight loss in children can lead to poor growth and other medical or psychological problems, and is therefore not recommended (NICE 2006). The SIGN Guidelines recommend weight maintenance or gradual weight loss (0.5-1 kg/month) in children who are overweight or obese and have no co-morbidities (SIGN 2010).

In the current trial, children lost 1 kg on average during the 3-month intensive phase. Six children lost more than 3 kg during this period, and the maximum weight loss recorded was 5 kg in two older children (Figure 32).

The average weight change over the 6-month intervention period was +0.3 kg, signifying that children roughly maintained their weight over this time (weight change spread is shown in Figure 33). Only one child lost more than the recommended 6 kg during this period, which was reported back to the mother who was then requested to have the child monitored closely by the GP. At 12 months, children gained 4.9 kg on average. The maximum weight loss at 12 months was 7.2 kg, which is well within the range recommended by SIGN (Figure 34).

8.2.5 Control group

In contrast to expectations, children in the control group maintained their BMI and waist circumference at 3 and 6 months (Tables 25 and 26). Generally, with growth, BMI and waist circumference in children are expected to increase over a 6-month period. It is argued that the same principle applies to obese children, but at a greater rate of increase. We additionally observed an unexpected increase in the physical activity levels of children in the control group from baseline to 6 months. This is a common finding in studies of similar design whereby treatment-seeking subjects in the delayed intervention groups appear to make positive lifestyle changes before participating in the intervention (Nemet, Barkan *et al*. 2005).

Thus, treatment-seeking families motivated to enter the trial may have become more physically active in the period between randomisation and beginning of the intervention at 6 months. This is also known as the Hawthorne effect (Ulmer 1976), a form of reactivity whereby subjects participating in a study positively change their behaviour, not due to experimental manipulation or intervention, but primarily as a response to their inclusion in the trial. Therefore, the observed positive, albeit unexpected outcomes observed among children in the control group may have limited the effects between groups, compared to a non-treatment-seeking, "real world" control group.

Conclusions

Hypothesis 1 for the MEND trial was "The MEND programme will reduce waist circumference and BMI z-scores by clinically significant amounts at 6 and 12 months in a group of obese 8-12 year old children, thereby improving their weight status."

Both waist circumference and BMI z-scores were significantly improved at both 6 and 12 months post-randomisation. The primary purpose of any childhood obesity intervention is to reduce adiposity, and in this respect, the intervention appeared successful. The magnitude of waist circumference reduction was sustained at 6 months post-randomisation (12 months from baseline), whereas a decrease in the magnitude of BMI change was observed. Further research is essential to establish the precise reduction in adiposity required to improve long-term health in obese children. Without established thresholds, the precise clinical significance of the observed reductions remains unclear (see Section 8.6).

No evident reductions in parental BMI were recorded at 12 months (Table 22), suggesting that the intervention does not effectively encourage weight loss in overweight and obese parents. Further emphasis on the role of parents and the importance of modelling positive lifestyle changes for the benefit of the whole family is recommended.

8.3 Changes in indicators of cardiovascular fitness

Regular physical activity during childhood is widely accepted as an effective preventative measure for a variety of health risk factors across all ages, genders, ethnic and socioeconomic groups (Jannsen 2010). However, across all age groups, levels of physical activity remain low (HSE 2008), while obesity rates continue to rise (Bridges and Thompson 2010). Overall, increasing energy expenditure while maintaining or decreasing energy intake is the mainstay of any successful childhood obesity management programme.

Cardiovascular fitness is an objective measure of health, and its improvement is associated with reduced central adiposity and positive health indices in children (Chomitz, McGowan *et al*. 2010; Ortega, Ruiz *et al*. 2010). In the current trial, cardiovascular fitness was measured using blood pressure, recovery heart rate and physical and sedentary activity levels.

8.3.1 Blood pressure

The majority of children in this trial were normotensive at baseline, and although blood pressure was reduced, no significant differences in systolic and diastolic blood pressure were observed between groups at 6 months (Tables 16 and 18).

However, systolic blood pressure was reduced at 3, 6 and 12 months (Tables 20, 21 and 23), and the magnitude of reduction increased over the 12-month period. There were no significant reductions in diastolic blood pressure.

One possible reason for the lack of significant differences between groups is that systolic blood pressure was unexpectedly reduced by 4.8 and 7.4 mmHg at 3 and 6 months, respectively, in the control group (Tables 25 and 26). This improvement in systolic blood pressure in the absence of intervention may be caused by a false increase in the baseline value due to the anxiety of being subjected to blood pressure measurements for the first time. Increased physical activity levels at 6 months (3.2 hours/week) may also be responsible for the improvements in cardiovascular fitness and systolic blood pressure in the control group.

Other studies have reported conflicting results. Shalitin and co-workers (2009) reported no changes in systolic blood pressure between groups in their sample of obese children (Shalitin, Ashkenazi-Hoffnung *et al*. 2009), while other researchers showed a reduction in systolic blood pressure in groups of obese children attending regular physical activity sessions (Weigel, Kokocinski *et al*. 2008; Farpour-Lambert, Aggoun *et al*. 2009).

Nonetheless, if accurate, this persistent reduction in systolic blood pressure at 3, 6 and 12 months within groups may be an important finding, given the health benefits of blood pressure reduction, even in children within the normotensive range (Berenson, Srinivasan *et al*. 1998; Kelishadi, Malekahmadi *et al*. 2012).

8.3.2 Recovery heart rate, physical and sedentary activity levels

Increased physical activity and reduced sedentary behaviours are essential components of multicomponent childhood obesity lifestyle interventions (NICE 2006). In the present trial, after the intervention (6 months), children appeared more physically active, with reduced sedentary activities and improved fitness (Table 18).

Analysis of physical activity data revealed that children performed 4.0 hours more physical activity per week at 12 months on average, compared to baseline (Table 22). However, the significant reduction in sedentary activity levels at 3 and 6 months was not maintained at 12 months, suggesting compliance issues with the intervention strategies to reduce screen time. This remains a target area for improvement in future applications of the intervention.

Recovery heart rate, measured using a validated step test, is a useful and convenient estimate of cardiovascular fitness. This parameter was significantly improved in the intervention group at 3 and 6 months, compared to controls (Tables 17 and 19), which was sustained at 12 months (Table 22). Our findings clearly suggest that the exercise component of the intervention improves cardiovascular fitness. However, we observed a small reduction in the magnitude of change at 12 months, compared to that at 6 months. This finding suggests that without ongoing support and provision of opportunities for children to exercise, the fitness benefits are lost, at least in part.

The types of fun-based physical and lifestyle activities promoted within the MEND programme seem more effective in helping children to maintain a healthy weight, compared to other studies evaluating structured exercises, such as calisthenics or aerobics (Epstein, Wing *et al*. 1985). Indeed, anecdotal evidence showed that children particularly enjoyed the exercise element of the intervention and looked forward to participating in the land and water-based activities at every session.

Interestingly, the control group also displayed increased physical activity levels at 6 months (Tables 25), possibly a seasonal effect, as 6-month measurements were mostly obtained in the summer when children had increased opportunity to be active. Another plausible explanation is that the group consisted of treatment-seeking families motivated to enter the trial who may have become more physically active in the period between randomisation and beginning of the intervention.

Reduction of sedentary behaviours can have long-term positive effects on overweight (DeMattia, Lemont *et al*. 2007). We found that children in the intervention group were spending almost 6 hours less in sedentary activities than controls at 6 months (Table 18).

Several studies have established the effectiveness of increasing physical activity and improving fitness in reducing overweight in children (Steele, van Sluijs *et al*. 2009). Notably, reduction of sedentary activities may additionally aid in promoting a more active lifestyle and positive health behaviours, even though the effects on weight itself are modest (DeMattia, Lemont *et al*. 2007). Central and total adiposity are lower in overweight and obese children with high cardiovascular fitness as a result of increased physical activity levels (Gutin, Barbeau *et al*. 2002; Nassis, Papantakou *et al*. 2005; Stigman, Rintala *et al*. 2009). However, the magnitude of physical activity required to achieve a significant change in body composition is yet to be determined (Gutin, Barbeau *et al*. 2002).

Aerobic exercise has a positive effect on visceral fat in obese children in the absence of total adiposity changes (Owens, Gutin *et al*. 1999; Gutin, Barbeau *et al*. 2002).

The findings that adjusted fat mass, BMI and waist circumference (an indicator of abdominal fat) are reduced, even in the absence of total % body fat reduction, suggest a beneficial effect of increased physical activity on levels of adiposity in this cohort, supporting current evidence (Nassis, Papantakou *et al*. 2005; Stigman, Rintala *et al*. 2009; Ortega, Ruiz *et al*. 2010).

However, due to the poor accuracy of the questionnaires used to measure physical and sedentary activity levels, no firm conclusions can be drawn from these results. Ideally, accelerometers (a more objective means of measuring physical and sedentary activities) should have been used, but this was not possible due to the lack of resources and high cost of these devices at the time of the trial.

<u>Conclusions</u>

Children in this trial participated in twice-weekly exercise sessions during the first 3 months and were provided with a family swimming pass to encourage continued physical activity until 6 months. In addition, parents were equipped with behavioural strategies to support them in reducing their children's levels of sedentary behaviours and encourage lifestyle activity.

Recovery heart rate was significantly improved, providing firm evidence of enhanced cardiovascular fitness. Sedentary activity levels were reduced at 6 months, but not maintained at 12 months, suggesting possible compliance issues with the intervention strategies to reduce screen time. Therefore, this was identified as an area for improvement in future applications of the intervention. Overall, in terms of physical and sedentary activities, results were promising, but potentially inaccurate due to methodological limitations.

Finally, blood pressure was not significantly reduced, which is unusual in this type of trial. However, it is important to note that the current population was normotensive at baseline. Overall, cardiovascular fitness was improved in children. The loss of significance in sedentary activity levels and reduced magnitude of change in recovery heart rates suggest that children may benefit from additional support to maintain the improvements seen at 6 months.

8.4 Changes in self-esteem

Self-esteem is an important element in the health and behaviour of growing children. Social adjustment, activity engagement, goal direction and self-confidence are factors in a child's development and functioning influenced by their self-esteem (Bandura 1986). Low self-esteem is related to a variety of psychological difficulties and personal problems, including substance abuse, loneliness, academic failure, teenage pregnancy, and criminal behaviour (Leary, Haupt *et al*. 1998; Leary, Tate *et al*. 2007). Thus, the issue of whether childhood weight management interventions cause adverse psychological consequences needs to be addressed (O'Dea 2005).

In the current trial, hypothesis 2 aimed to evaluate whether improvements in body composition and cardiovascular fitness lead to higher self-esteem. Our results showed that the global self-esteem score increased during the intervention and remained raised at 12 months (Tables 16, 18 and 22), suggesting that participation is associated with psychological benefits, rather than harm. These findings add to a small, but growing body of literature indicating that responsibly conducted paediatric weight management interventions effectively improve the emotional health of obese children (NICE 2006; Lowry, Sallinen *et al*. 2007; Shalitin, Ashkenazi-Hoffnung *et al*. 2009).

These positive findings support data from the systematic review conducted by Griffiths and co-workers, who concluded that multicomponent interventions produce significant improvements in global self-esteem (Griffiths, Parsons *et al*. 2010). Results from the current trial suggest that global self-esteem is improved at least 6 months post-intervention (i.e., 12 months after randomisation).

8.5 Changes in dietary intake

Successful treatment of childhood obesity requires a sustained negative energy balance. Modification of dietary intake is one method to achieve this goal. A meta-analysis examining dietetic interventions for the treatment of childhood obesity found that programmes including a dietary component were effective in achieving relative weight loss in overweight or obese children (Collins, Warren *et al*. 2006).

The most common methods for assessing children's habitual dietary intake are dietary recalls and food diaries. From ages 7-8 years onwards, children's contribution to the process is essential. However the best estimates are obtained in cases of cooperation between parents (home food consumption) and children (school/out of home food consumption) (Livingstone and Robson 2000; Livingstone, Robson *et al*. 2004). Owing to the considerable contribution of children in their assessment of dietary intake, retrospective methods, such as dietary recalls, may conceal memory bias, since children do not tend to recall events as well as adults.

Seven-day diet records are commonly used to provide accurate estimates of habitual energy intake. In children, a 9-10 day record is often required to ensure accuracy, owing to increased variability in food intake (Nelson, Black *et al*. 1989). However, the feasibility of maintaining such long-term food diaries for children is low, and in most studies, shorter versions are routinely used (3-7 days) (Livingstone and Robson 2000). Examples of studies implementing this method are detailed below.

Interestingly, recent evidence supports the use of multiple pass dietary recalls for the dietary assessment of 4-11 year old children (Burrows, Martin *et al*. 2010). However until recently, food diaries were considered the method of choice for children's populations, as recalls were found to be poor at the individual level and recommended mostly for groups (Nelson, Black et al. 1989; Livingstone and Robson 2000; Livingstone, Robson et al. 2004).

The majority of researchers in the childhood obesity field continue to use food diaries for dietary assessment. Most commonly, diaries are recorded for 3-4 days, including weekdays and weekends (Johnson, Mander *et al*. 2008; Waling, Lind *et al*. 2010; Jennings, Welch *et al*. 2011; Raynor, Van Walleghen *et al*. 2011; Banks, Williams *et al*. 2012; Coppinger, Jeanes *et al*. 2012; Looney and Raynor 2012; Ritchie 2012) or longer, e.g., 7-day diaries in adolescents (Hart, Jelalian *et al*. 2010) and UK national studies (Gibson, Peto *et al*. 2006; McCaffrey, Rennie *et al*. 2008), while recalls are employed in larger population studies (Keast, Nicklas *et al*. 2010; Diethelm, Jankovic *et al*. 2012).

In view of the above evidence, a 3-day diet record was selected in preference to a longer period in the current trial, with the aim of increasing compliance and reducing the time spent on data analysis. Parents and children were asked to maintain a 3-

day (two weekdays and one weekend day) diary of all foods and drinks consumed by the young participant.

At 3 months, children in the intervention group of the current trial had significantly reduced energy, total sugar, total fat, saturated fat and sodium intake, and maintained intake of protein, calcium and iron, compared to controls (Table 17).

These effects were not sustained at 6 months (Table 19). However, unexpected significant within-group positive dietary changes were observed in the control group from baseline to 6 months, suggesting that children in this group also made positive changes to their diets (Table 28). As stated earlier, this finding may be explained by the fact that the control group consisted of treatment-seeking families motivated to enter the trial, who may have implemented dietary changes within the period between randomisation and beginning of the intervention at 6 months.

As the majority of internationally available childhood weight management programmes contain a dietary component, additional research would be invaluable for determining the most effective dietary treatment. It must be acknowledged that dietary assessment is inherently challenging, particularly in obese subjects, and therefore, dietary analysis data should be interpreted with caution (Nelson, Black *et al*. 1989; Livingstone and Robson 2000).

8.6 Assessment of clinical effectiveness

Researchers agree on the core elements of successful childhood obesity interventions (NICE 2006; SIGN 2010), but consensus about the outcomes by which such interventions are judged as clinically effective is low. Since childhood obesity affects several body functions and systems, evaluation of effective interventions requires markers that reflect this diverse range. In addition to anthropometry, the most common markers are related to cardiovascular health (e.g., lipid profile, blood pressure), metabolic functioning (e.g., insulin resistance), psychological wellbeing (e.g., self-esteem) and behaviour (e.g., diet and physical activity).

The aim of secondary data analysis (Table 30) was to investigate whether physiological, behavioural and psychological changes are associated with different levels of BMI z-score change in children participating in the trial. In the current evaluation, the benefits of the intervention on cardiovascular fitness, blood pressure, physical and sedentary activities and self-esteem over 6 and 12 months did not differ according to the degree of BMI z-score reduction. Notably, even children with increased BMI z-score showed improvements in the majority of outcomes (Tables 31 and 32).

The only parameters associated with degree of BMI z-score reduction were waist circumference and its z-score. This was an expected finding, as BMI and waist circumference are correlated as measures of body composition (Tompkins, Moran *et al*. 2011). Overall, the results suggest that regardless of the magnitude and direction of change in BMI z-score, the intervention had beneficial effects on other important health outcomes.

These findings are supported by previous data showing improved health and psychosocial outcomes, even when small BMI z-score reductions are observed (Kirk, Zeller *et al*. 2005; Nowicka, Pietrobelli *et al*. 2007; Cummings, Henes *et al*. 2008; Hughes, Stewart *et al*. 2008; Farpour-Lambert, Aggoun *et al*. 2009; Pedrosa, Oliveira *et al*. 2011; Kolsgaard, Joner *et al*. 2012). More precisely, a 3-month physical activity intervention in obese pre-pubertal children has been shown to improve blood pressure and arterial stiffness at 6 months, regardless of body weight or fat reduction (Kolsgaard, Joner *et al*. 2012). Another intervention targeting obese children revealed no significant effect on BMI z-score, compared to standard care, but resulted in marked improvements in objectively measured physical activity and sedentary behaviours (Hughes, Stewart *et al*. 2008).

A recent multidisciplinary family intervention led to improvements in lipid profile and insulin resistance, although the average BMI z-score reduction was only -0.13 (Kolsgaard, Joner *et al*. 2012). In a similar study, a significant percentage of children displayed a shift from abnormal values for lipids and glucose metabolism indicators to normal while experiencing only a modest reduction in BMI z-score (-0.15) (Kirk, Zeller *et al*. 2005). Pedrosa and colleagues (2011) showed that a one-year intervention for overweight and obese pre-pubertal children reduced BMI z-score to a modest extent (-0.18), but improved metabolic syndrome indicators, such as triglycerides and HDL cholesterol (Pedrosa, Oliveira *et al*. 2011). Similar benefits in lipid profile and insulin resistance indicators, such as glucose and insulin levels and HOMA, have also been reported with only a moderate or no decrease in BMI z-score (Cummings, Henes *et al*. 2008; Tompkins, Moran *et al*. 2011; Kolsgaard, Joner *et al*. 2012).

In terms of psychological health, positive effects on self-esteem of 6 - 17 year-old obese children attending a low-intensity family therapy intervention and achieving a mean BMI z-score change of -0.12 was reported (Nowicka, Pietrobelli et al. 2007). The authors suggested that the beneficial effect in self-esteem is not correlated with the degree of BMI z-score reduction. Hence, in keeping with findings from the current trial, Nowicka *et al.* (2007) showed that psychological status is positively affected by the intervention, regardless of the degree of BMI z-score change. Moreover, the beneficial effects on behaviour and quality of life (improved physical activity levels, sedentary activities and self-esteem) cannot be measured by a single indicator of weight status.

Consistent with the available literature, our findings indicate that several important parameters (cardiovascular fitness, physical activity level, sedentary behaviours, blood pressure and self-esteem) improve in children participating in the current trial, regardless of the degree of BMI z-score change. Based on these results, it is apparent that setting a BMI z-score reduction cutoff solely to assess the effectiveness of childhood obesity interventions could be misleading, considering the value of other outcomes that may improve in the absence of BMI z-score change. As yet, we are uncertain of the optimal outcomes to assess the effectiveness of interventions (Oude Luttikhuis, Baur *et al*. 2009; Klesges, Williams *et al*. 2012), but propose that focusing on the single outcome of BMI z-score and neglecting other important health and psychosocial factors is premature and may undermine the evaluation of childhood obesity interventions, leading to the inappropriate exclusion of beneficial approaches.

8.7 Potential factors influencing outcomes

Several factors may influence outcomes following a childhood weight management intervention, as discussed below.

8.7.1 Socio-demographics

Interventions may operate less well for some groups than others, which could exacerbate existing inequalities through differential effectiveness (Lorenc, Petticrew *et al*. 2012). Many childhood weight management interventions have been evaluated in relatively small randomised control trials, which were not originally designed to investigate whether effects vary by gender, ethnicity or socio-economic status.

In our trial, BMI z-score and waist circumference z-score were not affected by gender, single parenthood, accommodation status (owned/rented), employment status and age. However, ethnicity affected BMI z-score, which was reduced by 0.38 in white and 0.21 in non-white children ($p = 0.01$) at 6 months, indicating that the intervention is more effective among white participants. Notably, this difference between white and non-white children was not significant at 12 months. The reasons underlying these differences are difficult to determine in the current trial, owing to lack of power for more in-depth analysis. A current population-level evaluation of the MEND UK implementation with sufficient power aims to examine the differential effects of MEND on different groups (Section 8.9.2) (Law 2010).

8.7.2 Intensity of multicomponent interventions

The intensity of interventions, including duration and frequency of contact between provider and participants, appears to influence the success of childhood weight management interventions. In the meta-analysis conducted in 2010, programmes that incorporated medium intensity (26 to 75 contact hours) or high intensity (over 75 contact hours) intervention achieved greater BMI reduction than those with lower intensity (Whitlock, O'Connor *et al*. 2010). Collins and co-workers observed that daily contact is associated with significantly greater weight reduction than weekly contact at 6 months follow-up. However, daily sessions would not be practical for many families (Collins, Warren *et al*. 2006). Researchers in Australia found that the rate of contact in effective interventions ranged from 0.2 (one contact in 6 months) to 11.3 (34 contacts in 3 months) (Sargent, Pilotto *et al*. 2011). Interventions with a monthly or less contact rate reported one to three significant outcomes in either anthropometry or behaviour change, while those with higher intensity (at least one contact every 2 weeks) led to two or more significant outcomes (Whitlock, O'Connor *et al*. 2010).

Table 37 presents a summary of the hours of contact, professional time and physical activity for samples of UK, USA and Australian childhood weight management interventions. Contact hours for the interventions ranged from 18 to 52, with an average of 35 hours. In terms of professional contact time with children and/or parents, total hours ranged from 45-104, with an average of 68 hours.

Table 37. Hours of contact, professional time and physical activity

Intervention	Contact hours	Professional Time (hours)	Hours of physical activity
HICKUPS (diet and physical activity) (Okely, Collins *et al*. 2010)	44	88	None
Parent-only treatment (Golan, Kaufman *et al*. 2006)	24	46	None
Obeldiks (Reinehr, de Sousa *et al*. 2006)	52	52	52 hours, 1 hour group session per week for 12 months
MEND (Sacher, Chadwick et al. 2011)	**36**	**72**	**18 hours (1 hour session twice weekly**
Lifestyle Triple P (West, Sanders *et al*. 2010)	18	45	Optional 3 hours pre- and post-programme
Bright Bodies (Savoye, Shaw *et al*. 2007)	90	90	60 hours (twice per week for 6 months, then fortnightly for 6 months)
Traffic Light Parent Only Trial, parent plus child arm (Boutelle, Cafri *et al*. 2011)	30	60	None
Watch It (Rudolf, Christie *et al*. 2006)	30	72	12 hours -1 hour per week (option to continue to 12 months)
PEACH (Golley, Magarey *et al*. 2007)	20	40	Optional 20 hours

Note: interventions are listed by decreasing magnitude of BMI z-score change

According to the definition of Whitlock *et al*. (2010), MEND is classified as a medium-intensity intervention. Notably, all contact took place during the 3-month intensive phase of the intervention. MEND contact and professional times were close to the average levels stipulated. The optimal intervention intensity that produces clinically significant and sustainable outcomes is yet to be determined (Whitlock, O'Connor *et al*. 2010).

8.7.3 Role of parents

Parental involvement is generally the core element of a successful childhood weight management programme, as the main aim of interventions is adoption of healthy lifestyle habits by the whole family. The behavioural change component needs to involve the whole family in order to achieve successful changes, provide support, and be sustainable and applicable to the child. Parental involvement in the treatment of children with overweight or obesity has been shown to increase the likelihood of improvements in anthropometry (Oude Luttikhuis, Baur *et al*. 2009).

In the current trial, parental BMI was measured where possible, due to the finding that parental and child obesity are linked (Zaninotto, Wardle *et al*. 2006). This is not surprising, since parents serve as role models and determine their children's physical and social environments (Ritchie, Welk *et al*. 2005). Five of the eight behaviour modification sessions were for parents alone (Table 6). These sessions focused on enabling parents to change their own children's behaviours. Children learn by modelling those around them, particularly their parents (Ritchie, Welk *et al*. 2005). Modelling was a key component of the intervention, whereby parents were encouraged to modify their own dietary and physical activity behaviours, with a view to encouraging the same in their child.

The degree of family engagement in obesity interventions appears to increase when parents perceive improvements in children's behaviour and psychosocial wellbeing, regardless of weight or BMI reduction. This finding has been verified in studies showing that parents seek obesity interventions that are significantly related to psychosocial outcomes, such as children's wellbeing, quality of life, and support for lifestyle changes, which are not necessarily related to weight loss or metabolic benefits (Stewart, Chapple *et al*. 2008; Stewart, Chapple *et al*. 2008). Moreover, the elements perceived by parents as important increase the chances of their involvement and commitment to the intervention, which is replicated in growing children, leading to an increase in their autonomy and active involvement (Stewart, Chapple *et al*. 2008). Indeed, according to anecdotal evidence from the current intervention, parents regarded the MEND programme as a ’safe haven for obese children’, a factor that no research analysis could quantify or measure.

In the present trial, parental BMI was not reduced at 6 or 12 months (Tables 21 and 22), suggesting that although the intervention was directed at the whole family, this did not translate into a significant BMI reduction in our group of largely overweight and obese parents. It is possible that parents did attempt lifestyle change themselves, but this was not assessed. Strategies to strengthen parental lifestyle change within a multicomponent childhood weight management programme are crucial for future studies, since family modelling is critical to support children’s efforts to reach a healthy weight, and as many parents are also overweight or obese, their support would serve a dual purpose.

8.7.4 Attendance and retention

One of the main problems in childhood obesity trials is high intervention dropout rates (NICE 2006). Several factors contribute to high dropout rates. i) Many interventions are delivered in hospitals or other medical settings, thereby ‘medicalising’ the problem, creating an expectation for a medical and not lifestyle solution. ii) Some childhood weight management programmes take place in schools and during school hours, which can lead to stigmatisation of overweight and obese children. iii) The location of the intervention site is an important factor, especially if the intervention is intensive, i.e., 1-2 visits per week (locations that are not easily accessible by families and require frequent visits lead to low attendance and high dropout rates). iv) Finally, interventions are often delivered by researchers who do not have the necessary group facilitation and social skills to engage with and motivate children and parents to continue attendance.

In the MEND trial, programme attendance and retention rates were very high (86% mean attendance and 4% dropouts, i.e., 2 children from the delayed intervention group), despite the fact that the intensive phase of the intervention involved 2-hour sessions twice weekly for 9 weeks.

Unfortunately, qualitative methods were not employed to establish whether and why families found the intervention beneficial, and the motivational factors that encouraged continuation of attendance. Future research would benefit from exploring these issues in greater detail.

8.7.5 Inclusion of physical activity

Earlier, a systematic review examining the efficacy of exercise for treating overweight in children and adolescents was conducted (Atlantis, Barnes *et al*. 2006), with the aim of establishing the isolated effects of exercise on obesity among children and adolescents. The authors concluded that exercise significantly reduced percent body fat in obese boys and girls aged 12 years. The current recommended doses of exercise/physical activity for treating overweight in children (30 to 60 minutes/day at moderate intensity most days of the week; 210 to 360 minutes/week)

(Daniels, Arnett *et al*. 2005; NICE 2006) are substantially higher than those tested in RCTs of obese children (Atlantis, Barnes *et al*. 2006). The findings suggest that significant effects on percent body fat are achievable, even with a lower dose of prescribed exercise than that currently recommended.

Interventions vary in their provision of physical activity, which is either included in the programme, not provided at all or optional. For interventions specifying the amounts of physical activity, hours of activity ranged from 18 – 60 hours, with an average of 43 hours (Table 37). In the current trial, children participated in 2 hours of moderate to vigorous physical activity per week and were encouraged to perform physical activity outside of the intervention. Similar to the findings of an Australian review, a reduction in fat mass (but not percent body fat) between groups was noted at 6 months, suggesting that twice-weekly exercise sessions are adequate to reduce fat mass (Atlantis, Barnes *et al*. 2006). Interestingly, both fat mass and percent body fat were reduced within groups at 6 months. In addition, the high attendance and retention rates suggest that the exercise sessions were enjoyed by children, but this was not confirmed, due to lack of qualitative evaluation.

The proven benefits of physical activity in prevention of weight gain, along with its positive effects on psychology and self-esteem, support its inclusion in intervention programmes (ADA 2006; NICE 2006; Barlow 2007; SIGN 2010).

8.7.6 Physical activity versus sedentary behaviour

Reducing sedentary behaviour can improve body composition, and both increased physical and reduced sedentary activity are necessary to improve health outcomes in children (Tremblay, LeBlanc *et al*. 2011). To date, interventions aimed at reducing sedentary behaviours have generally been more successful than those promoting physical activity (Epstein, Paluch *et al*. 2000; Ritchie, Welk *et al*. 2005; Salmon, Ball *et al*. 2005). This observation highlights the importance of targeting sedentary habits, rather than focusing solely on promotion of physical activity.

The main focus of the current study was on physical activity, due to the provision of exercise sessions. Additional information on reducing sedentary activities, such as television viewing time, was provided to parents. As the reduction in sedentary activity was not maintained at 12 months, additional focus on reducing screen time and other sedentary behaviours is recommended for future iterations of the intervention. Reducing inactivity among children is a challenging target, as their daily habits are closely tied with sedentary activities. Television, computer and video games, in particular, appear to be the most popular and easily accessible pursuits during leisure hours, which become increasingly prevalent as children grow into adolescents.

In conclusion, there is sufficient evidence to support the routine recommendation of increased physical and decreased sedentary activities within childhood obesity weight management interventions. The issue of whether inclusion of actual physical activity sessions within the intervention offers any benefit over education to increase physical activity or reduce sedentary behaviours outside of the intervention remains an important area for future research.

8.7.7 Types of maintenance strategies

Sustainability of positive lifestyle behaviour is the ultimate aim of childhood weight management interventions. Considering the importance of maintaining this type of lifestyle, relatively limited information is available on how to help families sustain changes and improvements in weight status following initial treatment (Oude Luttikhuis, Baur *et al*. 2009; Whitlock, O'Connor *et al*. 2010). To date, limited studies have evaluated the effects of different weight maintenance strategies on Iong-term outcomes. Available information suggests that multicomponent interventions including behavioural components can result in maintenance of BMI reductions at 2 years follow-up (Oude Luttikhuis, Baur *et al*. 2009). Additionally, continuation of increased physical activity levels post-intervention is suggested to promote weight maintenance over a longer term (DH 2011).

In the absence of specific guidelines on types of effective support following a childhood weight management intervention, no maintenance support was offered to families attending the MEND intervention, other than a free swimming pass. This was provided to encourage sustained family physical activity after the intensive phase. However, the pass was minimally used (on average, 5 times in 12 weeks, i.e., 1-2 times per month). Informal feedback from families on the reasons for poor use revealed: i) lack of planned swimming activities following the intensive structured programme, ii) lack of motivation, since individualised swimming was not as enjoyable as swimming with peers, and iii) inconvenience of the leisure centre location where free swimming was offered for the parent. Parents further expressed a willingness to travel further for the intensive programme, but not necessarily for free swimming.

Poor response to this part of the intervention suggests that sustained effects are largely attributable to the intensive phase, rather than provision of free access to swimming for 3 months. Following MEND RCT, further qualitative evaluation has been undertaken to develop effective maintenance strategies for families (Section 8.9.3) (Woolcock 2010).

Conclusions

Some of the factors possibly influencing outcomes of childhood weight management intervention have been discussed previously. Due to the complexity of generalising interventions and associating specific factors with specific outcomes, it is not possible to compare interventions for preferential selection.

Authoritative syntheses of evidence, both international (Oude Luttikhuis, Baur *et al*. 2009; Whitlock, O'Connor *et al*. 2010) and applied to UK settings (Kopelman, Jebb *et al*. 2007 ; NICE 2006; SIGN 2010), for treatment of childhood overweight and obesity have concluded that there is insufficient evidence to recommend one intervention over another.

8.8 Comparison of MEND RCT with MEND feasibility trial

The MEND feasibility trial programme conducted in 2002 was acceptable to participants, and positive health outcomes were achieved following a multicomponent lifestyle intervention (Sacher, Chadwick *et al*. 2005).

The feasibility trial consisted of the MEND programme, followed by a 3-month follow-up period during which no contact was made with the families. Feasibility and RCT included similar intervention programmes. However, in the RCT study design, an additional 3 months of intervention (consisting of a 3-month free family swimming pass) was included. It was anticipated that sustainability of outcome would be improved at 6 months by provision of free physical activity for the whole family.

Comparative analyses revealed the same mean BMI z-score at baseline (2.8) in both trials. The mean age of children in the feasibility trial was lower, specifically, 9.6 years, compared to 10.2 years in RCT. Children in the feasibility trial displayed reduced BMI by 0.9 kg/m^2 at 3 months and 0.8 kg/m^2 at 6 months (Table 11), compared to 0.9 kg/m^2 and 1.0 kg/m^2 (Tables 16 and 18) in RCT.

Waist circumference in the feasibility trial was reduced by 2.2 and 3.4 cm, and 3.3 and 4.2 cm at 3 and 6 months in RCT, respectively. Mean attendance in the feasibility trial was 78%, relative to 86% in RCT. Dropout rates were very low in both studies (10% for feasibility and 4% for RCT). Due to the small sample size of the feasibility trial, it was not possible to reach conclusions regarding additional benefits attributable to the extended RCT intervention.

Notably, the team delivering the intervention during the feasibility trial consisted of clinicians with a specialist background and interest in childhood obesity management, whereas some of the healthcare professionals delivering the RCT intervention had very limited, if any, experience in the treatment of childhood obesity. In fact, the majority of MEND leaders (dietitians and nutritionists) had little experience in managing childhood obesity using a lifestyle, group-based, multicomponent approach.

Thus, while the skills and expertise of the RCT delivery team were not as highly developed, the results obtained were comparable. This finding is significant, suggesting that even when delivered by non-specialists, the intervention appears to achieve similar results as those obtained by the specialist team who originally developed the programme.

8.9 Further research since completion of MEND RCT

Research should be generalisable in order to be applicable to a wide variety of settings. This research was performed with the intention that if the RCT revealed positive, sustained outcomes, the intervention could be implemented under service-level conditions and evaluated to determine whether it could fill the void of effective childhood obesity treatments in the UK. There are several examples of interventions that have produced positive outcomes in clinical trials but never been implemented (translated) and evaluated in real-life settings. A number of factors may explain this situation, one being insufficient planning to make the intervention generalisable prior to the evaluation stage. It is far more difficult to make an intervention generalisable after formalised assessment in a clinical trial and before assessment of its effects when implemented in a real-life setting.

Further research is in progress to determine the effects of the MEND intervention when implemented in UK community settings, internationally, and in the longer-term. Additional research was not formally conducted as part of my PhD, but has been included for completeness and to fully describe the entire process from development to evaluation and implementation of the MEND complex intervention (Craig, Dieppe *et al*. 2008).

8.9.1 Implementation: evaluation of a scaled-up intervention

Publication of trial results is essential, but only forms part of an implementation strategy. The fourth and final stage in the MRC Framework for the development and evaluation of complex interventions is implementation (Craig, Dieppe *et al*. 2008). Another term for implementation is “scaling up”, defined as a series of processes introducing innovations (such as weight management programmes) that are effective under research conditions, with the aim of improving coverage and equitable access (Mangham and Hanson 2010). There is a general lack of information about what happens when public health interventions deemed effective under research conditions are “scaled up” for delivery under service conditions, partly because outcome data are often not collected and/or collated.

Following the RCT, due to significant grant funding, the MEND programme was implemented widely across the UK. This provided a unique opportunity to determine whether results of the clinical trials could be replicated under service-level conditions (Sacher, Chadwick et al. 2011). The methods used were similar, but concessions were made due to measurements not being performed by trained researchers and lack of budget availability for expensive equipment and tests, such as electronic sphygmomanometers and deuterium dilution. Outcome measures for the RCT and UK implementation are compared in Table 38. In addition, the age range was widened to include 7- and 13-year olds as well as overweight children ($91^{st} \le$ BMI < 98^{th} centiles).

Table 38. Outcome measures for MEND RCT and UK implementation (Roll-out)

RCT	UK implementation
Anthropometry and body composition	
Child: • Height • Weight • Waist	Child: • Height • Weight • Waist
Deuterium dilution	-
Parent: weight and height	Parent: weight and height (2010 onwards)
Cardiovascular health	
Blood pressure	-
Step-test	Step-test
Dietary intake, physical and sedentary activities	
3-day food diaries	Dietary behaviours questionnaire
Physical activity questionnaire	Physical activity questionnaire
Psychological well-being	
Harter Self-Perception Profile	Rosenberg Self-Esteem Scale (adapted) Strengths and Difficulties Questionnaire(SDQ) Body Esteem Scale

Between 2007 and 2010, MEND programmes were delivered across the UK by a combination of NHS Primary Care Trusts, Local Authorities and Leisure Providers. In order to increase scalability and cost-effectiveness, almost 5000 non-clinical, health, exercise and social professionals were trained to deliver the programmes. Similar to the RCT, training, resources (Figure 37) and delivery of the programme were standardised. Moreover, due to further resources being available, a quality assurance framework involving regular programme visits by MEND staff as well as peer assessors was implemented. All family measurements were collected using a bespoke web-based data management system (OMMS: Operations Monitoring and Management System) (www.ommsonline.org).

Figure 37 MEND programme kit (2007-2010)

Between 2007 and 2010, 15,454 children participated in 2063 MEND programmes across the UK (Figure 38). Among the participants (45.5% boys; 24% BME; 34% single parents; 47% low SEC; mean age 10.4 years; BMI SDS 2.8) of the 10-week MEND programme, 10,173 (66%) had reliable pre and post-intervention data. This low level of reliable data was attributable to measurement collection by largely non-academic professionals, often with very little prior experience of measuring children and/or adults. Standardised measurement training and equipment were provided to all deliverers of the programmes. Poor data remains a significant limiting factor when scaling up interventions using a wider range of non-clinical and non-academic staff. However, large sample sizes partly diminish this limitation.

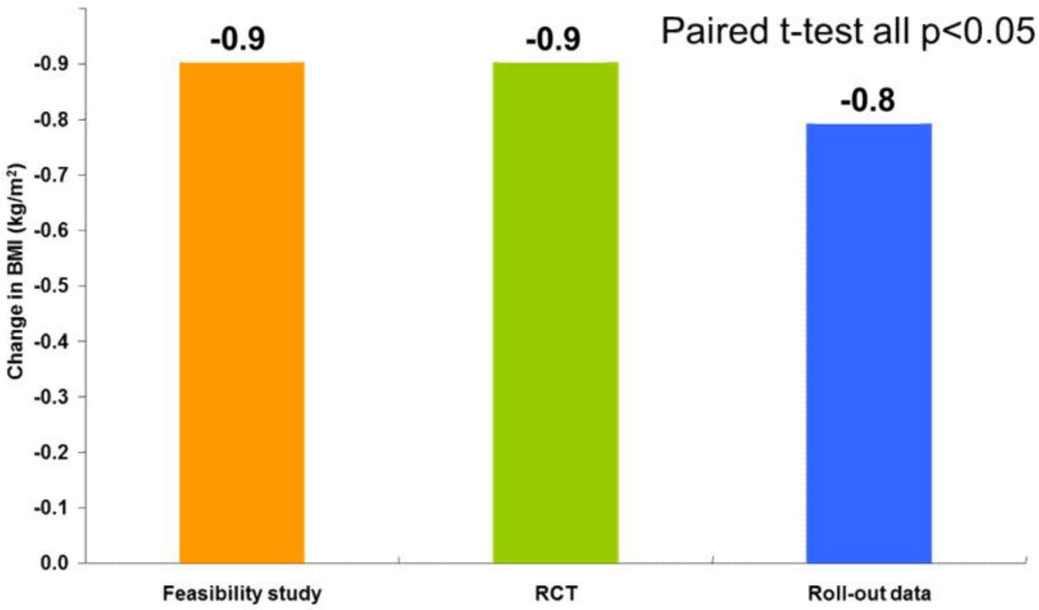
Figure 38. UK map of MEND programme locations (December 2010)

Results showed that mean BMI and waist circumference decreased by 0.8 kg/m^2 and 2.6 cm, while the z-scores decreased by 0.18 and 0.21, respectively (all $p < 0.0001$). Improvements were additionally noted in parent-reported physical activity levels (+3.6 hours per week), step-test recovery heart rate (-8.7 beats per minute), self-reported sedentary activities (-5.8 hours per week), and self-reported body-esteem (+4.1 points) (all $p < 0.0001$). Mean attendance of the 20 MEND sessions was 79%, with a recorded 89% retention rate (Table 35) (Sacher, Chadwick *et al*.

2011). We observed no significant differences at baseline for dropouts versus completers.

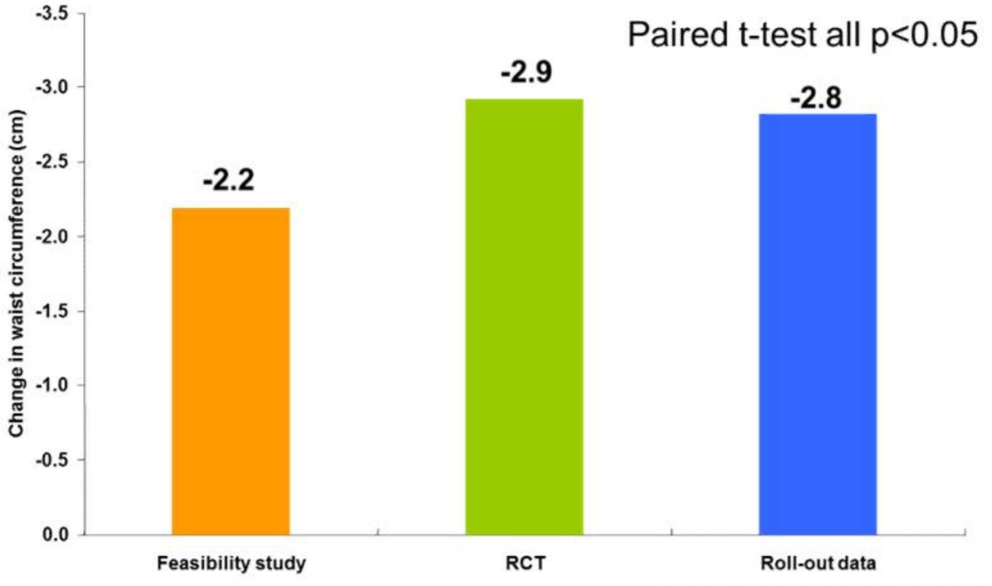
Comparison of BMI changes for the feasibility trial, RCT and UK implementation is depicted in Table 39 (Sacher, Chadwick *et al*. 2005; Sacher, Kolotourou *et al.* 2010; Sacher, Chadwick *et al*. 2011). BMI changes appeared comparable across the three trials.

Table 39. Changes in BMI at 3 months for the MEND feasibility trial, RCT and UK implementation (Roll-out)



Similarly, change in waist circumference, which compares the mean waist circumference change at 3 months, was comparable across all three trials (depicted in Table 40) (Sacher, Chadwick *et al*. 2005; Sacher, Kolotourou *et al*. 2010; Sacher, Chadwick *et al*. 2011).

Table 40. Change in waist circumference at 3 months for the MEND feasibility trial, RCT and UK implementation (Roll-out)



Mean attendance and retention rates were similar for all three evaluations, as presented in Table 41.

Table 41. Attendance and retention rates at 3 months for the MEND feasibility trial, RCT and UK implementation (Roll-out)

	Feasibility trial	RCT	UK implementation
Sample size (n)	11	117	10,173
Mean attendance (%)	78	86	78
Retention (%)	91	97	89

In summary, it appears that the MEND programme under service-level conditions has short-term beneficial effects on physical and psychological outcomes (anthropometry, cardiovascular fitness, physical activity habits, and body image), suggesting that the intervention is replicable and scalable in UK community settings. However, these early findings need to be examined in greater detail before positive conclusions can be reached.

8.9.2 Independent evaluation

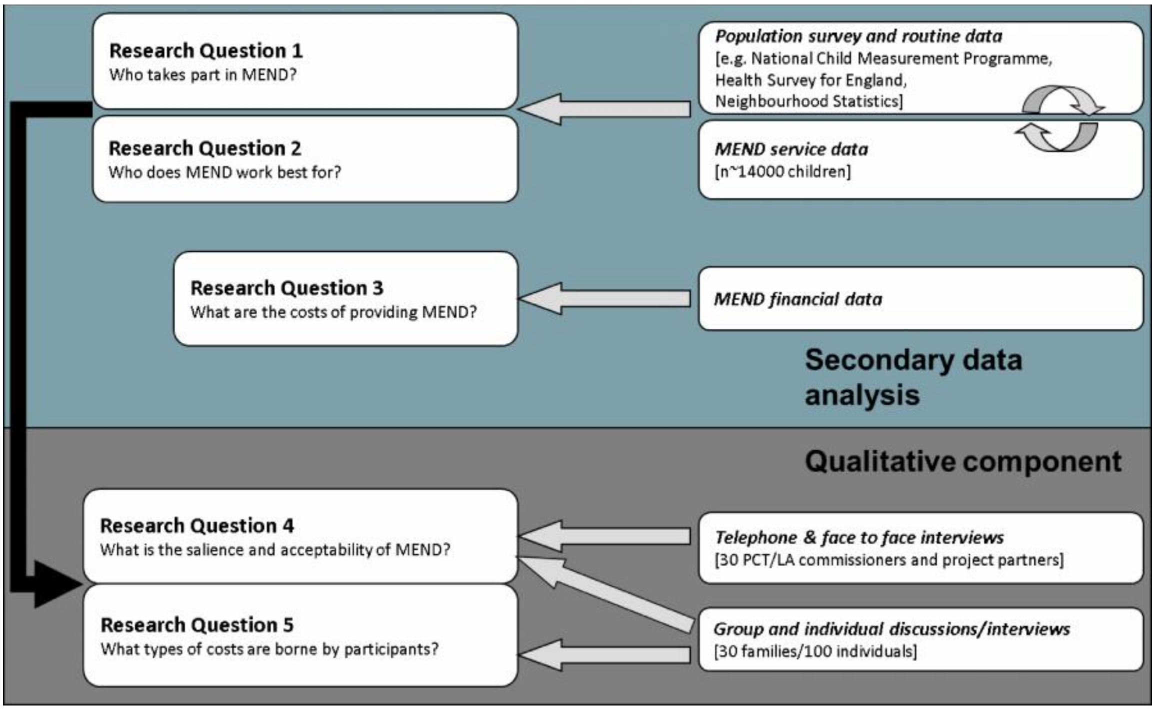
In December 2010, an independent population-level evaluation was initiated to assess the contribution of MEND in tackling childhood obesity, effectiveness in different contexts, the specific individuals affected, and the reasons underlying these effects (Law 2010). This evaluation aims to clarify the following specific research questions:

1. What are the characteristics of children participating in MEND when implemented at scale and under service conditions?
2. How do the outcomes associated with MEND vary, based on characteristics of children (sex, socio-economic circumstances and ethnicity), MEND centres (type of facility, funding source and programme group size) and areas of residence (in relation to area-level deprivation and the obesogenic environment)?
3. What is the cost of providing MEND per participant to the NHS and personal social services, how does this vary, and how is it related to variations in outcome?
4. What is the salience and acceptability of MEND for individuals who commission it, participate in full, participate but drop out, and those who may benefit but do not take up the intervention?

5. What types of costs, if any, are borne by families (and by which members) participating in MEND, and for sustaining a healthy lifestyle, subsequent to completion of the programme?

A schematic representation of the questions, their rationale and the methods used to address these issues are shown in Figure 39.

Figure 39. Schematic of population-level study design



Included with permission from Professor Catherine Law (personal communication)

Results of this evaluation will be available in late 2013, but some preliminary data have been published in the Abstract form (Fagg, Cole *et al*. 2012; Fagg and Law 2012).

Preliminary results

As discussed in Section 8.1.1, childhood obesity varies in relation to SEC, and differential access to public health interventions could potentially increase health inequalities (Lorenc, Petticrew *et al*. 2012). In an attempt to answer research question 1 (Who takes part in MEND; Figure 39), Fagg *et al*. (2012) examined UK service-level data for overweight and obese children participating in MEND programmes between 2007 and 2010 (n = 14,097). The group compared the socio-economic position (SEP) of these children with those in overweight and obese respondents from three routinely collected nationally representative datasets, specifically, Health Survey for England (HSE, n=3,382) (Bridges and Thompson 2010), Millennium Cohort Study (MCS, n=1,708) and National Child Measurement Programme (NCMP, n=379,756) (DH 2011).

The analysis revealed that MEND participants were more likely to be obese than overweight (89% exceeded the 98th BMI centile, compared to 47% of HSE respondents). MEND participants were as likely to reside in deprived neighbourhoods (15% in top decile of neighbourhood deprivation versus 14% in HSE), less likely to live with a lone parent (34% versus 44%), and more likely to live in social rented accommodation (34% versus 26%) and be members of families with an unemployed primary earner (26% versus 22%). Similar patterns were observed in comparisons with MCS and NCMP.

The authors concluded that access to MEND does not vary with regard to SEP, based on data obtained with the best indicator of SEP (neighbourhood deprivation). Family-level variables were less clear. On balance, this independent preliminary evaluation suggested that scaling up the MEND intervention was unlikely to widen socio-economic inequalities in childhood overweight and obesity, due to differential access. SEP and related social inequalities will be further explored in the qualitative element of the population-level evaluation (Fagg and Law 2012).

Question 2 (Who does MEND work for; Figure 39) examined whether results from the MEND RCT can be generalised to service delivery settings and how the intervention impacts health inequalities. Published preliminary data (Fagg, Cole *et al*. 2012) showed that BMI is reduced by similar amounts in the RCT and service delivery (RCT BMI change = –0.91 [95% CI: –1.13 to –0.68]), service BMI change = –0.75 [–0.78 to –0.73]. Service BMI reductions were clinically significant in all the socio-demographic groups analysed. However, in multilevel models, pre-BMI, age, ethnicity, unemployment status and programme attendance were independently associated with BMI change. For example, compared with white children, reductions in BMI were statistically significantly smaller for black and ethnic minority group children (Asian b=0.29, p <0.001, Black b=0.20, p <0.001) (positive coefficients indicate smaller BMI reduction). Similarly, BMI fell to a lower extent in children whose parents were unemployed (b=0.14, p <0.001, baseline employed parent). No significant differences were observed in relation to sex or neighbourhood factors.

These results suggest that clinically significant BMI changes, similar to those achieved under research conditions, may be replicable in service delivery settings for children of all socio-demographic groups analysed. However, at the population level, scaled-up programmes may have better effects on specific groups (Fagg, Cole *et al*. 2012).

8.9.3 Evaluation of maintenance strategies

Following completion of the RCT, due to the dearth of evidence with regard to weight maintenance after childhood obesity interventions, Woolcock and colleagues (2010) conducted a qualitative evaluation in 2008 to evaluate the strategies provided by UK community teams delivering the MEND intervention to overweight or obese children and their families (Woolcock 2010). These findings were not peer-reviewed, but have been included in this publication to provide useful insights, in view of the scarce evidence.

The evaluation explored parent perceptions of the need for follow-up support, their preferred support options and experiences of different support services. The aim of the study was to identify factors that impact on the successful implementation of preferred support options. Evaluation of local community teams was additionally included to determine the types of support currently offered to families attending the MEND programme and experience of delivering these services.

Three methods were used to collect data, including a telephone survey of parental motivation, postal surveys of parents, and an online survey of MEND programme managers who implemented the programmes in community-based settings. For parent surveys, a cross-sectional methodology was employed using a convenience sample of all families attending the programme between March 2007 and December 2008. The surveys were undertaken consecutively with different sample sizes, as the number of families attending the programmes increased over time. The telephone-based survey was used to inform the development of postal surveys for parents. Details of the parent surveys are outlined in Table 42. An online survey of local delivery teams was conducted between June and August 2008. The survey was sent to all 146 Programme Managers involved in MEND programme delivery at the time.

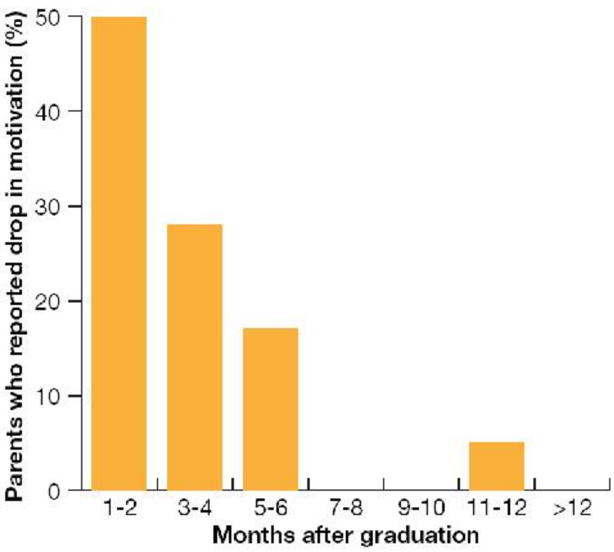
Table 42. Parent surveys on follow-up support

Survey type	Target	Response rate	Area explored	Method
Motivation survey	361 parents	51 (14%)	Explored parental perception of changes in motivation over time and included preliminary questions on preferences for different types of follow up support.	Telephone surveys were conducted with parents who had completed consent forms.
Health communication survey	361 parents	140 (39%)	Investigated how parents access health and weight management information, web usage patterns and the types of features parents might want on a supportive website.	Posted March 2007
Types of support survey	1764 parents	331 (19%)	Further explored the type of support wanted and questions on web and mobile phone access	Posted February 2008
Exercise and measurement survey	4654 parents	551 (12%)	Explored why families did or did not attend follow up sessions and parents perceptions about regularly measuring children	Posted January 2009

In addition to the parent survey response rates, 86% of programme managers, representing 116 delivery teams, completed an online survey. Four main areas were examined: i) whether or not parents need follow-up support, ii) the type of support families require, iii) participation in ongoing local follow-up support and iv) delivery of local follow-up support.

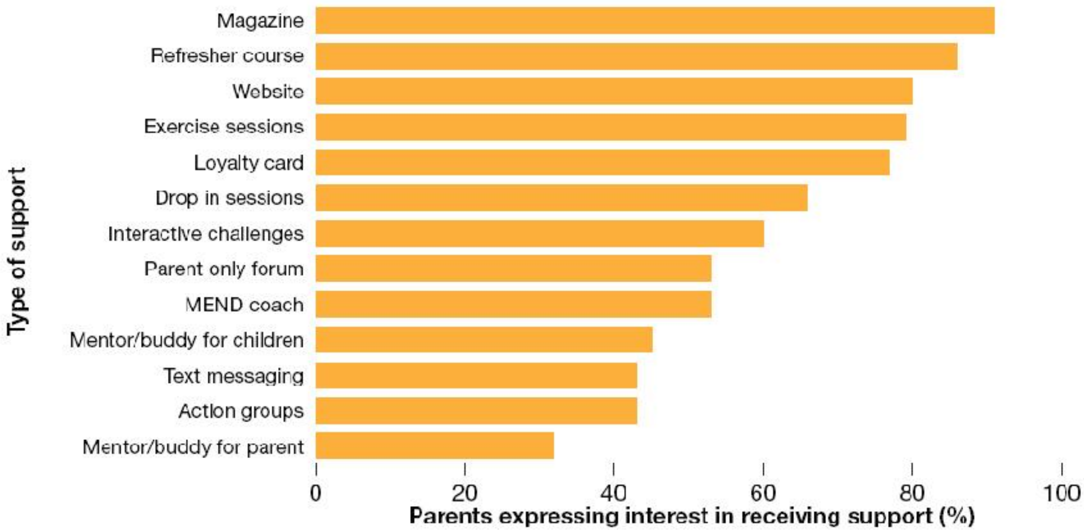
In response to the issue of whether parents need follow-up support, 51% of parents reported a decrease in family motivation to maintain healthy behaviour after completion of the programme. Although 87% of parents completed the programme between 6 and 18 months prior to the date of the survey, the most frequently reported drop in motivation occurred 1-2 months post-programme (Figure 40). The main reason cited by parents was loss of support and contact with the group. Overall, 78% of parents interviewed were interested in additional support during the post-programme period to maintain motivation.

Figure 40. Decrease in motivation after the MEND intervention



In terms of the types of support required by families, parents expressed high interest in receiving a broad range of options (Figure 41). Among these, parents were most likely to use a website, refresher course, exercise sessions, magazines and interactive challenges. Most families had or planned to have internet access at home (95%), and a high rate of mobile access (96%) was recorded. The features most likely to be used on a website were healthy recipes (81%), tracking healthy measurements, such as height and weight (74%), an online reference guide for healthy food products (70%), and simple games to refresh programme concepts (68%).

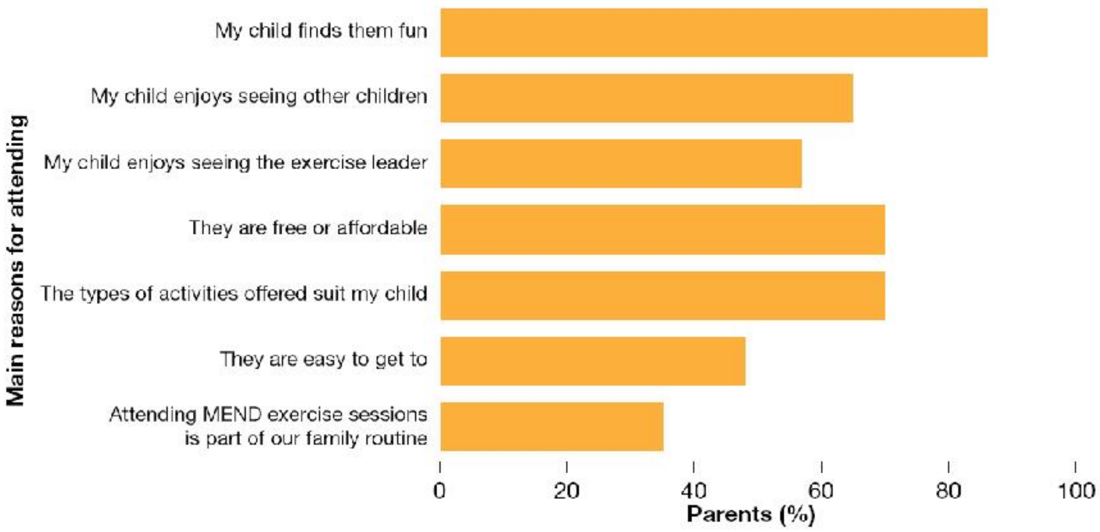
Figure 41. Types of follow-up support of interest to parents



Note: parents could select multiple types of support

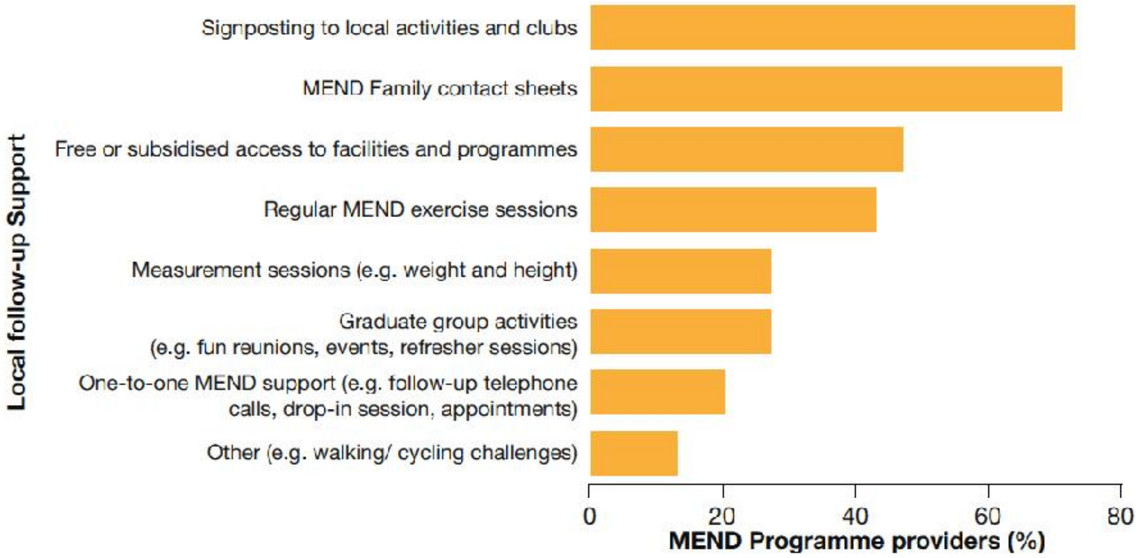
The third area examined was participation in the exercise sessions provided. Overall, 60% of families attended the exercise sessions offered. In cases where families had not been offered sessions, 97% of parents expressed an interest in attending exercise sessions if they became available. For families that were offered exercise sessions, the main reasons underlying attendance are outlined in Figure 42. The key reasons for not attending sessions included participation in other non-MEND exercise sessions (52%) or inconvenience of travel to the sessions (36%). Over 80% of parents claimed they would attend regular follow-up measurement sessions by MEND leaders, if offered.

Figure 42. Parental reasons for attending MEND post-programme exercise sessions



The final area to be evaluated was actual delivery of local follow-up support by programme providers. Local follow-up support was provided to families by 92% of programme managers. Most programmes provided multiple activities for families after the intervention period (Figure 43). Lack of staff availability (79%), funding (71%), poor family participation in follow-up activities (57%) and issues with access to venues (55%) were the most commonly cited barriers to providing post-programme support. Lack of participation was cited as the main reason for support services being withdrawn and the main barrier to providing follow-up measurements. Higher rates of family participation were reported by programme managers who used a planned, rather than *ad hoc* approach to providing follow-up support and those consulting with families during the development process.

Figure 43. Follow-up support by local programme providers



In summary, the majority of parents required post-programme support. Magazines, refresher courses, a website and exercise sessions were the most popular choices. The significant interest expressed in a wide range of support options suggests that a suite of follow-up services may be the best way to meet the varying needs of families after the programme. However, it should not be assumed that high interest will definitely translate into high levels of resource or service usage.

Discrepancies were evident between parental expression of interest in attending support services and actual attendance when services were offered. Provision of local opportunities for ongoing contact of families with providers of childhood weight management programmes or families, particularly in the months directly after the intensive phase of the programme, may be an effective way to address the reported loss of motivation. While parental views and needs are important in selecting post-programme strategies, potential issues with staffing, funding and partnerships should also be taken into account.

Based on these findings, a revised post-programme support structure for the MEND programme was proposed in 2010, whereby families were offered a combination of centralised and local services to meet their needs. This suite of services included a website, quarterly magazines, and interactive challenges provided by MEND, combined with the local provision of weekly exercise sessions, follow-up measurements and locally developed strategies to promote ongoing contact with families. Further feasibility testing and piloting of components of this strategy are currently underway. These findings may facilitate our understanding of how to support long-term behaviour maintenance in children following initial treatment of childhood obesity.

8.9.4 Evaluation of long-term follow-up

Surveillance, monitoring and long-term outcomes are crucial to determine the effectiveness of the intervention outside of an experimental study (Craig, Dieppe *et al*. 2008). Long-term follow up is particularly important for a childhood obesity intervention to determine the sustainability of outcomes. Further research is in progress to evaluate the longer-term effects of the MEND intervention (Table 43).

8.10 Research in progress

In addition to UK, MEND has been adapted and implemented in Australia, USA and Canada. Currently, major research trials are underway in the four countries to evaluate different aspects of MEND (efficacy, population level effectiveness, scale-up and spread, and long-term outcomes) (Table 43). These studies are expected to contribute to a deeper understanding of the effects of the intervention and provide additional valuable evidence on managing childhood obesity.

Table 43. Current independent clinical trials to evaluate the MEND intervention

Study title	Lead organisation	Funder
A population-level evaluation of a family-based community intervention for childhood overweight and obesity (MEND) (Chief Investigator: Catherine Law) (Law 2010)	University College London, UK	National Institute of Health Research (UK)
Scale-up and spread of MEND programs in Canada (Principal investigator: Diane Finegood)	Simon Fraser University, Canada	Canadian Institute of Health Research
US Childhood Obesity Research Demonstration Project (CORD). A RCT evaluation of MEND for children in underserved communities in Texas	Baylor College of Medicine and	USA Centers for Disease Control and Prevention

(Principal investigators: Nancy Butte and Deanna Hoelscher)	University of Texas, USA	(CDC)
Healthy eating and obesity prevention for preschoolers: a randomised controlled trial of the MEND programme for 2 to 4 year olds (Principal Investigator: Helen Skouteris) (Skouteris, McCabe *et al*. 2010)	Deakin University, Australia	Australian Research Council

Chapter 9 Strengths and limitations of MEND

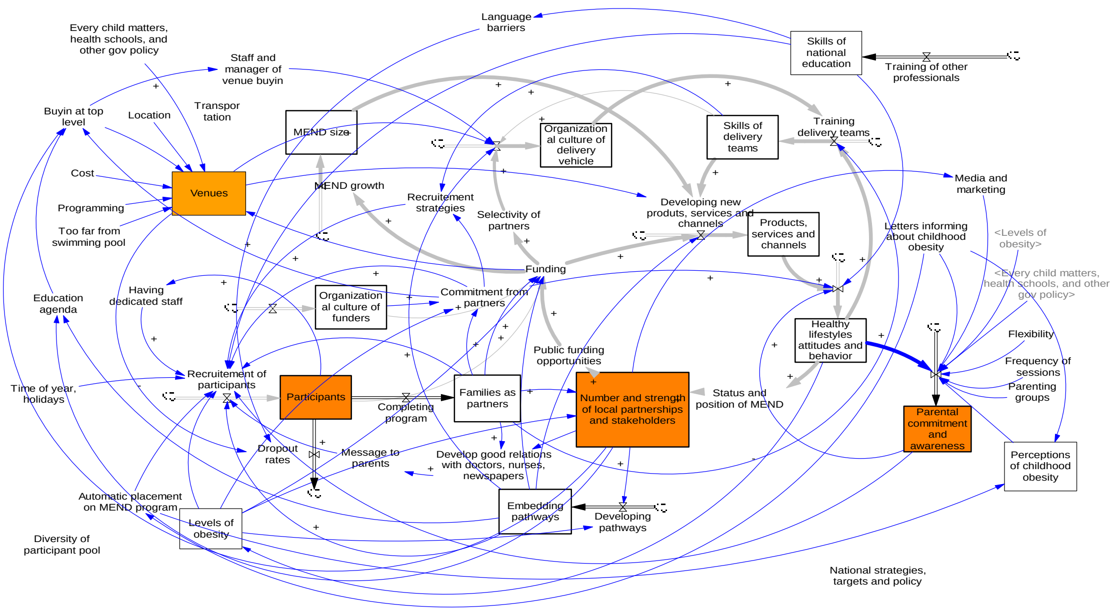
9.1 Strengths

9.1.1 MRC framework for developing and evaluating complex interventions

A major strength of MEND was that it was developed and evaluated in accordance with the MRC framework for complex interventions (Craig, Dieppe *et al*. 2008). The intervention was originally developed in 2001, evaluated in the form of a feasibility trial in 2002, and further refined and re-evaluated as a controlled trial in 2004 - 2007. External validity is crucial to determine whether the results of a RCT can be replicated in non-academic settings. To address this question, population-level evaluation of MEND's UK implementation is currently underway (Table 43, Section 8.9.2). The entire process should provide developers and evaluators with a clear understanding of the problems associated with development, assessment and implementation of a complex intervention in diverse community settings. It is envisaged that this emerging knowledge will lead to continued evolving improvements.

As an illustration of the complexity of implementing a community-based intervention, the MEND systems map below shows some of the interactions necessary to conduct a successful programme (Figure 44). This systems map demonstrates the complications of implementing community-based public health interventions and the dearth of evidence on operational delivery of such interventions in the literature. Consequently, process evaluation is a crucial component within the UK, USA and Canadian MEND trials. The authors of the systems map below are currently conducting a thorough multi-level evaluation of the scale-up and spread of MEND programmes across Canada (Table 43).

Figure 44. The MEND systems map



Hovmand P, Huang T, Finegood D, Sacher P. The MEND Systems Map (2010). Unpublished data.

9.1.2 Outcomes

A major strength of the current study was the variety of outcomes used to assess intervention effectiveness, including measures of physiological and psychological health. This was the first RCT to evaluate the effect of a community-based, childhood obesity intervention, using waist circumference as the primary outcome. Previous research on obese children employed BMI-based measures as the primary outcome to evaluate trial effectiveness (Young, Northern *et al*. 2007; Oude Luttikhuis, Baur *et al*. 2009). However, the value of this index is limited, as BMI does not provide information on body composition, and increases in BMI in childhood due to growth are mainly attributed to lean mass, rather than fat mass (Maynard, Wisemandle *et al*. 2001).

Accumulating evidence has shown that waist circumference is a superior predictor of CVD risk factors in children, compared to BMI (Savva, Tornaritis *et al*. 2000; Wells, Coward *et al*. 2002; McCarthy and Ashwell 2006), mainly due to the fact that waist circumference is an indicator of abdominal fat, which is associated with CVD risk factors and metabolic abnormalities in children (Flodmark, Sveger *et al*. 1994; Freedman, Serdula *et al*. 1999; Janssen, Katzmarzyk *et al*. 2005; McCarthy 2006; Despres 2007).

Over the last two decades, abdominal obesity in children has increased to a higher level than general fatness, as assessed using BMI. This finding further reinforces the use of waist circumference as a clinically useful tool for this group, as it provides an indication of abdominal fat, which appears to be a serious health hazard for children (Janssen, Katzmarzyk *et al*. 2004; McCarthy, Jarrett *et al*. 2005; Rudolf, Walker *et al*. 2007).

9.1.3 Acceptability to families

Many community-based interventions are unsuccessful due to poor uptake as well as low attendance and retention rates. Another key strength of the MEND intensive phase intervention was its acceptability to families. The majority (96%) of children starting the intervention completed the programme, with only two dropouts recorded in the delayed intervention group.

Moreover, the mean 86% programme attendance was higher than that for the feasibility trial and data reported for other childhood obesity interventions (Denzer, Reithofer *et al*. 2004; Golley, Magarey *et al*. 2007; Robertson, Friede *et al*. 2008).

An important consideration in terms of acceptability to families was that children's physical activity sessions were included in the multicomponent intervention. This appeared to increase cardiovascular fitness, which is associated with significant health benefits (Kirk, Zeller *et al*. 2005; Mota, Flores *et al*. 2006; Mitchell, Moore *et al*. 2012) and rarely reported in parent-only interventions. However, as mentioned previously, without conducting a thorough qualitative evaluation of family perceptions of the intervention, it is not possible to establish the specific components of the intervention that are acceptable. Nonetheless, the intensive phase of the intervention appeared acceptable and well tolerated by participating families in general.

9.1.4 Ethnicity and SEC

Ethnicity and SEC are relevant factors when developing and evaluating childhood weight management interventions, as socio-demographic inequalities exist in the distribution of childhood overweight and obesity. In total, 47% of children in the trial were classified as BME, compared to the overall UK population, which is predominantly white (national average, 91.9%) (Table 14) (2011).Therefore it could be argued that results of the trial are not applicable to most UK settings.

Children from ethnic minorities are generally more overweight than white children, and reported to have lower fitness levels and poorer diets, with more hours of television viewing (HSE 2008; DH 2011). For these reasons, it can be argued that improving weight status in BME children may be more challenging than that in white children.

Demographics of the implementation phase revealed that 24% of families were BME (UK average: 7.9%) (Table 34), 34% were single parents (UK average: 24%) and 47% did not own their own home (UK average: 31%), a proxy for SEC. Preliminary evaluations of the UK implementation data in over 14,000 children suggested that scaling up the MEND intervention is unlikely to widen socio-economic inequalities in childhood overweight and obesity, due to differential access (Fagg and Law 2012). Moreover, clinically significant BMI changes similar to those achieved in the RCT appear to be replicable in service delivery settings for children from all socio-demographic groups analysed. However, at the population level, scaled-up programmes may be more effective for some groups than others (Fagg and Law 2012). Overall, despite the RCT comprising a non-generalisable population of UK children, it appears that results may be generalised across the UK, at least in the short-term.

9.1.5 Community and group-based intervention

We further examined the efficacy of a community-based intervention for the management of childhood obesity. Several earlier interventions designed specifically for the management of childhood obesity have been delivered in hospitals and healthcare settings (Oude Luttikhuis, Baur *et al*. 2009).

Clinical or hospital-based delivery of these types of interventions is expensive and medicalises the problem. Moreover, the frequency of visits required makes hospital settings difficult for families living long distances away. Bearing in mind the scale and spread of the obesity epidemic, community-based interventions are preferable due to their reduced cost, ease of access for families, and reduced burden on the NHS (ADA 2006; NICE 2006; Barlow 2007; SIGN 2010).

Finally, the intervention was delivered to groups of children and their parents, making the programme more social for participants as well as cost-effective in terms of reaching multiple families simultaneously. Group therapy can facilitate the adoption of healthy habits as a result of positive peer pressure, role modelling and copying that simultaneously allows participants to feel that they are not facing the challenge alone, the whole process is a team project, and each "player's" performance affects everybody (Flodmark, Ohlsson *et al*. 1993; Bonet Serra, Quintanar Rioja *et al*. 2007).

9.1.6 Internal validity

Sustainability of health and psychosocial outcomes are the ultimate aims of a childhood obesity intervention. Lack of long-term controlled data is problematic within the entire field of childhood weight management (Oude Luttikhuis, Baur *et al*. 2009), but remains the most crucial element necessary to draw definitive conclusions regarding long-term effectiveness.

Due to the randomised, controlled design of this trial, a major strength of the RCT was high confidence regarding the internal validity of the intervention, particularly at 6 months from baseline. As the control group received the intervention at 6 months, it is more difficult to draw conclusions regarding the longer-term effects. The trial design included follow-up of the intervention group alone at 12 months in order to provide some indication of the sustainability of the intervention, but without controlled data, definitive conclusions could not be obtained. Consequently, a trial evaluating MEND in the USA has incorporated more intensive maintenance strategies as well as controlled follow-up at 12 months (Table 43). In addition, a planned evaluation is in progress to monitor children who completed the MEND programme in the Greater London area 2 to 3 years previously.

Further studies evaluating differing weight maintenance strategies are currently in progress in the UK (Woolcock 2010). These strategies aim to improve the maintenance of short-term behaviour changes following the MEND intervention (Section 8.9.3). Ultimately, until the evidence base evolves, it remains difficult to establish the optimal method for sustaining outcomes following a childhood weight management intervention. However, results of MEND remain the most positive, compared to other UK community-based, multicomponent interventions to date.

9.2 Limitations

9.2.1 Study design and methods

A major limitation of the feasibility and RCT evaluations was the lack of qualitative methodology. This type of evaluation is essential to provide additional insights into the study dynamics, which cannot be obtained from quantitative methodologies alone. Qualitative evaluation should provide information on the acceptability of the programme as well as the professionals delivering the intervention to families. In addition, process evaluation was not utilised to document and analyse the development and actual implementation of the programme. This approach would have assessed whether strategies were implemented as planned and the expected output was actually produced. A process evaluation would have allowed explanation of discrepancies between expected and observed outcomes and provided insights to aid implementation. Without process evaluation, it is not possible to determine the extent to which programme fidelity was maintained during the RCT. A quality assurance framework was established during implementation of MEND in the UK to facilitate the evaluation and reporting of programme fidelity to programme deliverers, commissioners/funders and MEND staff.

Despite the lack of process evaluation that did not provide confirmatory evidence, training and programme materials were standardised in order to promote programme fidelity. Standardisation of the programme materials and training were implemented to support successful delivery by community and hospital-based healthcare professionals with no significant expertise in the management of paediatric obesity or experience delivering a community-based child weight management programme. Moreover, standardisation allowed the intervention to be delivered at 5 sites, including one rural site during the RCT and hundreds more during the UK implementation stage. This limitation is being addressed in current evaluations of the MEND intervention taking place internationally (Table 43).

Another limitation was the relatively short follow-up (12 months from randomisation for the intervention group only), which limits conclusions about the long-term effects and sustainability of the intervention. Ideally the period of controlled comparison should be maximised to obtain data on the long-term effects of a childhood weight management intervention. Unfortunately, due to ethical committee constraints, the maximum period allowed for withholding intervention from treatment-seeking families in the current trial was 6 months.

Other childhood weight management interventions have varied in terms of length of the delayed intervention group, generally from 6 to 12 months (Savoye, Shaw *et al*. 2007; Hughes, Stewart *et al*. 2008; Okely, Collins *et al*. 2010). Ideally, a longer period of delay for provision of intervention to the control group would have been preferable from an evaluation perspective, but needs to be balanced with ethical considerations. Within-group analysis was the only alternative method for determining changes at 12 months.

9.2.2 Recruitment

Families had to volunteer to take part in the trial, which may have introduced volunteer or referral bias, as people choosing to participate in a study (or referred) are often different to non-volunteers/non-referrals. This bias usually, but not always, favours the treatment group, as volunteers tend to be more motivated and concerned about their health. However, since all clinical or non-academic childhood weight management programmes rely on families volunteering, this bias should not affect the external validity of the trial results. Moreover, the same bias would have been present in the control group, which also included treatment-seeking or referred families, and therefore, volunteer or referral bias should, at least in theory, be systematic in both groups.

9.2.3 Measurements

Researchers conducting the measurements did not manage to successfully implement a fully blinded measurement process, since families were very interested in discussing their children's progress, and therefore, in most cases, intentionally or unintentionally revealed their group allocation. To some extent, this may have created some expectation bias, whereby observers were influenced when measuring data towards the expected outcome. Such bias usually favours the treatment group. To reduce this bias, repeated measurements were performed in the presence of each site's Principal Investigator to ensure accuracy of the recorded measures. However, it is highly recommended that future trials include strict blinding procedures to diminish bias.

In addition, some measurement bias in this trial may have been attributed to systematic errors that occur during collection of relevant data. Self-reported dietary intake and physical activity levels may have been inaccurate due to recall or memory bias.

9.2.4 Baseline demographics

We observed no differences between groups at baseline, except for gender. This may have caused some selection bias, as the groups compared were statistically different. However, there were no differences in relation to gender at 6 or 12 months within groups, and therefore, this difference was unlikely to have influenced the outcomes.

9.2.5 Contamination bias

Some contamination bias in this trial was possible, as families in the control group were motivated to seek treatment and may therefore have made changes to their dietary and physical activity behaviours on their own accord. This may explain the unexpected positive changes in the trial control group. The bias may have minimised the differences in outcomes between the 2 groups. It is thus extremely difficult to eliminate contamination bias in treatment-seeking trial subjects.

9.2.6 Compliance bias

As the intervention involved lifestyle changes, it is likely that families responded to advice to varying degrees. This introduces compliance bias into the trial, whereby families responded to the components of the intervention in a heterogeneous manner. This bias is unavoidable, as all human beings respond differently to behavioural interventions, and this is similar in academic and real-world settings.

9.2.7 Waist circumference as a primary outcome

It is important to recognise that whilst BMI is a simple and convenient tool to assess the effectiveness of childhood obesity interventions, it has several limitations (Janssen, Katzmarzyk *et al*. 2004; McCarthy 2006). Accordingly, waist circumference was selected as a primary outcome measure, which was both a strength and limitation. A strength is that waist circumference provides additional information on body composition which is not obtained from BMI, and a drawback that few childhood obesity interventions have employed waist circumference as a complementary index for assessing effectiveness to date, despite increasing evidence supporting advantages of its inclusion in trial protocols (Rudolf, Greenwood *et al*. 2004; Tybor, Lichtenstein *et al*. 2011), making comparisons with other studies difficult.

9.2.8 Clinical significance of BMI

A limitation that applies to both this trial and the wider field of childhood obesity management is the lack of clarity over thresholds for determining clinical significance of reductions in BMI and BMI z-score. In the absence of these thresholds, it is difficult to establish benchmarks for success and compare effectiveness between interventions. Further research is required to address this important factor. Until then, the aim of childhood weight management interventions should be to reduce BMI and waist circumference z-scores and improve other measures of health and wellbeing, such as cardiovascular fitness, levels of physical activity, diet quality, quality of life and self-esteem.

9.2.9 Secondary data analysis

An important limitation of the secondary data analysis was that the trial was not originally powered to detect differences in outcomes according to levels of BMI z-score change. However, there was sufficient power to show the trend for waist circumference and its z-score. Therefore, if the trends had been as large for the other outcomes, the corresponding differences according to BMI z-score subgroup would have been significant. A related weakness of the study was that due to loss of follow-up data, the number of participants per group was small in some cases.

9.2.10 Physical and sedentary activities

A drawback of the trial was the use of non-validated physical and sedentary activity questionnaires, which are a common problem in studies with children, due to the nature of self-reported physical activity data (Jakicic and Otto 2005). Ideally, accelerometers should be used, but at the time of the trial, these devices were extremely expensive (approximately £400 each), and their purchase not possible within the trial budget. Consequently, firm conclusions could not be drawn from physical and sedentary activity level data.

However, physical and sedentary behaviours are important targets in childhood weight management. In this trial, it appeared that significant reductions in sedentary activity levels at 3 and 6 months were not maintained at 12 months, suggesting compliance issues with the intervention strategies to reduce screen time. This was identified as a target area for improvement following the RCT, and more emphasis on reducing sedentary behaviours has been incorporated in current programmes. These strategies will be more thoroughly evaluated in the USA evaluation of the MEND intervention (Table 43).

9.2.11 Poor dietary data

Dietary data were poor, particularly at 12 months. This is a common finding in studies involving dietary assessment, as completion of food diaries is laborious and requires the cooperation of both parents and children to obtain an accurate record (Livingstone and Robson 2000; Burrows, Martin *et al*. 2010; Collins, Watson *et al*. 2010). A method that has improved compliance in alternative trials is the provision of financial incentives to motivate families to complete the food diaries. However, insufficient resources were available to implement this strategy.

9.2.12 Poor quality puberty data

Children completed the puberty questionnaires themselves with no parental oversight. Unfortunately, this resulted in several cases of missing data (blank entries) and errors (changes in puberty that were not physiologically possible during the study period), and therefore, the data collected were judged as inaccurate and could not be used.

Based on current experience and other studies in children 6 to 12 years of age, we concluded that the self-assessment method was unsuitable for reliable determination of the breast Tanner stage of obese girls or pubic hair stage of boys (Bonat, Pathomvanich *et al*. 2002). This meant that the results could not be adjusted for puberty, which would have been ideal.

In future studies, this limitation will need to be addressed, especially if older children are included. One option is to employ a trained physician to perform puberty assessments in private. However, this action may affect trial cost as well as recruitment and retention.

9.2.13 Selective measurement dropout

Selective measurement dropout was another serious drawback, which may have influenced the results. At 6 months, 68% of children in the intervention group and 80% of children in the control group were measured. Interestingly, 83% of children in the intervention group were assessed either at 6 or 12 months. All children who missed 6-month measurements were assessed at 12 months, and had reduced or maintained their BMI and waist circumference z-scores, indicating that measurement avoidance was not due to poor adherence and fear of being measured.

The current trial measurement dropout rates were lower than those in earlier studies, including that reported by a research team at Yale University (Savoye, Shaw *et al*. 2007) (40% and 47% dropout rates at 6 and 12 months follow-up), who performed a similar childhood obesity management intervention. Shalitin and colleagues (2009) reported significantly higher dropout rates, as only 47% of their samples were followed up 9 months after the intervention and 26% of children withdrew from the study (Shalitin, Ashkenazi-Hoffnung *et al*. 2009).

Several factors may have contributed to the non-attendance of measurement sessions by families. One apparent and critical reason in the present trial was that only one opportunity existed to attend measurement sessions held at a single weekend at each community site. Conversations with families revealed that many were unable to attend due to other commitments, such as church attendance or illness.

This limitation will be addressed in future studies by offering additional opportunities for families to attend measurement sessions as well as conducting measurements at homes.

9.2.14 Economic evaluation

Economic evaluation of interventions is important to establish their cost-effectiveness. It is crucial that public health interventions are both efficacious and cost-effective. Unfortunately, cost-effectiveness analysis was not performed during this trial. However, since completion of the trial, an economic evaluation has been conducted in the form of a PhD thesis. The author of this thesis conducted a cost-effectiveness analysis and economic modelling technique as the subject of a PhD thesis in 2011 (Techakehakij 2011). It was calculated that if the MEND intervention was made available to all overweight and obese children in England in 2010, the intervention and medical costs saved would be £551.2 million and £216 million, respectively. The incremental cost-effectiveness ratio (ICER) of the programme was estimated to be £1,668 per quality adjusted life year (QALY) gained. The NICE threshold for assessing cost-effectiveness for public health interventions is £20,000 - £30,000 (NICE 2009). An ICER below this threshold is considered a cost-effective public health intervention. It was concluded from this evaluation that MEND is a cost-effective intervention.

9.3 Conclusions

The first trial hypothesis was that the MEND programme would reduce waist circumference and BMI z-scores by clinically significant amounts at 6 and 12 months in a group of obese 8-12 year old children, thereby improving their weight status. Waist circumference and BMI z-scores were reduced at 6 and 12 months, but determination of their clinical significance was not possible due to insufficient supportive literature. Additional research may establish thresholds for clinical effectiveness following childhood weight management interventions. The secondary data analysis presented raises the issue regarding assessment of effectiveness solely through use of BMI z-score. It is my belief that benefits to children attending a childhood weight management intervention cannot be captured using a single outcome, such as BMI. A more holistic approach is required to measure success based on a wider range of measures, such as cardiovascular fitness and psychosocial wellbeing.

The second hypothesis was that levels of self-esteem would improve with body composition and fitness. The results demonstrated an improvement in self-esteem at 6 and 12 months. It was not possible to determine the specific factors causing this increase in self-esteem. Nevertheless, this positive finding illustrates that childhood weight management programmes can improve children's psychological well-being.

A third hypothesis, which was not part of the current PhD, but a question that arose during the trial execution, was whether outcomes achieved in the MEND trial are similar to those achieved when the MEND intervention was implemented under service-level conditions across the UK. An independent evaluation is in progress to determine the generalisability of the MEND intervention, and in particular, its effects on health inequalities. In view of the promising preliminary data, conclusive results are eagerly awaited.

A weakness of the MEND evaluation to date is the lack of qualitative evaluation. However, trials in Australia and the USA are utilising both quantitative and qualitative methodologies to gain a deeper understanding of the full effects. Research in Canada is focusing on the actual process of scale-up and spread using the MEND intervention as a case study. It is envisaged that the findings from this study will help to inform the underdeveloped field of scale-up and provide useful lessons for public health interventions.

This thesis aimed to document 11 years of dedication to the development and evaluation of an effective and scalable childhood weight management programme. By the beginning of the 21st century, strong data demonstrating the global rise in childhood obesity were present. However, limited published evidence for interventions aimed at preventing or reversing this serious condition was available. Moreover, there were no clinical guidelines detailing effective treatment modalities.

Clinical guidelines have subsequently been published. Organisations, such as NICE and SIGN, have produced guidance documents for the treatment of childhood obesity, which is a positive step. Unfortunately, these guidelines have generally not been utilised adequately by providers of services within the NHS. NICE clinical guidelines state that “the prevention and management of obesity should be a priority for all” (NICE 2006). However, the majority of obese children in the UK do not have access to a NICE/SIGN compliant childhood weight management intervention due to a number of factors, including the financial climate, possible discrimination against obese individuals, negative governmental attitude and belief that obesity is a personal responsibility, lack of implementation and support of policies, lack of effective commissioning skills in NHS Primary Care Trusts and Local Authorities, transition of public health services from the NHS to Local Authorities, and the sheer complexity of the obesity system.

Unacceptably, over 4 million overweight and obese children do not have access to services, as recommended by NICE and SIGN. Questions about the inequity of services remain unanswered. Prevention and treatment are both crucial for addressing the childhood obesity epidemic, but in order to prevent all children progressing to adult obesity, a more equitable balance between prevention and treatment is necessary.

Results presented in this thesis represent the first peer-reviewed RCT of a complex, family-based treatment for childhood obesity designed to be run by non-obesity specialists in community settings within the UK. The intervention, which proved effective in families from low SEC and minority ethnic backgrounds, conforms to national guidelines.

The aim from the outset was to provide a detailed account of the intervention as well as a standard report of the evaluation methods and findings, to facilitate replication studies and larger scale implementation. It is envisaged that these results will be presented in the context of an updated systematic review at the time of the next update.

It is expected that by following the recommended steps for the development, evaluation and implementation of a complex intervention, as presented in the current thesis, sufficient evidence can be accumulated to provide both commissioners of childhood weight management services and families with obese children a potentially effective intervention.

To the best of my knowledge**,** the published results describe the most thoroughly evaluated and widely implemented community-based, childhood weight management intervention internationally.

9.4 Recommendations – future directions

MEND is currently one of many international childhood weight management interventions showing promising results in an academic setting. As confirmed by systematic reviews, multicomponent lifestyle interventions can improve weight status and other indicators of physiological and psychological health in the short-term.

Future research should focus on establishing the elements and drivers essential for generalising interventions and explore the ability to scale up interventions. Without this capacity, many interventions will remain on the pages of scientific journals and never be disseminated.

The MEND evaluation and early stage implementation results suggest that childhood weight management interventions can be delivered effectively by a wide range of professionals. This is crucial, since health professionals, such as dietitians and psychologists, often do not have capacity to deliver such interventions, and their relatively high salaries increase the cost of interventions. It is also crucial in times of financial austerity that interventions are assessed on the basis of cost as well as clinical effectiveness. Funders of childhood weight management services should balance the costs of interventions with the benefits and not simply focus on cost alone. Further studies are required to explore the long-term effects of childhood weight management interventions that are essential to convince policy makers to invest in such services. A positive cost-benefit analysis relies on long-term data, which supports the business case for intervening early to prevent obese children developing into obese adults.

In the UK, the majority of childhood weight management interventions are funded through the NHS, but outcomes confirming effectiveness have never been published. One cause for concern is that for many families, engagement in a weight management intervention, may only occur once, and therefore, it is the responsibility of all providers of childhood weight management services to ensure that these interventions are effective and provide families with the best chance of success.

References

(1993). "Social Trends: A Publication of the Government Statistical Service."

(1995). "Efficacy and safety of lowering dietary intake of fat and cholesterol in children with elevated low-density lipoprotein cholesterol. The Dietary Intervention Study in Children (DISC). The Writing Group for the DISC Collaborative Research Group." Jama. **273** (18):1429-1435.

(2011). "Census Key Statistics." Available at: http://www.ons.gov.uk/ons/guide-method/census/2011/index.html.

(2011). "Tipping the scales: Childhood obesity in London." Available at http://www.london.gov.uk/publication/tipping-scales.

ADA (2006). "Position of the American Dietetic Association: individual-, family-, school-, and community-based interventions for pediatric overweight." J Am Diet Assoc. **106** (6): 925-945.

Aeberli, I., M. Gut-Knabenhans, et al. (2012). "A composite score combining waist circumference and body mass index more accurately predicts body fat percentage in 6- to 13-year-old children." Eur J Nutr. Feb 10 [Epub].

Aeberli, I., G. A. Spinas, et al. (2009). "Diet determines features of the metabolic syndrome in 6- to 14-year-old children." Int J Vitam Nutr Res. **79** (1): 14-23.

Agostoni, C., C. Braegger, et al. (2011). "Role of dietary factors and food habits in the development of childhood obesity: a commentary by the ESPGHAN Committee on Nutrition." J Pediatr Gastroenterol Nutr. **52** (6): 662-669.

Amed, S., D. Daneman, et al. (2010). "Type 2 diabetes in children and adolescents." Expert Rev Cardiovasc Ther. **8** (3): 393-406.

Andersen, L. F., H. Tomten, et al. (2003). "Validation of energy intake estimated from a food frequency questionnaire: a doubly labelled water study." Eur J Clin Nutr. **57** (2): 279-284.

Atlantis, E., E. H. Barnes, et al. (2006). "Efficacy of exercise for treating overweight in children and adolescents: a systematic review." Int J Obes (Lond). **30** (7): 1027-1040.

Bandini, L. G., A. Must, et al. (2003). "Longitudinal changes in the accuracy of reported energy intake in girls 10-15 years of age." Am J Clin Nutr. **78** (3): 480-484.

Bandini, L. G., D. A. Schoeller, et al. (1990). "Validity of reported energy intake in obese and nonobese adolescents." Am J Clin Nutr. **52** (3): 421-425.

Bandura, A. (1986). "Social Foundations of Thought and Action: A Social Cognitive Theory."

Banks, J., J. Williams, et al. (2012). "Is healthy eating for obese children necessarily more costly for families?" Br J Gen Pract. **62** (594): e1-5.

Baranowski, T. and S. B. Domel (1994). "A cognitive model of children's reporting of food intake." Am J Clin Nutr. **59** (Suppl 1): 212S-217S.

Barlow, S. E. (2007). "Expert committee recommendations regarding the prevention, assessment, and treatment of child and adolescent overweight and obesity: summary report." Pediatrics. **120** (Suppl 4): S164-192.

Barlow, S. E. and W. H. Dietz (1998). "Obesity evaluation and treatment: Expert Committee recommendations. The Maternal and Child Health Bureau, Health Resources and Services Administration and the Department of Health and Human Services." Pediatrics. **102** (3): E29.

Barton, M. (2010). "Screening for obesity in children and adolescents: US Preventive Services Task Force recommendation statement." Pediatrics. **125** (2): 361-367.

Batch, J. A. and L. A. Baur (2005). "Management and prevention of obesity and its complications in children and adolescents." Med J Aust. **182** (3): 130-135.

Baur, L. A. and J. O'Connor (2004). "Special considerations in childhood and adolescent obesity." Clin Dermatol. **22** (4): 338-344.

Bautista-Castano, I., J. Doreste, et al. (2004). "Effectiveness of interventions in the prevention of childhood obesity." Eur J Epidemiol. **19** (7): 617-622.

Beaglehole, R., R. Bonita, et al. (2003). "Basic Epidemiology. WHO, Geneva." 85-88.

Belanger, M., K. Gray-Donald, et al. (2009). "When adolescents drop the ball: sustainability of physical activity in youth." Am J Prev Med. **37** (1): 41-49.

Bell-Anderson, K. S. and J. M. Bryson (2004). "Leptin as a potential treatment for obesity: progress to date." Treat Endocrinol. **3** (1): 11-18.

Bellisle, F. and A. Drewnowski (2007). "Intense sweeteners, energy intake and the control of body weight." Eur J Clin Nutr. **61** (6): 691-700.

Ben Ounis, O., M. Elloumi, et al. (2008). "Effects of two-month physical-endurance and diet-restriction programmes on lipid profiles and insulin resistance in obese adolescent boys." Diabetes Metab. **34** (6 Pt 1): 595-600.

Benfield, L. L., K. R. Fox, et al. (2008). "Magnetic resonance imaging of abdominal adiposity in a large cohort of British children." Int J Obes (Lond). **32** (1): 91-99.

Berenson, G. S., S. R. Srinivasan, et al. (1998). "Association between multiple cardiovascular risk factors and atherosclerosis in children and young adults. The Bogalusa Heart Study." N Engl J Med. **338** (23): 1650-1656.

Berkel, L. A., W. S. Poston, et al. (2005). "Behavioral interventions for obesity." J Am Diet Assoc. **105** (5 Suppl 1): S35-43.

Bibbins-Domingo, K., P. Coxson, et al. (2007). "Adolescent overweight and future adult coronary heart disease." N Engl J Med. **357** (23): 2371-2379.

Biro, F. M. and M. Wien (2010). "Childhood obesity and adult morbidities." Am J Clin Nutr. **91**(5): 1499S-1505S.

Bonat, S., A. Pathomvanich, et al. (2002). "Self-assessment of pubertal stage in overweight children." Pediatrics. **110**(4): 743-747.

Bonet Serra, B., A. Quintanar Rioja, et al. (2007). "Group therapy for the treatment of obesity in children and adolescents." An Pediatr (Barc). **67** (1): 51-56.

Boonpleng, W., C. G. Park, et al. (2012). "Timing of adiposity rebound: a step toward preventing obesity." Pediatr Nurs. **38** (1): 37-42.

Borys, J. M., Y. Le Bodo, et al. (2012). "EPODE approach for childhood obesity prevention: methods, progress and international development." Obes Rev. **13** (4): 299-315.

Bosy-Westphal, A., C. A. Booke, et al. (2010). "Measurement site for waist circumference affects its accuracy as an index of visceral and abdominal subcutaneous fat in a Caucasian population." J Nutr. **140** (5): 954-961.

Boutelle, K. N., G. Cafri, et al. (2011). "Parent-only treatment for childhood obesity: a randomized controlled trial." Obesity. **19** (3): 574-580.

Braet, C. and K. Wydhooge (2000). "Dietary restraint in normal weight and overweight children. A cross-sectional study." Int J Obes Relat Metab Disord. **24** (3): 314-318.

Brambilla, P., G. Bedogni, et al. (2006). "Crossvalidation of anthropometry against magnetic resonance imaging for the assessment of visceral and subcutaneous adipose tissue in children." Int J Obes (Lond). **30** (1): 23-30.

Branscum, P. and M. Sharma (2012). "After-school based obesity prevention interventions: a comprehensive review of the literature." Int J Environ Res Public Health. **9** (4): 1438-1457.

Bridges, S. and J. Thompson (2010). "HSE: Children's BMI, overweight and obesity."

Buijzen, M., J. Schuurman, et al. (2008). "Associations between children's television advertising exposure and their food consumption patterns: a household diary-survey study." Appetite. **50** (2-3): 231-239.

Burrows, T. L., R. J. Martin, et al. (2010). "A systematic review of the validity of dietary assessment methods in children when compared with the method of doubly labeled water." J Am Diet Assoc. **110** (10): 1501-1510.

Campbell, M. W., J. Williams, et al. (2011). "Is the adiposity rebound a rebound in adiposity?" Int J Pediatr Obes. **6** (2-2): e207-215.

Chanoine, J. P., S. Hampl, et al. (2005). "Effect of orlistat on weight and body composition in obese adolescents: a randomized controlled trial." JAMA. **293** (23): 2873-2883.

Chiavaroli, V., C. Giannini, et al. (2012). "Weight Loss in Obese Prepubertal Children: The Influence of Insulin Resistance." Endocr Res. Aug 22 [Epub].

Chomitz, V. R., R. J. McGowan, et al. (2010). "Healthy Living Cambridge Kids: a community-based participatory effort to promote healthy weight and fitness." Obesity (Silver Spring). **18** (Suppl 1): S45-53.

Christiansen, T., J. M. Bruun, et al. (2007). "Weight loss maintenance in severely obese adults after an intensive lifestyle intervention: 2- to 4-year follow-up." Obesity (Silver Spring). **15** (2): 413-420.

Cleland, V. J., K. Ball, et al. (2009). "Socioeconomic position and the tracking of physical activity and cardiorespiratory fitness from childhood to adulthood." Am J Epidemiol. **170** (9): 1069-1077.

Cole, K., J. Waldrop, et al. (2006). "An integrative research review: effective school-based childhood overweight interventions." J Spec Pediatr Nurs. **11** (3): 166-177.

Cole, T. J., M. C. Bellizzi, et al. (2000). "Establishing a standard definition for child overweight and obesity worldwide: international survey." BMJ. **320** (7244): 1240-1243.

Cole, T. J., J. V. Freeman, et al. (1995). "Body mass index reference curves for the UK, 1990." Arch Dis Child. **73** (1): 25-29.

Cole, T. J., M. S. Faith, et al. (2005). "What is the best measure of adiposity change in growing children: BMI, BMI %, BMI z-score or BMI centile?" Eur J Clin Nutr **59**(3): 419-425.

Collins, C. E., J. Warren, et al. (2006). "Measuring effectiveness of dietetic interventions in child obesity: a systematic review of randomized trials." Arch Pediatr Adolesc Med. **160** (9): 906-922.

Collins, C. E., J. Watson, et al. (2010). "Measuring dietary intake in children and adolescents in the context of overweight and obesity." Int J Obes (Lond). **34** (7): 1103-1115.

Collins, J. (2007). "Indicators, trends, and recommendations for living a longer, healthier life." J Am Coll Radiol. **4** (11): 832-840.

COMA (1991). "Dietary Reference Values for Food Energy and Nutrients for the United Kingdom."

Cook, S., M. Weitzman, et al. (2003). "Prevalence of a metabolic syndrome phenotype in adolescents: findings from the third National Health and Nutrition Examination Survey, 1988-1994." Arch Pediatr Adolesc Med. **157** (8): 821-827.

Cooper, T. V., L. M. Klesges, et al. (2006). "An assessment of obese and non obese girls' metabolic rate during television viewing, reading, and resting." Eat Behav. **7** (2): 105-114.

Coppinger, T., Y. M. Jeanes, et al. (2012). "Body mass, frequency of eating and breakfast consumption in 9-13-year-olds." J Hum Nutr Diet. **25** (1): 43-49.

Cox, R., H. Skouteris, et al. (2012). "Television viewing, television content, food intake, physical activity and body mass index: a cross-sectional study of preschool children aged 2-6 years." Health Promot J Austr. **23** (1): 58-62.

Craig, P., P. Dieppe, et al. (2008). "Developing and evaluating complex interventions: the new Medical Research Council guidance." BMJ. **29** (337).

Craigie, A. M., A. A. Lake, et al. (2011). "Tracking of obesity-related behaviours from childhood to adulthood: A systematic review." Maturitas. **70** (3): 266-284.

Croker, H., R. M. Viner, et al. (2012). "Family-based behavioural treatment of childhood obesity in a UK National Health Service setting: randomized controlled trial." Int J Obes. **36** (1): 16-26.

Cummings, D. M., S. Henes, et al. (2008). "Insulin resistance status: predicting weight response in overweight children." Arch Pediatr Adolesc Med. **162** (8): 764-768.

Cunningham, C. E., R. Bremner, et al. (1995). "Large group community-based parenting programs for families of preschoolers at risk for disruptive behaviour disorders: utilization, cost effectiveness, and outcome." J Child Psychol Psychiatry. **36** (7): 1141-1159.

Daniels, S. R., D. K. Arnett, et al. (2005). "Overweight in children and adolescents: pathophysiology, consequences, prevention, and treatment." Circulation. **111** (15): 1999-2012.

Das, U. N. (2008). "Perinatal nutrition and obesity." Br J Nutr. **99** (6): 1391-1392.

Daviglus, M. L., K. Liu, et al. (2004). "Relation of body mass index in young adulthood and middle age to Medicare expenditures in older age." JAMA. **292** (22): 2743-2749.

De Craemer, M., E. De Decker, et al. (2012). "Correlates of energy balance-related behaviours in preschool children: a systematic review." Obes Rev.**13** (Suppl 1): 13-28.

de Koning, L., A. T. Merchant, et al. (2007). "Waist circumference and waist-to-hip ratio as predictors of cardiovascular events: meta-regression analysis of prospective studies." Eur Heart J. **28** (7): 850-856.

de Onis, M., M. Blossner, et al. (2010). "Global prevalence and trends of overweight and obesity among preschool children." Am J Clin Nutr. **92** (5): 1257-1264.

de Onis, M., A. W. Onyango, et al. (2007). "Development of a WHO growth reference for school-aged children and adolescents." Bull World Health Organ. **85** (9): 660-667.

de Ruyter, J. C., M. R. Olthof, et al. (2012). "A trial of sugar-free or sugar-sweetened beverages and body weight in children." N Engl J Med. **367** (15): 1397-1406.

DeMattia, L., L. Lemont, et al. (2007). "Do interventions to limit sedentary behaviours change behaviour and reduce childhood obesity? A critical review of the literature." Obes Rev. **8** (1): 69-81.

Denzer, C., E. Reithofer, et al. (2004). "The outcome of childhood obesity management depends highly upon patient compliance." Eur J Pediatr. **163** (2): 99-104.

Despres, J. P. (2007). "Cardiovascular disease under the influence of excess visceral fat." Crit Pathw Cardiol. **6** (2): 51-59.

DH (2011). "Department of Health in association with the Welsh Government, the Scottish Government and the Food Standards Agency in Northern Ireland: The eatwell plate resources."

DH (2011). "Department of Health: National Child Measurement Programme: England, 2010/11 school year."

DH (2011). "Healthy Weight, Healthy lives: A Cross-Government strategy for England. Available at: http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publichealth/Healthimprovement/Obesity/HealthyWeight/index.htm."

DH (2011). "UK physical activity guidelines. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_127931."

Diethelm, K., N. Jankovic, et al. (2012). "Food intake of European adolescents in the light of different food-based dietary guidelines: results of the HELENA (Healthy Lifestyle in Europe by Nutrition in Adolescence) Study." Public Health Nutr. **15** (3): 386-398.

Digenio, A. G., J. P. Mancuso, et al. (2009). "Comparison of methods for delivering a lifestyle modification program for obese patients: a randomized trial." Ann Intern Med. **150** (4): 255-262.

Dollman, J., K. Norton, et al. (2005). "Evidence for secular trends in children's physical activity behaviour." Br J Sports Med. **39** (12): 892-897; discussion 897.

Doolen, J., P. T. Alpert, et al. (2009). "Parental disconnect between perceived and actual weight status of children: a metasynthesis of the current research." J Am Acad Nurse Pract. **21**(3): 160-166.

Dubois, L., A. Farmer, et al. (2007). "Regular sugar-sweetened beverage consumption between meals increases risk of overweight among preschool-aged children." J Am Diet Assoc. **107** (6): 924-934.

Dwyer, T., C. G. Magnussen, et al. (2009). "Decline in physical fitness from childhood to adulthood associated with increased obesity and insulin resistance in adults." Diabetes Care. **32** (4): 683-687.

Eisenberg, M. E., D. Neumark-Sztainer, et al. (2003). "Associations of weight-based teasing and emotional well-being among adolescents." Arch Pediatr Adolesc Med. **157** (8): 733-738.

Ekelund, U., G. Tomkinson, et al. (2011). "What proportion of youth are physically active? Measurement issues, levels and recent time trends." Br J Sports Med. **45** (11): 859-865.

El-Sayed, A. M., P. Scarborough, et al. (2011). "Ethnic inequalities in obesity among children and adults in the UK: a systematic review of the literature." Obes Rev. **12** (5): 516-34.

El-Sayed, A. M., P. Scarborough, et al. (2012). "Socioeconomic Inequalities in Childhood Obesity in the United Kingdom: A Systematic Review of the Literature." Obes Facts. **5** (5): 671-692.

Elliott, S. A., H. Truby, et al. (2011). "Associations of body mass index and waist circumference with: energy intake and percentage energy from macronutrients, in a cohort of Australian children." Nutr J. **10**: 58.

Ellis, K. J. (2000). "Human body composition: in vivo methods." Physiol Rev. **80** (2): 649-680.

Epstein, L. H. (1996). "Family-based behavioural intervention for obese children." Int J Obes Relat Metab Disord. **20** (1): S14-21.

Epstein, L. H., M. D. Myers, et al. (1998). "Treatment of pediatric obesity." Pediatrics. **101** (3 Pt 2): 554-570.

Epstein, L. H., R. A. Paluch, et al. (2008). "Increasing healthy eating vs. reducing high energy-dense foods to treat pediatric obesity." Obesity (Silver Spring). **16** (2): 318-326.

Epstein, L. H., R. A. Paluch, et al. (2000). "Decreasing sedentary behaviors in treating pediatric obesity." Arch Pediatr Adolesc Med. **154** (3): 220-226.

Epstein, L. H., R. A. Paluch, et al. (2000). "Problem solving in the treatment of childhood obesity." J Consult Clin Psychol . **8** (4): 717-721.

Epstein, L. H., R. A. Paluch, et al. (2007). "Family-based obesity treatment, then and now: twenty-five years of pediatric obesity treatment." Health Psychol. **26**(4): 381-391.

Epstein, L. H., A. Valoski, et al. (1994). "Ten-year outcomes of behavioral family-based treatment for childhood obesity." Health Psychol. **13** (5): 373-383.

Epstein, L. H. and R. R. Wing (1987). "Behavioral treatment of childhood obesity." Psychol Bull. **101** (3): 331-342.

Epstein, L. H., R. R. Wing, et al. (1985). "Effect of diet and controlled exercise on weight loss in obese children." J Pediatr. **107** (3): 358-361.

Fagg, J., T. J. Cole, et al. (2012). "From trial to population: effect of a weight management intervention on body mass index when scaled up." J Epidemiol Community Health. **66**: A2-A3.

Fagg, J. and C. Law (2012). "Does scaling up a family-based community intervention for childhood overweight and obesity impact socio-economic inequalities in health?" Obes Facts. **5** (Suppl 1): 1-280.

Farpour-Lambert, N. J., Y. Aggoun, et al. (2009). "Physical activity reduces systemic blood pressure and improves early markers of atherosclerosis in pre-pubertal obese children." J Am Coll Cardiol. **54** (25): 2396-2406.

FDA (2010). "Meridia (sibutramine): Market Withdrawal Due to Risk of Serious Cardiovascular Events. Available at: http://www.fda.gov/safety/medwatch/ safetyinformation/safetyalertsforhumanmedicalproducts/ucm228830.htm."

Finegood, D. T., T. D. Merth, et al. (2010). "Implications of the foresight obesity system map for solutions to childhood obesity." Obesity. **18** (1): S13-16.

Fisher, J. O., R. K. Johnson, et al. (2000). "Influence of body composition on the accuracy of reported energy intake in children." Obes Res. **8** (8): 597-603.

Fitzgibbon, M. L. and B. M. Beech (2009). "The role of culture in the context of school-based BMI screening." Pediatrics. **124** (Suppl 1): S50-62.

Flodmark, C. E., T. Ohlsson, et al. (1993). "Prevention of progression to severe obesity in a group of obese schoolchildren treated with family therapy." Pediatrics. **91** (5): 880-884.

Flodmark, C. E., T. Sveger, et al. (1994). "Waist measurement correlates to a potentially atherogenic lipoprotein profile in obese 12-14-year-old children." Acta Paediatr. **83** (9): 941-945.

Flynn, M. A., D. A. McNeil, et al. (2006). Reducing obesity and related chronic disease risk in children and youth: a synthesis of evidence with 'best practice' recommendations. Obes Rev. **7** (Suppl 1)**:** 7-66.

Ford, A. L., C. Bergh, et al. (2009). "Treatment of childhood obesity by retraining eating behaviour: randomised controlled trial." BMJ. **5** (340).

Ford, A. L., L. P. Hunt, et al. (2010). "What reduction in BMI SDS is required in obese adolescents to improve body composition and cardiometabolic health?" Arch Dis Child. **95** (4): 256-261.

Francis, K. and R. Feinstein (1991). "A simple height-specific and rate-specific step test for children." South Med J. **84** (2): 169-174.

Frank, L. and S. Kavage (2009). "A national plan for physical activity: the enabling role of the built environment." J Phys Act Health. **6** (Suppl 2): S186-195.

Freedman, D. S., W. H. Dietz, et al. (1999). "The relation of overweight to cardiovascular risk factors among children and adolescents: the Bogalusa Heart Study." Pediatrics. **103** (6 Pt 1): 1175-1182.

Freedman, D. S., M. K. Serdula, et al. (1999). "Relation of circumferences and skinfold thicknesses to lipid and insulin concentrations in children and adolescents: the Bogalusa Heart Study." Am J Clin Nutr. **69** (2): 308-317.

Freedman, D. S., J. Wang, et al. (2007). "The prediction of body fatness by BMI and skinfold thicknesses among children and adolescents." Ann Hum Biol. **34** (2): 183-194.

Froberg, K. and L. B. Andersen (2005). "Mini review: physical activity and fitness and its relations to cardiovascular disease risk factors in children." Int J Obes (Lond). **29** (Suppl 2): S34-39.

Galcheva, S. V., V. M. Iotova, et al. (2009). "Waist circumference percentile curves for Bulgarian children and adolescents aged 6-18 years." Int J Pediatr Obes. **4** (4): 381-388.

Garipagaoglu, M., Y. Sahip, et al. (2009). "Family-based group treatment versus individual treatment in the management of childhood obesity: randomized, prospective clinical trial." Eur J Pediatr. **168** (9): 1091-1099.

Gately, P. J., C. B. Cooke, et al. (2000). "The effects of a children's summer camp programme on weight loss, with a 10 month follow-up." Int J Obes Relat Metab Disord. **24** (11): 1445-1452.

Gibson, L. J., J. Peto, et al. (2006). "Lack of evidence on diets for obesity for children: a systematic review." Int J Epidemiol. **35** (6): 1544-1552.

Gibson, S. (2010). "Trends in energy and sugar intakes and body mass index between 1983 and 1997 among children in Great Britain." J Hum Nutr Diet. **23** (4): 371-381.

Glasser, N., K. Zellner, et al. (2011). "Validity of body mass index and waist circumference to detect excess fat mass in children aged 7-14 years." Eur J Clin Nutr. **65** (2): 151-159.

Glenny, A. M., S. O'Meara, et al. (1997). "The treatment and prevention of obesity: a systematic review of the literature." Int J Obes Relat Metab Disord. **21** (9): 715-737.

Golan, M. and S. Crow (2004). "Targeting parents exclusively in the treatment of childhood obesity: long-term results." Obes Res. **12** (2): 357-361.

Golan, M., V. Kaufman, et al. (2006). "Childhood obesity treatment: targeting parents exclusively v. parents and children." Br J Nutr. **95** (5): 1008-1015.

Golan, M., A. Weizman, et al. (1999). "Impact of treatment for childhood obesity on parental risk factors for cardiovascular disease." Prev Med. **29** (6 Pt 1): 519-526.

Goldfield, G. S., L. H. Epstein, et al. (2001). "Cost-effectiveness of group and mixed family-based treatment for childhood obesity." Int J Obes Relat Metab Disord. **25** (12): 1843-1849.

Golley, R. K., A. M. Magarey, et al. (2007). "Twelve-month effectiveness of a parent-led, family-focused weight-management program for prepubertal children: a randomized, controlled trial." Pediatrics. **119** (3): 517-525.

Goran, M. I. and M. S. Treuth (2001). "Energy expenditure, physical activity, and obesity in children." Pediatr Clin North Am. **48** (4): 931-953.

Gortmaker, S. L., A. Must, et al. (1993). "Social and economic consequences of overweight in adolescence and young adulthood." N Engl J Med. **329** (14): 1008-1012.

Gortmaker, S. L., B. A. Swinburn, et al. (2011). "Changing the future of obesity: science, policy, and action." Lancet. **378** (9793): 838-847.

Griffiths, L. J., T. J. Parsons, et al. (2010). "Self-esteem and quality of life in obese children and adolescents: a systematic review." Int J Pediatr Obes. **5** (4): 282-304.

Guinhouya, B. C. (2012). "Physical activity in the prevention of childhood obesity." Paediatr Perinat Epidemiol. **26** (5): 438-447.

Guran, T. and A. Bereket (2011). "International epidemic of childhood obesity and television viewing." Minerva Pediatr. **63** (6): 483-490.

Gutin, B., P. Barbeau, et al. (2002). "Effects of exercise intensity on cardiovascular fitness, total body composition, and visceral adiposity of obese adolescents." Am J Clin Nutr. **75** (5): 818-826.

Halford, J. C., E. J. Boyland, et al. (2008). "Beyond-brand effect of television food advertisements on food choice in children: the effects of weight status." Public Health Nutr. **11** (9): 897-904.

Han, T. S., P. Richmond, et al. (1997). "Waist circumference reduction and cardiovascular benefits during weight loss in women." Int J Obes Relat Metab Disord. **21** (2): 127-134.

Haroun, D., S. J. Taylor, et al. (2010). "Validation of bioelectrical impedance analysis in adolescents across different ethnic groups." Obesity (Silver Spring). **18** (6): 1252-1259.

Harris, K. C., L. K. Kuramoto, et al. (2009). "Effect of school-based physical activity interventions on body mass index in children: a meta-analysis." CMAJ. **180** (7): 719-726.

Hart, C. N., E. Jelalian, et al. (2010). "Early patterns of food intake in an adolescent weight loss trial as predictors of BMI change." Eat Behav. **11**(4): 217-222.

Harter, S. (1985). "Harter's Self-perception Profile for Children."

Herman, K. M., C. L. Craig, et al. (2009). "Tracking of obesity and physical activity from childhood to adulthood: the Physical Activity Longitudinal Study." Int J Pediatr Obes. **4** (4): 281-288.

Heyward, V. H. (1998). "Practical body composition assessment for children, adults, and older adults." Int J Sport Nutr. **8** (3): 285-307.

Hoare, P. and L. Cosgrove (1998). "Eating habits, body-esteem and self-esteem in Scottish children and adolescents." J Psychosom Res. **45** (5): 425-431.

Hoare, P., R. Elton, et al. (1993). "The modification and standardisation of the Harter self-esteem questionnaire with Scottish school children." Eur Child Adolesc Psychiatry. **2** (1): 19-33.

Holmes, B., K. Dick, et al. (2008). "A comparison of four dietary assessment methods in materially deprived households in England." Public Health Nutr. **11** (5): 444-456.

Hosking, J., B. S. Metcalf, et al. (2006). "Validation of foot-to-foot bioelectrical impedance analysis with dual-energy X-ray absorptiometry in the assessment of body composition in young children: the Early Bird cohort." Br J Nutr. **96** (6): 1163-1168.

HSE (2006). "Health Survey for England 2004: Health of Ethnic Minorities - Full Report."

HSE (2006). "Health Survey for England 2006: Obesity and other risk factors in children."

HSE (2008). "Physical activity and fitness: Summary of key findings."

Hughes, A. R., R. McLaughlin, et al. (2007). "The B'Active programme for overweight primary school children in Glasgow: determining the prevalence of overweight and obesity and piloting an activity intervention." Br J Nutr. **97** (1): 204-209.

Hughes, A. R., L. Stewart, et al. (2008). "Randomized, controlled trial of a best-practice individualized behavioral program for treatment of childhood overweight: Scottish Childhood Overweight Treatment Trial (SCOTT)." Pediatrics. **121** (3): e539-546.

Hunt, L. P., A. Ford, et al. (2007). "Clinical measures of adiposity and percentage fat loss: which measure most accurately reflects fat loss and what should we aim for?" Arch Dis Child. **92** (5): 399-403.

Huybrechts, I., C. Vereecken, et al. (2010). "Reproducibility and validity of a diet quality index for children assessed using a FFQ." Br J Nutr. **104** (1): 135-144.

Jackson, D. M., K. Djafarian, et al. (2009). "Increased television viewing is associated with elevated body fatness but not with lower total energy expenditure in children." Am J Clin Nutr. **89** (4): 1031-1036.

Jackson, L. V., N. K. Thalange, et al. (2007). "Blood pressure centiles for Great Britain." Arch Dis Child. **92** (4): 298-303.

Jain, A., S. N. Sherman, et al. (2001). "Why don’t low-income mothers worry about their preschoolers being overweight?" Pediatrics. **107** (5): 1138-1146.

Jakicic, J. M. and A. D. Otto (2005). "Physical activity considerations for the treatment and prevention of obesity." Am J Clin Nutr. **82** (1 Suppl): 226S-229S.

Jannsen, I. L., A (2010). "Systematic review of the health benefits of physical activity and fitness in school-aged children and youth." Int J Behav Nutr Phys Act. **7** (40): 1-16.

Janssen, I., W. M. Craig, et al. (2004). "Associations between overweight and obesity with bullying behaviors in school-aged children." Pediatrics. **113** (5): 1187-1194.

Janssen, I., P. T. Katzmarzyk, et al. (2004). "Waist circumference and not body mass index explains obesity-related health risk." Am J Clin Nutr. **79** (3): 379-384.

Janssen, I., P. T. Katzmarzyk, et al. (2005). "Combined influence of body mass index and waist circumference on coronary artery disease risk factors among children and adolescents." Pediatrics. **115** (6): 1623-1630.

Janz, K. F., S. Kwon, et al. (2009). "Sustained effect of early physical activity on body fat mass in older children." Am J Prev Med. **37** (1): 35-40.

Jennings, A., A. Welch, et al. (2011). "Diet quality is independently associated with weight status in children aged 9-10 years." J Nutr. **141** (3): 453-459.

Johnson, L., A. P. Mander, et al. (2008). "A prospective analysis of dietary energy density at age 5 and 7 years and fatness at 9 years among UK children." Int J Obes (Lond). **32** (4): 586-593.

Kalarchian, M. A., M. D. Levine, et al. (2009). "Family-based treatment of severe pediatric obesity: randomized, controlled trial." Pediatrics. **124** (4): 1060-1068.

Kalavainen, M. P., M. O. Korppi, et al. (2007). "Clinical efficacy of group-based treatment for childhood obesity compared with routinely given individual counseling." Int J Obes (Lond). **31** (10): 1500-1508.

Kamath, C. C., K. S. Vickers, et al. (2008). "Clinical review: behavioral interventions to prevent childhood obesity: a systematic review and metaanalyses of randomized trials." J Clin Endocrinol Metab. **93** (12): 4606-4615.

Keane, E., R. Layte, et al. (2012). "Measured parental weight status and familial socio-economic status correlates with childhood overweight and obesity at age 9." PLoS One. **7** (8): e43503.

Keast, D. R., T. A. Nicklas, et al. (2010). "Snacking is associated with reduced risk of overweight and reduced abdominal obesity in adolescents: National Health and Nutrition Examination Survey (NHANES) 1999-2004." Am J Clin Nutr. **92** (2): 428-435.

Kelishadi, R., M. Malekahmadi, et al. (2012). "Can a trial of motivational lifestyle counseling be effective for controlling childhood obesity and the associated cardiometabolic risk factors?" Pediatr Neonatol. **53** (2): 90-97.

Kelly, C., L. A. Ricciardelli, et al. (1999). "Problem eating attitudes and behaviors in young children." Int J Eat Disord. **25** (3): 281-286.

Khambalia, A. Z., S. Dickinson, et al. (2012). "A synthesis of existing systematic reviews and meta-analyses of school-based behavioural interventions for controlling and preventing obesity." Obes Rev. **13** (3): 214-233.

Kim, S. Y., J. L. England, et al. (2011). "Gestational diabetes mellitus and risk of childhood overweight and obesity in offspring: a systematic review." Exp Diabetes Res. 2011: 541308.

Kirk, S., M. Zeller, et al. (2005). "The relationship of health outcomes to improvement in BMI in children and adolescents." Obes Res. **13** (5): 876-882.

Klein, D. J., E. M. Cottingham, et al. (2006). "A randomized, double-blind, placebo-controlled trial of metformin treatment of weight gain associated with initiation of atypical antipsychotic therapy in children and adolescents." Am J Psychiatry. **163** (12): 2072-2079.

Klesges, L. M., N. A. Williams, et al. (2012). "External validity reporting in behavioral treatment of childhood obesity: a systematic review." Am J Prev Med. **42** (2): 185-192.

Klesges, R. C., M. L. Shelton, et al. (1993). "Effects of television on metabolic rate: potential implications for childhood obesity." Pediatrics. **91** (2): 281-286.

Kobayashi, T., M. Kamimura, et al. (2011). "Reproducibility and validity of the food frequency questionnaire for estimating habitual dietary intake in children and adolescents." Nutr Ju. **10**: 27.

Kolsgaard, M. L., G. Joner, et al. (2012). "Reduction in BMI z-score and improvement in cardiometabolic risk factors in obese children and adolescents. The Oslo adiposity intervention study - a hospital/public health nurse combined treatment." BMC Pediatr. **12** (77): 1471-2431.

Koopman, H. (1992). "Assessment of sodium and potassium intake by 24-hour recall." Br J Gen Practu. **42** (355): 77-78.

Kopelman, P., S. A. Jebb, et al (2007). Executive summary: Foresight 'Tackling Obesities: Future Choices' project, Obes Rev. Mar;8 Suppl 1:vi-ix.

Koster, A., M. F. Leitzmann, et al. (2008). "Waist circumference and mortality." Am J Epidemiol. **167** (12): 1465-1475.

Krekoukia, M., G. P. Nassis, et al. (2007). "Elevated total and central adiposity and low physical activity are associated with insulin resistance in children." Metabolism. **56** (2): 206-213.

Kuczmarski, R. J., C. L. Ogden, et al. (2002). "2000 CDC Growth Charts for the United States: methods and development." Vital Health Stat 11. (246): 1-190.

l'Allemand-Jander, D. (2010). "Clinical diagnosis of metabolic and cardiovascular risks in overweight children: early development of chronic diseases in the obese child." Int J Obes (Lond). **34** (Suppl 2): S32-36.

Lambert, J., C. Agostoni, et al. (2004). "Dietary intake and nutritional status of children and adolescents in Europe." Br J Nutr. **92** (Suppl 2): S147-211.

Lambiase, M. (2009). "Treating pediatric overweight through reductions in sedentary behavior: a review of the literature." J Pediatr Health Care. **23** (1): 29-36.

Lamichhane, A. P., R. Puett, et al. (2012). "Associations of built food environment with body mass index and waist circumference among youth with diabetes." Int J Behav Nutr Phys Act. **9**: 81.

Law, C. (2010) "A population-level evaluation of a family-based community intervention for childhood overweight and obesity." Protocol available at: http://www.phr.nihr.ac.uk/funded_projects/09_3005_05.asp.

Lazaar, N., J. Aucouturier, et al. (2007). "Effect of physical activity intervention on body composition in young children: influence of body mass index status and gender." Acta Paediatr. **96** (9): 1315-1320.

Leary, M. R., A. L. Haupt, et al. (1998). "Calibrating the sociometer: the relationship between interpersonal appraisals and state self-esteem." J Pers Soc Psychol. **74** (5): 1290-1299.

Leary, M. R., E. B. Tate, et al. (2007). "Self-compassion and reactions to unpleasant self-relevant events: the implications of treating oneself kindly." J Pers Soc Psychol. **92** (5): 887-904.

Lee, S. Y. and D. Gallagher (2008). "Assessment methods in human body composition." Curr Opin Clin Nutr Metab Care. **11** (5): 566-572.

Leibowitz, K. L., R. H. Moore, et al. (2009). "Cardiovascular disease risk factor (CVDRF) associated waist circumference patterns in obese-prone children." Int J Pediatr Obes. **4** (3): 150-159.

Levine, J. A. (2004). "Nonexercise activity thermogenesis (NEAT): environment and biology." Am J Physiol Endocrinol Metab. **286** (5): E675-685.

Li, M., S. Li, et al. (2008). "A systematic review of school-based intervention studies for the prevention or reduction of excess weight among Chinese children and adolescents." Obes Rev. **9** (6): 548-559.

Livingstone, M. B., A. M. Prentice, et al. (1990). "Accuracy of weighed dietary records in studies of diet and health." BMJ. **300** (6726): 708-712.

Livingstone, M. B. and P. J. Robson (2000). "Measurement of dietary intake in children." Proc Nutr Soc. **59** (2): 279-293.

Livingstone, M. B., P. J. Robson, et al. (2003). "An evaluation of the sensitivity and specificity of energy expenditure measured by heart rate and the Goldberg cut-off for energy intake: basal metabolic rate for identifying mis-reporting of energy intake by adults and children: a retrospective analysis." Eur J Clin Nutr. **57** (3): 455-463.

Livingstone, M. B., P. J. Robson, et al. (2004). "Issues in dietary intake assessment of children and adolescents." Br J Nutr. **92** (Suppl 2): S213-222.

Lloyd, L. J., S. C. Langley-Evans, et al. (2010). "Childhood obesity and adult cardiovascular disease risk: a systematic review." Int J Obes (Lond). **34** (1): 18-28.

Lloyd, L. J., S. C. Langley-Evans, et al. (2012). "Childhood obesity and risk of the adult metabolic syndrome: a systematic review." Int J Obes (Lond). **36** (1): 1-11.

Lobstein, T., L. Baur, et al. (2004). "Obesity in children and young people: a crisis in public health." Obes Rev. **5** (Suppl 1): 4-104.

Looney, S. M. and H. A. Raynor (2012). "Are changes in consumption of "healthy" foods related to changes in consumption of "unhealthy" foods during pediatric obesity treatment?" Int J Environ Res Public Health. **9** (4): 1368-1378.

Lorenc, T., M. Petticrew, et al. (2012). "What types of interventions generate inequalities? Evidence from systematic reviews." J Epidemiol Community Health. Aug. 8 [Epub].

Lowry, K. W., B. J. Sallinen, et al. (2007). "The effects of weight management programs on self-esteem in pediatric overweight populations." J Pediatr Psychol. **32** (10): 1179-1195.

Lumeng, J. C., V. P. Castle, et al. (2010). "The role of pediatricians in the coordinated national effort to address childhood obesity." Pediatrics. **126** (3): 574-575.

Maffeis, C. (2000). "Aetiology of overweight and obesity in children and adolescents." Eur J Pediatr. **159** (Suppl 1): S35-44.

Food and Nutrition Board; Institute of Medicine (2010). Bridging the Evidence Gap in Obesity Prevention: A Framework to Inform Decision Making. The National Academies Press.

Malik, V. S., B. M. Popkin, et al. (2010). "Sugar-sweetened beverages and risk of metabolic syndrome and type 2 diabetes: a meta-analysis." Diabetes Care. **33** (11): 2477-2483.

Malik, V. S., M. B. Schulze, et al. (2006). "Intake of sugar-sweetened beverages and weight gain: a systematic review." Am J Clin Nutr. **84** (2): 274-288.

Mangham, L. J. and K. Hanson (2010). "Scaling up in international health: what are the key issues?" Health Policy Plan. **25** (2): 85-96.

Manios, Y., G. Moschonis, et al. (2008). "Prevalence and independent predictors of insulin resistance in children from Crete, Greece: the Children Study." Diabet Med. **25** (1): 65-72.

Manus, H. E. and M. R. Killeen (1995). "Maintenance of self-esteem by obese children." J Child Adolesc Psychiatr Nurs. **8** (1): 17-27.

Marmot, M. and R. Bell (2012). "Fair society, healthy lives." Public Health. **126**(1): 10.

Marshall, S. J. (2009). "Dropping the ball and picking up fat: youth physical activity, body fatness, and the conundrum of causality." Am J Prev Med. **37** (1): 84-86.

Martinez, J. A., P. Cordero, et al. (2012). "Interplay of early-life nutritional programming on obesity, inflammation and epigenetic outcomes." Proc Nutr Soc. **71** (2): 276-283.

Mason, C. and P. T. Katzmarzyk (2009). "Effect of the site of measurement of waist circumference on the prevalence of the metabolic syndrome." Am J Cardiol. **103** (12): 1716-1720.

Mason, C. and P. T. Katzmarzyk (2009). "Variability in waist circumference measurements according to anatomic measurement site." Obesity (Silver Spring). **17** (9): 1789-1795.

Matheson, D. M., J. D. Killen, et al. (2004). "Children's food consumption during television viewing." Am J Clin Nutr. **79** (6): 1088-1094.

May, C., F. Mair, et al. (2007). "Process evaluation for complex interventions in primary care: understanding trials using the normalization process model." BMC Family Practice. **8** (1): 42.

Maynard, L. M., W. Wisemandle, et al. (2001). "Childhood body composition in relation to body mass index." Pediatrics. **107** (2): 344-350.

McCaffrey, T. A., K. L. Rennie, et al. (2008). "Energy density of the diet and change in body fatness from childhood to adolescence; is there a relation?" Am J Clin Nutr. **87** (5): 1230-1237.

McCallum, Z., M. Wake, et al. (2007). "Outcome data from the LEAP (Live, Eat and Play) trial: a randomized controlled trial of a primary care intervention for childhood overweight/mild obesity." Int J Obes (Lond). **31** (4): 630-636.

McCarthy, H. D. (2006). "Body fat measurements in children as predictors for the metabolic syndrome: focus on waist circumference." Proc Nutr Soc. **65** (4): 385-392.

McCarthy, H. D. and M. Ashwell (2006). "A study of central fatness using waist-to-height ratios in UK children and adolescents over two decades supports the simple message- 'keep your waist circumference to less than half your height'." Int J Obes (Lond). **30** (6): 988-992.

McCarthy, H. D., T. J. Cole, et al. (2006). "Body fat reference curves for children." Int J Obes (Lond). **30** (4): 598-602.

McCarthy, H. D., S. M. Ellis, et al. (2003). "Central overweight and obesity in British youth aged 11-16 years: cross sectional surveys of waist circumference." BMJ. **326** (7390): 624.

McCarthy, H. D., K. V. Jarrett, et al. (2001). "The development of waist circumference percentiles in British children aged 5.0-16.9 y." Eur J Clin Nutr. **55** (10): 902-907.

McCarthy, H. D., K. V. Jarrett, et al. (2005). "Trends in waist circumferences in young British children: a comparative study." Int J Obes (Lond). **29** (2): 157-162.

McGovern, L., J. N. Johnson, et al. (2008). "Clinical review: treatment of pediatric obesity: a systematic review and meta-analysis of randomized trials." J Clin Endocrinol Metab. **93** (12): 4600-4605.

Mei, Z., L. M. Grummer-Strawn, et al. (2007). "Do skinfold measurements provide additional information to body mass index in the assessment of body fatness among children and adolescents?" Pediatrics. **119** (6): e1306-1313.

Meichenbaum, D. (1987). "Facilitating treatment adherence: A practitioner's guidebook."

Misra, A. and L. Khurana (2009). "The metabolic syndrome in South Asians: epidemiology, determinants, and prevention." Metab Syndr Relat Disord. **7** (6): 497-514.

Misra, A. and L. Khurana (2011). "Obesity-related non-communicable diseases: South Asians vs White Caucasians." Int J Obes (Lond). **35** (2): 167-187.

Mitchell, N. G., J. B. Moore, et al. (2012). "Cardiovascular fitness moderates the relations between estimates of obesity and physical self-perceptions in rural elementary school students." J Phys Act Health. **9** (2): 288-294.

Molnar, D., K. Torok, et al. (2000). "Safety and efficacy of treatment with an ephedrine/caffeine mixture. The first double-blind placebo-controlled pilot study in adolescents." Int J Obes Relat Metab Disord. **24** (12): 1573-1578.

Morrison, A. C. and R. B. Ness (2011). "Sodium intake and cardiovascular disease." Annu Rev Public Health. **32**: 71-90.

Mota, J., L. Flores, et al. (2006). "Relationship of single measures of cardiorespiratory fitness and obesity in young schoolchildren." Am J Hum Biol. **18** (3): 335-341.

Mushtaq, M. U., S. Gull, et al. (2011). "Family-based factors associated with overweight and obesity among Pakistani primary school children." BMC Pediatr. **11**: 114.

Nader, P. R., M. O'Brien, et al. (2006). "Identifying risk for obesity in early childhood." Pediatrics. **118** (3): e594-601.

Nassis, G. P., K. Papantakou, et al. (2005). "Aerobic exercise training improves insulin sensitivity without changes in body weight, body fat, adiponectin, and inflammatory markers in overweight and obese girls." Metabolism. **54** (11): 1472-1479.

Nassis, G. P., G. Psarra, et al. (2005). "Central and total adiposity are lower in overweight and obese children with high cardiorespiratory fitness." Eur J Clin Nutr. **59** (1): 137-141.

Nassis, G. P. and L. S. Sidossis (2006). "Methods for assessing body composition, cardiovascular and metabolic function in children and adolescents: implications for exercise studies." Curr Opin Clin Nutr Metab Care. **9** (5): 560-567.

Nelson, M., A. E. Black, et al. (1989). "Between- and within-subject variation in nutrient intake from infancy to old age: estimating the number of days required to rank dietary intakes with desired precision." Am J Clin Nutr. **50** (1): 155-167.

Nelson, T. F., S. D. Stovitz, et al. (2011). "Do youth sports prevent pediatric obesity? A systematic review and commentary." Curr Sports Med Rep. **10** (6): 360-370.

Nemet, D., S. Barkan, et al. (2005). "Short- and long-term beneficial effects of a combined dietary-behavioral-physical activity intervention for the treatment of childhood obesity." Pediatrics. **115** (4): e443-449.

Ness-Abramof, R. and C. M. Apovian (2008). "Waist circumference measurement in clinical practice." Nutr Clin Pract. **23** (4): 397-404.

NHLBI (1998). "Clinical Guidelines On The Identification, Evaluation, and Treatment Of Overweight and Obesity In Adults."

NHLBI (2012). "Choosing Foods for Your Family. GO, SLOW, and WHOA Foods. Available at: http://www.nhlbi.nih.gov/health/public/heart/obesity/wecan/eat-right/choosing-foods.htm."

NHMRC (2003). "Dietary Guidelines for all Australians."

NICE (2006). "National Institute for Health and Clinical Excellence (NICE) guidance. Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children. Available at: http://guidance.nice.org.uk/CG43/guidance/section1/word/English."

NICE (2009). "Methods for the development of NICE public health guidance. Available at: http://www.nice.org.uk/media/2FB/53/PHMethodsManual110509.pdf."

NICE (2009). "Promoting physical activity, active play and sport for pre-school and school-age children and young people in family, pre-school, school and community settings."

NOO (2010). "Determinants of obesity: child physical activity."

NOO (2011). "Measuring diet and physical activity in weight management interventions."

NOO (2011). "Obesity and ethnicity."

Nova, A., A. Russo, et al. (2001). "Long-term management of obesity in paediatric office practice: experimental evaluation of two different types of intervention." Ambulatory Child Health. **7**: 239.

Nowicka, P., A. Pietrobelli, et al. (2007). "Low-intensity family therapy intervention is useful in a clinical setting to treat obese and extremely obese children." Int J Pediatr Obes. **2** (4): 211-217.

O’Connor, J., E. J. Ball, et al. (2001). "Comparison of total energy expenditure and energy intake in children aged 6-9 y." Am J Clin Nutr. **74** (5): 643-649.

O’Dea, J. A. (2005). "Prevention of child obesity: ’first, do no harm’." Health Educ Res. **20** (2): 259-265.

O’Donovan, G., A. J. Blazevich, et al. (2010). "The ABC of Physical Activity for Health: a consensus statement from the British Association of Sport and Exercise Sciences." J Sports Sci. **28** (6): 573-591.

Ocke, M. C., N. Larranaga, et al. (2009). "Energy intake and sources of energy intake in the European Prospective Investigation into Cancer and Nutrition." Eur J Clin Nutr. **63** (Suppl 4): S3-15.

Oddy, W. H. (2012). "Infant feeding and obesity risk in the child." Breastfeed Rev. **20** (2): 7-12.

OECD (2011). "Health at a Glance 2011: OECD Indicators, OECD Publishing (http://dx.doi.org/10.1787/health_glance-2011-en)."

Ogden, C. L., M. D. Carroll, et al. (2012). "Prevalence of obesity and trends in body mass index among US children and adolescents, 1999-2010." JAMA. **307** (5): 483-490.

Okely, A. D., C. E. Collins, et al. (2010). "Multi-site randomized controlled trial of a child-centered physical activity program, a parent-centered dietary-modification program, or both in overweight children: the HIKCUPS study." J Pediatr. **157** (3): 388-394.

Olds, T., C. Maher, et al. (2011). "Evidence that the prevalence of childhood overweight is plateauing: data from nine countries." Int J Pediatr Obes. **6** (5-6): 342-360.

Ortega, F. B., J. R. Ruiz, et al. (2010). "Cardiovascular fitness modifies the associations between physical activity and abdominal adiposity in children and adolescents: the European Youth Heart Study." Br J Sports Med. **44** (4): 256-262.

Oude Luttikhuis, H., L. Baur, et al. (2009). "Interventions for treating obesity in children." Cochrane Database Syst Rev. **21** (1).

Owens, S., B. Gutin, et al. (1999). "Effect of physical training on total and visceral fat in obese children." Med Sci Sports Exerc. **31** (1): 143-148.

Patrick, H. and T. A. Nicklas (2005). "A review of family and social determinants of children’s eating patterns and diet quality." J Am Coll Nutr. **24** (2): 83-92.

Pearson, N. and S. J. Biddle (2011). "Sedentary behavior and dietary intake in children, adolescents, and adults. A systematic review." Am J Prev Med. **41** (2): 178-188.

Pedrosa, C., B. M. Oliveira, et al. (2011). "Markers of metabolic syndrome in obese children before and after 1-year lifestyle intervention program." Eur J Nutr. **50** (6): 391-400.

Perusse, L., T. Rankinen, et al. (2005). "The human obesity gene map: the 2004 update." Obes Res. **13** (3): 381-490.

Phan, T. L., M. M. Maresca, et al. (2012). "Does body mass index accurately reflect body fat? A comparison of anthropometric measures in the longitudinal assessment of fat mass." Clin Pediatr (Phila). **51** (7): 671-677.

Pietrobelli, A., M. S. Faith, et al. (1998). "Body mass index as a measure of adiposity among children and adolescents: a validation study." J Pediatr. **132** (2): 204-210.

Plagemann, A. (2006). "Perinatal nutrition and hormone-dependent programming of food intake." Horm Res. **65** (Suppl 3): 83-89.

Poh, B. K., A. N. Jannah, et al. (2011). "Waist circumference percentile curves for Malaysian children and adolescents aged 6.0-16.9 years." Int J Pediatr Obes. **6** (3-4): 229-235.

Popkin, B. M. and P. Gordon-Larsen (2004). "The nutrition transition: worldwide obesity dynamics and their determinants." Int J Obes Relat Metab Disord. **28** (Suppl 3): S2-9.

Powell, L. M. and B. T. Nguyen (2012). "Fast-Food and Full-Service Restaurant Consumption Among Children and Adolescents: Effect on Energy, Beverage, and Nutrient Intake." Arch Pediatr Adolesc Med. Nov 5.1-7 [Epub].

Puhl, R. M. and J. D. Latner (2007). "Stigma, obesity, and the health of the nation's children." Psychol Bull. **133** (4): 557-580.

Raynor, H. A., E. L. Van Walleghen, et al. (2011). "The relationship between child and parent food hedonics and parent and child food group intake in children with overweight/obesity." J Am Diet Assoc. **111** (3): 425-430.

Redfern, J., C. McKevitt, et al. (2006). "Development of Complex Interventions in Stroke Care." Stroke. **37** (9): 2410-2419.

Reilly, J. J. (2005). "Descriptive epidemiology and health consequences of childhood obesity." Best Pract Res Clin Endocrinol Metab. **19** (3): 327-341.

Reilly, J. J. (2008). "Physical activity, sedentary behaviour and energy balance in the preschool child: opportunities for early obesity prevention." Proc Nutr Soc. **67** (3): 317-325.

Reilly, J. J., J. Kelly, et al. (2010). "Accuracy of simple clinical and epidemiological definitions of childhood obesity: systematic review and evidence appraisal." Obes Rev. **11** (9): 645-655.

Reilly, J. J. and Z. C. McDowell (2003). "Physical activity interventions in the prevention and treatment of paediatric obesity: systematic review and critical appraisal." Proc Nutr Soc. **62** (3): 611-619.

Reinehr, T. and W. Andler (2004). "Changes in the atherogenic risk factor profile according to degree of weight loss." Arch Dis Child. **89** (5): 419-422.

Reinehr, T., G. de Sousa, et al. (2006). "Long-term follow-up of cardiovascular disease risk factors in children after an obesity intervention." Am J Clin Nutr. **84** (3): 490-496.

Reinehr, T., M. Temmesfeld, et al. (2007). "Four-year follow-up of children and adolescents participating in an obesity intervention program." Int J Obes. **31** (7): 1074-1077.

Ritchie, L. D. (2012). "Less frequent eating predicts greater BMI and waist circumference in female adolescents." Am J Clin Nutr. **95** (2): 290-296.

Ritchie, L. D., G. Welk, et al. (2005). "Family environment and pediatric overweight: what is a parent to do?" J Am Diet Assoc. **105** (5 Suppl 1): S70-79.

Robertson, W., T. Friede, et al. (2008). "Pilot of "Families for Health": community-based family intervention for obesity." Arch Dis Child. **93** (11): 921-926.

Robinson, S. M. and K. M. Godfrey (2008). "Feeding practices in pregnancy and infancy: relationship with the development of overweight and obesity in childhood." Int J Obes (Lond). **32** (Suppl 6): S4-10.

Robinson, T. N. (1999). "Reducing children’s television viewing to prevent obesity: a randomized controlled trial." JAMA. **282** (16): 1561-1567.

Rodriguez, G. and L. A. Moreno (2006). "Is dietary intake able to explain differences in body fatness in children and adolescents?" Nutr Metab Cardiovasc Dis. **16** (4): 294-301.

Rokholm, B., J. L. Baker, et al. (2010). "The levelling off of the obesity epidemic since the year 1999--a review of evidence and perspectives." Obes Rev. **11** (12): 835-846.

Ross, R., T. Berentzen, et al. (2008). "Does the relationship between waist circumference, morbidity and mortality depend on measurement protocol for waist circumference?" Obes Rev. **9** (4): 312-325.

Rowlands, A. V., M. R. Stone, et al. (2007). "Influence of speed and step frequency during walking and running on motion sensor output." Med Sci Sports Exerc. **39** (4): 716-727.

Rudolf, M., D. Christie, et al. (2006). "WATCH IT: a community based programme for obese children and adolescents." Arch Dis Child. **91** (9): 736-739.

Rudolf, M. C., D. C. Greenwood, et al. (2004). "Rising obesity and expanding waistlines in schoolchildren: a cohort study." Arch Dis Child. **89** (3): 235-237.

Rudolf, M. C., J. Walker, et al. (2007). "What is the best way to measure waist circumference?" Int J Pediatr Obes. **2** (1): 58-61.

Sacher, P. M., P. Chadwick, et al. (2011). "Evaluating the effectiveness of the scale-up and spread of the MEND 7-13 childhood obesity program: UK national data (2007-2010)." Obesity (Silver Spring). **19** (Suppl 1): S52.

Sacher, P. M., P. Chadwick, et al. (2005). "Assessing the acceptability and feasibility of the MEND Programme in a small group of obese 7-11-year-old children." J Hum Nutr Diet. **18** (1): 3-5.

Sacher, P. M., M. Kolotourou, et al. (2010). "Randomized controlled trial of the MEND program: a family-based community intervention for childhood obesity." Obesity (Silver Spring). **18** (Suppl 1): S62-68.

SACN (2011). "Dietary Recommendations for Energy."

Saelens, B. E., J. F. Sallis, et al. (2003). "Environmental correlates of walking and cycling: findings from the transportation, urban design, and planning literatures." Ann Behav Med. **25** (2): 80-91.

Sallis, J. F. and K. Glanz (2006). "The role of built environments in physical activity, eating, and obesity in childhood." Future Child. **16** (1): 89-108.

Salmon, J., K. Ball, et al. (2005). "Reducing sedentary behaviour and increasing physical activity among 10-year-old children: overview and process evaluation of the 'Switch-Play' intervention." Health Promot Int. **20** (1): 7-17.

Sanchez-Bayle, M., M. T. Munoz-Fernandez, et al. (1999). "A longitudinal study of blood pressure in Spanish schoolchildren. Working Group of Cardiovascular Risk Factors in Childhood and Adolescence." Arch Dis Child. **81** (2): 169-171.

Sargent, G. M., L. S. Pilotto, et al. (2011). "Components of primary care interventions to treat childhood overweight and obesity: a systematic review of effect." Obes Rev. **12** (5).

Savoye, M., M. Shaw, et al. (2007). "Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial." JAMA. **297**(24): 2697-2704.

Savva, S. C., M. Tornaritis, et al. (2000). "Waist circumference and waist-to-height ratio are better predictors of cardiovascular disease risk factors in children than body mass index." Int J Obes Relat Metab Disord. **24** (11): 1453-1458.

Schmidt, M. D., T. Dwyer, et al. (2011). "Predictive associations between alternative measures of childhood adiposity and adult cardio-metabolic health." Int J Obes (Lond). **35** (1): 38-45.

Schoeller, D. A. (2002). "Validation of habitual energy intake." Public Health Nutr. **5** (6A): 883-888.

Schwandt, P., R. Kelishadi, et al. (2008). "First reference curves of waist circumference for German children in comparison to international values: the PEP Family Heart Study." World J Pediatr. **4** (4): 259-266.

Schwartz, M. B. and R. Puhl (2003). "Childhood obesity: a societal problem to solve." Obes Rev. **4** (1): 57-71.

Sealy, Y. M. (2010). "Parents' food choices: obesity among minority parents and children." J Community Health Nurs. **27** (1): 1-11.

Semiz, S., E. Ozgoren, et al. (2007). "Comparison of ultrasonographic and anthropometric methods to assess body fat in childhood obesity." Int J Obes (Lond). **31** (1): 53-58.

Senese, L. C., N. D. Almeida, et al. (2009). "Associations between childhood socioeconomic position and adulthood obesity." Epidemiol Rev. **31**: 21-51.

Shalitin, S., L. Ashkenazi-Hoffnung, et al. (2009). "Effects of a twelve-week randomized intervention of exercise and/or diet on weight loss and weight maintenance, and other metabolic parameters in obese preadolescent children." Horm Res. **72** (5): 287-301.

Shelton, D., K. Le Gros, et al. (2007). "Randomised controlled trial: A parent-based group education programme for overweight children." J Paediatr Child Health. **43** (12): 799-805.

Shrewsbury, V. and J. Wardle (2008). "Socioeconomic status and adiposity in childhood: a systematic review of cross-sectional studies 1990-2005." Obesity. **16** (2): 275-284.

SIGN (2010). "Management of Obesity: A national clinical guideline."

Singh, A. S., C. Mulder, et al. (2008). "Tracking of childhood overweight into adulthood: a systematic review of the literature." Obes Rev. **9** (5): 474-488.

Singh, G. K., M. D. Kogan, et al. (2008). "Racial/ethnic, socioeconomic, and behavioral determinants of childhood and adolescent obesity in the United States: analyzing independent and joint associations." Ann Epidemiol. **18** (9): 682-695.

Skouteris, H., M. McCabe, et al. (2010). "Healthy eating and obesity prevention for preschoolers: a randomised controlled trial." BMC Public Health. **10**: 220.

Slemenda, C. W., J. Z. Miller, et al. (1991). "Role of physical activity in the development of skeletal mass in children." J Bone Miner Res. **6** (11): 1227-1233.

Sothern, M. S., J. M. Loftin, et al. (2000). "Safety, feasibility, and efficacy of a resistance training program in preadolescent obese children." Am J Med Sci. **319** (6): 370-375.

Speiser, P. W., M. C. Rudolf, et al. (2005). "Childhood obesity." J Clin Endocrinol Metab. **90** (3): 1871-1887.

Spencer, S. J. (2012). "Early life programming of obesity: the impact of the perinatal environment on the development of obesity and metabolic dysfunction in the offspring." Curr Diabetes Rev. **8** (1): 55-68.

Srinivasan, S., G. R. Ambler, et al. (2006). "Randomized, controlled trial of metformin for obesity and insulin resistance in children and adolescents: improvement in body composition and fasting insulin." J Clin Endocrinol Metab. **91** (6): 2074-2080.

Stabouli, S., S. Papakatsika, et al. (2011). "The role of obesity, salt and exercise on blood pressure in children and adolescents." Expert Rev Cardiovasc Ther. **9** (6): 753-761.

Stamatakis, E., J. Wardle, et al. (2010). "Childhood obesity and overweight prevalence trends in England: evidence for growing socioeconomic disparities." Int J Obes (Lond). **34** (1): 41-47.

Stamatakis, E., P. Zaninotto, et al. (2010). "Time trends in childhood and adolescent obesity in England from 1995 to 2007 and projections of prevalence to 2015." J Epidemiol Community Health. **64** (2): 167-174.

Steele, R. M., E. M. van Sluijs, et al. (2009). "Targeting sedentary time or moderate- and vigorous-intensity activity: independent relations with adiposity in a population-based sample of 10-y-old British children." Am J Clin Nutr. **90** (5): 1185-1192.

Stewart, L., J. Chapple, et al. (2008). "Parents' journey through treatment for their child's obesity: a qualitative study." Arch Dis Child. **93** (1): 35-39.

Stewart, L., J. Chapple, et al. (2008). "The use of behavioural change techniques in the treatment of paediatric obesity: qualitative evaluation of parental perspectives on treatment." J Hum Nutr Diet. **21** (5): 464-473.

Stewart, L., J. Houghton, et al. (2005). "Dietetic management of pediatric overweight: development and description of a practical and evidence-based behavioral approach." J Am Diet Assoc. **105** (11): 1810-1815.

Stigman, S., P. Rintala, et al. (2009). "Eight-year-old children with high cardiorespiratory fitness have lower overall and abdominal fatness." Int J Pediatr Obes. **4** (2): 98-105.

Strauss, R. S. (2000). "Childhood obesity and self-esteem." Pediatrics. **105** (1): e15.

Summerbell, C. D., V. Ashton, et al. (2003). "Interventions for treating obesity in children." Cochrane Database Syst Rev. (3): CD001872.

Summerbell, C. D., E. Waters, et al. (2005). "Interventions for preventing obesity in children." Cochrane Database Syst Rev. **20** (3).

Techakehakij, W. (2011). "The cost-effectiveness of child obesity intervention. Available at: http://etheses.whiterose.ac.uk/1936/."

Tompkins, C. L., K. Moran, et al. (2011). "Physical activity-induced improvements in markers of insulin resistance in overweight and obese children and adolescents." Curr Diabetes Rev. **7** (3): 164-170.

Trabulsi, J. and D. A. Schoeller (2001). "Evaluation of dietary assessment instruments against doubly labeled water, a biomarker of habitual energy intake." Am J Physiol Endocrinol Metab. **281** (5): E891-899.

Treadwell, J. R., F. Sun, et al. (2008). "Systematic review and meta-analysis of bariatric surgery for pediatric obesity." Ann Surg. **248** (5): 763-776.

Tremblay, M. S., A. G. LeBlanc, et al. (2011). "Systematic review of sedentary behaviour and health indicators in school-aged children and youth." Int J Behav Nutr Phys Act. **8**: 98.

Trout, K. K. and L. Wetzel-Effinger (2012). "Flavor learning in utero and its implications for future obesity and diabetes." Curr Diab Rep. **12** (1): 60-66.

Trudeau, F., L. Laurencelle, et al. (1999). "Daily primary school physical education: effects on physical activity during adult life." Med Sci Sports Exerc. **31** (1): 111-117.

Tschamler, J. M., K. M. Conn, et al. (2010). "Underestimation of children's weight status: views of parents in an urban community." Clin Pediatr (Phila). **49** (5): 470-476.

Tybor, D. J., A. H. Lichtenstein, et al. (2011). "Independent effects of age-related changes in waist circumference and BMI z scores in predicting cardiovascular disease risk factors in a prospective cohort of adolescent females." Am J Clin Nutr. **93** (2): 392-401.

Ulmer, F. C. (1976). "The Hawthorne effect." Educ Dir Dent Aux. **1** (2): 28.

Vamosi, M., B. L. Heitmann, et al. (2010). "The relation between an adverse psychological and social environment in childhood and the development of adult obesity: a systematic literature review." Obes Rev. **11** (3): 177-184.

van Stralen, M. M., S. J. te Velde, et al. (2012). "Weight status of European preschool children and associations with family demographics and energy balance-related behaviours: a pooled analysis of six European studies." Obes Rev. **13** (Suppl 1): 29-41.

Viner, R. M., M. M. Haines, et al. (2006). "Body mass, weight control behaviours, weight perception and emotional well being in a multiethnic sample of early adolescents." Int J Obes (Lond). **30** (10): 1514-1521.

Wake, M., L. A. Baur, et al. (2009). "Outcomes and costs of primary care surveillance and intervention for overweight or obese children: the LEAP 2 randomised controlled trial." BMJ. **3** (339).

Wald, A. B. and N. K. Uli (2009). "Pharmacotherapy in pediatric obesity: current agents and future directions." Rev Endocr Metab Disord. **10** (3): 205-214.

Waling, M., T. Lind, et al. (2010). "A one-year intervention has modest effects on energy and macronutrient intakes of overweight and obese Swedish children." J Nutr. **140** (10): 1793-1798.

Wang, F., T. C. Wild, et al. (2009). "The influence of childhood obesity on the development of self-esteem." Health Rep. **20** (2): 21-27.

Wang, Y. and T. Lobstein (2006). "Worldwide trends in childhood overweight and obesity." Int J Pediatr Obes. **1** (1): 11-25.

Wang, Y. C., D. S. Ludwig, et al. (2009). "Impact of change in sweetened caloric beverage consumption on energy intake among children and adolescents." Arch Pediatr Adolesc Med. **163** (4): 336-343.

Wardle, J. (2005). "Understanding the aetiology of childhood obesity: implications for treatment." Proc Nutr Soc. **64** (1): 73-79.

Wardle, J. and L. Cooke (2005). "The impact of obesity on psychological well-being." Best Pract Res Clin Endocrinol Metab. **19** (3): 421-440.

Wardle, J., C. Volz, et al. (1995). "Social variation in attitudes to obesity in children." Int J Obes Relat Metab Disord. **19** (8): 562-569.

Waters, E., A. de Silva-Sanigorski, et al. (2011). "Interventions for preventing obesity in children." Cochrane Database Syst Rev. (12): CD001871.

Weigel, C., K. Kokocinski, et al. (2008). "Childhood obesity: concept, feasibility, and interim results of a local group-based, long-term treatment program." J Nutr Educ Behav. **40** (6): 369-373.

Wells, J. C., W. A. Coward, et al. (2002). "The contribution of fat and fat-free tissue to body mass index in contemporary children and the reference child." Int J Obes Relat Metab Disord. **26** (10): 1323-1328.

Wells, J. C., N. J. Fuller, et al. (1999). "Four-component model of body composition in children: density and hydration of fat-free mass and comparison with simpler models." Am J Clin Nutr. **69** (5): 904-912.

West, F., M. R. Sanders, et al. (2010). "Randomised clinical trial of a family-based lifestyle intervention for childhood obesity involving parents as the exclusive agents of change." Behav Res Ther. **48** (12): 1170-1179.

Whitaker, R. C., J. A. Wright, et al. (1997). "Predicting obesity in young adulthood from childhood and parental obesity." N Engl J Med. **337** (13): 869-873.

Whitlock, E. P., S. B. Williams, et al. (2005). "Screening and interventions for childhood overweight: a summary of evidence for the US Preventive Services Task Force." Pediatrics **116**(1): e125-144.

Whitlock, E. A., E. P. O'Connor, et al. (2008). "Effectiveness of weight management programs in children and adolescents." Evid Rep Technol Assess (Full Rep). 170: 1-308.

Whitlock, E. P., E. A. O'Connor, et al. (2010). "Effectiveness of weight management interventions in children: a targeted systematic review for the USPSTF." Pediatrics. **125** (2): e396-418.

Wilfley, D. E., R. I. Stein, et al. (2007). "Efficacy of maintenance treatment approaches for childhood overweight: a randomized controlled trial." JAMA. **298** (14): 1661-1673.

Williams, S. M. and A. Goulding (2009). "Patterns of growth associated with the timing of adiposity rebound." Obesity (Silver Spring). **17** (2): 335-341.

Williamson, D. A., H. Han, et al. (2011). "Longitudinal study of body weight changes in children: who is gaining and who is losing weight." Obesity (Silver Spring). **19** (3): 667-670.

Wilson, C. (2012). "Obesity: Sugar-sweetened beverages-fueling the epidemic of childhood obesity?" Nat Rev Endocrinol. Dec 8: (12). [Epub].

Woolcock, S. L., S.; Kolotourou, M.; Chadwick, P.; Sacher, P. (2010). "Long term weight maintenance strategies following initial treatment of childhood obesity." International Journal of Obesity. **5** (S1): 83.

Wright, C. M., A. Sherriff, et al. (2008). "Development of bioelectrical impedance-derived indices of fat and fat-free mass for assessment of nutritional status in childhood." Eur J Clin Nutr. **62** (2): 210-217.

Young-Hyman, D., L. J. Herman, et al. (2000). "Care giver perception of children's obesity-related health risk: a study of African American families." Obes Res. **8** (3): 241-248.

Young, K. M., J. J. Northern, et al. (2007). "A meta-analysis of family-behavioral weight-loss treatments for children." Clin Psychol Rev. **27** (2): 240-249.

Zametkin, A. J., C. K. Zoon, et al. (2004). "Psychiatric aspects of child and adolescent obesity: a review of the past 10 years." J Am Acad Child Adolesc Psychiatry. **43** (2): 134-150.

Zaninotto, P., H. Wardle, et al. (2006). "Forecasting Obesity to 2010."

Zhang, Y., R. Proenca, et al. (1994). "Positional cloning of the mouse obese gene and its human homologue." Nature. **372** (6505): 425-432.

Zimmermann, M. B. and I. Aeberli (2008). "Dietary determinants of subclinical inflammation, dyslipidemia and components of the metabolic syndrome in overweight children: a review." Int J Obes (Lond). **32** (Suppl 6): S11-18.

Appendices

Appendix 1 Other contributions to the field of childhood weight management

Peer-reviewed publications

1. Kolotourou M, Radley D, Chadwick P. Smith L, Orfanos S, Kapetanakis V, Singhal A, Cole TJ, Sacher PM. Is BMI alone a sufficient outcome to evaluate interventions for child obesity. Childhood Obesity. 2013:9 (4).

2. Smith LR, Chadwick P, Radley D, Kolotourou M, Gammon C, Rosborough J, Sacher PM. Assessing the short-term outcomes of a community-based intervention for overweight and obese children: The MEND 5-7 programme. BMJ Open. 2013: 3:e002607.

3. Skouteris H, McCabe M, Swinburn B, Newgreen V, Sacher P, Chadwick P. Parental influence and obesity prevention in pre-schoolers: a systematic review of interventions. Obesity Reviews. 2011:12(5):315-28.

4. Swain C, Sacher PM. Child obesity: a manageable condition. Nurse Prescribing. 2009:7(1):14-8.

5. Sacher PM, Wolman J, Chadwick P, Swain C. Mini-MEND: MEND's early year's healthy lifestyle programme for 2-4 year olds and their families. British Nutrition Foundation. 2008:33:364-7.

6. Wolman J, Skelly E, Kolotourou M, Lawson MS, Sacher PM. Tackling toddler obesity through a pilot community-based family intervention. Community Practitioner. 2008:81(1):28-31.

7. Chadwick P, Sacher PM, Swain C. Talking to families about overweight children. British Journal of School Nursing. 2008:3(6):271-6.

8. Sacher PM, Swain C. The MEND Programme: tackling childhood obesity. British Journal of School Nursing. 2007(2):4.

9. Oldham A, Aylott H, Sacher PM. Mending the growing problem of childhood obesity. The British Journal of Primary Care Nursing. 2007:4(6):297-9.

10. Sacher PM. Childhood obesity: consequences and control measures. Journal of Family Health Care. 2005:15.4(S1):4-5.

11. Sacher PM, Chadwick P, Hogan L. The obesity epidemic. Journal of Family Health Care. 2002:12(4):111.

Selected published abstracts

1. Kolotourou M, Radley D, Smith LR, Orfanos S, Chadwick P, Cole TJ, Sacher PM. Degree of zBMI Change and Health Benefits in Obese Children Attending a Community Weight Management Program. Obesity [In press].

2. Sacher PM, Lukeis S, Chadwick P, Kolotourou M, Radley D, Cole TJ, Singhal A. Evaluating the Effectiveness of the MEND 7-13 Childhood Obesity Program When Delivered at Scale in Community Settings in Australia and New Zealand. Obesity [In press].

3. Wilson TA, Laine L, Goodgame G, Adolph AL, Puyau MR, Barlow SE, Sacher PM, Radley D, Chadwick P, Butte NB. Effectiveness of the MEND Weight Management Program in Ethnically Diverse Children in the US. Obesity [In press].

4. Sacher PM, Chadwick P, Kolotourou M, Radley D, Cole TJ, Lawson M, Lucas A, Singhal A. Evaluating the effectiveness of the scale-up and spread of the MEND 7-13 childhood obesity program: UK national data (2007-2010). Obesity. 2011;19 (S1): S52.

5. Byrd-Williams C, Austin DM, Butte NF, Barlow SE, Wilson TA, Sacher PM, Radley R. Behavioral outcomes following a pilot study to test the USA version of the Mind, Exercise, Nutrition, Do it! (MEND) program to low income 7-14 year old obese children. Obesity. 2011; 19 (S1): S107.

6. Wilson TA, Butte NF, Barlow SE, Adolph AL, Houston MP, Sacher PM, Radley D. Predictors of BMI improvement in Hispanic children participating in

Mind, Exercise, Nutrition, Do it! (MEND) weight management program. Obesity. 2011; 19 (S1): S108.

7. Sacher PM, Chadwick P, Kolotourou M, Radley D, Chipperfield A, Stevenson A, Cole TJ, Lawson M, Lucas A, Singhal A. From clinical trial to large-scale community implementation: evaluation of the MEND multicomponent, family-based, child weight management programme in overweight and obese 7-13 year old children in the United Kingdom. Obesity Reviews. 2010; 11 (S1): 88.

8. Chadwick P, Stevenson A, Radley D, Kolotourou M, Sacher PM. Improvements in psychological health of overweight children during community-based weight management in the UK: The MEND 7-13 Programme. Obesity Reviews. 2010; 11 (S1): 290.

9. Woolcock S, Lukeis S, Kolotourou M, Chadwick P, Sacher PM. Long-term weight maintenance strategies following initial treatment of childhood obesity. International Journal of Pediatric Obesity. 2010; 5 (S1): 4.

10. Sacher PM, Chadwick P, Kolotourou M, Cole TJ, Lawson M, Lucas A, Singhal A. Preventing and controlling childhood obesity using a family and community-based approach. Applied Physiology, Nutrition, and Metabolism. 2009; 34 (2).

11. Kolotourou M, Chadwick P, Cole TJ, Lawson M, Singhal A, Sacher PM. The MEND Programme: national effectiveness data. Obesity Facts. 2009: 2 (S2).

12. Sacher PM, Chadwick P, Kolotourou M, Cole TJ, Lawson MS, Singhal A. The MEND Trial: Sustained Improvements on Health Outcomes in Obese Children at One Year. Obesity. 2007; 15: A92.

13. Sacher PM, Kolotourou M, Chadwick P, Singhal A, Cole TJ, Lawson M. The MEND Programme: effects on waist circumference and BMI in moderately obese children. Obesity Reviews. 2007; 8: 7-16: 12.

14. Sacher PM, Chadwick P, Kolotourou M, Cole TJ, Lawson M, Singhal A. The MEND RCT: Effectiveness on Health Outcomes in Obese Children. International. Journal of Obesity. 2007; 31: S1.

15. Sacher PM, Kolotourou M, Chadwick P, Singhal A, Cole TJ, Lawson M. The MEND Programme: effectiveness on health outcomes in obese children. Obesity Reviews. 2006; 7 (S2): 89.

16. Sacher PM, Kolotourou M, Chadwick P, Singhal A, Cole TJ, Lawson M. Is the MEND Programme effective in improving health outcomes in obese children? International Journal of Obesity. 2006; 30 (2): S41.

17. Sacher PM, Gray C, Lawson M. The MEND Programme is effective in reducing glycaemic load, total energy intake and waist circumference in a small group of obese 7-11 year old children. Obesity Reviews. 2005: S6 (1): 410: 121.

18. Sacher PM, Hogan L, Chadwick P, Lawson M. An integrated programme of nutrition, exercise and behavioural modification in a small group of obese 7-11 year old children. Proceedings of the Nutrition Society. 2003: 62 (OCA/B): 3A.

Manuals and books

1. Paul Sacher and Paul Chadwick. The MEND 7-13 theory leader's manual. Editions 1 – 7. 2001 – 2012.

2. Julia Wolman, Paul Chadwick and Paul Sacher. The MEND 2-4 theory leader's manual. 2008.

3. Paul Sacher. From Kid to Superkid. September 2005. Vermillion.

4. Gina Ford and Paul Sacher. The contented child's food bible. The complete guide to feeding 0-6 year olds. 2004. Vermilion.

5. Karmel A, Sacher PM. Superfoods for Babies and Children. 2001. Ebury Press.

Scientific presentations

2013

1. Invited speaker. Canadian Obesity Network Conference. 1st May. Canada

2012

1. Invited speaker. Obesity 2012 Conference. 24th October. UK.
2. Oral presentation. The Obesity Society Conference. 23rd September. USA.
3. Invited speaker. Industry Nutrition Strategy Group. 12th June. UK.
4. Invitation to give oral evidence. Academy of Royal Medical Colleges obesity review oral evidence session. 31st May. UK.
5. Invited speaker. Association of Children's Hospitals and Related Institutions (NACHRI) FOCUS on a Fitter Future III Conference. 23rd February. USA.
6. Invited speaker. The Partnership Overweight Netherlands (PON) Conference. 17th February. Netherlands.

2011

1. Oral presentation. International Diabetes Conference. 7th December. UAE
2. Invited speaker. International Action on Wellness Symposium. 10th October. Canada.
3. Oral presentation. The Obesity Society Conference. 2nd October. USA.
4. Invited speaker. British Dietetic Conference. 9th May. UK.
5. Invitation to provide oral evidence. House of Lords Behaviour Change Enquiry. 18th January. UK.

2010

1. Oral presentation. International Congress on Obesity. 9th July. Sweden.
2. Invited speaker. Pediatric Satellite of the International Congress on Obesity. 8th July. Sweden.
3. Invited speaker. Childhood Health – Fit for the Future. 26th May. UK
4. Invited speaker. Oxford Health Alliance Summit. 19th April. India.
5. Invited speaker. CMACE/Royal College of Obstetricians Conference. 19th March. UK.

2009

1. Invited Speaker. Health and Wellbeing in Education Conference. 10th November. UK.
2. Oral presentation. The Obesity Society Conference. 26th October. USA.
3. Invited speaker. National Obesity Forum Conference. 4-5th October. UK.
4. Oral presentation. Canadian Obesity Network Summit. 9th May. Canada.
5. Invited Speaker. Calgary University. 4th May. Canada.
6. Invited speaker. Oxford University. 11th March. UK.

2008

1. Invited speaker. National Obesity Forum. West Midlands Regional Meeting. 12th November. UK.
2. Invited Speaker. Holyrood Child Obesity Conference. Edinburgh. 10th November. Scotland.

3. Invited Speaker. 4th Annual Healthy Eating in Schools Conference. 29th October. UK.

4. Invited Speaker. The Obesity Epidemic. Opportunities and Challenges in the North West. Association for the Study of Obesity. 14th July. UK.

5. Invited Speaker. Public Policy Exchange. Children's services national conference: delivering the 2020 vision for children, young people and families. 18th June. UK.

6. Invited Speaker. National Obesity Forum Obesity Network Meeting. 17th June. UK.

7. Invited Speaker. British Medical Association. 175th Anniversary Conference. 11th June. UK.

8. Invited Speaker. Westminster Briefing. The new plan for children: delivering excellence, equity, health and happiness. 21st May. UK.

2007

1. Invited Speaker. British Nutrition Foundation 40th Anniversary Conference. 6th December. UK.

2. Invited Speaker. BDA Paediatric Group Study Day. 29th November. UK.

3. Invited Speaker. Westminster Diet & Health Forum. Toddlers Diets. 27th November. UK.

4. Invited Speaker. Royal Society of Medicine. 22nd November. UK.

5. Invited Speaker. National Obesity Forum Conference. 15th October. UK.

6. Invited Speaker. Sainsbury's Health Event. 11th October. UK.

7. Invited Speaker. Primary Care Live Conference. 10th October. UK.

8. Invited Speaker. 3rd Annual Obesity Conference. 25th June. Belgium.

9. Invited Speaker. European Congress on Obesity. 23rd April. Hungary.

10. Invited Speaker. UK Public Health Association. 28th March. UK.

Awards and bursaries

2011 British Dietetic Association: Rose Simmonds Award.

2010 Finalist (on behalf of MEND) Chief Medical Officer's Public Health Awards.

2003 Department of Health Nursing and Allied Health Professions (NIHR) – Researcher Development Award.

2002 British Dietetic Association Nutrition Educational Award.

2001 Great Ormond Street Hospital for Children NHS Trust - Michael Samuelson Bursary.

Appendix 2 MEND feasibility trial peer-reviewed publication

Assessing the acceptability and feasibility of the MEND Programme in a small group of obese 7–11-year-old children

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Keywords
behavioural modification, children, exercise, nutrition, obesity, treatment.

Abstract

Background and aims An uncontrolled, pilot study to evaluate feasibility and acceptability of a new community based childhood obesity treatment programme.

Methods The mind, exercise, nutrition and diet (MEND) programme was held at a sports centre, twice-weekly, for 3 months. The programme consists of behaviour modification, physical activity and nutrition education. The primary outcome measure was waist circumference. Secondary outcomes were body mass index (BMI), cardiovascular fitness (heart rate, blood pressure and number of steps in 2 min), self-esteem and body composition. BMI of parents was also measured. See http://www.mendprogramme.org.

Results Eleven obese children (7–11 years) and their families were recruited. Mean attendance was 78% (range 63–88%) with one drop out. Waist circumference, cardiovascular fitness and self-esteem were all significantly improved at 3 months and continued to improve at 6 months. BMI was significantly improved at 3 months but lost significance by 6 months. Deuterium studies showed a beneficial trend but were not significant. Of the 17 parents measured, seven were obese (BMI ≥ 30) and eight overweight (BMI ≥ 25).

Conclusions Although limited by the small number of participants and no control group, the MEND programme was acceptable to families and produced significant improvements in a range of risk factors associated with obesity that persisted over 3 months.

Introduction

Whilst tackling childhood obesity is a public health priority there is a lack of good quality evidence on the effectiveness of interventions on which to base national strategies or inform clinical practice (Summerbell *et al.*, 2003). The mind, exercise, nutrition and diet (MEND) programme has been developed to improve health outcomes in obese children and the aim of this pilot was to assess its acceptability, feasibility and compliance in a small group of obese children and their families.

Materials and methods

Obese children aged 7–11 years were recruited via school nurses, paediatricians and a local newspaper advertisement. GP's were informed of their patient's participation in the study. The programme required twice-weekly attendance over 3 months and was held in the evenings at a sports centre. All sessions were group-based and consisted of eight nutrition focussed education sessions, eight behavioural modification sessions, and 18 fun-based physical activity sessions. The primary outcome measure was waist circumference, a good predictor of insulin resistance and cardiovascular risk. Secondary outcomes were body mass index (BMI), cardiovascular fitness (number of steps in 2 min, heart rate and diastolic blood pressure after step test), self-esteem and body composition. If possible parents had their weight and height measured.

Assessments were carried out at the beginning and end of the 3-month programme with a 3-month follow-up. See http://www.mendprogramme.org for further information.

Results

Eleven subjects mean age 9.6 years were recruited. Demographics and body composition measurements are presented in Table 1. One family dropped out because of serious family health problems. Of the 17 parents measured, seven were obese (BMI ≥ 30) and 8 overweight (BMI ≥ 25). Mean attendance was 78% (range 63–88%). One child was referred by hospital paediatrician, five by school nurses and the rest self-referred. Seven subjects were followed up at 6 months.

Table 1 Demographics and body composition measurements

Age (yrs)	Sex	BMI *z*-score	Waist circumference *z*-score	BMI mother	BMI father
9.2	f	3.3	3.0	20	29.4
11.3	m	3.2	2.8	24.5	28.6
11.6	m	2.7	2.4	33.1	–
10.2	m	3.2	2.6	–	32.3
9.4	f	2.6	2.1	35.8	25.0
9.1	m	3.1	1.8	26.0	25.0
7.0	f	2.1	0.4	48.2	27.7
10.4	m	2.6	0.8	48.2	27.7
7.8	f	2.2	1.8	28.2	–
10.1	f	3.0	3.5	46.8	33.0

BMI, body mass index; f, female; m, male; –, no data available.

Waist circumference, BMI, cardiovascular fitness and self-esteem all improved significantly during the 3-month intervention (see Table 2). Benefits gained were sustained in the succeeding 3-month follow-up period. A significant improvement remained between baseline and 6 months for all parameters measured except BMI. Deuterium studies showed a trend towards decreased body fat and increased lean body mass but changes were not significant in this small sample.

Table 2 Summary of data at baseline (0 months), end of intervention (3 months) and follow-up (6 months) and mean changes from baseline at 3 and 6 months. Results are mean (SD)

Measure	0 months ($n = 10$)	3 months ($n = 10$)	6 months ($n = 7$)	0–3 months change	0–6 months change
Diastolic BP after step test (mmHg)	89.8 (6.4)	81.4 (5.9)	73.1 (7.0)	−8.4 (5.3)**	−18.6 (7.8)*
Heart rate after step test (bpm)	119.8 (15.0)	101.2 (13.7)	93.1 (14.8)	−18.6 (9.8)**	−31.7 (14.3)*
Number of steps in 2 min	163 (10.2)	203 (5.8)	240 (16.2)	40 (15.0)**	77 (23.3)*
Self-esteem score (range of possible scores: min = 36 to max = 144)	96.9 (8.6)	112.0 (11.7)	114.7 (6.9)	14.7 (8.1)**	13.2 (7.6)*
Waist circumference (cm)	82.9 (12.1)	80.7 (11.2)	82.1 (11.4)	−2.2 (2.6)*	−3.4 (2.0)*
BMI (kg m^{-2})	26.4 (3.4)	25.6 (3.5)	25.4 (3.7)	−0.9 (0.8)*	−0.8 (1.2)

BMI, body mass index.
*Paired *t*-test ≤ 0.05; **paired *t*-test ≤ 0.005.

Discussion

This was a small, uncontrolled, pilot study to assess feasibility of implementing the MEND community-based programme. Results indicate that the programme produced sustainable improvements in key indices of obesity-related health risk. Decreased waist circumference indicates reduced intra-abdominal fat which is associated with improvements in metabolic complications of obesity and cardiovascular risk (Pi-Sunyer, 1991). The sustained improvements in cardiovascular fitness at 6 months suggested that the children continued to be more active following the end of the programme. This is a positive outcome given that increased physical activity is a predictor of successful weight maintenance in treated obese children (Epstein *et al.*, 1984). As low self-esteem is a risk factor for the development of depression in obese children, improvements in this factor suggest that the programme may also act to improve psychological health (Wallace *et al.*, 1993).

The study indicates that overall improvements in health in obese children can be achieved by an intensive child-orientated multidisciplinary programme. Good attendance and a low drop out rate suggest that an intensive community based programme is acceptable to families and may be one of a range of strategies that could help to combat the rise in child obesity. These preliminary results warrant further investigation and a randomized controlled trial is planned for 2005.

Acknowledgements

We thank Lisa Hogan for helping in the conception of this study and also in data collection. This work was funded by Sainsbury's Supermarkets Ltd. We would also like to thank the management of the Oasis Sports Centre and Holmes Place Leisure Management Ltd.

References

Epstein, L.H., Wing, R.R., Koeske, R. & Valoski, A. (1984) Effect of diet plus exercise on weight change in parents and children. *J. Consult. Clin. Psychol.* **52**, 429–437.

Pi-Sunyer, F.X. (1991) Health implications of obesity. *Am. J. Nutr.* **53**, 1595S–1603S.

Summerbell, C.D., Ashton, V., Campbell, K.J., Edmunds, L., Kelly, S. & Waters, E. (2003) Interventions for treating obesity in children (Cochrane Review). In: *The Cochrane Library*, 3. Chichester, UK: John Wiley and Sons, Ltd.

Wallace, W.J., Sheslow, D. & Hassink, S. (1993) Obesity in children: a risk for depression. *Ann. N.Y. Acad. Sci.* **699**, 301–303.

Appendix 3 MEND RCT peer-reviewed publication

Randomized Controlled Trial of the MEND Program: A Family-based Community Intervention for Childhood Obesity

Paul M. Sacher[1], Maria Kolotourou[1], Paul M. Chadwick[2], Tim J. Cole[3], Margaret S. Lawson[1], Alan Lucas[1] and Atul Singhal[1]

The aim of this study was to evaluate the effectiveness of the Mind, Exercise, Nutrition, Do it (MEND) Program, a multicomponent community-based childhood obesity intervention (www.mendcentral.org). One hundred and sixteen obese children (BMI ≥ 98th percentile, UK 1990 reference data) were randomly assigned to intervention or waiting list control (6-month delayed intervention). Parents and children attended eighteen 2-h group educational and physical activity sessions held twice weekly in sports centers and schools, followed by a 12-week free family swimming pass. Waist circumference, BMI, body composition, physical activity level, sedentary activities, cardiovascular fitness, and self-esteem were assessed at baseline and at 6 months. Children were followed up 12 months from baseline (0 and 6 months postintervention for the control and intervention group, respectively). Participants in the intervention group had a reduced waist circumference *z*-score (−0.37; $P < 0.0001$) and BMI *z*-score (−0.24; $P < 0.0001$) at 6 months when compared to the controls. Significant between-group differences were also observed in cardiovascular fitness, physical activity, sedentary behaviors, and self-esteem. Mean attendance for the MEND Program was 86%. 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, and benefits in cardiovascular fitness, physical activity levels, and self-esteem were sustained. High-attendance rates suggest that families found this intensive community-based intervention acceptable. Further larger controlled trials are currently underway to confirm the promising findings of this initial trial.

INTRODUCTION

The recent dramatic rise in prevalence of childhood obesity is a major public health issue. The extent of the epidemic and its short and long-term effects on physical and psychological health, including a potential reduction in life expectancy for future generations, have made the prevention and treatment of childhood obesity a high priority (1).

International recommendations agree that the core elements of any initiative to address pediatric obesity should involve the whole family and include nutrition education, behavior modification and promotion of physical activity (1–4). However, available evidence is poor with the main weaknesses of the current literature being small sample sizes, noncomparable interventions, limited generalizability due to delivery in centers of academic or clinical excellence and other methodological issues (1,4–6).

Pragmatic controlled trials of child obesity treatments which address these limitations are clearly needed. The present study aimed to assess the efficacy of a multicomponent, community-based childhood obesity intervention (Mind, Exercise, Nutrition, Do it (MEND) Program). MEND, although fulfilling the expert recommendation criteria for an evidence-based intervention (1–3), has been designed to be delivered in community and primary care settings.

METHODS AND PROCEDURES

The study was conducted between January 2005 and January 2007 at the Medical Research Council Childhood Nutrition Research Centre, UCL Institute of Child Health (London, UK) and was approved by the Metropolitan Multi-Centre Research Ethics Committee (Current Controlled Trials ISRCTN 30238779).

Participants

Potential subjects were recruited from five UK sites by referrals from local health professionals (dieticians, school nurses, and general practitioners), or were self-referred. None of the sites had previously run a MEND Program. Children were eligible if they were obese (BMI ≥ 98th percentile, UK 1990 reference data) (7); had no apparent clinical problems, comorbidities, physical disabilities, or learning difficulties, which would interfere with their ability to take part in the program; were aged between 8 and 12 years; and had at least one parent/carer who was able to attend each of the program sessions.

The MEND Program was delivered at five different sites by separate teams of health, social, education, and exercise professionals. Sites had their own principal investigator who was present during data collection. All measurements were performed in community settings. Informed consent was obtained from the parents after provision of written participant

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information by post and explanation of the study objectives and methods in person.

Study design

This randomized controlled trial was designed to assess the effectiveness of a 6-month intervention consisting of the 9-week MEND Program (www.mendcentral.org) followed by a 12-week free-family swim pass. All eligible participants were assessed at baseline and then randomly allocated to start the program immediately (intervention group) or receive the intervention 6 months later (control group).

Children were consented in community venues to determine whether they met the inclusion criteria. Baseline measurements were performed and randomization was conducted by an independent researcher using a random permuted block design with blocks of size 6. The randomization schedule was computer generated. Both groups were measured again at 6 months (Figure 1) and at 12 months from baseline (6 months postintervention for the intervention group and immediately postintervention for controls).

Study intervention

The MEND intervention is an integrated, multicomponent healthy lifestyle program based on the principles of nutritional and sports science plus, from psychology, learning, and social cognitive theories and the study of therapeutic processes. The program engages families in the process of weight management by addressing the three components necessary for individual-level behavioral change; (i) education (ii) skills training, and (iii) motivational enhancement (8), while retaining a systemic understanding of the need to engage multiple, interacting systems of influence within the family context (9). The MEND intervention was successfully piloted before the current randomized controlled trial (10). The program consisted of 18 sessions delivered over 9 weeks (2-h group sessions held twice weekly in the early evening) by two MEND leaders and one assistant to groups of 8–15 children and their accompanying parents or carers and siblings in community settings such as sports (recreation) centers and schools. The sessions comprised an introduction meeting, 8 sessions focusing on behavior change, 8 sessions providing nutrition education, 16 physical activity sessions and a closing session. Following the 9-week programme, free-family access to a local community swimming pool was made available for a further 12 weeks. The program was delivered using standardized operating procedures. To ensure standardized delivery across sites, all trainers received 4 days of training and were provided with identical materials: theory and exercise manuals, children's handouts, program resources, and teaching aids. The manuals contained detailed methods for the delivery of all sessions.

Nutrition sessions. Sessions on nutrition education consisted of healthy eating advice customized for obese children and included healthy eating tips in the form of achievable weekly targets, instructions on the reading and understanding of food and drink labels and other simple advice designed to produce gradual changes in dietary habits (2). Families also took part in a guided supermarket tour and were given healthy recipes to try at home. In addition, sessions included preparation of healthy meals and fruit and vegetable sampling. A "nondieting" philosophy was advocated throughout the intervention; therefore children were discouraged from weighing themselves and encouraged to make small lifestyle changes to improve health rather than achieve rapid weight loss (1,2).

Behavior change sessions. These sessions focused on teaching parents and children to apply behavioural techniques such as; stimulus control, goal setting, reinforcement, and response prevention to establish a health-promoting home environment (5,9).

Exercise sessions. All sessions included 1 h of exercise for children only. Exercise sessions comprised alternating land and water-based multiskills activities focusing on noncompetitive group play, previously shown to facilitate safe and effective weight management in obese children (11).

Outcome measurements

Data were collected at baseline, 6 and 12 months by two researchers (P.M.S., M.K.) who were both dieticians and experienced in working with obese children under the supervision of the local principal investigators. Because of the delayed intervention, the intensive interaction between families and the researchers, and because participants were keen to discuss their measurements with the research team, blinding to the randomization was not possible. To compensate for the lack of blinding, measurements were taken independently by the two researchers.

Anthropometry

Body weight, height, and waist circumference were measured following standardized procedures (12). Weight and height were obtained for both children and their mothers, and were subsequently used to calculate BMI. Children were classified as obese if their BMI was >98th percentile for age and gender using the recommended cutoff for treatment or referral (7).

Body composition

Deuterium dilution was used to measure children's total body water, and hence fat mass and fat-free mass were derived (13).

Cardiovascular health

Cardiovascular fitness was assessed by the recovery in heart rate 1 min after a validated 3-min step test, standardized for height (14). Systolic and diastolic blood pressure was measured in supine position, on the left arm, with an appropriately sized cuff and an automated blood pressure monitor. Three blood pressure measurements were taken after a 10-min rest and the average of the last two was used for analysis (15).

Physical activity and inactivity

Levels of physical activity and the amount of sedentary behaviors were assessed using a nonvalidated questionnaire adapted from that developed by Slemenda *et al.* (16). This was administered by the researchers to parents and children and included the number and duration of physical education lessons, time spent on different types of vigorous activities (e.g., sports), and time spent on sedentary activities (e.g., television, computer).

Self-esteem

For self-esteem assessment, children completed the Harter Self-Perception Profile, a widely used assessment tool validated for UK children of this age group (17).

Socioeconomic classification

Social class was based on the occupation of the parent providing the main financial support for the family in accordance with the Standard Occupational Classification. Ethnic background was obtained from the parents based on the UK census categorization (18).

Statistical analysis

Based on our pilot study (10), sample size was calculated to detect a 3 cm difference in waist circumference between randomized groups, at 5% significance and 80% power. This required 40 children in each randomized group. To account for drop outs, we aimed to recruit 48 children per group (10).

The primary outcome was change in waist circumference from baseline to 6 months, with change in BMI and % body fat as secondary outcomes. Change was analyzed adjusted for the baseline value using linear regression, and adjusted mean change was compared in the two groups. Interactions of group by sex were also tested for. Groups were analyzed as randomized. Change from baseline to 12 months was studied in the intervention arm

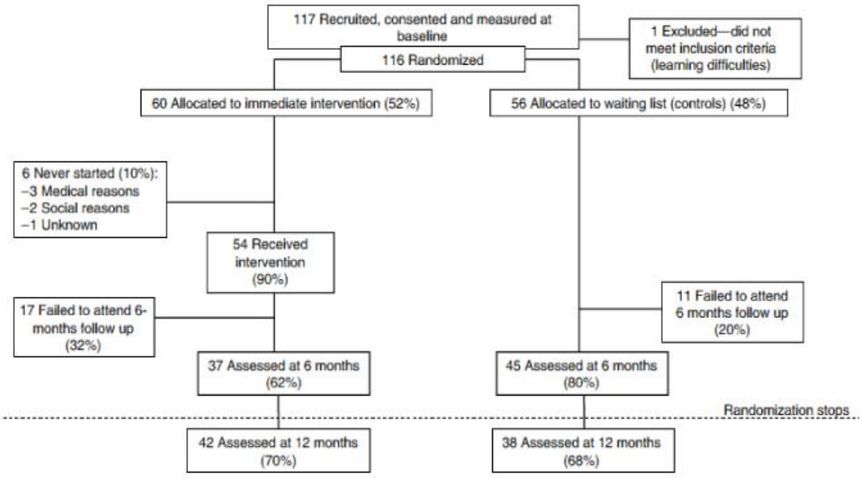

Figure 1 Study charts.

Table 1 Descriptive characteristics of the study population at baseline

	n	Intervention	*n*	Control	*P*
Gender—females	60	63% (38)	56	45% (25)	0.06
Ethnicity—white	60	50% (30)	56	50% (28)	1.0
Social class—nonmanual	60	40% (24)	56	38% (21)	0.9
Age (years)	60	10.3 (1.3)	56	10.2 (1.3)	0.5
Weight (kg)	60	59.2 (12.5)	56	58.3 (14.8)	0.7
Weight *z*-score	60	2.58 (0.63)	56	2.53 (0.77)	0.7
Height (m)	60	1.47 (0.08)	56	1.46 (0.10)	0.6
Height *z*-score	60	1.08 (0.98)	56	1.07 (1.17)	0.9
BMI (kg/m^2)	60	27.2 (3.7)	56	27.1 (4.9)	0.8
BMI *z*-score	60	2.77 (0.51)	56	2.76 (0.63)	0.9
Waist circumference (cm)	60	81.8 (8.3)	55	80.3 (8.6)	0.3
Waist circumference *z*-score	60	2.89 (0.54)	55	2.70 (0.62)	0.1
Lean body mass (kg)	51	35.1 (6.2)	49	35.1 (7.7)	0.9
Fat mass (kg)	51	23.3 (6.4)	49	23.8 (9.3)	0.8
Body fat (%)	51	39.6 (6.2)	49	39.4 (7.0)	0.9
Maternal BMI (kg/m^2)	47	29.3 (6.2)	44	30.5 (6.5)	0.4
Systolic blood pressure (mm Hg)	60	120.7 (13.4)	56	120.7 (11.7)	0.9
Diastolic blood pressure (mm Hg)	60	65.8 (7.8)	56	66.7 (7.7)	0.6
Recovery heart rate (beats/min)	53	115.3 (33.0)	48	106.6 (28.4)	0.5
Physical activity (h/week)	60	21.0 (10.5)	56	20.9 (8.8)	0.4
Sedentary activity (h/week)	60	7.2 (4.6)	56	7.8 (4.6)	0.9
Global self-esteem score (maximum 4)	60	2.8 (0.6)	56	2.8 (0.6)	0.8

Data are mean (s.d.) or % (*n*).

only. Statistical significance was set at $P < 0.05$. All analyses were conducted using SPSS 13.0 for Windows (SPSS, Chicago, IL).

RESULTS

One hundred and seventeen children were recruited, of whom 116 were randomized: 60 to the intervention and 56 to the control group (see **Figure 1**). Of the 60 intervention children, 54 started and all 54 completed the intensive phase of the intervention (9-week MEND Program), while 62% of the 60 were seen at 6 months and 83% either at 6 or 12 months. Groups were broadly similar at baseline, with a high percentage of children from nonwhite ethnic backgrounds and parents in manual occupations (**Table 1**). Mean attendance for the program was 86%, and no adverse effects were reported. In the subsequent 12 weeks, 32% of families used the free swimming pass, on average five times.

At 6 months, both waist circumference and BMI were highly significantly less in the intervention than the control group, adjusted for baseline (−4.1 cm and $-1.2\,kg/m^2$, respectively, or −0.24 and −0.37 z-scores (all $P < 0.0001$) (**Table 2**). Similar benefits of the intervention were observed for fat mass but not % body fat (**Table 2**). In the control group waist circumference and BMI did not change significantly during the 6 months (P = 0.3 and 0.8, respectively). Beneficial changes were also noticed for recovery heart rate, physical activity levels, sedentary activities, and global self-esteem (**Table 2**). There were no significant interactions of the intervention by sex ($P = 0.6$).

Table 3 shows the results from the start of the intervention to 6 months for the two randomized groups combined and to 12 months for the intervention group alone. There were highly significant reductions in waist circumference and to a lesser extent BMI in both periods. Improvements at 6 and 12 months were observed for blood pressure, recovery heart rate, physical activity level, and global self-esteem (**Table 3**).

There was no difference at baseline between children who attended at 6 months and those who did not ($P = 0.6$).

DISCUSSION

Participation in the MEND Program was associated with significant improvements in the degree of adiposity as well as indicators of cardiovascular health and psychological well-being. To our knowledge, this is one of the first randomized controlled trials of a complex family-based obesity intervention designed to be run by nonspecialists in community settings.

Table 2 Comparison of randomized groups at 6 months

	Intervention		Control		Difference (unadjusted)		Difference (adjusted for baseline)		
	n	Mean (s.d.)	n	Mean (s.d.)	Mean (CI)	P	n^a	Mean (CI)	P
Waist circumference (cm)	37	77.7 (7.2)	45	82.0 (8.6)	−4.3 (−7.8 to −0.8)	0.02	81	−4.1 (−5.6 to −2.7)	<0.0001
Waist circumference z-score	37	2.53 (0.58)	45	2.76 (0.61)	−0.23 (−0.50 to 0.03)	0.09	81	−0.37 (−0.49 to −0.25)	<0.0001
BMI (kg/m^2)	37	25.7 (3.3)	45	27.7 (5.2)	−1.9 (−3.8 to 0.0)	0.05	82	−1.2 (−1.8 to −0.6)	<0.0001
BMI z-score	37	2.47 (0.50)	45	2.75 (0.66)	−0.28 (−0.54 to −0.02)	0.03	82	−0.24 (−0.34 to −0.13)	<0.0001
Lean body mass (kg)	23	35.7 (5.9)	22	36.2 (7.4)	−0.5 (−4.5 to 3.5)	0.8	43	−0.8 (−2.6 to 0.9)	0.3
Fat mass (kg)	23	21.8 (4.5)	22	23.8 (9.7)	−2.1 (−6.7 to 2.6)	0.4	43	−2.4 (−4.8 to 0.0)	0.05
Body fat (%)	23	37.9 (4.8)	22	38.6 (7.7)	−0.7 (−4.6 to 3.1)	0.7	43	−1.6 (−5 to 1.9)	0.7
Maternal BMI (kg/m^2)	27	28.8 (5.6)	33	29.9 (6.8)	−1.1 (−4.3 to 2.2)	0.5	60	0.4 (−0.4 to 1.3)	0.3
Systolic blood pressure (mm Hg)	36	111.1 (10.2)	45	112.5 (9.0)	−1.5 (−5.7 to 2.8)	0.5	81	−1.0 (−6.4 to 4.4)	0.7
Diastolic blood pressure (mm Hg)	36	60.7 (7.9)	45	64.5 (7.8)	−3.9 (−7.4 to −0.4)	0.03	81	−3.9 (−8.1 to 0.4)	0.07
Recovery heart rate (beats/min)	37	92 (84, 100)	45	108 (88, 136)	—	0.001	79	−20.3 (−34.2 to −6.3)	0.003
Physical activity (h/week)	37	14.2 (8.2)	45	11.0 (7.8)	3.2 (−0.3 to 6.7)	0.07	82	3.9 (0.1 to 7.8)	0.04
Sedentary activity (h/week)	37	15.9 (7.2)	45	21.7 (9.2)	−5.8 (−9.5 to −2.2)	0.002	82	−5.1 (−9.0 to −1.1)	0.01
Global self-esteem score (maximum 4)	37	3.2 (0.7)	44	2.9 (0.7)	0.3 (0.0 to 0.6)	0.05	81	0.3 (0.0 to 0.7)	0.04

Data are mean (s.d.), mean difference (CI) or median (25th quantile, 75th quantile).
[a] n may deviate due to missing baseline data, CI: 95% confidence interval.

Table 3 Within subject changes at 6 and 12 months from start of intervention

	Change 0–6 months			Change 0–12 months		
	n^a	Mean (CI)	*P*	n^b	Mean (CI)	*P*
Waist circumference (cm)	71	−4.2 (−5.1 to −3.4)	<0.0001	42	−3.1 (−4.6 to −1.6)	<0.0001
Waist circumference *z*-score	71	−0.48 (−0.56 to −0.41)	<0.0001	42	−0.47 (−0.59 to −0.36)	<0.0001
BMI (kg/m²)	71	−1.0 (−1.4 to −0.6)	<0.0001	42	−0.1 (−0.7 to 0.4)	0.7
BMI *z*-score	71	−0.30 (−0.36 to −0.23)	<0.0001	42	−0.23 (−0.33 to −0.13)	<0.0001
Lean body mass (kg)	22	1.3 (0.3 to 2.2)	0.01	0	–	–
Fat mass (kg)	22	−1.4 (−2.5 to −0.2)	0.02	0	–	–
Body fat (%)	22	−2.2 (−3.6 to −0.7)	0.005	0	–	–
Maternal BMI (kg/m²)	49	0.0 (−0.3 to 0.3)	0.9	28	0.2 (−0.2 to 0.7)	0.3
Systolic blood pressure (mm Hg)	70	−5.0 (−7.9 to −2.2)	0.001	41	−6.5 (−10.7 to −2.3)	0.004
Diastolic blood pressure (mm Hg)	70	−4.3 (−6.6 to −2.0)	<0.0001	41	−2.5 (−5.6 to 0.6)	0.1
Recovery heart rate (beats/min)	70	−17.9 (−24.7 to −11.2)	<0.0001	40	−12.4 (−21.6 to −3.1)	0.01
Physical activity (h/week)	71	4.2 (2.2 to 6.2)	<0.0001	40	4.0 (1.9 to 6.0)	<0.0001
Sedentary activity (h/week)	71	−4.8 (−6.8 to −2.9)	<0.0001	41	−2.0 (−4.3 to 0.4)	0.1
Global self-esteem score (maximum 4)	67	0.2 (0.1 to 0.2)	0.007	40	0.3 (0.0 to 0.5)	0.03

Data are mean (CI), CI: 95% confidence interval.
[a]Includes children from both groups measured before and after the intervention (i.e., baseline and 6 months for the intervention group, 6 and 12 months for controls).
[b]Includes children from intervention group only.

The study examined the effects of the MEND intervention on three indicators of adiposity: waist circumference, BMI, and body composition. Waist circumference was designated as the primary outcome measure, an unusual choice in child obesity intervention studies. The reason for this was that the MEND intervention targets both diet and physical activity, aiming to reduce body fat and at the same time increase lean body mass. As BMI does not distinguish between fat and lean mass, it would be possible for a rise in lean to mask a fall in fat. Waist circumference is not susceptible to this effect, as it does not depend on lean mass (19). We felt that this advantage outweighed the known disadvantages of waist circumference—greater measurement error and variability over time compared to BMI.

Waist circumference decreased by 4.1 cm in children in the intervention group compared to controls, comparing favorably with the results reported by two other randomized studies of multidisciplinary lifestyle intervention for pediatric obesity (20,21) and three studies on the effects of pharmaceutical management of obesity (22–24). In adults, a large waist circumference has been shown to increase mortality risk by 20% (25) and its reduction has been associated with significant health benefits (26,27). The clinical significance of reducing waist circumference in children is currently unknown, but its measurement is being encouraged to better assess effectiveness of obesity treatment programs (19,28), given that excess abdominal fat in children is associated with several cardiovascular disease risk factors (29).

BMI was significantly reduced in the intervention group compared to the controls, with a mean adjusted reduction of 1.2 kg/m² for BMI and 0.24 for BMI *z*-score. This matches or exceeds results from other treatment trials (30–33). In another study (34), BMI at 6 months fell by 3.1 kg/m² compared to control, but the sample was more obese and mean BMI in the controls increased by 1 kg/m². By contrast the controls in our study remained stable (35). The observed reduction of 0.24 is four times the average decrease of 0.06 observed for lifestyle interventions in the most recent Cochrane review on childhood obesity (4). This analysis included four well-designed interventions in children aged up to 12 years old. In our study, the changes in favor of the intervention group occurred in the absence of a BMI *z*-score increase that one would expect to see in the controls (35).

Body composition was a third measure of the intervention's effect on adiposity. We found only small changes in body composition, with a trend toward reduced fat mass in the intervention group after adjusting for baseline (**Table 2**). It is possible that greater changes occurred in body fat distribution (as shown by the reduction in waist circumference) than in overall body composition, which may need more time to show itself. This is supported by Hunt *et al.*, who reported that BMI *z*-score needs to fall by at least 0.5 for definite % fat reduction, and represents subcutaneous fat rather than visceral fat loss (36). However, visceral fat—which is better predicted by waist circumference (37)—is the tissue linked to cardiovascular disease risk in children (38).

Physical activity and sedentary behaviors are an essential focus for a successful obesity intervention. In our study, after the intervention, children were more physically active, reduced their sedentary activities and were fitter as indicated by the reduction in recovery heart rate following the 3-min step test (**Table 2**). There was also a trend for blood pressure reduction which was nonsignificant with the exception of unadjusted diastolic blood pressure (**Table 2**). These beneficial changes were largely sustained at 12 months (**Table 3**) and may be linked to an improved cardiovascular disease risk profile (39).

Action to improve the physical health of obese children has been tempered by fears that pediatric weight-management interventions may have adverse psychological consequences (40). However, scores on the measure of global self-esteem significantly increased during the intervention (**Table 2**) suggesting that participation was associated with psychological benefit rather than harm. These results add to a small but growing body of literature indicating that responsibly conducted pediatric weight management may improve the emotional health of obese young people (41).

Sustainability of results is crucial in assessing weight-management programs. In this study, the benefits were sustained up to 9 months after participants had completed the intensive phase of the intervention (12 months from baseline) (**Table 3**). More precisely, waist circumference and BMI *z*-scores decreased by 0.47 and 0.23, respectively. Most of the secondary outcomes also improved indicating longer-term improvements in fitness and lifestyle (as indicated by the reductions in systolic blood pressure, recovery heart rate, and physical activity levels) as well as improved psychological well-being (as indicated by the increase in self-esteem). The poor use of the family swimming pass suggests that the effects of the intervention were largely due to the 9-week MEND Program (intensive phase) rather than provision of free access to a physical activity venue. These observations compare favorably to longer-term outcomes reported by other interventions (4).

Strengths and limitations

A key strength of the MEND Program was its acceptability to families—all the children who started completed it. Also, the mean 86% attendance was similar to our pilot study and higher than reported for other childhood obesity interventions (42,43). Therefore, the intensive program was acceptable and well-tolerated.

Standardization of the MEND Program allowed the intervention to be delivered by community practitioners who had no previous expertise in the management of pediatric obesity and had never delivered a MEND Program. Physical, behavioral, and emotional outcomes were similar to those obtained when the intervention was delivered by specialists (Pediatric Dietician, Consultant Clinical Psychologist, and Physiotherapist) (10). Maintenance of outcomes in the face of such substantial dilution of expertise in the delivery team, suggests that the MEND Program can be delivered effectively in a primary care setting.

In terms of the study design, some other advantages included the multicentre delivery of the intervention, the standardization of the intervention protocol for consistent delivery across settings, and the use of multiple health markers to gain a clear picture of the intervention effects.

This study has several limitations. First, there was a lack of blinding for measurement of outcomes as a consequence of the waiting list control study design. To minimize this bias, more subjective measurements (e.g., waist circumference) were independently performed by two researchers (P.S., M.K.) and all measurements were overseen by the principal investigator at each site.

As with all intervention studies, selective drop out may have influenced the results. However, 83% of children in the intervention group were seen either at 6 or at 12 months, and of these, all who missed the 6-month visit reduced or maintained their BMI and waist circumference *z*-scores from baseline to 12 months. This indicates that the high-drop out rate at 6 months was most likely due to logistical factors, as there was only one opportunity for measurement at each community site.

A third limitation was the relatively short follow-up (12 months from baseline for the intervention group only), which limits conclusions about the long-term effects of the intervention. This is a limitation of all similar intervention studies to date. To address these limitations a second UK randomized controlled trial is currently in progress.

In conclusion, participation in the MEND Program was effective in reducing adiposity in children and effects were sustained 9 months after the intensive part of the intervention. Importantly, the program is one of the few pediatric obesity interventions which conforms to expert recommendations and is deliverable in a primary care setting. These results suggest that the MEND Program is a promising intervention to help address the rising obesity problem in children. Further research is ongoing to measure the effectiveness of the program when delivered on a larger scale using methods that will address the limitations of the current trial.

ACKNOWLEDGMENTS

Financial and nonfinancial support (e.g., staff and venues) were provided by the following UK organizations: National Institute for Health Research, Sainsbury's Supermarkets Ltd., Bromley Mytime, Bromley Primary Care Trust (PCT), Great Ormond Street Hospital for Children NHS Trust, London Borough of Lewisham, MEND Central Ltd., New Cross Gate New Deal for Communities, Parkwood Leisure, Southwark PCT, The Lewisham Hospital NHS Trust, UCL Institute of Child Health, and Waveney PCT. T.J.C., A.L., and A.S. are funded by the MRC. The MEND research team would like to thank all the children and parents who participated in this trial.

DISCLOSURE

P.M.S. is currently employed as a Senior Research Fellow at the UCL Institute of Child Health as well as part-time Chief Research and Development Officer at MEND Central. P.M.S.'s employment at MEND Central commenced after completion of this trial. M.K. was employed as a Research Assistant at the UCL Institute of Child Health and is now employed part-time at MEND Central. P.C. was employed as a Clinical and Health Psychologist at Cancer Research UK Health Behaviour Research Centre, Department of Epidemiology and Public Health, UCL at the time that the research was conducted and is currently employed part-time as Clinical Director at MEND Central. T.J.C. and M.S.L. have no conflict of interest. MEND Central as a social enterprise has committed to return a proportion of its future revenue to the UCL Institute of Child Health so that research on child obesity can be further supported. Apart from a commitment to using such funds to forward public health research into obesity, A.L. has no other conflict of interest. A.S. supervised the research. Apart from the funds that will be derived from MEND to support research into child obesity (see above), A.S. has no other conflict of interest.

REFERENCES

1. Summerbell CD, Ashton V, Campbell KJ *et al.* Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2003:CD001872.
2. NICE. National Institute for Health and Clinical Excellence (NICE) Guidance. Obesity: the Prevention, Identification, Assessment and Management of Overweight and Obesity in Adults and Children. <http://guidance.nice.org.uk/CG43/guidance/section1/word/English> (2006).
3. Spear BA, Barlow SE, Ervin C *et al.* Recommendations for treatment of child and adolescent overweight and obesity. *Pediatrics* 2007;120(Suppl 4):S254–S288.
4. Oude Luttikhuis H, Baur L, Jansen H *et al.* Interventions for treating obesity in children. Cochrane Database Syst Rev 2009:CD001872.
5. Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. *Pediatrics* 1998;101:554–570.
6. Whitlock EP, O'Connor EA, Williams SB, Beil TL, Lutz KW. Effectiveness of Weight Management Programs in Children and Adolescents. Evidence Report/Technology Assessment No. 170 (Prepared by the Oregon Evidence-based Practice Center under Contract No. 290-02-0024). AHRQ Publication No. 08-E014. Rockville, MD: Agency for Healthcare Research and Quality. September 2008.
7. Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. *Arch Dis Child* 1995;73:25–29.
8. Fisher JD, Fisher WA. The information-motivation-behavioral skills model. In: DiClemente R, Crosby R, Kegler M (eds.). Emerging Theories in Health Promotion Practice and Research. Jossey Bass Publishers: San Francisco, CA, 2002, pp 40–70.
9. Christensen P. The health-promoting family: a conceptual framework for future research. *Soc Sci Med* 2004;59:377–387.
10. Sacher PM, Chadwick P, Wells JC *et al.* Assessing the acceptability and feasibility of the MEND Programme in a small group of obese 7-11-year-old children. *J Hum Nutr Diet* 2005;18:3–5.
11. Sothern MS. Exercise as a modality in the treatment of childhood obesity. *Pediatr Clin North Am* 2001;48:995–1015.
12. Lohman TG, Roche AF, Martorell R. Anthropometric Standardization Reference Manual. Human Kinetics: Champaign, IL, 1988, pp 55–80.
13. Wells JC, Fuller NJ, Dewit O *et al.* Four-component model of body composition in children: density and hydration of fat-free mass and comparison with simpler models. *Am J Clin Nutr* 1999;69:904–912.
14. Francis K, Feinstein R. A simple height-specific and rate-specific step test for children. *South Med J* 1991;84:169–174.
15. Sánchez-Bayle M, Muñoz-Fernández MT, González-Requejo A. A longitudinal study of blood pressure in Spanish schoolchildren. Working Group of Cardiovascular Risk Factors in Childhood and Adolescence. *Arch Dis Child* 1999;81:169–171.
16. Slemenda CW, Miller JZ, Hui SL, Reister TK, Johnston CC Jr. Role of physical activity in the development of skeletal mass in children. *J Bone Miner Res* 1991;6:1227–1233.
17. Harter S. Manual of the Self-Perception Profile for Children. University of Denver: Denver, 1985.
18. A Publication of the Government Statistical Service OoPCaS. *Standard Occupational Classification*. HMSO: London, 1993.
19. McCarthy HD, Jarrett KV, Emmett PM, Rogers I. Trends in waist circumferences in young British children: a comparative study. *Int J Obes (Lond)* 2005;29:157–162.
20. Hughes AR, Stewart L, Chapple J *et al.* Randomized, controlled trial of a best-practice individualized behavioral program for treatment of childhood overweight: Scottish Childhood Overweight Treatment Trial (SCOTT). *Pediatrics* 2008;121:e539–e546.
21. Shelton D, Le Gros K, Norton L *et al.* Randomised controlled trial: A parent-based group education programme for overweight children. *J Paediatr Child Health* 2007;43:799–805.
22. Srinivasan S, Ambler GR, Baur LA *et al.* Randomized, controlled trial of metformin for obesity and insulin resistance in children and adolescents: improvement in body composition and fasting insulin. *J Clin Endocrinol Metab* 2006;91:2074–2080.
23. Klein DJ, Cottingham EM, Sorter M, Barton BA, Morrison JA. A randomized, double-blind, placebo-controlled trial of metformin treatment of weight gain associated with initiation of atypical antipsychotic therapy in children and adolescents. *Am J Psychiatry* 2006;163:2072–2079.
24. Chanoine JP, Hampl S, Jensen C, Boldrin M, Hauptman J. Effect of orlistat on weight and body composition in obese adolescents: a randomized controlled trial. *JAMA* 2005;293:2873–2883.
25. Koster A, Leitzmann MF, Schatzkin A *et al.* Waist circumference and mortality. *Am J Epidemiol* 2008;167:1465–1475.
26. Han TS, Richmond P, Avenell A, Lean ME. Waist circumference reduction and cardiovascular benefits during weight loss in women. *Int J Obes Relat Metab Disord* 1997;21:127–134.
27. de Koning L, Merchant AT, Pogue J, Anand SS. Waist circumference and waist-to-hip ratio as predictors of cardiovascular events: meta-regression analysis of prospective studies. *Eur Heart J* 2007;28:850–856.
28. Janssen I, Katzmarzyk PT, Srinivasan SR *et al.* Combined influence of body mass index and waist circumference on coronary artery disease risk factors among children and adolescents. *Pediatrics* 2005;115:1623–1630.
29. McCarthy HD. Body fat measurements in children as predictors for the metabolic syndrome: focus on waist circumference. *Proc Nutr Soc* 2006;65:385–392.
30. McCallum Z, Wake M, Gerner B *et al.* Outcome data from the LEAP (Live, Eat and Play) trial: a randomized controlled trial of a primary care intervention for childhood overweight/mild obesity. *Int J Obes (Lond)* 2007;31:630–636.
31. Nemet D, Barkan S, Epstein Y *et al.* Short- and long-term beneficial effects of a combined dietary-behavioral-physical activity intervention for the treatment of childhood obesity. *Pediatrics* 2005;115:e443–e449.
32. Reinehr T, de Sousa G, Toschke AM, Andler W. Long-term follow-up of cardiovascular disease risk factors in children after an obesity intervention. *Am J Clin Nutr* 2006;84:490–496.
33. Kalavainen MP, Korppi MO, Nuutinen OM. Clinical efficacy of group-based treatment for childhood obesity compared with routinely given individual counseling. *Int J Obes (Lond)* 2007;31:1500–1508.
34. Savoye M, Shaw M, Dziura J *et al.* Effects of a weight management program on body composition and metabolic parameters in overweight children: a randomized controlled trial. *JAMA* 2007;297:2697–2704.
35. Nader PR, O'Brien M, Houts R *et al.*; National Institute of Child Health and Human Development Early Child Care Research Network. Identifying risk for obesity in early childhood. *Pediatrics* 2006;118:e594–e601.
36. Hunt LP, Ford A, Sabin MA, Crowne EC, Shield JP. Clinical measures of adiposity and percentage fat loss: which measure most accurately reflects fat loss and what should we aim for? *Arch Dis Child* 2007;92:399–403.
37. Brambilla P, Bedogni G, Moreno LA *et al.* Crossvalidation of anthropometry against magnetic resonance imaging for the assessment of visceral and subcutaneous adipose tissue in children. *Int J Obes (Lond)* 2006;30:23–30.
38. Savva SC, Tornaritis M, Savva ME *et al.* Waist circumference and waist-to-height ratio are better predictors of cardiovascular disease risk factors in children than body mass index. *Int J Obes Relat Metab Disord* 2000;24:1453–1458.
39. Meyer AA, Kundt G, Lenschow U, Schuff-Werner P, Kienast W. Improvement of early vascular changes and cardiovascular risk factors in obese children after a six-month exercise program. *J Am Coll Cardiol* 2006;48:1865–1870.
40. O'Dea JA. Prevention of child obesity: "first, do no harm". *Health Educ Res* 2005;20:259–265.
41. Lowry KW, Sallinen BJ, Janicke DM. The effects of weight management programs on self-esteem in pediatric overweight populations. *J Pediatr Psychol* 2007;32:1179–1195.
42. Denzer C, Reithofer E, Wabitsch M, Widhalm K. The outcome of childhood obesity management depends highly upon patient compliance. *Eur J Pediatr* 2004;163:99–104.
43. Golley RK, Magarey AM, Baur LA, Steinbeck KS, Daniels LA. Twelve-month effectiveness of a parent-led, family-focused weight-management program for prepubertal children: a randomized, controlled trial. *Pediatrics* 2007;119:517–525.

Appendix 4 Parent and child information sheets

Parent Information Sheet

The MEND Study

Title of study

Improving health in overweight children – the MEND study.

You and your child are being invited to take part in a research study. Before you both decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you and your child wish to take part. Thank you for reading this.

What is the purpose of this study?

MEND stands for Mind, Exercise, Nutrition and Diet and is a lifestyle programme designed to improve health and fitness. The purpose of this research is to allow us to study the effects of the programme on your child's health and fitness.

To obtain the best results you and your child will need to attend regular sessions. The sessions are designed to be fun and easy to understand. They are meant to help you and your child to make small, gradual changes in the types of foods you eat and the amounts of exercise you do. The study will last for one year.

Why have I been chosen?

You and your child have either been referred by a health professional (e.g. GP, school nurse or dietitian) who thinks your child may benefit from taking part in this study or you may have contacted us after seeing our newspaper or website advertisement.

Do I have to take part?

It is up to you and your child to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form but you are still free to withdraw from the study at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What do I have to do?

You will need to attend twice a week in the evenings (5-7pm) for 3 months, with a week's break in the middle for half-term. This works out to 18 visits in total (please see table on following page). There will be an **exercise session at each visit**, which will take place either in a swimming pool or in an exercise studio. Children who cannot swim will not be excluded. All swimming sessions will be monitored by qualified lifeguards and a MEND team member will be present at all times. At the end of the evening visits you will be given a further **3 months of free access to your local leisure centre**. It is up to you how many times you visit the leisure centre (note: visits will be recorded by the leisure centre).

Children can eat as much as they like as this is not a diet, but rather we guide them to make healthy decisions on the foods that they choose to eat. It is important that once you have joined the study, you participate in all sessions until the end. This ensures the best chance of obtaining a good result for you and your child.

What happens at each session?

The table below lists all the sessions and describes what happens at each one.

Session	Week	Description of content
1	1	Meet the trainers, find out what happens at each session, learn safety rules and procedures, fun-based educational and exercise activity.
2	2	Introduction to the MEND food guidelines.
3 (P)	2	Learn some basic concepts to help you motivate your child to achieve healthy goals.
4	3	How to eat healthy foods that help keep blood sugar levels constant.
5 (C)	3	Children learn to set goals to combat unhealthy eating habits.
6	4	Learn about the harmful effects of eating foods that are high in fats and sugars and practical ways to improve the diet.
7 (P)	4	Learn how to modify factors that cause children to eat unhealthily.
8	5	Learn how to read food labels and identify at a glance whether a food is healthy.
9 (P)	5	Learn which of your behaviours, may be preventing your child from achieving their goals.

Half-term break		
10	7	We demonstrate healthy alternatives for mealtimes and give lots of suggestions of foods to buy.
11 (P)	7	Learn how feelings of hunger and cravings can cause children to overeat.
12	8	Supermarket tour. Practice choosing healthy foods off the shelf.
13	8	A game-based session designed to teach children to identify what factors cause them to overeat.
14	9	Learn how to prepare healthy meals as a family.
15	9	Group discussion to allow trainers to solve individual problems.
16	10	Learn how to follow MEND guidelines at the most tempting of times e.g. birthday parties, holidays, eating out and at school.
17	10	The group will explore how low self-esteem can prevent children from achieving their potential.
18	11	Summing up and farewells. Presentation of certificates of achievement.

(P) = parents only (C) = children only

What will happen to me if I take part?

In order to be able to tell how effective the MEND programme is, we need to make comparisons. Children will be put into one of two groups and compared. The groups are selected by a computer which has no information about you or your child – i.e. by random selection. The only difference between the two groups is that one group will wait approximately 6 months before starting the programme. The reason for doing this is to compare children on the programme with those not attending yet. All families will start the programme within one year of agreeing to participate.

In order for us to evaluate the programme we need to do the following measurements:

a) We will measure your child's **weight, height and waist size**.
b) We will perform a measurement of **body fat** using a very low level electrical current (that can't be felt), passed between electrodes placed on the hand and foot. The test is harmless and painless and used at health clubs.
c) Measure the amount of **water** in your child's body. This measurement involves drinking some water containing heavy hydrogen molecules. These molecules are not radioactive, they simply weigh more than most hydrogen molecules and they

occur naturally in all of us. Before and after the drink your child will be asked to provide a saliva sample using chewable cotton wool.

d) To assess your child's level of **physical fitness** your child will be asked to step on and off a low bench for 3 minutes and have their heart rate and blood pressure measured.

e) You and your child will be asked to fill in some questionnaires which examine **self-esteem** and behaviour at mealtimes and during physical activity.

f) We will ask you to complete a **food diary** at home which involves writing down everything your child eats and drinks for 3 days. We will explain exactly how to do this.

g) Children above the age of 9 years will be asked to assess their **stage of puberty** (physical maturity) using pictures as a guide. A room where they can do this in private will be provided. Children will be asked to put their completed questionnaire into an envelope and then seal the envelope. Children will **not** be asked to undress and the information collected will be strictly confidential and not known to the people doing the measurements (optional).

h) We will also collect a **DNA sample** by rubbing the inside of your child's cheek with cotton wool. This sample will be used to look at genes and the effect of losing weight. The sample may be stored to look at the effect of genes on obesity and cardiovascular disease. All tests will not have any relevance to you or your child's health.

These measurements will be done **4 times in total at 0, 3, 6 and 12 months**. All these measurements have no harmful, adverse or side effects and will all take place at **Ladywell Leisure Centre**, 261 Lewisham High Street, Lewisham, London, SE13 6NJ.

What are the alternatives for treatment?

If you decide not to participate in the study, you may wish to discuss other options with your GP. These may include seeing a dietitian, doing regular exercise, being referred to a hospital obesity clinic or being put on a diet.

What are the side effects of any treatments received when taking part?

There are no expected side effects of any of the treatments or measurements.

What are the possible disadvantages and risks of taking part?

There are no foreseeable disadvantages or risks in participating in this study.

What are the possible benefits of taking part?

We hope that the MEND programme will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future overweight patients better. Our small pilot study suggested that the programme benefits body fat, general health, fitness and self-esteem.

What if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, a researcher will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw the researcher will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information the researcher might consider it to be in your best interest to withdraw you from the study. He will explain the reasons and arrange for your care to continue.

What happens when the research study stops?

You will receive a letter summarising the findings of the study once the results have been analysed and you will also be notified when the results are first published in a medical journal. You will be able to refer to the MEND website for up to date information.

What if something goes wrong?

This research has been approved by an independent Research Ethics Committee which believes that it is of minimal risk to your child. However, research can carry unforeseen risks and we want you to be informed of your rights in the **unlikely event** that any harm should occur as a result of taking part in this study.

This research is covered by a no-fault compensation scheme which may apply in the event of any significant harm resulting to you or your child from involvement in the study. Under this scheme it would not be necessary for you to prove fault. You also have the right to claim damages in a court of law. This would require you to prove fault on the part of the researchers.

Will my taking part in this study be kept confidential?

All information that is collected about you and your child during the course of the research will be kept strictly confidential. Any information about you which leaves the Leisure Centre or research site will have your name and address removed so that you cannot be recognised from it. Regulatory authorities will have access to the study records.

If your child is found to be suitable for the study it will be necessary for us to write to your child's GP. We will inform the GP of your child's participation in the study. If the GP does not feel they are suitable for the study, then they will not be able to attend the programme. If we find your child to be unsuitable then we would also like to notify your G.P. We will always ask your permission first before contacting your child's G.P.

What will happen to the results of the research study?

The results of this research will be published in a medical journal. It is possible that the results of this study may attract media interest; however, you or your child will not be identified in any report or publication or website. After the conclusion of the study, we may want to contact you again to see if the changes made during the study have remained.

Who is organising and funding the research?

The study organiser is the MRC Childhood Nutrition Research Centre, Institute of Child Health. The studies sponsors are the Department of Health and Sainsbury's Supermarkets Ltd. Some of the results of this study will be used as part of a PhD submission. Families involved in the study will not be charged for any of the services provided and all travel costs will be reimbursed. Children will receive 2 t-shirts, a backpack and a folder.

Who has reviewed the study?

This project has been reviewed and approved by the Department of Health and has received ethical approval from the Metropolitan Multi-Centre Research Ethics Committee.

What do I need to do to join the study?

After reading this information, if you and your child would like to participate, then please make an appointment to be assessed for the study (see back page).

Once the assessments are performed, only those children that meet our inclusion criteria will be recruited for the study. Unfortunately we cannot guarantee inclusion for all children.

Contact information

For further information, please ring Paul Sacher BSc (Med) Hons RD, Specialist Dietitian on **(020) 7905 2258** or **email** **Info@mendprogramme.org** or write to **The MEND Study**, **MRC Childhood Nutrition Research Centre, Institute of Child Health, 30 Guilford Street, London, WC1N 1EH.**

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 Paul Sacher. If the problems are not resolved, or you wish to comment in any other way, please contact the Chairman of the Metropolitan Multi-Centre Research Ethics Committee, by post via the Research Centre, University Hospital Lewisham, Lewisham High Street, London, SE13 6LH, or if urgent, by telephone on (020) 8333 3367 and the Committee administrator will put you in contact with him.

For more information and to see a short movie of the MEND pilot study please see **www.mendprogramme.org.** Please retain this copy of the information sheet and you will also get a copy of the signed consent form to keep.

Thank you for taking the time to read this information sheet.

Child Information Sheet

The MEND Project

You are being invited to take part in a project. Take time to decide if you want to say YES or NO to this. Please read, or have someone read to you, this information. Don't worry if you don't understand it straight away. Your parents have also been told about this, and you can ask them to help you understand. Thank you for reading this.

Why are we doing this?

We want to see if we can help overweight children to become healthier and fitter by teaching them about healthy foods and doing fun exercise with them.

Do I have to take part?

It is up to you to decide if you want to take part in the project or not. Even if you decide to take part, you can still leave the project at any time and you don't even have to give us a reason.

What do I have to do?

You will be asked to come to Kirkley Sports College twice a week, for 3 months, with a break in the middle for half-term. Each time you come we will talk to you and your parents about healthy foods and you will also get to take part in an **exercise class.** Some exercise will be indoors and some outdoors (in Summer only). After 3 months you will be allowed to use a **leisure centre for another 3 months**.

How can we tell if the programme works?

We will do some measurements to see if the programme works. The measurements will be done 4 times in one year. None of the measurements are dangerous or hurt:

i) We will **weigh** you on a scale and measure your **height** and your **waist size**.

j) We will measure your **body fat** using a machine that is often used in gyms. It is completely harmless and you don't feel a thing.

k) We will ask you to drink a small amount of **special water** (looks and tastes like water) which is also completely harmless. We will ask you to roll a piece of cotton wool in your mouth to collect some spit and this will help us to work out how much fat is in your body.

l) We will see how many times you can **step on and off a low step in 3 minutes** and measure how fast your heart beats and also your blood pressure.

m) We will ask you and your parent to answer some **questions.**

n) We will also ask you and your parent to write down everything you **eat and drink** for 3 days.

o) If you are over 9 years old, we will ask you to fill in another questionnaire which tells us how **developed your body** is. This will be done in a private room and then put in a sealed envelope so nobody can see. You will **not** be asked to undress. You do not have to do this if you do not want to.

p) We will collect a **sample** of your genes by rubbing inside of your cheek with some cotton wool. This will help us to study how genes affect your weight.

Is anything dangerous?

None of the treatments or measurements are dangerous.

Who will know about me taking part?

The people doing the research will know about you and we will also need to let your GP know that you are taking part. We will ask your permission first before writing to your GP. Nobody else will know you have taken part.

Who can I speak to if I have any questions?

You can speak to your parents who have also been given information about this project. One of the dietitians involved is Paul Sacher. You and your parents can always speak to him if you have any more questions. If you would prefer to speak to someone other than the MEND team or your parents, then you can call Louise Diss who is a counsellor on 01279 866010 or email her on ask.louise@toast-uk.org.uk (Toast stands for The Obesity Awareness and Solutions Trust). All calls are anonymous and confidential. Your parents also have some further contact details of people to speak to if they have any complaints or worries.

Contact information

Paul Sacher, Dietitian on **(020) 7905 2806** or **email Info@mendprogramme.org** or write to **The MEND Project**, **MRC Childhood Nutrition Research Centre, Institute of Child Health, 30 Guilford Street, London, WC1N 1EH.**

To see a short movie of other children doing the MEND programme please see **www.mendprogramme.org.**

Please keep this copy of the information sheet and you will also get a copy of the signed form to keep.

Thank you for taking the time to read this information sheet.

Appendix 5 Consent form

Institute of Child Health
and Great Ormond Street Hospital for Children NHS Trust
UNIVERSITY COLLEGE LONDON

MEND
Mind Exercise Nutrition Diet

The child first and always

PARENT'S CONSENT FORM

Improving health in overweight children – the MEND Study

Name of Researcher: Paul Sacher

MND ☐☐☐

Please initial box

1. I confirm that I have read and understand the parent information sheet for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I agree to my child's GP being informed of their participation in this study and also asked if there is any reason why my child should not participate. ☐
4. I consent to a sample of my child's DNA being stored and used for the purposes described in the information sheet. ☐
5. I agree to take part in the above study. ☐

____
Child's name

______________________	______________	______________
Parent's name giving consent	Date	Signature
Name of Researcher (if different from above)	Date	Signature

1 copy for participant; 1 copy for researcher

The Queen's Anniversary Prizes
For Higher and Further Education
2000

MRC Childhood Nutrition Research Centre
Institute of Child Health
30 Guilford Street, London WC1N 1EH
Tel: 020 7905 2806 *Email:* study@mendprogramme.org

UCL

Appendix 6 Assent form

Institute of Child Health

and Great Ormond Street Hospital for Children NHS Trust

UNIVERSITY COLLEGE LONDON

The child first and always

MEND

Mind Exercise Nutrition Diet

CHILD's ASSENT FORM

Improving health in overweight children – the MEND study

Name of Researcher: Paul Sacher MND: ☐☐☐

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to my GP being informed of my participation in this study and also asked if there is any reason why I should not participate. ☐

4. I consent to a sample of my DNA being stored and used for the purposes described in the information sheet. ☐

5. I agree to take part in the above study. ☐

Child's name	Date	Signature
Name of Researcher (if different from above)	Date	Signature

1 copy for participant; 1 copy for researcher

THE QUEEN'S ANNIVERSARY PRIZES FOR HIGHER AND FURTHER EDUCATION 2000

MRC Childhood Nutrition Research Centre
Institute of Child Health
30 Guilford Street, London WC1N 1EH
Tel: 020 7905 2806 *Email:* study@mendprogramme.org

UCL

Appendix 7 GP notification form (inclusion)

Institute of Child Health

and Great Ormond Street Hospital for Children NHS Trust

UNIVERSITY COLLEGE LONDON

MEND

Mind Exercise Nutrition Diet

The child first and always

Dr.

/ /2005

Dear Doctor

Re: **DOB:** / /

Address:

The above patient has granted us permission to inform you that they have been recruited to participate in a research study entitled: **Improving health outcomes in obese children: a randomised controlled trial of the MEND programme**.

This study is a randomized, cross-over trial that aims to improve body composition, fitness and self-esteem. There is no diet involved and we are not encouraging weight loss in accordance with the latest Royal College of Paediatrics and Child Health guidelines on the management of overweight and obesity in children.

I would be very grateful if could let me know if there are **any factors that may hinder their participation in this research.** This research has ethical approval from Metropolitan Multi-Centre Research Ethics Committee (MREC). Please let me know if you require any further information.

Many thanks

Yours faithfully

Paul Sacher

Specialist Dietitian

THE QUEEN'S ANNIVERSARY PRIZES
FOR HIGHER AND FURTHER EDUCATION
2000

MRC Childhood Nutrition Research Centre
Institute of Child Health
30 Guilford Street, London WC1N 1EH
Tel: 020 7905 2258 *Email:* p.sacher@ich.ucl.ac.uk

UCL

Appendix 8 Weight and height SOP

The Mend Study

Standard operating procedures for measuring weight and height

Weight (digital scales)

1. Operator checks that electronic scales are on level firm surface, away from any encumbrances and reading is zero.
2. Subject removes shoes and outer clothing, stands on centre of scales, keeping still, facing forwards and hands at sides.
3. Operator records measurement in kilograms to 2 decimal places.

Height (wall-mounted stadiometer)

1. Subject removes shoes and outer clothing. Subject stands straight with
   - (a) feet flat on floor,
   - (b) back, shoulders, head, buttocks (and calves if backboard reaches) against backboard of stadiometer,
   - (c) heels against heel plate, and
   - (d) head in horizontal Frankfurt (orbito-meatal) plane passing through upper margins of the external acoustic meatuses and the lower margin of the left orbit.
2. Subject breathes in normally and remains still.
3. Operator places head-plate on top of subject's head and records measurement in metres to 2 decimal places.

Appendix 9 Waist circumference SOP

The Mend Study

Standard operating procedure for waist circumference

Equipment: waist circumference tape measure

Method

1. Subject stands straight.

2. Operator finds the narrowest girth of the waist, usually about 4cm above the umbilicus. If this proves to be difficult then the subject may be asked to bend to the side and the operator then identifies the point at which the trunk folds, and uses this as the landmark.

3. Operator measures, and records, the waist circumference at this point with the tape horizontal.

Appendix 10 Body composition (deuterium dilution) SOP

The Mend Study

Standard operating procedure for deuterium preparation

1. Labelling of sample tubes and salivettes with subject reference details and date:

   (a) for aliquot of deuterium dose solution; green pen and add ‘dose’

   (b) for pre-dose saliva sample; red pen and add ‘pre’

   (c) post-dose saliva samples; blue pen and add ‘post’

2. Make up deuterium dose according to body weight:

   (a) use a nominal amount of 0.05g stock deuterium oxide (~ 99.9%) per kg body weight
   (b) use a nominal amount of 2g water per kg body weight(for example: 100g of water and 2.5g deuterium oxide for a 50kg child)
   (c) filter the deuterium dosing solution with 0.45 micropore filter.
   (d) label bottle with subject reference and date.
   (e) mix well and, using a clean pipette, obtain a sample (approx 1.5mls) from the middle of the bottle and place in a plain 2ml sample tube and label with subject reference (to correspond with dose bottle) and write ’dose’ (all in green pen). Place in freezer (-20^{o}C).

3. Place the dosing bottle in a plastic bag with a straw and seal.

4. Weigh dosing bottle (in bag with straw), record all details in the Deuterium Log Book and place bottle in fridge until use.

Deuterium Dosing

1. To obtain a saliva sample prior to dosing:

   (a) ensure that the subject has had nothing to eat, drink or teeth cleaning for at least 30 minutes prior to sampling

   (b) tip the cotton swab from the salivette labelled with subject details and 'pre' in RED pen into the subject's hand

   (c) the swab should be placed in the mouth and moved around, without chewing, until wet and then placed back into salivette.

2. The deuterium dosing solution is then drunk by the subjects, through the straw ensuring that as much as possible is swallowed with no spillage.

3. Place both the bottle and straw in the plastic bag and seal.

4. Record the time when the dose was given and fill in the time on the instruction sheet indicating when the post-dose sample should be taken (4 hours later for subjects of average weight and 5 hours later for obese subjects).

5. Give instructions to the subjects for recording any fluid intake between samples and for collecting the second saliva sample with the same procedure as for the pre-dose sample, but with salivette labelled with subject details and 'post' in BLUE pen.

6. Weigh the plastic bag containing dosing bottle and straw, and record.

7. Centrifuge salivettes at 3000 rpm for 8 mins.

8. Using clean pipettes for each sample, place sample in plain 2ml sample pot, appropriately labelled with RED pen for the pre-dose sample and BLUE pen for the post dose sample, and place in freezer. Dispose of used

transfer pipettes and salivettes in the yellow biohazard bags in the laboratory.

Safety Considerations:

Use of laboratory to prepare samples:

- Wear appropriate protective clothing whilst working in the laboratory ie, lab coats, latex/vinyl gloves and eye protection. When storing samples in the -70 freezer wear the blue gauntlet gloves provided to protect from the cold.

- All samples should remain in sealed plastic bags during transportation to the lab.

- The centrifuge should only be used by staff who have been trained in its use with supervision by the lab manager until deemed competent. Balances should be used as necessary to ensure an equal distribution of weight in the centrifuge.

Deuterium dilution SOP: May 2003.

MRC Childhood Nutrition Research Centre

Participant instructions for taking a saliva sample at home

Subject No:

We need you to take a sample of saliva after you get home and post it back to us in the envelope provided.

…….. hours after your deuterium drink, at ….... pm we would like you to take another saliva sample in the same way you did the first. **Do not eat, drink or clean your teeth for 30 minutes before taking the sample.** Move the swab around your mouth until wet **without** chewing on it.

It is **very important** that you take the sample at this time but if it is not possible it is better that you tell us the time it was taken.

Record here the time you took the sample …………......

We also need to know how much you drank in the period between the deuterium drink and the saliva sample you have taken at home.

Record the number of drinks you have had: ……….... cups

……....... mugs

……....... small glasses

…………. large glasses

……….... cans (330ml)

……….....bottles (500ml)

Place the cotton swab in the tube and replace the lid **firmly**. Put the tube in the plastic bag and seal carefully.

Please return this sheet and the sample in the stamped addressed envelope provided as soon as possible.

THANK YOU FOR TAKING PART IN THIS STUDY

Appendix 11 Height-specific and rate-specific step test SOP

The Mend Study

Standard operating procedure for height-specific and rate-specific step test

Ensure beforehand that the platform height is calculated for the specific height of each child and that the metronome is set correctly.

Calculation of platform height.

1. Hip angle optimum bend is 73^{o}.
2. Platform height = L_f x Subject height (cm) x (1 - cos 73^{o}):

   where; L_f. is femur length / stature, and is assumed to be constant (ie very small inter-individual variability).
3. Therefore, Platform height = 0.265 x 0.71 x Ht (cm).

   Platform height = 0.188Ht (cm)
4. (a) Each gradation on 'Reebok step' = 5cm.

   (b) Each gradation on platform inserts = 1.2cm.
5. (a) Platform height adjustment of 5cm = 26.6cm of subject height.

   (b) Platform height adjustment of 1.2cm = 6.38cm of subject height.

   (c) There are two 0.6cm inserts for adjustment of 3.2cm of subject height

Set metronome.

1. For males; 96 beats per minute.
2. For females; 88 beats per minute.

Step test.

1. Record subjects resting pulse rate for 15 secs.
2. Start metronome.
3. Subject steps up and down at the rate indicated by metronome, making one step per beat.
4. Time exercise for 3 minutes, ensuring that subject keeps to the middle of the step for safety and keeps to time.

5. Subject stops test and immediately sits down.

6. Record subjects immediate post-exercise pulse rate for 15 secs, starting as near to as zero time as possible.

7. Subject remains resting for another minute.

8. Record subjects resting pulse rate after one minute for 15 secs, starting as near to one minute later as possible.

Appendix 12 Blood pressure SOP

The MEND Study

Standard operating procedure for Accutorr Plus NIBP with printer (Datascope)(Automated blood pressure monitor)

1. Have subject sit quietly for several minutes before taking the measurement.
2. Select the largest cuff that fits the upper arm comfortably.
3. Wrap the cuff around the left arm, placing the circular figure immediately over the brachial artery.
4. Switch the machine on with ‘On/Standby’ switch bottom right – 20 second warm-up.
5. Connect the cuff to the tube from the machine.
6. Use ‘patient set-up’ to select patient type.
7. Ask subject to rest arm on a surface at level of heart.
8. Inflate cuff, using ‘Start NIBP’. Cuff will inflate to pre-set pressures for each patient group.
9. If subject is unable to tolerate the inflation – press ‘deflate’ button immediately.
10. After deflation, machine will give readings for Systolic, Diastolic, Mean arterial pressure (MAP) and Heart rate (HR).
11. If on the first inflation the machine is unable to take a measurement, the Accutorr will automatically re-inflate to a higher pressure.
12. Repeat the measurement 3 times at 2 minute intervals.
13. Record the average of the last 2 measurements
14. At the end of the sequence of measurements print-out the results using ‘print’ button.
15. If the pre-set pressures are not suitable for a particular patient group, the default pre-set pressures can be altered. For further information refer to ‘Accutorr Plus Service Manual’

Appendix 13 Children's physical activity questionnaire

The MEND Study

Exercise Data

Study Number: MND □□□

Child's name: ____________________ Date: ________

Mother / Father present (please circle)

Researcher to complete with child and parent/s

1. How many PE lessons do you have per week? ________________

2. How long is each PE lesson in minutes? ____________________

3. How many hours per week do you spend watching TV and videos, plus playing on the computer and video games (school nights only)? _____

4. How many hours per week do you spend watching TV and videos, plus playing on the computer and video games (weekend)? ___________

5. How many hours per week do you spend on each of these activities outside PE classes: ___________________________________

Riding bike _______________ Tennis _____________

Swimming _______________ Netball _____________

Running _________________ Hockey _____________

Football _________________ Basketball ___________

Aerobics/dancing ___________ Rugby _____________

Gymnastics _______________ Skating _____________

Walking _________________ Other sport ___________

Other, please specify ____

Parent's opinion of the child's physical activity levels

Total hours child spends in vigorous activity per week? _________________

Level of child's activity compared to peers? __________________________

1 = much less than peers 2 = less 3 = same 4 = more 5 = much more

Appendix 14 Children's self-esteem questionnaire

MEND

The MEND Study

Children's Questionnaire

Study Number: MND □□□

Your name: ____________________ Date: _________

This questionnaire collects information about you and your family. Please read and answer every question. If you get stuck or would like some help with filling in the questionnaire, please ask one of us to help you.

All information provided will be treated in strict confidence (which means it will be kept private) and will not be shared with your parents or anyone else.

EXAMPLE SENTENCE

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
a)	□	□	Some kids would rather play outside in their spare time	BUT	Other kids would rather watch TV	□	□

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
1.	☐	☐	Some kids feel they are very good at their school work	BUT	Other kids worry about whether they can do their school work	☐	☐
2.	☐	☐	Some kids find it hard to make friends	BUT	Other kids find it's pretty easy to make friends	☐	☐
3.	☐	☐	Some kids do very well at all kinds of sports	BUT	Other kids don't feel they are good when it comes to sports	☐	☐
4.	☐	☐	Some kids are happy with they way they look	BUT	Other kids are not happy with the way they look	☐	☐
5.	☐	☐	Some kids often do not like the way they behave	BUT	Other kids usually like the way they behave	☐	☐
6.	☐	☐	Some kids are often unhappy with themselves	BUT	Other kids are pretty pleased with themselves	☐	☐
7.	☐	☐	Some kids feel they are just as clever as other kids	BUT	Other kids aren't so sure and wonder if they are as clever	☐	☐
8.	☐	☐	Some kids have a lot of friends	BUT	Other kids don't have very many friends	☐	☐
9.	☐	☐	Some kids wish they could be a lot better at sports	BUT	Other kids feel they are good enough at sports	☐	☐
10.	☐	☐	Some kids are happy with their height or weight	BUT	Other kids wish their height or weight was different	☐	☐
11.	☐	☐	Some kids usually do the right thing	BUT	Other kids often don't do the right thing	☐	☐

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
12.	☐	☐	Some kids don't like the way they are leading their life	BUT	Other kids do like the way they are leading their life	☐	☐
13.	☐	☐	Some kids are pretty slow in finishing their school work	BUT	Other kids can do their school work quickly	☐	☐
14.	☐	☐	Some kids would like to have a lot more friends	BUT	Other kids have as many friends as they want	☐	☐
15.	☐	☐	Some kids think they could do well at any new sport	BUT	Other kids are afraid they do not do well at new sports	☐	☐
16.	☐	☐	Some kids wish their body was different	BUT	Other kids like their body the way it is	☐	☐
17.	☐	☐	Some kids usually behave the way they know they're supposed to	BUT	Other kids often don't behave the way they're supposed to	☐	☐
18.	☐	☐	Some kids are happy with themselves as a person	BUT	Other kids are often not happy with themselves	☐	☐
19.	☐	☐	Some kids often forget what they learn	BUT	Other kids can remember things easily	☐	☐
20.	☐	☐	Some kids are always doing things with a lot of kids	BUT	Other kids usually do things by themselves	☐	☐
21.	☐	☐	Some kids feel they are better at sports than their friends	BUT	Other kids don't feel they can play as well	☐	☐

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
22.	☐	☐	Some kids wish they looked different	BUT	Other kids like the way they look	☐	☐
23.	☐	☐	Some kids usually get in trouble because of things they do	BUT	Other kids don't do things that get them into trouble	☐	☐
24.	☐	☐	Some kids like the kind of person they are	BUT	Other kids often wish they were someone else	☐	☐
25.	☐	☐	Some kids do very well at their class work	BUT	Other kids don't do very well at their class work	☐	☐
26.	☐	☐	Some kids wish more people their own age liked them	BUT	Other kids feel that most people their own age do like them	☐	☐
27.	☐	☐	In games and sports some kids usually watch instead of play	BUT	Other kids usually play rather than just watch	☐	☐
28.	☐	☐	Some kids wish something about their face or hair was different	BUT	Other kids like their face and hair the way they are	☐	☐
29.	☐	☐	Some kids do things they know they shouldn't do	BUT	Other kids hardly ever do things they know they shouldn't do	☐	☐
30.	☐	☐	Some kids are very happy being they way they are	BUT	Other kids wish they were different	☐	☐
31.	☐	☐	Some kids have trouble working out the answers at school	BUT	Other kids almost always can work out the answers	☐	☐

	Really True for me	Sort of True for me				Sort of True for me	Really True for me
32.	☐	☐	Some kids are popular with others their own age	BUT	Other kids are not very popular	☐	☐
33.	☐	☐	Some kids don't do well at new outdoor games	BUT	Other kids are good at new games right away	☐	☐
34	☐	☐	Some kids think that they are good looking	BUT	Other kids think that they are not very good looking	☐	☐
35	☐	☐	Some kids behave themselves very well	BUT	Other kids often find it hard to behave themselves	☐	☐
36	☐	☐	Some kids are not happy with they way they do a lot of things	BUT	Other kids think the way they do things is fine	☐	☐

Thank you for completing this questionnaire.

Appendix 15 Social data questionnaire

The MEND Study

Social Data

Study Number: **MND** □□□

Child's name: ____________________ Date: ________

Mother / Father present (please circle)

Researcher to complete with parent/s

1. Number of people in home (incl. subject)? ______________________

2. Number of rooms in home (incl. dining, living, bedrooms, excl. kitchen and bathrooms)? ______________________

3. Is home own or rented? ☐ Own ☐ Rented

4. If home rented, is it from: ☐ Private landlord ☐ Council ☐ Housing association ☐ Irrelevant

5. Is mother married? ☐ Yes ☐ No ☐ Living with partner

6. Mother's date of birth ☐☐ / ☐☐ / ☐☐☐☐

> 1. No educational qualifications
> 2. < 3 CSE's or GCSE's below C grade
> 3. >3 CSE's or any O levels or GCSE grade A-C
> 4. A levels, ONC/OND/BEC/TEC, SCE Higher, NVQ level 3
> 5. Degree/HND/HNC professional training (including SRN, RGN, RM, RHV), NVQ levels 4/5, BEC/TEC Higher

7. Mother's educational attainments (highest completed) ______________

8. Mother's highest qualification? ______________________

9. Mother's occupation? ______________________

10. How many months employed in the last year? ______________

11. Father's date of birth ☐☐ / ☐☐ / ☐☐☐☐

12. Father's educational attainments (highest completed)? ______________

13. Father's highest qualification? ____________________________

14. Father's occupation? ____________________________________

15. How many months employed in the last year? __________________

16. Who is the primary earner for the family? ☐ Father ☐ Mother

☐Grandparent ☐ Both parents ☐ Missing

17. Social class (use primary earner's occupation) __________________

Code as: 1 =1, 2 = 2, 3N = 3, 3M = 4, 4 = 5, 5 = 6 on primary earner's occupation Single parent mother unsupported and not working = 7 Mother supported but partner and self never employed = 8 Adopted / fostered child = 9

17. Ethnic origin (Which box best describes your ethnic origin?

☐ White

☐ Black-Caribbean

☐ Black-African

☐ Black-other

☐ Indian

☐ Pakistani

☐ Bangladeshi

☐ Turkish

☐ Chinese

☐ Asian-other

☐ Other

☐ Refused

Appendix 16 Ethical approval letter

SL14 Favourable opinion following consideration of further information
Version 2, October 2004

NHS

Metropolitan Multi-centre Research Ethics Committee

University Hospital Lewisham
Research & Development Centre
Lewisham High Street
London
SE13 6LH

Tel: 020 8333 3367
Fax: 020 8333 3227
~~E-mail: cheryle.curtis@uhl.nhs.uk~~

CPW/YO
02 February 2005

Mr Paul Sacher

Research Fellow
Institute of Child Health
30 Guilford Street
London
WC1N 1EH

Dear Mr Sacher

Full title of study: *Improving health outcomes in obese children: a randomised controlled trial of the MEND (mind, exercise, nutrition and diet)childhood obesity treatment programme.*
REC reference number: *04/MRE11/42*
Protocol number:

Thank you for your letter of 14 January 2005, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

The further information was considered at the meeting of the Chair's Actions held on 31 January 2005.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The favourable opinion applies to the research sites listed on the attached form. Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed that they have no objection.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document Type:	Version:	Dated:	Date Received:
Application		11/10/2004	14/10/2004
Investigator CV	Paul Sacher	30/09/2004	14/10/2004
Investigator CV	Atul Singhal		14/10/2004
Investigator CV	Timothy James Cole		14/10/2004

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Investigator CV	Sally Brothers		14/10/2004
Protocol	13	17/09/2004	14/10/2004
Covering Letter		12/10/2004	14/10/2004
Summary/Synopsis	3	09/08/2004	14/10/2004
Statistician Comments		30/06/2004	14/10/2004
Compensation Arrangements		12/08/2004	14/10/2004
Copy of Questionnaire	1- girls	15/08/2004	14/10/2004
Copy of Questionnaire	1-boys	15/08/2004	14/10/2004
Copy of Questionnaire	1-food dairy	29/07/2004	14/10/2004
Copy of Questionnaire	1- Social Data	27/08/2004	14/10/2004
Copy of Questionnaire	1- Childrens what am I like	26/08/2004	14/10/2004
Copy of Questionnaire	1- Carer activity modeling	26/08/2004	14/10/2004
Copy of Questionnaire	1- Carer strengths & difficulties2	26/08/2004	14/10/2004
Copy of Questionnaire	1- Carer food practice3	26/08/2004	14/10/2004
Copy of Questionnaire	1- Exercise data	26/08/2004	14/10/2004
Copy of Questionnaire Carer's Questionaire(1) & Childrens Questionaire	Version 2	13/01/2005	02/02/2005
Copies of Advertisements	2- Website recruitment	08/09/2004	14/10/2004
Copies of Advertisements	2- Newspaper	08/09/2004	14/10/2004
Letters of Invitation to Participants	2	29/07/2004	14/10/2004
GP/Consultant Information Sheets	4-notification of recruitment letter	20/09/2004	14/10/2004
GP/Consultant Information Sheets	2- notification of unsuitability for study letter	11/08/2004	14/10/2004
Participant Information Sheet	An approach to weight management		14/10/2004
Participant Information Sheet	Blue leaflet		14/10/2004
Participant Information Sheet	8-Parent	01/10/2004	14/10/2004
Participant Information Sheet Parent Information Sheet	version 9	13/01/2005	02/02/2005
Participant Information Sheet Child Information Sheet	version 5	13/01/2005	02/02/2005
Participant Information Sheet	4-Child	22/09/2004	14/10/2004
Participant Information Sheet	Blue Leaflet		14/10/2004
Participant Information Sheet	Healthy eating booklet		14/10/2004
Participant Consent Form	2-Child	11/08/2004	14/10/2004

Participant Consent Form	4-Parent	01/10/2004	14/10/2004
Response to Request for Further Information		14/01/2005	02/02/2005
Other	Margaret Lawson		14/10/2004
Media Waiver form	2-Media waiver form	03/08/2004	14/10/2004
Other	1-SOP Bioeletrical impedance analysis	19/07/2004	14/10/2004
SOP Deuterium test	1-SOP Deuterium test	19/07/2004	18/10/2004
SOP Waist circumference	1 SOP Waist circumference	19/07/2004	14/10/2004
SOP blood pressure	1 -SOP blood pressure	16/09/2004	14/10/2004
SOP weight and Height	1-SOP weight and Height	19/07/2004	14/10/2004
SOP Genotype	1-SOP Genotype	01/10/2004	14/10/2004

Management approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final management approval from the R&D Department for the relevant NHS care organisation.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

04/MRE11/42	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project,

Yours sincerely,

pp

Canon Ian Ainsworth-Smith
Chair

E-mail: metropolitanmrec@uhl.nhs.uk

Enclosures *Standard approval conditions*

Site approval form (SF1)

Appendix 17 Declaration of end of study letter

SL39 End of study
Version 3, June 2005

NHS

SOUTHAMPTON & SOUTH WEST HAMPSHIRE
RESEARCH ETHICS COMMITTEE (A)
1st Floor, Regents Park Surgery
Park Street, Shirley
Southampton
Hampshire
SO16 4RJ

Tel: 023 8036 2466
023 8036 3462
Fax: 023 8036 4110

Email: GM.E.hio-au.SWHRECA@nhs.net

STA/kl

31 January 2007

Mr Paul Sacher
Research Fellow
Institute of Child Health
30 Guilford Street
London
WC1N 1EH

Dear Mr Sacher

Study title: **Improving health outcomes in obese children: a randomised controlled trial of the MEND (mind, exercise, nutrition and diet) childhood obesity treatment programme**
REC reference: **04/MRE11/42**

Thank you for sending the declaration of end of study form, notifying the Research Ethics Committee that the above study concluded on 13 January 2007. I will arrange for the Committee to be notified.

A summary of the final research report should be provided to the Committee within 12 months of the conclusion of the study. This should report on whether the study achieved its objectives, summarise the main findings, and confirm arrangements for publication or dissemination of the research including any feedback to participants.

04/MRE11/42	**Please quote this number on all correspondence**

Yours sincerely

Mrs Sharon Atwill
Committee Co-ordinator

E-mail: GM.E.hio-au.SWHRECA@nhs.net

Appendix 18 No-fault compensation insurance cover letter

Institute of Child Health

and Great Ormond Street Hospital for Children NHS Trust

UNIVERSITY COLLEGE LONDON

30 Guilford Street, London, WC1N 1EH. Telephone: 020 7242 9789 Fax: 020 7905 2201

The child first and always

17th February 2005
Dr A Singhal (c/o Paul Sacher)
Nutrition ICH

Dear Dr Singhal

No-fault Compensation Insurance Cover
02NT03 Improving health outcomes in obese children: a randomized controlled trial of the MEND (mind, exercise, nutrition and diet) childhood obesity treatment programme

Thank you for returning the insurance proposal form for the above study. I would like to confirm that your project is eligible for the Institute's insurance cover, which will extend for the study's duration.

You must inform this office if there are *any* changes to the project or if you wish to extend its duration beyond the study's end date.

In order to ensure that your patients/subjects are informed of the insurance arrangements in place, you should include the following standard statement in the information sheet/letter:

This project has been approved by an independent research ethics committee who believe that it is of minimal risk to you. However, research can carry unforeseen risks and we want you to be informed of your rights in the unlikely event that any harm should occur as a result of taking part in this study.

This research is covered by a no-fault compensation scheme which may apply in the event of any significant harm resulting to your child from involvement in the study. Under this scheme it would not be necessary for you to prove fault. You also have the right to claim damages in a court of law. This would require you to prove fault on the part of the Hospital/Institute and/or any manufacturer involved.

Yours sincerely

Louise Forster
Research Governance Co-ordinator
Research and Development Office
E-mail: l.forster@ich.ucl.ac.uk
Tel: 020 7905 2249

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