

# Randomized Controlled Trial of the MEND Program: A Family-based Community Intervention for Childhood Obesity

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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](http://www.mendcentral.org)). One hundred and sixteen obese children (BMI  $\geq$  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 (dietitians, 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  $\geq$  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](http://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 programme 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 dietitians 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

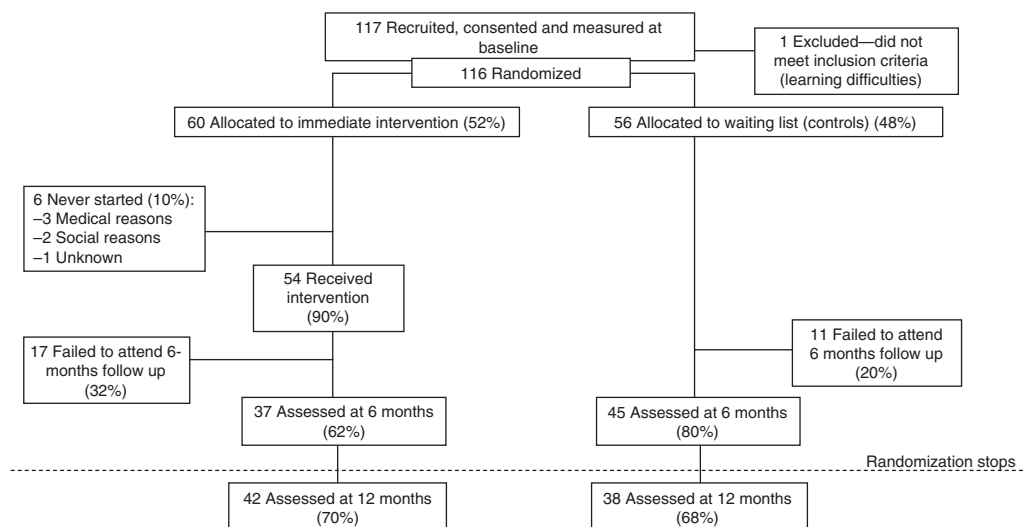


Figure 1 Study charts.

Table 1 Descriptive characteristics of the study population at baseline

	<i>n</i>	Intervention	<i>n</i>	Control	<i>P</i>
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 <sup>2</sup> )	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 <sup>2</sup> )	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<sup>2</sup>, 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)		
	<i>n</i>	Mean (s.d.)	<i>n</i>	Mean (s.d.)	Mean (CI)	<i>P</i>	<i>n</i> <sup>a</sup>	Mean (CI)	<i>P</i>
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 <sup>2</sup> )	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 <sup>2</sup> )	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).  
<sup>a</sup>*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		
	<i>n</i> <sup>a</sup>	Mean (CI)	<i>P</i>	<i>n</i> <sup>b</sup>	Mean (CI)	<i>P</i>
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/m <sup>2</sup> )	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/m <sup>2</sup> )	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.

<sup>a</sup>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).

<sup>b</sup>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/m<sup>2</sup> 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/m<sup>2</sup> compared to control, but the sample was more obese and mean BMI in the controls increased by 1 kg/m<sup>2</sup>. 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

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### 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. has no conflict of interest. M.S.L. has 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 earlier), A.S. has no other conflict of interest.

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## REFERENCES

- Summerbell CD, Ashton V, Campbell KJ *et al.* Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2003;CD001872.
- 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).
- 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.
- Oude Luttikhuis H, Baur L, Jansen H *et al.* Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2009;CD001872.
- Epstein LH, Myers MD, Raynor HA, Saelens BE. Treatment of pediatric obesity. *Pediatrics* 1998;101:554–570.
- 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.
- Cole TJ, Freeman JV, Preece MA. Body mass index reference curves for the UK, 1990. *Arch Dis Child* 1995;73:25–29.
- 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.
- Christensen P. The health-promoting family: a conceptual framework for future research. *Soc Sci Med* 2004;59:377–387.
- 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.
- Sothorn MS. Exercise as a modality in the treatment of childhood obesity. *Pediatr Clin North Am* 2001;48:995–1015.
- Lohman TG, Roche AF, Martorell R. *Anthropometric Standardization Reference Manual*. Human Kinetics: Champaign, IL, 1988, pp 55–80.
- 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.
- Francis K, Feinstein R. A simple height-specific and rate-specific step test for children. *South Med J* 1991;84:169–174.
- 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.
- 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.
- Harter S. *Manual of the Self-Perception Profile for Children*. University of Denver: Denver, 1985.
- A Publication of the Government Statistical Service OoPCaS. *Standard Occupational Classification*. HMSO: London, 1993.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.
- Koster A, Leitzmann MF, Schatzkin A *et al.* Waist circumference and mortality. *Am J Epidemiol* 2008;167:1465–1475.
- 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.
- 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.
- 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.
- McCarthy HD. Body fat measurements in children as predictors for the metabolic syndrome: focus on waist circumference. *Proc Nutr Soc* 2006;65:385–392.
- 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.
- 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.
- 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.
- 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.
- Savoie 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.
- 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.
- 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.
- 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.
- Sava SC, Tornaritis M, Sava 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.
- 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.
- O'Dea JA. Prevention of child obesity: "first, do no harm". *Health Educ Res* 2005;20:259–265.
- 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.
- 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.
- 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.