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Outcomes and costs of primary care surveillance and intervention for overweight or obese children: the LEAP 2 randomised controlled trial

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Outcomes and costs of primary care surveillance and intervention for overweight or obese children: the LEAP 2 randomised controlled trial

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ABSTRACT

Objective To determine whether ascertainment of childhood obesity by surveillance followed by structured secondary prevention in primary care improved outcomes in overweight or mildly obese children.

Design Randomised controlled trial nested within a baseline cross sectional survey of body mass index (BMI). Randomisation and outcomes measurement, but not participants, were blinded to group assignment.

Setting 45 family practices (66 general practitioners) in Melbourne, Australia.

Participants 3958 children visiting their general practitioner in May 2005-July 2006 were surveyed for BMI. Of these, 258 children aged 5 years 0 months up to their 10th birthday who were overweight or obese by International Obesity Taskforce criteria were randomised to intervention (n=139) or control (n=119) groups. Children who were very obese (UK BMI z score ≥3.0) were excluded.

Intervention Four standard consultations over 12 weeks targeting change in nutrition, physical activity, and sedentary behaviour, supported by purpose designed family materials.

Main outcomes measures Primary measure was BMI at 6 and 12 months after randomisation. Secondary measures were mean activity count/min by 7-day accelerometry, nutrition score from 4-day abbreviated food frequency diary, and child health related quality of life. Differences were adjusted for socioeconomic status, age, sex, and baseline BMI.

Results Of 781 eligible children, 258 (33%) entered the trial; attrition was 3.1% at 6 months and 6.2% at 12 months. Adjusted mean differences (intervention − control) at 6 and 12 months were, for BMI, −0.12 (95% CI −0.40 to 0.15, P=0.4) and −0.11 (−0.45 to 0.22, P=0.5); for physical activity in counts/min, 24 (−4 to 52, P=0.09) and 11 (−26 to 49, P=0.6); and, for nutrition score, 0.2 (−0.03 to 0.4, P=0.1) and 0.1 (−0.1 to 0.4, P=0.2). There was no evidence of harm to the child. Costs to the healthcare system were significantly higher in the intervention arm.

Conclusions Primary care screening followed by brief counselling did not improve BMI, physical activity, or nutrition in overweight or mildly obese 5-10 year olds, and it would be very costly if universally implemented. These findings are at odds with national policies in countries including the US, UK, and Australia.

Trial registration ISRCTN 52511065 (www.isrctn.org)

INTRODUCTION

Childhood obesity is now endemic in many countries.[1 2] The long term physical, emotional, social, reproductive, and economic ramifications are likely to be immense. While prevention and intervention are expected to be needed throughout life for much of the population, effective strategies during childhood may best minimise psychosocial and physical morbidity.[3 4] However, because of the sheer scale of the problem, tackling childhood obesity in the secondary or tertiary health care sector is not feasible for any but those who are most severely affected.

Primary care physicians, such as general practitioners (GPs), seem ideally placed to take on this issue because in many countries they are the only source of primary health care accessible to families across most of the social spectrum. GPs experience barriers in tackling childhood obesity, yet see it as extremely important and are optimistic that they can make a difference.[5 6] National policies in countries including the United Kingdom,[7] United States,[8] and Australia[9] currently endorse the GP or family physician as central to surveillance for childhood overweight and obesity and counselling.

Evidence supporting such an approach in primary care, however, is conspicuously lacking.[10] Despite high political appeal, two recent systematic reviews could not recommend screening because of the poor sensitivity and specificity of body mass index (BMI) cut points, lack of management strategies with demonstrated efficacy, and lack of evidence that benefits outweigh the harms.[11 12] We could locate two trials (one randomised,[13] one non-randomised[14]) in which a

brief primary care intervention was offered to young children whose overweight/obese status was ascertained through office surveillance; neither was effective in reducing BMI relative to controls. However, both were hampered by small sample sizes, and, given the clear policy imperatives to locate childhood obesity management in primary care, further research is clearly warranted.

This paper reports 12 month outcomes from the LEAP2 randomised controlled trial. Its primary aim was to reduce BMI gain in overweight or mildly obese 5-10 year old children identified through surveillance in primary care. Secondary aims were to increase physical activity and improve child nutrition, to quantify any harms experienced by the child, and to compare the costs and consequences of the intervention from a health sector perspective.

METHODS
Study design and setting
A randomised controlled trial was nested within a large, cross sectional survey of BMI in family practices in Melbourne (population 3.7 million), Australia.

General practitioner recruitment and education
A non-representative sample of 66 general practitioners in 45 family medical practices was recruited by personalised letters sent to 1709 GPs via a paediatric special interest group spanning 11 Melbourne divisions of general practice, the Health Insurance Commission, GPs from the LEAP1 trial, and contacts made through these networks; the letter was followed by recruitment evenings and practice visits. GPs attended two 2½ hour group training sessions for instruction in the "stages of change" model[15] and training in brief, solution focused, family therapy.[16] They received a 30 minute DVD, developed for the trial, showing role model scenarios of GPs using solution focused therapy in consultations for healthy family lifestyle.

Each GP then conducted two simulated patient sessions (an "initial LEAP2 consultation" of 30 minutes, and a "follow-up consultation" of 20 minutes) during standard working hours supported by a mock patient file and materials. These visits mimicked the forthcoming intervention consultations, except that a child did not attend with the actor portraying the parent. After each consultation, the actor evaluated the GP's performance on 10 items, gave feedback to the GP, and communicated a summed "global score" (out of 10) via text message to the research team. GPs were paid $A100 per simulated patient consultation. The two GPs who were given a global score ≤5 for the second visit were offered an extra set of visits; one withdrew, while the other received higher scores and continued his involvement.

Participants
All children aged 5 years 0 months up to their 10th birthday attending participating practices for any reason during May 2005 to July 2006 were eligible to be invited into the BMI survey by practice staff.

Researchers also ran one or two dedicated measuring sessions in each of the larger practices, to which parents of all suitably aged children registered with the practice were invited by letter. Children in the survey were eligible for the trial if they were not receiving an ongoing weight management programme and were overweight or obese according to the cut-off points of the International Obesity Taskforce.[17] Children were excluded if their BMI z score was ≥3.0 (transformed using the LMS method[18] and the 1990 UK Growth Reference[19]), on the basis that a brief secondary prevention approach was inappropriate. The research team then mailed an informed consent form and baseline questionnaire to interested parents with eligible children, and randomisation occurred once the completed forms were received by the research team. Follow-up was as close as possible to six and 12 months after randomisation, which equated to a mean of 9.0 months (SD 1.1) and 15.2 months (SD 1.2) from the baseline measurements. Thus, recruitment occurred in May 2005-July 2006, intervention delivery in October 2005-December 2006, the first follow-up in April 2006-March 2007, and the second follow-up in October 2006-September 2007.

Randomisation
Randomisation by child was stratified by GP and by overweight versus obese status; it was performed by an independent biostatistician using computer generated random numbers. The randomisation sequence was concealed from the study investigators, and the researchers collecting data remained blind to participants' trial status until follow-up was complete. Intervention families were notified by the non-blinded member of the research team (BG) and assisted in making the first doctor's appointment. Control families were notified via letter; general practice records of control children were subsequently audited to assess possible contamination (that is, attendances for discussion of weight). General practitioners knew the assignment status of any of their children who were in the intervention group, but did not otherwise know who among their large client base was enrolled in the survey or trial, so were generally unaware of control group membership.

Intervention design
The intervention had the same components as in the LEAP1 trial,[20] designed using an intervention mapping technique within a behavioural epidemiology framework. GPs used a brief, solution focused approach[21] to set and record appropriate, healthy lifestyle goals, assisted by a 16 page "family folder" written at a 12 year old reading level to be sure that virtually all parents could understand it. This folder included five topic sheets, each targeting one area of behavioural change (sedentary time, physical activity, water consumption, family eating habits, and lower fat options for food). Each sheet summarised supporting evidence, modelled solutions to challenges, and made suggestions as to how each goal might be reached.

Intervention delivery

Before the first appointment, the GP received the child's named intervention materials, BMI, and a two page summary of parent responses from the baseline questionnaire regarding current nutrition, physical activity patterns, and concern regarding their child's weight status. Parents were offered four consultations over a 12 week period. Visit date, content discussed, and contracts made were recorded on a LEAP2 form in the child's medical record. If any "non-LEAP2" visits occurred, the GP was asked to reinforce any LEAP2 strategies previously discussed.

Measures

Follow-up data were collected via written parent questionnaire (at baseline and six and 12 months after randomisation), child questionnaire (at six and 12 months), anthropometric measurement (baseline and six and 12 months), and accelerometry measurement (six and 12 months). The primary outcome measure was BMI (weight (kg)/(height (m)^2)). Weight was measured in light clothing to the nearest 100 g using digital scales (Tanita, Japan, ModelTHD-646) and height was measured (twice) to the nearest 0.1 cm using a portable rigid stadiometer (Invicta, Oadby, Leicester, Model IPO955). The average of the height measurements was used in analyses; if the two differed by ≥0.5 cm a third measurement was taken and the mean of the closest two values was used. BMI z score was also calculated using the US Centers for Disease Control (CDC) 2000 sex-specific BMI-for-age growth charts.[22]

Secondary outcome measures are shown in table 1. Socioeconomic status, a potential prognostic factor, was quantified using the Australian census based Index of Relative Socio-economic Disadvantage score for the participant's home postal code (mean score for Victoria 1020.3 (SD 59.4)).[23] Costs were evaluated from a healthcare perspective and calculated in Australian dollars ($A) at 2007 costs. Resources required to provide the LEAP2 intervention were recorded by the research team and via an audit of GP visits for intervention and control families. Resource use was valued using appropriate salary scales, travel cost allowances, and fee rates from the Medicare Benefits Schedule.[24]

Sample size

We aimed to reduce the expected increase in BMI from 0.8 to ≤0.5 over 12 months. In the LEAP1 trial, the standard deviation of BMI values was 2.2 at both baseline and at 12 months after randomisation, and the correlation between the baseline and 12 month values was 0.88. Using these values, we calculated that 190 overweight or mildly obese children in each group would ensure 80% power at the 5% level of significance (two sided) to detect a reduction in mean BMI increase as small as 0.3 units.

Table 1 | Secondary outcome measures used in analysis of primary care surveillance and intervention for overweight or obese children

Construct	Measure	Additional information
Child waist circumference	Lufkin Executive Steel Tape (W606PM); measured	Average of two waist measurements; if they differed by ≥1 cm, a third measurement was taken and the mean of the closest two used
Maternal and paternal body mass index	Weight (kg)/(height (m)^2); measured and self reported	Baseline values reported for self and partner by responding parent. Values at 6 and 12 months measured for the parent(s) present with the child and reported; measured data used preferentially
Physical activity	Actical Accelerometer (Mini Mitter); measured	Worn for 7 full days; ≥5 valid days required. Valid days had ≥10 hours of non-missing data between 6 am-11 pm. Missing data were segments with ≥20 minutes of consecutive "0" counts, or counts ›0 that were constant for ≥10 minutes. Outcomes across all valid days: mean activity counts/min, and % time spent in moderate to vigorous physical activity
Physical activity	4 day activity diary; parent report	Parent rating of child's activity on 7 point scale (1=sedentary, 7=intense activity) for each of the 12 15-minute intervals between 3 30 pm and 6 30 pm over two weekdays and two weekend days (total of 48 intervals at each follow-up). Ratings dichotomised as high (≥4 (≥most children's play)) v low activity
Nutrition	4 day food diary; parent report	Parents reported child's consumption of each of 10 food and drink items (0, 1, 2, ›2 times) for two weekdays and two weekend days, from which were derived dichotomous ("yes" v "no") variables for five "healthy behaviours" (high fruit, vegetables, and water; low fatty/sugary foods and non-diet sweet drinks) for each day. The number of healthy behaviours per day was summed to give a score between 0 and 5 (higher score indicating more healthy behaviour), thus providing 4 measurements at each wave
Health status	Paediatric quality of life inventory (PedsQL 4.0) self report and parent-proxy versions[34]	23 items that yield total, physical summary, and psychosocial summary scores, each with a possible range of 0-100 (100=best possible health); quantitative variable
Body dissatisfaction	Body figure perception questionnaire[35]; child self report	Child picture scale of 1-7 (1=underweight, 7=obese) from which child picks perceived and ideal selves. "Perceived" minus "Ideal" self yields a discrepancy index, with positive and negatives scores representing desires to be thinner and fatter, respectively
Physical appearance and self worth	Modified from Harter's perceived competence scale; child self report	Six pairs of statements with binary response format; children choose the statement from each pair that is closest to their competence. Each of the 6 responses was then coded as being either "positive/better perception" or "negative/worse perception". The 6 responses were analysed as a single outcome

Statistical analysis

We used Stata 9.2 software.[25] Participants were analysed in the groups to which they were randomised. Linear and logistic regression models (for quantitative and dichotomous outcomes respectively) were fitted for unadjusted and adjusted models. In the latter, all comparisons were adjusted for socioeconomic disadvantage,[23] age at randomisation, sex, and baseline score for the outcome (where collected). All analyses except BMI z score were also adjusted for raw BMI at baseline.

For some outcomes, each subject accrued several scores (that is, the 48 scores for parents' reports of their child's physical activity and four scores for child's nutrition—see table 1). For these measures, random effects ("multilevel") models using maximum likelihood estimation[26] for quantitative outcomes, and marginal models using generalised estimating equations[27] for dichotomous outcomes, were fitted for the regression analyses to allow for within-subject correlation. The six dichotomous items on physical appearance and global self worth (see table 1) were analysed as a multivariate outcome, again using the generalised estimating equations method for logistic regression to allow for within-subject correlations.

Sensitivity analyses that additionally allowed for correlation between children seen by the same general practitioner provided essentially the same results as the main analyses, so we report only the latter here. Because some quantitative outcomes were non-symmetrical, results were validated using bias-corrected accelerated bootstrap confidence intervals.[28]

RESULTS

Table 2 reports baseline characteristics of the children, which were similar in the two trial arms. The location of participating practices covered the sociodemographic spectrum, with the median practice close to the 50th centile (range from <10th to >90th centile) on the Index of Relative Socio-economic Disadvantage.[23]

The figure shows the participant flow throughout the trial: 139 and 119 participants were allocated to the intervention and control arms, respectively. Overall attrition rates for anthropometry data collection was 3.1% (250) at six months and 6.2% (242) at 12 months. Completion rates at six and 12 months, respectively, for questionnaires were 97.3% (251) and 91.9% (237); 89.5% (231) and 77.9% (201) for useable accelerometry data; and 93.8% (242) and 88.4% (228) for 4 day food and nutrition diaries.

Primary outcome (body mass index)

Tables 3 and 4 show unadjusted and adjusted outcome comparisons between the intervention and control arms at six months and 12 months after randomisation respectively. At six months, the adjusted mean BMI of the intervention group was 0.12 lower than that of the control group (adjusted mean difference −0.12 (95% CI −0.40 to 0.15, P=0.38), and, at 12 months, the adjusted mean BMI was 0.11 lower (adjusted mean difference −0.11 (−0.45 to 0.22, P=0.51). Mean BMI z score (not shown) and waist circumference were similar in the two trial arms.

Secondary outcomes

Overall physical activity, as measured by accelerometry, was slightly but not significantly higher in the intervention than control group at six months (mean difference 24 counts/min (95% CI −4 to 52, P=0.09)) and at 12 months (mean difference 11 counts/min (−26 to 49, P=0.55)). Similarly, overall nutrition scores were only marginally better in the intervention group (mean difference at six months 0.2 (95% CI −0.03 to 0.4, P=0.10) and at 12 months 0.1 (−0.1 to 0.4, P=0.24)). Parents reported lower consumption of soft drinks in the intervention group at both time points, but no marked differences in fruit, vegetable, fat, or water consumption.

There was no evidence that the intervention was harmful as perceived by the children, whose reports of health related quality of life, body dissatisfaction, and self esteem were similar to those of control children. Compared with control parents, however, parents in the intervention group reported improved child health related quality of life at six months (mean difference 3.1 points higher (95% CI 0.6 to 5.7, P=0.02)) and at 12 months (3.1 points higher (0.2 to 6.0, P=0.03)), which was evident for both the physical and psychosocial summary scores.

Process evaluation

All GPs attended at least one of the GP education sessions—65 (98.5%) attended the first, and 64 (97%) attended the second—and all completed the two simulated patient consultations.

Table 2 | Baseline characteristics of 258 overweight or mildly obese children aged 5-10 years who participated in study. Values are percentages (numbers) of participants unless stated otherwise

Characteristic	Intervention group (n=139)*	Control group (n=119)*
Female	60 (83)	61 (73)
Mean (SD) age (years)	7.4 (1.4)	7.6 (1.4)
Mean (SD) social disadvantage score	1028 (70)	1028 (63)
Maternal education:		
Did not complete high school	31 (42)	33 (39)
Completed high school	35 (47)	32 (38)
University degree	34 (45)	34 (40)
BMI category†:		
Overweight	75 (104)	78 (93)
Obese	25 (35)	22 (26)
Mean (SD) BMI	20.2 (2.3)	20.3 (1.9)
Mean (SD) BMI z-score	1.9 (0.5)	1.9 (0.5)
Mean (SD) physical activity score	3.4 (0.8)	3.4 (0.8)
% time spent in high activity (parent report)	24.2%	22.1%
Mean (SD) nutrition score	3.7 (1.1)	3.5 (1.2)
Mean (SD) PedsQL (parent report)	74.6 (14.3)	74.6 (14.5)

BMI=body mass index. PedsQL=paediatric quality of life inventory.
*Sample size ranges from 131 to 139 in intervention arm and 111 to 119 in control arm.
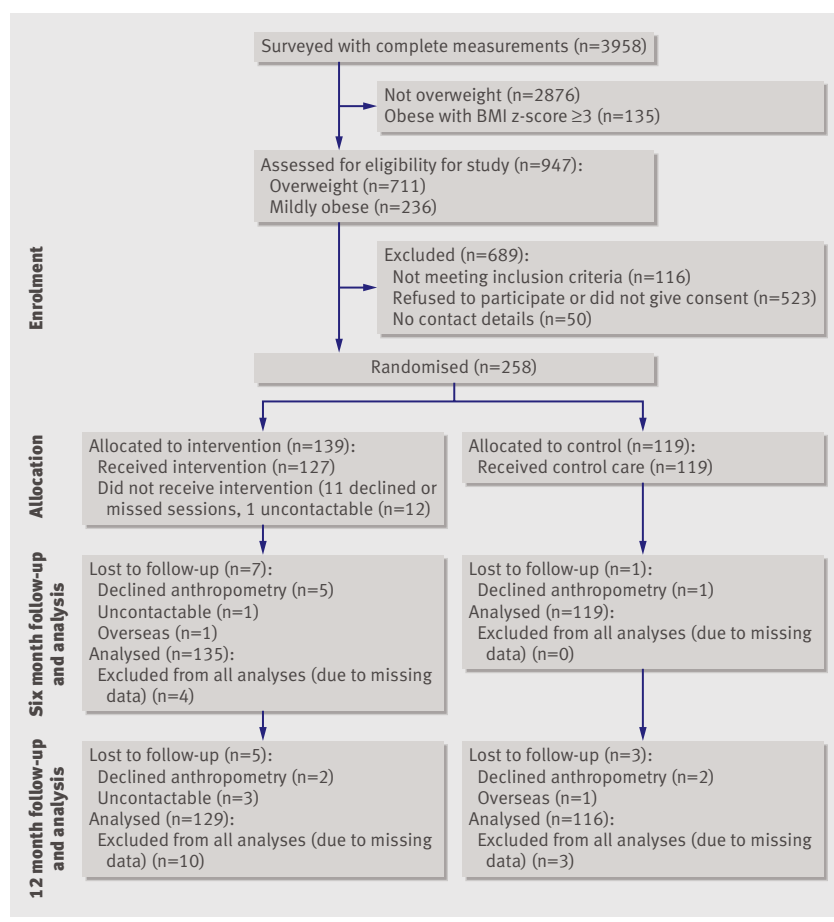†Based on cut points of International Obesity Taskforce.

Fig 1 | Flow of participants in trial

Surveyed with complete measurements (n=3958)

Not overweight (n=2876)
Obese with BMI z-score ≥3 (n=135)

Assessed for eligibility for study (n=947):
 Overweight (n=711)
 Mildly obese (n=236)

Excluded (n=689):
 Not meeting inclusion criteria (n=116)
 Refused to participate or did not give consent (n=523)
 No contact details (n=50)

Randomised (n=258)

Enrolment

Allocation

Allocated to intervention (n=139):
 Received intervention (n=127)
 Did not receive intervention (11 declined or missed sessions, 1 uncontactable (n=12)

Allocated to control (n=119):
 Received control care (n=119)

Six month follow-up and analysis

Lost to follow-up (n=7):
 Declined anthropometry (n=5)
 Uncontactable (n=1)
 Overseas (n=1)
Analysed (n=135):
 Excluded from all analyses (due to missing data) (n=4)

Lost to follow-up (n=1):
 Declined anthropometry (n=1)
Analysed (n=119):
 Excluded from all analyses (due to missing data) (n=0)

12 month follow-up and analysis

Lost to follow-up (n=5):
 Declined anthropometry (n=2)
 Uncontactable (n=3)
Analysed (n=129):
 Excluded from all analyses (due to missing data) (n=10)

Lost to follow-up (n=3):
 Declined anthropometry (n=2)
 Overseas (n=1)
Analysed (n=116):
 Excluded from all analyses (due to missing data) (n=3)

Fifty one (37%) of the 139 children in the intervention arm attended all four of the intervention consultations, 31 (22%) attended three, 29 (21%) attended two, 16 (12%) attended one, and 12 (9%) attended none. Intervention families had a mean of 2.7 LEAP2 consultations. During the 12 months after allocation, intervention and control children both had a mean of 0.9 incidental visits to their LEAP2 GP, and incidental visits to a non-LEAP2 GP were also similar (1.4 for the intervention children and 1.6 for the controls). The general practice record audit indicated minimal contamination among the control children: five were weighed and/or measured by their LEAP2 GP during these visits, but there was no indication in their records that weight or weight management was discussed.

Health sector costs

The cost to the health sector of providing the LEAP2 intervention (BMI surveillance, GP recruitment and training) to the 66 participating GPs was $A152000. Including the costs of all GP consultations with participating families, costs borne by the health sector were $A1317 per intervention child and $A81 per control, a difference of $A1236 (95% CI $A1205 to $A1267). It should be noted that the GPs in the LEAP2 trial provided the intervention to an artificially small number of children (2.1 per GP). These costs would fall if the

intervention were provided to a greater number of children per GP—for example, to $A412 (95% CI $A381 to $A442) if each GP managed 30 children. This still, however, represents a marked increase in costs for no real improvement in the primary or secondary outcomes.

Meta-analysis

Although we aimed for 190 children in each arm of this trial, only 127 remained in the intervention arm and 115 in the control arm at 12 months. This meant that the smallest difference in BMI between the trial arms that could be detected with 80% power was 0.38, rather than the desired 0.30. However, the similarity of design and content provided an opportunity to combine the results from both LEAP trials in a meta-analysis. With a combined total of 196 subjects in the intervention arm and 191 subjects in the control arm at 12 months, the smallest BMI difference detectable with 80% power was 0.30. A fixed effects meta-analysis of combined LEAP2 and LEAP1 data showed that the adjusted mean BMI difference at six months was −0.16 (95% CI −0.38 to 0.06) and at 12 months was −0.06 (−0.34 to 0.22). Thus, although a mean improvement in the intervention arm as large as 0.3-0.4 is possible, the body of evidence points towards no important difference between the trial arms.

Post hoc analyses

Since national policies often use the proportion overweight, rather than mean BMI, as the target for assessing effective intervention, we also examined outcomes according to dichotomised BMI (that is, overweight/obese versus not overweight/obese) using the International Obesity Taskforce cut points. At 12 months, 77.2% of the LEAP2 intervention children remained overweight/obese compared with 82.6% of the controls (difference −5.4% (95% CI −15.5% to 4.6%, P=0.29)). Similar values were obtained in the meta-analysis (80.2% v 84.8%; difference −4.6% (−12.2% to 2.9%, P=0.23)).

There was no evidence at the 5% level in adjusted models that socioeconomic status (using scores from the disadvantage index) modified the effect of the intervention on the main outcomes of BMI, activity, or nutrition at six or 12 months. Similarly, there was no strong evidence that attending more consultations improved BMI at six months (P=0.18) or at 12 months (P=0.60) after adjustment for baseline BMI.

DISCUSSION

Principal findings

This trial suggests that current international policy directions for primary care surveillance and brief counselling are unlikely to be effective in reducing childhood obesity. Neither the primary outcome (BMI) nor key secondary outcomes (physical activity, nutrition, parental BMI) showed marked improvement. Although there was no evidence that the child experienced physical or psychosocial harm as a result of the intervention, a significant investment of healthcare

resources was incurred that could be used to greater effect elsewhere.

Strengths and limitations of study

Strengths of the study include its randomised design, the objective measures of anthropometry and physical activity, the strong uptake by families and GP practices spanning the range of socioeconomic status, follow-up for a full year, and the extremely high retention rate. Because of the large sample size, the confidence intervals were sufficiently narrow to conclude that any benefit to BMI trajectory was not clinically important. There was no evidence that contamination explains the null findings. Though we could not be sure that GPs implemented the intervention as intended, GPs could only proceed to LEAP families once the two simulated patient visits had been delivered satisfactorily.

Limitations include the select volunteer nature of the participating GPs, but it seems unlikely that less committed or interested GPs would achieve a better result. Only a third of the families with a child identified as eligible chose to take up the intervention; again, it seems unlikely that those who were not recruited to the trial would have fared better, and this would be a problem at the public health level only had the intervention been effective. It was not possible to blind the families to group membership, but this limitation would typically be expected to increase, not reduce, between-group differences on self reported measures.

Interpretation in light of other studies

These negative findings are congruent with two smaller trials of brief, individualised primary care approaches targeting overweight or mildly obese children identified by screening.[13 14] Therefore, the most likely interpretation is that such interventions are ineffective in reducing BMI. This could be due to insufficient intervention intensity or duration; in recent studies in tertiary obesity clinics, sustained BMI reduction occurred only when interventions occurred over 9-12 months.[29 30] Interventions in this BMI range might be more effective when initiated by families seeking help rather than via a screening process. However, this would be unlikely to address the public health issue adequately, as only a minority are sufficiently concerned to seek help for their overweight children, and individual effects have uniformly been modest[31 32] or absent.[33]

Conclusions and policy implications

This brief, physician led, primary care intervention produced no long term improvement in children's BMI, physical activity, or nutrition. These findings cast doubt on many countries' current policies that support universal surveillance coupled with brief, individualised secondary prevention by the primary care sector to reduce childhood obesity. Thus far, each new study has progressively added weight to the view that overweight and mild obesity in primary school

Table 3 | Outcomes of trial of primary care surveillance and intervention for overweight or obese children, 6 months after randomisation

Outcome	Intervention		Control		Unadjusted difference		Adjusted difference†	
	No of participants	Measure*	No of participants	Measure*	Mean (95% CI)	P value	Mean (95% CI)	P value
Anthropometry:								
Child BMI	132	20.5 (2.6)	118	20.6 (2.2)	−0.13 (−0.74 to 0.48)	0.7	−0.12 (−0.40 to 0.15)	0.4
Child waist circumference	131	70.1 (8.4)	117	70.4 (8.2)	−0.30 (−2.37 to 1.77)	0.8	0.12 (−0.98 to 1.22)	0.8
Maternal BMI	125	28.4 (5.7)	115	27.3 (5.1)	1.08 (−0.31 to 2.47)	0.1	0.18 (−0.27 to 0.64)	0.4
Paternal BMI	101	27.9 (4.0)	83	27.9 (3.7)	−0.08 (−1.20 to 1.05)	0.9	−0.21 (−0.72 to 0.30)	0.4
Accelerometry:								
Activity (counts/min)	122	346 (120)	109	320 (100)	26 (−3 to 54)	0.08	24 (−4 to 52)	0.09
% of time spent in MVPA	122	16.1 (5.5)	109	15.2 (4.3)	0.9 (−0.4 to 2.2)	0.2	0.7 (−0.5 to 2.0)	0.2
Parent-proxy report:								
"High" v "low" activity	127	18.3%	115	19.8%	0.82 (0.61 to 1.09)‡	0.2	0.75 (0.55 to 1.04)‡	0.08
Nutrition score	125	3.9 (1.0)	114	3.6 (1.2)	0.3 (0.1 to 0.5)	0.01	0.2 (−0.03 to 0.4)	0.1
PedsQL total:	133	77.6 (12.8)	118	74.5 (14.1)	3.2 (−0.2 to 6.5)	0.06	3.1 (0.6 to 5.7)	0.02
Physical summary	133	80.2 (16.6)	118	76.0 (17.7)	4.2 (−0.1 to 8.4)	0.06	4.0 (0.6 to 7.3)	0.02
Psychosocial summary	133	76.3 (12.6)	118	73.7 (13.9)	2.6 (−0.7 to 5.9)	0.1	2.7 (−0.001 to 5.3)	0.05
Child self report:								
PedsQL total:	130	78.8 (12.3)	117	77.8 (11.8)	1.0 (−2.1 to 4.0)	0.5	1.3 (−1.7 to 4.4)	0.4
Physical summary	130	82.6 (11.6)	116	82.1 (11.6)	0.5 (−2.4 to 3.4)	0.7	0.6 (−2.4 to 3.6)	0.7
Psychosocial summary	130	76.7 (14.5)	116	75.4 (14.2)	1.3 (−2.4 to 4.9)	0.5	1.8 (−1.8 to 5.5)	0.3
Body dissatisfaction	130	1.1 (1.0)	115	1.0 (1.0)	0.11 (−0.15 to 0.36)	0.4	0.09 (−0.17 to 0.34)	0.5
"Positive" v "negative" appearance/self worth	130	70.1%	115	69.6%	1.05 (0.75 to 1.48)‡	0.8	1.12 (0.79 to 1.58)‡	0.5

BMI=body mass index. MVPA=moderate to vigorous physical activity. PedsQL=paediatric quality of life inventory.
*Values are means (standard deviations) unless stated otherwise. Mean differences are shown for quantitative outcomes and odds ratios for dichotomous outcomes.
†Comparisons adjusted for social disadvantage index, age at randomisation, sex, baseline score for the outcome (where collected), and raw BMI at baseline. Analyses of child self reported measures were not adjusted for baseline, as only collected at 6 and 12 month follow-ups. Sample size in adjusted analyses at least 88 in the intervention arm and 75 in the control arm.
‡Values are odds ratios (95% CI).

Table 4 | Outcomes of trial of primary care surveillance and intervention for overweight or obese children, 12 months after randomisation

Outcome	Intervention No of participants	Intervention Measure*	Control No of participants	Control Measure*	Unadjusted difference Mean (95% CI)	P value	Adjusted difference† Mean (95% CI)	P value
Anthropometry:								
Child BMI	127	20.8 (2.8)	115	21.0 (2.4)	−0.11 (−0.77 to 0.55)	0.7	−0.11 (−0.45 to 0.22)	0.5
Child waist circumference	125	72.2 (9.1)	114	72.2 (8.4)	−0.02 (−2.27 to 2.22)	1.0	0.12 (−1.12 to 1.37)	0.8
Maternal BMI	121	28.5 (6.0)	110	27.2 (5.5)	1.29 (−0.21 to 2.79)	0.09	0.41 (−0.18 to 1.00)	0.2
Paternal BMI	88	27.8 (4.0)	78	28.2 (3.8)	−0.41 (−1.62 to 0.79)	0.5	−0.14 (−0.54 to 0.25)	0.5
Accelerometry:								
Activity (counts/min)	110	344 (136)	91	332 (131)	12 (−26 to 49)	0.5	11 (−26 to 49)	0.6
% of time spent in MVPA	110	16.1 (5.9)	91	15.4 (5.5)	0.7 (−0.9 to 2.3)	0.4	0.6 (−1.0 to 2.2)	0.5
Parent-proxy report:								
"High" v "low" activity	122	21.5%	105	17.6%	1.20 (0.85 to 1.68)‡	0.3	1.23 (0.88 to 1.73)‡	0.2
Nutrition score	119	3.9 (1.0)	104	3.7 (1.1)	0.2 (0.004 to 0.4)	0.05	0.1 (−0.1 to 0.4)	0.2
PedsQL total:	124	78.9 (12.1)	113	75.9 (12.8)	3.1 (−0.1 to 6.2)	0.06	3.1 (0.2 to 6.0)	0.03
Physical summary	124	81.2 (17.3)	112	79.0 (16.0)	2.3 (−2.0 to 6.6)	0.3	2.0 (−1.8 to 5.9)	0.3
Psychosocial summary	124	77.7 (12.0)	113	74.4 (13.3)	3.3 (0.1 to 6.6)	0.04	3.5 (0.6 to 6.5)	0.02
Child self report:								
PedsQL total:	125	80.2 (12.1)	112	79.4 (12.7)	0.8 (−2.4 to 4.0)	0.6	1.6 (−1.5 to 4.7)	0.3
Physical summary	125	83.1 (11.1)	112	81.2 (14.4)	1.9 (−1.3 to 5.2)	0.2	2.4 (−0.8 to 5.7)	0.1
Psychosocial summary	125	78.6 (14.0)	112	78.4 (13.5)	0.2 (−3.3 to 3.7)	0.9	1.1 (−2.3 to 4.5)	0.5
Body dissatisfaction	125	0.9 (1.1)	112	0.9 (1.0)	−0.02 (−0.29 to 0.25)	0.9	−0.07 (−0.33 to 0.19)	0.6
"Positive" v "negative" appearance/self worth	125	76.4%	112	73.8%	1.12 (0.76 to 1.67)‡	0.6	1.19 (0.79 to 1.77)‡	0.4

BMI=body mass index. MVPA=moderate to vigorous physical activity. PedsQL=paediatric quality of life inventory.
*Values are means (standard deviations) unless stated otherwise.
†Comparisons adjusted for social disadvantage index, age at randomisation, sex, baseline score for the outcome (where collected), and raw BMI at baseline. Analyses of child self reported measures were not adjusted for baseline, as only collected at 6 and 12 month follow-ups. Sample size in adjusted analyses at least 84 in the intervention arm and 71 in the control arm.
‡Values are odds ratios (95% CI).

children do not meet criteria for the introduction of screening programmes.[12] Resources may be better divided between primary prevention at the community and population levels, and enhancement of clinical treatment options for children with established obesity.

WHAT IS ALREADY KNOWN ON THIS SUBJECT

With around 25% of all children worldwide now overweight or obese, hospital services cannot hope to provide adequate weight management services

National policies in many countries (including the US, UK, and Australia) promote primary care surveillance and brief counselling to reduce childhood obesity

Two systematic reviews have highlighted that there is no evidence to support this approach

WHAT THIS STUDY ADDS

Primary care screening followed by brief counselling did not improve body mass index, physical activity, or nutrition in overweight or mildly obese 5-10 year olds, and the approach would be very costly if universally implemented

These findings are at odds with current national policies

Resources may be better spent on primary prevention strategies at the community and population levels, and on enhancing treatment options

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