International Journal of Obesity (2007) 31, 630–636
 0307-0565/07 $30.00
www.nature.com/ijo

PEDIATRIC HIGHLIGHT

Outcome data from the LEAP (Live, Eat and Play) trial: a randomized controlled trial of a primary care intervention for childhood overweight/mild obesity

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Objectives: To reduce gain in body mass index (BMI) in overweight/mildly obese children in the primary care setting.
Design: Randomized controlled trial (RCT) nested within a baseline cross-sectional BMI survey.
Setting: Twenty nine general practices, Melbourne, Australia.
Participants: (1) BMI survey: 2112 children visiting their general practitioner (GP) April–December 2002; (2) RCT: individually randomized overweight/mildly obese (BMI *z*-score <3.0) children aged 5 years 0 months–9 years 11 months (82 intervention, 81 control).
Intervention: Four standard GP consultations over 12 weeks, targeting change in nutrition, physical activity and sedentary behaviour, supported by purpose-designed family materials.
Main outcome measures: Primary: BMI at 9 and 15 months post-randomization. Secondary: Parent-reported child nutrition, physical activity and health status; child-reported health status, body satisfaction and appearance/self-worth.
Results: Attrition was 10%. The adjusted mean difference (intervention–control) in BMI was $-0.2\,kg/m^2$ (95% CI: -0.6 to 0.1; $P=0.25$) at 9 months and $-0.0\,kg/m^2$ (95% CI: -0.5 to 0.5; $P=1.00$) at 15 months. There was a relative improvement in nutrition scores in the intervention arm at both 9 and 15 months. There was weak evidence of an increase in daily physical activity in the intervention arm. Health status and body image were similar in the trial arms.
Conclusions: This intervention did not result in a sustained BMI reduction, despite the improvement in parent-reported nutrition. Brief individualized solution-focused approaches may not be an effective approach to childhood overweight. Alternatively, this intervention may not have been intensive enough or the GP training may have been insufficient; however, increasing either would have significant cost and resource implications at a population level.
International Journal of Obesity (2007) **31**, 630–636. doi:10.1038/sj.ijo.0803509; published online 12 December 2006

Keywords: childhood obesity; primary care; randomized controlled trial; secondary prevention; overweight

Introduction

Childhood obesity is now epidemic in the Western world.[1] In Australia, the prevalence trebled between 1985 and 1997[2,3] and has since continued to rise.[4] Concerningly, increases since the late 1990s appear greater among children of lower socioeconomic status.[5] Effective prevention or intervention strategies for overweight and obesity in

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Received 22 May 2006; revised 18 September 2006; accepted 24 September 2006; published online 12 December 2006

childhood stand the best chance of avoiding associated psychosocial[6] and physical morbidity.[1]

Calls have been made for general practitioners (GPs) to tackle 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 themselves see child overweight/obesity as extremely important, but experience barriers in tackling this issue such as lack of time, a practical approach and resources.[7] A primary care approach could supplement the developing range of community prevention and tertiary management strategies which have been the focus of most previous research.[8] However, it must be shown that such an approach effectively reduces child body mass index (BMI) and does not lead to unintended consequences or harm.

In response to the expressed need and observed gap in the effectiveness literature, we designed and trialed a GP intervention for childhood overweight and obesity based on brief solution-focused therapy, supported by an evidence-based family information resource on healthy living. The specific aims of the Live, Eat and Play (LEAP) study were to:

1. Reduce BMI gain at 6 and 12 months in overweight/mildly obese children aged 5 years 0 months–9 years 11 months.
2. Improve child nutrition and increase physical activity.
3. Quantify any harm to child functional health status, body image and/or global self-worth resulting from the intervention.
4. Evaluate the costs of the LEAP intervention.

Methods

Study design and setting

We used a randomized controlled trial (RCT) design nested within a large cross-sectional BMI survey conducted in 28 general medical practices in Melbourne (population 3.6 million), Australia.[9] The study was approved by the Royal Children's Hospital Ethics Committee (EHRC 2109) and registered with an international trials registry (ISRCTN 45068927). All children aged 5 years 0 months–9 years 11 months attending participating practices for any reason during April–December 2002 were eligible to be invited to participate in the BMI survey, in which practice staff measured each child's height and weight and invited the parent to provide contact details if they were interested in participating in a new intervention research study.

General practitioner recruitment and education

GPs from sociodemographically diverse practices spread across most of Melbourne were invited by letter to information evenings at which they signed a Memorandum of Understanding detailing their own and the study team's responsibilities. They received a standardized education package regarding delivery of the intervention comprising three evening group sessions. As well as didactic and reflective teaching regarding childhood obesity, the core component was training in brief solution-focused therapy techniques.[9] These encourage the clinician to explore the patient's own lifestyle behaviour change solutions which, in turn, might lead to the adoption of achievable and realistic goals.[10] GPs practised both this approach and use of the family resources in role play with simulated families.

Participants

All children classified as overweight or mildly obese in the BMI survey, who were not receiving ongoing weight management in a secondary or tertiary care programme and whose parents had provided contact details, were eligible to take part in the LEAP RCT. The study team contacted parents by telephone and, if interested, mailed an informed consent form and detailed baseline questionnaire. These were completed before randomization. Recruitment occurred in June 2002–March 2003, intervention delivery in July 2002–June 2003, the first follow-up in January–November 2003 and the second follow-up in August 2003–March 2004. Before randomization participants were excluded from the RCT for any chromosomal, endocrine or medical condition/disability/medication which, in the judgement of the investigators, could have an impact on their weight or growth. This resulted in five children being excluded.

Randomization

Children were categorized into non-overweight, overweight and obese categories according to the International Obesity TaskForce (IOTF) cutoff points.[11] BMI was transformed to standardized *z*-scores based on sex and exact age, using the LMS method[12] and the 1990 UK Growth Reference,[13] which enabled exclusion of 'very obese' children (BMI *z*-score $\geqslant 3.0$) for whom a brief secondary prevention approach was considered inappropriate. Randomization was stratified by GP and overweight versus obese status (classified according to IOTF obesity cut-points). Randomization was performed by a third-party biostatistician using a pre-generated computerized sequence. Blinding was maintained throughout allocation and data collection. Following randomization, intervention families were contacted by a non-blinded member of the research team and the first GP appointment made. Control families were notified of their status via letter and were not identified to the GPs at any time. General practice records of children in the control group were subsequently audited to assess the extent of possible contamination (that is, attendances for discussion of weight). Assessors of the 6- and 12-month follow-ups were blinded to randomization status.

Intervention design

When developing the intervention, modifiable behavioural determinants of obesity were identified using an intervention mapping approach, in which known and theoretic barriers and facilitators of change were identified and explicitly translated into a concrete and practical intervention.[14] GPs used a brief solution-focused approach[10] to set and record appropriate, healthy lifestyle goals with the family, assisted by a personalized 20-page 'Family Folder' designed at a 12-year-old reading level and previously piloted. This included seven topic sheets, each targeting one area of behavioural change required to reduce overweight and comprising a brief summary of supporting evidence, modelled solutions to challenges and additional suggestions as to how each goal might be reached.

Intervention delivery

Intervention families were notified by telephone and assisted in making the first doctor's appointment. Before this appointment, the LEAP team provided the GP with the child's personalized intervention materials, BMI and a two-page summary of parent responses extracted from the baseline questionnaire regarding current nutrition, physical activity patterns and concern regarding their child's weight status. Parents were asked to attend four consultations over a 12-week period. GPs did not routinely weigh or measure children at these visits, as the intervention focused on behavioural change rather than weight change. Visit date, content discussed and contracts made were recorded on a LEAP form in the child's medical record. If any 'non-LEAP' visits occurred (*e.g.* acute care consultations), the GP was also asked to briefly encourage and reinforce any strategies previously discussed.

Measures

Follow-up was planned at 6 and 12 months post-randomization for repeat anthropometry and completion of parent and child questionnaires. The primary outcome measure was BMI (kg/m^2), measured by trained researchers using standard protocols and equipment. BMI *z*-score outcomes are reported using the US Centers for Disease Control (CDC) 2000 gender-specific BMI-for-age growth charts,[15] which came into wide use after commencement of the study.

The secondary outcome measures have been previously described.[9] Briefly, child physical activity, sedentary behaviour and nutrition were measured using 4-day food and activity diaries. Parents were given a list of 14 food and drink items, which were later broken down into 'healthy' and 'less healthy' food and drink categories by the study team. They reported their children's consumption of each food category (0 = none, 1 = once, 2 = twice or more) over each of four 24 h periods (two weekdays and two weekend days). After reverse coding the 'less healthy' categories, an average daily nutrition score was derived (possible range 0–28), with a higher score indicating better nutrition. Using the validated Bouchard after-school activity diary,[16] parents were given a list of seven activity categories. Average daily activity scores were calculated from parent ratings of children's activity on a scale of 1 (sedentary) to 7 (intense activity) at 15 min intervals between 15.30 and 18.30 h over 4 days. Children's activity was also dichotomized into percentage of time spent in low-level activity (ratings 1–3) vs higher level of activity (ratings 4–7, reported as percentage time spent in moderate–vigorous activity). Child health status was measured using the Total Scores from the 23-item PedsQL Parent Proxy and Child Self-report,[9] and child body satisfaction and physical appearance and global self-worth using the Collins body figure perception[17] and the modified Harter[18] scales, respectively.

Socioeconomic status (SES) was assigned according to postal code of residence using the Index of Relative Socio-economic Disadvantage (mean 1000, s.d. 100) from the Australian Bureau of Statistics census-based Socio-Economic Indexes for Areas (SEIFA).[19]

Intervention costs and health-care service use were evaluated from a health-care perspective and calculated in 2003 Australian dollars. Resources required to provide the LEAP 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 Medicare Benefits Schedule fee rates.[20]

Sample size

Figures regarding short-term population increment in BMI for children of this weight category and age are not readily available. We anticipated that the intervention would reduce the increase in BMI from 0.8 to 0.4 kg/m^2 over 12 months. We estimated an s.d. of change in BMI of 0.8, based on an s.d. of BMI of 1.7 using data from overweight and obese children aged 5–10 years from one wave of the HOYVS study[3] and a year-on-year correlation of 0.9 in BMI obtained from an English study.[21] We calculated that to have an 80% chance at a two-sided 5% significance level to detect a halving of the mean increase in BMI to $+0.4\,kg/m^2$ in the intervention group, 63 participants would be required in each of the trial groups. Allowing for up to 20% attrition, we aimed for 79 in each group.

Statistical analysis

The STATA 9.0 statistical package[22] was used throughout. All variables were checked for accuracy, missing values and appropriateness of their distributions for the proposed analyses. Comparison of the trial arms was based on the intention-to-treat principle. The method of random effects linear regression[23] was used for analysis in order to allow for the correlation between responses of participants seen by the same GP. Both unadjusted and adjusted analyses were

implemented. All comparisons were adjusted for socioeconomic status (using SEIFA scores).[19] All comparisons were adjusted for age and sex except BMI *z*-score, for which age and sex are already adjusted. Analyses were adjusted for the baseline measures of the outcomes except the child self-reported measures, which were not collected at baseline.

Because some of the outcomes were non-symmetrical, results from the random effects models were validated using bias-corrected accelerated bootstrap confidence intervals (CI).[24] As the Wald-based CI from the random effects models were essentially the same as the bootstrap ones, the former are reported.

Results

Table 1 reports baseline characteristics of the children, which were comparable between the trial arms with the exception that higher socioeconomic groups were better represented in the intervention arm. 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.[19]

Figure 1 shows participant flow throughout the trial. Although we aimed to see participants 6 and 12 months post-randomization, mean times to follow-up were in fact 9.1 months (s.d. 0.9) (hence reported as '9-month follow-up') and 15.0 months (s.d. 1.6) ('15-month follow-up'). Nine (11%) subjects in the intervention group and one (1%) subject in the control group were not visited at 9 months. Those lost to follow-up at 9 months were slightly heavier (20.8 vs 20.2 kg/m^2) and had lower mean total PedsQL parent scores (69.0 vs 77.5) at baseline than those retained, but other baseline characteristics were similar. A total of 12 (15%) subjects in the intervention group and five (6%) subjects in the control group were not visited at 15 months. Questionnaire return rates were 85% and 82% at 9 and 15 months, respectively. Because they required completion of a 4-day food and activity diary, there were substantial missing data for the outcomes of daily physical activity and daily nutrition (see Table 2).

Primary outcome (BMI)

Table 2 shows unadjusted and adjusted outcome comparisons between the intervention and control arms. At 9 months, the adjusted BMI of the intervention group was 0.2 kg/m^2 less than that of the control group (95% CI: −0.6, 0.1; $P=0.25$), and there was a 0.09 BMI *z*-score relative decrement from baseline (95% CI: −0.20, 0.02; $P=0.12$). At 15 months, there was no difference in adjusted BMI of the intervention group compared with the control group (95% CI: −0.5, 0.5; $P=1.00$), and there was a −0.03 BMI *z*-score relative decrement from baseline (95% CI: −0.17, 0.10; $P=0.62$).

Secondary outcomes

Compared with controls, the intervention group showed a significant improvement in nutrition score, sustained at 15 months. This was due to a reduction in high-fat milk and an increased consumption of low-fat milk and water in the intervention families. There was evidence of a small,

Table 1 Characteristics of children at baseline

Characteristic	*Total* (n = *163*)	*Intervention group* (n = *82*)	*Control group* (n = *81*)
Female, *n* (%)	84 (52)	40 (49)	44 (54)
Age in years, mean (s.d.)	7.4 (1.6)	7.5 (1.6)	7.4 (1.6)
SES[a], *n (%)*			
1 (highest)	44 (27)	24 (29)	20 (25)
2	25 (15)	16 (20)	9 (11)
3	25 (15)	11 (13)	14 (17)
4	27 (17)	14 (17)	13 (16)
5 (lowest)	42 (26)	17 (21)	25 (31)
BMI category[b]			
Overweight, *n* (%)	117 (72)	57 (70)	60 (74)
Mildly obese, *n* (%)	46 (28)	25 (30)	21 (26)
BMI, mean (s.d.)	20.3 (2.0)	20.5 (2.2)	20.0 (1.8)
UK BMI *z*-score, mean (s.d.)	1.9 (0.5)	2.0 (0.5)	1.9 (0.5)
% time spent being active (weekdays)[c], mean (s.d.)	38.9 (21.4)	39.7 (22.5)	38.1 (20.3)
Daily physical activity[d], mean (s.d.)	3.3 (0.6)	3.3 (0.7)	3.3 (0.6)
Daily nutrition[e], mean (s.d.)	16.3 (2.8)	16.3 (2.9)	16.2 (2.8)
PedsQL Parent Proxy[f], mean (s.d.)	76.9 (13.3)	75.2 (13.7)	78.8 (12.8)

Abbreviations: BMI, body mass index; SES, socioeconomic status. [a]Socioeconomic status by population quintile for SEIFA Index of Relative Socio-economic Disadvantage. [b]International Obesity TaskForce cutpoints. [c]*n* is 79 for intervention arm and 81 for control arm. [d]*n* is 72 for intervention arm and 72 for control arm. [e]*n* is 65 for intervention arm and 69 for control arm. [f]*n* is 80 for intervention arm and 76 for control arm.

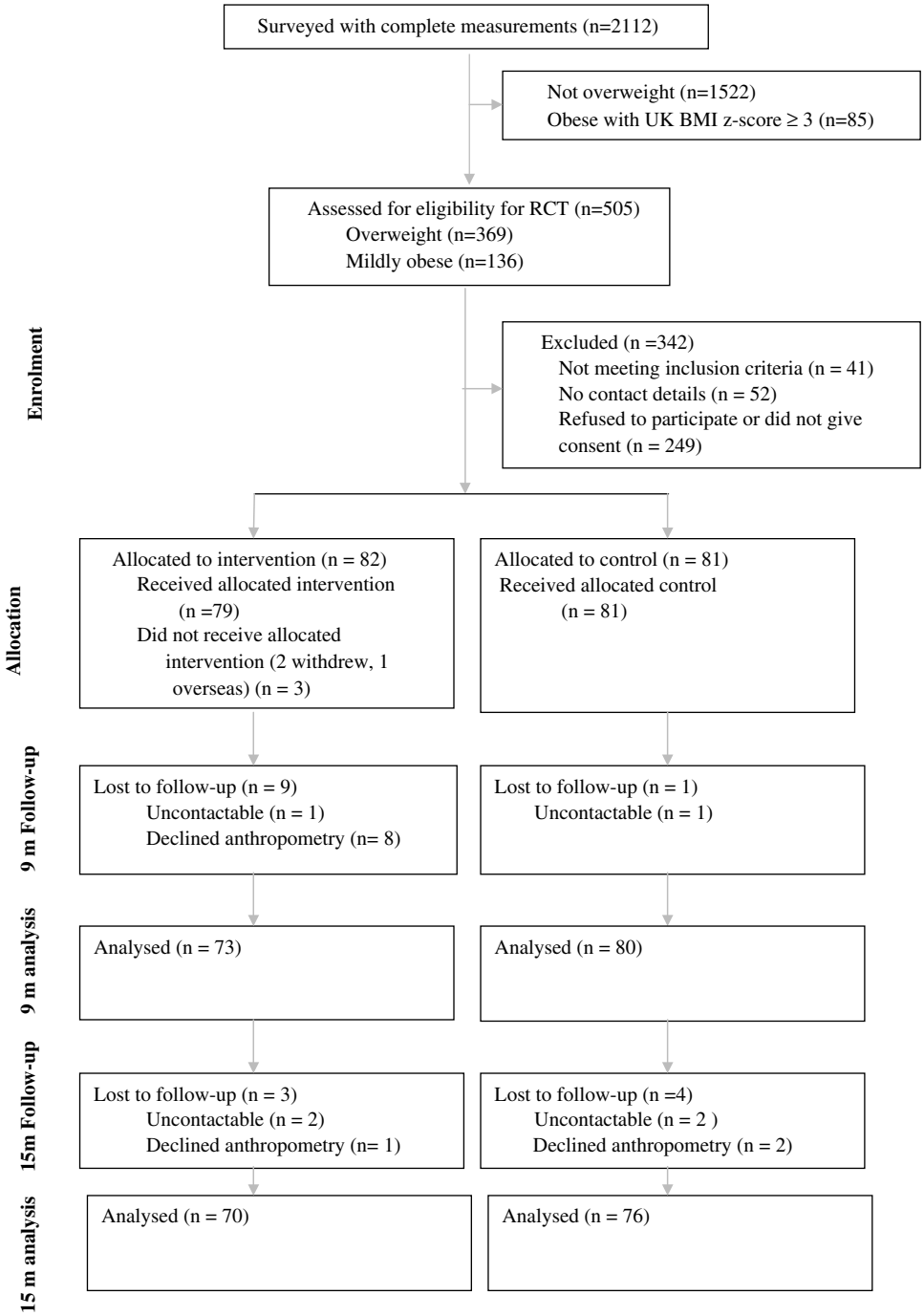

Figure 1 Participant flow chart for BMI survey and RCT.

significant, although unsustained increase in percentage of after-school time spent in moderate–vigorous physical activity at 9 months in intervention children and weak evidence, in adjusted analyses only, of an improvement in daily physical activity in the intervention arm that was sustained at 15 months. There was little evidence of either harm or benefit of the intervention with respect to parent- and child-reported child health status and child-reported body satisfaction and appearance/self-worth.

Thirty-four (41%) of the 82 children in the intervention arm attended all four sessions. Seventeen (21%), 14 (17%), 14 (17%) and three (4%) children attended three, two, one and no GP LEAP sessions, respectively. General practice record audit to assess the extent of possible contamination

Table 2 Outcomes by randomization group

Outcome	*Intervention*		*Control*		*Unadjusted difference (I–C)*		*Adjusted difference (I–C)*	
	n	*Mean (s.d.)*	n	*Mean (s.d.)*	*Mean (95% CI)*	P-*value*	*Mean (95% CI)*	P-*value*
Nine months								
BMI	73	21.0 (2.6)	80	20.8 (2.2)	0.2 (−0.6 to 0.9)	0.61	−0.2 (−0.6 to 0.1)	0.25
UK BMI *z*-score	73	1.96 (0.64)	80	1.93 (0.57)	0.04 (−0.16 to 0.23)	0.71	−0.09 (−0.20 to 0.02)	0.12
% of activity time spent in moderate–vigorous activity	59	42.9 (15.5)	72	36.1 (20.5)	6.8 (0.8 to 12.9)	0.03	6.1 (−0.0 to 12.2)	0.05
Daily physical activity	45	3.3 (0.5)	61	3.2 (0.6)	0.1 (−0.1 to 0.3)	0.45	0.2 (−0.0 to 0.4)	0.08
Daily nutrition	43	19.0 (2.7)	54	16.5 (2.5)	2.5 (1.5 to 3.5)	<0.001	2.1 (1.3 to 2.9)	<0.001
PedsQL Parent Proxy	58	79.1 (10.3)	67	82.6 (12.3)	−3.5 (−7.5 to 0.4)	0.08	−1.9 (−4.9 to 1.2)	0.23
PedsQL Child Self-Report	73	77.5 (11.1)	80	76.7 (12.2)	0.9 (−2.8 to 4.5)	0.65	0.7 (−3.0 to 4.4)	0.70
Body satisfaction	73	1.2 (1.3)	80	1.0 (1.2)	0.2 (−0.2 to 0.6)	0.43	0.1 (−0.3 to 0.5)	0.58
Physical appearance and global self-worth	73	1.4 (0.5)	80	1.3 (0.5)	0.0 (−0.1 to 0.2)	0.72	0.0 (−0.1 to 0.2)	0.65
15 months								
BMI	70	21.7 (3.1)	76	21.2 (2.4)	0.5 (−0.4 to 1.3)	0.31	−0.0 (−0.5 to 0.5)	1.00
UK BMI *z*-score	70	2.00 (0.68)	76	1.92 (0.59)	0.08 (−0.12 to 0.29)	0.42	−0.03 (−0.17 to 0.10)	0.62
% of activity time spent in moderate-vigorous activity	59	39.2 (19.3)	70	35.2 (20.5)	3.7 (−3.1 to 10.4)	0.29	3.2 (−2.8 to 9.5)	0.29
Daily physical activity	49	3.3 (0.5)	58	3.2 (0.5)	0.1 (−0.1 to 0.3)	0.37	0.2 (−0.0 to 0.3)	0.08
Daily nutrition	48	18.7 (2.0)	55	16.1 (2.7)	2.7 (1.8 to 3.5)	<0.001	1.6 (0.9 to 2.3)	<0.001
PedsQL Parent Proxy	63	78.1 (13.2)	69	78.8 (12.9)	−0.7 (−5.1 to 3.7)	0.76	0.2 (−3.1 to 3.5)	0.91
PedsQL Child Self-Report	72	78.8 (12.2)	74	76.5 (13.3)	2.2 (−1.9 to 6.4)	0.29	2.7 (−1.3 to 6.8)	0.19
Body satisfaction	72	1.0 (1.1)	74	0.8 (1.0)	0.2 (−0.2 to 0.5)	0.32	0.2 (−0.1 to 0.5)	0.30
Physical appearance and global self-worth	72	1.4 (0.5)	74	1.4 (0.5)	−0.0 (−0.2 to 0.1)	0.73	−0.0 (−0.2 to 0.1)	0.64

Abbreviations: BMI, body mass index; CI, confidence interval.

(that is, attendances for discussion of weight) showed minimal contamination.[9] All 34 GPs recruited were retained throughout the study period, and all had the opportunity to deliver the intervention.

Health sector costs

The cost of providing the LEAP intervention (education and materials) to 34 GPs was AUD $57 812. Total costs borne by the health sector were AUD $873 per intervention child and AUD $64 per control, a difference of AUD $809. However, the GPs in LEAP provided the intervention to an artificially small number of children (2.4 per GP). The additional health care costs associated with LEAP would fall as the intervention is provided to a greater number of children per GP, for example to $196 if each GP treated 30 children.

Discussion

To our knowledge, this brief, family-based intervention is the first reported RCT of a secondary prevention approach to childhood overweight in the primary care setting. Although parents in the intervention arm reported a sustained improvement in child nutrition score, there was no sustained improvement in BMI.

The strengths of the study include its randomized design, the strong uptake by families and GP practices spanning the range of socioeconomic status, follow-up for more than a year and the high retention rate. However, as our GPs were a select volunteer group we cannot generalize our high attendance and retention rates to all GPs.

LEAP provides encouragement that a primary care-based, secondary prevention approach to overweight in the middle childhood years is feasible and acceptable. However, it did not meet its primary aim of a reduction in BMI increment relative to the control arm. Several ideas can be advanced to explain this. First, the intervention may be ineffective. The 'dose' of intervention may have been too small with either more sessions required or over a more extended period of time; the relatively unstructured 'solution-focused' approach may have allowed families to set lifestyle change goals that would by their nature be insufficient to have any great impact on BMI increment. Second, despite the high attendance rate by intervention families, we were not able to objectively monitor whether the GPs actually delivered the programme as planned or acquired the necessary skills in brief behavioural change strategies, despite positive and detailed self-report feedback from the GPs and families on topics discussed in consultations. Future studies would be advised to either observe primary care consultations or use techniques such as simulated patients who can report on their experiences.[25] Third, contamination could have masked an effective intervention, although this seems highly unlikely (based on the findings of our audit of case notes, exit parent questionnaires and the rate of rise in BMI in both groups).

It is critical to determine whether primary care can be an effective setting for secondary prevention efforts targeted to overweight primary school children, because for vast numbers of affected children in many countries there are no other

services available. Based on this trial, however, we cannot recommend that GPs adopt brief solution-focused behavioural strategies for this purpose. Given the policy and health relevance of the child obesity epidemic, we suggest that the time is ripe for a planned suite of primary care studies, possibly under the umbrella of a prospective international meta-analysis, in which differing components (such as intensity/duration, group vs individual, GP vs allied health care delivery and approach e.g. didactic vs motivational interviewing) can be systematically and efficiently trialed.

Acknowledgements

Contributors: The project was initiated and funding obtained by MW, ZM, JG, LB, KG and EW. All authors contributed to developing the protocols and reviewing, editing and approving the final version of the paper. The trial was implemented by ZM and MW who oversaw all stages. ZM, BG and JS carried out recruitment and data collection; ZM, BG and OU conducted the analyses with the exception of the economic analysis which was performed by LG. ZM and MW wrote the paper. ZM is the guarantor and accepts full responsibility for the conduct of the study, had access to the data, and controlled the decision to publish. Sharon Foster, Helen Cahill and Denise Findlay contributed medical education expertise and Christy Collins assisted in early recruitment of families.

Ethical approval: The project was approved by the Royal Children's Hospital Ethics in Human Research Committee (EHRC 2109).

Funding: ZM was funded via Public Health Postgraduate National Health and Medical Research Council Scholarship (ID 216745). The LEAP trial was funded via a grant from the Australian Health Ministers' Advisory Council for Priority Driven Research (AHMAC PDR 2001/15).

Statement of competing interests: This study was funded by an Australian Health Ministers' Advisory Council Priority Driven Research Project Grant (AHMAC PDR 2001/15). The supporting source had neither involvement in the design and conduct of the study nor control or influence over the writing and submission of this manuscript. There is no conflict of interest.

Sources of support: Australian Health Ministers' Advisory Council Strategic Research Fund; National Health and Medical Research Council Public Health Postgraduate Scholarship.

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