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Can Australian general practitioners tackle childhood overweight/obesity? Methods and processes from the LEAP (Live, Eat and Play) randomized controlled trial

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Background: General practitioners (GPs) could make an important contribution to management of childhood overweight. However, there are no efficacy data to support this, and the feasibility of this approach is unknown.
Objectives: To determine if GPs and families can be recruited to a randomized controlled trial (RCT), and if GPs can successfully deliver an intervention to families with overweight/obese 5- to 9-year-old children.
Methods: A convenience sample of 34 GPs from 29 family medical practices attended training sessions on management of childhood overweight. Practice staff trained in child anthropometry conducted a cross-sectional body mass index (BMI) survey of 5- to 9-year-old children attending these practices. The intervention focused on achievable goals in nutrition, physical activity and sedentary behaviour, and was delivered in four solution-focused behaviour change consultations over 12 weeks.
Results: General practitioners were recruited from across the sociodemographic spectrum. All attended at least two of the three education sessions and were retained throughout the trial. Practice staff weighed and measured 2112 children in the BMI survey, of whom 28% were overweight/obese (17.5% overweight, 10.5% obese), with children drawn from all sociodemographic quintiles. Of the eligible overweight/obese children, 163 (40%) were recruited and retained in the LEAP RCT; 96% of intervention families attended at least their first consultation.
Conclusions: Many families are willing to tackle childhood overweight with their GP. In addition, GPs and families can participate successfully in the careful trials that are needed to determine whether an individualized, family-based primary care approach is beneficial, harmful or ineffective.

Key words: childhood obesity; feasibility; primary care; randomized controlled trial.

In 1998, the World Health Organization designated obesity as a global epidemic.[1] The prevalence of childhood obesity trebled in Australian children between 1985 and 1997[2,3] and may still be rising.[2] If overweight and obesity could be effectively prevented or treated in childhood, some associated psychosocial[4] and physical morbidity[5] might be avoided.

To tackle this issue at a population level, both prevention and targeted early management strategies suitable for large-scale application will almost certainly be needed. In late 2003, the National Health and Medical Research Council (NHMRC) released its evidence-based report *Clinical Practice Guidelines for the Management of Overweight and Obesity in Children and Adolescents*.[6] This study addresses the urgent need identified by the NHMRC report for 'simple, well-designed intervention studies in obese children and adolescents, which can be translated into usual clinical practice'.

Primary health care services have the capacity to deliver relatively brief interventions targeting prevention and management to large numbers of individuals. In Australia, general practitioners (GPs) may be well-placed to identify and manage the large numbers of young children who are already overweight. They provide individual health care to virtually all Australian school children,[7] and the prevalence of overweight and obesity in their practices mirrors or exceeds that in the general population.[8] General practitioners have been effective in other health promotion areas, such as smoking,[9] alcohol,[10] adolescent health care.[11] The National Asthma Campaign was successful in both educating GPs and enhancing the asthma management by both GPs and parents, resulting in reduced hospital admission rates and asthma mortality.[12,13] Controlled primary care trials have shown some effectiveness targeting adult overweight, healthy eating and physical activity.[14] However, no reported trials have yet examined the efficacy of GPs in managing childhood overweight and mild obesity, and the feasibility of this approach is unknown.

OBJECTIVES

The Live, Eat and Play (LEAP) study aimed to engage GPs and the families of their overweight child patients, and to trial a brief, sustainable and reproducible intervention for use in the primary health care sector. Unknowns included whether families and GPs were willing to tackle the issue of childhood overweight together, and whether they could do this within the constraints of the randomized controlled trial (RCT) design necessary to

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determine whether an individualized, family-based primary care approach is likely to be beneficial, harmful or ineffective.

In this paper, we address the following aims:

1. Report recruitment, training and retention of GPs and families in the trial.
2. Report the results of the baseline cross-sectional survey of child body mass index (BMI) as a method of ascertainment and recruitment to an RCT for childhood overweight.
3. Discuss the challenging methodological issue of individual versus clustered randomization.
4. Report preliminary process data from the LEAP RCT.

METHODS

Study design and setting

The LEAP study comprised an RCT, described in detail later, nested within a large cross-sectional BMI survey conducted in 29 family medical practices in Melbourne, Australia (population 3.6m). The project was approved by the Royal Children's Hospital Ethics in Human Research Committee.

General practitioner recruitment

Personalized letters of invitation were sent to members of a large GP paediatric special interest group (more than 600 GP members spanning five divisions of general practice surrounding Melbourne's Royal Children's Hospital, covering a wide sociodemographic arc) and of a large division of general practice in south-east Melbourne. Several recruitment evenings were subsequently held locally. General practitioners participated as co-investigators and signed a memorandum of understanding along with members of the research team outlining the responsibilities of both parties.

Cross-sectional BMI survey

Patient eligibility and recruitment

All children aged 5–9 years attending the 29 participating practices for any reason during April–December 2002 were eligible for the BMI survey. Practice staff offered parents the options of not participating in the survey; participating in the survey anonymously; or participating and providing contact details in case they were eligible for the LEAP trial. Brief written information stated that the trial would be about GPs trying to help families to lead a healthier lifestyle in an environment in which 'many children, like adults, are heavier and less active than they used to be'.

Data collection methods

A pilot of the BMI survey conducted in June–July 2001 confirmed the feasibility of our recruitment targets (88% of children attending two GPs were weighed and measured over 2 weeks) and acceptability of the measurement and recruitment process to staff and parents.

Because many practices were poorly equipped to routinely and accurately weigh and measure children, the study team provided each practice with an Invicta portable rigid stadiometer, which measures to the nearest 1 mm to a height of 207 cm,[15] and a set of accurate digital scales (Tanita THD Model 646) which were calibrated at the beginning, middle and end of the recruitment period. Two researchers, experienced in measuring child height and weight, trained 117 staff in the 29 practices to acceptable accuracy in recruitment protocols and measurement techniques using standardized height poles and adult and child subjects. General practitioners gave written consent to contact the Health Insurance Commission to ascertain how many 5- to 9-year-old children attended in the time frame, and thence the proportion who were actually measured.

In addition to weight and height, parents recorded their child's gender and date of birth (and contact details if interested in the subsequent RCT). Practice staff mailed the completed height and weight data forms to the study team weekly, at which time the research team calculated each child's BMI and determined eligibility for the trial.

LEAP RCT

Patient eligibility and recruitment

Recruitment occurred between April 2002 and March 2003; 6 month follow-up occurred between January and September 2003; and 12 month follow-up between July 2003 and March 2004. All 5- to 9-year-old children classified as overweight or mildly obese in the BMI survey were contacted by the research team via telephone, at which time any exclusion criteria were ascertained (e.g. receiving ongoing weight management in a secondary or tertiary care programme). Eligible parents were considered recruited on receipt of contact details, written consent and baseline questionnaire. We excluded very obese children (UK BMI z-score ≥ 3.0, see *Randomization*, later), whom we considered inappropriate for a brief and untried secondary prevention approach. These children were referred back to their GP for possible referral to tertiary paediatric weight management service.

The baseline questionnaire, mailed back in a reply-paid envelope, covered parent perceptions of the child's weight, physical activity, nutritional practices, health-related quality of life, family environment and their relationship with their GP. On receipt of the completed questionnaire and consent, the research team randomized children to the intervention or control group. Control families were notified of their control status via letter, and were not identified to the GPs at any time; intervention families were notified by telephone and assisted in making the first doctor's appointment.

Before the first appointment, the LEAP team provided the GP with the child's personalized intervention materials and the child's calculated BMI. In addition, GPs received a single sheet of parent responses extracted from the baseline questionnaire regarding current nutrition, physical activity patterns and concern regarding their child's weight status. Although the bulk of the baseline questionnaire was collected for research purposes, some questions were collected in order to feedback to the GP to commence the intervention process. We reasoned that if the LEAP were implemented more widely, ideally GPs would identify overweight during incidental child visits, discuss the issue briefly with the family, and invite the parent to complete a short questionnaire before returning for a longer consultation when the child was well. The single sheet of responses was designed to replicate this process without imposing additional respondent burden on the family.

GP education

An initial 'pre-quiz' established the GPs' knowledge, skills and attitudes to childhood obesity and their current practice in managing overweight and obese children. They then attended three $2^1/_2$-h training sessions at local venues. A 'post-quiz' after these sessions established changes in knowledge and encouraged review of materials. Doctors were instructed in the 'stages of

change' model[16] and provided with brief training in solution-focused family therapy.[17] We hoped that, within primary care time constraints, the flexible solution-focused approach would assist the practitioner in moving away from medical 'problem solving' models to allow the family to explore their own lifestyle behaviour change solutions which, in turn, might lead to the adoption of achievable and realistic goals.[18] The education sessions used a range of adult learning styles: didactic presentations, reflective discussion, demonstration consultations using role-plays with simulated families including child actors, and small group role-plays.

Randomization

Children were categorized into non-overweight, overweight and obese categories according to the International Obesity Task Force (IOTF) gender and age-specific cut-off points.[19] Body mass index was transformed to standardized z-scores based on gender and exact age, using the LMS method[20] and the 1990 UK Growth Reference,[21] which enabled us to identify and exclude the 'very obese' children (UK BMI z-score ≥ 3.0). For each GP, subjects were stratified by overweight or obese status. Randomization was performed by a third party using a pregenerated sequence, following recruitment and collection of baseline data to prevent differential recruitment. Blinding was maintained throughout data collection.

There has been much debate in the literature around the respective benefits of individual versus cluster randomization in RCT in primary care.[22,23] Randomization at the individual patient level has the potential for contamination when controls are exposed to the intervention, either because the participating doctors change their practice for all patients or due to interaction with the intervention group. Cluster randomization reduces the risk of contamination, but may result in loss of baseline equivalence if 'control practices' recruit and enrol patients differently to 'intervention practices'. It also requires an increase in sample size by an inflation factor that takes into account the expected correlations within each cluster (i.e. the recruited individuals attending each practice).

Because the intervention aimed for complex behaviour change, to increase individuals' behaviours that might be 'unpopular' (e.g. ceasing consumption of desired foods, increasing physical activity), we felt that contamination of the non-intervention group would be low and therefore elected to individually randomize. Being aware that this decision would be somewhat controversial, we carefully sought evidence of contamination through: (i) an audit of practice files for control children, including attendance record and whether the child was measured and/or weight management issues discussed; (ii) surveying the GPs about their management of control children, use of the LEAP materials, and approach with patients other than the LEAP intervention children; and (iii) control parent report.

Intervention

Long-term maintenance of healthy weight has been most successfully achieved when the intervention is family based[24] and when behaviour changes are achievable and sustainable. We followed an intervention mapping technique,[25,26] in which theoretical and empirical knowledge about modifiable determinants and barriers to and facilitators of change are translated into a concrete and practical intervention (in our case regarding childhood overweight, particularly physical activity and nutrition). Based on this, we specifically aimed to *increase* access to play equipment (by parents providing, and supporting their children to use simple play equipment at home, and by using available local resources), time spent outdoors, parent support of and child preference for physical activity, water drinking, regular meals and healthier snacks; and to *decrease* fat intake, sweet drinks, sedentary behaviour and perceived barriers to physical activity.

An evidence-based set of materials was created to assist the GPs and families in appropriate healthy lifestyle behavioural changes. A personalized 20-page 'family folder' was designed to assist in setting and recording appropriate goals. To help select goals, seven topic sheets were included (topics sheets: Childhood overweight – what are the issues?; Water – the drink for children; Importance of breakfast, regular meals and snacks; Choosing the lower fat options; Healthy food for the family: Avoiding battles; More active – it's easy!; Doing nothing: Not a good option.) Each sheet focused on one area of behavioural change believed important in reducing overweight and comprised a brief summary of supporting evidence, modelled solutions to challenges, and provided additional suggestions as to how each goal might be reached. Additional materials included work sheets, a wall chart and reward stickers, and a shopping tips fridge chart and notepad designed to emphasize lower fat alternatives to popular foods. Parent participation was encouraged by family-based reinforcement techniques such as shared meals and activities, using praise and non-food rewards, and contracting. All materials were designed at a 12-year-old reading level. Materials were edited and refined according to expert opinion and GP feedback and then piloted successfully with families attending a weight management clinic. This confirmed that the materials were useful and non-offensive and that families were readily able to select areas relevant to them in making healthier lifestyle choices.

Parents were asked to attend four consultations over a 12-week period. General practitioners did not routinely weigh or measure children at these visits, as interventions focused on behavioural change rather than weight loss. Date, content discussed and contracts made were recorded on a LEAP form in the child's medical record. The GP was also asked to briefly encourage and reinforce any strategies previously discussed at non-LEAP visits, for example, acute care consultations.

Main outcome measures

Change in BMI was the primary outcome measure, which required direct assessment of each child at 6 and 12 months after the first consultation. A range of secondary outcome measures were also collected: child waist circumference; child health-related quality of life;[27] behaviour, self-esteem and family activities,[28] parental concern regarding child's weight[29] and readiness to change;[30] child physical activity and sedentary behaviour;[29,31–33] child and family nutrition[31,34] and relationship with GP.[35]

General practitioners were asked to report practice demographics;[36] practice and attitude regarding management of child overweight[37] as well as feedback on conduct of the study.

Statistical analysis

Socioeconomic status (SES) was assigned according to postal code of residence using the Australian Bureau of Statistics Socio-Economic Indexes for Areas (SEIFA).[38] Each Victorian postal code has a SEIFA Index of Relative Socioeconomic Disadvantage with a value ranging from 725.749 to 1162.479. Using 1996 Census data, we divided the Victorian population into quintiles and derived SEIFA ranges for each. These SEIFA quintile values were then applied to the 1899 children for whom postcode was available to determine the distribution of the study participants across the socioeconomic strata. We looked for a socioeconomic gradient in prevalence of overweight using a test for trend (likelihood ratio (LR) χ^2), in which SES quintile was entered as a continuous variable with BMI status dichotomized into 'normal

weight' versus 'overweight' (combined overweight, obese and very obese (BMI z-score $\geq$3) categories, based on IOTF BMI cut-points).

RESULTS

Doctor participation and characteristics

Of the 598 GPs contacted by letter, 53 attended a recruitment evening at which 33 were recruited. A further eight were recruited following a practice visit. Of these 41 doctors, 34 GPs from 29 practices were able to participate in the required education sessions. All 34 attended at least two of the three education sessions (75% attended all three), with 85% reporting good or very good relevance to general practice.

The location of participating practices covered the sociodemographic spectrum, with the median SES of practice close to the 50th centile (range from <10th to >90th centile) on the Index of Relative Socioeconomic Disadvantage. All 34 recruited GPs were retained throughout the study period, and all but one said they would participate in LEAP again. Of the 28 GPs who completed both baseline and follow-up questionnaires, 27 reported they felt competent managing childhood overweight after compared with 12 before LEAP began, and 22 felt they could make a significant difference to children's weight compared to two beforehand.

Characteristics of participants in the BMI survey

Table 1 shows the characteristics of the 2112 children participating in the BMI survey. Health Insurance Commission data suggest that a mean of 50% (range 16–82%) of children were measured. This figure is lower than our projected numbers based on the pilot study. This appeared to reflect practical staffing and logistic difficulties in weighing and measuring all children attending the practice, since very few parents were reported to have declined offers for their child to be weighed and measured. Nonetheless, both BMI and demographic status covered the full spectrum, with children living in areas of lowest and highest demographic status well-represented. The overall prevalence of overweight was 17.5% and obesity 10.5%. Prevalence of overweight/obesity rose markedly as SES fell (22.6%, 24.8%, 26.5%, 30.3% and 34.5% in SES quintiles 1 (highest), 2, 3, 4 and 5 (lowest), respectively). This SES gradient was highly statistically significant (LR $\chi^2 = 19.88$; $P < 0.0001$, OR = 1.16, 95% CI: 1.09, 1.23). Figure 1 shows participant flow to the end of recruitment and randomization.

Characteristics of participants in the LEAP RCT

Parents of approximately 40% of all children identified as overweight/obese in the survey agreed to take part in the LEAP RCT. Characteristics of these 163 children are shown in Table 2. Non-recruited families were more likely to have a female child and be from a lower SES quintile. They did not differ from the recruited sample in baseline BMI nor mean age. Intervention children's records indicate 96% attended their first LEAP consultation, 79% attended two or more and 63% attended three or more of the four consultations. Based on an audit of all control children's case notes during the 6 months following recruitment, contamination appears very low. Despite 50/81 (62%) control children seeing their GP during the period of the intervention, only nine had weight and height recorded, and discussion of weight, physical activity and nutrition issues was not recorded for any control child.

Follow-up rates

At 6 months, 94% (153/163) of children were seen for direct measurements and interview measures, and mail-back questionnaires were received for 84% (137/163) of families.

DISCUSSION

Although primary care is increasingly perceived as being well-placed to address childhood overweight and obesity,[39] there is a near-total absence of published trials tackling the issue in this setting. Known barriers to successful trials in primary care include participant recruitment, resources, time and remuneration.[40] In this study, more than a quarter of the sampled 5- to 9-year-old children were overweight/obese, and we achieved our targeted recruitment rate (approximately 40%) of parents accepting proactive identification and being willing to join with their GP in a secondary prevention approach to the issue. We have previously shown that 50% of Victorian parents of obese children and 80% of parents

Table 1 Cross-sectional BMI survey sample characteristics ($n = 2112$)

Characteristic	Total	Weight category†			
		Non-overweight	Overweight	Obese	Very obese‡
Total (*n* (%))	2112	1522 (72.1)	369 (17.5)	136 (6.4)	85 (4.0)
BMI (median)	16.7	16.0	19.2	22.3	26.8
BMI *z*-score (mean (SD))	0.6 (1.2)	0.2 (0.7)	1.7 (0.4)	2.6 (0.2)	3.5 (0.4)
Age (mean (SD))	7.3 (1.4)	7.3 (1.4)	7.5 (1.5)	7.4 (1.4)	7.2 (1.4)
Sex (*n* (%))					
Female	1048	723 (69.0)	202 (19.3)	87 (8.3)	36 (3.4)
Male	1064	799 (75.1)	167 (15.7)	49 (4.6)	49 (4.6)
SES§ (*n* (%))					
1 (highest)	554	429 (77.4)	88 (15.9)	24 (4.3)	13 (2.4)
2	234	176 (75.2)	39 (16.7)	14 (6.0)	5 (2.1)
3	279	205 (73.5)	41 (14.7)	21 (7.5)	12 (4.3)
4	327	228 (69.7)	58 (17.7)	28 (8.6)	13 (4.0)
5 (lowest)	505	331 (65.6)	95 (18.8)	44 (8.7)	35 (6.9)

†International Obesity Taskforce cut-points[19]; ‡UK Growth Standard BMI z-score ≥ 3[21]; §Socioeconomic status by population quintile for SEIFA Index of Relative Socioeconomic Disadvantage[38]. Postcodes were available for 1899 children. Percentages may not add up to 100%, due to rounding. BMI, body mass index; SEIFA, Socio-Economic Indexes for Areas.

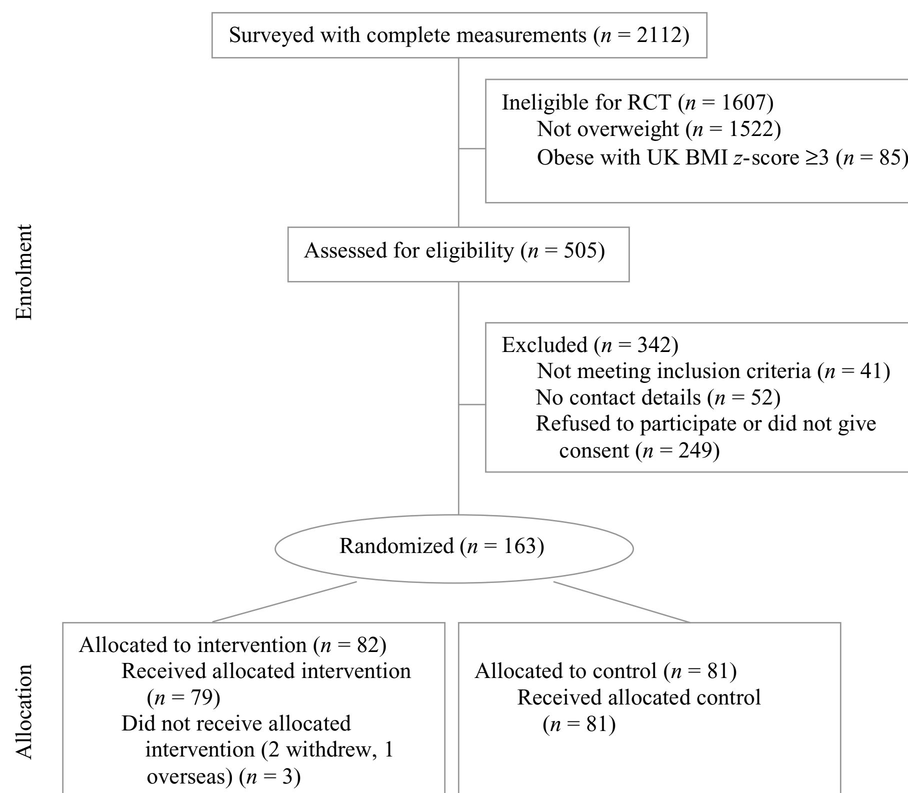

Fig. 1 Flowchart of randomized controlled trial.

of overweight children are not concerned about their child's weight.[29] Therefore, many families were at best likely to be in the precontemplation phase according to the stages of change model. Families could select from a variety of evidence-based suggestions those most likely to work for them, assisted by a GP trained in brief solution-focused therapy. General practitioners in practices across a broad sociodemographic range reported that this approach was relevant to them, and all were successfully retained throughout the trial. The intervention could be delivered within standard consultations so, if effective, could potentially be widely applicable within the current Australian health care and remuneration system. Alternative primary care models (such as interventions delivered by allied health personnel) also deserve rigorous trial, although at this stage there is no universally-available funding for such models.

Table 2 LEAP RCT sample characteristics ($n = 163$)

Characteristic	Total	Group	
		Intervention	Control
Total	163	82	81
BMI category† (*n* (%))			
Overweight	117 (71.8)	57 (69.5)	60 (74.1)
Obese	46 (28.2)	25 (30.5)	21 (25.9)
BMI (median)	19.9	20.2	19.7
BMI *z*-score (mean (SD))‡	1.9 (0.5)	2.0 (0.5)	1.9 (0.5)
Sex (*n* (%))			
Female	84 (51.5)	40 (48.8)	44 (54.3)
Male	79 (48.5)	42 (51.2)	37 (45.7)
Age in years (mean (SD))	7.4 (1.6)	7.5 (1.6)	7.4 (1.6)

†International Obesity Task Force cut-points[19]; ‡UK Growth Standard BMI *z*-score ≥ 3[21]. Percentages may not add up to 100%, due to rounding. BMI, body mass index; LEAP, Live, Eat and Play; RCT, randomized controlled trial.

Although broader applicability remains to be demonstrated, we have also demonstrated that it is feasible to conduct a tightly-controlled primary care-based RCT tackling childhood overweight. Complex decisions are required in mounting such a trial, including choice of study design. Although others have argued convincingly for cluster randomization,[22] we chose individual randomization in the belief that contamination would pose a lesser threat to validity than the baseline inequivalence characteristic of cluster controlled trials. Thus far, this belief appears justified, with audits of intervention and control child case notes revealing that extent of contamination within the practice to be minimal.

The prevalence of overweight/obesity of 28% is higher than reported in the most recent epidemiologic studies of child overweight/obesity in Victoria and other Australian states, which are now 6 or more years old.[2] This may indicate a continuing rise in prevalence, in keeping with the marked rise in South Australian 4-year-olds between 1995 and 2002.[41] Alternatively, our sample could be biased because heavier children were more likely to be weighed and measured by practice staff, or because overweight children are more likely to attend health care professionals with a range of problems such as asthma, skin rashes and injuries.[42,43] A rising proportion of overweight/obesity with falling SES would strengthen existing concerns that children are now following the adult pattern of a higher prevalence of obesity among lower sociodemographic populations.[44] Because our sample is not representative our data cannot confirm this, but ongoing Australian surveys studying the changing epidemiology of childhood overweight/obesity are urgently needed.

Although we designed the intervention with population applicability and cost considerations in mind, the study itself was

a tightly-controlled 'efficacy' study. In addition to the LEAP approach itself, the participating GP 'research volunteers' had to shoulder a heavy research load in the absence of any assurance that the approach would be beneficial. Although the proportion of contacted GPs who took part was therefore small and unlikely to be representative of all GPs, the broad socioeconomic demographic of their practices does support the idea that a family-focused, GP-facilitated primary care intervention could have applicability for families of widely differing social circumstance. We considered a 40% uptake by eligible families to be acceptable, particularly given that more than 80% of Victorian parents of overweight children, and more than 40% of parents of obese children, do not report concern about their child's weight.[32] A great strength of the general practice system is the ongoing contact with families over time. For a chronic, stable condition such as childhood overweight,[33] there would be multiple future opportunities to work with families who initially decline if an effective approach were available, consistent with the stages of change model.

Outstanding information includes 6 and 12 month follow-up results (available in 2005), and an analysis of cost which will have implications for the programme's replicability if effective. The next step would be to test whether the approach has applicability for a larger proportion of GPs in a more naturalistic approach – the so-called 'effectiveness' or 'pragmatic' study.

Should efficacy and cost-effectiveness be demonstrated in this and similar studies, we would hope that primary care strategies could take their place within a coordinated, evidence-based suite of universal prevention, secondary prevention and tertiary management approaches for childhood overweight/obesity.

WHAT THIS STUDY ADDS

Although there is an urgent need for primary care strategies to address the pressing child public health problem of overweight/obesity, there is a notable lack of published studies in this setting. This may reflect a perception that such studies are simply too difficult to tackle, or too unlikely to be acceptable to parents or GPs.

In this paper, we report early process and feasibility data for a randomized controlled trial of secondary prevention of overweight for 5- to 9-year-old children by Australian GPs. General practitioners and parents of widely-varying sociodemographic circumstances were willing both to address the issue of child overweight and to take part in a rigorous randomized controlled trial. If efficacy is also demonstrated, the next challenge would be to demonstrate applicability to a more representative sample of GPs.

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