A Parent-Focused Intervention to Reduce Infant Obesity Risk Behaviors: A Randomized Trial

WHAT’S KNOWN ON THIS SUBJECT: While obesity-promoting eating, sedentary and physical activity behaviors, and increased prevalence of adiposity are evident from early life, few high-quality studies have evaluated interventions that seek to influence the development of these behaviors in very early childhood.

WHAT THIS STUDY ADDS: This study highlights the receptivity of first-time parents to interventions focused on their new infant’s eating and active play and provides evidence of effectiveness on some obesity-promoting behaviors in very early childhood.

abstract

OBJECTIVE: To assess the effectiveness of a parent-focused intervention on infants’ obesity-risk behaviors and BMI.

METHODS: This cluster randomized controlled trial recruited 542 parents and their infants (mean age 3.8 months at baseline) from 62 first-time parent groups. Parents were offered six 2-hour dietitian-delivered sessions over 15 months focusing on parental knowledge, skills, and social support around infant feeding, diet, physical activity, and television viewing. Control group parents received 6 newsletters on nonobesity-focused themes; all parents received usual care from child health nurses. The primary outcomes of interest were child diet (3 × 24-hour diet recalls), child physical activity (accelerometry), and child TV viewing (parent report). Secondary outcomes included BMI z-scores (measured). Data were collected when children were 4, 9, and 20 months of age.

RESULTS: Unadjusted analyses showed that, compared with controls, intervention group children consumed fewer grams of noncore drinks (mean difference = −4.45; 95% confidence interval [CI]: −7.92 to −0.99; P = .01) and were less likely to consume any noncore drinks (odds ratio = 0.48; 95% CI: 0.24 to 0.95; P = .034) midintervention (mean age 9 months). At intervention conclusion (mean age 19.8 months), intervention group children consumed fewer grams of sweet snacks (mean difference = −3.69; 95% CI: −6.41 to −0.96; P = .008) and viewed fewer daily minutes of television (mean difference = −15.97; 95% CI: −25.97 to −5.96; P = .002). There was little statistical evidence of differences in fruit, vegetable, savory snack, or water consumption or in BMI z-scores or physical activity.

CONCLUSIONS: This intervention resulted in reductions in sweet snack consumption and television viewing in 20-month-old children. Pediatrics 2013;131:652–660

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KEY WORDS RCT, obesity prevention, infant, diet, physical activity, TV viewing

ABBREVIATIONS CI—confidence interval ICC—intraclass correlation coefficient LGA—local government areas MCH—Maternal and Child Health RCT—randomized controlled trial SEP—socioeconomic position zBMI—BMI z-scores

(Continued on last page)
Worldwide, 43 million children aged 0 to 5 years are overweight or obese, representing a relative increase in prevalence of 60% since 1990. A recent analysis of the impact of early childhood weight on later adiposity confirms that body size in children as young as 5 to 6 months and weight gain from 0 to 2 years are consistently predictive of high subsequent body size at age 13 years. Furthermore, upward crossing of major weight-for-length percentiles in the first 6 months of life is associated with high obesity rates at ages 5 and 10 years. Prevention of excess weight gain in early life is clearly of paramount importance, yet the most recent Cochrane Review of childhood obesity prevention identified just 1 rigorous obesity prevention study in early childhood. Given the opportunity for early prevention, an urgent need exists for studies demonstrating the potential of interventions to reduce obesity-risk behaviors.

Parents are a key influence on the development and maintenance of children’s behaviors and are a rational target for child obesity prevention. They are also an attractive target given their focus on child health. In Victoria, Australia, parents access health services an average of 35 times in the first year of their child’s life, primarily to seek advice on promoting health and wellness. The free, universal service provided by Maternal and Child Health (MCH) nurses engages ~66% of all first-time parents in groups that run over a 6- to 8-week period in the first 3 months of a child’s life. Most of these MCH nurse-initiated groups subsequently become independent social groups that continue to meet (fortnightly on average) for ~18 months. These preexisting social groups provide an opportunity for the promotion of knowledge, skills, and strategies likely to promote healthy child behaviors and present an ideal setting for obesity prevention interventions.

In this cluster randomized controlled trial (RCT), we tested the hypotheses that an obesity prevention intervention delivered to first-time parents in preexisting social groups would improve aspects of child diet, increase child time spent physically active, and reduce child television viewing time. We also hypothesized that child BMI z-score would be lower in the intervention group children. This study is reported by using the framework of the CONSORT statement for parallel group randomized trials.

**METHODS**

**Study Design**

This study was a cluster RCT with balanced (1:1) randomization. Fourteen local government areas (LGAs) were randomly selected from the 28 eligible LGAs located within a 60-km radius of the research center, situated within the major metropolitan city of Melbourne, Australia (population 4 million). One eligible LGA declined to participate and was replaced with the next LGA on the randomly ordered list. Good representation of LGAs across socioeconomic groups was achieved, with an area-level index of relative disadvantage indicating selection of 3 LGAs in each of the lowest and highest tertile-defined categories and eight classified as middle category.

**Sample Selection**

Fifty percent of eligible first-time parents’ groups (rounded to next even number) within each LGA were randomly selected (62/103 groups) and approached by research staff for recruitment during 1 of the standard nurse-facilitated group sessions. Individual parents were eligible to participate if they gave informed written consent, were first-time parents, and were able to communicate in English. Parent groups were eligible if ≥8 parents enrolled or ≥6 parents enrolled in areas of low socioeconomic position (SEP) because mothers in areas of low SEP are less likely to attend first-time parent groups. When first-time parents’ groups declined to participate, another randomly selected group was approached.

Randomization of first-time parents’ groups (clusters) occurred after recruitment to avoid selection bias. Randomization (stratified by LGA) was conducted by an independent statistician. Although parents were not blinded to allocation, they were not informed of the study aims or hypotheses. Staff measuring height and weight were not blinded to intervention status because they also delivered the intervention. All dietary recalls, data entry, and analyses were conducted with staff blinded to participant’s group allocation.

**Intervention**

**Intervention Arm**

Intervention delivery occurred from June 2008 to February 2010 with individual groups involved for 15 months. The dietitian-delivered intervention comprised six 2-hour sessions delivered quarterly during the first-time parents’ group regular meeting. Data collection occurred at child age 4 months (baseline) and when children were 9 months of age (midintervention) and 20 months of age (postintervention). If parents did not attend these sessions, data collection occurred in the home. Program (intervention) materials were sent to nonattending parents, and a researcher telephoned to invite questions. Program fidelity was audited via checklists by researchers attending but not delivering the intervention.

The intervention is described in detail elsewhere. In summary, it sought to build knowledge, skills, and social support regarding infant feeding, physical activity, and sedentary behaviors. Messages were anticipatory in nature, such that concepts were...
presented before the associated child developmental phase. Social cognitive theory\textsuperscript{14} guided program development, incorporating a range of delivery modes and educational strategies including group discussion and peer support, as well as exploration of facilitators and barriers to uptake of key messages. Intervention materials incorporated 6 purpose-designed key messages (for example, “Color Every Meal With Fruit and Veg,” “Eat Together; Play Together,” “Off and Running”) within a purpose-designed DVD and written materials. A newsletter reinforcing key messages was sent to participants between sessions.

**Control Group**

Control parents received usual care from their MCH nurse, who may have provided lifestyle advice. The provision of this information was not assessed. Researchers met with control families in their first-time parent groups at the 3 data collection occasions. For those no longer attending groups, data collection occurred in the home. Control families received 6 newsletters regarding unrelated aspects of child health or development (eg, literacy, common illnesses). Intervention and control group families’ participation was acknowledged by small gifts (maximum value AUD$15.00) on receipt of completed questionnaires.

**Measures**

*24-Hour Dietary Recall*

Child’s dietary intake (3 days, including 1 weekend day) was assessed by trained nutritionists at mid- and postintervention data collections by telephone-administered multipass 24-hour recall with parents.\textsuperscript{15} To limit bias of responses, calls were unscheduled when possible (98% of all calls). When necessary (4% of recalls), food diaries were completed by other carers during child-care periods on scheduled days. These were then used by parents to provide detailed 24-hour recalls. Coding of the dietary data involved matching each food/beverage item to an appropriate nutrient composition and quantity, using the 2007 Australian Food and Nutrient Database (AUSNUT) Database.\textsuperscript{16} Data were checked for accuracy by dietitian review of interviews following coding.

Participants with <2 days of dietary recall were excluded from analyses (\(n = 53\) midintervention; \(n = 82\) postintervention). Average daily intakes of fruits (excluding juice), vegetables (excluding potatoes), noncore sweet foods (eg, chocolate, candy, cakes), noncore savory foods (eg, crisps, savory biscuits), noncore drinks (ie, fruit juice, soft drinks), and water were calculated.

**Objectively Assessed Physical Activity**

Physical activity was assessed by using ActiGraph accelerometers (Model GT1M, Pensacola, FL) postintervention.\textsuperscript{17} Children wore the accelerometer over the right hip for 8 days, removing only for sleeping and bathing. Those with \(\geq 4\) days of valid data were included in analyses (\(n = 288\)) as 4 days of data (\(\geq 7.4\) hours per day) in this sample provided an acceptable reliability estimate (intraclass correlation coefficient [ICC] >0.70) for light- to vigorous-intensity physical activity.\textsuperscript{18} Light-, moderate-, and vigorous-intensity physical activity was examined together as the intervention promoted participation in physical activity of any intensity.

**Television Viewing Time**

At each time point, parents completed a questionnaire assessing infant time spent watching television on a typical day. A 2-week test-retest assessment of question reliability in a separate (unrelated) sample of 60 mothers of 9-month-old infants and 51 mothers of 18-month-old infants showed good reliability (ICC = 0.86, 95% confidence interval [CI] 0.77 to 0.91 and ICC = 0.84, 95% CI 0.72 to 0.90, respectively).

**BMI**

Children’s height/length and weight without clothes were measured by trained staff at each time point. Height/length was measured to 0.1 cm using a calibrated measuring mat (Seca 210, Seca Deutschland, Germany) or portable stadiometer (Invicta IP0955, Oadby, Leicester). Weight was measured to 10 g using calibrated infant digital scales (Tanita 1582, Tokyo, Japan). The average of 2 measures was used in analyses. BMI (\(kg/m^2\)) and BMI z-scores (\(zBMI\)) were calculated by using World Health Organization gender-specific BMI-for-age growth charts.\textsuperscript{19}

**Process Evaluation**

Process evaluation was undertaken at each session and sought participants’ feedback on the usefulness and relevance of the program (ie, “How useful was the session overall?” and “How relevant was this session to you and your family?”). Respondents were asked to rate on a 4-point scale from “not at all useful/relevant” to “very useful/relevant.”

**Economic Analysis**

Resources used for dietitian training, coordination, and session delivery were recorded prospectively via time-use logs kept by the research team. Resources were valued in 2010 Australian dollars by using existing national estimates for labor time and travel and market prices for venue and materials.

**Sample Size and Power**

Sample size was based on those outcomes for which data on the mean and SD in 18-month-old Australian children were available (sweetened drinks, potato crisps, confectionary, cake, fruit, and vegetables).\textsuperscript{20} The sample required to detect a 25% increase in vegetable...
consumption (considered the minimum meaningful change required) was the largest of those calculated and was therefore the final study sample size. Three days of food data on 18-month-old Australian children indicated that they ate 32 g (SD 15 g) of vegetables (not including potato) per day. For 80% power at the 5% level of significance, the total number of participants required for a trial that randomizes individuals is 112 (56 in each arm) to detect a vegetable increase from 32 to 40 g. To account for within-parent group clustering the sample size was increased by the design effect/inflation factor of 2.8, based on assumptions of each cluster consisting of ~10 people and a conservatively high intracluster (intraparent group) correlation coefficient of 0.2.21 This meant the study required 160 participants (10 participants from each of 16 parent group clusters) in each trial arm (ie, 320 participants). To our knowledge, this is the first study to recruit and deliver an intervention using first-time parent groups, and thus there were no data available to inform estimates of individual or cluster attrition. In light of this, and the likelihood that missing data at any time point would further constrain our usable sample size, we conservatively oversampled with a view to doubling the number of clusters in each study arm (ie, 64 parent group clusters).

Statistical Analysis

All analyses were conducted on an intention-to-treat basis with participants analyzed according to the trial arm to which they were randomized where they provided outcome data (ie, analysis of completers). Physical activity was assessed at postintervention only, and wear-time was adjusted for in analyses. Random effects linear regression models, estimated using maximum likelihood, were fitted to compare continuous outcomes between the trial arms, specifying parent groups as random effects to take account of clustering. Because some of the outcomes were highly skewed, the nonparametric bootstrap method22 was used to validate the CIs, based on 2000 resamples, for all linear regression models. Because the CIs were virtually the same, we report the model-based confidence intervals and P values. For those outcomes in which a large proportion of children (particularly in the mid-intervention data) had scores of zero due to their young age (noncore drinks, sweet snacks, savory snacks, and TV viewing), additional analyses were conducted to assess the effect of the intervention on the odds of consuming/viewing any compared with none. Marginal logistic regression models, estimated using generalized estimating equations with information sandwich ("robust") standard errors, were fitted to compare these binary outcomes between the trial arms, taking account of clustering. An exchangeable correlation structure was specified for these analyses. Because baseline child BMI data were available, models of the zBMI outcomes were adjusted for these analyses. Differences in outcomes between the intervention and control arms at study completion (mean child age 19.8 months (SD 2.7)) are also presented in Table 2. Intervention group children had lower noncore-drink intake than control group children. This difference remained when results were adjusted for prognostic factors. Intervention group children also had lower sweet snack intakes in the adjusted analyses.

Differences in outcomes between the intervention and control arms at study completion (mean child age 19.8 months (SD 2.7)) are also presented in Table 2. Intervention group children had lower noncore-drink intake than control group children. This difference remained when results were adjusted for prognostic factors. Intervention group children also had lower sweet snack intakes in the adjusted analyses.

Table 3 shows the effects of the intervention on the odds that children consumed any noncore food/drinks and watched any television. Intervention group children had reduced odds of consuming noncore drinks mid-intervention, and this association remained when adjusting for covariates. No other intervention effects were found for children’s likelihood of consuming noncore food/drinks or viewing television at either time point.

Of those participants in the intervention arm who completed the trial, 68% attended the majority of intervention sessions (≥4 of 6 sessions), whereas just 9% attended <2 sessions. Mothers...
consistently reported high levels of program usefulness and relevance (Table 4).

The total estimated cost of delivering the program, based on the costs of the intervention adjusted for the fact that a trial setting sees an artificially small number of families included relative to the workforce employed, was approximately AUD $500 per family.

**DISCUSSION**

This study provides evidence that sweet snack consumption and television viewing time in young children can be reduced by a relatively low-dose group-level intervention focused on parent knowledge and skills. At the conclusion of the program, intervention group children were watching ~25% less television and consuming ~25% fewer sweet snacks than controls. Although small changes to diet and sedentary behaviors may confer health benefits from a very early age.
TABLE 2 Distribution of the Outcomes and Assessment of the Effects of the Intervention on These Outcomes at Mid- (T2) and Postintervention (T3)

<table>
<thead>
<tr>
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<th>Control</th>
<th>Intervention</th>
<th>Effects of the Intervention</th>
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<tr>
<td></td>
<td>Mean (SD)</td>
<td>Median (IQR)</td>
<td>Mean (SD)</td>
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<tr>
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<tr>
<td><strong>Distribution of the Outcomes</strong></td>
<td></td>
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<tr>
<td>zBMI</td>
<td>0.2 (1.0)</td>
<td>0.2 (0.0 to 0.8)</td>
<td>0.2 (1.0)</td>
</tr>
<tr>
<td>Fruita intake (g/d)</td>
<td>150.0 (50.0)</td>
<td>86.0 (46.7 to 141.4)</td>
<td>157.2 (72.3)</td>
</tr>
<tr>
<td>Vegetable intake (g/d)</td>
<td>105.5 (37.3)</td>
<td>79.9 (54.5 to 131.2)</td>
<td>107.8 (77.9)</td>
</tr>
<tr>
<td>Water intake (g/d)</td>
<td>112.2 (80.7)</td>
<td>82.5 (43.0 to 168.2)</td>
<td>108.2 (80.7)</td>
</tr>
<tr>
<td>Noncore drink intake (g/d)</td>
<td>6.6 (26.8)</td>
<td>0.0 (0.0 to 0.0)</td>
<td>2.1 (13.2)</td>
</tr>
<tr>
<td>Water intake (g/d)</td>
<td>105.5 (37.3)</td>
<td>79.9 (54.5 to 131.2)</td>
<td>107.8 (77.9)</td>
</tr>
<tr>
<td>Physical activity (min/d)</td>
<td>36.6 (50.7)</td>
<td>19.3 (0.0 to 0.0)</td>
<td>35.5 (68.3)</td>
</tr>
<tr>
<td>Television viewing (min/d)</td>
<td>36.6 (50.7)</td>
<td>19.3 (0.0 to 0.0)</td>
<td>35.5 (68.3)</td>
</tr>
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**Effects of the Intervention Accounting for Correlates**

<table>
<thead>
<tr>
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<th>Mean Difference(^c) (95% CI)</th>
<th>P</th>
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<tbody>
<tr>
<td>zBMI</td>
<td>-0.01 (0.01 to 0.11)</td>
<td>.89</td>
</tr>
<tr>
<td>Fruita intake (g/d)</td>
<td>7.80 (6.26 to 21.86)</td>
<td>.28</td>
</tr>
<tr>
<td>Vegetable intake (g/d)</td>
<td>4.27 (1.03 to 16.47)</td>
<td>.49</td>
</tr>
<tr>
<td>Water intake (g/d)</td>
<td>-3.72 (1.85 to 11.07)</td>
<td>.62</td>
</tr>
<tr>
<td>Noncore drink intake (g/d)</td>
<td>-4.55 (0.79 to 9.83)</td>
<td>.55</td>
</tr>
<tr>
<td>Physical activity (min/d)</td>
<td>-1.08 (10.46 to 8.45)</td>
<td>.82</td>
</tr>
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\(^c\)Random effects linear regression models, estimated using maximum likelihood with bootstrapped standard errors, were fitted to compare continuous outcomes between the trial arms, taking account of clustering. The model that assessed the effect of the intervention on zBMI adjusted for baseline zBMI. The model that assessed the effect of the intervention on physical activity (20 month only) adjusted for accelerometer wear time because this differed significantly between groups. The model that assessed the effect of the intervention on physical activity (20 month only) adjusted for accelerometer wear time because this differed significantly between groups. The model that assessed the effect of the intervention on zBMI adjusted for baseline zBMI. The model that assessed the effect of the intervention on physical activity (20 month only) adjusted for accelerometer wear time because this differed significantly between groups.
first-time mothers of infants before weaning and adds important support to a growing body of evidence endorsing a focus on early childhood. This focus for obesity prevention has gained considerable currency since this study commenced, with 1 published protocol, 28 2 pilot studies, 29, 30 and 1 additional RCT published. 31 Data from the pilots and RCTs, targeting mothers and infants <6 months of age, provide additional support for a focus on early childhood with 1 nonrandomized trial (n = 80) reporting a trend to reductions in television viewing 32 and another (n = 110) reporting a lower weight-for-length percentile in intervention children (P = .009). 29 Wen's RCT intensive home visiting intervention 31 targeting families living in socially and economically disadvantaged areas of Sydney, Australia (n = 667), reports lower BMI and improvements in some obesity-promoting behaviors at age 2 years in the intervention compared with the control group. The previously mentioned RCT in a Cochrane review 4 (n = 43) reported evidence of lower child energy intake in the intervention group (P = .06) but no differences in BMI. 5

Generalizability and Implications

The high levels of participation observed in this trial, in terms of recruitment, retention, and program attendance, likely reflect parents' receptivity and desire to learn at this time in child's development. This is also reflected in positive ratings of program usefulness and relevance.

The public health utility of this intervention is important to acknowledge. This was a low-dose, low-cost intervention that could feasibly be translated to real-world settings. The economic cost of the delivery of programs needs to be considered in terms of the overall impact of interventions. In this intervention, we have also demonstrated improvements in intervention group mothers' dietary patterns 32 and improvements in parental knowledge and attitudes regarding television viewing, active play, and diet. 33 The utility of the program is based on the impact on the family as a whole and over time. The "ripple" effects of this intervention on other family members and over time will be the subject of future studies.
**Strengths and Limitations**

Study strengths are the RCT design and use of gold standard measures for diet and physical activity, but it is important to acknowledge that intervention-arm parents may have been more likely to provide socially desirable responses when recalling diet (and television viewing), although one might expect such error to occur for all self-reported outcomes. Women from all socioeconomic strata were recruited; however, high SEP women (as assessed by education) were overrepresented. Low SEP women (as assessed by education) were no more likely to drop out of the study yet were more likely to have missing data at midintervention, but not postintervention. This may have implications for generalizability of midintervention findings.

The analysis of data across early childhood is challenging because measures of our primary outcomes are not meaningful at baseline; for example, at 3 months of age, our cohort consumes only breast or formula milk and is not yet physically active. This may be considered as a limitation in our analyses. It reflects, however, the fact that our cohort is almost identical on measures of diet and activity at baseline (having a baseline of zero).

**CONCLUSIONS**


Dr Campbell (lead chief investigator) conceptualized, designed, and managed all aspects of the study and analyses; wrote the initial manuscript; and revised the final manuscript. Dr Loret undertook and managed the majority of data analyses. Dr McNaughton (associate investigator) designed and managed all dietary data collection and analyses. Dr Crawford (chief investigator) was involved in the conceptualization, design, and management of all aspects of the study and analyses. Dr Salmon (chief investigator) was involved in the conceptualization, design, and management of all aspects of the study and analyses. Dr Ball (chief investigator) was involved in the conceptualization, design, and management of all aspects of the study and analyses. Dr Abbott undertook the bootstrapping analyses for this manuscript and provided substantive input into the conceptualization, design, and management of all aspects of the study and analyses. Dr Cameron provided expert input to data analyses. Ms Hnatiuk (PhD Student) undertook all management of physical activity intervention delivery, and data collection and management. Dr Spence (PhD student) participated in day-to-day management of recruitment, intervention delivery, data collection and management. Dr Hesketh (lead chief investigator 2) conceptualized, designed, and managed all aspects of the study and analyses. All authors critically reviewed the manuscript and approved the final manuscript as submitted.

This trial has been registered with the ISRCTN Register (http://isrctn.org) (identifier ISRCTN81847050).

Ethical approval for this study was obtained from the Deakin University Human Research Ethics Committee (ID number: EC 175-2007) and by the Victorian Office for Children (Ref: CDF/07/1138).

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