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RESEARCH

Effectiveness of home based early intervention on children's BMI at age 2: randomised controlled trial

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Abstract

Objective To assess the effectiveness of a home based early intervention on children's body mass index (BMI) at age 2.

Design Randomised controlled trial.

Setting The Healthy Beginnings Trial was conducted in socially and economically disadvantaged areas of Sydney, Australia, during 2007-10.

Participants 667 first time mothers and their infants.

Intervention Eight home visits from specially trained community nurses delivering a staged home based intervention, one in the antenatal period, and seven at 1, 3, 5, 9, 12, 18 and 24 months after birth. Timing of the visits was designed to coincide with early childhood developmental milestones.

Main outcome measures The primary outcome was children's BMI (the healthy BMI ranges for children aged 2 are 14.12-18.41 for boys and 13.90-18.02 for girls). Secondary outcomes included infant feeding practices and TV viewing time when children were aged 2, according to a modified research protocol. The data collectors and data entry staff were blinded to treatment allocation, but the participating mothers were not blinded.

Results 497 mothers and their children (75%) completed the trial. An intention to treat analysis in all 667 participants recruited, and multiple imputation of BMI for the 170 lost to follow-up and the 14 missing, showed that mean BMI was significantly lower in the intervention group (16.53) than in the control group (16.82), with a difference of 0.29 (95% confidence interval −0.55 to −0.02; P=0.04).

Conclusions The home based early intervention delivered by trained community nurses was effective in reducing mean BMI for children at age 2.

Trial registration Australian Clinical Trial Registry No 12607000168459.

Introduction

Childhood obesity is a serious public health challenge.[1] In 2010, 43 million preschool age children were overweight or obese, with a prevalence of 6.7% worldwide.[2] In Australia, about one in five children aged 2-3 are overweight or obese.[3] There is accumulating evidence that excess weight and fast weight gain in early childhood are related to overweight later in life.[4-10] The adverse health consequences of childhood obesity are well documented.[11,12] It has been argued that efforts to prevent childhood obesity should begin in the early years and even before birth.[13]

Infant feeding practices, including breast feeding[14,15] and the timing of the introduction of solids,[16,17] as well as children's eating habits[18] and time spent watching television (TV),[19,20] are among the most identifiable factors contributing to early onset of childhood obesity.[13] Infant feeding practices not only influence children's eating behaviours but also lay the foundation for adult eating habits.[21] There is also evidence that the early risk factors for obesity are more prevalent in lower socioeconomic groups.[22] Few high quality interventions aimed at preventing early onset overweight or obesity among young children have been implemented effectively or rigorously evaluated.[23] A 2010 updated systematic review of interventions to prevent obesity in 0-5 year olds concluded that behaviours that contribute to obesity can be influenced positively in a range of settings.[24] The review noted, however, that most research has lacked good design, long term follow-up, or weight measurement.

In 2007, we started the Healthy Beginnings Trial to deal with this evidence gap.[25] This is a randomised controlled trial

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Appendix: Detailed information on the Healthy Beginnings intervention and control conditions designed to test the effectiveness of an early childhood obesity intervention in the first two years. It is a staged home based early intervention designed to improve infant feeding practices, eating habits, and active play and to reduce TV viewing time, as well as improve family behavioural risk factors for childhood obesity. The trial was undertaken in some of the most socially and economically disadvantaged areas of Sydney, where there is a great need for social support. We have previously reported significant improvements at 12 months in duration of breast feeding, appropriate timing of introduction of solids, and practice of "tummy time" (a colloquial term used to encourage parents to ensure that their babies spend time in the prone position when they are not sleeping) among those receiving the intervention.[26] We examined whether this home based early intervention could be also effective in reducing body mass index (BMI) for children at age 2.

Methods

Study design

This parallel randomised controlled trial was conducted in south west Sydney, Australia, from June 2007 to December 2010. A detailed research protocol has been published elsewhere.[25]

Participants and recruitment

Research assistants gave pregnant women attending antenatal clinics a letter of invitation and information about the study. Women were eligible for the trial if they were aged 16 and over, expecting their first child, between weeks 24 and 34 of pregnancy, able to communicate in English, and lived in the local area. The recruitment took almost 12 months to complete. Of 2700 mothers who were approached by research assistants, 780 were eligible. We could not establish the eligibility of the others as they declined to participate when approached and we were not able to obtain further information.

Once eligibility was established and consent obtained, women were asked to complete a registration form to allow the nurses to make arrangements for baseline data collection. One of four research nurses conducted the baseline assessments at the woman's home before randomisation. Because of resource (research staff) constraints we were not able to complete the baseline assessment and randomisation for all participating mothers as planned before they gave birth. Four hundred and nine women were interviewed before birth and 258 after birth.

Sample size

The sample size calculation was based on the primary outcome, BMI, which was assumed to have a SD of 1.5. To have 80% power to detect a difference in mean BMI of 0.25 units between the groups at age 2 at the two sided 5% significance level, we needed a sample size of 252 per group. To allow for an estimated 20% drop out we aimed to recruit 630 first time mothers.

Randomisation

Random allocation was concealed by sequentially numbered, sealed opaque envelopes containing the group allocation, which was determined by a computer generated random number with a block size of 50 with a 1:1 allocation ratio. Immediately after baseline data collection, the nurse opened the sealed envelope and informed the mother of her group.

Blinding

Two research assistants not involved in the implementation of the intervention collected outcome data in the woman's home. The data collectors and data entry staff were blinded to treatment allocation, but the participating mothers were not blinded.

Intervention group

This staged and home based intervention was based on home visiting programmes that have been established as effective interventions for improving the health and wellbeing of parents and children from vulnerable and disadvantages families.[27-29] It was developed through a pilot study[30] and guided by health promotion principles. A description of the programme and all intervention resources developed for this study is available online (www.healthybeginnings.net.au/). The intervention resources promoting breast feeding, appropriate timing of introduction of solids, "tummy time," and active play, as well as family nutrition and physical activity, were based on various Australian National Guidelines.[31 32] The key intervention messages included (also see appendix):

- Breast is best
- No solids for me until 6 months
- I eat a variety of fruit and vegetables every day
- Only water in my cup
- I am part of an active family.

Four community nurses were recruited and trained to ensure consistency of delivering the intervention. The nurse visited participating families in the intervention group eight times at home, once at 30-36 weeks' gestation and seven times after the birth (at 1, 3, 5, 9, 12, 18 and 24 months). The timing of the visits corresponds to milestones in early childhood development. At each visit, the nurse spent about one to two hours with the mother and infant. The nurse not only taught the mother specific skills and knowledge in relation to healthy infant feeding practices and active play (the key messages of the programme) but also discussed any issues and concerns raised by the mother. A visit checklist with standard minimum information plus additional discussion points for each key area plus appropriate resources to support each key message was developed. Four key areas included infant feeding practices, child nutrition and active play, family physical activity and nutrition, and social support. After each visit, the nurses documented all aspects of their visits with the participating families and provided regular reports to the investigators on questions and issues arising.

Control group

Families in both the control and intervention group received the usual childhood nursing service from community health service nurses. All new mothers in the state of New South Wales receive at least one nurse visit for general support at home. Some vulnerable families are offered multiple home visits. To maximise the retention rate in this study, we posted home safety promotion materials to women in the control group at six and 12 months.

Primary and secondary outcomes

The primary outcome at 24 months was the child's anthropometric measures for BMI. Secondary outcomes were eating habits (intake of fruit and vegetables, consumption of chips and snacks, and having a meal in front of the TV), time spent watching TV, and active play time, as well as the mothers' dietary behaviours, time spent watching TV, and physical activity. Measurements were undertaken during a home interview with the mother. The primary outcomes at six months, including exclusive breast feeding and timing of introduction of solids and "tummy time," were collected by a telephone interview, and those at 12 months, including breastfeeding, cup use, bottle at bedtime, and having food as a reward, were collected by research assistants in the home. These have been reported elsewhere.[26]

BMI—We calculated children's BMI (weight (kg)/length $(m)^2$) at age 2. BMI is one of the best measures of change in adiposity in growing children.[33] We also categorised BMI as overweight, obese, or not overweight or obese based on internationally accepted criteria.[34] The healthy BMI ranges for children aged 2 are 14.12-18.41 for boys and 13.90-18.02 for girls.[33 34]

Length—A research assistant took two measurements of length with the child in a supine position on a level floor (with a SECA 210 Infant Measuring Mat, Hamburg, Germany) and recorded it to the nearest 0.1 cm; a third measure was taken if the first two measurements differed by 0.5 cm or more, and the mean of these two or three values was calculated.

Weight—The research assistant used digital scales (Tanita model 1583 Baby Scale, Tokyo, Japan) to weigh children in light clothes and no shoes. The measures were recorded to the nearest 0.1 kg.

Eating habits—Mothers reported their child's eating habits using a short food frequency questionnaire that was specifically designed to assess children's eating habits, the validity and reliability of which were tested before this study.[35] The questionnaire asked about servings of fruit and vegetables; frequency of eating snack foods (biscuits, cakes, donuts, muesli bars), potato crisps and drinking cups of soft drinks/cordials, juice, and water; and frequency of eating in front of the TV and having food as reward.

TV viewing time and outdoor play time—Mothers reported the total time their child spent watching TV or outdoor play time each day in a usual week using a set of validated questions.[36]

Mothers' nutrition and physical activity—Mothers' own dietary behaviours and physical activity were assessed with questions sourced from the New South Wales Health Survey Program[37] in New South Wales, Australia. These questions have been validated in an adult population and are widely used in population health surveys in New South Wales. We have reported mothers' dietary behaviours during pregnancy in details elsewhere.[38]

Other outcomes, including consumption of "junk food" by mothers and children, were assessed with questions from the validated questionnaire and the New South Wales Adult Health Surveys.[35 37]

Sociodemographic characteristics

At baseline we collected sociodemographic data including age, employment status, education level, marital status, language spoken at home, and country of birth of mothers, using the standard New South Wales Health Survey questions.[31]

Analysis

For most analyses, BMI was used as a continuous variable. We also categorised children at age 2 as overweight/obese or not, based on the age standardised cut points for BMI recommended by the International Obesity Taskforce.[33] We examined the outcome variables including eating habits/dietary behaviours, physical activity/outdoor play, and TV viewing time for their distribution, then recategorised them dichotomously according to the median intake of vegetables or fruit or the national guidelines for physical activity, as appropriate. For example, the National Physical Activity Guidelines recommend that screen time for children aged 2-5 is 60 minutes a day maximum and that adults spend at least 150 minutes in moderate intensity physical activity each week.[32] Median intake a day was two servings of vegetables or fruit, as reported by participating mothers at the baseline.[38]

We performed a complete case analysis and intention to treat analyses for each outcome. For the complete case analysis, we compared outcomes at 24 months between intervention and control groups using the two sample *t* test for the continuous outcome (BMI) and Pearson's χ^2 test for categorical data. We also calculated risk differences with 95% confidence intervals. All P values are two sided and significance was set at 5%.

For intention to treat analyses, we used multiple imputation by chained equations to impute missing values. We imputed the BMI values that were missing for 14 infants who remained in the study at 24 months. We also imputed all missing values of BMI and the other outcomes at 24 months for a full intention to treat analysis of all 667 randomised participants. In both cases the imputation model predicting BMI was based on all plausible observed values of BMI and covariates at baseline and at 6, 12 and 24 months' follow-up. The imputation models for the binary outcomes were logistic regression models containing exclusive breast feeding, introduction of solid food regularly, and daily practice of "tummy time" at 6 months, and being given food for reward and drinking from a cup at 12 and 24 months. We used 20 imputations each time, which gave a relative efficiency of 99%. We then calculated pooled estimates of the difference in mean BMI and of the odds ratio of having each of the binary outcomes for those in the intervention group compared with the control group. All analyses were performed with Stata version 10 (StataCorp, College Station, TX).

Results

Recruitment and follow-up

Of 2700 mothers who were approached, 780 mothers were eligible, but 113 declined with no reasons being given. Of the 667 first time mothers recruited, 337 were randomised to the intervention and 330 to the control group (figure⇓). A total of 106 mothers were lost to follow-up at six months, a further 34 at 12 months, and another 30 at 24 months. Of the 170 lost to follow-up, 82 were from the intervention group and 88 from the control. The main reasons for loss to follow-up were: could not be contacted (70%), moved out of the area (10%), no longer interested (9%), too busy (4%), and illness or death (5%). This was similar across both groups.

Baseline characteristics

The women's ages ranged from 16 to 47 with a mean of 26 (SD 5.5). Most (582, 88%) were either married or living with a partner. In total, 163 (24%) had completed tertiary education, 71 (11%) spoke a language other than English at home, 138 (21%) were unemployed, and 208 (31%) had a household income before tax of less than $A40 000 a year (£25 300, €31 300, $39 000). Table 1⇓ shows the baseline characteristics of participating mothers, which were similar for the two groups.

We could not complete the baseline assessment and randomisation before birth, as planned, for 258 women (129 intervention, 129 control). There was no significant difference between these 258 and the 409 (208 intervention, 201 control) who were assessed and randomised before birth for any of the characteristics shown in table 1.

Primary outcome

At 24 months, an intention to treat analysis using all 667 participants recruited, and imputation of BMI for the 170 lost to follow-up and the 14 missing values, showed that mean BMI was significantly lower in the intervention group (16.53) than the control group (16.82), with a difference of 0.29 (95% confidence interval 0.02 to 0.55, P=0.04) (table 2⇓). For the complete cases analysis, the overall mean BMI was 16.67 (SD 1.70). The mean BMI was also significantly lower in the intervention group (16.49, SD 1.76) than in the control group (16.87, SD 1.62; P=0.01), with a difference of 0.38 (0.08 to 0.68) (table 2⇓). Adjustment for the child's exact age with linear regression gave a similar result: a difference of 0.40 (0.09 to 0.70; P=0.01). The result was unchanged when we used multiple imputation to impute 14 missing values for the 497 who remained at 24 months. Table 2 also shows that there were no significant differences between the groups in children's mean length or weight. In addition, 11.2% (28/249) of the intervention group and 14.1% (33/234) of the control were categorised as overweight or obese, a difference of 2.9% (−3.0% to 8.3%).

Secondary outcomes

As shown in table 3⇓, children in the intervention group (89%) were significantly more likely to eat one or more servings of vegetables a day than those in the control group (83%, P=0.03) and significantly less likely to be given food for reward (62% *v* 72%, P=0.03). The percentage of children eating dinner in front of the TV, or having the TV on during the meal, was significantly lower in the intervention group than in the control group (56% *v* 68%, P=0.01; and 66% *v* 76%, P=0.02; respectively). The intervention group also had a significantly lower percentage of children watching TV for more than 60 minutes a day than the control group (14% *v* 22%, P=0.02). There were no significant differences between the groups with regard to consumption of fruit, consumption of "junk food," or time spent in outdoor play.

Table 3 shows that mothers in the intervention group were significantly more likely to eat more than two servings of vegetables a day than those in the control group (52% *v* 36%, P<0.001) and to spend 150 minutes or more a week on physical activity than those in the control group (48% *v* 38%, P=0.04). There were no significant differences between the groups for other dietary behaviours assessed except for frequency of eating processed meat. The results from the intention to treat analysis with multiple imputation were consistent with those from the complete case analysis, as shown in table 4⇓.

Discussion

Principal findings of the study

A home based intervention to prevent early childhood obesity in the first two years of life was effective, with a mean reduction in BMI of 0.29 for children at age 2. The intervention also showed some positive effects on children's vegetable consumption, not being given food as reward, and TV viewing time, as well as mothers' vegetable consumption and physical activity.

Interpretation

To date, there is accumulating evidence linking excess weight gain and fast weight gain in early childhood to overweight later in life[4-10] and a general consensus that obesity is intrinsically an intergenerational process, with early childhood being an important stage. Therefore, early prevention of obesity is important.[24] Given that BMI is one of the best measures of change in adiposity in growing children,[33] the reduced mean BMI of 0.38 could be important in terms of population health as it should translate to a reduction in the prevalence of overweight and obesity of children at age 2 (2.9% in this study). Such a reduction in prevalence could potentially lead to reduced overweight and obesity later in life. Whether this early intervention has a longer term effect on child and family eating patterns, television viewing, physical activity, and BMI, however, remains to be tested. Nevertheless, the effect size in this study is large in the context of other obesity intervention studies in older children.[24] Currently, a long term follow-up and cost effectiveness analysis of the Healthy Beginnings Trial is underway.[39]

What the study adds

The importance of early intervention programmes is based on the premise that the first few years of a child's development are crucial in setting the foundation for lifelong learning, behaviour, and health outcomes.[40] The intervention effect on children's BMI suggests that, in preventing early onset of childhood obesity, a range of potential risk behaviours needs to be tackled. In contrast with previous studies,[24] the unique aspect of this study was that the intervention dealt with several risk factors for early obesity including infant feeding practices, children's eating habits, and sedentary behaviours in a systematic and timely fashion.

The concept of using home visiting programmes as a means of preventing health and developmental problems in children is not new.[27-29] To our knowledge, however, they have not been applied previously to deal with risk factors for childhood obesity. Important aspects of the current intervention design were the use of community nurses and consistency of health information on infant feeding practices, nutrition, and physical activity with current recommendations that correspond to milestones in early childhood development and that were tailored to the needs of individual families.

Unanswered questions and future research

Costs could be an argument against home based interventions, and a recent review highlighted the importance of the cost effectiveness analysis.[24] The effect of the intervention on traditional service delivery models and its cost effectiveness on a large scale are unknown and require further investigation. It is possible that the intervention nurse home visits have in turn saved the cost of the clinic visits; this is the focus of ongoing analyses in this trial cohort. Cost effectiveness analysis and longer term follow-up studies are needed.[39]

Strengths and limitations

The intervention was built on evidence supporting the use of sustained home visiting programmes in improving child health. The overall research plan was transparent, with a published research protocol.[25] The randomised controlled trial design means that many of the confounders are taken into account. The study was adequately powered to detect a mean difference in BMI of 0.25 between the groups. The main outcome measures were assessed with validated, well developed, and widely used population survey tools. We applied blinding to treatment allocation for data collection, data entry, and analysis, and applied intention to treat analyses with multiple imputations in data analyses.

The study has several limitations. Firstly, the generalisability might be limited because of the locality of the study area. Secondly, we could not examine all of the social, cultural, economic, and environmental factors that are likely to influence childhood obesity and could not measure some secondary outcomes as planned, including parent-child interaction and family support. Furthermore, the study was limited because participating mothers could not be blinded, measures of behaviour were self reported, and a quarter (170/667) of the sample was lost to follow-up. The loss to follow-up could lead to incomplete study results and might have biased the results, although the main reasons for loss to follow-up (such as women could not be contacted, had moved out of the area, or were no longer interested or too busy, and illness or death) were similar across both groups. In addition, the loss to follow-up could potentially violate the assumption of multiple imputation by chained equations (data are missing at random), but taking interim BMI measurements into account in the multiple imputation analysis should help to reduce the bias.

In conclusion, the early onset of childhood overweight and obesity would require health promotion intervention programmes to start as early as possible and to be family focused. A home based, staged intervention of multiple home visits to deal with the risk factors for childhood obesity was effective in improving children weight status and risk factors.

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Contributors: LMW, LAB, and CR conceived the Healthy Beginnings Trial and contributed to the development of the trial and the procurement of the funding. In this study, LMW undertook the literature review, data analysis and interpretation, and wrote the original draft. JMS provided advice on data analysis. LAB, JMS, and CR commented on the draft. KW coordinated the implementation of the intervention and commented on the draft. VF provided advice on dietary measures and commented on the draft. All authors have read and approved the final manuscript. LMW is guarantor.

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Ethical approval: This study was approved by the ethics review committee of Sydney South West Area Health Service (RPAH Zone, Protocol No X10-0312 and HREC/10/RPAH/546).

Data sharing: No additional data available.

1 World Health Organiaation. Childhood overweight and obesity, 2011. www.who.int/dietphysicalactivity/childhood/en/.
2 de Onis M, Blossner M, Borghi E. Global prevalence and trends of overweight and obesity among preschool children. *Am J Clin Nutr* 2010;92:1257-64.
3 2007 Australian National Children's Nutrition and Physical Activity Survey, 2008. www.health.gov.au/internet/main/publishing.nsf/Content/66596E8FC68FD1A3CA2574D50027DB86/$File/childrens-nut-phys-survey.pdf.
4 Stocks T, Renders CM, Bulk-Bunschoten AMW, Hirasing RA, Buuren S, Seidell JC. Body size and growth in 0- to -4-year-old children and the relation to body size in primary school age. *Obes Rev* 2011;12:637-52.
5 Laitinen J, Power C, Jarvelin M. Family social class, maternal body mass index, childhood body mass index, and age at menarche as predictors of adult obesity. *Am J Clin Nutr* 2001;74:287-94.
6 Tsukada H, Miura K, Kido T, Saeki K, Kawashima H, Ikawa A, et al. Relationship of childhood obesity to adult obesity: a 20-year longitudinal study from birth in Ishikawa Prefecture, Japan. *Jpn J Publ Health* 2003;50:1125-34.
7 Ong KK, Emmett PM, Noble S, Ness A, Dunger DB, ALSPAC Study Team. Dietary energy intake at the age of 4 months predicts postnatal weight gain and childhood body mass index. *Pediatrics* 2006;117:e503-8.
8 Gardner DSL, Hosking J, Metcalf BS, Jeffery AN, Voss LD, Wilkin TJ. Contribution of early weight gain to childhood overweight and metabolic health: a longitudinal study (EarlyBird 36). *Pediatrics* 2009;123:e67-73.
9 Stettler N, Iotova V. Early growth patterns and long-term obesity risk. *Curr Opin Clin Nutr Metab Care* 2010;13:294-9.
10 Ciampa PJ, Kumar D, Barkin SL, Sanders LM, Yin HS, Perrin EM, et al. Interventions aimed at decreasing obesity in children younger than 2 years: a systematic review. *Arch Pediatr Adolesc Med* 2010;164:1098-104.
11 Leunissen RWJ, Kerkhof GF, Stijnen T, Hokken-Koelega A. Timing and tempo of first-year rapid growth in relation to cardiovascular and metabolic risk profile in early adulthood. *JAMA* 2009;301:2234-42.
12 Monteiro P, Victora C. Rapid growth in infancy and childhood and obesity in later life—a systematic review. *Obes Rev* 2005;6:143-54.
13 Taveras EM, Gillman MW, Kleinman K, Rich-Edwards JW, Rifas-Shiman SL. Racial/ethnic differences in early-life risk factors for childhood obesity. *Pediatrics* 2010;125:686-95.
14 Arenz S, Rükerl R, Koletzko B, von Kries R. Breast-feeding and childhood obesity—a systematic review. *Int J Obes Relat Metab Disord* 2004;28:1247-56.
15 Armstrong J, Reilly JJ. Breastfeeding and lowering the risk of childhood obesity. *Lancet* 2002;359:2003-4.
16 Griffiths LJ, Smeeth L, Hawkins SS, Cole TJ, Dezateux C. Effects of infant feeding practice on weight gain from birth to 3 years. *Arch Dis Child* 2009;94:577-82.
17 Kramer MS. Breastfeeding, complementary (solid) foods, and long-term risk of obesity. *Am J Clin Nutr* 2010;91:500-1.
18 Griffiths LJ, Smeeth L, Hawkins SS, Cole TJ, Dezateux C. Effects of infant feeding practice on weight gain from birth to 3 years. *Arch Dis Child* 2009;94:577-82.
19 Dennison B, Erb T, Jenkins P. Television viewing and television in bedroom associated with overweight risk among low-income preschool children. *Pediatrics* 2002;109:1028-35.
20 Salmon J, Campbell K, Crawford D. Television viewing habits associated with obesity risk factors: a survey of Melbourne schoolchildren. *Med J Aust* 2006;184:64-7.
21 Birch LL. Development of food preferences. *Annu Rev Nutr* 1999;19:41-62.
22 Wake M, Hardy P, Canterford L, Sawyer M, Carlin JB. Overweight, obesity and girth of Australian pre-schoolers: prevalence and socio-economic correlates. *Int J Obesity* 2007;31:1044-51.
23 Summerbell CD, Waters E, Edmunds LD, Kelly S, Brown T, Campbell KJ. Interventions for preventing obesity in children. *Cochrane Database Syst Rev* 2005;3:CD001871.
24 Hesketh KD, Campbell KJ. Interventions to prevent obesity in 0-5 year olds: an updated systematic review of the literature. *Obesity* 2010;18:S27-35.
25 Wen LM, Baur LA, Rissel C, Wardle K, Alperstein G, Simpson JM. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). *BMC Public Health* 2007;7:76.
26 Wen LM, Baur LA, Simpson JM, Rissel C, Flood VM. Effectiveness of an early intervention on infant feeding practices and "tummy time": randomized controlled trial. *Arch Pediatr Adolesc Med* 2011;165:701-7.
27 Olds DL, Eckenrode J, Henderson C R, Kitzman J, Powers J, Cole R, et al. Long-term effects of home visitation on maternal life course and child abuse and neglect. *JAMA* 1997;278:637-43.
28 Olds D, Kitzman H, Hanks C, Cole R, Anson E, Sidora-Arcoleo K, et al. Effects of nurse home visiting on maternal and child functioning: age-9 follow up of a randomised trial. *Pediatrics* 2007;120:e832-45.
29 Armstrong KL, Fraser JA, Dadds MR, Morris J. Promoting secure attachment, maternal mood and health in a vulnerable population: a randomised controlled trial. *J Paediar Child Health* 2000;36:555-62.
30 Wen LM, De Domenico M, Elliott D, Bindon J, Rissel C. Evaluation of a feasibility study addressing risk factors for childhood obesity through home visits. *J Paediar Child Health* 2009;45:577-81.
31 National Health and Medical Research Council. Dietary guidelines for children and adolescents in Australia: incorporating the infant feeding guidelines for health workers. Commonwealth of Australia, 2003. www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/n34.pdf.
32 Australian Department of Health and Aged Care. National physical activity guidelines for adults and children. Australian Government. www.health.gov.au/internet/main/publishing.nsf/content/health-pubhlth-strateg-phys-act-guidelines#guidelines_adults.
33 Cole TJ, Faith MS, Pietrobelli A, Heo M. What is the best measure of adiposity change in growing children: BMI, BMI%, BMI z-score or BMI centile? *Eur J Clin Nutr* 2005;59:807.
34 Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition of child overweight and obesity worldwide: international survey. *BMJ* 2000;320:1240-3.
35 Flood V, Wen LM, Hardy L, Thrift A, Simpson J, Rissel C, et al. Reliability and validity of a short food frequency questionnaire to assess diet among 2-5 year olds. *Obes Res Clin Pract* 2010;4(suppl 1):S61.
36 Wen LM, Van der Ploeg HP, Kite J, Cashmore A, Rissel C. A validation study of assessing physical activity and sedentary behavior in children aged 3 to 5 years. *Pediatr Exerc Sci* 2010;22:408-20.
37 Centre for Epidemiology and Research. 2006 report on Adult Health from the New South Wales Population Health Survey. NSW Department of Health, 2007.
38 Wen LM, Flood V, Simpson J, Rissel C, Baur L. Dietary behaviours during pregnancy: findings from first-time mothers in southwest Sydney, Australia. *Int J Behav Nutr Phys Act* 2010;7:13.

What is already known on this topic

Many children are already overweight or obese at age 2, which could have adverse effects on later health

Early infant feeding practices and sedentary behaviours are important contributing factors associated with early onset of childhood obesity

There is little high quality research on interventions on infant feeding practices and sedentary behaviours for obesity prevention in the first two years of life

What this study adds

This randomised controlled trial to test the effectiveness of a childhood obesity prevention programme, a home based early intervention delivered by trained community nurses was associated with a reduction in mean BMI for children aged 2

39 Wen LM, Baur LA, Rissel C, Flood V, Simpson JM, Hayes A, et al. Healthy Beginnings Trial phase 2 study: follow-up and cost-effectiveness analysis. *Contemp Clin Trials* 2012;33:396-401.

40 Gauntlett E, Hugman R, Kenyon P, Logan P. A Meta-analysis of the impact of community-based prevention and early intervention, 2001. www.fahcsia.gov.au/about/publicationsarticles/research/socialpolicy/Documents/prp11/PRP_No_11.pdf.

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Tables

Table 1| **Baseline characteristics of 667 women in study of effect of home based early intervention on BMI in children. Figures are numbers (percentage) of women (number might not sum to total because of missing data)**

Variables	Intervention (n=337)	Control (n=330)
Age (years):		
≤24	144 (43)	135 (41)
25-29	112 (33)	114 (34)
≥30	81 (24)	81 (25)
Marital status:		
Married/living with partner	286 (86)	296 (90)
Never married	48 (14)	33 (10)
Employment status:		
Employed/paid or unpaid maternity leave	177 (53)	186 (56)
Unemployed	76 (22)	62 (19)
Home duties/student/other	83 (25)	82 (25)
Income ($A):		
<39<thin>999	106 (32)	102 (31)
40<thin>000-79<thin>999	113 (33)	102 (31)
≥80<thin>000	118 (35)	126 (38)
Education:		
Up to school certificate (year 10, age 15-16)	66 (19)	71 (22)
HSC to TAFE certificate or diploma*	180 (54)	184 (56)
University	90 (27)	73 (22)
Country of birth:		
Australia	213 (63)	216 (66)
Other	123 (37)	113 (34)
Language spoken at home:		
English	303 (90)	289 (88)
Other	33 (10)	39 (12)
When recruited:		
Before birth	208 (62)	201 (61)
After birth	129 (38)	129 (39)

*HSC=Higher School Certificate (year 12), TAFE=Technical and Further Education.

Table 2| **Differences in mean BMI, mean weight (kg), and mean length (cm) at 24 months in study of effect of home based early intervention on BMI in children**

	Mean (95% CI)			
	Intervention	**Control**	**Intervention–control (95% CI)**	**P value**
Complete cases analysis (n=249 in intervention, 234 in control)*				
BMI	16.49 (16.27 to 16.71)	16.87 (16.66 to 17.08)	−0.38 (−0.68 to −0.08)	0.01†
Weight	12.98 (12.77 to 13.19)	13.15 (12.96 to 13.35)	−0.17 (−0.46 to 0.11)	0.24†
Length	88.73 (88.28 to 89.17)	88.42 (87.96 to 88.88)	0.31 (−0.34 to 0.95)	0.35†
Age (months)	24.16 (24.09 to 24.23)	24.25 (24.16 to 24.34)	− 0.09 (−0.02 to 0.20)	0.12†
Multiple imputation analysis (n=255 in intervention, 242 in control)‡				
BMI	16.49 (16.27 to 16.71)	16.87 (16.66 to 17.07)	−0.38 (−0.68 to −0.08)	0.01§
Weight	12.99 (12.79 to 13.20)	13.15 (12.96 to 13.35)	−0.16 (−0.44 to 0.12)	0.27§
Length	88.75 (88.31 to 89.19)	88.41 (87.94 to 88.88)	0.34 (−0.30 to 0.98)	0.30§
Multiple imputation analysis (n=337 in intervention, 330 in control)¶				
BMI	16.53 (16.33 to 16.72)	16.82 (16.64 to16.99)	−0.29 (−0.55 to −0.02)	0.04§
Weight	13.02 (12.82 to 13.21)	13.15 (12.95 to 13.35)	−0.13 (−0.43 to 0.16)	0.37§
Length	88.71 (88.15 to 89.28)	88.51 (87.93 to 89.10)	0.20 (−0.66 to 1.06)	0.64§

*14 missing BMI values among 497 remaining at 24 months.

†*t* test.

‡In 497 remaining at 24 months, with 14 missing values imputed.

§F test.

¶In all 667 randomised, with 184 missing values imputed.

Table 3| **Differences in dietary behaviours, TV viewing, and physical activity at 24 months in study of effect of home based early intervention on BMI in children and mothers**

Secondary outcomes (yes v no)	Intervention	Control	Intervention–control (95% CI)	P value*
Children				
Dietary behaviours:				
Vegetable ≥1 serving/day†	228/255 (89)	200/242 (83)	7 (1 to 13)	0.03
Fruit ≥1 serving/day†	230/255 (90)	224/242 (93)	−2 (−7 to 3)	0.43
Food for reward	158/253 (62)	172/240 (72)	−9 (−17 to −1)	0.03
Water >3 cups/day	62/254 (24)	45/242 (19)	6 (−1 to 13)	0.12
Hot chips/French fries	219/254 (86)	212/242 (88)	−1 (−7 to 5)	0.65
Salty snack	166/254 (65)	169/242 (70)	−5 (−13 to 4)	0.29
Sweet snack every day	186/255 (73)	186/242 (77)	−4 (−12 to 4)	0.31
Soft drink	60/253 (24)	64/242 (26)	−3 (−10 to 5)	0.48
Physical activity and TV watching‡:				
Outdoor play ≥120 minutes/day	154/249 (62)	144/235 (61)	1 (−8 to 9)	0.90
TV on during meal	167/254 (66)	183/242 (76)	−10 (−18 to −2)	0.02
Eat dinner in front of TV	141/254 (56)	162/240 (68)	−12 (−21 to −3)	0.01
Viewing TV >60 minutes/day	30/222 (14)	46/212 (22)	−8 (−15 to −1)	0.02
Mothers				
Dietary behaviours:				
Vegetable >2 servings/day†§	133/255 (52)	86/241 (36)	16 (8 to 25)	<0.001
Fruit >2 servings/day†§	57/255 (22)	44/242 (18)	4 (−3 to 11)	0.25
Water ≥8 cups/day	42/255 (16)	40/242 (17)	−0.1 (−7 to 6)	0.99
Soft drink ≥7 cups/week	113/255 (44)	126/242 (52)	−8 (−17 to 1)	0.08
Hot chips/French fries	206/255 (81)	209/242 (86)	−6 (−12 to 1)	0.09
Fast food	211/255 (83)	208/242 (86)	−3 (−10 to 3)	0.33
Processed meat ≥3 times/week	51/255 (20)	68/240 (28)	−8 (−16 to −1)	0.03
Physical activity‡ and TV watching¶:				
Total activity time ≥150 minutes/week	114/237 (48)	85/221 (38)	10 (1 to 19)	0.04
Watching TV ≥120 minutes/day	166/254 (65)	156/242 (64)	0.9 (−7 to 9)	0.84

*Pearson's χ^2 test.

†One serving of vegetables=half cup cooked or one cup of salad; one serving of fruit=one medium piece or two small pieces or one cup of diced pieces. One cup=250 mL.

‡National Physical Activity Guidelines recommend that children aged 3-5 are physically active every day for at least three hours, spread throughout the day and that screen time for children aged 2-5 is 60 min/day maximum. For adults guidelines recommend at least 30 minutes of moderate intensity physical activity on most, preferably all, days.[28]

§At baseline median intake/day was two serving of vegetables or fruit.[32]

¶No national guidelines for adults, but for children aged 12-18, recommended maximum is 2 hours/day.[28]

Table 4| **Comparison of dietary behaviours, TV viewing, and physical activity at 24 months in study of effect of home based early intervention on BMI in children and mothers; complete case analysis and intention to treat analysis. Figures are odds ratios* (95% confidence interval) and P values**

Secondary outcomes (yes *v* no)	Complete cases analysis (n=497)	Intention to treat analysis (n=667)
Children		
Dietary behaviours:		
Vegetable ≥1 serving/day†	1.77 (1.05 to 2.98), 0.03	1.67 (1.03 to 1.72), 0.04
Fruit ≥1 serving/day†	0.74 (0.39 to 1.39), 0.35	0.77 (0.38 to 1.54), 0.45
Food for reward	0.66 (0.45 to 0.96), 0.03	0.68 (0.46 to 1.01), 0.05
Water >3 cups/day	1.41 (0.92 to 2.18), 0.12	1.36 (0.88 to 2.11), 0.17
Hot chips/French fries	0.89 (0.52 to 1.49), 0.65	0.93 (0.56 to 1.55), 0.79
Salty snack	0.81 (0.56 to 1.19), 0.29	0.82 (0.57 to 1.17), 0.27
Sweet snack everyday	0.81 (0.54 to 1.22), 0.32	0.86 (0.57 to 1.29), 0.45
Soft drink	0.86 (0.58 to 1.30), 0.48	0.86 (0.55 to 1.36), 0.52
Physical activity and TV watching‡:		
Outdoor play ≥120 minutes/day	1.02 (0.71 to 1.48), 0.90	0.98 (0.69 to 1.39), 0.91
TV on during meal	0.62 (0.42 to 0.92), 0.02	0.63 (0.44 to 0.92), 0.02
Eat dinner in front of TV	0.60 (0.42 to 0.87), 0.01	0.64 (0.44 to 0.92), 0.02
Viewing TV >60 minutes/day	0.56 (0.34 to 0.93), 0.03	0.57 (0.34 to 0.94), 0.03
Mothers		
Dietary behaviours:		
Vegetable >2 servings/day†§	1.96 (1.37 to 2.82), <0.0001	1.90 (1.34 to 2.70), <0.0001
Fruit >2 serving/day†§	1.30 (0.83 to 2.01), 0.25	1.24 (0.78 to 1.97), 0.37
Water ≥8 cups/day	0.99 (0.62 to 1.60), 0.99	0.93 (0.59 to 1.48), 0.77
Soft drink ≥7 cups/week	0.73 (0.51 to 1.04), 0.08	0.72 (0.50 to 1.02), 0.07
Hot chips	0.66 (0.41 to 1.07), 0.10	0.67 (0.41 to 1.10), 0.12
Fast food	0.78 (0.48 to 1.28), 0.33	0.81 (0.46 to 1.41), 0.45
Processed meat ≥3 times/week	0.63 (0.42 to 0.96), 0.03	0.61 (0.39 to 0.94), 0.03
Physical activity‡ and TV watching¶:		
Total activity time ≥150 minutes/week	1.48 (1.02 to 2.15), 0.04	1.50 (1.06 to 2.12), 0.02
Watching TV ≥120 minutes/day	1.04 (0.72 to 1.50), 0.84	1.06 (0.72 to 1.56), 0.76

*Odds ratio of having primary outcome for those in intervention group compared with control group.

†One serving of vegetables=half cup cooked or one cup of salad; one serving of fruit=one medium piece or two small pieces or one cup of diced pieces. One cup=250 mL.

‡National Physical Activity Guidelines recommend that children aged 3-5 are physically active every day for at least three hours, spread throughout the day and that screen time for children aged 2-5 is 60 min/day maximum. For adults guidelines recommend at least 30 minutes of moderate intensity physical activity on most, preferably all, days.[28]

§At baseline median intake/day was two serving of vegetables or fruit.[32]

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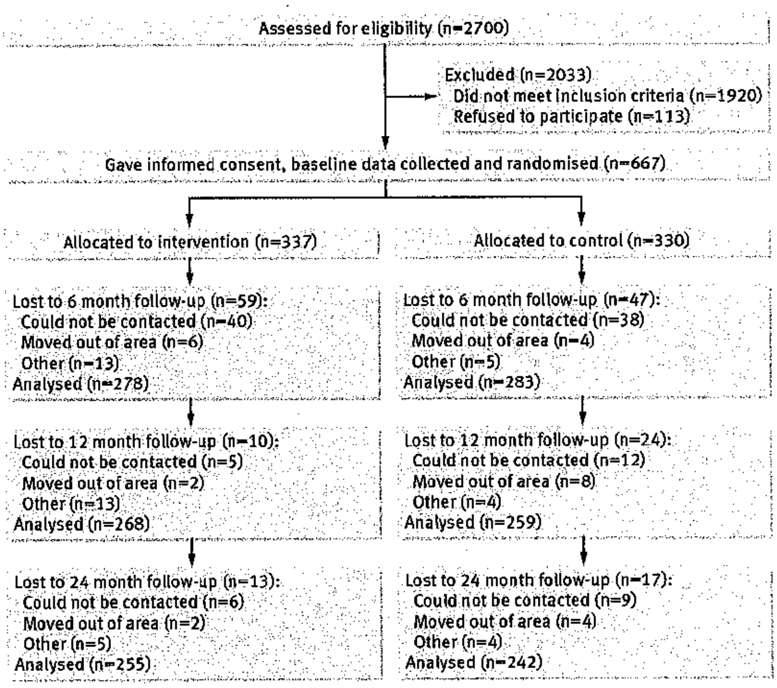
Figure



Flow of participants through study of effect of home based early intervention on BMI in children

Original Investigation

Sustainability of Effects of an Early Childhood Obesity Prevention Trial Over Time
A Further 3-Year Follow-up of the Healthy Beginnings Trial

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IMPORTANCE Little evidence exists on whether effects of an early obesity intervention are sustainable.

OBJECTIVE To assess the sustainability of effects of a home-based early intervention on children's body mass index (BMI) and BMI *z* score at 3 years after intervention.

DESIGN, SETTING, AND PARTICIPANTS A longitudinal follow-up study of the randomized clinical Healthy Beginnings Trial was conducted with 465 participating mothers consenting to be followed up at 3 years after intervention until their children were age 5 years. This study was conducted in socially and economically disadvantaged areas of Sydney, Australia, from March 2011 to June 2014.

INTERVENTIONS No further intervention was carried out in this Healthy Beginnings Trial phase 2 follow-up study. The original intervention in phase 1 comprised 8 home visits from community nurses delivering a staged home-based intervention, with one visit in the antenatal period and 7 visits at 1, 3, 5, 9, 12, 18, and 24 months after birth.

MAIN OUTCOMES AND MEASURES Primary outcomes were children's BMI and BMI *z* score. Secondary outcomes included dietary behaviors, quality of life, physical activity, and TV viewing time of children and their mothers.

RESULTS In total, 369 mothers and their children completed the follow-up study, a phase 2 completion rate of 79.4% (80.9% for the intervention group and 77.7% for the control group). The differences between the intervention and control groups at age 2 years in children's BMI and BMI *z* score disappeared over time. At age 2 years, the difference (intervention minus control) in BMI (calculated as weight in kilograms divided by height in meters squared) was −0.41 (95% CI, −0.71 to −0.10; $P = .009$), but by age 5 years it was 0.03 (95% CI, −0.30 to 0.37). No effects of the early intervention on dietary behaviors, quality of life, physical activity, and TV viewing time were detected at age 5 years.

CONCLUSIONS AND RELEVANCE The significant effect of this early life home-visiting intervention on child BMI and BMI *z* score at age 2 years was not sustained at age 5 years without further intervention. Obesity prevention programs need to be continued or maintained during the early childhood years.

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There is an upward trend in the prevalence of overweight or obese preschool-age children (age range, 0-5 years), from 4.2% in 1990 to 6.7% in 2010, that is occurring worldwide.[1] Obesity in young children may progress to obesity in later childhood[2,3] and potentially into adulthood.[4-7] It is increasingly argued that childhood obesity prevention should begin in the early years.[8] Tackling childhood obesity now represents an important opportunity to reduce the effect of heart disease, diabetes mellitus, and other serious preventable chronic diseases in the future while immediately improving the health of children.[9] The importance of early obesity intervention has been emphasized by the increased number of intervention research studies[10-15] in recent years.

Some promising results from recent randomized clinical trials suggest that prevention interventions directed to mothers in the first years of their child's life can reduce bottle use and energy intake,[13] support the development of healthy infant feeding practices,[12] lead to reductions in sweet snack consumption and TV viewing,[11] and reduce the mean body mass index (BMI) (calculated as weight in kilograms divided by height in meters squared) by 0.38 (95% CI, 0.08-0.68) of children at age 2 years.[10] The Healthy Beginnings Trial (HBT) phase 1 was the first randomized clinical trial to show the effectiveness of an early childhood obesity intervention delivered in the first 2 years of life.[10,16] The provision of healthy infant feeding education, with increased active play and reduced TV viewing time, remains central to these early interventions. A 2014 systematic review of the effect of interventions to prevent obesity or improve obesity-related behaviors in preschool-age children (age range, 0-5 years) concluded that early intervention effects are modest but promising.[15] The authors of the review called for high-quality studies with longer-term follow-up. Indeed, without a long-term follow-up, the sustainability of early intervention effects remains unknown.

To address this evidence gap, children who participated in the HBT phase 1 were followed up for 3 years after intervention (ie, from age 2-5 years) to ascertain whether the benefits at age 2 years were sustained at age 5 years and to examine the quality of life of child participants. The HBT phase 1 used a home-based early intervention designed to improve family and behavioral risk factors for childhood obesity. The rationale and method for this follow-up study (HBT phase 2) were reported in a published protocol[17] before study commencement and involved (1) a longer-term follow-up of the cohort of children at ages 3.5 and 5 years and (2) an economic evaluation of the intervention, which has been reported elsewhere.[18]

At a Glance

- Prevention interventions directed to mothers in the first years of their child's life can improve infant feeding practices and reduce mean BMI
- Little evidence exists on whether effects of an early obesity intervention are sustainable
- To address this evidence gap, a further follow-up of the Healthy Beginnings Trial was conducted 3 years after intervention
- No effects of the early intervention on children's mean BMI and other obesity-related behaviors were detected at age 5 years

Methods

HBT Phase 1

In 2007, we commenced the HBT phase 1 with 667 first-time mothers (337 intervention and 330 control) to investigate the effectiveness of a home-based early intervention primarily on children's BMI at age 2 years and, secondarily, on dietary behaviors, physical activity, and TV viewing time of children and their mothers. The intervention comprised 8 home visits from community nurses delivering a staged home-based intervention, with one visit in the antenatal period and 7 visits at 1, 3, 5, 9, 12, 18, and 24 months after birth. It was delivered from 2007 to 2010 in one of the most socially and economically disadvantaged areas of Sydney, Australia.[10,16,19]

Participants and Consent of the HBT Phase 2

In 2011, we started the follow-up HBT phase 2 study to investigate the long-term effects of the HBT intervention. We asked 497 participating families who had completed phase 1 (255 intervention and 242 control) whether they were willing to participate in a further 3-year study with no intervention from age 2 years onward. In total, 465 of 497 (93.6%) consented to follow-up. No further intervention was carried out in this study from March 2011 to June 2014. Written parental consent was obtained by mail or through home visits by 2 research assistants. Phase 2 baseline was taken as the home visit when the child was aged 2 years. Ethics approval was obtained for the study from Sydney Local Health District Research Ethics Review Committee X10-0312.

Data Collection

Two research assistants who were not involved in the HBT phase 1 collected the follow-up data and were blinded to intervention or control status. To ensure measurement consistency, they were trained by experienced early childhood nurses in anthropometry measures and semistructured interviews in the home setting. Data were collected when the children were ages 3.5 and 5 years. At each visit, the child's anthropometric measurements were undertaken, and a face-to-face questionnaire interview was conducted with the mother.

Main Outcome Measures

Primary Outcomes

The primary outcomes were children's BMI and BMI z score. Height and weight were measured using standard techniques in the home using a portable stadiometer and electronic scales. Body mass index was calculated,[2] and BMI z score was calculated using a software program (AnthroPlus; World Health Organization).[20] We also categorized BMI as overweight, obese, or not overweight or obese based on internationally accepted criteria.[21]

For weight, measurements were taken using digital scales (TI1582136K; http://www.wedderburn.com.au) by a research assistant from children wearing lightweight clothes and no shoes. The measures were recorded to the nearest 0.1 kg.

For measuring height we used a portable stadiometer with a vertical backboard and movable headboard, the child stood erect against the backboard, and the back of the head, shoulder blades, buttocks, and heels made contact with the backboard of the stadiometer. Two measurements were taken by a research assistant and recorded to the nearest 0.1 cm. A third measure was taken if the first 2 measurements differed by 0.5 cm or more, and the mean of these 2 or 3 values was calculated.

Secondary Outcomes

The secondary outcomes included dietary behaviors, quality of life, physical activity, and TV viewing time of children and their mothers according to a published research protocol.[17] We used a validated set of short questions[22,23] to assess young children's dietary patterns and physical activity. The TV viewing behavioral questions were based on those used in phase 1 of the HBT.[10] Indicators of dietary patterns included the following: questions on daily servings of fruits and vegetables; quantity of specified beverages, including sugary drinks; frequency of snack foods; and eating behaviors, including eating when watching TV or in front of the TV. Indicators of physical activity and TV viewing time included mother-reported outdoor playtime and time spent on small screens on a typical weekday and weekend day.

Children's health-related quality of life was assessed using parent proxy reports of a pediatric quality-of-life instrument (PedsQL; http://www.pedsql.org/) comprising 4 generic core subscales pertaining to physical, emotional, social, and school functioning. At 3.5 years, we used the parent report for toddlers (age range, 2-4 years). At 5 years, we used the parent report for young children (age range, 5-7 years).

Secondary outcomes also included the mothers' eating habits and physical activity, as well as TV viewing time. Information on these outcomes was collected using existing survey instruments, including the New South Wales Adult Health Surveys,[24] which were also used in phase 1 of the HBT.[10]

Sociodemographic Characteristics

At phase 1 baseline, we collected sociodemographic data, including age, employment status, educational level, marital status, language spoken at home, and country of birth of mothers using the standard New South Wales Population Health Survey questions.[24] At phase 2 baseline, we re-collected information on employment status, educational level, and marital status.

Retention Strategies

To maintain participants' interest in the follow-up study, several retention strategies were used, including the following: (1) sending thank-you cards at the end of the HBT phase 1, (2) sending Christmas or New Year greeting cards, (3) obtaining contact numbers of participants' relatives (updated at each contact visit), (4) providing brief feedback to participants on their child's weight and height, and (5) text message reminders for follow-up visits. In addition, small gifts (less than US $8) of appreciation were sent to all participants after completing the 3.5-year data collection.

Statistical Analysis

Using χ^2 tests, we compared characteristics of the study participants between the intervention and control groups at baseline of the HBT phase 2 (at age 2 years) and ages 3.5 and 5 years. We also compared characteristics of those remaining in the study and those lost to follow-up at ages 3.5 and 5 years.

The primary outcome variables, BMI and BMI *z* score, were treated as continuous variables. Secondary outcomes, including eating habits and dietary behaviors, physical activity and outdoor play, and TV viewing time, were dichotomized as for phase 1 of the HBT.[10] For example, cut points were based on the national guidelines for physical activity for children and adults, while the median intake of fruits and vegetables of the study participants was used.

To assess sustained short-term and long-term effects of the intervention on the primary outcomes (child BMI and BMI *z* score) and secondary outcomes (dietary behaviors, physical activity, and TV viewing time), outcomes were compared between the intervention and control groups at ages 3.5 and 5 years. For continuous variables, including BMI and BMI *z* score, the means were compared using *t* tests and then using multiple linear regressions to adjust for baseline differences (at 2 years). For categorical variables, χ^2 tests were used, followed by multiple logistic regressions to adjust for baseline differences (at 2 years). The regression analyses were limited to those with 3.5-year or 5-year follow-up data. For the PedsQL quality-of-life subscales, Tobit models were used, specifying right censoring at the maximum subscale score of 100. All models were adjusted for mother's marital status and employment status, which were found to be significantly different ($P < .05$) between the intervention and control groups at the beginning of the phase 2 study. Other variables (eg, child sex or when the mother was recruited) were assessed for their confounding effect and then dropped from the models. Adjusted regression coefficients (β levels) were calculated with 95% CIs and *P* values.

Data were analyzed using statistical software (Stata, version 12; StataCorp LP). Intent-to-treat principles were used in all primary analyses (ie, we analyzed the results based on participants' initial group allocation at baseline of the HBT phase 1).

Results

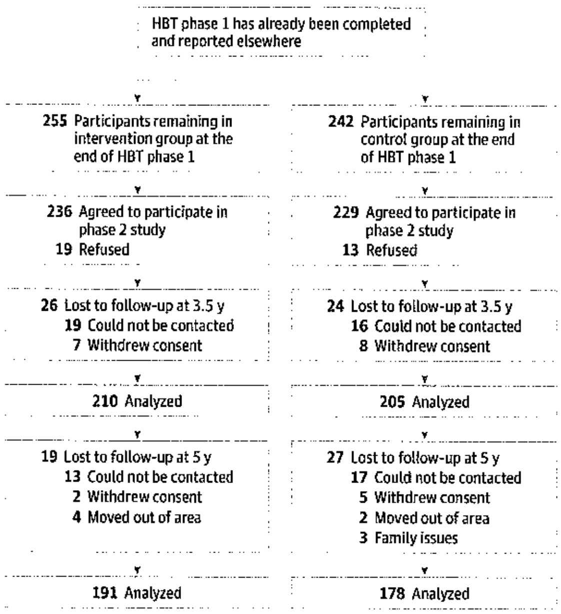
Follow-up and Retention

Of 497 participants who completed the HBT phase 1, 465 (236 intervention and 229 control) agreed to participate in this follow-up study, a consent rate of 93.6% (**Figure 1** and **Figure 2**). Fifty mothers were lost to follow-up at 3.5 years and a further 46 mothers at 5 years. In total, 369 mothers (191 intervention and 178 control) remained at 5 years, giving an overall retention rate of 79.4% over the 3-year period. Of 96 lost to follow-up in phase 2, a total of 45 were from the intervention group, and 51 were from the control group. The main reasons for loss to follow-up were similarly distributed across both groups (Figure 1).

Characteristics of the Study Participants

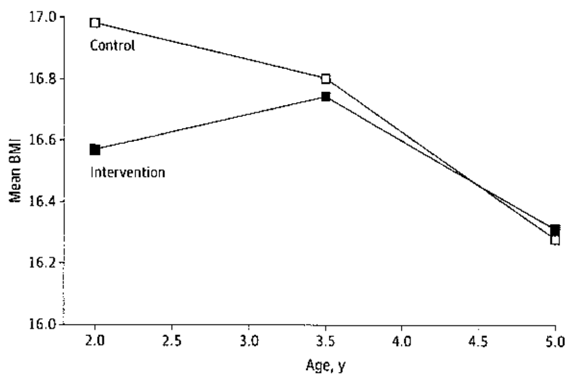
Table 1 lists characteristics of the study participants at phase 2 baseline and follow-up of the children at ages 3.5 and 5 years. At baseline, most characteristics were similar in the 2 groups, but there were higher proportions of married or de facto part-

Figure 1. Consolidated Standards of Reporting Trials Diagram



Flowchart of participants for the Healthy Beginnings Trial (HBT) phase 2.

Figure 2. Mean Body Mass Index (BMI) for the Groups at 2 Years, 3.5 Years, and 5 Years



The sample sizes were 465 participants, 415 participants, and 369 participants at 2 years, 3.5 years, and 5 years, respectively. BMI is calculated as weight in kilograms divided by height in meters squared

ner and employed (93.9% and 64.2%, respectively) mothers in the control group than in the intervention group (88.1% and 57.4%, respectively) ($P = .03$ and $P = .02$, respectively). Comparisons of characteristics were also made between those retained in the study and those lost to follow-up. Regardless of group, mothers who were lost to follow-up were more likely to be younger, unmarried, and unemployed and have lower annual household income and lower educational levels.

Primary Outcomes

At phase 2 baseline, the success of the phase 1 intervention meant that the mean BMI was lower in the intervention group (16.57) than in the control group (16.98). The difference (intervention minus control) was −0.41 (95% CI, −0.71 to −0.10) ($P = .009$) (**Table 2**). The mean BMI z score was also lower in the intervention group (0.55 vs 0.84, $P = .006$). However, there were no differences in these variables between the intervention and control groups when children were aged 3.5 years or 5 years. This was true when either unadjusted (eg, BMI difference at age 5 years was 0.03; 95% CI, −0.30 to 0.37) or after adjusting for baseline differences using multiple linear regression (eg, BMI difference at age 5 years was 0.27; 95% CI, −0.01 to 0.56). Figure 2 and **Figure 3** show BMIs and BMI z scores for the groups at 2, 3.5, and 5 years based on observed values.

Body mass index or BMI z score at 2 years was positively associated with BMI (β level, 0.52; 95% CI, 0.42-0.61; $P < .001$) or BMI z score (β level, 0.52; 95% CI, 0.44-0.62; $P < .001$) at 3.5 years after controlling for maternal marital status and employment status at baseline. Similarly, BMI or BMI z score at 2 years was also positively associated with BMI (β level, 0.52; 95% CI, 0.44-0.60; $P < .001$) or BMI z score (β level, 0.51; 95% CI, 0.43-0.58; $P < .001$) at 5 years.

At 3.5 years, 27.4% of the intervention group and 29.6% of the control group were categorized as overweight or obese ($P = .34$). At 5 years, 22.6% of the intervention group and 21.7% of the control group were categorized as overweight or obese ($P = .73$).

Secondary Outcomes

As summarized in **Table 3**, χ^2 tests and multiple logistic regression analyses found no differences between groups in dietary behaviors, physical activity, or TV viewing time of children and their mothers at 3.5 and 5 years. Children's consumption of fruits and vegetables remained steady in both groups at 3.5 and 5 years, as did children's physical activity and TV viewing time.

Quality of life, as measured by the median (interquartile range) total subscale score of the PedsQL, was the same for intervention and control participants at 3.5 years. These median (interquartile range) values at 3.5 years were 91.7 (85.7-95.2) for the intervention group and 91.7 (87.5-95.2) for the control group ($P = .89$). The median (interquartile range) values at 5 years were 93.5 (89.1-97.2) for the intervention group and 93.5 (88.9-97.2) for the control group ($P = .92$). Similarly, there were no differences between the 2 groups at 3.5 and 5 years in their physical, emotional, social, and school functioning subscale median scores.

Discussion

Principal Findings of the Study

This follow-up study shows that the differences in children's BMI and BMI z score between the intervention and control groups at age 2 years disappeared over time. By age 5 years, no difference was detected nor were any effects of the early intervention on dietary behaviors, quality of life, physical activity, and TV viewing time detected across time.

Table 1. Characteristics of the Study Participants in the Healthy Beginnings Trial Phase 2[a]

Variable	No. (%)									
	Phase 2 Baseline at 2 y		At 3.5 y				At 5 y			
			Retained		Lost to Follow-up (n = 50)	P Value[b]	Retained		Lost to Follow-up (n = 96)	P Value[b]
	Intervention (n = 236)	Control (n = 229)	Intervention (n = 210)	Control (n = 205)			Intervention (n = 191)	Control (n = 178)		
Mother's age, y										
≤24	88 (37.3)	81 (35.4)	73 (34.8)	67 (32.7)	29 (58.0)	.002	62 (32.5)	55 (30.9)	52 (54.2)	
25-29	83 (35.2)	85 (37.1)	76 (36.2)	77 (37.6)	15 (30.0)		69 (36.1)	70 (39.3)	29 (30.2)	<.001
≥30	65 (27.5)	63 (27.5)	61 (29.0)	61 (29.8)	6 (12.0)		60 (31.4)	53 (29.8)	15 (15.6)	
Marital status		c		c				c		
Married or de facto partner	208 (88.1)	215 (93.9)	187 (89.0)	195 (95.1)	41 (82.0)	.02	172 (90.1)	171 (96.1)	80 (83.3)	.003
Never married	28 (11.9)	14 (6.1)	23 (11.0)	10 (4.9)	9 (18.0)		19 (9.9)	7 (3.9)	16 (16.7)	
Mother's employment status	(n = 235)	c	(n = 209)	c					(n = 95)	
Employed or paid or unpaid maternity leave	135 (57.4)	147 (64.2)	126 (60.3)	135 (65.9)	21 (42.0)	.01	119 (62.3)	119 (66.9)	44 (46.3)	
Unemployed	54 (23.0)	30 (13.1)	46 (22.0)	26 (12.7)	12 (24.0)		40 (20.9)	22 (12.4)	22 (23.2)	.005
Home duties, student, or other	46 (19.6)	52 (22.7)	37 (17.7)	44 (21.5)	17 (34.0)		32 (16.8)	37 (20.8)	29 (30.5)	
Annual household income, US $										
<40 000	60 (25.4)	57 (24.9)	49 (23.3)	47 (22.9)	21 (42.0)	.02	44 (23.0)	38 (21.3)	35 (36.5)	
40 000-79 999	74 (31.4)	68 (29.7)	66 (31.4)	64 (31.2)	12 (24.0)		59 (30.9)	55 (30.9)	28 (29.2)	.02
≥80 000	102 (43.2)	104 (45.4)	95 (45.2)	94 (45.9)	17 (34.0)		88 (46.1)	85 (47.8)	33 (34.4)	
Mother's educational level	(n = 235)		(n = 228)	(n = 204)	(n = 49)			(n = 177)	(n = 95)	
Primary school to school certificate	34 (14.5)	38 (16.7)	26 (12.4)	31 (15.2)	15 (30.6)	.003	23 (12.0)	23 (13.0)	26 (27.4)	
HSC to TAFE certificate or diploma[d]	131 (55.7)	130 (57.0)	115 (54.8)	119 (58.3)	27 (55.1)		104 (54.5)	104 (58.8)	53 (55.8)	<.001
University	70 (29.8)	60 (26.3)	69 (32.9)	54 (26.5)	7 (14.3)		64 (33.5)	50 (28.2)	16 (16.8)	
Mother's country of birth	(n = 235)	(n = 228)	(n = 209)	(n = 204)			(n = 190)	(n = 177)		
Australia	148 (63.0)	150 (65.8)	129 (61.7)	134 (65.7)	35 (70.0)	.38	123 (64.7)	115 (65.0)	60 (62.5)	.67
Other	87 (37.0)	78 (34.2)	80 (38.3)	70 (34.3)	15 (30.0)		67 (35.3)	62 (35.0)	36 (37.5)	
Language spoken at home	(n = 235)	(n = 2227)	(n = 209)	(n = 203)			(n = 190)	(n = 176)		
English	214 (91.1)	207 (91.2)	190 (90.9)	186 (91.6)	45 (90.0)	.77	174 (91.6)	162 (92.0)	85 (88.5)	.32
Other	21 (8.9)	20 (8.8)	19 (9.1)	17 (8.4)	5 (10.0)		16 (8.4)	14 (8.0)	11 (11.5)	
Mother recruited										
Before giving birth	158 (66.9)	135 (59.0)	140 (66.7)	123 (60.0)	31 (62.0)	.88	125 (65.4)	107 (60.1)	61 (63.5)	
After giving birth	78 (33.1)	94 (41.0)	70 (33.3)	82 (40.0)	19 (38.0)		66 (34.6)	71 (39.9)	35 (36.5)	
Child sex										
Male	128 (54.2)	110 (48.0)	112 (53.3)	101 (49.3)	25 (50.0)	.86	103 (53.9)	83 (46.6)	52 (54.2)	.51
Female	108 (45.8)	119 (52.0)	98 (46.7)	104 (50.7)	25 (50.0)		88 (46.1)	95 (53.4)	44 (45.8)	

Abbreviations: HSC, high school certificate; TAFE, technical and further education.

[a] Some values do not sum to heading totals because of missing data.

[b] χ^2 Test comparing retained vs lost to follow-up.

[c] $P < .05$ for the intervention vs control group.

[d] Completed high school or technical college certificate.

Meaning of the Study

It is clear that the initial significant effect of this early life home-visiting intervention was not sustained without further intervention with the participants. The design of health promotion interventions and policies aimed at reducing the prevalence of childhood obesity needs to be considered within a life course framework, requiring frequent interventions addressing multiple factors at various stages of life.[25,26] These fac-

Table 2. Descriptive Statistics of BMI and BMI *z* Score of Children by Group Allocation and Comparisons of BMI and BMI *z* Score Between Groups Using Multiple Regression Analyses at 2 Years, 3.5 Years, and 5 Years

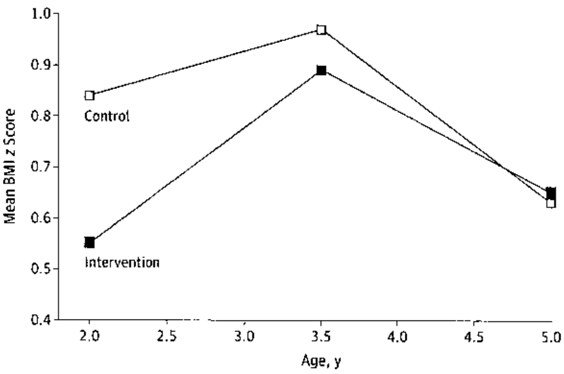
	Cross-sectional Analyses			Multiple Regression Analyses	
Group Allocation	Mean (SD)	Median (Range)	Intervention Minus Control Mean Difference (95% CI)	Adjusted Mean Difference (95% CI)	*P* Value
At 2 y (n = 465)					
Child BMI					
Intervention	16.57 (1.65)	16.6 (12.8 to 22.7)	−0.41 (−0.71 to −0.10)	−0.40 (−0.71 to −0.10)	.01[a]
Control	16.98 (1.61)	16.9 (13.8 to 25.1)	NA	NA	
Child BMI *z* score					
Intervention	0.55 (1.17)	0.63 (−2.87 to 4.21)	−0.29 (−0.50 to −0.08)	−0.29 (−0.50 to −0.07)	.01[a]
Control	0.84 (1.08)	0.87 (−1.97 to 5.37)	NA	NA	
At 3.5 y (n = 415)					
Child BMI					
Intervention	16.74 (1.93)	16.4 (11.4 to 24.9)	−0.06 (−0.41 to 0.28)	0.15 (−0.16 to 0.46)	.33[b]
Control	16.80 (1.64)	16.6 (13.6 to 25.3)	NA	NA	
Child BMI *z* score					
Intervention	0.89 (1.29)	0.79 (−3.54 to 5.92)	−0.08 (−0.30 to 0.16)	0.08 (−0.12 to 0.28)	.44[b]
Control	0.97 (1.06)	0.89 (−1.43 to 5.46)	NA	NA	
At 5 y (n = 369)					
Child BMI					
Intervention	16.31 (1.70)	16.0 (12.8 to 23.3)	0.03 (−0.30 to 0.37)	0.27 (−0.01 to 0.56)	.06[b]
Control	16.28 (1.56)	16.0 (11.8 to 23.1)	NA	NA	
Child BMI *z* score					
Intervention	0.65 (1.04)	0.53 (−2.12 to 4.60)	0.02 (−0.19 to 0.22)	0.17 (−0.0004 to 0.36)	.06
Control	0.63 (0.97)	0.52 (−3.18 to 3.89)	NA	NA	

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); NA, not applicable.

[a] Adjusted for mother's marital status and employment status.

[b] Adjusted for mother's marital status, mother's employment status, and child's BMI (or BMI *z* score) at 2 years.

Figure 3. Mean Body Mass Index (BMI) *z* Score for the Groups at 2 Years, 3.5 Years, and 5 Years



The sample sizes were 465 participants, 415 participants, and 369 participants at 2 years, 3.5 years, and 5 years, respectively.

tors can range from the social or built environment (macroenvironment) through behavior and physiology.[26] Our results also reaffirmed that overweight or obesity is already established in the early years of life. Sustainable intervention programs are essential to address the social, cultural, economic, and environmental factors that are associated with childhood obesity over all life stages.

What the Study Adds

First, without the findings of the HBT phase 2, it is unlikely that appropriate recommendations for early childhood prevention programs could have been made purely based on the results of the HBT phase 1. The effectiveness and sustainability of this early intervention program in the Australian context would remain unknown. Our results are consistent with findings from a recent meta-analysis[27] of early obesity intervention programs that involve parents, which concluded that interventions with parental involvement are effective at short-term follow-up but that effects were not retained in the long run.

Second, a Cochrane review of interventions for preventing obesity in children[28] indicated that there were promising findings in those aged 0 to 5 years, particularly for interventions conducted in home or health care settings. At the same time, the research gaps evident from that review included the need to study the effectiveness of interventions for this age group. Our phase 2 study is the first to date to address this research gap of a lack of long-term follow-up studies. Other (possibly differently designed) intervention strategies are needed with longer-term follow-up.

Table 3. Comparisons of Dietary Behaviors, Physical Activity, and TV Watching of Children and Their Mothers Between the Intervention vs Control Group at 3.5 Years and 5 Years[a]

	At 3.5 y					At 5 y				
	No. (%)					No. (%)				
Secondary Outcome	Intervention (n = 211)	Control (n = 204)	*P* Value[b]	aOR (95% CI)[c]	*P* Value	Intervention (n = 191)	Control (n = 178)	*P* Value[b]	aOR (95% CI)[c]	*P* Value
Children										
Dietary behaviors										
Vegetables ≥2 servings per day[d]	94 (44.5)	92 (45.1)	.95	0.95 (0.62-1.45)	.82	81 (42.4)	77 (43.3)	.90	0.89 (0.56-1.40)	.61
Fruits ≥2 servings per day[e]	147 (69.7)	140 (68.6)	.82	1.11 (0.71-1.74)	.65	139 (72.8)	120 (67.4)	.30	1.31 (0.81-2.14)	.27
Food for reward	172 (81.5)	155 (76.0)	.27	1.56 (0.93-2.62)	.09	119 (62.3)	116 (65.2)	.52	0.97 (0.61-1.53)	.89
Salty snack	154 (73.0)	143 (70.1)	.80	1.14 (0.72-1.81)	.58	125 (65.4)	120 (67.4)	.69	0.95 (0.60-1.50)	.83
Confectionery	169 (80.1)	163 (79.9)	.96	1.05 (0.63-1.75)	.85	151 (79.1)	153 (86.0)	.06	0.71 (0.40-1.28)	.25
Soft drink	70 (33.2)	59 (28.9)	.35	1.26 (0.80-1.99)	.32	71 (37.2)	70 (39.3)	.67	0.91 (0.58-1.42)	.67
Physical activity and TV watching[f]										
Outdoor play ≥120 min/d	140 (66.4)	139 (68.1)	.65	0.96 (0.62-1.48)	.86	129 (67.5)	116 (65.2)	.63	1.07 (0.67-1.71)	.77
TV is on during meal	137 (64.9)	149 (73.0)	.07	0.84 (0.54-1.31)	.45	134 (70.2)	127 (71.3)	.80	1.12 (0.69-1.80)	.65
Eat dinner in front of TV	135 (64.0)	136 (66.7)	.56	0.95 (0.62-1.46)	.82	106 (55.5)	98 (55.1)	.93	1.15 (0.74-1.77)	.54
TV viewing time <60 min/d	24 (11.4)	13 (6.4)	.07	1.68 (0.79-3.58)	.18	19 (10.0)	17 (10.0)	.90	0.89 (0.44-1.83)	.76
Mothers										
Dietary behaviors										
Vegetables ≥2 servings per day[d]	133 (63.0)	145 (71.1)	.08	0.71 (0.45-1.11)	.13	140 (73.3)	125 (70.2)	.51	1.07 (0.64-1.80)	.80
Fruits ≥2 servings per day[e]	109 (51.7)	98 (48.0)	.49	1.15 (0.77-1.74)	.50	79 (41.4)	81 (45.5)	.42	0.78 (0.50-1.22)	.27
Soft drink ≥7 cups per week	65 (30.8)	69 (33.8)	.51	0.87 (0.55-1.37)	.54	37 (19.4)	33 (18.5)	.84	1.15 (0.65-2.04)	.64
Fast food	164 (77.7)	173 (84.8)	.06	0.64 (0.37-1.09)	.10	148 (77.5)	146 (82.0)	.28	0.77 (0.45-1.34)	.36
Processed meat ≥3 times per week	50 (23.7)	45 (22.1)	.69	1.16 (0.71-1.90)	.56	35 (18.3)	39 (21.9)	.39	0.82 (0.48-1.41)	.48
Physical activity and TV watching[g]										
Total physical activity time ≥150 min/wk	93 (44.1)	95 (46.6)	.59	0.83 (0.54-1.28)	.40	155 (81.2)	155 (87.1)	.12	0.62 (0.33-1.17)	.14
Watching TV <120 min/d	132 (62.6)	139 (68.1)	.32	1.38 (0.89-2.14)	.15	94 (49.2)	81 (45.5)	.45	0.88 (0.57-1.36)	.57

Abbreviation: aOR, adjusted odds ratio.

[a] The numbers of participants in the intervention and control groups differ in the tables because of missing data for some variables.

[b] χ^2 Test comparing intervention vs control.

[c] Using multiple logistic regression adjusted for mother's marital status, mother's employment status, and baseline difference of the outcome.

[d] One serving is ½ cup of cooked vegetables or 1 cup of salad vegetables. The median intake per day was 2 servings of vegetables.

[e] One serving is 1 medium piece or 2 small pieces of fruits or 1 cup of diced pieces. The median intake per day was 2 servings of fruits.

[f] For children's physical activity, the national physical activity guidelines recommend that children aged 3 to 5 years should be physically active every day for at least 3 hours spread throughout the day. The national physical activity guidelines recommend that screen time for children aged 2 to 5 years should be less than 60 minutes per day.

[g] For physical activity, the national physical activity guidelines for adults recommend at least 30 minutes of moderate-intensity physical activity on most days and preferably all days. For TV viewing time, no national guidelines exist for adults, but it is recommended that this should be a maximum of 2 hours per day for children ages 12 to 18 years.

Third, a systematic review of effective strategies for reducing screen time among young children[29] has identified several research gaps, one of which was limited long-term follow-up data (>6 months). The review called for more work to be done to understand the potential for interventions in children younger than 6 years and in low-income and racial/ethnic or minority participants.

Unanswered Questions and Future Research

Early life interventions that target modifiable maternal and child risk factors hold significant promise, but potentially sustained benefits beyond the intervention period are possibly moderated by obesogenic environments. Long-term follow-up by similar studies is required to build a better understanding of whether weight-related behavioral changes attributed to intensive early child obesity interventions are sustainable. Potentially, the success of interventions such as the HBT diminishes across time, presumably because obesogenic factors within communities that put families and young children at risk of engaging in weight-related behaviors remain in place. Future research needs to explore early interventions beyond individual behaviors and family conditions that are related to overweight and obesity.

Strengths and Limitations

The HBT phase 1 study demonstrated the effectiveness of a home-based early childhood obesity intervention, with a mean reduction in BMI of 0.38 for children at age 2 years.[10] The HBT phase 2 study, a further 3-year follow-up of the phase 1 participants, has generated new knowledge about the sustainability of the early intervention. Evidence produced by this study can enable policy makers and health care professionals to refocus on the life course approach to obesity prevention with a long-term commitment to tackle the obesity epidemic. A sustained and continuing support to mothers with young children is vital, particularly in socially and economically disadvantaged communities.

The study plan was transparent with a published research protocol.[17] The participation rate was high, with 93.6% of families who remained at the end of the HBT phase 1 being recruited for phase 2. The retention rate of 79.4% over the 3-year follow-up period after intervention was reasonable. Characteristics of the study participants were similar in the 2 groups except for marital status at the end of this study. The main outcome measures were assessed using validated, well-developed, and widely used population survey tools.[21-23] Blinding to treatment allocation was applied for data collection, data entry, and analysis.

However, the study has several limitations. First, conducting an overall 5-year longitudinal study of the HBT phases 1 and 2 provides challenges for maintaining the study cohort.[30] As a result, loss to follow-up may have led to incomplete study results and may have biased the results, although the main reasons for loss to follow-up were similar across both groups. Second, the study was limited by nonblinded participating mothers and self-reported behavioral measures. Third, we did not assess many other potential factors (eg, environmental, school, and community) that may also have influenced mothers' and children's physical activity and dietary behaviors. Fourth, the results may have been substantially biased because only those participants who completed all of phase 1 and phase 2 were included. However, it is likely that if sustained effects were to be seen, they would be in this most highly engaged group. Nevertheless, with the analysis limited to this group, no detectable effect at age 3.5 or 5 years was noted.

Conclusions

In conclusion, the effect of this early life home-visiting intervention on child BMI was not sustained without further intervention. With a substantial proportion of young children being overweight or obese, there is a need for ongoing research to identify intervention programs.

ARTICLE INFORMATION

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Study concept and design: Wen, Baur, Rissel.
Acquisition, analysis, or interpretation of data: Wen, Simpson, Xu, Hayes.
Drafting of the manuscript: All authors.
Obtained funding: Wen, Baur, Simpson, Hayes, Hardy, Rissel.
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REFERENCES

1. de Onis M, Blössner M, Borghi E. Global prevalence and trends of overweight and obesity among preschool children. *Am J Clin Nutr*. 2010;92(5):1257-1264.

2. Gardner DS, Hosking J, Metcalf BS, Jeffery AN, Voss LD, Wilkin TJ. Contribution of early weight gain to childhood overweight and metabolic health: a longitudinal study (EarlyBird 36). *Pediatrics*. 2009;123(1):e67-e73. doi:10.1542/peds.2008-1292.

3. Stocks T, Renders CM, Bulk-Bunschoten AM, Hirasing RA, van Buuren S, Seidell JC. Body size and growth in 0- to 4-year-old children and the relation to body size in primary school age. *Obes Rev*. 2011;12(8):637-652.

4. Monteiro PO, Victora CG. Rapid growth in infancy and childhood and obesity in later life: a systematic review. *Obes Rev*. 2005;6(2):143-154.

5. Taveras EM, Gillman MW, Kleinman K, Rich-Edwards JW, Rifas-Shiman SL. Racial/ethnic differences in early-life risk factors for childhood obesity. *Pediatrics*. 2010;125(4):686-695.

6. Tsukada H, Miura K, Kido T, et al. Relationship of childhood obesity to adult obesity: a 20-year longitudinal study from birth in Ishikawa Prefecture, Japan [in Japanese]. *Nihon Koshu Eisei Zasshi*. 2003;50(12):1125-1134.

7. Nader PR, O'Brien M, Houts R, et al; National Institute of Child Health and Human Development Early Child Care Research Network. Identifying risk for obesity in early childhood [published correction appears in *Pediatrics*. 2006;118(5):2270]. *Pediatrics*. 2006;118(3):e594-e601. doi:10.1542/peds.2005-2801.

8. Balbus JM, Barouki R, Birnbaum LS, et al. Early-life prevention of non-communicable diseases. *Lancet*. 2013;381(9860):3-4.

9. World Health Organization. Commission on Ending Childhood Obesity. http://www.who.int/dietphysicalactivity/end-childhood-obesity/en/. Accessed October 12, 2014.

10. Wen LM, Baur LA, Simpson JM, Rissel C, Wardle K, Flood VM. Effectiveness of home based early intervention on children's BMI at age 2: randomised controlled trial [published correction appears in *BMJ*. 2013;346:f1650]. *BMJ*. 2012;344:e3732. doi:10.1136/bmj.e3732.

11. Campbell KJ, Lioret S, McNaughton SA, et al. A parent-focused intervention to reduce infant obesity risk behaviors: a randomized trial. *Pediatrics*. 2013;131(4):652-660.

12. Daniels LA, Mallan KM, Nicholson JM, Battistutta D, Magarey A. Outcomes of an early feeding practices intervention to prevent childhood obesity. *Pediatrics*. 2013;132(1):e109-e118. doi:10.1542/peds.2012-2882.

13. Bonuck K, Avraham SB, Lo Y, Kahn R, Hyden C. Bottle-weaning intervention and toddler overweight. *J Pediatr*. 2014;164(2):306-12.e1, 2. doi:10.1016/j.jpeds.2013.09.029.

14. Sanders LM, Perrin EM, Yin HS, Bronaugh A, Rothman RL; Greenlight Study Team. "Greenlight study": a controlled trial of low-literacy, early childhood obesity prevention. *Pediatrics*. 2014;133(6):e1724-e1737. doi:10.1542/peds.2013-3867.

15. Laws R, Campbell KJ, van der Pligt P, et al. The impact of interventions to prevent obesity or improve obesity related behaviours in children (0-5 years) from socioeconomically disadvantaged and/or indigenous families: a systematic review. *BMC Public Health*. 2014;14:779.

16. Wen LM, Baur LA, Simpson JM, Rissel C, Flood VM. Effectiveness of an early intervention on infant feeding practices and "tummy time":

a randomized controlled trial. *Arch Pediatr Adolesc Med*. 2011;165(8):701-707.

17. Wen LM, Baur LA, Rissel C, et al. Healthy Beginnings Trial Phase 2 study: follow-up and cost-effectiveness analysis. *Contemp Clin Trials*. 2012;33(2):396-401.

18. Hayes A, Lung T, Wen LM, Baur L, Rissel C, Howard K. Economic evaluation of "healthy beginnings": an early childhood intervention to prevent obesity. *Obesity (Silver Spring)*. 2014;22(7):1709-1715.

19. Wen LM, Baur LA, Rissel C, Wardle K, Alperstein G, Simpson JM. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). *BMC Public Health*. 2007;7:76.

20. World Health Organization. WHO AnthroPlus software. http://www.who.int/growthref/tools/en/.http://www.who.int/childgrowth/software/en/. Accessed February 27, 2015.

21. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. *BMJ*. 2000;320(7244):1240-1243.

22. Flood V, Wen LM, Hardy LL, et al. Reliability and validity of a short food frequency questionnaire to assess diet among 2-5 year olds. *Obes Res Clin Pract*. 2010;4(suppl 1):S61.

23. Wen LM, van der Ploeg HP, Kite J, Cashmore A, Rissel C. A validation study of assessing physical activity and sedentary behavior in children aged 3 to 5 years. *Pediatr Exerc Sci*. 2010;22(3):408-420.

24. Centre for Epidemiology and Research. *2006 Report on Adult Health From the New South Wales Population Health Survey*. Sydney: NSW Dept of Health, Australia; 2007.

25. Hector D, King L, Hardy LL, et al. *Evidence Update on Obesity Prevention: Across the Life-Course: Prepared for NSW Ministry of Health*. Sydney, Australia: Physical Activity Nutrition Obesity Research Group; 2012.

26. Dixon B, Peña MM, Taveras EM. Lifecourse approach to racial/ethnic disparities in childhood obesity. *Adv Nutr*. 2012;3(1):73-82.

27. Yavuz HM, van Ijzendoorn MH, Mesman J, van der Veek S. Interventions aimed at reducing obesity in early childhood: a meta-analysis of programs that involve parents [published online October 8, 2014]. *J Child Psychol Psychiatry*. doi:10.1111/jcpp.12330.

28. Waters E, de Silva-Sanigorski A, Hall BJ, et al. Interventions for preventing obesity in children. *Cochrane Database Syst Rev*. 2011;(12):CD001871.

29. Schmidt ME, Haines J, O'Brien A, et al. Systematic review of effective strategies for reducing screen time among young children. *Obesity (Silver Spring)*. 2012;20(7):1338-1354.

30. Viney L, Goodwin M. Tackling the challenges in conducting a 5-year longitudinal study of the Healthy Beginnings Trial. *Health Promot J Austr*. 2014;25(1):65-66.

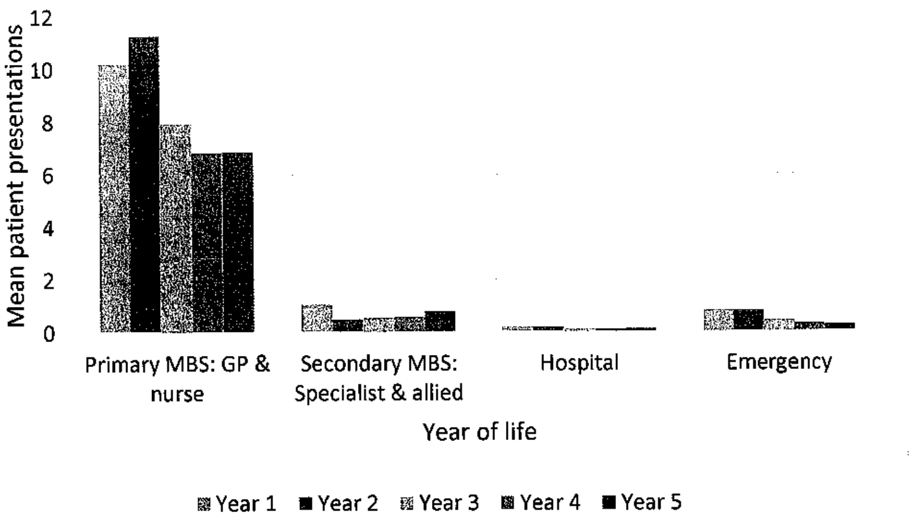

Figure 1 Mean number of presentations per year, over first 5 years of life, by type

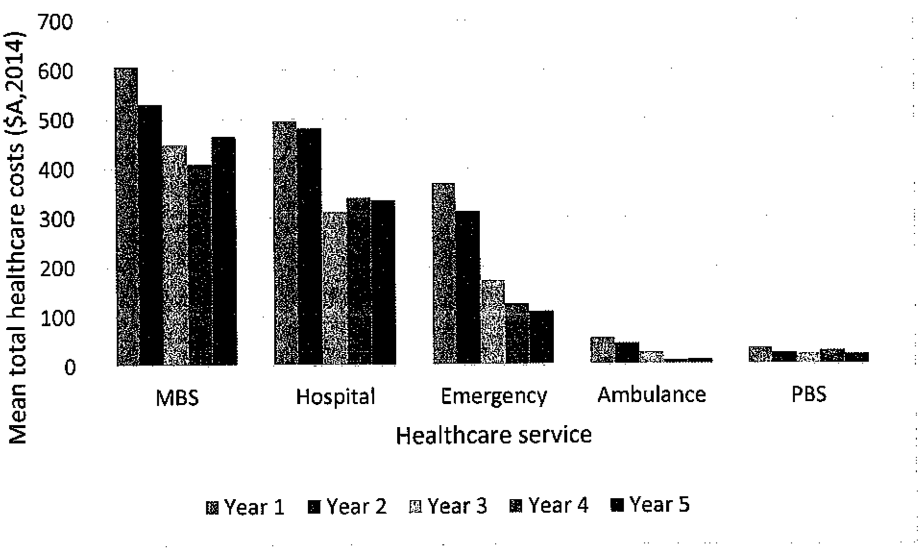

Figure 2 Mean cost per annum ($AUD 2014) over first 5 years of life

Early Childhood Obesity: Association with Healthcare Expenditure in Australia

Alison Hayes[1], Anna Chevalier[1,2], Mario D'Souza[1,3], Louise Baur[1,4], Li Ming Wen[1,5], and Judy Simpson[1]

Objective: To determine whether overweight or obesity among children (aged 2 to ≤5 years) is associated with direct healthcare costs, after adjusting for child, household, and socioeconomic characteristics.
Methods: A longitudinal cohort analysis was performed in 350 children aged 2 years assessed over 3 years of follow-up. Child weight status was determined from mean BMI *z*-scores at 2, 3.5, and 5 years, and healthcare utilization including medicines, nonhospital, hospital, and emergency care was determined by data linkage. Using adjusted multivariable regression analyses, the relationship between total 3-year healthcare costs and weight status was examined. Observations took place in Sydney, Australia, between 2011 and 2014.
Results: After adjustment for significant maternal and sociodemographic characteristics, healthcare costs of children with obesity (BMI *z*-score >2SD) were 1.62 (95% CI 1.12-2.34, $P = 0.01$) times those of children with healthy weight. However, costs of overweight children were similar to those of healthy weight ($P = 0.96$). The additional 3-year costs of healthcare for a child with obesity compared with healthy weight were $AUD 825 (95% CI $135-$2,117) for general patients and $AUD 1332 (95% CI $174-$4,280) for concession card holders.
Conclusions: Prevention of obesity in early childhood may have concurrent benefits in reducing healthcare expenditure.

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Introduction

Childhood obesity is a serious public health challenge (1) and is becoming an increasing problem in very young, preschool children, under 5 years (2). Worldwide, the estimated prevalence of overweight and obesity for children under 5 was reported to be 6.9% in 2010, while in countries such as the USA, UK, and Australia, this figure may be as high as 20% to 23% (3-5). This is important, not only because of tracking to poorer health outcomes in later childhood, adolescence, and adulthood (6-8), but also because, at a health system level, overweight and obesity represents a major economic burden.

The economic argument for early prevention of childhood obesity is usually framed with respect to improving outcomes of chronic disease that occur in later life, thus reducing long-term but not necessarily short-term costs (9). However, there is also evidence in school-age children for an association between overweight and obesity and higher medication use (10), higher hospitalization costs, (11) higher nonhospital costs (12,13) and more outpatient and emergency department (ED) visits (14). Few of these studies have examined total healthcare costs across all these sectors. In their recent review, John et al. (15) conclude most studies find excess healthcare costs associated with childhood obesity but suggest more detailed analyses are required. A particular gap is the evidence relating to the association between healthcare costs and obesity in very early childhood, under 5 years. As this represents a period of relatively high healthcare use (16,17), it is also potentially a time when the healthcare costs of children with obesity and overweight could be substantial.

In this study, we examine the association between total healthcare costs and weight status in a prospective cohort of preschool-aged children between 2 and ≤5 years, while controlling for child and family sociodemographic characteristics. These data were collected during the 3-year follow-up of a randomized controlled trial to reduce childhood obesity, the Healthy Beginnings Trial (HBT) (18,19). Associated healthcare costs were determined through

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participant-level data linkage to four separate administrative databases covering medicine use, hospital and nonhospital care, and emergency care. Our hypothesis was that overweight or obesity among preschool-aged children was associated with higher direct healthcare costs than children with healthy weight.

Methods

Study design and population

We conducted an observational longitudinal analysis of 350 preschool children aged 2 to ≤5 years who were part of the HBT Phase 2 follow-up study (18). The HBT tested the effectiveness of an early childhood obesity intervention, with the active intervention (Phase 1) delivered in the first 2 years of life (20,21). In this health promotion intervention, qualified early childhood nurses visited parents in their homes for individual support and education for breastfeeding, healthy infant nutrition, and physical activity. Participants were firstborn children of mothers in a socioeconomically disadvantaged area of Sydney, Australia. Eligibility criteria included singleton births and a minimum gestational age of 37 weeks. Mothers were aged 16 years and over and spoke conversational English. The study details have been reported previously (21). The present analysis examined data from HBT Phase 2 (18) between 2011 and 2014, which followed children over the 3 years between their second and fifth birthdays, after the intervention had been completed. As there were no significant differences in outcomes between the intervention and control groups during Phase 2 (19), and no differences in direct healthcare costs between the groups ($P = 0.42$), we carried out these analyses without stratification by treatment allocation.

The HBT study was approved by the Sydney Local Health District Research Ethics Review Committee (X10 0312). Data linkage was approved by the New South Wales (NSW) Population Health Services Research Committee (HREC/11/CIPHS/29). Informed consent of parents was obtained for all participants.

Primary outcome: Total healthcare costs

HB participants who consented to Phase 2 of the study were invited at the child's 3.5-year assessment to take part in an economic substudy, which required giving consent for healthcare data linkage. Total healthcare utilization, including hospital, nonhospital, emergency, and medicine use was determined retrospectively and prospectively over the 3-year period from the child's second birthday, by participant-level data linkage to four administrative databases. Data on general practitioner (GP) and specialist consultations, tests, and diagnostics were recorded via each child's unique Medicare number under the Medicare Benefits Scheme (MBS). Data on medicine use were recorded through the Pharmaceutical Benefits Scheme (PBS). The Australian Government's Medicare provides access to medical services, including free or subsidized doctor and specialist treatment and the PBS provides access to listed medicines at reduced cost. MBS and PBS administrative data capture costs of all subsidized treatment and include both government and patient out-of-pocket contributions. The level of out-of-pocket contributions is determined by patient status as concessional or general. Families may qualify for a concession card through work status, low income, and/or certain health conditions.

Hospitalizations and ED use were determined through data linkage to the NSW Admitted Patient Data Collection, and the NSW Emergency Department Data Collection. Data linkage was carried out by the Centre for Health Record Linkage using probabilistic matching on participant's name, birth date, and address. Hospital episodes were costed using guidelines from NSW Cost of Care Standards (22), using Australian Refined Diagnostic Related Group (AR-DRG) primary diagnosis codes provided in the linked data sets, and cost weights (relative to the average cost of hospital separations). Presentations at emergency were costed according to the triage category using urgency and disposition cost weights applied to the average cost of an emergency presentation (22). The cost of ambulance transportation was estimated using NSW Ambulance Service current rates and included in the cost of emergency care.

All items were valued in Australian dollars with a base year of 2014, inflated appropriately using the health consumer price index (23). We determined healthcare costs from a government perspective, since most healthcare in Australia is paid for by the government. Australians are entitled to free treatment at public hospitals and emergency, but for MBS and PBS items, there is some level of patient co-payment. These patient out-of-pocket costs were reported separately but not used in the analyses.

Measurement of weight status

Height and weight were measured by research assistants at home visits undertaken when children were 2, 3.5, and 5 years old. Height was measured to the nearest 0.1 cm using a portable stadiometer. Two height measurements were taken; a third measurement was taken if the first two differed by 0.5 cm or more, then the mean of these values was calculated. Weight was measured to the nearest 0.1 kg using digital scales (Wedderburn, Sydney Australia), while children were wearing light clothes and no shoes. BMI for age z-scores at 2, 3.5, and 5 years were calculated from height and weight using World Health Organization (WHO) software, AnthroPlus (24); then child weight status was determined from the mean of the three BMI z-score readings. In recognition of the complexities in definition of weight status in childhood, and in order to simplify nomenclature, we defined underweight (<-2 SD), healthy weight (-2 to 1 SD), overweight (>1 to ≤ 2 SD), and obesity (>2 SD), based on WHO criteria for children (25).

Child, mother, and family characteristics

Children's birth weight categories were determined from linked hospital data and dichotomized as low birth weight (<2,500 g) or not. Breastfeeding status was collected during telephone interviews at 6 months of age. Sociodemographic characteristics were collected at trial baseline, using standard questions from the NSW Population Health Survey (26). These included questions on maternal age, country of birth, marital status, education and employment status, and household questions on income and language spoken at home. Patient status as concessional or general was determined from children's PBS claims history.

Statistical analysis

All analyses were conducted in Stata v13.0 (27). Descriptive statistics of child and family characteristics and mean healthcare costs by each characteristic were determined. The main analysis examined the association between total healthcare costs (including, medicines, nonhospital, hospital, and emergency care) and weight status. As 99.7% of participants incurred healthcare expenditure over the 3 years of follow-up, the standard two-part cost models were unnecessary. For the analyses of total healthcare costs, we used a logarithmic transformation of cost data; this accounted for the skew and provided easy interpretation of regression coefficients. For one child with zero costs between age 2 to ≤5, we imputed the median 3-year costs of participants with 0- to 2-year costs in the same range (lowest 5th percentile) in order to calculate the logged costs. We used univariable linear regression to examine the association between logged total healthcare costs and child and family characteristics. A multivariable model investigating the association of healthcare costs and BMI category was adjusted for all covariates with $P < 0.20$ in the univariable analyses, and the final adjusted multivariable model was presented with all coefficients with $P < 0.05$.

Supplementary analyses were carried out to identify what were the drivers and potential reasons for differences in total costs by weight status. We wanted to identify whether higher total healthcare costs might be explained by higher use of a particular sector or a higher cost of care. We examined healthcare costs by each sector as both aggregated (total) and disaggregated mean costs per child over 3 years and presented the results graphically. We then determined whether the probability of using each healthcare service was associated with weight status, using adjusted multivariable logistic regression. For those with nonzero costs in each of the four health sectors (i.e., any use), we also determined the mean cost of care, by weight status.

Finally, using descriptive statistics, we also examined broad reasons for hospitalizations based on AR-DRG Major Diagnostic Categories (http://www.aihw.gov.au/hospitals-data/ar-drg-data-cubes/).

Results

There were 465 participants of HBT Phase 2 and of the 369 children completing follow-up, 363 consented to data linkage. Of these, 13 were not successfully linked to one or other of the healthcare administrative databases, leaving 350 participants (95%) for analysis. Summary characteristics of these participants are shown in Table 1. Mean total healthcare costs per child over 3 years from a government perspective were $2,698 and mean out-of-pocket costs were $138. Most children (61%) were classified overall as having a healthy weight, while 29% were overweight, and 9% had obesity. The mean 3-year healthcare costs for children of healthy weight were $2,516, for those who were overweight were $2,609, and for those with obesity were $4,124.

In the univariable analyses, significant predictors of higher children's healthcare costs were child obesity, mother's employment status as home duties/student, and being a concession card holder (Table 2). These predictors remained significant in the adjusted model, and additionally children of unemployed mothers had significantly lower healthcare costs over 3 years. The total healthcare costs of children with obesity were 1.62 (95% CI 1.12-2.34, $P = 0.01$) times that of children with healthy weight, from back transformation of the coefficient for obesity (= exp [0.48]), but the costs for overweight children were very similar to children with healthy weight ($P = 0.96$). After controlling for other significant predictors of healthcare costs, the additional cost of healthcare over 3 years for a child with obesity compared with healthy weight was $825 (95% CI $135-$2,117) for general patients and $1,332 (95% CI $174-$4,280) for concession card holders. These costs were obtained from the coefficients in the adjusted multivariable models (Table 2). For example, concessional patients average 3-year healthcare costs were $3,478 (=$e^{(7.19 + 0.48 + 0.48)}$) for children with obesity and $2,146 (=$e^{(7.19 + 0.48)}$) for children with healthy weight, difference $1,332.

Examination of costs by type of healthcare and weight status indicated that the higher total healthcare costs of children with obesity were due mostly to the higher cost of hospitalizations (Figure 1). The probability of using each of the different healthcare sectors by weight classification is shown in Table 3. There were no significant differences in use of medicines, nonhospital, and emergency care across weight classifications. However, the odds of being hospitalized was significantly higher for children with obesity than children with healthy weight (Table 3; OR = 2.66, 95% CI 1.24-5.73, $P = 0.01$). Of those with nonzero costs, the mean 3-year costs in all sectors were higher for children with obesity, but these results were not significant (Table 4).

Examination of the four most common primary diagnosis codes for hospitalizations (which accounted for 67% (94/140) of all admissions over 3 years) suggests compared with healthy weight, children with obesity were more likely to be hospitalized for: diseases and disorders of the ear, nose, mouth and throat, respiratory disorders, digestive system disorders, and musculoskeletal conditions (Table 5).

Discussion

Our study found that obesity in preschool children, aged between 2 and ≤5 years, was associated with significantly higher contemporaneous healthcare expenditure. Over the 3-year period of the study, total healthcare costs of children with obesity were 1.62 (95% CI 1.12-2.36) times that of children with healthy weight. However, healthcare costs of overweight children were very similar to those of children with healthy weight. After adjustment for significant maternal and socioeconomic characteristics, the excess healthcare costs associated with obesity were $825 (general patients) and $1,438 (concession patients) over 3 years.

The probability of using prescription medicines, nonhospital, and emergency services was not associated with weight status, but young children with obesity were significantly more likely to be hospitalized than their healthy weight counterparts (OR = 2.66 95% CI 1.24-5.73, $P = 0.01$). For those with hospitalizations, the mean costs per child of hospital care were similar across all weight status groups. Hence it appears the higher total healthcare costs during early childhood are driven mainly by greater likelihood of hospitalization among children with obesity, rather than higher cost of hospital treatment.

While a number of studies in older school-age children have reported higher hospital costs (11), nonhospital costs (12), and higher medication use (28) in children with overweight or obesity (12), our study is the first to show that excess healthcare costs during very early childhood are associated with obesity. Our results are very similar to findings in adult populations in which many studies have found higher healthcare costs associated with obesity but not overweight status (29,30). Our finding that higher healthcare costs were associated with concession status is expected, as these families

TABLE 1 Child, maternal, and household characteristics of 350 participants of Phase 2 Healthy Beginnings Trial, and mean 3-year healthcare costs ($AUD) between age 2 and ≤5 years

	Participants (*n* = 350)		3-year healthcare costs, mean (SD)
	N	%	
Child characteristics			
Weight status			
Underweight	1	<1	$6,774 (0)
Healthy weight	215	61	$2,516 (2,543)
Overweight	103	29	$2,609 (3,085)
Obesity	31	9	$4,124 (4,618)
Gender			
Boys	181	52	$2,692 (2,760)
Girls	169	48	$2,704 (3,191)
Birth weight (g)[a]			
<2,500	16	5	$2,313 (2,653)
2,500+	333	95	$2,710 (2,991)
Breastfeeding status at 6 months[a]			
Breastfeeding	136	39	$2,704 (2,754)
Not breastfeeding	195	56	$2,750 (3,194)
Maternal characteristics			
Age (years)			
16–24	111	32	$2,948 (3,404)
25–29	129	37	$2,501 (2,906)
30+	110	31	$2,677 (2,562)
Language spoken at home[a]			
English	318	91	$2,752 (2,972)
Other	29	8	$2,278 (3,086)
Country of birth[a]			
Australia	229	65	$2,674 (2,781)
Other	119	34	$2,772 (3,335)
Marital status			
Married/de facto	324	93	$2,650 (2,908)
Never married	26	7	$3,293 (3,696)
Education[a]			
University	110	31	$2,392 (2,621)
Not university	239	68	$2,756 (2,853)
Employment status			
Employed	228	65	$2,606 (2,807)
Unemployed	56	16	$2,122 (2,636)
Home duties/student/other	66	19	$3,504 (3,612)
Household characteristics			
Annual income			
<$40,000	78	22	$3,080 (3,828)
$40,000 to <$80,000	107	31	$2,579 (2,369)
$80,000+	165	47	$2,594 (2,863)
Concession status			
Yes	143	41	$3,209 (3,381)
No	207	59	$2,345 (2,603)
Total	350		$2,698 (2,972)

[a]Missing data: <1% (1/350) child's birth weight; 5% (19/350) breastfeeding status; 1% (3/350) mother's language spoken at home; 1% (2/350) mother's country of birth; <1% (1/350) mother's education.

TABLE 2 Univariable and multivariable regression models of logged total healthcare costs by child and household characteristics ($n = 350$)

	Unadjusted (univariable models)			Adjusted multivariable model		
	Coef.	95% CI	P	Coef.	95% CI	P
Child's average weight status						
Healthy weight	ref			ref		
Underweight	1.44	−0.56 to 3.44	0.16	1.15	−0.78 to 3.08	0.24
Overweight	−0.05	−0.29 to 0.19	0.66	−0.01	−0.24 to 0.22	0.96
Obesity	0.42	0.03 to 0.80	0.03	0.48	0.11 to 0.85	0.01
Female	−0.08	−0.13 to 0.30	0.46			
Birth weight <2,500 g	−0.20	−0.71 to 0.32	0.45			
Breastfeeding at 6 months	−0.003	−0.23 to 0.22	0.98			
Mother's age (years)						
30+	ref					
25–29	−0.18	−0.44 to 0.08	0.17			
16–24	0.04	−0.23 to 0.31	0.80			
Mother does not speak English at home	−0.10	−0.29 to 0.49	0.61			
Mother born overseas	0.03	−0.26 to 0.19	0.80			
Mother never married	−0.03	−0.44 to 0.38	0.88			
Mother university educated	0.13	−0.10 to 0.36	0.25			
Mother's employment status						
Employed (paid/unpaid maternity leave)	ref			ref		
Unemployed	−0.28	−0.57 to 0.02	0.06	−0.51	−0.82 to −0.21	0.001
Home duties/student/other	0.38	0.11 to 0.66	0.007	0.30	0.02 to 0.57	0.03
Household annual income						
$80,000+	ref					
$40,000 to <$80,000	0.09	−0.16 to 0.34	0.48			
<$40,000	0.09	−0.19 to 0.37	0.52			
Concession card holder	0.39	0.17 to 0.60	<0.001	0.48	0.25 to 0.70	<0.001
Constant				7.19	7.02 to 7.36	<0.001

have lower co-payment thresholds for medicines, GP, and specialist consultations: thus the government as the healthcare funder pays for a greater proportion of their healthcare. The significant effects of mother's employment suggest those who are unemployed may have difficulty accessing or cannot afford more healthcare for their children, while those with "home duties" may have more opportunity to interact with healthcare system. Factors found to be significant predictors of healthcare use in other studies such as child sex, language spoken at home, and maternal education were not significant in this study, possibly due to the relatively small sample size, but the direction of the coefficients was consistent with existing literature.

The analysis of reasons for hospitalization, although not powered for rigorous statistically analysis does shed some light on the theoretical pathways through which obesity in children under 5 years could impact on higher rates of hospitalization. Our findings are consistent with the known increased prevalence of the following disorders in young children with obesity: obstructive sleep apnea (31), which may necessitate adenotonsillectomy; asthma, airways obstruction, and asthma-like symptoms; and fractures, sprains, and musculoskeletal pain (32).

The strengths of the study include the use of measured height and weight rather than self-reported at three separate time points and the use of BMI z-score for age in the calculation of weight status.

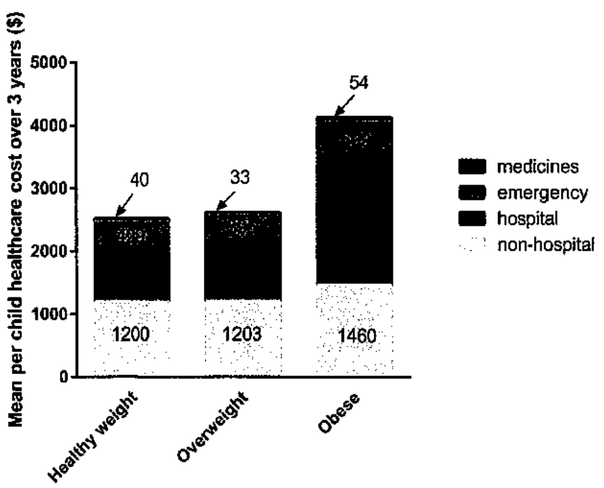

Figure 1 Mean participant healthcare costs (aggregated and disaggregated) between age 2 and ≤5 years by average weight status ($n = 349$). Numbers on the bar chart are mean 3-year costs.

TABLE 3 Number and percent of children using different health services over 3 years by weight status and odds ratios (OR) from logistic regression with healthy weight as referent

	Healthy weight ($N = 215$), n (%)	Overweight ($N = 103$)			Obesity ($N = 31$)		
		n (%)	OR (95% CI)[a]	P	n (%)	OR (95% CI)[a]	P
Medicines	97 (45)	41 (40)	0.80 (0.50–1.29)	0.37	12 (39)	0.77 (0.63–1.10)	0.50
Nonhospital	215 (100)	102 (99)	[b]	-	30 (97)	[b]	-
Emergency	107 (50)	52 (50)	1.03 (0.64–1.65)	0.91	19 (61)	1.60 (0.74–3.45)	0.23
Hospital	56 (26)	27 (26)	1.01 (0.59–1.72)	0.98	15 (48)	2.66 (1.24–5.73)[c]	0.01

[a]OR adjusted by concession status and mother's employment.
[b]OR cannot be computed because 100% of reference group had costs.
[c]Significant at $P < 0.01$.

TABLE 4 Mean per child healthcare costs in different healthcare sectors over 3 years by weight status, for those children with nonzero costs

	Healthy weight ($N = 215$)		Overweight ($N = 103$)			Obesity ($N = 31$)		
	N	Mean (SD)	N	Mean (SD)	P[a]	N	Mean (SD)	P[a]
Medicines	97	90 (136)	41	83 (120)	0.80	12	139 (134)	0.23
Nonhospital	215	1,200 (777)	102	1,215 (931)	0.88	30	1,508 (969)	0.06
Emergency	107	862 (772)	52	783 (632)	0.56	19	1,141 (1237)	0.16
Hospital	56	3,252 (2239)	27	3,730 (2953)	0.44	15	3,951 (3277)	0.36

[a]P values for comparison with healthy weight and adjusted by concession status, mother's age, and employment.

Another major strength of our study is we have captured all forms of healthcare utilization of participants, including medicines, primary, secondary, hospital, and emergency care. Healthcare utilization was derived from participant-level data linkage; hence our healthcare cost data are comprehensive and reliable and do not suffer from attrition or bias. While this is a relatively small study, the linked healthcare data form a very rich data set with over 11,000 records in 3 years. Other strengths of our analysis are that we were able to control for many factors found in previous studies to be associated with healthcare costs, such as birth weight, breastfeeding status (33), and maternal and household sociodemographic characteristics.

Our preschool cohort was drawn from a low-socioeconomic region of Sydney, and while the study sample also included high-income and university-educated parents, our results are not necessarily generalizable to the wider population of preschool children in Australia. A final limitation is only hospitalizations and emergency presentations within NSW were captured; these could be underestimated if participants receive treatment in different states of Australia.

The economic benefit of early obesity prevention programs has previously only acknowledged later savings in healthcare costs resulting from reduced chronic disease in later life. Indeed, modeled economic evaluations of interventions to prevent obesity in children generally only estimate long-term savings in direct healthcare costs attributable to reducing chronic disease in adulthood (34). Our results are important for healthcare funders and policy makers because interventions to prevent obesity in early childhood may have short-term benefits in reducing healthcare expenditure as well as longer term impacts in later childhood, adolescence, and

TABLE 5 Number and percent of children hospitalized for selected diagnoses by weight status

AR-DRG primary diagnosis code for hospital admission	Healthy weight ($n = 215$)	Overweight ($n = 103$)	Obesity ($n = 31$)	Total ($n = 349$)[a]
Ear, nose, mouth, and throat	27 (13%)	6 (6%)	7 (23%)	40 (11%)
Respiratory	9 (4%)	5 (5%)	4 (13%)	18 (5%)
Digestive system	5 (2%)	3 (3%)	2 (6%)	10 (3%)
Musculoskeletal system and connective tissue	4 (2%)	3 (3%)	2 (6%)	9 (3%)

[a]Data for one underweight participant not reported.

adulthood. The immediate economic consequences of obesity among preschool-aged children may be much greater than previously acknowledged, which adds weight to targeting obesity prevention initiatives in the early years. Finally, these results may be used in health economic modeling of obesity interventions delivered in early childhood, by providing estimates of direct healthcare costs associated with obesity, overweight, and healthy weight.

Future research should be conducted in other countries and healthcare settings in order to confirm these results. Large longitudinal studies may further elucidate the reasons for higher hospitalization rates among children with obesity. Preschool-aged children have been under-represented in obesity prevention and treatment programs (35), yet there is evidence that treatment of obesity is more successful in preschoolers than older children (35). As noted by Kleinert and Horton (36,37), preventing child obesity is key to achieving healthy lives in adulthood and reversing obesity prevalence. For any successful intervention among 2- to 5-year-olds, the implication is that for every child avoiding obesity, there are likely to be immediate savings in direct healthcare costs. We suggest that preventing obesity in the *very early childhood years* may be a cost-effective way to tackle the obesity crisis, improve the nation's health, and reduce the economic burden of obesity.**O**

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References

1. Managing the tide of childhood obesity. *Lancet* 2015;385:2434.
2. de Onis M, Blossner M, Borghi E. Global prevalence and trends of overweight and obesity among preschool children. *Am J Clin Nutr* 2010;92:1257-1264.
3. Wake M, Hardy P, Canterford L, Sawyer M, Carlin JB. Overweight, obesity and girth of Australian preschoolers: prevalence and socio-economic correlates. *Int J Obes* 2007;31:1044-1051.
4. Anderson SE, Whitaker RC. Prevalence of obesity among US preschool children in different racial and ethnic groups. *Arch Pediatr Adolesc Med* 2009;163:344-348.
5. Emerson E. Overweight and obesity in 3- and 5-year-old children with and without developmental delay. *Public Health* 2009;123:130-133.
6. Stettler N. Nature and strength of epidemiological evidence for origins of childhood and adulthood obesity in the first year of life. *Int J Obes* 2007;31:1035-1043.
7. Singh AS, Mulder C, Twisk JW, van Mechelen W, Chinapaw MJ. Tracking of childhood overweight into adulthood: a systematic review of the literature. *Obes Rev* 2008;9:474-488.
8. Wheaton N, Millar L, Allender S, Nichols M. The stability of weight status through the early to middle childhood years in Australia: a longitudinal study. *BMJ Open* 2015;5:e006963.
9. Park MH, Falconer C, Viner RM, Kinra S. The impact of childhood obesity on morbidity and mortality in adulthood: a systematic review. *Obes Rev* 2012;13:985-1000.
10. Solmi F, Morris S. Association between childhood obesity and use of regular medications in the UK: longitudinal cohort study of children aged 5-11 years. *BMJ Open* 2015;5:e007373.
11. Trasande L, Liu Y, Fryer G, Weitzman M. Effects of childhood obesity on hospital care and costs, 1999-2005. *Health Affairs* 2009;28:w751-w760.
12. Au N. The health care cost implications of overweight and obesity during childhood. *Health Serv Res* 2012;47:655-676.
13. Clifford SA, Gold L, Mensah FK, et al. Health-care costs of underweight, overweight and obesity: Australian population-based study. *J Paediatr Child Health* 2015;51(12):1199–206.
14. Lynch BA, Finney Rutten LJ, Jacobson RM, et al. Health care utilization by body mass index in a pediatric population. *Acad Pediatr* 2015;15:644–50.
15. John J. Economic perspectives on pediatric obesity: impact on health care expenditures and cost-effectiveness of preventive interventions. *Nestle Nutr Workshop Ser Paediatr Programme* 2010;66:111-124.
16. Siminski P, Bezzina AJ, Lago LP, Eagar K. Primary care presentations at emergency departments: rates and reasons by age and sex. *Aust Health Rev* 2008; 32:700-709.
17. Lowthian JA, Curtis AJ, Cameron PA, Stoelwinder JU, Cooke MW, McNeil JJ. Systematic review of trends in emergency department attendances: an Australian perspective. *Emerg Med J* 2011;28:373-377.
18. Wen LM, Baur LA, Rissel C, et al. Healthy beginnings trial phase 2 study: follow-up and cost-effectiveness analysis. *Contemp Clin Trials* 2012;33:396-401.
19. Wen LM, Baur LA, Simpson JM, et al. Sustainability of effects of an early childhood obesity prevention trial over time: a further 3-year follow-up of the healthy beginnings trial. *JAMA Pediatr* 2015;169:543-551.
20. Wen LM, Baur LA, Simpson JM, Rissel C, Wardle K, Flood VM. Effectiveness of home based early intervention on children's BMI at age 2: randomised controlled trial. *BMJ* 2012;344:e3732.
21. Wen LM, Baur LA, Rissel C, Wardle K, Alperstein G, Simpson JM. Early intervention of multiple home visits to prevent childhood obesity in a disadvantaged population: a home-based randomised controlled trial (Healthy Beginnings Trial). *BMC Public Health* 2007;7:76.
22. NSW Department of Health. *NSW Costs of Care Standards 2010*. Ministry of Health, New South Wales.
23. AIHW. *Health Expenditure Australia 2010-2011*. 47 Cat no. HWE 56 Canberra: Australian Institute of Health and Welfare.
24. World Health Organization. *WHO AnthroPlus for Personal Computers, Version 1.0.4, 2011: Software for Assessing Growth and Development of the World's Children*. Geneva: WHO. Available from: http://www.who.int/childgrowth/software/en/. Last cited 2011.
25. World Health Organization. *Growth Reference Data for 5-19 Years 2006*. Available from: http://www.who.int/childgrowth/en/. Last cited December 2015.
26. NSW Department of Health. *2006 Report on Adult Health From the New South Wales Population Health Survey*. Sydney: Centre for Epidemiology and Research; 2007.
27. StataCorp. *Stata Statistic Software: Release 13*. College Station, Texas, StataCorp LP; 2013.
28. Kuhle S, Fung C, Veugelers PJ. Medication use in normal weight and overweight children in a nationally representative sample of Canadian children. *Arch Dis Childhood* 2012;97:842-847.
29. Cawley J, Meyerhoefer C. The medical care costs of obesity: an instrumental variables approach. *J Health Econ* 2012;31:219-230.
30. Finkelstein EA, Trogdon JG, Cohen JW, Dietz W. Annual medical spending attributable to obesity: payer-and service-specific estimates. *Health Affairs* 2009;28: w822-w831.
31. Marcus CL, Brooks LJ, Draper KA, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics* 2012;130:e714-e755.
32. Paulis WD, Silva S, Koes BW, van Middelkoop M. Overweight and obesity are associated with musculoskeletal complaints as early as childhood: a systematic review. *Obes Rev* 2014;15:52-67.
33. Clifford TJ. Breast feeding and obesity. *BMJ* 2003;327:879-880.
34. Hollingworth W, Hawkins J, Lawlor DA, Brown M, Marsh T, Kipping RR. Economic evaluation of lifestyle interventions to treat overweight or obesity in children. *Int J Obes* 2012;36:559-566.
35. Haemer MA, Ranade D, Baron AE, Krebs NF. A clinical model of obesity treatment is more effective in preschoolers and Spanish speaking families. *Obesity* 2013;21:1004-1012.
36. Kleinert S, Horton R. Rethinking and reframing obesity. *Lancet* 2015;385:2326-2328.
37. Lobstein T, Jackson-Leach R, Moodie ML, et al. Child and adolescent obesity: part of a bigger picture. *Lancet* 2015;385:2510-2520.