

Economic Evaluation of "Healthy Beginnings" an Early Childhood Intervention to Prevent Obesity

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Objective: To determine the costs and cost-effectiveness of an early childhood home visiting program delivered to families in socio-economically disadvantaged areas of Sydney, Australia during 2007-2010.

Methods: Economic evaluation of a randomized controlled trial, the healthy beginnings (HB) trial, from the perspective of the health funder. Intervention resources were determined from local health district records in 2012 \$AUD. Health-care resource utilization was determined through patient-level data linkage.

Results: The cost of HB intervention in the clinical trial over 2 years was \$1309 per child (2012 \$AUD). The incremental cost-effectiveness ratio was \$4230 per unit BMI avoided and \$631 per 0.1 reduction in BMI z-score. It was estimated that the program could be delivered in practice for \$709 per child; with incremental cost-effectiveness ratios of \$2697 per unit BMI avoided and \$376 per 0.1 reduction in BMI z-score.

Conclusions: We present the first economic evaluation of an effective obesity prevention initiative in early childhood. HB is a moderately priced intervention with demonstrated effectiveness that offers similar or better value for money than existing obesity prevention or treatment interventions targeted at older children.

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Introduction

Worldwide, ~6.7% of pre-school-aged children are overweight or obese (1). Indeed, in Australia about 1 in 5 is overweight or obese just prior to school entry (2). Such data are of concern not only due to the potential for persistence of overweight and obesity from childhood into adulthood (3,4) and the escalating cost and health burden that ensues, but also because of the more immediate health impacts on young children and increased costs to the government. An analysis of linked data has shown that overweight and obesity among children aged 4-5 years are responsible for an additional \$AUD \$9.8million in spending by the Australian public health system between ages 5 and 10 years (5). Similar effects have been found in the United Kingdom, where 6% of National Health Service costs amongst children have been attributed to elevated BMI (6), and in the United States, where obesity in childhood is associated with greater prescription drug use, outpatient visits and emergency visits (7).

Because of the immediate and future burden of this problem, there is a growing interest in interventions to prevent obesity in early childhood. Recent systematic reviews have found that while these studies are gaining momentum, a major limitation is their failure to report any cost-effectiveness analyses (8,9). Between 2007 and 2010 we undertook the healthy beginnings (HB) trial, a randomized controlled trial of a home visiting intervention, delivered by specially trained community nurses in the first 2 years of life (10,11). The trial demonstrated a significant reduction in BMI of 0.29 kg m⁻² at age 2 years for children who received the intervention compared to those who received usual care (10).

This study raises important questions regarding the cost of the intervention and whether it could be cost-effective (12). In the present study, we examine both the total costs of the intervention and its cost-effectiveness in the first 2 years of life.

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Author contributions: AH designed the economic evaluation and carried out the cost-effectiveness analyses. TL contributed to cost-effectiveness analysis. LMW, LB, and CR conceived the HBT, and contributed to the development of the trial and the procurement of the funding. KH provided advice on all aspects of economic evaluation. AH wrote the manuscript with assistance from TL, LMW, LB, CR, and KH. AH had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Additional Supporting Information may be found in the online version of this article.

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Methods

Study design and setting

We conducted a trial based retrospective economic evaluation of HB compared with usual care, from the perspective of the health care funder. This perspective was chosen because the health funder will benefit most from any savings in healthcare utilization, and is the most likely decision maker for any potential roll out of the program. Phase 1 of the study covered the intervention period i.e., up to age 2 years, and was completed in 2010. Phase 2 of the study due for completion in 2014 covers the subsequent follow-up of participants at 3.5 and 5 years, without further intervention (13). The economic evaluation substudy presented here is a complete-case analysis of the costs and cost-effectiveness of HB during the intervention phase, up to age 2 years only.

Randomized controlled trial

The healthy beginnings trial tested the effectiveness of an early childhood obesity intervention delivered in the first 2 years of life. The study details have been reported previously (10,13). Briefly, the study included 667 first time mothers and their infants, recruited from antenatal clinics in a socially and economically disadvantaged area of Sydney. The intervention consisted of eight home visits by specially trained community nurses, including one visit at 30-36 weeks gestational age, and seven visits at 1, 3, 5, 9, 12, 15, and 24 months after birth. These visits included one-on-one consultations of ~1-h duration at which age-appropriate education and advice on feeding, nutrition and physical activity were provided. Both control and intervention participants received the usual childhood nursing service from their local Area Health Service, consisting of one home visit by a community nurse within a month of birth plus visits to the local clinic. The control group also received home safety information sent by mail at 1, 3, 5, 9, and 18 months.

Measurement of outcomes

Anthropometric measures were determined at the 2-year visit. Weight measurement of children wearing light clothes and no shoes was taken using digital scales (Tanita model 1583 Baby Scale, Tokyo, Japan) and recorded to the nearest 0.1 kg. Length was taken supine (using SECA 210 Infant Measuring Mat, Hamburg, Germany) on a level floor and recorded to the nearest 0.1 cm. Children's BMI at 2 years was calculated as weight/length² (kg m⁻²) and BMI z-score was calculated using WHO Anthro (14).

Measurement of costs

Costs were estimated from a health funder perspective and included the direct costs of delivering the intervention over 2 years plus any downstream costs due to healthcare utilization of the participants. Consistent with the perspective of the analysis, no attempt was made to determine "out of pocket" costs to the family. The base year for all analyses was 2012, representing the most recent year for which cost data were available. Costs were aggregated across all participants in both arms of the trial to obtain a mean cost per participant and presented in 2012 Australian dollars (\$AUD).

Direct costs of the intervention

We collected data retrospectively on the costs to deliver the intervention during the first 2 years of life, including staff time, vehicle

purchase, vehicle running costs for home visits, costs of training community nurses, educational materials, and equipment costs of scales and portable stadiometers. Costs were obtained in equivalent 2012 prices or were extracted from South Western Sydney and Sydney Local Health Districts (SWSLHD) records, over the period 2007-2010 and inflated by the appropriate health consumer price index (15) to give costs in 2012 \$AUD. We included the cost of any resources needed to deliver the program, but excluded the research and development costs and any costs associated with evaluation or administration of the clinical trial. We estimated the cost of the usual care home-visit as \$90, based on HB visits but with shorter travel time. We have assumed participants in both arms of the trial had these usual visits.

Healthcare service costs

To capture healthcare use retrospectively and accurately, we determined participant health care utilization until age 2 years from linked data on doctor and specialist visits, medicines, in- and out-patient hospital stays and emergency department admissions. We excluded costs associated with birth but included all healthcare costs from age 1 month, corresponding to the time of the first postnatal visit by the HB nurse. Australia has a comprehensive system of healthcare coverage in which claims for doctor, specialist visits and drug prescriptions are recorded via a unique Medicare number. Deidentified claims details for individual patients under the Medicare Benefits Scheme and Pharmaceutical Benefits Scheme, were provided by Medicare Australia. Data linkage to New South Wales Admitted Patient Data Collection, for hospitalizations and the NSW Emergency Department Data Collection, for emergency presentations was carried out by the Centre for Health Record Linkage using probabilistic matching on name, birth date and address. Ethics approval for data linkage was obtained from the NSW Population and Health Services Research Ethics Committee (HREC/11/CIPHS/29). Hospital episodes (public or the private system) were costed using guidelines from New South Wales Cost of Care Standards (16), Australian Refined Diagnostic Related Group primary diagnosis codes provided in the linked datasets, and cost weights (relative to the average cost of hospital separations). Presentations at emergency departments (ED) were costed according to the triage category using urgency and disposition cost weights applied to the average cost of an ED presentation. The cost of ambulance transportation was estimated using NSW Ambulance Service current rates. To account for the differential timing of costs and outcomes, we used a discount rate of 5% per year, in line with current Australian reimbursement guidelines (17).

Statistical analysis

Cost-effectiveness analysis was undertaken from the funder perspective and all analyses were carried out using Stata version12.0. Total costs of the intervention were compared between HB and usual care participants. Costs and effects were derived from patient-level data; therefore we used bootstrapping to estimate a distribution around costs and health outcomes. Incremental cost-effectiveness ratios (ICER) were calculated which represent the additional expenditure required to deliver each additional unit of benefit. The ICERs were expressed as cost per BMI unit avoided and cost per 0.1 BMI z-score reduction. To examine their joint probability distribution, we generated one thousand cost and outcome pairs by bootstrap sampling with replacement and plotted these on an incremental cost-effectiveness plane. A cost-effectiveness acceptability curve was derived to capture uncertainty around the probability

that the intervention is cost-effective, given a decision maker's willingness to pay for reductions in BMI and BMI *z*-score (18).

Scenario analysis

The costs of delivering the HB program in a "real world" setting are likely to be lower than those incurred during the RCT due to potential economies of scale. Nurse time for each home visit was the major contributor to the cost of the intervention, and in the RCT, included 70-min consultation time, and 90 min for return travel and administration time. We investigated the impact of more realistic travel time for home visits, based on actual travel distances/times of usual care community health nurses in an urban setting in NSW. In the scenario analysis, consultation time and the number of visits per child were unchanged, but round trip distance was reduced from 52 to 4 km and travel plus administration time reduced from 90 min to a more realistic 20 min per visit.

Results

Of the 465 participants consenting to the Phase 2 study, 340 consented to data linkage, and complete data on 324 participants were obtained, representing 70% of the Phase 2 participants (Supporting Information Figure 1). Intervention and control participants of the economic evaluation were very similar with regard to demographic characteristics of the mother, sex of child and mean birth weight and length (Table 1).

Unit costs of delivering HB per child are presented in Supporting Information Tables 1 and 2. The major cost of HB was the cost of the visits, with each home visit costing ~\$164, and the major component of these costs was nurse time. The cost of the intervention over 2 years, as delivered in the RCT was \$1309 per child (Table 2). The mean (95% CI) costs of other healthcare, over the first 2 years of life, were \$2706 (\$2238-\$3175) in the intervention and \$2582 (\$2199-\$2964) for usual care (P = 0.65, Table 2). The biggest component of healthcare costs was doctor/specialist visits and hospitalizations, each costing ~\$950 per child over 2 years. Almost all participants visited a doctor over the 2 years—on average once per month—whereas only 25-30% of participants had hospital admissions. Over 60% of the participants presented to emergency departments, and these contributed an average cost of ~\$600 per child. When HB, usual care and all other healthcare costs were included, the mean (95% CI) total discounted costs per participant in the trial were \$4091 (\$3637-\$4602) for the intervention group and \$2622 (\$2223-\$3006) for the control group (P < 0.001) (Table 3).

Total costs (HB) were much lower in year 2 than year 1, reflecting both the lower frequency of visits and lower health care utilization, whilst the usual care arm of the trial had similar costs across both years (Figure 1). Notably the difference in total costs between intervention and control was not significantly different from zero during the 2nd year in either the RCT or the scenario analysis (cost difference and 95% CI: RCT \$277 [-\$71, \$624]; scenario \$137 [-\$214, \$481]).

The point estimate and bootstrapped estimates of incremental cost and incremental benefit of the HB intervention are presented in cost-effectiveness planes (Figures 2 and 3) together with the associated cost-effectiveness acceptability (CEA) curves. In the RCT, the ICER was \$4230 per BMI unit avoided or \$607 per 0.1 BMI z-score

TABLE 1 Characteristics of parent and child participants of economic evaluation substudy (n = 324) by intervention group status of the healthy beginnings trial

	Control (<i>N</i> = 158)	Intervention (N = 166)	P ^a
Parent characteristics at baseline			
Age (years)			
<25	45 (28)	54 (33)	0.429
Household income			
<\$40,000	34 (22)	39 (23)	0.671
Mother's education			
University/higher	43 (27)	60 (36)	0.084
Mother's employment status			
Employed	110 (70)	105 (63)	0.225
Marital status			
Married/de-facto	151 (96)	149 (90)	0.046
Language spoken at home			
English	145 (93)	149 (90)	0.310
Child characteristics			
Sex			
Male	79 (50)	92 (55)	0.329
Birth weight (kg)	3.38 (0.59)	3.36 (0.58)	0.746
Birth length (cm)	51.21 (3.45)	51.14 (3.48)	0.855
Overweight or obese at age 2	22 (15)	20 (12)	0.519

Values presented as n (%) or mean (sd).

 $^{\mathrm{a}}\mathrm{Difference}$ in characteristics tested with Chi squared (percentages) or t test (continuous variables).

avoided. Under a more realistic model of intervention delivery with shorter travel times for home visits, the cost of the intervention was estimated at \$709 per child or \$89 per visit (Supporting Information Table 3) and the ICER was \$2697 per BMI unit avoided and \$376 per 0.1 BMI z-score reduction. The probability of HB being cost-effective could be increased substantially if travel plus administration time for home visits was reduced from 90 to 20 min (Figures 2 and 3). For example, at an acceptability threshold of \$500 for a 0.1 BMI z-score reduction, HB as delivered in the trial had a 0.3 probability of being cost-effective, but in a realistic scenario with shorter travel times, the probability would be 0.66 (Figure 3).

Discussion

HB has already been shown to be effective at reducing BMI among 2-year olds; to our knowledge this is the first cost-effectiveness analysis of an obesity prevention intervention in this age group. The cost of the intervention in the RCT was \$1309 per child over 2 years or \$164 per visit and comprised about one-third of total healthcare costs for intervention participants. In the RCT the ICERs were \$4230 per unit BMI avoided and \$607 per 0.1 BMI *z*-score reduction.

Recruitment of eligible participants for the RCT was necessarily from a wide geographical area, and resulted in the high travel

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TABLE 2 Intervention and healthcare utilization costs per child in 2012 \$AUD (undiscounted) up to age 2 years for intervention and control participants of Healthy Beginnings

Intervention costs	Source	Any use (%)	Mean use	Mean cost (SD)	Any use (%)	Mean	Mean
	LLID recerde				(/0)	use	cost (SD)
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Training of HBT nurses SWS	LHD records	100	1	70.42	-	-	-
Scales and measuring mats SWS	LHD records	100	1	75.33	-	-	-
Vehicle depreciation SWS	LHD records	100	1	107.61	-	-	-
Vehicle running costs (eight visits) SWS	LHD records	100	1	262.1 ^a	-	-	-
Nurse travel and admin time (eight visits) SWS	LHD records	100	1	460.9 ^b	-	-	-
Nurse consultation time (eight visits) SWS	LHD records	100	1	332.9	-	-	-
TOTAL (INTERVENTION)		100	1	1309 ^c	-	-	-
USUAL CARE COST (1 visit)		100	1	90 ^d	100	1	90 ^d
Healthcare costs							
Doctor/specialist visits/diagnostics Linke	ed MBS data	96	24.6	944 (586)	94	24.6	972 (592)
Medicine costs Linke	ed PBS data	38	2.3	60 (361)	35	1.9	19 (44)
Hospitalisation Linke	ed data APDC	27	0.43	975 (1936)	33	0.43	907 (1593)
Emergency admissions Links	ed data EDDC	65	1.7	635 (889)	61	1.5	581 (744)
Ambulance transportation Links	ed data EDDC	8	0.12	92 (375)	10	0.13	102 (368)
TOTAL (HEALTHCARE)				2706 (3059)			2582 (2434)
GRAND TOTAL COSTS ^e				4105 (3059)			2672 (2434)

a\$20.2 in scenario analyses.

component—which would certainly not be the case if HB were implemented in clinical practice. In the scenario analysis, with travel plus admin time set at a more realistic 20 min rather than 90 min, and without changing the frequency or duration of visits, the intervention cost was \$709 per child over 2 years or \$89 per visit and

ICERs were estimated as \$2697 per BMI unit avoided and \$376 per 0.1 BMI *z*-score reduction. Decision uncertainty, presented by way of cost-effectiveness acceptability curves, shows that the probability of HBT being cost-effective can be increased substantially if the travel time for home visits is reduced.

TABLE 3 Mean outcomes, total costs (discounted 2012 AUD\$) and difference per participant at 2 years by intervention and control, for 1000 bootstrapped pairs and point estimate of ICERs

	Intervention mean (boot- strapped 95% CI)	Control mean (boot- strapped 95% CI)	Mean difference (boot- strapped 95% CI)	ICER
BMI at 2 years	15.84 (15.58,16.10)	16.17 (15.92,16.42)	0.33 (-0.043,0.662)	
Total cost per participant (RCT)	4091 (3637,4602)	2622 (2223,3006)	1466 (865-2112)	4230 ^a
Total cost per participant (scenario analysis)	3498 (3043,4009)	2622 (2223,3006)	876 (271,1518)	2697 ^a
BMI z-score at 2 years	0.582 (0.405,0.759)	0.815 (0.650,0.980)	0.23 (-0.026, 0.475)	
Total cost per participant (RCT)	4091 (3637,4602)	2622 (2223,3006)	1466 (865-2112)	631 ^b
Total cost per participant (scenario analysis)	3498 (3043,4009)	2622 (2223,3006)	876 (271,1518)	376 ^b

^aICER per unit BMI avoided (4.2% of the bootstrapped pairs were dominated).

b\$102.4 in scenario analyses.

c\$709 in scenario analyses.

dEstimated using NSW health records.

eIntervention and usual care visit costs plus healthcare costs; MBS Medicare benefits scheme; PBS Pharmaceutical benefits scheme; APDC admitted patient data collection; EDDC emergency department data collection. More details on costs are presented in Supporting Information Tables (1 and 3).

bICER per 0.1 BMI z-score reduction in (3.4% of the bootstrapped pairs were dominated).

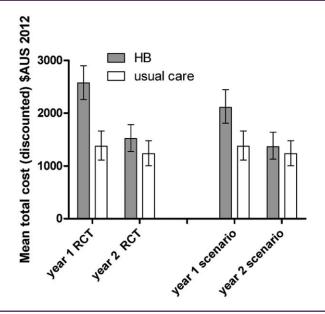
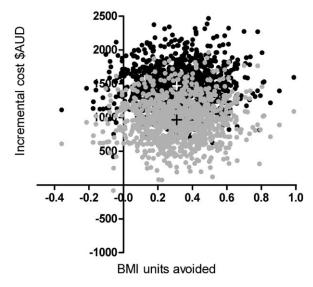


Figure 1 Mean total costs (bootstrapped 95% CI) per participant in first and second year of intervention, for RCT and scenario analysis. Grey bars = HB intervention; white bars = usual care.

The major strength of the study is that it is based on data from a randomized control trial and that best practice methods have been used in the economic evaluation. The use of participant-level linked data allowed a comprehensive and accurate assessment of all downstream healthcare costs, that was more reliable and less biased than use of self-reported data, and was collected unobtrusively, without burdening participants. The retrospective nature of the economic evaluation is a limitation, as only participants continuing to Phase 2 of the trial could be approached to take part. Nevertheless, the intervention effect in the economic evaluation substudy of mean (95% CI) BMI reduction of 0.33 (-0.04-0.66) was very similar to the 0.29 (0.02-0.55) BMI reduction reported for the randomized trial (10). Moreover, the numbers of control and intervention participants in the economic evaluation were balanced and their demographic characteristics were very similar.

We have not conducted a cost-utility analysis because there are no preference based quality of life instruments available for children in this age group, but have instead focused on cost-effectiveness analyses of the primary trial outcomes of BMI and BMI z-score. We recognize that our analyses do not capture all the benefits of the intervention, as we have not valued health benefits accruing to others not directly targeted in the intervention such as parents, siblings and other family members. Thus our calculated ICERs are likely to be conservative.

There are few childhood obesity interventions that include an economic evaluation with which to compare our results and no published cost-effectiveness analyses of primary prevention of childhood obesity targeted at preschoolers. Two recent reviews (19,20) of the cost of obesity interventions among older children found that they ranged from one dollar per child (\$AUD) for reduction of TV advertising, through £662 (\$AUD1502 ppp in 2012) for an intervention delivered by sports coaches, dieticians and psychologists to the



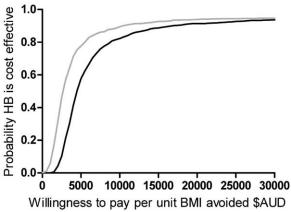


Figure 2 Incremental cost-effectiveness plane and cost effectiveness acceptability curves for reducing BMI by 1 unit Crosses = point estimates of ICERs; Black dots = bootstrapped replicates of incremental costs and outcomes from RCT; Grey dots = bootstrapped replicates of incremental costs and outcomes from scenario analysis; black line = probability cost-effective in RCT; grey line = probability cost-effective in practice.

most expensive at \$AUD31,553 for laparoscopic banding. In comparison to this range of costs, HB would be considered a moderately priced intervention. While the incremental cost per child (Table 2) was much greater than a recent community obesity prevention intervention in Australia (21), it was similar to the LEAP2 intervention for already obese children (22) and the APPLE community based obesity prevention project in New Zealand (23).

Few studies, even in older children, explicitly report an ICER for unit reduction in BMI or BMI z-score, but HB compares favorably with those that do. In individual or family based interventions in the USA for already obese children, ICERs of £432 (\$AUD 946 ppp in 2012) (24) and US\$758 (\$AUD 505) per 0.1 reduction in BMI SDS (25) have been reported. "Be active eat well," a community-based obesity prevention intervention in Australia, in somewhat older participants, reports a much more favorable ICER of AUD\$576 per BMI unit saved, but although it was cost-effective in the funded phase, this was not sustained at the 3-year follow-up (26). The

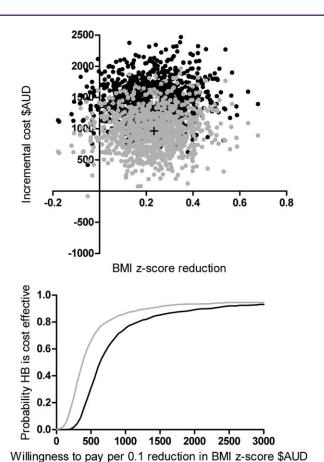


Figure 3 Incremental cost-effectiveness plane and cost effectiveness acceptability curves for reducing BMI z-score by 0.1 unit Crosses = point estimates of ICERs; Black dots = bootstrapped replicates of incremental costs and outcomes from RCT; Grey dots = bootstrapped replicates of incremental costs and outcomes from scenario analysis; black line = probability cost-effective in PRCT; grey line = probability cost-effective in practice.

LEAP2 treatment intervention for already obese 5- to 10-year olds did not report an ICER and had a similar incremental cost per child (\$1236) as HB, but it achieved no long term improvements in BMI (22). In all of these studies, undertaken in older children, a unit decrease in BMI or BMI z-score is a smaller relative change in weight status than it would be in a 2-year-old child, and this highlights the difficulties of interpreting ICERs in this age group. Similarly, judgment of whether the intervention is cost-effective depends on a decision maker's willingness to pay for prevention of a certain BMI gain among 2-year olds—information which is currently lacking. Nevertheless, our explicit calculation of ICERs will serve as a benchmark for future economic evaluation of the many preventive programs now targeted at preschoolers.

Prevention of excessive weight gain in infancy can be achieved with healthy beginnings at moderate additional cost to the health funder, representing around one third of the usual healthcare costs of children in this socio-demographic group. In Australia, where there is a national health care system, the government is the major health funder but in other contexts, our results might be more relevant to private health insurance providers or patient out-of-pockets costs. In our scenario analysis we identified potential cost savings in deliver-

ing the intervention through reduced travel times for visits. These potential travel time savings would be possible in urban or suburban settings and would not necessarily be achievable in rural or remote regions. The existing home visiting service by community nurses in NSW is a potential platform to deliver this more specialized intervention.

Healthy beginnings is an obesity prevention initiative which has no further intervention costs beyond 2 years, and was designed to achieve long term changes in risk factors for obesity by addressing family functioning and behaviors. Our present analysis only measures the short term benefit of the program using 2 year outcome data, but when longer term cost and outcome data are available from the 3.5 and 5 year visits they will allow us to determine the sustainability of the effectiveness of HB. We will also measure quality of life of participants at age 5 years and carry out cost-utility analysis. These data will inform modeling of costs and benefits over a longer time horizon, and the persistence of the effectiveness and the long term cost-effectiveness of HB will be established. O

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