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Healthy beginnings trial phase 2 study: follow-up and cost-effectiveness analysis

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Healthy beginnings trial phase 2 study: follow-up and cost-effectiveness analysis

Abstract

Background: In 2007, we commenced the Healthy Beginnings Trial (HBT) Phase 1 study, which is the first randomised controlled trial (RCT) to test the effectiveness of an early childhood obesity intervention in children aged up to 2 years. The results were promising with significant improvements in infant feeding practices and a lower mean body mass index (BMI). The aims of this proposed Phase 2 study are to determine if the early intervention will lead to a lower mean BMI, lower screen time, improved dietary behaviours and demonstrated costeffectiveness of the intervention, in children aged 3½ and 5 years. **Methods/design:** In Phase 1 of HBT 667 families participated in the RCT. No further intervention will be carried out in HBT Phase 2. In this study the intervention and control groups will be compared for children's outcomes at ages 3½ and 5 years. Primary outcome measures will be 1) BMI, 2) selected dietary measures using a validated survey tool, and 3) physical activity and screen time using a new generation of tri-axial accelerometers. Intention to treat principles will be used in the analysis. Multiple imputation will be used to impute outcomes for subjects lost to follow-up. A cost-effectiveness analysis (CEA) and cost-utility analysis for both HBT Phase 1 and 2 will also be conducted. **Discussion:** This is the first time that a home-based early intervention strategy has been implemented to prevent the development of childhood obesity and obesity-conducive behaviours. The results of this trial will ascertain whether early intervention during the first 2 years of life is effective and cost-effective in preventing childhood overweight and obesity at 3½ and 5 years old.

Keywords

Healthy, beginnings, trial, phase, study, follow, cost, effectiveness, analysis

Disciplines

Arts and Humanities | Life Sciences | Medicine and Health Sciences | Social and Behavioral Sciences

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Healthy Beginnings Trial Phase 2 study: Follow-up and cost-effectiveness analysis

Li Ming Wen, Louise A. Baur, Chris Rissel, Vicki Flood, Judy M. Simpson, Alison Hayes, Louise L. Hardy, and Karen Wardle

Keywords: Randomised controlled trial; Obesity intervention; Children; Cost-effectiveness analysis; Multiple imputation

Abstract

Background: In 2007, we commenced the Healthy Beginnings Trial (HBT) Phase 1 study, which is the first randomised controlled trial (RCT) to test the effectiveness of an early childhood obesity intervention in children aged up to 2 years. The results were promising with significant improvements in infant feeding practices and a lower mean body mass index (BMI). The aims of this proposed Phase 2 study are to determine if the early intervention will lead to a lower mean BMI, lower screen time, improved dietary behaviours and demonstrated cost-effectiveness of the intervention, in children aged 3½ and 5 years.

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Discussion: This is the first time that a home-based early intervention strategy has been implemented to prevent the development of childhood obesity and obesity-conducive behaviours. The results of this trial will ascertain whether early intervention during the first 2 years of life is effective and cost-effective in preventing childhood overweight and obesity at 3½ and 5 years old.

1. INTRODUCTION

The early onset of obesity is evident with 6.7% of preschool-aged children being overweight or obese worldwide [1]. However, to date, no early interventions have been shown to be effective in preventing the early onset of overweight and obesity among young children [2]. Several factors that increase the risk of childhood obesity have been identified. Some, such as genotype and ethnicity [3] and [4], are immutable; others, such as the type of infant feeding, dietary macronutrient intake, family eating patterns, or levels of physical activity and screen time, are potentially modifiable [5], [6], [7], [8], [9], [10], [11] and [12].

Numerous studies have investigated interventions for preventing childhood obesity in school-aged children, but the results of many remain inconclusive due to the lack of long-term follow-up [2]. Dietary education and modification, with increased physical activity and reduced sedentary behaviours, remain central to any intervention. Multi-dimensional intervention approaches involving the family, school, community and government are required to prevent childhood obesity [13]. Ideally, these interventions should commence very early in life, as significant correlations have been demonstrated between infant and childhood BMI, and subsequent risk of progression to adult overweight and obesity [14] and [15].

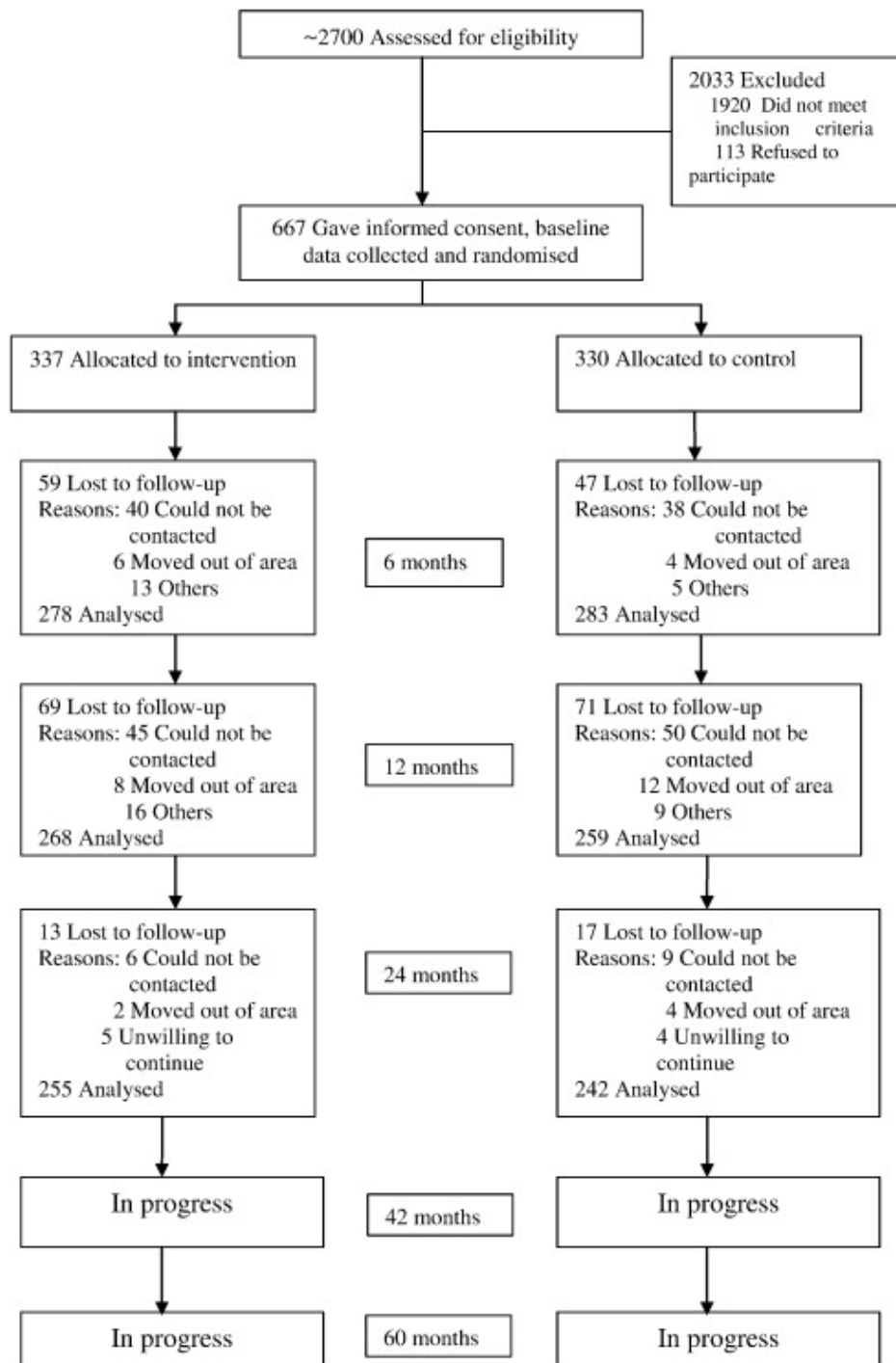
Multiple home visits are well established as interventions in areas such as cardiothoracic, geriatric and paediatric medicine. They have produced particularly good results for child health and social outcomes. Research in the US [16], UK [17] and Australia [18] indicates that home visits are suitable as a means of providing social support to parents and children in disadvantaged communities. Furthermore, such an intervention should ideally commence before the child is born, and continue into the early years of their life.

In 2007, we commenced the Healthy Beginnings Trial (HBT) [19], funded by a grant from the Australian National Health and Medical Research Council (NHMRC), to address this evidence gap. HBT, the first randomised controlled trial (RCT) to test the effectiveness of an early childhood obesity intervention delivered in the first 2 years of life, is a home-based early intervention designed to improve family and behavioural risk factors for childhood obesity. HBT is registered with the Australian Clinical Trial Registry (ACTRN012607000168459) and divided into two phases. Phase 1, which encompasses the intervention (from 0 to 2 years of age), has now been completed. Phase 2, which is the focus of this protocol, involves: 1) longer term follow-up of the cohort of children at ages 3½ and 5 years, and 2) economic evaluation of the intervention in both Phases 1 and 2.

In HBT Phase 1, the intervention group received eight home visits from a specially trained community nurse delivering the staged intervention, which comprised one home visit at gestational age 30–36 weeks, and seven visits at 1, 3, 5, 9, 12, 15 and 24 months after birth [19]. The timing of the visits corresponded to milestones in early childhood development and parent–child interactions, particularly with regard to healthy feeding practice, nutrition and the development of gross movement skills necessary for being physically active. The nurse provided staged advice in accordance with the NHMRC Dietary Guidelines [20] and the Australian National Physical Activity Guidelines for adults and children [21]. Parent–child interaction, parenting style and family support were discussed at each visit. A series of intervention materials were developed for each home visit. The control group received usual care (one-off visit by a community nurse) and intervention materials on home safety and smoking. Details of the HBT intervention can be found at the HBT website (www.healthybeginnings.net.au).

HBT Phase 1 was completed in December 2010. We recruited 667 first-time mothers from socially disadvantaged areas of south-western Sydney, Australia and 497 families were still participating at 24 months, a follow-up rate of 75% (see Fig. 1). The results of HBT Phase 1 at 12 months and 24 months are very encouraging. At 12 months, the intervention led to significant improvements in some infant feeding practices, including longer duration of breastfeeding, delayed introduction of solids, and increased use of a cup, and also resulted in earlier daily practice of “tummy time” [22]. The 24 months results are currently under review, but preliminary findings indicate significant improvements in children's vegetable

consumption, food not be used as a reward, less TV viewing time and a mean reduction in BMI for children in the intervention group.



HBT Phase 2 has been funded by the NHMRC (ID number: 1003780) and commenced in February 2011. The study will be completed in late 2014. The aims and protocol for this study are detailed below.

2. AIMS AND HYPOTHESES

The aim of HBT Phase 2 is to determine whether the Phase 1 early intervention has a longer term effect on child and family eating patterns, television viewing, physical activity and BMI. In addition, we will carry out a cost-effectiveness analysis of HBT in order to determine the cost in dollars of achieving the benefits of the intervention.

We hypothesise that, in children aged 3½ and 5 years, relative to the control group (receiving usual care), the intervention will result in:

Primarily

- lower mean body mass index (BMI);
- lower screen time i.e. TV, DVDs and computers;
- higher physical activity (i.e. active play) levels;
- improved dietary intake and eating behaviours:
 - increased vegetable and fruit consumption;
 - reduced sugary drink consumption and increased water consumption;
 - eating fewer meals in front of the television;
 - eating breakfast daily;
- demonstrated cost-effectiveness of the intervention;

Secondarily

- improved parenting behaviours related to healthy weight development;
- improved nutrition and physical activity levels and reduced small screen recreation in mothers and families; and
- improved quality of life of children, as measured by PedsQL and the Health Utilities Index.

3. DESIGN AND METHODS

In HBT Phase 2, we will conduct 1) follow-up data collection at ages 3½ and 5 years, and 2) cost-effectiveness analysis of the intervention. No intervention will be carried out in HBT Phase 2 (see Fig. 1). The study has been approved by the Ethics Review Committee of Sydney South West Area Health Service (RPAH Zone) and NSW Population and Health Services Research Ethics Committee (CINSW 2011/05/324).

3.1. The follow-up study

3.1.1. Study participants and recruitment

All 497 participating families who were still participating in HBT Phase 1 at 2 years are eligible for the Phase 2 study. At the end of Phase 1 an information sheet about the proposed study explaining the details of the further research involved will be distributed to participants and their consent to HBT Phase 2 will be sought. Participation in the study is voluntary and participants can withdraw at any time.

3.1.2. Retention strategies

Retention strategies employed during Phase 1 will continue into Phase 2 for all participants, and include: a) thank-you cards at the end of Phase 1, b) Christmas/New Year greeting cards,

c) promoting the study's identity through branding all study materials with the HBT logo, and d) obtaining contact numbers of participants' relatives (updated at each contact visit). Additional retention strategies for HBT Phase 2 include: 1) establishing a dedicated website about HBT; 2) birthday cards for participating children; 3) providing brief feedback to participants on their child's weight and height measures as well as accelerometry data; and 4) text message reminders for follow-up visits. In addition, a specially prepared newsletter on "Kids' Safety" will be sent 4 times a year to both control and intervention groups

3.1.3. Sample size estimation

Based on a 13.5% annual loss to follow-up (as in Phase 1), or 35% loss to follow-up over 3 years, we estimate that we will have a total of 324 participants remaining in the study by the end of HBT Phase 2. This would allow us to detect with 95% confidence and 80% power at age 5 the following differences between control and intervention groups: a) 0.36 kg/m² in mean BMI (SD = 1.15) (e.g. from current median BMI for 5 year old boys of 15.60 kg/m² to 15.24 kg/m², equal to a reduction in weight from 19.6 kg to 19.1 kg at median height 112 cm [23]); b) a 15% absolute difference in the percentage of children watching TV \geq 2 hours per day (current 65% v 50%) [23]; and c) a 15% absolute difference in the percentage of children consuming \geq 2 serves/day of vegetables, including potatoes (current 20% v 35%) [23].

3.1.4. Data collection

Two research assistants who have not been involved in HBT Phase 1 intervention will collect the data and will be blinded to participants' intervention/control status. To ensure measurement consistency, the Chief Investigators, together with experienced early childhood or paediatric nurses, will train the research assistants in the measurement of height, weight, and waist circumference in children, and in how to conduct semi-structured interviews in the home setting.

Participating families will be visited by a research assistant when the child is aged 3½ and 5 years. Appointments will be made at mutually convenient times with the parent or main carer (hereafter referred to as the parent). At each visit, the child's anthropometric measurements will be made and questionnaires will be administered. Objective information on the child's and the parent's physical activity will be collected by accelerometry. We will request that the child and the parent wear an accelerometer, while awake, for 5 consecutive days in order to capture habitual activity patterns. Parents will be shown how to fit and remove the accelerometers during the first visit and a time will be arranged to collect the accelerometer the following week.

3.1.5. Key outcome measures

The primary outcomes for HBT Phase 2 are child's BMI, screen time, physical activity, selected dietary intakes and eating behaviours. Secondary outcomes are parenting style, child quality of life measures, and the parent's physical activity, screen time and food habits.

3.1.5.1. Anthropometry: Height, weight and waist circumference will be measured using standard techniques in the home using a portable stadiometer, electronic scales and a non-extensible tape. BMI will be calculated as weight (kg)/height (m)².

3.1.5.2. Measurement of physical activity and sedentary behaviours (including screen time): Tri-axial accelerometry (GTX3, Actigraph, Pensacola, FL), released in 2009, will be used to measure children's activity objectively, including sitting time [24]. These accelerometers, the size of a matchbox and worn under the child's clothing, provide real-time data on the child's physical movement in 15-second epochs. This time frame will capture the

typical sporadic 'stop-start' movement of young children and provide precise information on both physical activity and, uniquely, time spent sitting and lying. The accelerometer is worn while awake for five consecutive days in order to capture habitual movement patterns. Parents will also be asked to report their child's screen time (TV, DVD/video and computer) separately for a usual weekday and weekends [25] and [26].

3.1.5.3. Measurement of dietary intake and eating behaviours: We will use a validated set of short questions to assess young children's food consumption and behaviours based on similar questions used by Epidemiology Branch of New South Wales (NSW) Health and validated in preschool-aged children in NSW [27] and [28]. Question topic areas include fruit and vegetable serves; quantity of specified beverages including sugary drinks; type of milk; frequency of consumption of processed meat, lean meats and snack foods; and eating behaviours including eating while watching TV and breakfast eating habits.

3.1.5.4. Secondary outcomes: Secondary outcomes include the parent's healthy eating habits and physical activity, TV viewing time and family function. Information on these outcomes will be collected using existing survey instruments in order to relate the findings to existing data, thereby contributing more systematically to the epidemiological picture. Survey items will include measures from the NSW Children and Adult Health Surveys, which have been developed and tested by the Epidemiology Branch of NSW Health [26] and [29]. The parenting style questions will be selected from the questionnaire used in Growing up in Australia: The Longitudinal Study of Australian Children (LSAC) [30]. Quality of Life will be assessed using the parent proxy report of PedsQL™, a paediatric quality of life instrument [31].

4. DATA ANALYSIS

Outcomes will be compared between the intervention and control groups at ages 3½ and 5 years. For continuous variables, means will be compared using *t*-tests, or non-parametric equivalents. For categorical variables, chi-squared tests will be used. Data will be analysed using Stata (StataCorp, College Station, Texas).

BMI will be calculated from height and weight data. Overweight and obesity will be defined using the International Obesity TaskForce cut-points for children [32]. Accelerometry data will be used to calculate the child's mean (or median depending on skewness) time (mins/day) spent sitting, standing without moving, and at different metabolic intensities of physical activity (i.e., light, moderate and vigorous), based on published cut-points [33]. Information on the type and context of the child's physical activity participation and screen time will be reported by the parent and integrated with accelerometry data to calculate, separately, time spent watching TV, DVD/videos and computer use, and time spent indoors and outside. The mean time (min/day) the parent spends in light, moderate and vigorous physical activity, and screen time will be determined from accelerometry and self-report questionnaire.

The short food frequency questionnaire will provide information about common food consumption patterns and habits. The mean, median or proportion within categories of responses, as appropriate, will be tested to assess differences between intervention and control groups, focusing particularly on fruit and vegetable consumption, cups of sugary drinks (fruit juice, soft drinks and cordials), water consumption, and the proportions consuming breakfast daily and eating in front of the TV.

'Intention to treat' principles will be used in all primary analyses. Multiple imputation will be used to impute outcomes for HBT Phase 2 participants lost to follow-up. In secondary analyses, predictors of BMI will be explored using hierarchical linear regression models to take into account within-child correlation.

4.1. The cost-effectiveness analysis (CEA) of the intervention

We will carry out both cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) of the intervention, undertaken from the perspective of the health care provider. We will collect data retrospectively on the costs to deliver the intervention program during the first 2 years of life from Sydney South-West Area Health Service financial records. These will include the costs of all resources needed to reproduce the program, but will exclude the research and development costs of the study and any evaluation costs. Hence intervention costs will only be accrued during the first 2 years of the study. The downstream costs of health service utilisation for children from birth to age 5 will be determined from a) GP visits and prescription costs as recorded in the Medical Benefits Schedule (MBS) and the Pharmaceutical Benefits Schedule (PBS), b) hospital costs from confidential linkage to NSW hospital and emergency department admission data. Consent to access MBS/PBS data and NSW hospital data will be sought separately from each parent. Aggregate costs will be determined for the intervention and control, and then costs/savings in healthcare utilisation associated with the intervention will be calculated.

During Phase 1, the primary outcome measures of the trial will be used to assess the cost-effectiveness of the program compared with usual care. Incremental cost-effectiveness ratios will be calculated in terms of the incremental cost: a) per additional infant breastfed to 6 months; b) per additional infant breastfed to 12 months and c) per unit BMI reduction at 2 years.

In the Phase 2 cost-effectiveness analysis, incremental cost-effectiveness ratios will be calculated in terms of the incremental cost a) per BMI reduction at 3½ and 5 years and b) per extra child achieving a clinically significant increase in physical, psychosocial and total score of the PedsQL paediatric quality of life instrument. For the cost-utility analysis, incremental cost-effectiveness ratios will be calculated per quality adjusted life year (QALY) gained within the first 5 years of life. We will determine preference-based quality of life weights using the Health Utilities Index (HUI2) [34], a validated questionnaire which may be used in children aged 5 years.

Incremental cost-effectiveness ratios will be calculated using standard techniques. In order to reflect the variation in mean costs and outcomes, bootstrapping will be used to estimate a distribution around these variables, and to calculate confidence intervals around the incremental cost-effectiveness ratio. Cost-effectiveness acceptability curves will be constructed. These provide information about the probability that an intervention is cost-effective, given a decision maker's willingness to pay for incremental benefits. The cost-utility analysis will enable policy makers to compare the benefits of this intervention with quite disparate interventions since the output metric in quality adjusted life years is common.

5. DISCUSSION

We believe that the results of HBT Phase 2 will fill an important knowledge gap. First, without HBT Phase 2, it is unlikely that an appropriate weight-focused evaluation can be

made of HBT Phase 1. Longer follow-up beyond the initial 2 years will determine whether, and for how long, this intervention is able to modify obesity-related behaviours and prevent childhood overweight/obesity during the first 5 years of life. Longer-term follow-up will provide important information on the overall evaluation and efficacy of a home-based intervention aimed at children who are at high risk of developing overweight and obesity, and will also determine whether the HBT is acceptable within the community and is sustainable.

Second, the Cochrane review of childhood obesity prevention interventions in school-aged children [2] indicated that most interventions were short-term (< 1 year), and were effective in modifying dietary education and levels of physical activity but not in preventing obesity in children in the long term. This indicates the need for other, possibly differently designed, intervention strategies and the need to have long-term follow-up.

Third, through extended follow-up, studies using home-based interventions for other health outcomes have shown long-term positive outcomes. In a US study, mothers and babies who received home visits until age 2 years were followed for a total of 9 years after enrolment. Compared with the control group, the intervention group showed better outcomes related to mothers' fertility and children's functioning at 2, 4, and 7 years [16]. Without the long-term follow-up of HBT participants, the effectiveness and sustainability of this early intervention program in the Australian context will remain unknown.

Fourth, a number of studies on changing children's recreational screen time, and TV time in particular, have concluded that the promising results could only be detected over a long period in older children. This supports the need for following up children, post-intervention, for several years [35] and [36].

Finally, the economic evaluation will enable policy makers to assess both the cost of this intervention and the cost-effectiveness i.e. whether the demonstrated benefits represent 'good value for money'. Furthermore, where outputs in QALYs are possible (within a cost-utility analysis), comparison of the intervention with quite disparate interventions/health outcomes is possible. It will help inform policy decisions about which interventions for childhood obesity might be the most suitable to fund within a limited healthcare budget.

In conclusion, HBT is the first study of an early home-based intervention aimed at preventing overweight in young children. Novel aspects of the current study are the planned longer-term follow-up of children to age 5 years, and the economic evaluation. This long-term prospective cohort study will generate new knowledge about the appropriateness, effectiveness and sustainability as well as cost effectiveness of this strategy. Evidence produced by this study will enable policy makers and health professionals to determine appropriate public health responses to tackle the obesity epidemic.

Competing interests: All authors declare that they have no competing interests in this Healthy Beginnings Trial.

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