

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

Infant feeding practices, including breast feeding<sup>14 15</sup> and the timing of the introduction of solids,<sup>16 17</sup> as well as children's eating habits<sup>18</sup> and time spent watching television (TV),<sup>19 20</sup> are among the most identifiable factors contributing to early onset of childhood obesity.<sup>13</sup> Infant feeding practices not only influence children's eating behaviours but also lay the foundation for adult eating habits.<sup>21</sup> There is also evidence that the early risk factors for obesity are more prevalent in lower socioeconomic groups.<sup>22</sup> Few high quality interventions aimed at preventing early onset overweight or obesity among young children have been implemented effectively or rigorously evaluated.<sup>23</sup> 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.<sup>24</sup> 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.<sup>25</sup> This is a randomised controlled trial

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Extra material supplied by the author (see <http://www.bmj.com/content/344/bmj.e3732?tab=related#webextra>)

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.<sup>26</sup> 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.<sup>25</sup>

### 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 disadvantaged families.<sup>27-29</sup> It was developed through a pilot study<sup>30</sup> 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/](http://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.<sup>31 32</sup> 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.<sup>26</sup>

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

**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.<sup>35</sup> 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.<sup>36</sup>

**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<sup>37</sup> 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.<sup>38</sup>

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.<sup>35, 37</sup>

## 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.<sup>31</sup>

## 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.<sup>33</sup> 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.<sup>32</sup> Median intake a day was two servings of vegetables or fruit, as reported by participating mothers at the baseline.<sup>38</sup>

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  $\chi^2$  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 1). 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<sup>4-10</sup> 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.<sup>24</sup> Given that BMI is one of the best measures of change in adiposity in growing children,<sup>33</sup> 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.<sup>24</sup> Currently, a long term follow-up and cost effectiveness analysis of the Healthy Beginnings Trial is underway.<sup>39</sup>

### 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.<sup>40</sup> 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,<sup>24</sup> 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.<sup>27-29</sup> 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.<sup>24</sup> 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.<sup>39</sup>

### 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.<sup>25</sup> 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.

We thank all the participating families; the associate investigators (Anita Bundy and Lynn Kemp) and the members of the steering committee and working group for their advice and support; members of the project team including Carol Davidson, Cynthia Holbeck, Dean Murphy, Lynne Ireland, Brooke Dailey, Kerrie Ruff, Emma Wood, Kim Caines. and Angela Balafas; Maria Domenico for conducting the telephone interview at six months; James Kite and Therese Carroll for their support in setting up the database and Hui Lan Xu for assisting with data entry and analysis; and Garth Alperstein for his contribution to the development of the trial and the procurement of the funding.

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.

Funding: This study was funded by the Australian National Health and Medical Research Council (ID No 393112).

Competing interests: All authors have completed the ICMJE uniform disclosure form at [www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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.

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**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

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**Accepted:** 04 May 2012

Cite this as: *BMJ* 2012;344:e3732

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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 (95% CI)	P value
	Intervention	Control		
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 to 16.99)	−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*
<b>Children</b>				
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
<b>Mothers</b>				
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  $\chi^2$  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.<sup>28</sup>§At baseline median intake/day was two serving of vegetables or fruit.<sup>32</sup>¶No national guidelines for adults, but for children aged 12-18, recommended maximum is 2 hours/day.<sup>28</sup>

**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)
<b>Children</b>		
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
<b>Mothers</b>		
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.

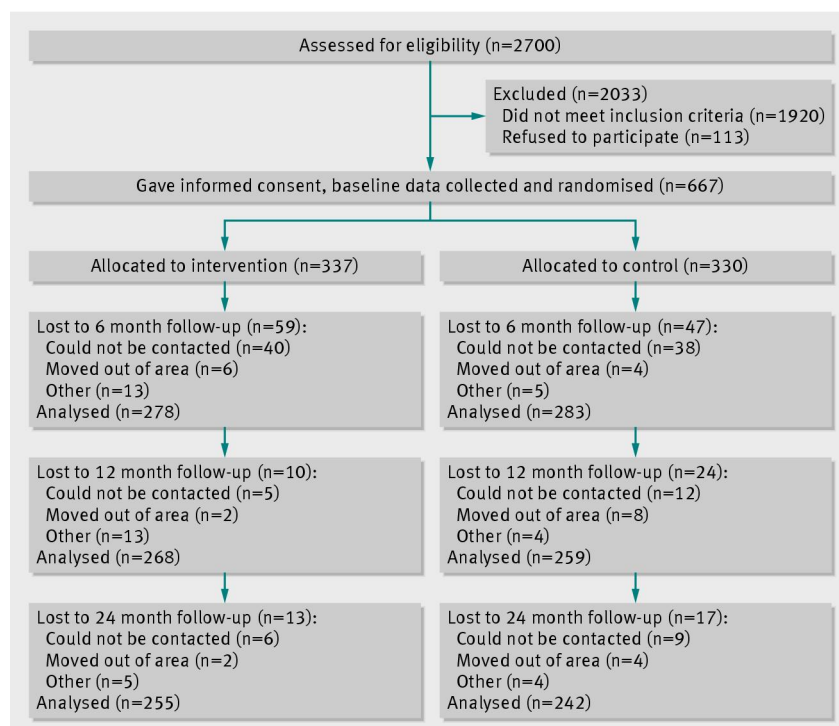
†One serving of vegetables=half cup cooked or one cup of salad; one serving of fruit=one medium piece or two small pieces or one cup of diced pieces. One cup=250 mL.

‡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.<sup>28</sup>

§At baseline median intake/day was two serving of vegetables or fruit.<sup>32</sup>

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

## Figure



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