The Melbourne Infant Feeding, Activity and Nutrition Trial (InFANT) Program Follow-Up

Kylie D Hesketh[a]*, Karen Campbell[a], Jo Salmon[a], Sarah A McNaughton[a], Zoe McCallum[b], Adrian Cameron[a], Kylie Ball[a], Lisa Gold[c], Nick Andrianopoulos[a], David Crawford[a]

[a] Centre for Physical Activity and Nutrition Research, Deakin University, 221 Burwood Hwy, Burwood, Melbourne VIC Australia, 3125

[b] Department of Paediatrics, University of Melbourne, Royal Children's Hospital, 50 Flemington Rd, Parkville, Melbourne VIC Australia, 3052

[c] Deakin Health Economics, Deakin University, 221 Burwood Hwy, Burwood, Melbourne VIC Australia, 3125

Email: Kylie D Hesketh* - kylie.hesketh@deakin.edu.au; Karen Campbell - karen.campbell@deakin.edu.au; Jo Salmon - jo.salmon@deakin.edu.au; Sarah A McNaughton - sarah.mcnaughton@deakin.edu.au; Zoe McCallum - Zoe.McCallum@rch.org.au; Adrian Cameron - adrian.cameron@deakin.edu.au; Kylie Ball - kylie.ball@deakin.edu.au; Lisa Gold - lisa.gold@deakin.edu.au; Nick Andrianopoulos - nick.andrianopoulos@deakin.edu.au; David Crawford - david.crawford@deakin.edu.au

*Corresponding Author. Tel: +61-3-9244 6812. Fax: +61-3-9244 6017

Abstract

Background: The Melbourne Infant Feeding, Activity and Nutrition Trial (InFANT) Program, is a community-based, cluster-randomised controlled trial of an obesity prevention intervention delivered to first-time parents of infants from age 3- to 18-months. Conducted from 2008 to 2010, the program had high uptake and retention and showed positive impacts on some dietary outcomes and television viewing. Funding was secured for a follow-up study of participants two and 3.5 years post intervention (at child ages ~3.5 and 5 years). The follow-up study aims to assess intervention effects, mediators and moderators of effects, and program cost-effectiveness over the longer term.

Methods/design: The 492 families still enrolled in the Melbourne InFANT Program at intervention conclusion will be recontacted and renewed consent sought to participate in this follow-up study. No further intervention will occur. Home visit data collections will occur approximately two and 3.5 years post intervention. Main outcomes to be assessed include child body mass index, waist circumference, diet (3 x 24-hour recalls; food frequency questionnaire), physical activity (8 days ActiGraph accelerometer data; parent reported active play) and sedentary time (8 days ActiGraph accelerometer and ActivPAL inclinometer data; parent reported screen time).

Discussion: Follow-up of participants of the Melbourne InFANT Program, at two and 3.5 years post intervention will allow assessment of longer term intervention effects, investigation of potential mediators and moderators of such effects, and economic evaluation of the longer term outcomes. This information will be valuable to researchers and policy makers in progressing the field of early childhood obesity prevention.

Trial registration: Current controlled Trials ISRCTN81847050

Keywords: randomized controlled trial, early childhood, obesity, prevention

List of Abbreviations

InFANT: Infant Feeding, Activity and Nutrition Trial

Background

The prevention of childhood overweight and obesity is an international health priority [1]. Similar to other developed nations, the prevalence of overweight and obesity in young children in Australia is high, with 17% of 2-3 year olds overweight and 4% obese [2]. The high prevalence of overweight and obesity in young children is concerning as weight gain in the first two years of life is associated with a 2-3 fold increase in risk of later overweight [3, 4] and most excess weight gained before puberty is gained by the age of five years (91% girls, 70% boys) [5]. Further, excess weight is recognised to have negative impacts on children's health and wellness during childhood and through to adult life [6, 7].

Behaviours that promote unhealthy weight gain over the life-course are acquired during early childhood [5, 8] and show evidence of tracking [9-14]. Data [15-19] show that from an early age many children consume large amounts of high energy foods and drinks and relatively few fruits and vegetables. For example, 90% of 18-month old Australian children consume energy-dense snack foods daily, with foods considered as "non-core" providing 27% of total energy intake [16]. Evidence of low levels of physical activity and high levels of sedentary behaviours (e.g. television viewing) in early childhood also exists. For example, international studies [20-22] report that 3-5 year old children spend only 3-12% of their time in moderate- to vigorous-intensity physical activity. Similarly, Australian 3-5 year old children spend only 16% of their time in physical activity (of which 5% of their time is in moderate-to-vigorous physical activity), with 84% of their time spent in sedentary pursuits [23]. Further, Certain [14] reported that 17% of 0-11 month olds, 48% of 12-23 month olds, and 41% of 2-3 year olds in the United States watch more than two hours of television per day.

Early childhood thus provides a unique opportunity to establish lifestyle behaviours that will promote health and minimise the risk of obesity and its associated co-morbidities throughout life.

Despite this, few interventions have targeted early childhood and fewer still have focused on the first two years of life when dietary, physical activity and sedentary behaviour habits are first being acquired [24]. Reviews of existing childhood obesity prevention interventions [24-26] highlight that parent involvement is a key component of intervention success in this age group, that most existing interventions are too intensive and unlikely to be adopted into existing public-health service delivery infrastructures, and that limitations of most existing interventions include a lack of follow-up post intervention and failure to include economic evaluation.

In 2008, we commenced the Melbourne Infant Feeding, Activity and Nutrition Trial (InFANT) Program, designed to address these gaps in evidence. The Melbourne InFANT Program is registered with the International Standard Randomised Controlled Trial Number Register (ISRCTN81847050) and the protocol for the intervention phase of the study has been published [27]. In brief, the Melbourne InFANT Program was a cluster-randomised controlled trial of a community-based early obesity prevention program which has capacity to be integrated into existing service delivery systems. The intervention comprised 6 x 2 hour sessions delivered every 3 months to first-time parents from when infants were approximately three months of age. Sessions were delivered within existing first-time parent groups that are established by community Maternal and Child Health Nurses as part of the free universal health care system in Melbourne, Australia, and have been shown to continue without facilitation for approximately 18-months [28]. The Melbourne InFANT Program commenced where the Maternal and Child Health Nurse involvement with the groups ceased and parents took over their own management of the groups (at approximately child age 4-months). The Program sessions took an anticipatory guidance approach, focusing on what and how to feed, active play opportunities, alternatives to screen time and restraint, and parent modelling of healthy eating, physical activity and reduced sedentary behaviours. The group format promoted discussion of strategies, successes and overcoming barriers to key messages. The control group received usual care as well as quarterly newsletters (six in total) on general child health topics not related to obesity-promoting behaviours. Strengths of the study included: comprehensive

assessment of targeted behaviours using gold standard methods (objective assessment of body mass index (BMI), physical activity and sedentary time, and three 24-hour dietary recalls); use of existing social groups to facilitate support and increase intervention dose by non-facilitated contacts between sessions; public health utility as the program has been developed to be both low dose and community-based allowing feasible transfer into existing public health infrastructures; high recruitment and retention rates; and incorporation of an economic evaluation.

The intervention phase of the Melbourne InFANT Program concluded in March 2010. A total of 62 first-time parent groups (84% response) from 14 local government areas in Melbourne, Australia (three low, eight mid and three high socio-economic areas) were enrolled in the study. Within these groups 542/630 parents (86% response) consented to take part in the study. At intervention conclusion 91% of participants were retained in the sample. Results of the intervention phase of the Melbourne InFANT Program are currently under review and indicate parents found the program to be useful and relevant and, compared with the control group, there were more favourable lifestyle behaviours of infants and their mothers in the intervention group. Infants in the intervention group had significantly lower consumption of non-core drinks mid-intervention (mean age 9.1 (SD= 1.2) months). At intervention conclusion (mean child age 19.9 (SD= 2.7) months), children in the intervention group consumed fewer sweet snacks and spent less time watching television than children in the control group, and their mothers had more favourable dietary patterns. While no intervention effect was found for child BMI z-score, it is plausible that over the longer term, persistent changes in parenting practices and obesity-promoting behaviours may have a flow on effect to weight change.

The Australian National Health and Medical Research Council (NHMRC) has funded (Project Grant No. 1008879) follow-up of the Melbourne InFANT Program participants two and 3.5 years post intervention (at ages approximately 3.5 and 5 years; see Figure 1). Follow-up commenced mid-2011

and is due to be completed by the end of 2013. This paper details the aims and protocols for this follow-up study.

Aims and hypotheses

The aim of the Melbourne INFANT Program follow-up is to assess whether differences observed between intervention and control groups at the conclusion of the obesity prevention intervention (mean child age 20 months) are maintained two and 3.5 years post intervention (child age approximately 3.5 and 5 years) without further intervention, whether any longer term effects of the intervention are observed, and to assess mediators and moderators of any intervention effect. In addition, an economic evaluation of the program will be undertaken.

Our primary hypotheses are that:

In comparison with control group children, children whose parents received the intervention will, at 3.5 and 5 years of age:

- have lower BMI z-score;
- have smaller waist circumference;
- demonstrate higher levels of physical activity;
- demonstrate less time spent sedentary;
- consume a greater quantity and variety of fruits;
- consume a greater quantity and variety of vegetables;
- consume less non-core drinks;
- consume less energy-dense snack foods

Secondarily, we hypothesise intervention success for child adiposity, diet, physical activity and sedentary behaviours will be explained by mediators and moderators[1] including:

- parenting constructs - feeding practices; feeding strategies; practices and rules regarding limiting children's sedentary time; knowledge, beliefs and attitudes regarding child nutrition, physical activity and sedentary time; modelling of healthy eating, physical activity and sedentary time; parental self-efficacy (confidence) regarding their ability to positively influence their child's diet, physical activity and sedentary behaviours;
- home environment characteristics - food availability, physical activity opportunities (e.g. play equipment), sedentary behaviour opportunities (e.g. televisions, electronic games);
- family characteristics (e.g. socio-economic position);
- parent characteristics (e.g. maternal age); and
- child characteristics (e.g. child temperament).

Further, we hypothesise that this intervention will provide a cost-effective approach to early life obesity prevention.

Methods/Design

The Melbourne INFANT Program follow-up will involve data collection two and 3.5 years post intervention. No further intervention will be carried out in this phase of the program. The study has been approved by the Deakin University Human Research Ethics Committee (2007-175).

Study participants and recruitment

All 492 families who were still enrolled in the program at the end of the intervention are eligible for the follow-up phase of the study. All families will be recontacted and invited to participate in the

[1] *all will be tested as mediators with the exception of child gender, maternal education and socioeconomic position which will be tested as moderators.*

follow-up; renewed written consent will be sought. Retention strategies have been employed since the completion of the intervention including annual newsletters, birthday and season's greetings cards.

Sample size estimation

At intervention conclusion, the retained sample in the Melbourne InFANT Program was 492 families with similar numbers lost from intervention and control groups. Assuming a further 20% loss to follow-up at each of the two follow-up assessments, we estimate having sample sizes of 394 (73% of original sample) and 315 (58%) families at the two and 3.5 years post intervention follow-ups respectively (child age 3.5 and 5 years respectively), with approximately equal numbers in intervention and control groups.

Australian data [2] on the primary outcomes of this study show that mean (SD) BMI, weight and waist measurements are 16.5(1.5)kg/m2, 16.4(2.2)kg and 51.1(3.8)cm respectively for 3 year olds and 16.4(1.7)kg/m2, 21.3(3.6)kg and 54.5(4.6)cm for 5 year olds. Three and 5 year old children, respectively, consume an average of 85(82)g / 92(85)g of vegetables (not including potato), 202(129)g / 229(145)g of fruit and 78(121)mL / 125(194)mL of non-core drinks daily [2], and spend an average of 117(30)min/day / 108(27)min/day being active and 662(71)min/day / 676(61)min/day being sedentary [23].

Assuming 5% Type I and 20% Type II error rates and approximately equal numbers of participants in the intervention and control groups, the minimum detectable difference between groups, with a set overall sample size (N) is calculated as: % detectable difference = SD*√32/(mean*√N)

Thus, the estimated sample sizes of 394 and 315 at the two follow-up data collections will allow us to detect differences between intervention and control groups at 3.5 and 5 years of age, respectively, of at least: 3/3% in BMI (i.e. 0.4/0.5kg/m2); 4/5% in weight (i.e. 0.6/1.2kg); 2/3% in waist circumference (i.e. 1.1/1.5cm); 28/29% in vegetable consumption (i.e. 23/27g, equivalent to

approximately ⅓ of a serve a day); 18/20% in fruit consumption (i.e. 37/46g, equivalent to approximately ½ a serve a day); 44/50% in sweetened drink consumption (i.e. 34/62mL/day); 7/8% in active time (i.e.9/9min/day); and 3/3% in sedentary time (i.e. 21/20min/day).

Data collection

All data will be collected via home visits. Research staff will schedule visits at times convenient to the families. Questionnaires will be posted to families prior to home visits and collected at the visit. Where questionnaires have not been completed prior to the visit, parents will be given the option to complete the questionnaire with the assistance of research staff at the home visit or to return the questionnaire by post once completed. Dietary recalls will be conducted after the home visits, and will be unscheduled to minimise bias. Based on our previous experience, it is estimated the average time taken for parents to complete the questionnaires will be approximately 45 minutes, home visit assessments will take approximately 15 minutes, and each of the dietary recalls will take approximately 20 minutes. Parents will be compensated for their time with a $20 gift voucher at each wave of assessment.

Key outcome measures

Anthropometry

Height, weight and waist circumference will be measured by study staff who will undergo training with a paediatrician specialised in clinical nutrition. Weight will be measured using a calibrated scale and height using a calibrated stadiometer. Waist circumference (minimum circumference between the lower border of the ribs and iliac crest) will be measured using a calibrated non-stretch tape measure. BMI z-score will be calculated using WHO growth standards [29].

Measurement of physical activity and sedentary behaviours

At the home visit children will be fitted with an ActiGraph accelerometer which they will wear for eight consecutive days (which will capture weekday and weekend day activity and sedentary patterns) [30]. ActiGraph monitors are small, light and unobtrusive and are worn on a belt around the waist. This methodology was successfully employed during the intervention conclusion data collection when children were aged approximately 20 months. ActiGraph counts correlate (up to r=0.70) with energy expenditure estimated by direct observation and doubly-labelled water respectively, among 3-5 year old children [31, 32] and correlate highly (r=0.87) with energy expenditure estimated by indirect calorimetry among children [33]. Counts will be recorded at 15-second epochs to accurately capture the sporadic and intermittent activity patterns of young children. Data will be downloaded and then reduced to total counts/day, minutes/day and percentage of time spent sedentary, and in light-, moderate- and vigorous-intensity physical activity using age-appropriate cut points [34]. In addition, indirect measures of children's physical activity will be assessed by parental report including: parental engagement in physically active play and number of hours the child typically spends playing outdoors on weekdays and weekend days.

In addition, children's time spent sitting throughout the day will be objectively assessed using activPAL monitors [35-37], worn for eight consecutive days at the same time as the accelerometer. These monitors are small, light and unobtrusive, attach midway between the knee and hip (positioned at the front of the thigh), with the unit enclosed in a small pocket in an elasticised belt worn on or under clothing. ActivPAL monitors contain an inclinometer which provides information on the vertical or horizontal position of the femur (upper leg) and can therefore record when the child is sitting/lying or standing up and data are recorded in 'real time'. In addition, parents will be asked to indicate how much time (hours/minutes) their child usually spends watching television/DVD and playing electronic games in a typical week (Monday-Friday) and on a typical weekend (Saturday and Sunday). Test-retest reliability of these items in a previous study ranged from ICC= 0.5-0.9 [38]. Parental reports of their child's "usual" TV viewing has been shown to

correlate with both videotaped observations of the child's TV viewing [39] and with parental diaries of viewing [40].

Measurement of dietary intake and eating behaviours

Data will be collected using the 24-hour recall method [41]. Primary carers will be interviewed by telephone on three non-consecutive days, including one weekend day (thus capturing three separate days of dietary data) and asked to recall all food and drink consumed by their child during the past 24 hours. In the event that children were cared for in this period by persons other than the primary carer, this person(s) will be contacted within 48 hours of the nominated dietary recall period to obtain additional information using standardised procedures [42]. Visual aids will be provided to primary carers in advance of interviews to help in estimation of quantities of food consumed. Data will be coded using the dietary analysis program 'Foodworks' [43] which utilises the most up to date food composition data for Australian children [44]. Parents will also be asked to complete a 79-item food frequency questionnaire which will be validated against the recall data.

Assessment of mediators and moderators

Potential mediators and moderators will be assessed via parent-completed written questionnaires. Data collected will cover: parenting constructs such as feeding behaviours and strategies [45], knowledge, beliefs, attitudes, self-efficacy [46] and modelling (assessing parents' own diet [47], physical activity [48] and sedentary behaviours [49]); home environment characteristics including food availability [50], physical activity and sedentary home environment [38, 51]; family, parent and child characteristics including family composition, parental education, employment status, child temperament, child sleep and time spent in childcare; and cost consequences including use of health related services and resources. Where possible validated instruments will be used and where these are not available for this age group, purpose-designed questions will be developed and test-retest

reliability and internal reliability analyses will be conducted. In addition maternal height and weight will be measured by research staff at home visits where possible or self-reported.

Data analyses

Intervention effects will be assessed based on intention to treat principles and taking into account the cluster-based sampling design. Longitudinal regression models will be used to compare primary outcome variables between intervention and control groups, adjusted for baseline values where appropriate (infants were not consuming foods nor mobile at baseline, i.e. 3 months of age, hence adjustment for diet or physical activity variables is not possible). Appropriate adjustment for multiple outcome comparisons will be considered as well as comparative interpretation of results based on effect sizes.

Investigation of mediators of intervention outcomes will be undertaken using sequential linear regression analyses, adjusting coefficients for clustering associated with the sampling design. After having assessed the direct effect of the intervention on each of the key outcome variables (τ), regression analyses will assess the impact of the intervention (i.e. compare intervention and control groups) on each of the proposed mediators (α). Impact of mediator variable residual change scores (i.e. change in mediator variable adjusted for baseline) on key outcomes will then be assessed, controlling for intervention group and baseline level of key outcome where possible (baseline measures of child diet and physical activity are not possible in this young sample)(β). An estimate of the magnitude of the mediating effect will be assessed by multiplying α by β, using the products of coefficient method[52] which assesses statistical significance by dividing the products of the α and β coefficients by its standard error. The percentage of any longer term outcomes that is explained by each of the potential mediators is then calculated as the magnitude of the mediating effect divided by the direct effect of the intervention ($\alpha*\beta/\tau$).

Investigation of moderators of longer term intervention effects will be undertaken using linear regression analyses to assess differences in the key outcomes (all continuous variables) between intervention and control groups, with investigation of potential moderating variables i.e. child gender, maternal education, family- and area-level socioeconomic position.

Economic evaluation

Economic evaluation of interventions is important, particularly when assessing public health utility. To assess the cost-effectiveness of the program, an economic evaluation will be designed, building on and extending the current Melbourne INFANT Program cost-consequences analysis. The economic evaluation will present a cost-consequences analysis as a first step, to compare incremental costs of the intervention (costs accrued in the intervention arm compared to costs accrued in the control arm) to the full list of incremental outcomes at child age 3.5 and 5 years, all expressed in their natural units of measurement. The economic analysis will then assess the longer-term cost-effectiveness of the Melbourne InFANT Program in terms of the additional cost per additional unit change in BMI as the pre-specified primary outcome measure of the intervention. Uncertainty in the cost and outcome data, and sensitivity of economic evaluation results to the methods of evaluation chosen, will be tested through extensive sensitivity analyses. Uncertainty in the cost and outcome data, and sensitivity of economic evaluation results to the methods of evaluation chosen, will be tested through extensive sensitivity analyses. Probabilistic sensitivity analysis will be used to reflect statistical variation in the trial data and to assess the impact of uncertainty in unit cost estimates and evaluation parameters (such as the discount rate) on cost-effectiveness results.

Discussion

A valid criticism of intervention research in the field of obesity prevention is the consistent failure to assess longer term effects of interventions [24, 26]. This is particularly important when considering

obesity prevention interventions in children as parental knowledge, skills and practices have the capacity to influence obesity-promoting behaviours over the longer term [53]. Research suggests that without intervention, parents' self-efficacy regarding their capacity to influence their child's lifestyle behaviours diminishes over the first five years of life [46]. This reduction in self-efficacy is associated with less desirable child eating and sedentary behaviours [46]. Further, evidence suggests that diet quality [2] and physical activity levels [22] decline while time spent in sedentary pursuits increases [22] across the early childhood years. Assessing maintenance of intervention outcomes observed in the Melbourne InFANT Program, across the critical early childhood period (0-5 years), is therefore important, as is assessment of whether early intervention results in the emergence of new benefits over the longer-term regardless of initial intervention effect.

Interventions are generally designed to impact intermediary factors (mediators) that consequently lead to changes in the primary outcomes. The investigation of mediator variables can help to explain how an intervention achieves and/or maintains success [54] (i.e. which factors the intervention may have changed that in turn led to desired changes in the outcomes of interest; the mechanisms of behaviour change). Mediating variables can also help to explain why an intervention did not achieve or maintain success, thus investigation of such variables is not predicated on an intervention having achieved changes in the outcomes of interest. Individuals receiving the same intervention may have different outcomes, with some achieving and/or maintaining behaviour change while others do not. Investigation of moderating variables can help identify for whom an intervention achieves and/or maintains success (i.e. which characteristics of participants predict successful maintenance of intervention effects or longer term impacts, e.g. gender, socioeconomic position). Such information may assist in tailoring early childhood obesity prevention interventions to different population groups for maximal effect.

It has been shown that variables that predict behaviour change are not necessarily the same variables that predict maintenance of behaviour change [55]. Further, it has been argued that some

mediators may be more important in the short-term (e.g. cognitive processes), while other mediators (e.g. parenting practices) may be more important in the long-term [56]. Assessing mediators and moderators of short-term intervention effects, and of variables that may mediate maintenance of successful outcomes of the Melbourne InFANT Program will help to identify aspects of the intervention that are important for longer term success, information that will help inform future early childhood obesity prevention strategies.

In conclusion, the Melbourne InFANT Program is a novel, community-based early obesity prevention program for parents delivered within existing social groups which had high uptake and retention. Some positive outcomes were observed at conclusion of the intervention. Follow-up of participants will allow assessment of maintenance of intervention effects and whether additional effects are evident over the longer term to child age 3.5 and 5 years. A novel aspect of the follow-up study is assessment of potential mediators and moderators of intervention effects which will allow a more in-depth understanding of the mechanisms by which the intervention achieved its effects and the groups for whom the intervention had most impact. Both the initial intervention and the follow-up incorporate economic evaluations allowing assessment of the cost-effectiveness of the intervention.

Competing Interests

The authors declare that they have no competing interests.

Author's contributions

KH took the lead in writing and designing the follow-up study subsequently funded by a National Health and Medical Research Council Grant. She also led the modification of this grant for publication.

KC contributed to the overall concept and design of the follow-up study and assisted with the writing of the grant and this manuscript.

DC, JS, SM, ZM, AC, KB, LG, NA provided expert input and support overall for the writing of the grant and this manuscript.

All authors read and approved the final manuscript.

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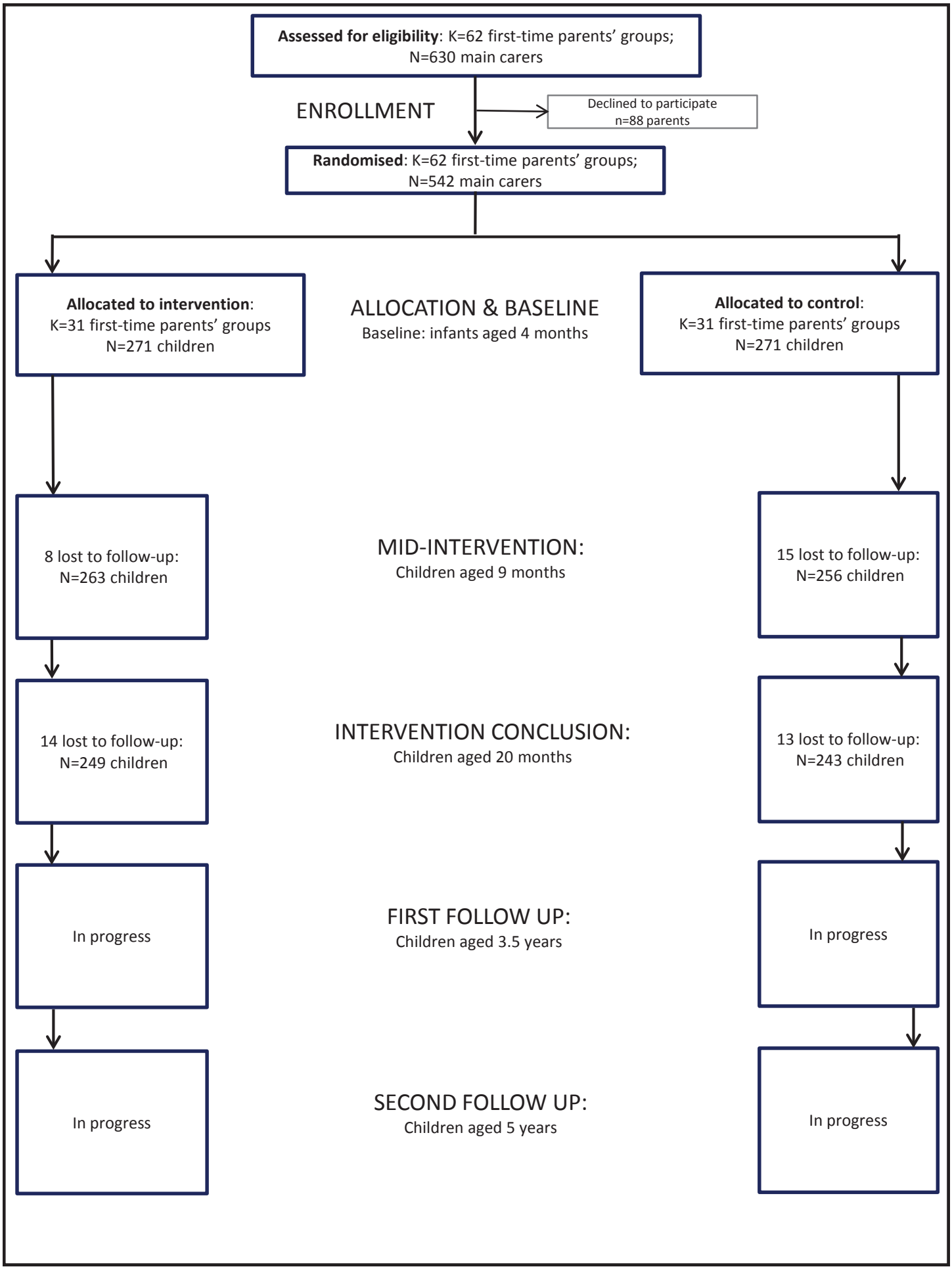
Figure 1: Flowchart of participants and timing of data collection for the Melbourne InFANT Program.

Attached


Assessed for eligibility: K=62 first-time parents' groups; N=630 main carers
ENROLLMENT
Declined to participate n=88 parents
Randomised: K=62 first-time parents' groups; N=542 main carers
Allocated to intervention: K=31 first-time parents' groups N=271 children
ALLOCATION & BASELINE
Baseline: infants aged 4 months
Allocated to control: K=31 first-time parents' groups N=271 children
8 lost to follow-up: N=263 children
MID-INTERVENTION:
Children aged 9 months
15 lost to follow-up: N=256 children
14 lost to follow-up: N=249 children
INTERVENTION CONCLUSION:
Children aged 20 months
13 lost to follow-up: N=243 children
In progress
FIRST FOLLOW UP:
Children aged 3.5 years
In progress
In progress
SECOND FOLLOW UP:
Children aged 5 years
In progress