

The Infant Feeding Activity and Nutrition Trial (INFANT) an early intervention to prevent childhood obesity: cluster-randomised controlled trial

Submission date 07/11/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 07/01/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/04/2023	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.deakin.edu.au/health/cpan/infant/index.php>

Contact information

Type(s)

Scientific

Contact name

Dr Karen Campbell

Contact details

221 Burwood Highway
Burwood, Victoria
Australia
3125

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

425801

Study information

Scientific Title

The Infant Feeding Activity and Nutrition Trial (INFANT) an early intervention to prevent childhood obesity: cluster-randomised controlled trial

Acronym

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

Study objectives

Aim:

This study aims to test the effectiveness of a childhood obesity prevention intervention delivered to first-time parents and focused on parenting skills which support the development of positive diet and Physical Activity (PA) behaviours, and reduced Sedentary Behaviours (SB) in infants.

Hypotheses:

In comparison to the control group infants, over the course of the intervention, the intervention group infants will:

1. Demonstrate greater increases in consumption of fruits and vegetables, and smaller increases in consumption of cordials, soft-drinks and juices and energy-dense snack foods
2. Demonstrate greater increases in time spent being physically active and smaller increases in time spent in sedentary behaviours, specifically Television (TV) viewing
3. Exhibit reduced incremental Body Mass Index (BMI) gain

In comparison to the control group parents, the intervention group parents will demonstrate greater increases in:

4. The frequency with which they offer fruit and vegetables, water and milk (rather than cordials, soft-drinks and juices), and smaller increases in the frequency with which they offer energy-dense snack foods to their child
5. Knowledge regarding infant eating, physical activity and sedentary behaviours and greater development of positive attitudes/beliefs regarding their capacity to influence these behaviours
6. The adoption of desired feeding strategies, including the division of responsibility in feeding and in providing opportunities for modelling of healthy eating
7. The adoption of strategies, including modelling, for increasing opportunities for physical activity and reducing opportunities for sedentary behaviours

Ethics approval required

Old ethics approval format

Ethics approval(s)

Deakin University Human Research Ethics Committee - Health Medicine Nursing and Behavioural Sciences Subcommittee, 21/09/2007, ref: EC 175-2007

Study design

Cluster-randomised controlled trial conducted with first-time parents

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Health promotion for infants and families in the area of obesity, nutrition and sedentary behaviour.

Interventions

Control:

Control no treatment, but the group will receive a generic health news letter every three months on child development.

Intervention:

The intervention will be delivered within the first-time parents' group scheduled meetings by a health worker with expertise in early childhood and in education. The development of intervention resources will be supported by the research team who collectively have extensive experience in the design of resources promoting healthy diet, physical activity, and reduced sedentariness, across childhood. The intervention will draw on parenting support theory, which emphasises children's psychological and behavioural goals, logical and natural consequences, mutual respect and encouragement techniques. Emphasis will be placed on parent understanding of how improved parenting skills can facilitate the development of appropriate eating and activity behaviours in children. The intervention will use an anticipatory guidance framework, to coincide with opportunities to support parents regarding feeding, physical activity and sedentary behaviour issues for children prior to their evolution. This involves the mapping of the period encompassed by the intervention - from 3 months to 18 months (intervention will run for 15 months). The intervention will incorporate a range of modes of delivery and educational strategies including brief didactic sessions, use of group discussion and peer support, use of visual and written messages, follow-up delivery of messages by text-messaging and mail-outs. See below for further details:

At 3 months:

Emerging Behaviours:

1. Early weaning and introduction of solids
2. Introduction of energy-dense, nutrient poor foods
3. Increased muscle control, strength and coordination

Anticipatory Guidance Intervention Aims:

1. To support parents to delay weaning/introduction of solids to 6 months
2. To provide advice regarding appropriate foods for weaning

3. To explore expectations regarding weaning and early feeding, movement and muscle control
4. To introduce basic concepts regarding parental feeding styles and how these might relate to beliefs about parenting

At 6 months:

Emerging Behaviours:

1. Adoption by parents of a feeding style
2. Food rejection by infants
3. Infant starts to:
 - 3.1. Sit briefly unsupported
 - 3.2. Reaches with one hand
 - 3.3. Rolls over
4. Adoption by parents of TV viewing for infant

Anticipatory Guidance Intervention Aims:

To develop parents' understanding regarding:

1. Feeding styles and impact on children's eating
2. Basic nutrition principals
3. Sedentary behaviours in families and limits to acceptability

At 9 months:

Emerging Behaviours:

1. Increasing use of TV
2. Parents' increased awareness of child mobility
3. Infant crawls and pulls self upright and walks with handhold

Anticipatory Guidance Intervention Aims:

To develop understanding regarding:

1. Parental modeling of eating, sedentary and physical activity behaviours
2. Impact of eating, activity and sedentary behaviours on health of children and adults and the provision of opportunities

At 12, 15 and 18 months:

Emerging Behaviours:

1. Increasing autonomy of child in eating and activity
2. Infant stands without support and beginning to walk

Anticipatory Guidance Intervention Aims:

Continued development of themes/skills regarding:

1. Eating and moving for health - parents and children
2. How to feed/how to manage food rejection and demands
3. Providing fail-safe food and activity environments

Intervention Type

Behavioural

Primary outcome measure

Parent and infant data will be collected using parent self-completion questionnaires, apart from dietary intake data which will be collected by telephone interview. All data (appropriate to the age of the child) will be collected every three months, corresponding with the six intervention sessions. Repeated data collection is necessary given the rapid changes in height, weight, eating and activity behaviours in infants. The measures collected are detailed below:

1. Dietary intake: dietary intake for the mother and father will be assessed using The Cancer Councils Dietary Questionnaire for Epidemiological Studies (Version 3) at baseline and study conclusion. This questionnaire is an updated version of the semi-quantitative food frequency questionnaire specifically developed for the Melbourne Collaborative Cohort Study. Childs dietary intake will be assessed by telephone-administered multi-pass 24-hour recall with parents. Visual aids will be provided to primary carers in advance of interviews to help in the estimation of quantities of food consumed. Three days of dietary data will be collected (including one weekend day) at 9 and 18 months
2. Physical activity: parents will report their frequency and duration in physical activity during the previous week using the Active Australia Survey. Given the lack of validated measures of physical activity for infants, this outcome will be assessed using parent report of the:
 - 2.1. Child's enjoyment of playing with parents
 - 2.2. Child's enjoyment of physical activity (movement, play)
 - 2.3. Childs enjoyment of playing with objects and toys
 - 2.4. Child is curious and explores environment through a variety of physical activities
 - 2.5. Child moves in new ways when challenged with interesting activitiesIn addition, at 12 and 18 months parents will be asked to report the number of hours their child typically spends playing outdoors on weekdays and weekend days
3. Sedentary behaviours: parents will be asked the amount of time the infant spends watching television on a typical weekday and on a typical weekend day, and to estimate the amount of time each day that the child spends immobile. Parents will also report the total time they spend watching television during their leisure-time in a typical week
4. Home food environment: three aspects of the home food environment will be assessed. Aspects of nutrition knowledge focused around nutrition targets of the intervention will be assessed using modified subscales of the validated Nutrition Knowledge Questionnaire, Parent Feeding Style will be assessed using the Child Feeding Questionnaire (CFQ), the Caregivers Feeding Style Questionnaire CFSQ (Hughes 2005). Home food availability and accessibility will be assessed using a self-reported shelf inventory on the availability of foods and fluids
5. Family physical activity and sedentary environment: parents will be asked general questions relating to their knowledge about physical activity in early childhood, to estimate the time they spend playing with their child, the frequency with which they take their child to the park or playground and an audit checklist on the physical activity and sedentary home environment
6. Standard demographic and socio-economic information will be collected by parental report
7. Anthropometric measures (height/length and weight) on the infant and parents will be collected by trained staff

Secondary outcome measures

Current secondary outcome measures as of 22/08/2012:

The majority of questions relating to parent-child interaction will be assessed via the primary outcome measures. The study will, however attempt to assess parenting styles and its relationship with diet, physical activity and sedentary behaviour at baseline and the 18 month conclusion within scheduled questionnaires. In terms of knowledge and attitudes specific to obesity and acceptability of the intervention these will be assessed by questions developed by the team which are specific to content relating to the intervention and assessed at baseline, 9 months and 18 months.

Primary and secondary outcome measures will be reassessed 2 and 3.5 years post intervention.

Previous secondary outcome measures until 22/08/2012:

The majority of questions relating to parent-child interaction will be assessed via the primary outcome measures. The study will, however attempt to assess parenting styles and its relationship with diet, physical activity and sedentary behaviour at baseline and the 18 month

conclusion within scheduled questionnaires. In terms of knowledge and attitudes specific to obesity and acceptability of the intervention these will be assessed by questions developed by the team which are specific to content relating to the intervention and assessed at baseline, 9 months and 18 months.

Overall study start date

01/02/2008

Completion date

31/03/2014

Eligibility

Key inclusion criteria

Participation in this study would require participants to be a member of a 'first-time parents group'. More specifically, participation entails being a parent for the first time and regularly attending a first-time parents group which is linked to a Maternal and Child Health Centres (MCHC) within a randomly selected recruited Local Government Areas (LGA). Parents will also be eligible to participate if they are able to freely give informed consent and can communicate in English.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

600 first-time parents participating in a first-time parents group (300 in each arm, control/ intervention) will be recruited. This will incorporate approximately 62 MCHC across 14 LGA.

Total final enrolment

510

Key exclusion criteria

Parents will be excluded from the study if:

1. They are unable to give informed consent
2. They are unable to communicate in English

Infants with chronic health problems that are likely to influence height, weight, levels of physical activity or eating habits will be excluded from analyses, but will be permitted to participate in the study.

Date of first enrolment

01/02/2008

Date of final enrolment

31/03/2014

Locations

Countries of recruitment

Australia

Study participating centre

221 Burwood Highway

Burwood, Victoria

Australia

3125

Sponsor information

Organisation

National Health and Medical Research Council (NHMRC) (Australia)

Sponsor details

GPO Box 9848

Canberra ACT

Australia

2601

Sponsor type

Research council

Website

<http://www.nhmrc.gov.au/>

ROR

<https://ror.org/011kf5r70>

Funder(s)

Funder type

Research council

Funder Name

Intervention phase: National Health and Medical Research Council (NHMRC) (Australia) - Primary Health Care Project Grant (ref: 425801).

Funder Name

Follow-up phase: National Health and Medical Research Council (NHMRC) (Australia) - Project Grant (ref: 1008879)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	31/03/2008		Yes	No
Results article	results	01/09/2010		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	01/06/2012		Yes	No
Results article	results	01/08/2012		Yes	No
Results article	results	01/09/2012		Yes	No
Protocol article	follow-up protocol	01/01/2013		Yes	No
Results article	results	01/04/2013		Yes	No
Results article	results	01/01/2014		Yes	No
Results article	results	04/11/2014		Yes	No
Results article	internet use results	23/01/2019	25/01/2019	Yes	No
Results article	results	11/12/2019	13/12/2019	Yes	No
Results article	Contributed data to results	01/01/2019	03/03/2020	Yes	No
Results article	long-term results	25/07/2020	28/07/2020	Yes	No
Results article		30/03/2021	13/04/2021	Yes	No
Results article		17/10/2021	28/03/2022	Yes	No
Results article		14/04/2023	28/04/2023	Yes	No