

Randomised controlled trial of a brief GP intervention to reduce overweight in Victorian primary school children - Live, Eat and Play (LEAP 2)

Submission date 06/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/09/2009	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
334309; ACTRN12607000443493

Study information

Scientific Title

Acronym
LEAP 2

Study objectives

Added as of 16/08/2007:

1. A brief parent-focused behavioural intervention delivered by General Practitioners (GPs) to overweight/obese 5 - 9 year olds will halve the body mass index (BMI) gain (the primary outcome) at 6 and 12 months in the intervention group relative to the non-intervention group
2. A brief parent-focused behavioural intervention delivered by GPs will lead to a range of secondary outcomes at 6 and 12 months for children and their families in the intervention compared to the non-intervention group, including:
 - 2.1. Smaller measured child waist circumference
 - 2.2. Greater measured child physical activity
 - 2.3. Parent-reported increases in child physical activity, reductions in sedentary activity, changes in child eating patterns
3. The intervention will be acceptable, feasible and cost-effective within Australian GP settings

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 16/08/2007:

Approved by the Royal Children's Hospital Ethics in Human Research Committee (EHRC) on 23rd March 2005 (ref: 25006 A)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Overweight and mild obesity

Interventions

Four consultations with the family doctor, employing a brief family-centred, solution-focused approach aiming to increase physical activity and reduce fat and sugar intake.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Added as of 16/08/2007:

BMI at 6 and 12 months, adjusted for baseline BMI.

Secondary outcome measures

Added as of 16/08/2007:

1. Accelerometry
2. Measured child waist circumference
3. Parent-reported child nutrition
4. Parent-reported physical activity
5. Parent-reported child functional health status (the Pediatric Quality of Life Inventory™ [PedsQL™])
6. Child-reported functional health status (PedsQL™)
7. Child-reported body satisfaction
8. Child-reported appearance/self-worth

Overall study start date

01/07/2005

Completion date

30/09/2007

Eligibility**Key inclusion criteria**

Healthy children aged 5.0 - 9.0 years inclusive who are overweight or mildly obese (International Obesity Task Force [IOTF] cutpoints; children with UK BMI z-score greater than or equal to 3.0 excluded). Sample drawn from BMI survey of all children aged 5.0 - 9.0 years attending their family doctor in 50 participating practices Jul 2005 - Feb 2006.

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

Added as of 16/08/2007: 420

Key exclusion criteria

Added as of 16/08/2007:

1. Very obese children (UK BMI z-score more than or equal to 3.0)
2. Children who are currently receiving ongoing weight management in a secondary or tertiary care program
3. Children who have a known endocrine or chromosomal cause for their overweight
4. Children who have major disabilities or health conditions as judged by the investigators prior to randomisation

Date of first enrolment

01/07/2005

Date of final enrolment

30/09/2007

Locations

Countries of recruitment

Australia

Study participating centre

Centre for Community Child Health

Parkville

Australia

3052

Sponsor information

Organisation

Murdoch Children's Research Institute (Australia)

Sponsor details

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Sponsor type

Research council

ROR

<https://ror.org/048fyec77>

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council (NHMRC) (Australia) (ref: 334309)

Alternative Name(s)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/09/2009		Yes	No