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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

Registration date
16/09/2005

Overall study status
Completed

Last Edited
10/09/2009

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)

Added as of 16/08/2007:
BMI at 6 and 12 months, adjusted for baseline BMI.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
9 Years

Sex
All

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)

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)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

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