

Increasing weight-bearing physical activity and calcium-rich foods to promote bone mass gains among 9-11 year old girls: the Cal Girls study

Submission date 02/05/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/02/2008	Condition category Musculoskeletal Diseases	<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

Protocol serial number

R01 HD 037743

Study information

Scientific Title

Acronym

Cal Girls

Study objectives

It was hypothesised that the behavioural intervention would result in increases in dietary Calcium (Ca) intake and weight-bearing physical activity (PA), and in the rate of bone mass accrual. Innovative aspects of the present study included:

1. Its focus on changing eating and PA behaviors to increase bone mass growth
2. Its focus on pre-adolescent girls, a group at risk for declines in Ca intake and PA levels as they develop into adolescence
3. Its unique collaboration with a community-based organisation (the Girl Scouts of America) as a channel to implement a health behaviour intervention

Ethics approval required

Old ethics approval format

Ethics approval(s)

The study was reviewed and approved by the University of Minnesota Research Participants Internal Review Board.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Osteoporosis prevention

Interventions

Thirty 5th-grade Girl Scout troops were recruited and randomised to a two-year behavioural intervention program (n = 15 troops) or to a no-treatment control group (n = 15 troops). The behavioural program was implemented during 5th and 6th grades by trained troop leaders as part of the regular troop meetings. The intervention program was based on Social Cognitive Theory and consisted of ten 90-minute activity-based sessions during each of the two years. It focused on the development of behavioural skills to choose Ca-rich foods and to engage in weight-bearing physical activity. Behavioural goals for the intervention were to increase daily dietary Ca intake to 1300 mg/day (increase of 4 daily servings of Ca rich foods; about 800 Ca mg/day) and to increase weight-bearing physical activity to 120 minutes per week. A continuously available, interactive web-based program, and a one-week summer camp between 5th and 6th grade years, were implemented as components of the intervention program. Parents were also targeted through the web-based program.

Control troops did not receive any program and conducted their usual troop meeting activities during the two-year intervention period.

Evaluation was conducted with individual girls and a parent at clinic visits at baseline prior to randomisation, at one-year follow-up, and at the end of the study (two year follow-up).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Change in areal bone mineral content (aBMC) was the primary outcome variable for the study because it best reflects bone mass change in developing children.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/01/2004

Eligibility**Key inclusion criteria**

30 5th-grade Girl Scout troops from the Minneapolis and St Paul metropolitan area were recruited to take part in the study through mailed fliers to troop leaders and troop leader meeting announcements. Troop eligibility criteria were:

1. Troop size greater than or equal to 8 girls
2. Parental consent and girl assent from each troop member to participate in troop meetings with intervention program activities
3. Troop plans to remain together at minimum two more years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2003

Date of final enrolment

01/01/2004

Locations

Countries of recruitment

United States of America

Study participating centre

Division of Epidemiology

Minneapolis

United States of America

55454

Sponsor information

Organisation

University of Minnesota (USA)

ROR

<https://ror.org/017zqws13>

Funder(s)

Funder type

Government

Funder Name

National Institutes of Health (NIH) (USA) (ref: R01 HD 037743)

Results and Publications

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	19/07/2005		Yes	No