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

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| **Submission date**<br>02/05/2005 | **Recruitment status**<br>No longer recruiting |
| **Registration date**<br>03/05/2005 | **Overall study status**<br>Completed |
| **Last Edited**<br>15/02/2008 | **Condition category**<br>Musculoskeletal Diseases |

[ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Quality of life

## Participant information sheet

## 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 measure
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.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/2003

### 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

### Age group

Child

**Sex**
Female

**Target number of participants**
322

**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
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# Sponsor information

**Organisation**
University of Minnesota (USA)

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**Sponsor type**
University/education

**ROR**
https://ror.org/017zqws13

# Funder(s)

**Funder type**
Government

**Funder Name**
National Insititutes of Health (NIH) (USA) (ref: R01 HD 037743)

# 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 | 19/07/2005 | | Yes | No |