Clinical Trial ID:

NCT00000413

Title:

Osteoporosis Prevention in Preadolescent Girls

Summary:

This study will test an osteoporosis prevention program aimed at preadolescent girls between the ages of 10 and 12 who have not yet started their menstrual periods. Girls in this age group are adding large amounts of new bone to their skeletons. Adding more bone at this time of life can reduce a person's chances of developing osteoporosis (thinning bones) in later years.

We will look at how this osteoporosis prevention program affects the amount of calcium in the girls' diets, the amount of weight-bearing exercise they do, and their bone mass measured using ultrasound testing of the heel.

Detailed Description:

The study's objective is to demonstrate the efficacy of a behavioral/educational intervention in increasing levels of dietary calcium intake and weight-bearing exercise

within an at-risk population in a stage of rapid accrual of bone mass-specifically, premenarchal girls between the ages of 10 and 12. We will use cluster randomization to randomize girls to either the intervention or a program of education only. We will randomize eighteen groups of girls into each arm of the study.

The intervention consists of six interactive sessions using various media (i.e., overhead transparencies, graphics, and three-dimensional demonstrations) to present instructional material. Topics include an explanation of osteoporosis and its modifiable and nonmodifiable risk factors, prevention of osteoporosis via healthy food choices (i.e., high calcium, low fat foods), and prevention of osteoporosis via weight-bearing exercise.
Each girl monitors her own progress toward the goal of 1350 to 1500 milligrams of calcium per day. A similar method allows simple self-monitoring of weight-bearing activity. The intervention program is reinforced via monthly self-monitoring for 18 months. The education-only program consists of six generic sessions on healthy eating, physical fitness, and healthy lifestyle choices.

The primary outcomes of interest are higher calcium intake and higher levels of weight-bearing exercise. A secondary outcome of interest is increased broadband ultrasound attenuation of the os calcis, assessed using quantitative ultrasound. In summary, the group of girls targeted is ideal for this intervention because they are at a stage of rapid accrual of bone mass.

Eligibility Criteria:

Inclusion Criteria:

- **9- and 10-year-old premenarchal girls (girls who have not started their periods).**

Exclusion Criteria:

- **Comorbid conditions or medications that are associated with decreased bone density such as the following: corticosteroids; anticonvulsants; thiazide diuretics; history of cancer; Type I diabetes; thyrotoxicosis; hyperparathyroidism; Cushing's syndrome; juvenile rheumatoid arthritis; connective tissue disease or hemolytic anemia; asthma**

which may limit ability to participate in the exercise intervention; known history

of dietary disorder, including anorexia, bulimia or lactose intolerance;

postmenarchal.

Gender:

Female

Minimum Age:

9 Years

Maximum Age:

13 Years

Phase:

Phase 2

Conditions:

- Osteoporosis

Interventions:

- Psychoeducational program

Locations:

- University Hospitals of Cleveland, Cleveland, Ohio