

Large Research Studies

Introduction:

As people age, their bones become less dense and more likely to fracture (break). Some people claim that taking calcium supplements is a good way to increase bone density. The evidence for this claim is conflicting. Some small research studies support the claim. Other small research studies do not support this claim.

Claim:
Taking calcium supplements increases bone density.

When testing claims, large research studies that include a large sample size (many people) are more likely to be reliable than small research studies. There are two different ways to collect and analyze data for a large research study.

- Conduct one big study – a **large-scale health study**
- Combine data from many small studies – a **meta-analysis study**

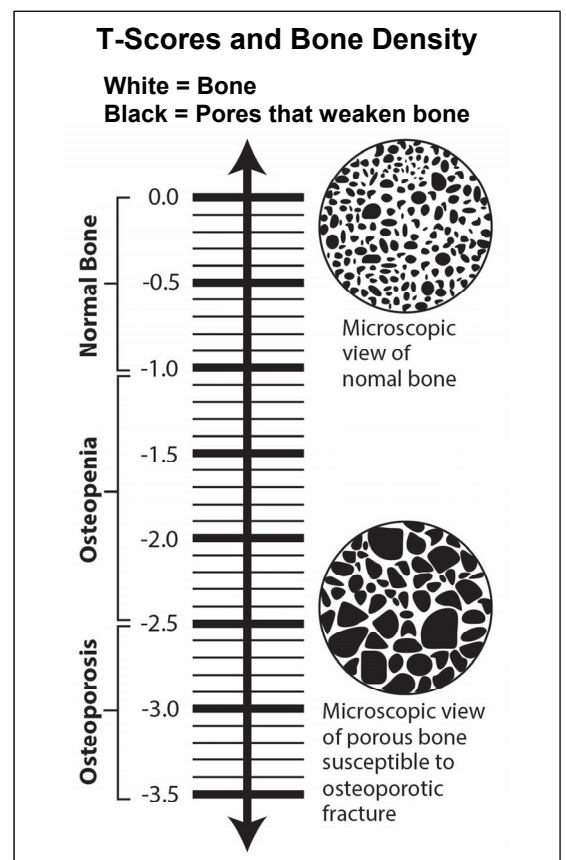
Part 1: A Large-Scale Health Study

A team of six scientists has conducted a **large-scale health study** to test the claim that taking calcium supplements increases bone density. The scientists recruited 2000 women (ages 50–60 years old) who agreed to be research subjects and participate in this three year study. Women in the study will have their bone density tested. The results of the bone density tests will be expressed as T-Scores.

Base your answers to questions 1-5 on the illustration on the right.

1. As a woman's bones become less dense and weaker, will her T-Scores increase or decrease?

2. Women with normal bone density will have T-Scores greater than _____.
3. Women with osteoporosis have a high risk of bone fractures. Their bone density T-Score is less than _____.
4. Women with T-Scores between -2.5 and -1.0 have a condition called _____.
5. If someone has a T-Score of -0.1, would their bones be unusually strong or weak? _____



Expectations for participants enrolled in the three year study include:

- Have a baseline bone density test of the hip bone to determine their T-Score at the beginning of the health study.
- Take two capsules per day for three years.
 - Participants in the experimental group will take capsules that contain calcium.
 - Participants in the control group will take **placebo** capsules (capsules with no calcium).

Note: The participants will not be told whether they are in the experimental group or the control group, and they will not know if the capsules are placebos or calcium supplements.

- Have a final bone density test of the hip bone to determine their T-Score after three years.
- All participants will be told their T-Scores (results of bone of their bone density tests) at the end of the health study.

6. What is the independent variable in this research study?

7. What is the dependent variable in this research study?

8. It would be easier to do a research study with a sample size of 200 research subjects instead of 2000 research subjects. Explain why it is better to do research studies that involve a large sample size.

9. Make a list of at least four difficulties that the team of scientists may encounter when they try to recruit research subjects and collect data for this large health study project.

- _____
- _____
- _____
- _____

The budget for the large-scale three year health study includes:

- \$100,000 per year for each scientist's salary for three years
- \$500 for each participant who completes all research study expectations
- \$300 for each bone density test
- \$50 per participant for a one year supply of capsules (calcium or placebo)

10. Approximately how much should be budgeted for this large-scale three year health study? You should budget for six scientists and all 2000 women completing the study. Show your work.

11. Who should pay for large-scale health studies to determine if calcium supplements are effective in preventing osteoporosis - the government (taxpayers) or companies that produce the supplements? Explain your answer.

12. Only 705 out of 1000 women in the experimental group and 698 out of 1000 women in the control group completed the research study expectations. List at least two possible explanations for why many of the participants did not complete the study?

- _____
- _____

At the end of the large-scale health study, mathematicians analyzed the data and prepared statistical summaries to compare the T-Scores for the control group and the experimental groups. This data analysis is presented in the table below.

Baseline T-Scores		Final T-Scores	
Control Group	Experimental Group	Control Group	Experimental Group
Median = - 2.1	Median = - 2.1	Median = - 2.1	Median = - 2.1
First Quartile = - 2.5	First Quartile = - 2.6	First Quartile = - 2.5	First Quartile = - 2.4
Third Quartile = - 1.1	Third Quartile = - 1.0	Third Quartile = - 1.2	Third Quartile = - 0.9
Minimum = - 3.9	Minimum = - 3.4	Minimum = - 3.3	Minimum = - 3.9
Maximum = - 0.1	Maximum = - 0.1	Maximum = 0	Maximum = - 0.2

13. On the separate handout entitled **Box and Whiskers Plot Grid**, make box and whiskers plots to help you visualize the distribution of the T-Score data in the table above.

- Refer to the information on the **Reference Sheet: Statistical Summary and a Box and Whiskers Plots** for information on how to plot the T-Score data and what this data means.
- Make your plots on the separate handout entitled **Box and Whiskers Plot Grid**. *Be sure to look at the labels to make sure your plots are done in the appropriate grid*

14. Are the median baseline (starting) T-scores for the control group and the experimental group similar enough for this to be a fair test of the claim? Be specific.

The **median** is the middle value for the T-Scores. Half of the T-Scores will be above the median and half will be below the median.

15. Does this large-scale health study support the claim that taking calcium supplements increases bone density? Support your conclusion with specific evidence from the box and whiskers plots.

16. State one advantage of a large-scale health study.

17. State one disadvantage of a large-scale health study.

Part 2: A Meta-Analysis Study

A scientist wants to conduct a **meta-analysis study**. Meta-analysis studies combine data already collected during many small research studies. He wants to test the claim that taking calcium supplements increases bone density as measured by T-Scores.

Claim:
**Taking calcium supplements
increases bone density.**

The scientist has identified 7 small research studies that investigated the effect of calcium supplements on T-Scores that measure bone density. He summarized information on the design of these 7 studies that might provide data for the meta-analysis.

1. For the meta-analysis, it is important that the scientist only use data from controlled research studies that are fair tests for the claim. Read the 7 cards that describe the design for each of the small research studies.
 - Choose the four research studies that you think should not be included in the meta-analysis because they are least likely to be unbiased (fair) tests of the claim.
 - Complete the chart below by writing the names of the authors for the four studies you would exclude (not include). For each study that you excluded, explain why you think the study is not likely to be an unbiased test of the claim.

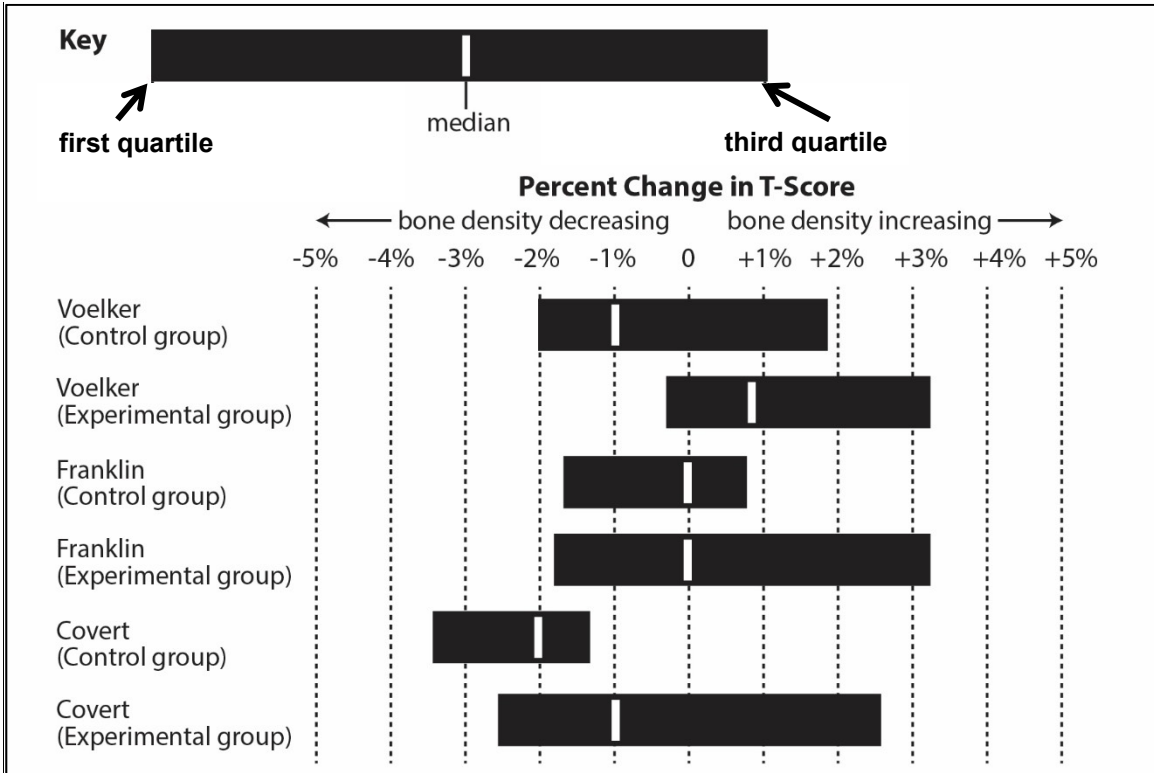
RESEARCH STUDIES TO BE ELIMINATED (NOT INCLUDED):

Last name of the author of the research study	Reason for excluding the research study

2. Ask your teacher for a **Checklist for a Well Designed Research Study**. Did the information on this checklist cause you to change which studies you would want to eliminate? If so, use cross-outs and a different color of pen to change the chart above.

Base your answers to questions 3 through 10 on the following information.

The scientist chose three of the research studies for meta-analysis. Data from these studies was analyzed to determine the percentage (%) change between the baseline and final T-Score data. The results of this analysis are shown in the graphs below.



3. What was the unit of measurement for the dependent variable in the graph for this meta-analysis study? Be specific and include the units of measurement.

4. Can you tell what the maximum and minimum values for % change in T-Score are for these graphs? Explain why or why not.

5. Which researcher found that the median % change in T-Scores were the same for both the experimental group and the control group?

6. Which researcher found that the experimental group had median T-Scores that improved?

7. Based only on the research done by Dr. Voelker, what would you conclude about the effect of calcium supplements on bone density (T-Scores)? Support your conclusion with specific evidence from the graph.

8. Based only on the research done by Dr. Franklin, what would you conclude about the effect of calcium supplements on bone density (T-Scores)? Support your conclusion with specific evidence from the graph.

9. Based only on the research done by Dr. Covert, what would you conclude about the effect of calcium supplements on bone density (T-Scores)? Support your conclusion with specific evidence from the graph.

10. Based on all of the information in the graphs on the previous page, does the meta-analysis provide clear evidence that the use of calcium supplements increase bone density and prevent osteoporosis? Support your answer with specific evidence from the meta-analysis.

11. State one advantage of a meta-analysis study.

12. State one disadvantage of a meta-analysis study.

13. Which type of large research study is better for testing the claim that taking calcium supplements increases bone density - a large-scale health study or a meta-analysis study? Support your answer.
