



ACTIVITY 9

Evaluating Randomized Controlled Trials

DATA ANALYSIS



← The quality of a research study depends on how well it was designed and the strength of its evidence.



9: EVALUATING RANDOMIZED CONTROLLED TRIALS

GUIDING QUESTION

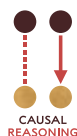
How can randomized controlled trials be evaluated?

INTRODUCTION

As you saw in previous activities, a larger sample size can help ensure that a research study's findings are not a result of coincidence or random chance. One of the largest and most widely known clinical trials ever conducted was in 1955 for a polio vaccine. There is no cure for polio; before the vaccine, the polio virus paralyzed tens of thousands of children across the world, and large hospital wards were filled with patients on respirators. In less than one year, 1.8 million people participated in the study to test the polio vaccine. The fact that so many people were tested helped to make both researchers and the public confident in the results—the vaccine was both safe and effective.

Besides sample size, you've learned about other study design elements and analysis methods of research studies that can help boost confidence in their results. For instance, the polio vaccine study was done in different locations across the United States, Canada, and Finland to look for consistency across different settings. Also, the trials had a very large effect size, with a 90% success rate at preventing paralysis in children. If the results had shown only a 10% success rate, then it would have been more likely that this effect came about by chance. However, there was also another way the study was designed that made it valuable. The polio vaccine was tested on children, not adults, because children were the *target group* for the vaccine—the group most affected by polio, and the ones who needed the vaccine the most. In this activity, you will analyze the following characteristics: sample size, target group, consistency across settings, and effect size in randomized controlled trials (RCTs) to help evaluate the effectiveness of the four different well-being strategies that Salas High School is considering.

CONCEPTUAL TOOLS



MATERIALS LIST

FOR EACH STUDENT

STUDENT SHEET 9.1
"Comparing RCTs
Related to the
Well-Being Strategies"



People of all ages line up to receive polio vaccines in Los Angeles, California, 1960.

PROCEDURE

PART A: EVALUATING A RANDOMIZED CONTROLLED TRIAL (RCT)

- 1 With your group, read the following fictional scenario.

The Well-Being Task Force is ready to dig deeper into each of the four well-being strategies that Salas High School is considering. The task force decides to compare randomized controlled trials (RCTs) for each strategy.



- 2 Each group member will be assigned an RCT to analyze for a different well-being strategy. Follow your teacher's instructions to form an expert group with other students who have the same RCT study.
- 3 Work with your expert group to read your assigned study. Complete Section 1 on Student Sheet 9.1, "Comparing RCTs Related to the Well-Being Strategies" for your RCT. Be ready to share your findings with your original group afterward.

FIGURE 9.1

Research Summary for a Randomized Controlled Trial on Gratitude Writing

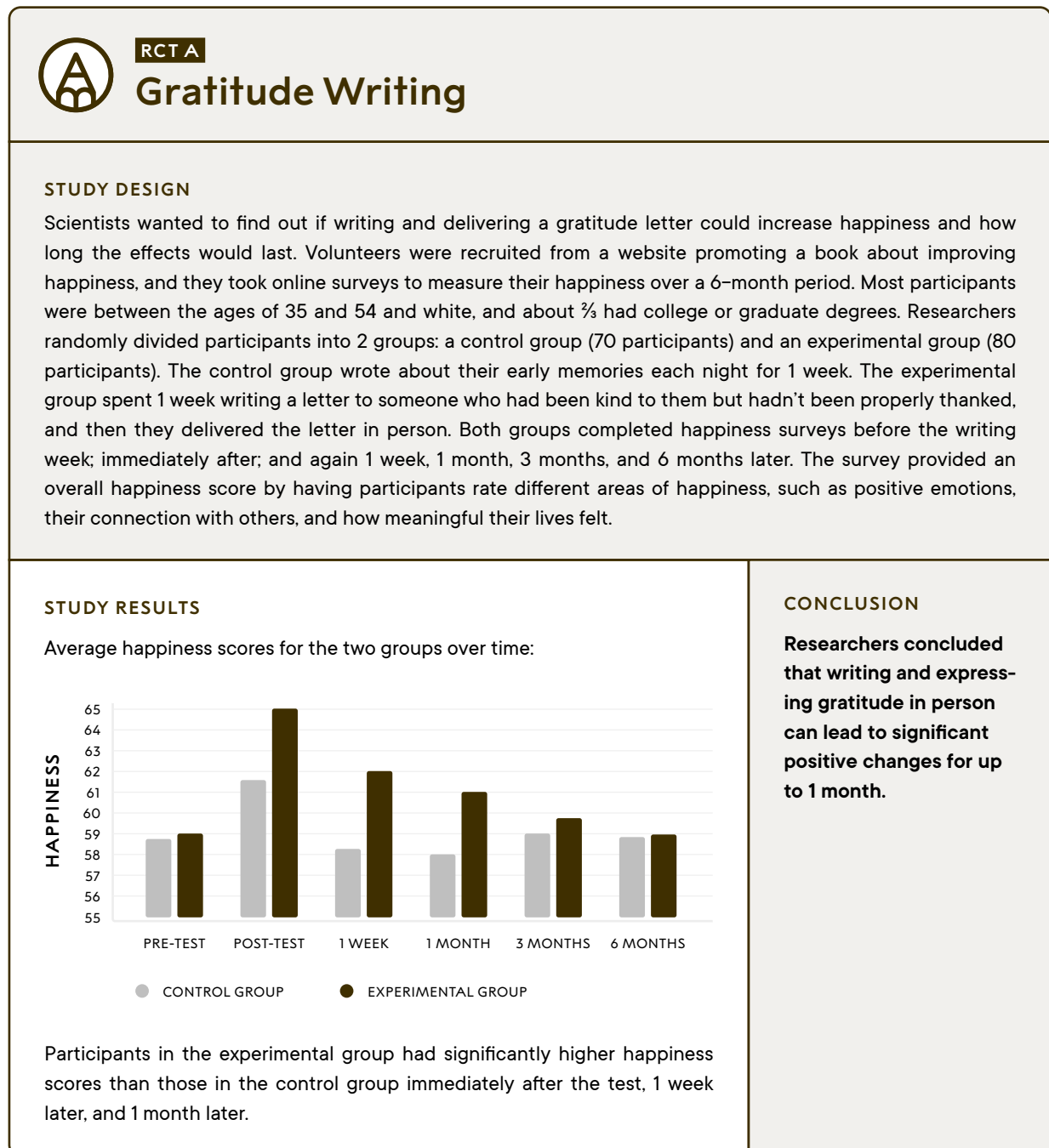


FIGURE 9.2

Research Summary for a Randomized Controlled Trial on Pet Therapy



RCT B

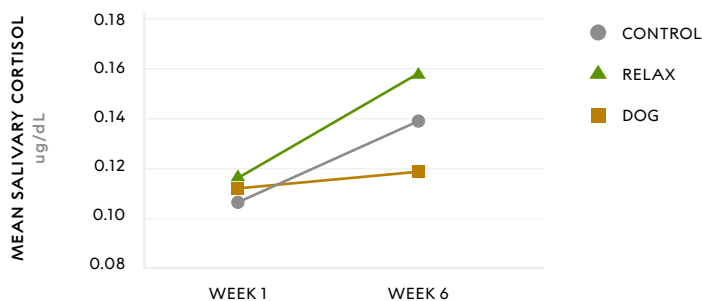
Pet Therapy

STUDY DESIGN

Scientists wanted to study how spending time with dogs affects stress by measuring cortisol, a hormone the body releases in response to stress. Higher cortisol levels mean more stress. The study involved students aged 8–10 from 4 elementary schools in the United Kingdom. Students were randomly divided into 3 groups: control group, no treatment (19 students), experimental group 1, dog treatment (33 students), and experimental group 2, relaxation (35 students). The control group continued with their regular school lessons as usual. Experimental group 1 spent about 20 minutes interacting with and learning about a dog. Experimental group 2 had about 20 minutes of activities such as stretching or listening to a story. Both experimental groups 1 and 2 had 2 20-minute sessions each week for 4 weeks. Before and after the experiment, saliva samples were taken 3 times a day for 3 days in a row, and the average cortisol levels were calculated before and after each treatment or control period.

STUDY RESULTS

Average cortisol levels from saliva samples for the three groups:



Students in experimental group 1 (dog group) did not show a noticeable change in their average cortisol levels. However, students in the control group and experimental group 2 (relaxation group) showed significant increases in cortisol levels, meaning that their stress levels went up. In other words, spending 20 minutes with a dog helped the children keep their cortisol levels steady, while the other groups experienced more stress.

CONCLUSION

Researchers concluded that spending time with dogs may help lower stress in children at school.

FIGURE 9.3

Research Summary for a Randomized Controlled Trial on Quality Sleep

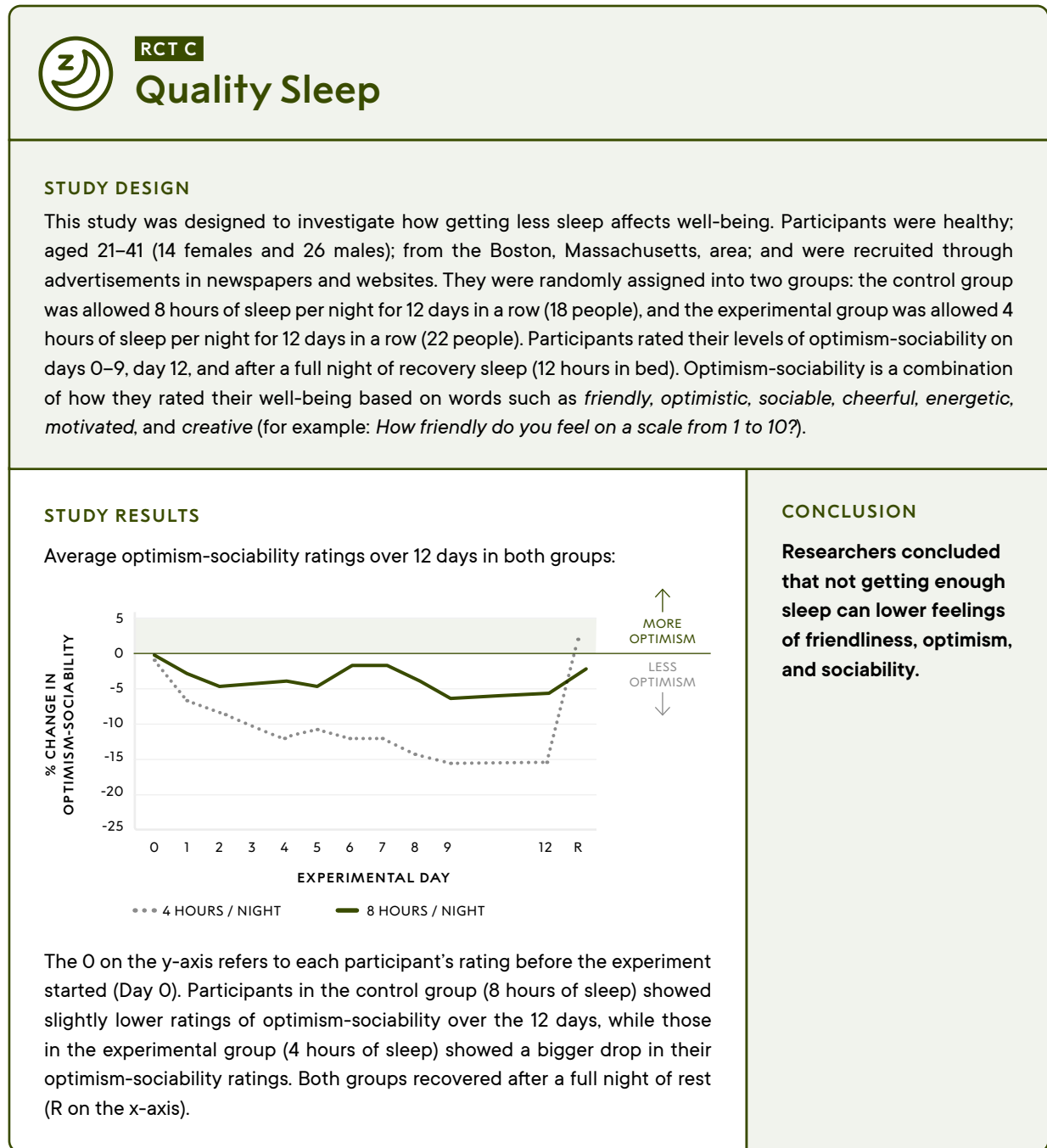


FIGURE 9.4
Research Summary for a Randomized Controlled Trial on Green Spaces



RCT D

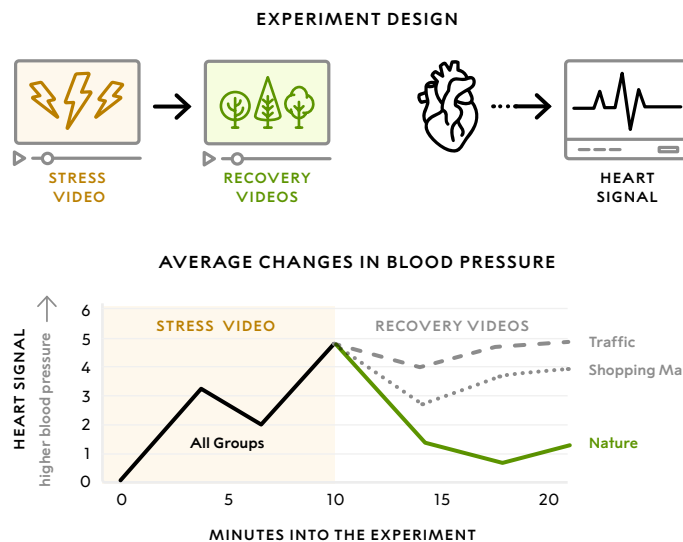
Green Spaces

STUDY DESIGN

Researchers wanted to test if watching videos of nature or urban environments could reduce stress levels. The study involved 120 university students (60 males and 60 females, mostly between the ages of 18 and 22) from a university in the Northeast United States. Each participant was monitored throughout the experiment by recording electrical signals from their heart. Participants also rated their well-being before and after the experiment. Each participant sat in a comfortable chair during all 3 parts of the experiment. In Part 1 (baseline), normal stress levels were recorded for 2–5 minutes. In Part 2, stress was triggered by a 10-minute video showing work accidents with injuries. In Part 3, participants were randomly assigned to 1 of 3 groups to watch different 10-minute stress-recovery videos: a control group (shopping mall) watched a video of an outdoor shopping area with people but no cars (40 students); experimental group 1 (nature) watched a video of trees, plants, and sounds of birds or a stream (40 students); experimental group 2 (traffic) watched a video of a commercial street with traffic (40 students).

STUDY RESULTS

Experiment design and average changes in blood pressure for the 3 groups:



All groups showed an increase in blood pressure during Part 2 compared to the control/baseline (0 on the graph). However, in Part 3, participants in experimental group 1 (nature video) had bigger and faster decreases in blood pressure than those in experimental group 2 (traffic video) or the control group (shopping mall video). Those in experimental group 1 (nature video) also had greater reductions in fear, negative feelings, and anger. There were no significant differences in sadness ratings between the groups.

CONCLUSION

Researchers concluded that watching nature videos help people recover from stress more quickly and completely than watching urban videos. Researchers suggested that nature may lower stress by activating the nervous system's calming and resting functions.

- 4 Return to your original group and have each group member share their study information. Complete Section 1 of the student sheet for the other three studies.
- 5 Review the text for the four RCTs again. Work as a group to search for the study design elements and analysis methods listed below and record your answers for each RCT in Section 2 of the student sheet.
 - a **Sample size**
How many participants were tested in each group of the experiment?
 - b **Target group of the study**
Which age was chosen to be studied?
 - c **Consistency across settings**
What location(s) and/or type(s) of people (gender, occupation) were included in the study?
 - d **Effect size**
Was there a difference between the groups and, if so, how large was it?
- 6 As a class, evaluate the studies by discussing how each study was designed and which confounds could have affected the results. Record those ideas about possible confounds for each of the four studies in Section 3 on the student sheet.
- 7 In your group, evaluate the strengths and limitations of each study based on the characteristics you recorded in Steps 5 and 6. Discuss how sure your group is of each study's conclusion(s) and record that in the last row of Section 3 on the student sheet. Use a scale of 0–5, where 0 means no relevant evidence and 5 means extremely strong evidence. Record your ideas in your science notebook.

BUILD UNDERSTANDING

- ① Of the four RCTs you investigated in this activity, which one do you think supports its conclusion with:

- a the most convincing evidence?
- b the least convincing evidence?

Consider the characteristics of confounds, sample size, target population, and effect size for the four different RCTs. Use your responses from Procedure Step 7 to back up your claims and include your group's rating (on a scale of 0–5) for how strong the evidence is in supporting the study's conclusion.

- ② Imagine that you are about to recommend adding a school garden at Salas High School to increase student access to green spaces to improve students' well-being. Then you come across another RCT for green spaces. In that study, researchers added green walls with living plants to four classrooms.

The classrooms were in two elementary schools in a medium-sized city in the Netherlands. The green walls were all the same size and placed in the same location in each classroom. Researchers tested students for attention to task and well-being before adding the plants and again two and three months after the plants were added. Compared to classrooms without green walls, students' attention scores increased. However, there was no measurable effect on student's self-reported well-being.

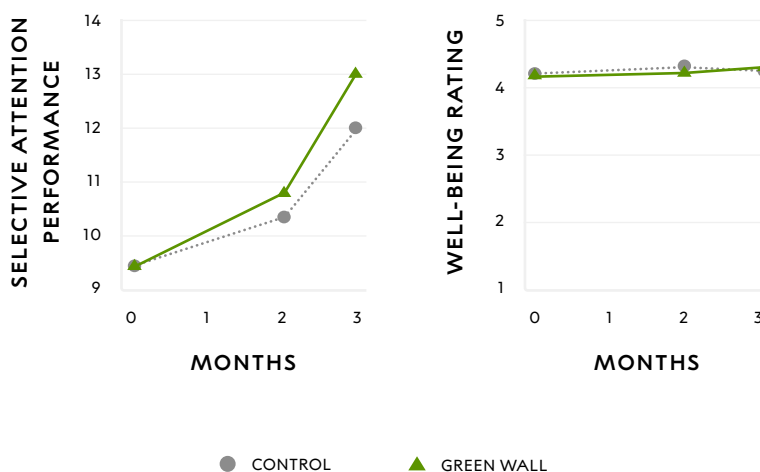


An example of a green wall at a school in Australia.

COURTESY OF [Evergreen Infrastructure](#)

FIGURE 9.5

Changes in Attention and Well-Being With and Without Green Walls



- a Does the data support the claim that access to green spaces improves well-being? Why or why not?
- b What are the main limitations of this study? Explain how the limitations affect your confidence in the study results.
- c Given your answers to (a) and (b) and other evidence from this activity, would you still recommend the green spaces well-being strategy for Salas High School? Explain why or why not.

CONNECTIONS TO EVERYDAY LIFE

- ③ Think about a well-being claim you've seen in the media. Using what you've learned about sample size, consistency across settings, and effect size, how could you design an experiment to test if that well-being claim is true?