

ACTIVITY 9

Evaluating Randomized Controlled Trials

DATA ANALYSIS

ACTIVITY 9

Evaluating Randomized Controlled Trials

ACTIVITY SUMMARY

Groups analyze short summaries of peer-reviewed randomized controlled trials (RCTs) related to the four well-being strategies being considered for Salas High School. Students examine key characteristics of each study, such as effect size, consistency across different settings, and sample size, to assess their confidence in the results. This prepares students for the final activity in which they will examine the data they have collected over the course of the unit to help them determine the best well-being strategy for Salas High School.

ACTIVITY TYPE
DATA ANALYSIS

NUMBER OF 40-50 MINUTE CLASS PERIODS 2

KEY CONCEPTS & PROCESS SKILLS

- 1 Confidence in a cause-and-effect relationship should depend on the quality, variety, and consistency of the evidence supporting it.
- 2 Randomized controlled trials (RCTs) are the most reliable method for identifying cause-and-effect relationships because they reduce the likelihood that alternative factors are influencing the effect.

NEXT GENERATION SCIENCE STANDARDS (NGSS) CONNECTION:
Compare and contrast various types of data sets (e.g., self-generated, archival) to examine consistency of measurements and observations.
(Science and Engineering Practice: Analyzing and Interpreting Data)

CONCEPTUAL





MATERIALS & ADVANCE PREPARATION

FOR THE TEACHER

- VISUAL AID 1.3
 "Proposed Well-Being
 Strategies for Salas
 High School"
 (OPTIONAL)
- VISUAL AID 9.1
 "Scoring Guide:
 Analyzing and
 Interpreting Data
 (AID)"
- ITEM-SPECIFICSCORING GUIDE:Activity 9, BuildUnderstanding Item 2

FOR EACH STUDENT

- STUDENT SHEET 9.1
 "Comparing RCTs Related to the Well-Being Strategies"
- STUDENT SHEET 1.2 "Unit Concepts and Skills" (OPTIONAL)
- SCORING GUIDE:
 Analyzing and
 Interpreting Data (AID)
 (OPTIONAL)

TEACHING NOTES

Suggestions for discussion questions are highlighted in gold.

Strategies for the equitable inclusion of diverse students are highlighted in lime.

GETTING STARTED (10 MIN)

1 Remind students of the key features of a well-designed study.

- Let students know that after designing and testing their own randomized controlled trial (RCT) for
 one of the proposed well-being strategies, they will now evaluate data from published RCTs for all
 four strategies. This will help them decide which strategy Salas High School should choose. Emphasize that using the published RCT evidence to make this decision depends on understanding
 what makes a research study strong and reliable.
- Have students read the Introduction in the Student Book, either as a class or individually. For students who need more reading support, consider having students share the reading responsibilities within a group of four. One pair completes the first paragraph and shares the information with the other pair who then completes the second paragraph. Then the group of four works together to summarize both paragraphs.
- Ask, What are the design elements that can make you more sure that the results are accurate? Encourage students to consider the progression of what they have learned about RCTs in the previous activities and from the Introduction they just read. Students should be able to answer this question by offering the main ideas from previous Activities 6–8. As students respond to the prompt, make a list on the board for students to refer to during the activity. Alternatively, you may wish to display optional Visual Aid 6.2, "Study Design Elements and Analysis Methods" as you review the concepts. Make sure the following main ideas are included:
 - A large sample size makes it less likely that the results are from random chance.
 - Testing a variety of groups and settings provides a way to determine if the results are consistent.
 - Controlling as many variables as possible makes it more likely that the result is not from a variable other than the one you are testing. It helps to prevent confounds.
 - A larger effect size shows a stronger association between variables, indicating it is less likely that the results happened by chance.
 - Your target group is the group you want to learn about. If you test a different group, the results might not be the same for your target group (the results may not apply to who you want to study or treat).

UNIT 4: INVESTIGATING EVIDENCE FOR CAUSATION AC

2 Introduce students to the studies they will analyze.

- Have students read the fictional scenario presented in Procedure Step 1. Reading the scenario
 aloud can better support comprehension for many students, including neurodiverse students and
 emerging multilingual learners who often have more highly developed listening and oral skills than
 reading comprehension skills. Alternatively, students can read the scenario independently.
- If it would be helpful for your students, consider reviewing the list of four possible strategies to improve well-being shown on optional Visual Aid 1.3, "Proposed Well-Being Strategies for Salas High School," to remind students of the strategies that the Salas High School Task Force is considering.
- In Procedure Step 2, assign a different RCT study (A, B, C, or D) to each student in a group of four. Let students know that these four RCT studies correspond to one of the well-being strategies being considered by Salas High School. Have students rearrange their groups so they are sitting with three other students who were assigned to the same RCT study. Each student in these new groups will become an expert on one of the four RCT studies.
- Facilitate the engagement of students with learning disabilities and neurodiverse learners by
 providing targeted support for the text in the studies. Consider how to best adapt the activity to
 meet the needs of your particular students. Students who need more time processing language
 (such as students with dyslexia) can be provided with the four study summaries in advance of
 the day's activity.

3 Jigsaw groups to compare across RCT studies.

- In Procedure Step 3, hand out Student Sheet 9.1, "Comparing RCTs Related to the Well-Being Strategies." Students work in their expert groups to read and complete Section 1 on Student Sheet 9.1 for their assigned RCT. For students who need more support reading the RCTs, have students divide into pairs and preread them. They can describe the RCT summary by using whatever modality is most comfortable, such as verbal (story) or visual (drawing). If there is time, students could find a generic picture on the Internet that matches each description. Alternatively, you can model the process of analyzing the text and work through Student Sheet 9.1 together as a class. Consider providing an example to help students recognize each study design element or analysis method listed in the first column of the Student Sheet.
- In Procedure Step 4, after expert groups have worked together to analyze their RCTs, students will return to their original groups. Each original group should now have at least one expert for each of the four RCT studies so group members can share one another's findings as they complete Section 1 for all four studies on Student Sheet 9.1. This "jigsaw" approach increases students' access to the information as they analyze the four RCT studies.
- In Procedure Step 5, students work together in their original groups to complete Section 2 of Student Sheet 9.1. It may be helpful to revisit the list of design elements that you compiled and

posted from Teaching Step 1 or optional Visual Aid 6.2, "Study Design Elements and Analysis Methods." Remind students that these elements of a research study are helpful when reviewing the RCTs and can lead to more confidence in the results.

• After students have completed Procedure Step 5, let them know that they have not yet considered alternative explanations for the findings from confounds. Ask, Based on how the studies were designed, what are possible confounds that could have affected the results? When leading the discussion, allow students to brainstorm potential confounds and alternative explanations. Have the class work together to complete Section 3 of the student sheet. If needed, ask the following questions to help students identify potential confounds. Ask, In the gratitude-writing study, do you think seeing someone important to them might have improved the experimental group's well-being instead of the letter itself? Students should respond in a way that shows they understand how another factor besides the treatment (e.g., interacting with an important person) could have affected the well-being of the experimental group. Continue with similar questioning for the remaining studies.

SYNTHESIS OF IDEAS (10 MIN)

4 Facilitate a discussion about the strengths and limitations of the studies.

- After completing Procedure Step 7, have groups briefly share and justify the ratings they gave for
 each study's findings. Ask, Which study did your group find most convincing and why? Student responses may include reasons such as large sample size, target group, fewer confounds, large effect
 size, etc. A sample student response for Student Sheet 9.1 can be found at the end of this activity.
- When discussing the strengths and weaknesses of the studies, address the misconception that studies must include all the study design elements and analysis methods that students identified in this activity (large sample size, matching target group, consistency across settings, and large effect size). Emphasize that studies with limitations can still provide valuable evidence; depending on how those limitations affect the study results or the researchers' conclusions, the evidence from the study may still be useful.
- Another key point to discuss with students is the amount of evidence provided by the RCT studies in this activity. Ask, Is one RCT enough evidence to convince you that a strategy works? Have students explain why or why not. Students should respond that one study is not convincing, unless it was a very large experiment run over a long time. Even if a study is well designed and well conducted, there is a threshold amount of data that makes people sure of the results. That threshold, as previously discussed, depends on the decision being made from the results.

5 Assess student growth, using the Analyzing and Interpreting Data Scoring Guide for Build Understanding item 2.

- Remind students of the Analyzing and Interpreting Data Scoring Guide. You may wish to project Visual Aid 9.1, "Scoring Guide: Analyzing and Interpreting Data (AID)," for your students to review each level and clarify your expectations.
- Do not share the item-specific version of the Scoring Guide (Item-Specific Scoring Guide: Activity 9, Build Understanding Item 2) with students as it provides specific information on how to respond to the item prompt. Review the Item-Specific Scoring Guide to support scoring this specific item.
- Remind students that you expect to see them demonstrate growth in their understanding and explanation of causal reasoning. They may want to review their responses to the assessment from Activity 4 (Build Understanding Item 2) and/or Activity 7 (Build Understanding Item 3).
- Sample responses for Levels 1–4 are provided in the Build Understanding section that follows. Review these responses to get an idea of what is expected for each level alongside the Item-Specific Scoring Guide. See Appendix 2: Assessment Resource at the end of the Teacher's Guide for more guidance and information on using the Scoring Guides and assessment system with your students.
- Depending on your students, you may want to have them provide feedback on one another's work
 for revision prior to turning in their work to you for scoring. Alternatively, consider having students
 turn in a rough draft to you for feedback and revision.

6 Revisit some of the key concepts of the unit that have been introduced.

- You may wish to revisit optional Student Sheet 1.2, "Unit Concepts and Skills," to help students formally organize the ideas introduced in the unit so far. This is the final opportunity for students to summarize their learning on the student sheet. Students can place the headings of the main ideas related to randomized controlled trials into the organizer and add examples from their class-room experiences in Activities 7–9. See the end of Activity 1 in the Teacher's Edition for a sample student response.
- Let students know that in Activity 10, the final activity of the unit, they will be able to apply their
 analysis from this activity. They will compare multiple lines of evidence from different studies to
 help choose which of the four well-being strategies to recommend to Salas High School.
- Finish the activity by revisiting the Guiding Question, *How can randomized controlled trials be evaluated?* Use responses to this question to formatively assess the student's understanding of key concepts and process skills related to study designs for randomized controlled trials such as sample size, effect size, and random assignment of participants into groups.

SAMPLE STUDENT RESPONSES

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.

Answers may vary depending on which study design elements students found most relevant. One sample response is given below:

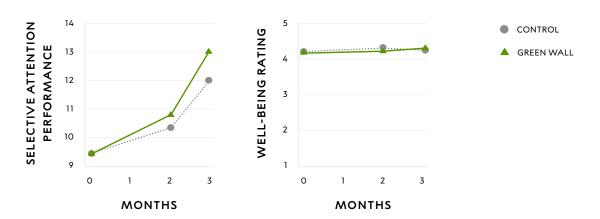
- a We thought that RCT D: Green Spaces had the most convincing evidence. This is because it had a pretty large effect on both a physical and mental measurement of stress and a pretty large sample size (120 participants). Also, it did not have as many confounds as the other studies, even though they tested college students and not high school students. Because of all this, we rated the evidence 4.5 for how strong it was in showing that videos of green spaces can reduce stress.
- b We thought RCT B: Pet Therapy had the least convincing evidence for its conclusion. Cortisol is a good indicator of stress, so the results suggest that time with a dog can help prevent stress. However, they only measured cortisol levels, not how stressed students actually felt. Also, the sample was small, especially the control group, which only had 19 students. This makes it harder to rule out random chance. Lastly, the study only included students aged 8–10 from a few schools in the United Kingdom, so the results might not apply to older students or other students in other areas. Overall, we rated the evidence 3 for whether it showed that time with dogs can prevent stress.

2 AID ASSESSMENT

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.

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.

Level 4 response

- a This data does not support the claim that access to green spaces improves well-being, because the well-being scores remained about the same during the experiment, which means that there was no effect for this experiment.
- b This study was only performed in four classrooms, so the sample size is small. Also, the well-being ratings were pretty high before the study. If the sample size was larger and included classrooms where the well-being scores started lower, the study might have gotten different results. Researchers also only tested elementary school students in their classrooms, so there could be different results with different age groups, in different settings, or with different types of green spaces.
- c I would still recommend the green spaces strategy for Salas High School. The evidence from the RCT with the nature videos is very strong. The limitations in the study for green walls are pretty significant. When you add the evidence together, overall I still think there is a cause-and-effect relationship between green spaces and well-being.

Level 3 response

a This data does not support the claim that access to green spaces improves well-being because the well-being scores did not change.

- **b** The sample size is small. Also, the well-being ratings were pretty high before the study. They also only tested elementary school students in their classrooms. I am less confident in the results.
- c I would still recommend the green spaces strategy for Salas High School. The evidence from the RCT with the nature videos is very strong. I still think there is a cause-and-effect relationship between green spaces and well-being.

Level 2 response

- a The well-being scores did not change.
- **b** The sample size is small.
- c I would still recommend the green spaces. The other evidence is good.

Level 1 response

- a It doesn't.
- **b** They had lots of limitations.
- c I think green spaces is a good idea.

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?

One claim I've seen is that drinking a lot of water every day can improve your skin. To test this, I could ask a lot of people (sample size), not just a few friends, about their experience with drinking more water and if they noticed a difference in their skin. I'd also ask people from different places, like at school, home, and even online, to see if the results are the same everywhere (consistency across settings). Finally, I'd look at how noticeable the difference was in their skin to see if there was a big improvement (effect size). If lots of people from different places say it worked and the difference in their skin is easy to see, it would make the claim seem more likely to be true.

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STUDENT SHEET 9.1

SECTION 1 Study Information	RCT A Gratitude Writing	RCT B Pet Therapy	RCT C Sleep Quality	RCT D Green Spaces
Control groups vs. Experimental group(s) (describe each)				
Well-being variable(s) that were measured (list the variables)				
Main conclusion(s) of the study (describe each)				

STUDENT SHEET 9.1

COMPARING RCTs RELATED TO THE WELL-BEING STRATEGIES

NAME

SECTION 2 Study Design Elements and Analysis Methods	RCT A Gratitude Writing	RCT B Pet Therapy	RCT C Sleep Quality	RCT D Green Spaces
Sample Size Number of participants in each group				
Target group of the study Age of the participants				
Consistency across settings Types of people and locations included in the study				
Effect size Size of the difference between the groups				

UNIT 4: INVESTIGATING EVIDENCE FOR CAUSATION

SECTION 3 Evaluation	RCT A Gratitude Writing	RCT B Pet Therapy	RCT C Sleep Quality	RCT D Green Spaces
What is an alternative explanation for the results? HINT: Is there a possible confound or inadequate sample size?				
On a scale of 0–5, how well does the evidence support the study's conclusion(s)?				

SECTION 1 Study Information	RCT A Gratitude Writing	RCT B Pet Therapy	RCT C Sleep Quality	RCT D Green Spaces
Control groups vs. Experimental group(s) (describe each)	CONTROL GROUP 1 week of writing about memories EXPERIMENTAL GROUP 1 week writing a gratitude letter and giving it to someone	CONTROL GROUP normal class EXPERIMENTAL GROUP 1 20 minutes with a dog EXPERIMENTAL GROUP 2 20 minutes stretching or listening to a story	CONTROL GROUP 8 hours of sleep each night for 12 nights EXPERIMENTAL GROUP 4 hours of sleep each night for 12 nights	CONTROL GROUP shopping mall video EXPERIMENTAL GROUP 1 nature video EXPERIMENTAL GROUP 2 traffic video
Well-being variable(s) that were measured (list the variables)	happiness score (based on positive emotion, sense of connection, and how meaningful their lives felt)	stress by measuring cortisol levels	optimism-sociability levels (how friendly, energetic, motivated someone feels)	heart signal (related to blood pressure) and self-rated feelings (fear, anger, sadness)
Main conclusion(s) of the study (describe each)	Writing a gratitude letter and giving it to someone can increase happiness for up to one month.	Spending time with dogs can keep stress levels down compared to no time with dogs or relaxation techniques.	Not enough sleep can decrease how social or optimistic someone feels (which includes how friendly, energetic, creative someone is feeling).	Watching nature videos helps people recover from stress more quickly and completely compared to watching videos of traffic or malls. This may happen because of the way the nervous system reacts to nature.

UNIT 4: INVESTIGATING EVIDENCE FOR CAUSATION

SECTION 2 Study Design Elements and Analysis Methods	RCT A Gratitude Writing	RCT B Pet Therapy	RCT C Sleep Quality	RCT D Green Spaces
Sample Size Number of participants in each group	CONTROL GROUP 70 EXPERIMENTAL GROUP 80	CONTROL GROUP 19 EXPERIMENTAL GROUP 1 33 EXPERIMENTAL GROUP 2 35	CONTROL GROUP 18 EXPERIMENTAL GROUP 22	CONTROL GROUP 40 EXPERIMENTAL GROUP 1 40 EXPERIMENTAL GROUP 2 40
Target group of the study Age of the participants	most: 35–54	8–10	21-41	18-22
Consistency across settings Types of people and locations included in the study	Most were white and had a college degree. It was done online, but there is no information on where most participants lived.	students from four elementary schools in the United Kingdom	healthy people in the area of Boston, Massachusetts	college students from a university in the Northeast United States
Effect size Size of the difference between the groups	Happiness scores were 4 points higher after giving the letter and 3 points higher after 1 month, compared to the control group.	Cortisol levels stayed about the same for the dog group over 6 weeks, but cortisol levels went up significantly by 0.02 to 0.04 µg/dL in the other two groups.	The optimism-sociability score went down by up to 15% in participants who had 4 hours of sleep but only decreased up to 5% for participants who got 8 hours of sleep.	Bigger and faster decreases in blood pressure and fear, negative feelings, and anger when people watched nature videos compared to people watching traffic or mall videos.

SECTION 3 Evaluation	RCT A Gratitude Writing	RCT B Pet Therapy	RCT C Sleep Quality	RCT D Green Spaces
What is an alternative explanation for the results? HINT: Is there a possible confound or inadequate sample size?	Maybe writing about early memories reduced positive emotions. But this isn't very likely.	Maybe any break from school lessons reduces stress. But it's more likely the dog actually helped.	Maybe being told not to sleep more than 4 hours made the experimental group mad. But it's more likely it was the amount of sleep they got.	Maybe looking at traffic and the mall continued the stress, and the nature group was neutral. But that's not as likely as the nature group's video being calming.
On a scale of 0–5, how well does the evidence support the study's conclusion(s)?	3.5	3	4	4.5

VISUAL AID 9.1

SCORING GUIDE: ANALYZING AND INTERPRETING DATA (AID)

WHEN TO USE THIS SCORING GUIDE:

This <u>Scoring Guide</u> is used when students analyze and interpret data that they have collected or that has been provided to them.

WHAT TO LOOK FOR:

- Response describes patterns and trends in data.
- Response interprets patterns and trends to describe possible causal relationships.

LEVEL	GENERAL DESCRIPTION		
Level 4 Complete and correct	The student analyzes the data with appropriate tools, techniques, and reasoning. The student identifies and describes patterns in the data and interprets them completely and correctly to identify and describe relationships. When appropriate, the student: • makes distinctions between causation and correlation. • states how biases and errors may affect interpretation of the data. • states how study design impacts data interpretation.		
Level 3 Almost there	The student analyzes the data with appropriate tools, techniques, and reasoning. The student identifies and describes patterns in the data BUT incorrectly and/or incompletely interprets them to identify and describe relationships.		

CONTINUED

VISUAL AID 10.1

LEVEL	GENERAL DESCRIPTION
Level 2 On the way	The student analyzes the data with appropriate tools, techniques, and reasoning. The student identifies and describes, BUT does not interpret, patterns and relationships.
Level 1 Getting started	The student attempts to analyze the data BUT does not use appropriate tools, techniques and/or reasoning to identify and describe patterns and relationships.
Level 0 Missing or off task	The student's analysis is missing, illegible, or irrelevant to the goal of the investigation.
х	The student had no opportunity to respond.

ITEM-SPECIFIC SCORING GUIDE

ACTIVITY 9, BUILD UNDERSTANDING ITEM 2

WHEN TO USE THIS SCORING GUIDE:

This Scoring Guide is used when students analyze and interpret data that they have collected or that has been provided to them.

WHAT TO LOOK FOR:

- · Response describes patterns and trends in data.
- Response interprets patterns and trends to describe possible causal relationships.

LEVEL

GENERAL DESCRIPTION

ITEM-SPECIFIC DESCRIPTION

Level 4 Complete and correct

The student analyzes the data with appropriate tools, techniques, and reasoning.

The student identifies and describes patterns in the data and interprets them completely and correctly to identify and describe relationships.

When appropriate, the student:

- · makes distinctions between causation and correlation.
- states how biases and errors may affect interpretation of the data.
- · states how study design impacts data interpretation.

The student response:

- · describes the pattern in the data and why the data does not support the claim.
- thoroughly describes at least two limitations and provides reasoning for how these limitations affect confidence in the study results.
- provides a well-reasoned explanation of why they are or are not recommending the strategy referencing evidence.

ACTIVITY 9: EVALUATING RANDOMIZED CONTROLLED TRIALS

UNIT 4: INVESTIGATING EVIDENCE FOR CAUSATION

GENERAL DESCRIPTION

Level 3 Almost there

LEVEL

The student analyzes the data with appropriate tools, techniques, and reasoning.

The student identifies and describes patterns in the data BUT incorrectly and/or incompletely interprets them to identify and describe relationships.

ITEM-SPECIFIC DESCRIPTION

The student response:

· describes the pattern in the data and why the data does not support the claim.

The student response may have minor errors or limited responses to:

- · describing at least two limitations and providing reasoning for how these limitations affect confidence in the study results.
- providing a reasoned explanation of why they are or are not recommending the strategy referencing evidence.

UNIT 4: INVESTIGATING EVIDENCE FOR CAUSATION

GENERAL DESCRIPTION

Level 2 On the way

LEVEL

The student analyzes the data with appropriate tools, techniques, and reasoning.

The student identifies and describes, BUT does not interpret, patterns and relationships.

ITEM-SPECIFIC DESCRIPTION

The student response:

 describes the pattern in the data but may not explain why the data does not support the claim.

The student response may have errors or limited responses/reasoning to:

- · describing at least one limitation and may not provide reasoning for how the limitation affects confidence in the study results.
- stating whether they are or are not recommending the strategy and may not describe evidence.

ITEM-SPECIFIC SCORING GUIDE

LEVEL	GENERAL DESCRIPTION	ITEM-SPECIFIC DESCRIPTION
Level 1 Getting started	The student attempts to analyze the data BUT does not use appropriate tools, techniques, and/or reasoning to identify and describe patterns and relationships.	The student response: • describes the pattern in the data, may be general, or contain errors. The student response may have significant errors or very limited responses/reasoning to: • describing general limitations. • stating whether they are or are not recommending the strategy.
Level 0 Missing or off task	The student's analysis is missing, illegible, or irrelevant to the goal of the investigation.	
х	The student had no opportunity to respond.	