**EPBI 3101 Lab 2: Randomized Controlled Trial (25 points total)**

Study Description

You have been asked to evaluate the effectiveness of a drug abuse prevention program (DAPP) targeted to 8th-grade middle school students. You know from your public health training that a randomized controlled trial (RCT) will be the best way to determine if the program works to prevent drug use, specifically, alcohol use in 9th grade. You determine your experimental (intervention) and control conditions:

* Experimental. DAPP consists of attending workshops during lunchtime and completing homework assignments.
* Control. For this study, you decide that students in the control condition will receive information about healthy eating.

You set up your RCT:

1. First, you assemble your study cohort of middle school students.
2. Then you collect relevant baseline data on your entire cohort.
3. Next, you randomize your cohort into intervention (experimental) and comparison (control) groups: you randomly assign students to receive either DAPP (intervention) or nutritional information (control condition).

Questions

1. 1,800 8th grade students have parental permission to participate in your study. You randomly assign the students to two equal-sized groups (DAPP or control). The outcome you are interested in is student-reported use of alcohol in the 9th grade. Draw the basic RCT design diagram for your study below. Show the number of students in each study group. *Leave space to fill in the numbers of students reporting each outcome (i.e., used alcohol or did not use alcohol), as you will collect this information at follow-up. (2 pts.)*

1800 8th graders 900 control 530 used alcohol

370 did not use alcohol

900 DAPP 300 used alcohol

600 did not use alcohol

1. You are concerned about adherence (students sticking with their assigned exposure). Propose two ways you could monitor your study to track whether students stayed with their assigned groups. (2 pts.)
   1. Track attendance to DAPP programs
   2. Grade homework assignments for participation and correctness
2. To assess your outcome of alcohol use in 9th grade, you give self-administered questionnaires to the students during their 9th grade school year. Assume that you are able to track and survey 100% of the students from your study (Note: This only happens in EPBI 3101, not in real life). You observe that 300 students who received DAPP used alcohol in 9th grade, and 530 students in your control group used alcohol. Use these results to fill in the numbers and complete your diagram in Question
3. Construct a 2x2 table reporting your study results. (5 pts.)

|  |  |  |  |
| --- | --- | --- | --- |
|  | Used alcohol | Did not use alcohol | Total |
| DAPP | 300 | 600 | 900 |
| Control | 530 | 370 | 900 |
| Total | 830 | 970 | 1800 |

1. Calculate the incidence of alcohol use among students who received DAPP. Write the formula and show your work. (3 pts.)

Incidence = total # of new cases / total population at risk \* 1000 = 300/900 \* 1000 = 333.33 per 1000 population

1. Calculate the incidence of alcohol use among students in the control group. Write the formula and show your work. (3 pts.)

Incidence = total # of new cases / total population at risk \* 1000 = 530 / 900 \* 1000 = 588.89 per 1000 population

1. Calculate the relative risk of alcohol use in those randomized to DAPP compared to those who received the control. Write the formula and show your work. Write one sentence explaining this result. (3 pts.)

Relative risk = incidence in exposed / incidence in nonexposed = 333.33 / 588.89 = 0.57

The risk of alcohol use among 9th graders who attended DAPP in 8th grade was 0.57 the risk of those that did not attend.

1. Can you determine causality with this study? Please explain your answer. (2 pts.)

Randomized control trials can be used to determine causality. Experimental trials are used for causality.