PHW250B Journal Club Assignment #3
Trials and Case-control studies

Assignment Policies:

Formatting

Each problem is followed by a box with a text field in which you can write your answer. Your answer should be contained within the box AND adhere to the max number of lines listed in the problem. Even if you have the ability, you should not remove page breaks, add pages or otherwise change the location of questions. This formatting makes the assignments easier for us to grade, meaning we can get them back to you sooner. On the first assignment there will be no penalty for improper formatting. In subsequent assignments (and exams!) only answers in the proper location are eligible for full credit.

Group Work

You may work with each other on problem sets. If you choose to do so, please submit your problem set individually but indicate below whether you worked with other students in the class (and list their names). You may also complete the problem set on your own. Other Students with whom you worked:

Grading

We will grade up to three questions in each problem set (we will not announce which questions in advance).

Solutions

We will post detailed solutions to each problem set after all problem sets are submitted. It is your responsibility to compare your solutions to the ungraded problems to our posted solutions to ensure that you correctly answered the question.

<u>**Questions about Null et al., 2018**</u>

Note: some of the questions below (e.g., Problems 1-2) ask you to answer questions about the study that are not necessarily mentioned in the article itself. We encourage you to read the article and then apply principles from the class to answer these questions.

Problem 1. Why was a factorial design appropriate for this research question? Explain your answer. (2-4 sentences)

Problem 2. Why was a cluster-randomized design appropriate for this research question? Explain your answer. (2-4 sentences)

Problem 3. Was this an efficacy or effectiveness trial? Describe the rationale for your response. (2-4 sentences)

Problem 4. Study participants were not blinded in this trial. How do you think this affected the risk of bias in this study for analyses of outcomes that were A) self-reported ("subjective") and B) not self-reported ("objective")? (2-3 sentences each)

Problem 5. Review the random sequence generation process for this study and provide an assessment of possible selection bias. (2-4 sentences)

Problem 6. Review the allocation concealment in the this study and provide an assessment of possible selection bias. (2-4 sentences)

Problem 7. Briefly describe the level of intervention adherence in years 1 and 2 of this trial reported in Table 2. Which interventions had the highest adherence? (4-6 sentences)

Problem 8. For interventions with imperfect intervention adherence, how would you expect this to affect the estimated measures of association (using an intention-to-treat analysis)? (2-3 sentences)

Problem 9. The authors used an intention-to-treat analysis. Describe how they could have conducted a per protocol analysis. What is one advantage and one disadvantage of a per-protocol approach compared to an intention-to-treat approach? (4-6 sentences)

Problem 10. In Table 5, in the column "Difference vs. active control", what kind of measure of association is reported?

Problem 11. Assess loss to follow-up in this trial. Was it more or less than the amount expected by investigators? Was it differential by intervention arm? How would any loss to follow-up have influenced study findings? (4-6 sentences)

Problem 12. Assess whether there was selective outcome reporting in this trial. (2-3 sentences)

Problem 13. If there had not been equipoise for this research question, what would the implications have been for this study? (2-3 sentences)

Questions about Reingold et al., 1989

Problem 14. Was a primary or secondary study base used in this study? Justify your answer. (2-3 sentences)

Problem 15. What type of control sampling (case cohort, density, or cumulative sampling) did the study use? Justify your answer. (1-2 sentences)

Problem 16. What measure of association does the odds ratio estimate in this study? How do you know? (1 sentence)

Problem 17. Name two advantages and disadvantages of using friend controls (see the second Wacholder et al. 1992 paper).

Problem 18. What steps did the authors take to meet the deconfounding principle? (1-2 sentences)

Problem 19. List and describe three advantages of using age- and neighborhood-matched controls.

Problem 20. Was the comparable accuracy principle met? Justify your answer. (2-3 sentences)

Problem 21. Review Table 1. How comparable were cases, friend controls, and age- and neighborhood matched controls? (1-2 sentences)

Problem 22. Was there evidence that "super" absorbent tampons led to a higher odds of TSS than "regular" tampons? Justify your answer. (3-4 sentences)