Homework 1: Study designs

STAT218

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*Instructions: type up your answers and submit your work electronically. Questions with a learning outcome indicated in brackets will be evaluated for credit; other questions are provided for additional practice. You are expected to answer all questions.*

## Education and injury prevention

Suppose you wish to study the efficacy of physical activity and exercise education as a means of sports injury prevention. Your research question is, “does knowledge about injury prevention during physical activity and exercise reduce the risk of injury?”. Imagine that ASI offers a short injury prevention training.

Your initial study proposal is as follows:

150 Cal Poly students will be selected for the study: 75 from among those who completed the injury prevention training voluntarily, and 75 from among those who did not. Participants will be followed for a year to determine how many in each group experience an injury related to physical activity at any point during the study period. At the end of the study, injury rates will be compared between those that participated in the injury prevention training and those that did not.

1. [L2] Is this an observational study or an experiment? Explain your answer.

This is an observational study because the study design doesn’t involve any experimental intervention: participants \*voluntarily\* participate (or don’t) in the training program and are then followed for a period of time to collect data on injury; the researchers impose no conditions or treatments on study subjects.

*A satisfactory answer here must:*

* *appeal to the absence of an experimental intervention*
* *explain what that means in the context of the study proposal*

1. [L1] How would you go about selecting study participants at random? Propose a specific means of identifying and contacting students to participate in the study.

*Answers here may vary but should provide:*

* *a way to identify training participants and nonparticipants*
* *a way to select participants*
* *a means of contacting selected participants.*

*Answers should \*not\* allow prospective participants to self-select (e.g., mass email requesting volunteers).*

*For example:* Obtain email addresses of training participants from ASI records and student emails from the university; remove training participant emails from the student email list, then select 75 at random from each list and contact them via email.

1. [L2] Imagine you found that those who completed the training are less likely to experience injury. Are these results potentially subject to confounding? If you answer yes, give a hypothetical example of a confounding factor; if you answer no, explain why confounding is not a concern.

Yes, results are subject to confounding because this is an observational study; there could be unmeasured factors associated with both voluntary training participation and the likelihood of injury. For example, possibly a greater proportion of training participants had sustained previous injuries and are thus at higher risk for injury during the study period.

*A satisfactory answer should:*

* *be affirmative*
* *cite the study type as justification*
* *explain what confounding means in the context of the study*
* *give an example of a possible confounding factor*

1. [L1] If you answered that it is an observational study, propose an experiment that would address the same question. If you answered that it is an experiment, propose an observational study that would address the same question.

An experiment might recruit 150 participants, randomly allocate half to participate in the ASI training, and follow study participants for a year to observe injury occurrences. The random allocation of ASI training constitutes an experimental intervention. The same outcomes – injury rates between ASI trainees and non-trainees – would be compared.

*A satisfactory answer should:*

* *Propose a study design with an experimental intervention*
* *Explain what outcomes would be measured*

*If students propose an observational study based on mistakenly having answered that the original study was experimental, answers can be marked as satisfactory provided they meet analogous criteria, in this case, proposing a study without any intervention and explaining the outcomes that would be measured. However, students should still revise this answer if they provide revisions, so a comment should be left indicating: consistent with prior answers, and satisfactory, but should be revised if revisions are submitted.*

1. [L2] Suppose the alternate study you proposed in (4) indicated that those who completed the training are less likely to experience injury. Are these results potentially subject to confounding? If so, give a hypothetical example of a confounding factor; if not, explain why confounding is not a concern.

Random allocation of the ASI training controls for confounding factors, so no, the study results are not subject to confounding. Any unobserved factors will not be associated with the group assignment (ASI trainee vs. non-trainee) due to the random allocation.

*Satisfactory answers should:*

* *Provide an answer consistent with previous responses*
* *Appeal to the study design as justification*
* *Explain what confounding/no confounding means in the context of the study*

1. Is the original proposal a retrospective or prospective study? Explain your answer.
2. If you answered that it is retrospective, determine an alternate study to investigate the same research question that is instead prospective; if you answered that it is prospective, determine an alternate study that is retrospective. Write a short proposal similar to the above for your alternate study.

## Peanut allergies

Consider the Learning Early About Peanut allergy (LEAP) study discussed in class and in your reading:

For the LEAP study, 640 infants in the United Kingdom were enrolled with risk factors for peanut allergies (eczema or egg allergy); 530 passed a skin test at the start of the study showing no peanut allergy. Each infant was randomly assigned to peanut consumption (6g peanut protein per day) or peanut avoidance (no peanut consumption) groups. At 5 years of age, an allergy test was administered to each study participant; the rates of peanut allergy were compared between the two groups.

1. [L1] Propose a retrospective observational study to investigate the research question, “is early peanut exposure associated with a lower risk of developing peanut allergies?” Include a specific description of how you might enroll participants.

Children 5-8 years of age with known peanut allergy status will be recruited through pediatric care centers; their parents or caregivers will be requested to complete surveys regarding peanut exposure in diets during infancy to estimate level of peanut protein consumed during infancy. The study will compare levels of consumption between the participants with allergies and those without allergies to determine whether relatively more children with peanut allergies had lower levels of exposure during infancy.

*Satisfactory answers should:*

* *Propose recruiting children/participants after having developed allergies (or not)*
* *Include an allergy and a non-allergy group of participants*
* *Identify some mechanism for finding study participants (e.g., pediatric care centers, schools, etc.)*
* *Identify data that would be collected (should be relevant to research question)*