

Stat 1040 Recitation 1 Solutions (with two extra problems at the end)

1. A 1999 study claimed that

Infants who sleep at night in a bedroom with a light on may be at higher risk for myopia (nearsightedness) later in childhood.

The researchers surveyed parents of 479 children aged 2 to 16 seen in the ophthalmology outpatient department of a children's hospital. A questionnaire asked about the child's nighttime light exposure at the time of the survey and before age two. They noticed a positive association between myopia and nighttime light exposure.

- (a) Explain how you know that this is an observational study. *We know it is an observational study because they simply gave a questionnaire asking about how much nighttime light exposure the children had already been exposed to. They did not intervene or control the amount of exposure.*
- (b) What would they need to do to set up a carefully designed experiment to see whether sleeping with the light on caused myopia? Explain in enough detail so that I can tell that you know what you are talking about. (You do not have to comment on whether or not your experiment is practical). *For it to be a controlled experiment, they would have needed to control how much nighttime light the children received. They would need to recruit babies whose parents agreed for them to be part of the study. They would assign some of the children to get no nighttime light and others to get nighttime light. They would assign the children to these groups at random, using an objective chance procedure. At the end of the study, they would have an unbiased eye doctor determine whether or not each child had myopia and compare the myopia rate for the group that got light to the group that did not get light. They could not make it blind because the children and their parents would know which group the children were in, but they could try to control what the eye doctors knew and what they told the patients and their parents about the expectations of the study.*
- (c) Explain why this is *not* strong evidence that sleeping with a light on *causes* myopia by suggesting a possible confounding factor and explaining clearly how this confounding factor could account for the association they observed.

There are many possible confounding factors. Possibly the most convincing one is that if the parents have myopia, they are more likely to leave the light on so that they can see better. Their children may be likely to inherit the myopia if there is a genetic component. So it may be nothing to do with the light causing the myopia - it may just be due to the parents' poor vision being passed down to the child and also causing the parents to leave the light on for their own convenience. Other possibilities include ethnic differences in myopia rates and in behavior (perhaps the ethnicities that tend to leave the light on also happen to have high rates of myopia); age (perhaps the older children were more likely to have developed myopia due to their age and perhaps nightlights were more popular when they were young than they are right now); reading (perhaps kids who read a lot tend to leave the light on at night because they fall asleep reading and perhaps too much reading causes myopia). NOTE: genetics alone is not a convincing confounding factor unless you explain why people who are genetically prone to myopia might leave the lights on.

2. The following paragraph appears on the website www.alternative-medicine-and-health.com

Elmer Cranton, M.D., in his book, "Bypassing Bypass", indicates that a ten year, 24 million dollar study conducted by the National Heart, Lung and Blood Institute, which screened 16,000 patients who underwent coronary artery bypass at eleven leading medical centers, revealed no increase in post-surgical survival rates as compared with a matched group of non-surgically treated patients.

You may assume that the "matched group" was selected to resemble the original 16,000 with respect to age, sex and type of heart disease.

- (a) Based on what you read in the paragraph, was the study randomized? Explain clearly. *No, it was not randomized because they did not randomly pick who would get the surgery and who would not get the surgery. They just compared those who had surgery to those who did not.*
 - (b) Was the study blind? Explain clearly. *No, it was not blind because the patients knew whether they had surgery or not.*
 - (c) Explain the major problem with a study such as this one, and why it would probably not give very reliable results. *The major problem is that there will always be confounding factors. In this example, they tried to "control" for the confounding effects of age, sex and type of heart disease, but there is a lot of evidence that in studies like this the control group will differ with respect to things like general health, severity of the disease, ability to withstand surgery, socioeconomic level, and many other confounding factors. For example, suppose (extreme case) that the very urgent patients got surgery. These urgent patients might otherwise have had a very high death rate, and the surgery might just bring their death rate down to what it would be for the non-surgery group. Hence the surgery might not look as effective as it should do. In this case, the confounding factor would be the urgency of the condition and we are suggesting that urgency could be associated with getting the surgery and could also be associated with non-survival.*
3. A recent study in Europe looked at a large group of women of childbearing age. The researchers asked each woman how much alcohol they had consumed over the past 12 months. The researchers found that women who drank moderate amounts of alcohol were somewhat less likely to have infertility than women who did not (November, 2001). The study said it "controlled for age, income and religion".
- (a) Based on the information above, was this a controlled experiment or an observational study? Explain briefly. *This is an observational study because they did not tell the women how much alcohol to drink.*
 - (b) Why did they "control for" age, income and religion? *They "controlled for" age, income and religion because these are possible confounding factors. For example, it is well known that older women have more infertility. Perhaps the women who drink a lot tend to be younger than the ones who don't. Then it could appear that drinking prevents infertility, but really it's just age differences that are important.*
 - (c) Is this convincing evidence that infertility would decrease if women with infertility started to drink moderate amounts of alcohol? (Note: we are only asking about infertility. There may be other problems introduced by such behavior, but ignore these for answering this question). *No, because we do not know whether age, income and religion are the only confounding factors. Association is not causation - just because drinking alcohol is associated with lower infertility does not mean that it causes lower infertility.*

- (d) Suggest a possible confounding factor (other than age, income, or religion) and clearly explain why you think it might be a confounding factor. *A possible confounding factor could be marital status. Perhaps singles drink more than married women and perhaps singles are less likely to know if they have infertility.*
4. A randomized, controlled, double-blind study published in March, 2008 shows the well-known “placebo effect” works even better if the placebo costs more. In the study, volunteers were given an electric shock and took a pill. Volunteers in the treatment group were told it was an expensive painkiller, while those in the control group were told it was a discounted painkiller. In fact, all the pills were placebos, but 85% of the volunteers who thought they were getting an expensive painkiller said they felt less pain after taking it, compared to 61% of those who thought they were getting a discounted painkiller.
- (a) What is a placebo? *A placebo is something that resembles the treatment but lacks the active ingredient. For example, a saline shot or a sugar pill.*
- (b) Why is a placebo used in a controlled experiment? *A placebo is used so that the experimnt can be blind, i.e. so that people do not know which group they are in. This is done so that any differences we see between the two groups are due to the treatment itself, not just to the idea of treatment.*
5. Here is the beginning of an article from the YAHOO Health News web site on January 7, 1998:

“Wednesday January 7, 1998 For Yahoo News by Reuters

Daily Two-Mile Walk Halves Death Risk

NEW YORK (Reuters) — Walking two miles or more per day can cut the overall risk of dying in half, according to a new study. It also reduces the risk of dying from cancer — and appears to cut the risk of death due to cardiovascular diseases, US researchers report. Between 1980 and 1982, multicenter researchers in the Honolulu Heart Program studied 707 nonsmoking, retired men, aged 61 to 81 years, and collected mortality data on these men over the following 12 years. During the study, 208 of the men died. The study results show that while 43.1% of men who walked less than one mile per day died, only half this figure – 21.5% – of the men who walked more than two miles per day died.”

- (a) Is the research described in the article an experiment or an observational study? (Please circle your answer.)
It’s an observational study because they did not control whether or not the men walked.
- (b) List two different possible confounding factors that are likely to have an effect on the outcome of this study. Carefully explain exactly why you think these are confounding factors. *Health problems would be a possible confounding factor. Men who have health problems are more likely to die, and men who have health problems are less likely to be able to walk more than two miles a day. In this case, walking is simply an indication of good health, not a cause of good health. Another possible confounding factor might be age. Perhaps men who were older when the study started were less capable of walking more than 2 miles and we know than men who were older at the start of the study would be more likely to die during the study. Another possible confounding factor would be diet (or alcohol consumption or smoking). Men who walk at least 2 miles a day would be likely to take care of themselves in other ways (diet and healthy lifestyle) and perhaps it is one of these other things that prevents death, not necessarily the walking itself.*

- (c) Based on the description in the body of this article, is the headline (“Daily Two-Mile Walk Halves Death Risk”) justified? **Yes** or **No**? Circle your answer and give a brief explanation. *No, it is not justified because this headline is saying that walking CAUSES them to live longer, and we cannot make that sort of conclusion from a single observational study because there are lots of possible confounding factors.*

6. Read the following news article:

“Wrap up” advice to stop colds

Scientists say cold noses reduce ability to fight virus attacks

Monday, November 14, 2005; Posted: 4:47 p.m. EST (21:47 GMT)

LONDON, England (CNN) – British researchers into the common cold say “catching a chill” really does help colds develop – and are advising to “wrap up warm” to keep viruses at bay.

Mothers and grandmothers have long warned that chilling the surface of the body, through wet clothes, feet and hair, causes common cold symptoms to develop. But much previous research has dismissed any link between chilling and viral infection as having no scientific basis.

Now researchers in Cardiff, Wales, say they can prove drops in temperature to the body really can cause a cold to develop.

Claire Johnson and Professor Ron Eccles, from Cardiff University’s Common Cold Center, recruited 180 volunteers, half of whom they got to immerse their feet in ice and cold water for 20 minutes.

The other 90 in tests during the common cold “season” sat with their feet in an empty bowl.

During the next four or five days, almost a third (29 percent) of the chilled volunteers developed cold symptoms – compared to just 9 percent in the control group, the scientists said.

- (a) Is this an observational study or a designed experiment? Explain briefly. *This is a designed experiment because they changed people’s behavior. An example of an observational study, they might ask people if they had got cold and wet in the last 2 months and ask them how many colds they had in the last 2 months.*
- (b) What is the “treatment” in this study? *The treatment is putting your feet in ice and cold water for 20 minutes.*
- (c) The article does not say how the researchers divided up the 180 people into two groups of 90. How *should* they do this? Explain clearly. *They should do this at random (e.g. by tossing a coin: heads you get the ice, tails you don’t.)*
- (d) Is the study blind? Explain briefly. *No it is not blind because the people know whether or not their feet have been in ice water.*
- (e) Are there any possible confounding factors or problems with the study? Explain clearly. *Possible confounding factors relate to the fact that the experiment is not blind. For example, perhaps the people who had their feet in ice water behaved differently from those who did not (although I would think they might be more careful not to get exposed to germs and this would tend to have the effect of reducing the rate of colds in this group, and we are looking for things that would tend to increase the rate of colds and hence account for the observed difference). Perhaps the treatment group expected to get a cold, so ones with mild symptoms might be more likely to answer “yes I got a cold” than those in the control group who had similar symptoms.*

7. Researchers think that eating “trans-fats” lowers the particle size of LDL molecules (so-called “bad cholesterol”) in the body and hence increases the risk of heart disease. Stick margarine is high in “trans-fats” while butter is low in “trans-fats”.

In a recent randomized, controlled, double-blind study, subjects were put on special diets for a period of 3 months. The *treatment group* received a special diet in which 20% of the calories came from stick margarine, while the *control group* received a special diet in which 20% of the calories came from butter. The food was prepared by taking the same low-fat diet and mixing either stick margarine or butter into foods such as muffins, casseroles, and hot cereals. Participants were required to eat all of the food provided in the special diets, and nothing else. At the end of the study, researchers measured the LDL particle size and found that the average LDL particle size for the treatment group was smaller than the average LDL particle size for the control group, and that the difference was “statistically significant”.

- (a) Clearly explain what it means for the study to be *randomized*. *It means that subjects were assigned to the butter and margarine groups using an objective chance procedure like tossing a coin or using random numbers from a computer.*
 - (b) Clearly explain what it means for the study to be *double-blind*. *It means that neither the subjects nor the people who interacted with them or measured the particle size knew which group they were in.*
 - (c) Why is it better to compare two groups like this instead of just putting all the people on the treatment diet (margarine) and comparing their LDL particle size at the beginning of the study to their LDL particle size at the end of the study? *In some ways this would be a better thing to do because it reduces variability between people (we are comparing a person at the end to the same person at the beginning). However, the problem with this is that at the end of the day we would not be able to figure out if the differences were due to the margarine or the diet itself.*
 - (d) Why was the margarine or butter mixed into foods instead of being used as a spread? *This was probably done to maintain the blind - people are more likely to be able to tell the difference between margarine and butter if it is used as a spread than if it is mixed in.*
8. **Does Aspartame Cause Cancer?** Aspartame is an artificial sweetener found in thousands of products – sodas, chewing gum, dairy products and even many medicines. Some research has suggested that aspartame can cause lymphoma or leukemia in rats.

A recent study by the National Cancer Institute involved 340,045 men and 226,945 women, ages 50 to 69. From surveys they filled out in 1995 and 1996 detailing food and beverage consumption, researchers calculated how much aspartame they consumed. Over the next five years, 2,106 developed cancers such as lymphoma or leukemia. No association was found between aspartame consumption and occurrence of these cancers.

- (a) Was the study a controlled experiment or an observational study? Why?
It was an observational study because the subjects decided how much aspartame to consume. For this to be an experiment, the researchers would have had to control how much aspartame the subjects consumed, e.g. by providing them with beverages or telling them which sort of beverages to buy.
- (b) Suggest a possible confounding factor for this study and explain why your confounding factor might make you doubt their results.
A confounding factor might be exercise. The subjects who consumed aspartame might have been trying to control their weight and therefore might have been more likely to

exercise than those who did not consume aspartame. Exercise might have had a protective effect against cancer. So, it's possible that aspartame does cause cancer but the other things they were doing compensated for the increased risk.

- (c) “It’s very reassuring. It’s a large study with a lot of power,” said Richard Adamson, a senior science consultant to the American Beverage Association, the leading industry group. Does the large sample size prove that aspartame does not cause cancers such as lymphoma or leukemia? Explain.

The study was observational, so even though it was large, the results are not very convincing. If this had been a large, randomized, double-blind experiment, it would be much more reassuring.