Problem 1 (Problems 7.10 – 7.14 in the book)

Suppose the incidence ratio of MI (myocardial infarction) per year was 5 per 1000 among 45- to 54-year-old men in 1990. To look at changes over time, 5000 45- to 54-year old men were followed for 1 year staring in 2000. Fifteen new cases of MI were found.

a) Test the hypothesis that incidence rates of MI changed from 1990 to 2000.

Suppose that 25% of MI cases in 1990 died within 24 hours. This proportion is called the 24-hour case-fatality rate.

b) Of the 15 new MI cases in the preceding study, 5 dies within 24 hours. Test if the 24-hour case-fatality rate changed from 1990 to 2000.

c) 1. Suppose we eventually plan to accumulate 50 MI cases during the period 2000–2005. Assume that the 24-hour case-fatality rate is truly 20% during this period. How much power would such a study have in distinguishing between case-fatality rates in 1990 and 2000–2005 if a two-sided test with significance level .05 is planned?
   2. How large a sample is needed to achieve 90% power?

Problem 2 (Problem 7.21 in the book)

Suppose we identify fifty women 50 to 54 years old who have both a mother and a sister with a history of breast cancer. Five of these women themselves have developed breast cancer at some time in their lives. If we assume the expected prevalence rate of breast cancer in women whose mothers have had breast cancer is 4%, does having a sister with the disease add to the risk?

Problem 3 (Problem 7.22 in the book)

The probability of bearing twins in the United States is approximately 1 in 90. This proportion is thought to be affected by a number of factors, including age, race, and
parity. To study the effect of age, hospital records are abstracted. Of 538 deliveries for women under 20, 2 resulted in twins. What can be said about the effect of maternal age on having twins?

Problem 4 (Problem 7.72 in the book)
Refer to the data set nifed.txt. The file is on the CD-ROM that came with the book, use read.csv to read in the comma separated file. The format of the file is explained on page 157 in the book.

Use hypothesis-testing methods to assess if either treatment affects blood pressure or heart rate in patients with severe angina.

Problem 5 (Problems 7.73 – 7.75 in the book)
A combination of photochemotherapy with oral methoxsalen (psoralen) and ultraviolet A radiation (called PUVA treatment) is an effective treatment for psoriasis. However, PUVA is mutagenic, increase the risk of squamous-cell skin cancer, and can cause irregular, pigmented skin lesions. Stern et al.\(^1\) performed a study to assess the incidence of melanoma among patients treated with PUVA. The study identified 1380 patients with psoriasis who were first treated with PUVA in 1975 or 1976. Patients were subdivided according to the total number of treatments received (\(< 250\) or \(\geq 250\) from 1975 to 1996). Within each group, the observed number of melanomas was determined from 1975 to 1996 and compared with the expected number of melanomas as determined by published U.S. age- and sex-specific melanoma incidence rates. The results were as in table 7.6.

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Expected</th>
</tr>
</thead>
<tbody>
<tr>
<td>(&lt; 250) treatments</td>
<td>5</td>
<td>3.7</td>
</tr>
<tr>
<td>(\geq 250) treatments</td>
<td>6</td>
<td>1.1</td>
</tr>
</tbody>
</table>

1. Suppose we want to compare the observed and expected number of events among the group with \(< 250\) treatments. Perform an appropriate hypothesis test.
2. Provide a 95% confidence interval for the expected number of events in the group with \(\geq 250\) treatments.
3. Interpret the results in 1. and 2.

Problem 6 (Problems 7.81 – 7.82 in the book)

An investigator wants to test a new eye drop that is supposed to prevent ocular itching during allergy season. To study the drug she uses a contralateral design whereby for each participant one eye is randomized to get active drug (A) whereas the other eye gets placebo (P). Ten participants are randomized into the study. The randomization assignment is given in Table 7.8.

Table 7.8: Randomization assignment

<table>
<thead>
<tr>
<th>Subject</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left eye</td>
<td>A</td>
<td>P</td>
<td>A</td>
<td>A</td>
<td>P</td>
<td>A</td>
<td>A</td>
<td>P</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Right eye</td>
<td>P</td>
<td>A</td>
<td>P</td>
<td>P</td>
<td>A</td>
<td>P</td>
<td>P</td>
<td>A</td>
<td>P</td>
<td>P</td>
</tr>
</tbody>
</table>

1. What is the principal advantage of the contralateral design?
2. More left eyes seem to be assigned to A than to P, and the investigator wonders if the assignments are really random. Perform a hypothesis test to assess how well the randomization is working.

Problem 7 (Problems 8.1 – 8.3 in the book)

Twenty volunteers adopt a low-cholesterol diet for 3 months. The mean ±1 sd of change (baseline – 3 months) in serum cholesterol over the 3-month period was 20.0 ± 35.0 mg/dL.

a) Test for significant changes in mean cholesterol over 3 months.

An important component of cholesterol is HDL cholesterol, which is widely believed to have a beneficial effect on heart disease. The mean ±1 sd of change (baseline – 3 months) in HDL cholesterol over the 3-month period was 3.0 ± 12.0 mg/dL. The mean ±1 sd of weight loss over the 3-month period was 5.2 ± 8.0 lb.

b) 1. Test for significant changes in mean HDL cholesterol over 3 months.
   2. Test for significant changes in mean weight over 3 months.