1. The trial was conducted because anecdotal information had suggested that the lumpectomy might be just as beneficial for treating breast cancer. However, they also state they do not know why a lumpectomy was performed in the first place because there was no biological proof that it would be superior. They decided to do more research since this procedure was growing in popularity without much clinical evidence to support it.

2. Patients were randomly assigned to one of three treatment groups: total mastectomy, segmental mastectomy, or segmental mastectomy with radiation treatment. The primary endpoints were disease-free survival, distant disease-free survival, and overall survival.

3. The eligibility requirements were that a participant have stage I or II cancer, and that their tumor be smaller than 4 cm. There also could be no skin involvement, and the cancer had to be confined to the breast. Those with more advanced cancer were excluded because their treatment would probably need to be more rigorous to cure them, and therefore the lumpectomy would not have helped them. The researchers did not want people with more advanced cancer to not get the treatment they needed.

4. After the experiment began, it was found that some of the participants should not be included. Some were found to be ineligible after the randomization, some had non-invasive tumors, but most of the lost participants did not accept their randomization. I do not think that this is a large weakness of the study, since many participants are usually lost in a large study. I also do not think that the largest factor, people not accepting their randomization assignment, could have been avoided. Before they were randomized, the participants were informed of the conditions and different levels and risks of the experiment. This may have made some people want one over the other. However, it is necessary to explain each level in order to be ethical.

5. I do think that these people should be included in the analysis. It is like the principle for the intent to treat. In real life, some people who have had segmental mastectomies will later go on to have total mastectomies. The data should be analyzed this way. However, I could see how this could influence the data. If participants that first had a lumpectomy and then later had a mastectomy did better than participants that only had a lumpectomy, it may be evidence that the mastectomy was better. If they do really well, the data will say it was the lumpectomy, not the total mastectomy.

6. The main conclusion was that radiation therapy is the best choice, whether receiving a lumpectomy or a total mastectomy. However, the results also supported the notion that a lumpectomy was just as beneficial. The best therapy was a lumpectomy or total mastectomy with radiation therapy.

7. Yes, the experiment has a great impact on breast cancer treatment, and lumpectomy is widely used today.

8. I think that with such low numbers for 5-year follow-up, little can be certain. On a study with almost two thousand people, assumptions should not be made on the treatment success of less than a hundred. This sample could have greatly skewed the data for the 5-year follow-up outcome.

9. I think that the researchers were interested in having a satisfactory cosmetic result. In the selection of patients section, it mentioned that the researchers excluded people that were not likely to have an acceptable cosmetic result after surgery. I found it odd that this was included in selection criteria. The researchers might have included it because patients with a cosmetically
acceptable result would look at their surgery and the trial more positively, and therefore have a better outcome. However, I do not think that people should have necessarily been excluded because of this. In real life practice, there will be a wide variety of patients.

10. It was interesting, and I am very swayed by the results. However, I do think that the number of five-year follow up participants is very misleading and could have skewed data.

11. In Pittsburg 1990, the coordinating center for the study received two documents from the Montreal center. These documents were supposed to be copies; however, they were different from each other. This led to an investigation.

12. After the initial error was detected in Montreal, an investigation occurred. The investigation uncovered several other errors in data. They also discovered that the data was being falsified by Roger Poisson, the primary investigator in Montreal. In 1991, Poisson was dismissed from the study, and the Montreal participants were no longer included in the study. Fisher and Redman from the coordinating center informed the NCI and the Office of Research Integrity. In 1994, the Chicago Tribune found out about the falsification, and ran an article about it. They also informed the NEJM of the fraud.

13. Drs. Angell and Kassirer were very upset that NEJM had not been informed by Fisher and Redman about the fraud when it happened. They stated that though they informed the NCI, it was not enough, and that they should have informed NEJM. They also stated that no one involved had acted appropriately. Another point was that the researchers did not publish reanalyzed data, and that NEJM should have been informed that the data might be compromised. They said that it was not up to the researchers to decide if the data was changed or not by the falsification, but that the readers should decide.

14. Dr. Poisson was to blame, for falsifying the data and compromising the study. I think that maybe Fisher should have informed NEJM, though they did not have to. The editorial states that the coordinating center is to blame for not questioning why Poisson enrolled twice as many participants. However, I do not think anyone is to blame for that.

15. Poisson explained that he was acting in the best interest of his patients. He criticized the eligibility requirements for being too strict. He also stated that his patients would have received better care being in the trial than not.

16. Both Dr. Fisher and Carol Redman were fired from their posts at the University of Pittsburg. However, do to demand they were reinstated years later. Dr. Poisson was removed as the principle investigator; however, he did not receive criminal charges for fraud.

17. This study had many effects on medical practice. Patients may not be willing to undergo treatments that they knew were performed in this study. Doctors may believe that it is all right to falsify data. In addition, the results of this study were questioned, even though they are probably correct. Patient trust has definitely been decreased because of this study. People may be unwilling to participate in a study, or if they do, they will be suspicious of their doctors. People have lost trust in some of the medical profession. Clinical trials are now more careful of their data and research. There are more precautions in place to prevent fraud. The NCI now requires audits of all data. This has been very inconvenient, costly, and time consuming for clinical trials.

18. The paper states that data audits are unnecessary and more harmful than helpful. It also states that excessive audits will reduce the number of doctors willing to participate in the study. It also states that there was no need for a data reanalysis (unlike what the NEJM editorial stated) because 1400 patients in Montreal were properly randomized and should have been included. The main argument is that the few ineligible participants in the study should not have affected the data of such a large study.
19. I do not think that Fisher and Redman were treated fairly. They were not the ones responsible for the data falsification, and they should not have been treated as guilty. I do not think they should have been fired or held accountable for something they did not do. They also were not required to tell the NEJM, therefore they cannot be held accountable for that. Dr. Poisson, I think was treated too nicely. I think falsifying trial data is a very horrible thing, and I think he should have gotten a worse punishment.

20. I think that if Dr. Poisson had gotten a worse punishment for his crime, other researchers and doctors would think twice about falsifying data. If he had been prosecuted with fraud charges, it would have sent a clear message about falsifying data.