**Online Supplementary Material to T. L. Swift, "Sham Surgery Trial Controls: Perspectives of Patients and Their Relatives," *Journal of Empirical Research on Human Research Ethics*, *7*(3), 15–28.**

**Box 1. Placebo response explanation, justification for using placebo-controlled trials, and hypothetical sham surgery scenario provided to patients for their consideration.**

**Research study: The ethics of testing new surgical operations for Parkinson's Disease**

**The problem of the placebo effect**

Sometimes after taking a medicine or having an operation people think they feel better even if the medicine or the operation hasn't actually worked. Doctors call this the **placebo effect**.

New medicines and operations are being developed all the time but not all of them will work. When testing new treatments the **placebo effect** sometimes makes it difficult for doctors to know if they work or not.

**How can we tell if a new treatment works and is not just the placebo effect?**

Medicines and operations are tested in research trials. To account for the placebo effect in a new operation for Parkinson's Disease, some doctors recently suggested using a trial involving a **placebo group**. A placebo group is a group of people who do not actually get the real treatment but a sham one instead. They still might feel better because of the **placebo effect** but doctors can see if a group who got the real treatment did better or worse.

Placebo groups are sometimes used in trials to test new medicines but are not usually used in trials to test new operations. This is because taking a 'fake' tablet is very easy but undergoing a sham operation involves a lot more.

We are now going to look at a research trial that involved a sham operation:

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A few years ago, doctors at a hospital in the United States decided to run a research trial to test a new experimental brain operation for people with severe Parkinson's Disease. It was hoped that the operation would permanently improve patients' movement and reduce tremor.

If people felt better after the operation, the doctors wanted to make sure it was not just because of the *placebo effect* (when people think they feel better even if an operation did not work). To check this, the doctors decided to divide the people in the trial into two groups so they could compare how the two groups did.

The people in the first group were to be given the real operation. The people in the second group were to be given only a sham operation but the doctors would make it seem like the real one so the patient could not tell the difference (and so might experience a *placebo effect*). A computer would decide randomly (by chance) who ended up in which group. Before people decided whether or not to take part, the doctors told them six important things about the research trial:

1) That if they entered the trial, each patient had a fifty-fifty chance of getting the sham operation (they would be told a year later which operation they actually got).

2) That the doctors did not know if the real operation would work.

3) That if the patient got the real operation, it may improve their Parkinson's symptoms but there was also a chance it might make them worse.

4) That if the patient got the sham operation, they would still have to have a local anaesthetic, a surgical frame fitted to their head, a scan done of their brain, and have two holes a few millimetres deep drilled partway into their skull so that they couldn't guess if they were getting the sham operation.

5) That if they got the sham operation in the trial, they would be offered the real operation after the trial had finished (if the trial showed that the real operation worked).

6) That they could continue to take their medication the same as usual except on the day of the surgery.

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**Box 2. Some key questions in the interview guide used in interviewing patients with Parkinson's Disease and their relatives regarding their attitudes to sham surgery and to hypothetical participation in a sham-controlled trial (full interview guide including vignette can be obtained from author).**

1. Would you agree to take part in a trial which had a fifty-fifty chance of you getting a sham operation instead of the real one? What reasons lead you to that decision?
2. Do you think the severity of your Parkinson's Disease might affect whether you agreed to take part or not?
3. If you were one of the people who had agreed to take part in the trial just described, which group would you be hoping to be in, the real operation group or the sham group, and why?
4. Imagine again you were one of the people who decided to take part in the trial. You find out afterwards you were allocated to the group getting the *sham* operation. How do you feel about this?
5. Possible results:
    i. Imagine that at the end of the research, the doctors found out that the real operation did not work any better than the sham one. How do you now feel about getting the sham operation? Does this change how you feel?
    ii. Imagine that the doctors found out that the patients who had the real operation did slightly worse than those who had the sham operation. In other words, the real operation was actually slightly harmful. How does this make you feel about getting the sham operation?
    iii. Imagine that the doctors found out that the real operation worked. How does this make you feel about getting the sham operation (bearing in mind you will now be offered the real operation)?
6. Now imagine you find out afterwards that you were allocated to the *real* operation. Imagine that at the end of the research, the doctors found out that the real operation was actually slightly harmful and you have done worse than those who were in the sham group. How does this make you feel?
7. Imagine if the hospital ethics committee had decided that a trial with a sham operation group should not go ahead because it is unfair for some patients to have sham surgery. How do you feel about this?
8. Overall, do you agree or disagree with the idea of there being a group of people in the research trial who get a sham operation?

**Thank you for taking the time to consider these questions.**