

V000 BRANCHPOINT: IF THIS IS NOT A SELF-RESPONDENT (A009 NOT 1), GO TO END OF MODULES

IF R IS ASSIGNED TO MODULE 8 (X009=8), CONTINUE ON TO V000

OTHERWISE, GO TO V000 BRANCHPOINT FOR MODULE 9 (X009=9)

V000_ModuleIntro

Although we have finished the interview, we would like to ask you a few new questions. Some questions may be similar to questions we have already asked you, but the researchers are interested in how people respond when the questions are changed just a little.

- | | | |
|-----|---------------------------------|----------------------|
| 1. | R is willing | |
| 9. | R refused at Module Intro | GO TO END OF MODULES |
| 99. | R refused after starting Module | GO TO END OF MODULES |

V351_INTRO

Alzheimer's disease is a brain disorder that usually affects older people. People with Alzheimer's slowly lose their ability to think, to remember, and to perform daily tasks. Over time, they become totally dependent on others.

4.5 million Americans have Alzheimer's and there is no known cure.

To find effective treatments, researchers need to study people with Alzheimer's.

But many people with Alzheimer's are unable to make informed decisions about whether to take part in research and it is not clear if such persons should be enrolled in research.

We want to find out your opinions about research with people with Alzheimer's who cannot make their own decisions.

- | | |
|----|----------|
| 1. | Continue |
| 8. | DK |
| 9. | RF |

NOTE: RS ARE RANDOMLY ASSIGNED TO RECEIVED ONLY ONE OF THE FOLLOWING QUESTIONS: V353, V354, V355 OR V356. THE RANDOM VARIABLE V352 IS USED TO MAKE THAT ASSIGNMENT.

V353 BRANCHPOINT: IF V352 NOT 1, GO TO V354 BRANCHPOINT

SCENARIO 1: LUMBAR PUNCTURE STUDY

V353_ALLOW_LUMBAR

Researchers want to study the fluid that surrounds the brain in patients with Alzheimer's.

The fluid is removed by a process called a lumbar puncture. In a lumbar puncture, a doctor inserts a long needle through the lower back into the spinal canal. The patients are given numbing medicine but they may experience a small amount of pain.

About 5% of patients get headaches that go away with Tylenol. About 1% get a severe headache that requires a procedure which involves inserting a needle into the lower back again.

The study will not directly benefit these patients. But it may lead to better understanding of Alzheimer's disease that may help future patients.

If patients cannot make their own decisions about being in studies like this one, should our society allow their families to make the decision in their place?

1. Allow
5. Not allow
8. DK
9. RF

NOTE: R's RESPONSE TO THIS QUESTION IS ASSIGNED TO VARIABLE V357.

V354 BRANCHPOINT: IF V352 NOT 2, GO TO V355 BRANCHPOINT

SCENARIO 2: NEW DRUG STUDY**V354_ALLOW_NEWDRUG**

Researchers want to test a new drug to see how well it treats Alzheimer's disease. One half of the subjects will receive the new drug, and the other half of the subjects will get a sugar pill (that has no drug in it). The subjects will be randomly assigned (by chance, like flipping a coin) to get either the drug pill or the sugar pill. The new drug can cause upset stomach in some people, and in rare cases, bleeding in the stomach.

The study may benefit some of these patients if the drug proves to be safe and effective. On the other hand, the drug may not work and it has the risks that I mentioned.

If patients cannot make their own decisions about being in studies like this one, should our society allow their families to make the decision in their place?

1. Allow
5. Not allow
8. DK
9. RF

NOTE: R's RESPONSE TO THIS QUESTION IS ASSIGNED TO VARIABLE V357.

V355 BRANCHPOINT: IF V352 NOT 3, GO TO V356 BRANCHPOINT

SCENARIO 3: VACCINE STUDY**V355_ALLOW_VACCINE**

Researchers are developing a vaccine for Alzheimer's disease. It involves getting one shot every three months (for a total of five shots) and two lumbar punctures (in which a long, thin needle is inserted into the lower back to obtain fluid from the spinal canal).

In a previous study, 18 out of 300 persons (or 6%) who got the vaccine developed brain inflammation. This brain inflammation caused one or more of the following symptoms: confusion, headache, sleepiness, vomiting, seizures, and difficulty with balance and speech. 7 of the 18 persons had permanent problems. However, in 60 out of 300 persons (or 20%), the vaccine seemed to help their symptoms slightly.

Researchers have now changed the vaccine to try to make it safer.

The vaccine may directly benefit some patients who enter this study. On the other hand, the vaccine may not work and could cause brain inflammation.

If patients cannot make their own decisions about being in studies like this one, should our society allow their families to make the decision in their place?

1. Allow
5. Not allow
8. DK
9. RF

NOTE: R's RESPONSE TO THIS QUESTION IS ASSIGNED TO VARIABLE V357.

V355 BRANCHPOINT: IF V352 NOT 4, GO TO V358

SCENARIO 4: GENE TRANSFER STUDY

V356_ALLOW_GENETRANS

Researchers want to begin testing a treatment for Alzheimer's disease where doctors insert genetic material (DNA) into the brains of Alzheimer's patients using brain surgery.

This is to be the first study of this kind involving humans and the main purpose is to test its safety in just a few people, before moving on to larger studies.

One risk of brain surgery is a 1-4% chance of bleeding into the brain. This is usually minor, but rarely it can cause serious harm. It is possible that gene transfer could make Alzheimer's symptoms worse, cause brain tumors or cause brain inflammation. No one knows how likely these risks are.

If patients cannot make their own decisions about being in studies like this one, should our society allow their families to make the decision in their place?

1. Allow
5. Not allow
8. DK
9. RF

NOTE: R's RESPONSE TO THIS QUESTION IS ASSIGNED TO VARIABLE V357.

V358_PARTICIPATE

Suppose you wanted to give a close family member instructions for the future, in case you ever became unable to make decisions for yourself.

Would you say you would want to participate in the study?

1. YES
5. NO
8. DK
9. RF

V359_LEEWAY

IF R WOULD WANT TO PARTICIPATE IN THE STUDY (V358=1):

How much freedom or leeway would you give the close family member to go against your preference and instead not enroll you in the study?

IF R WOULD NOT WANT TO PARTICIPATE IN THE STUDY (V358 NOT 1):

How much freedom or leeway would you give the close family member to go against your preference and instead enroll you in the study?

1. No leeway
3. Some leeway
5. Complete leeway
8. DK
9. RF

END OF MODULE 8 — GO TO END OF MODULES