

Regrets? Opting out of clinical trials may prompt more than a few

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Women who choose not to participate in a clinical trial may be significantly more likely to later regret that decision than women who choose to participate in the study, according to a team of Penn State researchers.

The finding may help hospitals and health researchers attract more recruits for <u>clinical trials</u>, a task which many physicians consider the biggest obstacle to conducting these trials, according to the researchers. Typically, as many as 20 percent of a given population of patients are eligible to participate in clinical research. However, of those, only 2 to 7 percent choose to do so.

"Clinical trials are crucial, they are what we use to make discoveries in the medical field," said James Dillard, professor of communication arts and sciences. "Every time a doctor makes a directive, that information is generally based on the results of clinical trials."

The researchers, who report their findings in the current issue of *Patient Education and Counseling*, said emotions played a strong role in the decisions of women who entered a recent clinical trial. Of 100 healthy women surveyed, 72 responded that they had agreed to participate.

The women who participated in the clinical trial reported more <u>positive</u> <u>emotions</u> and significantly fewer negative emotions than those who did not participate. Participants saw their participation in the trial as a way to help other people and that their involvement was helpful to the process



of finding medical treatments. People who did not participate were 36 times more likely to suffer negative emotions, such as regret, for not participating, said Dillard, who worked with Bonnie J. F. Meyer, professor of educational psychology, Denise H. Solomon, research professor of communication arts and sciences and Andrea Manni, professor of medicine.

Low enrollment in clinical studies could create non-representational studies with findings that may not cover the general population, according to the researchers. To increase enrollments in clinical trials, the researchers suggest that organizers disclose information about the positive emotional benefits of participating, as well as the negative emotional effects of not taking part.

"Recruiters, for example, should focus on how the study is a way to help others, as well as informing possible participants of the potential for regret and other negative feelings for not participating," said Dillard. "In fact, it's ethically responsible to disclose this type of information."

The researchers also found that both economic costs and time commitments remain an obstacle for participation in studies.

"Prior research has shown—and our study also points out—that clinical trials need to make it easier in time and travel costs for the participants," said Dillard. "But, what's new in our study is that the data also suggest that emotions are important to figure into the recruitment process."

To conduct the study, the researchers asked participants to take part in a telephone survey after they decided to either join or not join an actual clinical trial investigating reducing <u>breast cancer risk</u>.

Although the study focused on breast cancer, Dillard said he expected similar results from both male and female participants in other types of



clinical trials.

Provided by Pennsylvania State University

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