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Improving patient consent without diminishing clinical trial enrollment

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Patients who have the wrong idea about the goals of clinical research may become better informed through a non-burdensome scientific reframing intervention, according to a study published September 20, 2017, in the open-access journal *PLOS ONE* by Paul Christopher from Brown University, United States, and colleagues.

When patients don't understand core differences between clinical research and clinical care— for example, that it may be unclear whether an experimental treatment is better than the standard of care, —the validity of the patients' informed consent is undermined, which may make trials less ethical. This problem is common in clinical research, and is known as therapeutic misconception.

In this study, Christopher and colleagues examined the effect of a 12-minute computerized slideshow that emphasized distinctions between clinical research and clinical care. They tested the slideshow intervention in the context of mock enrollment for hypothetical clinical trials. They recruited 154 participants from cardiology, oncology, psychiatry, and family medicine clinics at UMass Memorial Health Care in the United States for mock enrollment in a hypothetical trial. Therapeutic misconception scores were about 6 points lower for participants who received the slideshow compared with those who didn't. Whilst there is concern that reducing therapeutic misconception could also hamper recruitment of participants, the intervention was found to have no significant effect on participants' desire to participate in clinical research , and therapeutic misconception scores were similar between those who

were inclined to participate and those who were not.

To the author's knowledge, this is the first study that demonstrates an effective intervention designed to reduce therapeutic misconception among a patient group similar to those who would be recruited for clinical trials. However, participants in this study were disproportionately white, female and well educated, so the tool's efficacy in other populations still needs to be determined. The next step is to test this intervention during informed consent for real clinical trials.

More information: Christopher PP, Appelbaum PS, Truong D, Albert K, Maranda L, Lidz C (2017) Reducing therapeutic misconception: A randomized intervention trial in hypothetical clinical trials. *PLoS ONE* 12(9): e0184224. doi.org/10.1371/journal.pone.0184224