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Protecting Research Participants: How Can We Reduce "Therapeutic Misconception" in Clinical Research Trials?

History/Background

"Therapeutic misconception" (TM) describes when a clinical research trial participant fails to understand the difference between participating in a clinical trial versus receiving conventional treatment, i.e., treatment as usual.[1-2] Individuals experiencing TM mistakenly assume that by enrolling in a clinical research trial they will receive the latest experimental treatment, without understanding the differences including that they will be randomly assigned to either an experimental or a conventional control group.[1-2] Patients in conventional treatment receive personalized treatment plans, which allow for treatment changes that are best for a particular patient. Conversely, patients in clinical trials receive treatment controlled by a strict clinical research protocol.

Prior research has demonstrated that clinical research trial participants are often unable to differentiate between experimental and conventional care.[3] TM research shows that some research participants consent to participating in a clinical research trial without fully understanding the research process.[4] To protect the rights of participants in clinical research trials, researchers should ensure that participants fully understand what it means to be in a clinical research trial so they can make informed decisions about whether or not to participate.

Therapeutic Misconception and Scientific Reframing is a National Institute of Mental Health funded study led by Charles Lidz, Ph.D. The study's goals are to:

- Develop an innovative procedure that educates participants about clinical research trials to reduce TM; and
- Test this innovative procedure in a hypothetical clinical research trial to reduce TM without reducing study enrollment rates.

Methodology/Design

Study participants were randomly divided into two groups: an experimental group and a control group. Members of each group watched a narrated educational Power Point presentation about the hypothetical clinical research trial they were being asked to pretend to consent to. Members of the experimental group watched an additional presentation explaining exactly what a clinical research trial is, and how participating in a clinical research trail may be different than receiving conventional care.

After viewing the presentation(s), all study participants completed a survey that included background information, a measure of TM, and the participant's decision about whether they would agree to participate in the hypothetical clinical research trial they learned about during the presentation(s).

Preliminary Outcomes/Future Impact

Preliminary analyses show no significant differences between the groups regarding their decision about whether or not to participate in the hypothetical clinical research trial. However, results indicate a statistically significant difference in TM scale scores, suggesting experimental group participants were less likely to experience TM. This suggests that including a brief educational presentation about the purpose, nature, and design of clinical research trials during the informed consent process does not negatively impact recruitment, and can help reduce TM.

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