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EFFECTS OF INFORMED CONSENT ON RESEARCH PATIENTS AND STUDY RESULTS

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The authors present material from some of their studies in which patients were given information and instructions not usually given in such research. They found that clinic outpatients come into studies with deep feelings of trust and expectations of marked improvement, and they often do not believe they are subjected to research or are given inert medication, even when research paraphernalia are obvious or they are informed of the nature of the treatment. In some of the research, patients were given information usually withheld because such knowledge might have a detrimental effect on patients and study results. The authors found no evidence that this information had negative effects on either patients or findings. In fact, in a non-blind placebo trial (Park & Covi, 1965) in which the patients were informed that they were being given a "sugar pill," the patients showed more symptomatic improvement than patients who participated in other double-blind drug studies.

The authors discuss those factors which might account for patients showing positive responses as a result of being informed. First, the refreshing openness, uniqueness and yet harmless nature of the treatment plan, along with a requirement that the patient be willing to participate, may have had a positive effect. The amusement and willingness to cooperate in the trial may also reflect, for some patients, the relief that their conditions were mild enough for inclusion in an optional and novel research project. Secondly, results of this trial indicated that patients with clear ideas about the nature of treatment showed more improvement. Perhaps attempts to keep secrets from patients, such as the research nature of a treatment, in conjunction with obvious clues that the treatment is research can leave patients uneasy and unclear about what is really going on. Thirdly, the researcher may have been relieved of the problem of medical ethics and the discomfort about concealing information from patients, making the doctor-patient relationship more comfortable. There was evidence that even in a short term drug evaluation the doctor-patient relationship was more important to the patient than the various research procedures.

A basic purpose of this paper is to suggest that the present anxiety about informed consent may be based partly on preconceived bias and that the process of informing patients is worthy of research in itself. The issues of the patient's welfare and informed consent have become so prominent in clinical research that perhaps very few clinical psychiatric studies should be performed in the future in which critical information is withheld or false information is given, unless there is a control group in which the correct information is furnished to patients.
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