Clinical Trial of Psychotherapies Is Under Way

The NIMH hopes to learn whether clinical trials are feasible in psychotherapy and also why treatment helps depressed patients

The National Institute of Mental Health (NIMH) is conducting a 3-year, $3.4-million, multi-institutional clinical trial comparing drugs to two forms of psychotherapy in the treatment of depression. The trial, which was conceived 5 years ago but begun only last year, resembles studies used to test the efficacy of drugs. It is the first study of its scope attempted in the field of psychotherapy. If it is successful, the NIMH may request funds for further research along the same lines.

According to Morris Parloff, an NIMH psychologist who is a principal planner and director of the study, the project, which was initiated for purely scientific reasons, has taken on political importance as well. Insurance companies and the government are increasingly concerned about whether to reimburse for psychotherapy and, if so, whether all forms of psychotherapy should be equally reimbursable (*Science*, 1 February 1980, p. 506). In addition, the courts have ruled that patients in mental hospitals have the right to refuse treatment and that they are entitled to "the right treatment." So, although many members of the professional community are convinced that psychotherapy works, a number of legislators and legal experts are awaiting more rigorous evidence than has been provided to date.

Opinions are divided on whether the clinical trial model should be used to test the efficacy of psychotherapy. Hans Strupp, a psychologist at Vanderbilt University, argues that it should not, saying, "As far as psychotherapy is concerned, I happen to believe that the [clinical trial] model doesn't fit. If you have a powerful drug like penicillin, you can inject a patient and get results. The patient's attitudes and the doctor's attitudes make little difference. But in psychotherapy, the interactions between the patient and the therapist are crucial and the skill of the therapist is tremendously important."

Strupp believes that the skill of the therapist is far more crucial to the success of the treatment than the particular technique the therapist uses. So a clinical trial comparing psychotherapeutic techniques is not, he suggests, the wisest use of the limited funds available to the NIMH. He would rather see the money spent on researching the interactions between therapists and patients.

On the other hand, Donald F. Klein, a psychiatrist at Columbia University, maintains that the NIMH study "is a very important step." The hypothesis that the type of therapy used may be less important than the skill of the therapist is legitimate, he believes. But the NIMH study should provide a test of that hypothesis. If the patients do equally well on all the therapies tested, Klein says, "that would be a powerful argument that there isn't specificity." Basically, he thinks that psychotherapies should be tested in clinical trials because "we must study how psychotherapy works and who it works on."

The goals of the NIMH study, however, are broader than simply determining whether clinical trials are appropriate or feasible in the field of psychotherapy. According to Irene Elkin Waskow, an NIMH psychologist who played a major role in planning the study and who is now coordinating it, the study may lead to a new understanding of psychotherapy by showing how and why it helps depressed people, if indeed it does. The NIMH chose to study depression therapies in part because depression is a major public health problem and in part because several specific forms of therapy seemed ripe for testing.

For the past year, 27 therapists have been in training to participate in the study by learning one of two psychotherapies or by learning a drug treatment regimen using imipramine, a tricyclic antidepressant or a placebo. Next year 144 patients whose depression has been carefully documented will be randomly assigned to one of these four treatments. In addition, 36 patients will be assigned to a "treatment as usual" group. They will be referred to experienced therapists, who will treat them as they treat their other depressed patients. The efficacy of the therapies will be determined both by asking the patients and the therapists whether the therapy relieved the patients' symptoms of depression and by conducting an independent clinical evaluation.

"Depression," says NIMH psychiatrist Robert Hirschfield, "has been called the common cold of psychiatry." It is estimated that 25 percent of Americans become depressed to the point of needing professional help at some point during their lives. But depression is not nearly as benign as the common cold—it is the leading cause of suicide. Depressed persons usually have difficulty eating or sleeping and have low self-esteem. Their marriages may fail and they may have few friends. They feel sad, irritable, empty, or apathetic. According to an NIMH study, 50 percent of depressed patients recover and never relapse, but 15 percent never recover. The NIMH estimates that 75 percent of all psychiatric hospitalizations are for depression.

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Treatments available for depression include drugs and various types of psychotherapies. Since the late 1960's the tricyclic antidepressants have been widely prescribed, but although they help many patients they are no panacea. Some people cannot take them because of other medical conditions. Of those who can take them, says Aaron T. Beck of the University of Pennsylvania, only 60 to 65 percent show definite improvement.

In addition, says Hirschfield, "Many patients think it is wrong to take medications for depression. They think depression is an emotional problem." The tricycle antidepressants have side effects such as dry mouth and blurred vision. "They are not the most pleasant drugs to take," Hirschfield notes. "Most patients want to get off the drugs as soon as they feel better." But psychiatrists generally

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recommend that patients take the medication for about 1 year—the length of the usual depressive episode.

Most depressed patients, including those who take drugs, receive some form of psychotherapy. Yet, Waskow says, "We really don't know as much as we would like to know about the effectiveness of specific forms of psychotherapy for depressed patients. One of the real problems with trying to draw conclusions from past research is that the results of different studies are not comparable. Patients have been diagnosed differently, or the treatments they have been given have not been defined, and the studies have had different criteria for evaluating outcome."

Two forms of psychotherapy, however, have reached a stage of development where they seem suitable for a clinical trial. Both were specifically developed to treat depressed patients, both have been tested by their developers in small-scale trials, and both seemed at least as effective as drugs in these studies. In addition, there are manuals spelling out what the therapies consist of and how they should be employed.

The first of these treatments, cognitive behavioral therapy, was developed during the past 20 years by Beck and his associates. In 1979 Beck published a manual describing the therapy. There have been 12 recent studies comparing congnitive therapy to other treatments of depression, including several comparing it to, and showing it superior to, drugs. But, says Beck, "None of these studies is perfect. One of their major limitations is that they did not have the degree of objectivity that you would like." And the fact that one of the studies was done at the University of Pennsylvania is a drawback, Beck says. "Penn appears to be a mecca for cognitive therapy. Any study done here would be suspect unless it was replicated elsewhere."

Beck developed cognitive behavioral therapy in the course of trying to prove the classical psychoanalytic theory of depression—that depressed patients feel guilty and want punishment. He reasoned that if depressed patients were put in a situation where they failed at a task, they would feel, if anything, better than nondepressed people. He found, however, that depressed patients felt even worse than the nondepressed when they failed and felt better when they succeeded. This experiment led him to doubt the classical psychoanalytic theory and to develop his cognitive theory of depression, which he explains as the cognitive theory of depression is "the notion that, in depression, thinking processes are diverted. Depressed people see things in a completely negative way. Positive events are just blotted out completely."

The aim of cognitive therapy is to demonstrate to patients that they are reacting too negatively to ordinary events. The therapist asks the patient to describe events that made him feel worthless, a failure. Then the therapist show the patient that other interpretations of the events are possible, that the patient is seeing things unrealistically. In addition, the patient is given "homework"—forms to fill out that force him to examine his behavior.

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The second therapy to be tested in the NIMH study is interpersonal psychotherapy, developed by Gerald Klerman of Massachusetts General Hospital, Myrna Weissman of Yale University, and others in the New Haven–Boston Collaborative Depression Project. Interpersonal psychotherapy, according to Waskow, has not been developed as precisely as cognitive behavioral therapy and has not been as widely used or extensively studied. But a manual for the therapy was published in 1979 and the New Haven–Boston group has conducted two studies, one showing that the treatment is superior to no treatment at all, and the other showing that it is effective as drugs and that a combination of drugs and interpersonal therapy is more effective than either treatment alone.

Interpersonal therapy, says Weissman, differs from cognitive behavioral therapy in part because it is not based on a new theory of depression. It was developed out of what was the usual psychotherapeutic practice in treating depression. "In 1967, we felt that there were specified dosages and types of drugs to treat depression. We needed similar information about psychotherapy. We wrote down what we were doing and what was common practice with depressed patients," Weissman says. From this grew interpersonal psychotherapy.

Interpersonal psychotherapy is based on the premise that depressed persons have difficulty getting along with other people. Either the depression may follow from the disturbed relation with others or the disturbed relation may follow from depression. In either case, the aim of this psychotherapy is to help depressed patients improve their social functioning, the theory being that if social functioning improves, other symptoms of depression will also improve. There is little attempt to delve into unconscious motivations for behavior or childhood experiences that may have led to the depression. As Weissman explains, "The therapy focuses on an immediate here-and-now approach."

According to Waskow, the two therapies to be tested reflect two major approaches in psychotherapy today. Cognitive behavioral therapy is an example of the behavioral approach, typified by a strong emphasis on changing the patient's thinking patterns. Interpersonal psychotherapy exemplifies the psychodynamic approach, with its emphasis on improving social relations.

The NIMH is investing an enormous effort in training therapists so that they will be employing cognitive or interpersonal therapy as intended. Those who will use cognitive therapy are being trained at the University of Pennsylvania under Beck's direction. The others are being trained in interpersonal therapy at Yale under Weissman. As part of their instruction, the therapists are taped as they treat depressed patients, and this may provide evidence that those learning the different approaches do treat patients in the expected ways. Psychologists who do not know what approach the therapists are following will hear tapes of the therapy sessions, and will try to distinguish the cognitive behavioral from the interpersonal therapists.

It is, of course, possible that the NIMH study will not show any striking differences between the efficacies of the three treatments. But demonstration that psychotherapy is at least as useful as drugs in treating depression would be important, Beck feels. "Unfortunately, psychotherapy has been receiving bad press in the popular media. In order to overcome the enormous skepticism regarding the efficacy of short-term psychotherapy, one practically has to prove beyond a shadow of a doubt that it is effective."—GINA BARI KOLATA