

## Perspective

# Telepsychiatry Treatment Outcome Research Methodology: Efficacy versus Effectiveness

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### ABSTRACT

The use of videoconferencing technology to provide mental health services (telepsychiatry) offers hope for addressing longstanding problems regarding work force shortages and access to care, especially in remote or rural areas. However, data on treatment outcomes (i.e., based on randomized clinical trials) from telepsychiatry applications are virtually nonexistent, representing an important gap in the literature. An important methodological decision point in developing treatment outcome research is whether to take an efficacy or effectiveness approach. Efficacy approaches offer enhanced internal validity; however, they may have limited generalizability to real-world settings. Effectiveness approaches offer enhanced external validity. But, they are typically less controlled than efficacy studies, thereby limiting the assumptions that can be made about causality. The current state of telepsychiatry research necessitates efficacy studies, the outcomes from which can be used to inform future effectiveness studies.

### INTRODUCTION

**A** GROWING BODY OF LITERATURE suggests that the use of videoconferencing technology to provide mental health services (telepsychiatry) offers hope for solving longstanding problems regarding work force shortages and access to care, especially in remote or rural areas. Recent reviews of this literature<sup>1-4</sup> indicate that: (1) there are many novel case studies and descriptive reports of telepsychiatry programs from around the world, (2) there is solid em-

pirical evidence that clinical assessments can be reliably and validly conducted via videoconferencing technology, and (3) there is moderate empirical evidence that mental health consumers and clinicians in many settings are satisfied with telepsychiatry services. However, data on clinical outcomes from telepsychiatry applications are lacking. In fact, there are virtually no extant randomized clinical trials (RCTs) at this point, representing an important gap in the literature. A critical methodological decision point in developing the

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needed treatment outcome research is whether to take an efficacy or effectiveness approach to the questions at hand. In this paper, we discuss the relative strengths and limitations of each approach as applied to the current telepsychiatry literature and discuss methodological implications for future telepsychiatry outcomes research.

### EFFICACY AND EFFECTIVENESS IN MENTAL HEALTH INTERVENTIONS RESEARCH

Studies on mental health treatment outcome generally represent either an efficacy or effectiveness methodological approach. In fact, this is a continuum of study design features rather than a discrete dichotomy. Furthermore, we have yet to reach full agreement with regard to a precise definition of these terms. A common set of general principles for efficacy and effectiveness have emerged and can be discussed in reference to telepsychiatry research.<sup>5-8</sup>

In telepsychiatry research, efficacy studies are essentially carefully controlled laboratory research projects that typically include all or most of the following: narrow subject inclusion/exclusion criteria; randomized assignment of individual subjects to treatment conditions; inclusion of rigid control groups; careful stratification of patients across groups by relevant variables, such as race or psychiatric comorbidity; highly specific treatment protocols (e.g., manualized psychotherapy, fixed-dose medications); fixed duration of treatment and follow-up; ongoing training and treatment integrity ratings to ensure care is provided as specified in the research protocol; comprehensive and standardized individual outcome assessment batteries that focus on clinical symptoms and functioning; and blinded clinician outcome ratings.

Effectiveness studies are generally less controlled research projects conducted in "real-world" practice settings and are characterized by some or all of the following features: broad subject inclusion/exclusion criteria, so as to represent the clinical practice setting population of interest; randomization of sites or clinicians, as well as randomization of individual

subjects; more flexible treatment protocols; more flexible treatment duration periods; use of actual practice setting clinicians to provide care; less comprehensive (i.e., more feasible) outcome assessment of individuals on clinical variables; examination of systemic outcome variables, such as hospitalization rates, medication compliance, and other variables related to costs and cost-effectiveness, as well as individual outcomes.

Efficacy studies generally enhance internal validity, while effectiveness studies enhance external validity. The former are necessary to establish causation under highly controlled conditions, while the latter are necessary to establish that treatments actually work and facilitate dissemination and translation of interventions to real-world practice settings. Thus, the two approaches are complementary, with efficacy studies usually preceding effectiveness studies.

### AN EFFICACY APPROACH TO TELEPSYCHIATRY

At this early stage of the telepsychiatry interventions literature, where there is virtually no clinical outcome data to support the use of mental health services via videoconferencing, a good argument can be made for the use of efficacy designs. The strengths of such an approach allow for a more controlled study and enhanced internal validity, which are especially important in the early stages of literature development; enhanced feasibility regarding subject recruitment, informed consent, assessment, and randomization; and the opportunity to work out a range of potential difficulties in a more controlled "laboratory" setting.

Because there are no empirical outcome data on the use of telepsychiatry to provide treatment for specific psychiatric populations (e.g., those with post-traumatic stress disorder), it seems prudent to conduct such studies in a manner that is as controlled as possible. Because treatment for subjects in both conditions can be provided at the same site, researchers can be sure they are recruiting a subject sample that is representative of the patients treated at a particular clinic, and that they are receiv-

ing the same treatment in each condition, with the only difference being mode of treatment delivery. In other words, there is not a natural selection bias that might result if, for example, rural patients formed the "telepsychiatry" group, whereas more urban patients formed the "same room" comparison group. Additionally, researchers can be sure that all subjects face a similar transportation "burden" and hospital experience. In this way, variables such as differences in driving times, traffic or parking hassles, or the social context of the medical center do not have a differential impact on the two groups.

Feasibility and patient safety concerns are also major issues in a decision to follow an efficacy approach in the early stages of research development. In an efficacy study, research project staff can recruit subjects, obtain informed consent, conduct study assessments, and implement randomization assignments in person, without the difficulties and costs associated with having to travel to remote sites. Additionally, trained personnel (e.g., study therapists) can be sitting in the room with patients in the "telepsychiatry" condition, as opposed to an inexperienced and unfamiliar clinician at a remote site, serving as a "safety net" in case of a patient emergency during a session. With experience and empirical data to support the use of telepsychiatry with various patient populations, these concerns will become less prominent and allow for future research to establish the effectiveness of this treatment delivery mode.

Although this efficacy approach has a number of strengths, several important limitations must be recognized. These include the possibility that the therapeutic context may be too "artificial" for subjects to feel comfortable, different cost-benefit ratios for telepsychiatry conditions when the travel-saving features are not evident, and reduced external validity or generalizability. While an efficacy approach would tell us something about the efficacy of telepsychiatry under very controlled conditions, it tells us little about how this mode of service delivery will work in the "real world." In fact, it is even conceivable that the artificial nature of the conditions could lead to some distortion in the results. For example, subjects in "telepsychia-

try" may learn that their therapist is relatively nearby. They may, therefore, not take the treatment sessions seriously if the treatment mode seems unnecessarily complicated or lacking in credibility. In a related issue, because subjects in the "telepsychiatry" group will not have been saved meaningful travel time and costs ordinarily associated with the use of telepsychiatry under usual circumstances, they may find it more difficult to appreciate some of the real benefits of this mode.

### AN EFFECTIVENESS APPROACH TO TELEPSYCHIATRY

An effectiveness approach also has several notable strengths and limitations in the context of telepsychiatry research. It may be more feasible to implement in some ways; it also offers enhanced external validity. Furthermore, treatment effectiveness is the ultimate goal of any line of treatment outcome research. On the other hand, it may be quite costly due to the nature of multisite studies with large samples, offers less control over extraneous variables and reduced internal validity, and poses feasibility challenges to a number of research issues (including informed consent, randomization, and management of acute psychiatric emergencies) and relevant ethical concerns related to patient safety and confidentiality.<sup>2</sup> For these reasons, and despite the apparent limitations of the efficacy approach, the use of effectiveness approaches at this stage of research in the telepsychiatry arena in many instances may be premature. However, assuming the efficacy of telepsychiatry treatment can be established, the next logical research step will be to evaluate the effectiveness of "telepsychiatry" service delivery in applied practice settings.

Future research is likely to involve the use of telepsychiatry to provide specialized treatment to various patient populations through such systems as departments of mental health and VA Medical Centers. This would allow appropriately trained and experienced clinicians to provide specialty mental health care in areas where expert clinicians do not exist. Study designs could incorporate methodological strategies that randomize by site or by subject. Out-

come variables could include systemic variables (e.g., use of other health services, pharmacy records), and could include cost analysis. Such research would benefit from reduced artificiality and enhanced external validity, but it might also be costlier to conduct due to the need for research staff at (or strong coordination and cooperation from) remote sites, the need for purchasing additional videoconferencing equipment, and the need for larger sample sizes associated with multisite studies.

### IMPLICATIONS FOR FUTURE TELEPSYCHIATRY RESEARCH

Treatment outcome research on telepsychiatry is needed for both general and specific psychiatric disorders, across a range of settings (e.g., rural, military, prison settings). Both efficacy and effectiveness approaches have something to offer, and both are necessary. However, at this early stage of development, an efficacy approach may make more sense in most cases because of enhanced internal validity, feasibility, and cost advantages. Mixed approaches (i.e., selecting features of both) may also make a great deal of sense, and, in the end, design considerations will depend on the nature of the specific research questions of interest and the development of the extant literature. Ultimately, the vast majority of telepsychiatry treatment outcome research will lean toward the effectiveness end, but there is room for efficacy studies at this early stage to provide empirical support for the risks and costs inherent in an effectiveness approach.

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