A Discussion of Evidence-Based Practices and a

Proposal for the Recovery Unplugged Research Plan

Overview of Document

This document provides a discussion of evidence-based practices and some tensions that exist in the field regarding how and when interventions should be classified as evidence-based. In discussing these issues, a comparison is made between efficacy trials and effectiveness trials. Efficacy trials typically feature randomly assigning participants to two or more comparison conditions (e.g., the treatment you are testing vs. no treatment). Although efficacy trials are good at establishing a causal connection between the intervention and outcome (e.g., exposure to treatment *caused* a reduction in substance use behaviors), they are often divorced from the realities of everyday clinical practice and consequently lack pragmatism (or what researchers refer to as generalizability). In contrast, effectiveness trials tend to favor pragmatism and the generalizability of the results (to real-world practice contexts). The studies we are proposing for the research phase of the project would be considered effectiveness studies. These proposed studies would fit rather seamlessly into the current service delivery system at Recovery Unplugged. Results of such studies will produce an abundance of very impactful information about treatment fidelity, in-treatment client outcomes, and distal (i.e., post-treatment) client outcomes. Although these effectiveness studies possess many strengths that are described in more detail below, results of such studies are generally not considered adequate to establish a treatment as “evidence-based.” This issue is also described in more detail below and some of the requirements proposed by SAMHSA are discussed. Fortunately, in the substance abuse treatment field, there is precedence for effectiveness-style studies, and researchers, clinicians, and other stakeholders value the information they yield and the results of studies of this kind continue to be published in the top journals in the field (e.g., *Journal of Substance Abuse Treatment*).

Evidence-Based Practices

*Conceptualization*. The term evidence-based practices and similar terms (e.g., empirically supported treatments) have been used by authors in many disciplines including clinical psychology (e.g., Chambless & Hollon, 1998), music therapy (e.g., Abrams, 2010), and medicine (Sackett et al., 1996), to name a few. Although definitions and decisions about what constitutes evidence varies, the organizing spirit of evidence-based practices is to use research as a means of accruing scientific evidence for the efficacy of a given treatment. The idea is that with an evidence base to draw from, clinicians can base their practice on treatments that have empirical support. Fields vary with respect to the size of the evidence base. For example, in the substance use field more generally, over 1,000 controlled clinical trials have been used to evaluate treatment outcomes for individuals seeking to alter their tobacco, alcohol, and/or illicit drug use (Miller et al. 2005).

*Sequence of research activities*. The typical (and generic) sequence of events giving rise to evidence-based practices is as follows. First, a researcher develops a treatment based on existing research on etiological factors and behavior change principles relevant to the presenting problem of concern. Second, the researcher pilot tests the treatment on a small group of clients. Third, the researcher conducts one or more tightly controlled efficacy trials to test the relative efficacy of the developed treatment against some comparison condition (e.g., no treatment, treatment as usual, or an existing treatment in the area). Efficacy trials are marked by tight researcher control and random assignment of participants to various conditions. Fourth, the researcher conducts one or more effectiveness trials in which the intervention is delivered in clinical settings that are more representative of the clinical world rather than the research world. For example, in this stage of research, the researcher might test the effectiveness of the intervention in a community mental health center (rather than a university clinic) and with clients with more pressing clinical problems (e.g., comorbid conditions that would activate the exclusion criteria in the efficacy trials). Between each of these four general phases are myriad sub-phases that might be pursued. This sequence of research activities typically takes a lot of time (could constitute the bulk of one’s career) and costs a lot of money (usually funded by government or local agency grants).

*What about practitioners?* This typical sequence of events is researcher driven, not practitioner driven. Practitioners and some researchers have noticed this and have been vocal critics of this system (Goldfried & Wolfe, 1998; Persons & Silberschatz, 1998). More recently, as the evidence-based practices movement has garnered support and lists of evidence-based practices have been created, critics have cautioned the field regarding some significant limitations of the movement (e.g., Trickett & Beehler, 2014). Although a full discussion of these limitations is beyond the scope of this document, one of the major limitations discussed in these debates centers around the generalizability of the findings from research-based trials to the realities of everyday clinical practice. The argument takes on the following form, “What good are the trials and resulting evidence base if the therapies are theoretically pure and the therapists receive an inordinate amount of supervision and the clients represent pure diagnostic groups rarely seen in typical clinical practice?” This potential lack of generalizability from research activities to the realities of everyday clinical practice represents a possible public health problem because most individuals treated for a given disorder are treated in non-university affiliated systems of care. The following quote illustrates this public health perspective:

A highly efficacious treatment that cannot be diffused into usual care settings will have little impact on population health, even though it may be highly beneficial for a small number of individuals, whereas a modestly efficacious treatment that is adopted and diffused easily can have much greater impact at the population level (Tucker & Roth, 2006, p. 924).

*Prioritizing causality over generalization to everyday clinical settings*. One way to frame this issue is to argue that researchers have favored the causal inference prioritized by the tightly controlled randomized controlled trial, over a more diversified set of pragmatic inferences related to treatment and client heterogeneity—or, whether an intended treatment will work in a diversity of settings with a diversity of clients. In addition to driving the evidence-based practices movement, researchers have also been vociferous in establishing the various evidence hierarchies used to value some studies and methodologies over others. In other words, results from *this kind of study* would constitute high evidence whereas results from *this other kind of study* would constitute little or no evidence. In such discussions, the randomized controlled trial has been considered the gold standard for establishing a treatment as efficacious and, consequently, results from randomized controlled trials have typically been regarded as providing the strongest evidence. This perspective has been questioned by community researchers (e.g., Trickett & Beehler, 2014) and by methodologists working in the area of substance abuse research (e.g., Tucker & Roth, 2006). For example, Tucker and Roth argue for an “evidentiary pluralism” that recognizes other methodologies that can also provide useful information about treatment effectiveness and client outcomes. In other words, they argue there are a plurality of methods and types of studies that can give rise to meaningful conclusions (and could also count as evidence). Part of their justification rests on two premises specific to substance abuse treatment outcome research: (1) in general, many different kinds of interventions have proven effective in substance use treatment (see Miller et al. 2005), and as discussed above (2) clients studied in tightly controlled research trials are not necessarily representative of clients seen in community-based treatment centers (for discussion of this latter issue in the context of alcohol treatment research, see Humphreys et al. 2005). We offer a third premise based on the recognition that much existing knowledge of client outcomes in the area of substance abuse treatment derives from naturalistic effectiveness studies examining client outcomes after exposure to publically operated substance abuse treatment facilities (Simpson, 2004). For example, in the 1970s, such data were collected as part of the Drug Abuse Reporting Program. In the 1980s, such data were collected as part of the Treatment Outcome Prospective Study, and, in the 1990s, such data were collected as part of the Drug Abuse Treatment Outcome Studies (Simpson, 2004). In other words, researchers in the substance abuse treatment field have placed a higher value on effectiveness research relative to some other related fields (e.g., treatment outcome studies in clinical psychology). Consistent with this spirit of effectiveness research, and building on this prior research literature, the research plan we are proposing can be conceptualized as naturalistic effectiveness research. The term naturalistic suggests that the study takes place in its natural environment, which is the Recovery Unplugged treatment center. The term effectiveness suggests that the individuals being studied and the treatment being delivered is what typically occurs in clinical practice (at Recovery Unplugged).

The Recovery Unplugged Research Plan

The research plan that we are proposing will involve a series of longitudinal studies that will collect meaningful data on three important clinical outcomes: (1) treatment process/fidelity, (2) in-treatment client progress, and (3) distal client outcomes. The word longitudinal suggests that clients will be followed over time, allowing for the examination of change. Although results from such naturalistic studies generally fail to satisfy more stringent criteria for evidence-based practices, they can be used to justify systematic study of treatment delivery, in-treatment client progress, and distal client outcomes. As discussed above, these outcomes are more valued in the context of effectiveness research and less valued in the context of efficacy research. Fortunately, researchers in the field of substance abuse treatment have valued both kinds of studies (efficacy trials and naturalistic effectiveness studies) and have established a strong precedence for the kinds of studies we are proposing.

In Tables 1 and 2 (below), we compare a study of the type we are proposing to criteria for inclusion in SAMHSA’s National Registry of Evidence Based Programs and Practices (Table 1) and to more specific elements of the research reports that are also evaluated (Table 2). Our proposed study satisfies two of three criteria for inclusions (Table 1). As such, results from such a study would not satisfy these current submission criteria (to be considered in SAMHSA’s registry). With the exception of elements related to designs that feature group comparisons (e.g., between treated and untreated individuals), our study has the potential to score well on the remaining three domains (Table 2). (It is worth noting that how our study scored on these domains would be partly a function of the results and could not be predicted prior to data collection and analysis.)

Table 1.

SAMHSA’s Criteria for Program Review for Inclusion in its Registry

|  |  |
| --- | --- |
| Criteria | Satisfied by proposed study |
| 1. Research has assessed mental health or substance use outcome among individuals or communities | Yes |
| 1. Evidence of these outcomes has been demonstrated in at least one study using an experimental or quasi-experimental design | No |
| 1. Results of these studies have been published in a peer-reviewed journal or other professional publication, or documented in a comprehensive evaluation report, published within the previous 25 years | Yes\* |

\*Peer-reviewed publication will be highest priority, but is not guaranteed.

Table 2.

SAMHSA’s Four Dimension of Review, by Outcome Measure

|  |  |
| --- | --- |
| Criteria | Score based on proposed study |
| 1. Rigor: Many elements are related to comparison designs (comparing groups), but others are related to measurement reliability, attrition (or participant loss), and sound statistical procedures | Our study could score higher on non-comparison design features like measurement reliability |
| 1. Effect size | We would report effect sizes and other ways to quantify potency or magnitude of effect (which speaks to how helpful the intervention was) |
| 1. Program fidelity | We would monitor service delivery and fidelity, so would have relevant data |
| 1. Conceptual framework – including goals, components, and theory of change | These issues would be laid out formally in a document that could be conceptualized as a treatment manual |

*Strengths of the proposed study*. First, the proposed study will take place in its natural environment using the currently operating treatment delivery system – a hallmark of effectiveness research. Second, the proposed study will collect systematic empirical data on several significant dimensions of treatment-related and client-related outcomes that are examined in the context of treatment outcome research. These data should be able to be used to provide justification for treatment effects to third party entities (like insurance companies) (see Simpson, 2004). Third, widely accepted research procedures will be used to increase confidence in the data obtained—including the use of valid and reliable measures of relevant constructs, proper handling of missing data, and sophisticated statistical models to examine change over time on relevant constructs. Fourth, when relevant, data will be collected and monitored in real-time to make flexible decisions regarding client care (e.g., to extend treatment from 30 to 37 days). Fifth, the study we are proposing has a strong precedence in the substance abuse treatment outcome literature and the information it will yield is consistent with recommendations made by methodologists and researchers in the field. For example, some in the field have talked about shifting focus away from outcomes and more to treatment processes (Simpson, 2004). Our study will collect data on both important classes of outcomes. In addition, our study will incorporate elements of concurrent recovery monitoring systems to help monitor client progress and make data-based decisions about care (for a description, see McClellen et al. 2004). Sixth, research reports will be submitted to peer-reviewed journals so that research-related procedures (and outcomes) can be judged by independent impartial reviewers.

*Limitations of the proposed study*. The primary limitation of the proposed study has to do with failing to compare individuals treated at Recovery Unplugged to individuals treated at some other facility (or receiving no treatment at all). This limitation should be lessened to the extent that the outcomes reported by Recovery Unplugged clients are similar to outcomes reported by treated participants in trials testing treatments that are considered evidence-based or “state of the art.” There is precedence for the use of such comparisons in effectiveness studies (for an example in the field of anxiety research, see Franklin et al. 2000).

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