#### REVIEW

# Variations in therapist effectiveness in the treatment of patients with substance use disorders: an empirical review

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#### Abstract

Despite the widespread use of psychotherapy for patients with substance use disorders, the effectiveness of psychotherapists conducting such treatment has received little research attention. In this paper, empirical studies of therapists' differences in patient outcome and dropout rates are comprehensively reviewed. The main conclusions are that therapists show diverse rates of effectiveness, and that such differences appear independent of both therapists' professional background and of patient factors at the start of therapy. The primary therapist characteristic thus far associated with higher effectiveness is the possession of strong interpersonal skills. Guidelines for research on therapist effectiveness are presented.

#### Introduction

Psychotherapy and counseling are generally recognized as effective treatment for patients with substance use disorders. 1,2 Indeed, 97-99% of drug and alcohol treatment programs offer some form of psychotherapy or counseling.3,4 Nevertheless, the role of the therapist in the treatment of substance use disorders has received little research attention.5-11 According to Imhof et al.,6,7 "all major (treatment) reviews consistently omit the role of the therapist"6 (p. 492), focusing almost exclusively on differences in treatment techniques or patient variables. However, several authors have suggested that the therapist may be one of the most important factors in effective psychotherapy for patients with substance use disorders. 7,8,12 In the general literature on psychotherapy research, therapists have shown wide-ranging differences in effectiveness<sup>13-15</sup> and patient outcome has been found to be more highly related to therapists' skill than to their theoretical orientation.<sup>13,16</sup>

Differences among therapists who treat substance use disorder patients may be even greater than among therapists in general. Cartwright<sup>5</sup> has observed that variations are typically greater among therapists who work with more difficult patient populations; patients with substance use disorders, on the whole, have greater difficulty than many other patients in life functioning (in areas such as family, employment, legal, housing and health problems associated with addiction). Substance use disorder patients are also considered more difficult in the therapy setting than other patients due to their sometimes extreme emotional reactions (which may be associated with drug effects, withdrawal or recovery from psychoactive substances), high rates of co-morbid psychiatric diagnoses<sup>17</sup> and the difficulty of engaging them in effective treatment until absti-

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nence is achieved. <sup>18</sup> The typical lack of specific training for many therapists treating such patients, <sup>19</sup> and the notoriously high dropout and relapse rates of such patients <sup>20, 21</sup> also suggest that therapists treating them may be particularly prone to variable rates of effectiveness.

Existing studies on psychotherapy for substance use disorders have typically studied the therapist, if at all, in two predominant ways. One is the comparison of "types" of therapists (e.g. paraprofessional versus professional, recovering versus non-recovering).<sup>22</sup> After more than 50 studies of this sort, however, no significant differences among such categories of therapists have been found.<sup>22</sup> The other major attempt to study therapists has been based on adherence ratings, in which therapists' conformity to manual-based treatments is assessed.8 However, adherence ratings are mainly used for research studies to standardize therapist performance, rather than to study therapists as they typically perform in clinical settings.<sup>23</sup>

The purpose of this paper is to review comprehensively studies in the substance abuse literature on the effectiveness of therapists who are ostensibly similar (in training, experience, theoretical orientation, clinical setting, etc.). Greater knowledge of the naturalistic variability in therapist performance may be helpful in several ways. Clinical settings, for example, generally do not monitor the effectiveness of therapists, yet increased attention to therapist performance could help to raise the standard of care by identifying therapists for hiring or targeting therapists who may need additional training.24,25 For research purposes, accurate knowledge of therapist factors can increase the validity of psychotherapy process and outcome studies<sup>23,26,27</sup> and can enhance theoretical attempts to understand successful treatment.

Four questions will be addressed: (1) How much do therapists vary in effectiveness when treating patients with substance use disorders? (2) What characteristics are related to therapist effectiveness (e.g. personality variables, socio-demographic characteristics, in-session behavior)? (3) How should research studies be best designed to study therapist effectiveness? (4) What therapist characteristics are hypothesized to increase effectiveness with substance abuse patients?

"Therapist effectiveness" will be defined as the amount of patient improvement that can be at-

tributed solely to the therapist, rather than to patient characteristics, type of treatment or other influences.28 Clearly, these factors can be difficult to tease apart and a full understanding of patient outcome must take into account all contributing aspects as well as their complex interaction. In this paper, however, we will pursue only that portion of the literature that addresses the therapist's impact on patient improvement. Two aspects of therapist effectiveness will be reviewed: effectiveness based on patient outcome ratings (symptomatic improvement from pre- to post-treatment) and patient dropout rate (premature termination of treatment). Both of these indices have been found to differentiate therapists in previous studies.28 Studies will be included in this review if they report data for each therapist in the study (rather than, as in most psychotherapy studies, simply averaging across all therapists). 13 Also, works will be limited to English-language studies of individual, adult psychotherapeutic treatment with patients whose primary diagnosis is a major psychoactive substance use disorder. Theoretical works will be included to highlight issues but will not be reviewed comprehensively.

# How much do therapists vary in effectiveness when treating patients with substance use disorders?

Differences in outcome

We located three studies that reported outcome differences among therapists treating patients with substance use disorders; all three showed substantial variability in therapist performance. Miller et al. 29 studied nine paraprofessional therapists conducting short-term behavioral treatment with alcoholics. The outcome measure was patients' drinking at 7 months. When outcome results for all patients within each therapist's case-load were averaged, the least effective therapist showed only a 25% rate of successful patient outcomes while the most effective therapist had a rate of 100%. Luborsky et al.8 evaluated nine therapists in a study of three different forms of psychotherapy for opiate addicts in methadone maintenance treatment. There were significant differences between therapists on each of seven outcome measures, with therapists' average effect size for the patients in their case-loads ranging from 0.13 (the least effective therapist) to 0.74 (the most effective therapist). A later study

by McLellan et al.<sup>22</sup> examined five counselors who had treated patients in a methadone maintenance program. One counselor was found to be significantly worse than the others, whereas another counselor was significantly better (based on five patient outcome measures). They concluded that "Some (counselors) promote rapid and sustained change in their caseloads and others actually detract from the effectiveness of the other components of treatment" (p. 430).

In the latter two studies, 8,22 the authors determined that patient factors at the start of treatment could not account for outcome differences reported among therapists. For example, Luborsky et al.8 found that only four of 22 baseline patient variables differed across counselors, and deemed these differences insufficient to explain therapists' results. In the study by McLellan et al.,22 therapist case-loads were equivalent at baseline, including such characteristics as history and severity of substance use, prior treatment, number of arrests and socio-demographic characteristics.

In all three of the reported studies, therapists were relatively homogeneous in professional background characteristics (to the extent that they were described). Thus, differences in outcome for therapists did not appear related to therapist training, 8,29 experience, 22,29, or theoretical orientation. 8,29 It is important to emphasize, however, that given the limited number and quality of studies in this area, such a conclusion must be verified by future research.

#### Differences in dropout rate

The phenomenon of patients dropping out of treatment prematurely is a common occurrence in psychotherapy in general, and is even more prevalent in drug and alcohol treatment programs. <sup>30</sup> We located four studies that reported on dropout rates for therapists working with substance use disorder populations. Similar to the outcome studies above, all four of these reports showed wide-ranging therapist differences, an absence of baseline patient variables that could account for the differential therapist effects observed, and relatively homogeneous therapist professional backgrounds.

Two early studies of this type were conducted at Boston City Hospital, one on inpatients and the other on outpatients. Raynes & Patch<sup>31</sup> found that inpatients with substance use disorders were more likely to leave treatment prematurely (either against medical advice (AMA) or without leave (AWOL)), than other diagnostic groups. Moreover, AWOL rates among eight psychiatric residents studied during a 1-year period ranged from 0 to 40% per resident. Two residents in particular had significantly more AWOL patients than the others. Patient sociodemographic characteristics were not related to AMA or AWOL status. The authors concluded that "The resident appears to have a direct influence on this type of discharge, communicating his wish for noninvolvement with the patient, probably due to attitudes and countertransference problems" (p. 478). Rosenberg et al. 32 evaluated 16 alcohol counselors at Boston City Hospital, also during a 1-year period. They found that counselors' average patient attendance rates ranged from 27 to 67% during 18 weeks of treatment. As early as 9 weeks into treatment, a significant difference in dropout rate could be found among counselors. Neither patient variables nor completion of a 1-year training program by the counselor affected retention rate.

Kleinman et al.33 studied therapists' rates of retaining cocaine-addicted patients in treatment for four or more sessions. They found rates ranging from 14 to 81% among seven therapists. Indeed, therapist assignment was found to be the strongest predictor of early dropout from treatment; no patient characteristic (ethnicity, age, number of arrests, education, global SCL-90 score, severity of marijuana or cocaine use) was a significant predictor. All therapists used manually guided treatments, and conducted either family therapy or supportive-expressive therapy. Finally, McCaul & Svikis<sup>24</sup> found that successful patient discharge status among seven therapists at an outpatient drug clinic ranged from 17 to 54% during 1 year under study.

Summary and critique of outcome and dropout studies

All seven studies reported above document widely ranging rates of therapist effectiveness. In the four studies that assessed patient characteristics at baseline, these did not account for the differences found among therapists. Moreover, varying rates of effectiveness were found despite the use of therapists who appeared relatively homogeneous within studies (in training, theor-

etical orientation, experience and clinical setting). These studies are notable for their use of multi-dimensional assessments of both therapists and patients, and their diversity of therapists and settings: inpatient<sup>31</sup> and outpatient;<sup>24</sup> paraprofessionals<sup>29</sup> and professionals;<sup>8</sup> novices<sup>31</sup> and experienced therapists;<sup>22</sup> behavioral therapists,<sup>29</sup> supportive–expressive and family therapists<sup>33</sup> and substance abuse counselors.<sup>22,32</sup>

None the less, the studies have numerous methodological limitations that render their findings suggestive but not yet conclusive. For example, all of the studies except one<sup>32</sup> were retrospective rather than prospective. Assignment of patients to therapists was not random by design in any study, and the number of cases assigned to each therapist often varied or sometimes was not reported. In addition, most of the studies provided only limited descriptions of the therapists, therapist sample sizes were generally quite small, and most studies used either trainees or paraprofessional therapists. No study has yet reported on therapist effectiveness using both outcome and dropout rates. It is also quite difficult to disentangle treatment modality effects from therapist effects<sup>8, 23,26</sup> since most studies did not employ manualized treatments nor measure adherence to a particular model. Crits-Christoph et al.23 have pointed out the importance of these steps in minimizing differences among therapists.

How do results regarding therapists' contribution to outcome and retention within the substance use disorder literature compare with the general psychotherapy field? Overall, they are highly consistent in several respects. First, the general psychotherapy field, while slightly more advanced in this area, also neglected the topic of individual therapist differences until relatively recently. Luborsky et al. 13 observed that among over 500 psychotherapy outcome studies published prior to 1986, virtually none analysed the therapist as an independent factor; the myth of the "uniformity of therapists"34 was prominent in that area as well. Secondly, once the topic was addressed, substantial differences among therapists' effects were found.8, 13, 28 (See Lambert15 for a review.) In the most thorough meta-analysis available on this topic, Crits-Christoph35 found an average effect size in the "moderate" range for therapists across 15 psychotherapy outcome studies, with results for particular studies ranging from no differences among therapists up to 48.7% of the outcome variance accounted for by therapists. Whether therapist professional characteristics contributed to such therapist differences is unclear, however. Both Luborsky et al.<sup>13</sup> and Crits-Christoph et al.<sup>35</sup> found that the therapist contribution was greater than that of theoretical orientation. Crits-Christoph et al.<sup>35</sup> found that experience level related to outcome only for less experienced therapists.

Do therapists of patients with substance use disorders show wider divergence than other therapists? It is too premature to answer this question, given the paucity of outcome studies and the need to compare results for therapists in comparable ways across studies. (Therapist outcome results are variously reported, for example, as per cent improved, per cent worsened or average on outcome measures within caseloads.) However, Luborsky et al. 13 did provide a direct comparison of therapist effects in four outcome studies, of which one, the VA-Penn Study, targeted substance use disorder patients; the other three studies sampled heterogeneous outpatients. It was found that the VA-Penn Study had the second highest rate of outcome variance accounted for by therapists (summarized in Lambert). 15 With regard to retention rates, however, we know of no comparison between therapists in the substance use disorder field and other therapists.

## What characteristics are related to therapist effectiveness?

Since therapists appear to show substantial differences in effectiveness, a natural question is why. In this section, we will review studies that have empirically linked therapist characteristics to effectiveness. The studies are divided into two sections below: first, studies that show therapists' behavior during treatment; and secondly, studies that evaluate pre existing therapist characteristics (e.g. personality, socio-demographic data). Using the model of therapist variables described by Beutler et al., 36 the former might be called "therapy-specific" and the latter "extratherapy" characteristics.

Therapy-specific characteristics. The most frequently studied therapist characteristic found to be associated with therapists' effects has been insession interpersonal functioning. In the study by Miller et al.<sup>29</sup> reviewed above, "accurate empa-

thy" on the Truax Scale (rated by therapists' colleagues) was found to account for 67% of the therapists' outcome results. Therapists' experience level was not related to either empathy or outcome. Similarly, Luborsky et al.8 (also described above) found that the development of a "helping alliance" was correlated with outcome. In one of the most rigorous studies of this topic, Valle<sup>11</sup> found a strong positive association between the interpersonal functioning of eight alcohol counselors and their patients' abstinence from drinking from 6 to 24 months after treatment. Interpersonal functioning referred to "empathy, genuineness, respect, and concreteness" based on counselors' written responses to stimulus statements (a method previously validated). Valle observed that the counselors ranged widely on interpersonal functioning, reinforcing the finding in the previous section of this review that ostensibly similar, experienced therapists may vary considerably in performance. This study was notable for a high sample size (247 patients) and random assignment of patients to counselors.

Another domain of interest has been negative affects conveyed by therapists. Milmoe et al.<sup>37</sup> determined, on the basis of audio-tape ratings, that the level of anger and anxiety in doctors' voices (n = 9) during an initial interview was inversely proportional to the likelihood that patients would follow through on alcoholism treatment.

Finally, in the study by Luborsky et al.<sup>8</sup> described above, outcome was associated with therapists' "purity" of techniques (the degree to which therapists conformed to a treatment manual and only to that treatment manual). Purity was related to better outcome across all therapists in the study and within therapist case-loads, highlighting the interaction that can occur between the therapist and the treatment techniques the therapist uses.

Extra-therapy characteristics. Only a few studies exist on this topic, and they use such different measures that it is difficult to draw even preliminary conclusions. In the study by Rosenberg et al. 32 described above, therapists completed a battery of three personality measures prior to the study and provided socio-demographic data. They found that counselors with higher patient retention rates were female, older, and more introverted on the Eysenck Personality Inven-

tory. Snowden & Cotler<sup>38</sup> studied 25 recovering counselors on the staff of an urban drug counseling center. Counselors participated in an extensive battery of five measures, including the MMPI; their effectiveness was measured by three patient outcomes—missed medications, random urine screen results and attendance at counseling. They found unusual results on the the best counselors were hypochondriacal, paranoid, manic and were lower in ego strength. The authors concluded that "It can be inferred from the present study that certain factors, usually regarded as non-adjustive or even pathological, may include characteristics which are adaptive and promote success in counseling heroin addicts" (p. 336). The more effective counselors were also lower on the "can't say" scale of the MMPI (suggesting non-defensiveness). No other measures were significant.

Thrower & Tyler<sup>39</sup> studied the counseling staff at five addiction treatment centers (all recovering paraprofessionals). Peers and supervisors of the counselors provided effectiveness ratings. The authors found that therapists who appeared more "dominant" and less "deferential" on the Edwards Personal Preference Schedule (EPPS) were more effective. Other significant results in this study were a positive association between effectiveness and EPPS sub-scale "heterosexuality" and a negative correlation with the sub-scale "order".

Summary and critique of studies of therapist characteristics

Research on therapist characteristics in relation to effectiveness is, at this stage, quite limited. The only consistent finding has been that therapists' in-session interpersonal functioning is positively associated with greater effectiveness. 8,11,29 This finding mirrors results for the general psychotherapy literature, in which therapists' individual outcome and retention rates have been found related to their capacity to establish an alliance,8,28 as well as to other facets of interpersonal functioning such as their warmth and friendliness, affirmation and understanding, helping and protecting, and an absence of belittling and blaming.<sup>28</sup> All other results reviewed above were unique to a particular study and require further validation: negative affects conveyed by therapists' voices,37 conformity to a treatment manual,8 socio-demographic charac-

teristics,<sup>32</sup> and personality characteristics.<sup>32,39</sup>, Indeed, the number of results that were not significant across these studies far outnumbers those that were significant. It is also difficult to make comparisons with the general psychotherapy literature for these other variables due to the scant findings. However, Crits-Christoph et al. 35 found that use of a treatment manual was associated with less of an effect size for therapists (that is, less divergence among their results) in their meta-analysis of 15 outcome studies. This complements the finding of Luborsky et al.8 that better outcomes were associated with the use of a treatment manual, and suggests that use of manualized treatment can lead to both better outcomes and less divergence among therapists. There are few in-depth process studies in the general psychotherapy field related to individual therapist effects, and all use different measures than the few substance use disorder studies (see, for example, Lafferty et al.14 and Najavits & Strupp<sup>28</sup>).

Studies of therapy-specific characteristics have been somewhat more rigorous than studies of extra-therapy characteristics in that they have used measures specifically designed to assess therapist qualities: e.g. the Truax Scale,29 helping alliance and conformity to a treatment manual,8 and interpersonal functioning scores.11 Studies of extra-therapy characteristics typically used personality scales with no previously validated relevance to therapists, no theoretically grounded rationale, and no a priori hypotheses. 32,38,39 One exception was the use of the Marcus Alcoholism Questionnaire,32 a previously validated scale to assess treaters' attitudes towards alcoholics. It is likely that as greater attention is directed to therapist effects in outcome and dropout studies, more refined assessment of therapist characteristics may occur.

#### Studying the therapist: guidelines for research

It is clear from the studies reviewed above that the unique qualities of therapists may influence treatment outcome in patients with substance use disorders. Further delineation of those characteristics that are most helpful in working with this group of patients is needed, and may represent an opportunity to help to improve treatment outcome in this population. Adequate study of therapist factors must include, however, rigorous research design as well as a careful selection of variables of study. Guidelines are suggested in these two domains.

Designing a study: methodological issues

In designing a psychotherapy study of substance abusers, it is highly recommended to test for therapist effects even if the main question of interest is not the difference between therapists. Studies that do not do so can lead to erroneous conclusions about the efficacy of treatments.23,26 As many therapists as possible should be included to maximize statistical power to detect inter-therapist differences. A wide range of therapists from the community is also desirable; many studies sample only highly motivated, welltrained therapists, producing a skewed sample and restriction of range. An alternative would be to minimize therapist performance differences via training, adherence measurement, supervision and careful selection of therapists, 23 although this would not allow the study of therapists, but only of treatment types. The therapists should also be as homogeneous as possible in professional background characteristics (for example, theoretical orientation, training and experience) unless those variables are of major interest and enough therapists of the different types can be included to assess between-group differences. Therapists should be described in detail;40 in some studies reviewed above, even the most basic information is lacking, such as years of experience and training. If the primary goal of a research project is the study of therapist differences, patient samples should be relatively homogeneous (e.g. diagnosis, severity) and assignment of therapists to cases should be randomized. Lambert15 also suggests that a useful design for studying therapists would be to select therapists who have a reputation for excellence, and to compare them with an unselected group of therapists. Whether or not therapists are the main object of study, one should evaluate therapist case-loads at pre-treatment for possible differences in the patient samples assigned to them, particularly if the study is not randomized. Otherwise, outcome differences may be based on an initial bias in assignment of cases. Most of the studies mentioned above conducted such an analysis. Therapist differences will also be most visible when patients are difficult5 and in the

early phase of the patients' treatment<sup>9</sup> since most dropouts and relapses occur early.

A few statistical caveats are also advised. According to Martindale<sup>41</sup> and Crits-Christoph et al.,23 the therapist has mistakenly been treated as a fixed rather than random factor in most outcome studies. They recommend that the therapist should be tested as a random factor (which changes the significance testing and degrees of freedom), so that results about therapists can be generalized validly to other populations of therapists. Murphy<sup>42</sup> adds that therapists should be a random factor nested within treatments, using a hierarchical design. The consistency of therapist results within case-loads should also be assessed, although no study reviewed above addressed this issue. That is, while seeking a summary score of effect for each therapist, the range of therapist's results within case-loads is also important (comparable to obtaining the standard deviation in addition to the mean). A therapist may have several good cases mixed with several poor ones to attain a moderate total score; or the same moderate score could be obtained by the therapist's consistently having only moderate resultstwo quite different scenarios with potentially different training and supervision implications. The consistency of therapists can also be tested using the intraclass correlation, a statistic commonly used to evaluate reliability.43 Finally, if particular patient variables are different at pretreatment among therapist case-loads (as discussed above), it may help to control statistically for those variables. One should also control for the number of sessions patients attended. 42

### Designing a study: therapist variables to consider

Following our definition of therapist effectiveness (observable improvement or deterioration in the patient which can be attributed to the therapist), the evaluation of therapists' effects could include any outcome measure believed to reflect change in the patient. In the studies reviewed above, effectiveness variables included changes in symptoms on paper-and-pencil measures (e.g. SCL-90, MMPI), behavioral indices such as urine screens, medication compliance, rehospitalization, length of stay in treatment (or, conversely, dropout rate), substance abuse relapse, AMA/AWOL discharges and negative outcomes (cases that show deterioration during treatment).

Other variables believed to be related to effectiveness include competence (a minimum standard on some test, such as a state licensing exam), experience (number of years in practice), expertise (a therapist's reputation as an expert) and consumer satisfaction (the degree to which the patient reports satisfaction with the therapist).<sup>44</sup>

The study of process variables—what therapists do during treatment that relates to their ultimate effectiveness—has received relatively little attention for substance use disorder populations. In the general psychotherapy literature, a few process variables have been found to be related to individual therapist effects and may be a guide for research within the substance use disorder field. Variables associated with more effective therapists include empathy, supportiveness, valuing of intellectual goals,14 warmth, affirmation and understanding, helping and protecting,28 effort, support of patients' autonomy and effective use of resources outside of therapy.45 Less effective therapists are associated with variables such as valuing comfort and stimulation,14 depression, withdrawal, feeling overwhelmed,45 and negative ways of relating to patients, such as watching and managing, belittling and blaming, ignoring and neglecting and attacking and rejecting.28 Also, an intriguing set of findings indicates that less effective therapists provided more positive self-ratings than more effective therapists (on supportiveness, the involvement of patients in treatment14 and ratings of the quality of sessions).28 Other process variables studied thus far in relation to individual therapist effects include skill ratings (ratings of the quality of the therapist's interventions, such as how carefully interpretations are made), adherence (the degree to which the therapist conforms to a particular treatment manual) and purity of orientation (how much a therapist performs only a specified treatment and not others). Broadly, one might categorize six basic domains for studying therapist process variables: knowledge (of techniques, substance abuse, etc.); emotional attitudes (liking of patients, interest in helping); general personality style (extrovert/introvert, humorous/serious); relational style during treatment (degree of alliance, use of support, confrontation); socio-demographics (years of experience, training, sex, age) and job characteristics (salary, job satisfaction, perceived power and

responsibility). 46 Most of these have not yet been studied in relation to individual therapist effects.

Some writers have suggested that therapists working with substance use disorder patients may require a set of traits uniquely necessary for this population. 12,39 The therapist must be more active than with other patients;12,47 more able to tolerate anger and to control one's own anger;6 less rigid;48 more patient and more insistent on imposing values such as AA;18 more charismatic, emotional and inspiring; 12,49 and more conscious of averting power struggles.50,51 The appropriate use of confrontation is also emphasized due to the high degree of denial characteristic of substance dependent patients. 49,50 The therapist should enjoy working with addicts,52 be able to handle issues associated with addiction such as poverty, AIDS and Axis II disorders,25 and be resistant to burn-out.24 It is also hypothesized that with substance use disorder populations, negative countertransference may be more easily triggered than with other patients, although we are aware of no data on this topic as yet. Negative countertransference toward substance dependent patients would include viewing them as outcasts, manipulative, or deserving special indulgence due to their sometimes severe psychosocial histories.6 Signs of countertransference include indifference to the patient's complaints, cynicism, assuming the patient to be a liar, hostility, a wish to control the patient, "slippage" in ground rules of treatment, such as the therapist's chronic lateness, missed sessions, or laxity in enforcing limits, boredom, over-solicitousness, premature ending of treatment, withdrawal or burnout and intense or unstable feelings about the patient. 6,50,53

In summary, research on therapist effects with substance use disorder patients is at an early stage of development. The development of more rigorous studies and new measures of therapists' process variables will be needed to more accurately gauge and understand therapists' impact on this patient population.

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